From: s22
To: IRIS
Cc: s22 ; s22 ; s22 ; s22
Subject: RE: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Friday, 2 August 2019 4:05:35 PM
Attachments: image002.png
02329(C) EN only w lang list.pdf

Attention: s22 ,

Dear s22
Thanks for your call yesterday Regarding DIR 58685, and thank you for providing me the AER details. It appeared that you may have been dialing our Fax Number, however I have gone into eBs and updated Pharmacovigilance Contact details immediately, so this should not recur again.

I have been in contact with the s22 from the US Manufacture Fziomed overnight and confirmed the following the following actions on the part of the Manufacturer.

s22 advised:

"Fziomed Inc received notification of the device incident report from you at TGA, File Reference E19-612208, concerning Oxiplex/AP overnight on 31 July.

We first received word of the reported incident from our distributor in Australia and the surgeon on Tuesday, 30 July, 2019. s22 *and our* s22 *, spoke with the surgeon on the same day. I was also on the call.*

Fziomed agree with your assessment that the product was used off label for two reasons; 1) Oxiplex/AP has not been evaluated in children and 2) Oxiplex/AP has not been evaluated following opening of the bowel.

FzioMed has received no other reports of this nature. Our initial assessment of the reported incident concluded that it was not reportable.

As clarification, please note that the one case report in horses of product identified in the blood mentioned in the surgeon's report to TGA was not following use of a FzioMed device."

I have attached the IFU leaflet supplied with the device for your information where the "precautions" are quite clear. There should be no need to consider IFU modification at present.

As we know there is less clarity around reporting of adverse events in relation to "Off-Label" use such as this situation where the surgeon has relied on clinical experience and judgement. e.g https://www.tga.gov.au/reporting-adverse-events

Our practice is "if in doubt – report" and we have reminded the Distributor to advise us of all reports. This incident would have been a 30 day report.

Regards,

s22 .
s22 .

s22
5 Yatama Place, (PO Box 339)
Currumbin Waters, QLD 4223
Phone: +61 7 55224880
Mobile: s22
www.advantagempc.com.au
s22 @advantagempc.com.au

From: IRIS <IRIS@health.gov.au>
Sent: Thursday, August 1, 2019 2:53 PM
To: s22 @advantagempc.com.au' <s22 @advantagempc.com.au>
Subject: FW: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22

Further to our telephone conversation please find attached the completion letter for DIR 58685 a user report.

Regards
s22

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)
Email: iris@tga.gov.au
Fax: 02 6232 1713
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers can use the online Medical Device Incident Reporting (MDIR) system using a TGA eBusiness Service (eBS) user name and password. The MDIR system allows sponsors and manufacturers to submit initial, follow-up and final reports and to review reports already submitted to the TGA. A user guide and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.

If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link to access the appropriate forms:
http://www.tga.gov.au/form/ebusiness-services-forms
If you have any issues please contact TGA eBS on 1800 010 624 or email: eBS@tga.gov.au

Online reporting ~
Sponsors / Manufacturers: http://www.tga.gov.au/safety/problem-device-report-industry.htm
Medical Device Healthcare Professionals/Users: http://www.tga.gov.au/safety/problem-device-report-user.htm

---

From: IRIS [mailto:IRIS@health.gov.au]
Sent: Thursday, 1 August 2019 1:12 PM
Subject: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 ,

Please see the attached letter in relation to a Device Incident Report (DIR) that was submitted to the Therapeutic Goods Administration (TGA) by **a healthcare professional/user.**

Kind regards,

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

Oxiplex®/AP

Absorbable Adhesion Barrier Gel

Manufactured by:
FzioMed
www.fziomed.com

FzioMed, Inc.
231 Bonetti Drive
San Luis Obispo, CA 93401
USA

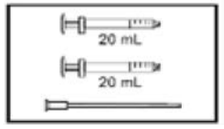
FzioMed Australia Pty Ltd
5 Yatama Place
Currumbin Waters QLD 4223
Australia

EC REP OBELIS S. A
Bd. Général Wahls, 53
1030 Brussels, Belgium
Tel: +32.2.732.59.59
Www.obelis.net

Not for distribution in the USA

STERILE CE 0344

Contents: 2 – Syringe 20mL
1 – Applicator tip



02329(C) EN only

DESCRIPTION

Oxiplex/AP is a clear, single use flowable gel. The gel is a sterile, absorbable combination of polyethylene oxide (PEO) and sodium carboxymethylcellulose (CMC). The gel is calcium stabilized, isotonic, and has been shown in preclinical studies to clear the peritoneal cavity within 30 days.

INTENDED USE

Oxiplex/AP is intended for use as a mechanical barrier to adhesion formation.

INDICATIONS

Oxiplex/AP is intended to be used as an adjunct to intrauterine or peritoneal surgery for reducing the incidence, extent, and severity of postoperative adhesions at the surgical site.

CONTRAINDICATIONS

Do not use Oxiplex/AP in the presence of infection.

WARNINGS

Do not inject intravenously.

PRECAUTIONS

Oxiplex/AP is supplied sterile. Do not use beyond the expiry date. Safety and efficacy of Oxiplex/AP have not been studied under conditions of reuse of device and/or applicator. Reuse may lead to immunological response and/or infection due to cross contamination, improper storage and/or handling.

Oxiplex/AP has not been studied in combination with other adhesion prevention products, in the presence of intraperitoneal medicinal agents or hemostatic agents, or as a distention medium.

Oxiplex/AP has not been evaluated in children or pregnant or nursing women. Therefore, patients should be advised to avoid conception during the first menstrual cycle after the application of Oxiplex/AP.

Oxiplex/AP has not been evaluated in the presence of malignancies.

Oxiplex/AP has not been evaluated following opening of the bowel, bladder, or other visceral organs. The gel has not been evaluated in the presence of bile.

As with any implanted material, foreign body reactions may occur with Oxiplex/AP.

Application of multiple layers of gel in the peritoneal cavity increases the risk of gel becoming dislodged from the intended site of application, and in some of these cases, a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later. Residual gel was not associated with clinical sequelae.[3,4]

STORAGE AND HANDLING

Store at room temperature (2 - 25 °C).

HOW SUPPLIED

Oxiplex/AP is supplied sterile in a thermoform tray. The thermoform tray contains two 20mL syringes of gel and one gel applicator. The exterior of the package and outer contents are not sterile. Self-adhesive labels are provided for documentation purposes. The labels identify the product and production lot.

INSTRUCTIONS FOR USE

PRE-PROCEDURE

Oxiplex/AP is to be used by physicians only. Use Oxiplex/AP according to the instructions for use.

Risk is inherent in the use of all medical devices. To minimize residual risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device.

Patients known to have a history of hypersensitivity to Oxiplex/AP or its components should not be treated with Oxiplex/AP.

The gel serves as a barrier between tissues to prevent adhesions from forming. Tissue must be separated by gel for effective adhesion prevention.

DEVICE PREPARATION AND DISPOSAL

Oxiplex/AP is for single use only. Do not reuse/re-sterilize.

1. Remove packaging containing the Oxiplex/AP filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open.
3. Using sterile technique, introduce syringes and applicator into the sterile operating field.
4. Remove cap from luer lock end of syringe. When using the applicator for peritoneal use, connect the gel applicator to the luer lock end of the syringe; rotate until firmly attached. (The same applicator is to be used for both syringes, if needed.)
5. After use, discard syringes, any remaining gel, and applicator. The used Oxiplex/AP device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

INTRAUTERINE SURGERY

1. Apply gel at the conclusion of the procedure after aspiration of all fluids and distention media.
2. Attach the syringe luer lock to the hysteroscope. Fill the hysteroscope with gel by compressing the syringe plunger until gel appears at the tip end of the hysteroscope.
3. Begin application of the gel at the fundus of the uterus. Gradually apply gel to completely fill the uterus and cervical canal by compressing the syringe plunger while slowly withdrawing the hysteroscope. See Figure 1.
4. Conclude the procedure according to the standard technique of the surgeon.

PELVIC GYNECOLOGICAL AND PERITONEAL SURGERIES

1. Apply gel at the conclusion of the procedure after aspiration of all irrigation fluid. It is recommended that the patient be placed in a reverse Trendelenburg position for the most efficient removal of residual irrigation fluid.
2. Cover all anatomical sites where adhesion prevention is desired with a single layer of Oxiplex/AP.* Applicator dispenses the gel in a “ribbon.” Only a single-layer gel ribbon (about 2 mm in depth) should be used to coat the tissue surfaces for which adhesion prevention is intended. See Figure 2.

3. Use only enough gel to place a single layer of gel on the tissues as described. It is not necessary to use all 40mL of gel.
4. Do not reposition gel with probes or other instruments once it has been applied. If gel falls into a pool of irrigation fluid, its ability to adhere to peritoneal tissues may be compromised. Therefore, it should be removed from the peritoneal cavity and new gel should be applied to the site.
5. Conclude the procedure according to the standard technique of the surgeon.

*ADDITIONAL GEL APPLICATION INSTRUCTIONS: PELVIC GYNECOLOGICAL SURGERIES

1. Lift ovary away from pelvic sidewall and apply a single layer of gel to cover the ovarian fossa and posterior surface of the ovary.
2. Return ovary to normal anatomical position and apply a single layer of gel to cover the anterior portion of the ovary.
3. Apply a single layer of gel to cover the Fallopian tube, including the ampulla and the mesosalpinx.
4. Apply a single layer of gel to cover the lateral aspect of the uterus facing the adnexa.

Typically 15mL of gel is sufficient to cover a single adnexa and adjacent structures, including the ovarian fossa and lateral margin of the uterus.

ADVERSE REACTIONS

No device-related adverse reactions were reported in clinical studies.[1-4] Although not necessarily attributable to the use of Oxiplex/AP, the following adverse events have been reported: pain, fever, swelling, inflammation, foreign body reaction, and poor performance.

REFERENCES

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Figure 1

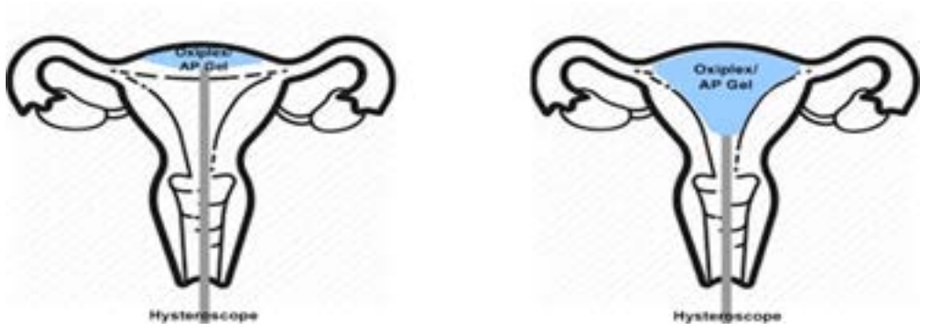
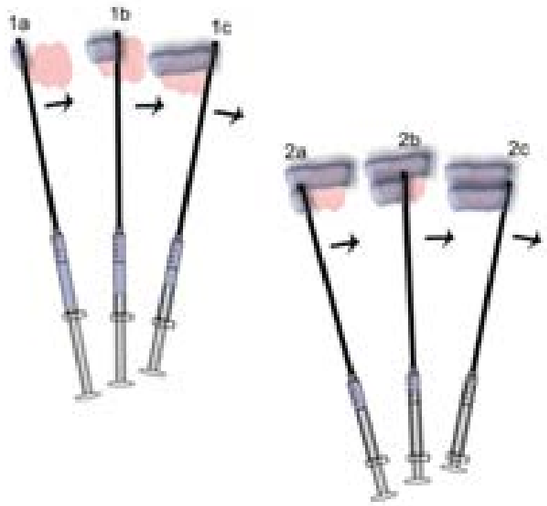


Figure 2



1a Position the gel-filled applicator by aligning the applicator slot over a margin of the desired site.
1b Sweep the applicator tip laterally over the site while depressing the syringe plunger to apply a 2 mm deep ribbon of gel.
1c After completely covering the site once, do not apply additional gel to that site.
2a,b,c If the site is not adequately covered by a single layer of gel, additional layers can be applied next to previously applied gel. Avoid applying additional layers of gel on top of one another.

Translated into:
Arabic
Bulgaria
Czech
Danish
German
Greek
Spanish (EU)
Finnish
French
Hungarian
Italian
Latvian
Dutch
Norwegian
Polish
Portuguese (EU)
Russian
Slovakian
Slovenian
Swedish
Turkish

From: s22
To: IRIS
Subject: Read: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 1 August 2019 5:33:29 PM

From: Mail Delivery Subsystem
To: s22 @advantagempc.com.au
Subject: Relayed: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 1 August 2019 3:00:04 PM
Attachments: FW_ DIR 58685 - Sponsor Completion Letter SECOFFICIAL ACCESSCommercial (1.85 KB).msg

---

Your message

To: s22 @advantagempc.com.au'
Subject: FW: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Sent: 1/08/2019 2:53 PM

From: IRIS
To: "s22 @advantagempc.com.au"
Subject: FW: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 1 August 2019 2:53:23 PM

From: IRIS
To: s22 @advantagempc.com.au
Subject: FW: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 1 August 2019 2:53:22 PM
Attachments: DIR 58685 - Sponsor Completion Letter.pdf

Dear Mr s22

Further to our telephone conversation please find attached the completion letter for DIR 58685 a user report.

Regards
s22

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)
Email: iris@tga.gov.au
Fax: 02 6232 1713
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers can use the online Medical Device Incident Reporting (MDIR) system using a TGA eBusiness Service (eBS) user name and password. The MDIR system allows sponsors and manufacturers to submit initial, follow-up and final reports and to review reports already submitted to the TGA. A user guide and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.

If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link to access the appropriate forms:
http://www.tga.gov.au/form/ebusiness-services-forms
If you have any issues please contact TGA eBS on 1800 010 624 or email: eBS@tga.gov.au

Online reporting ~
Sponsors / Manufacturers: http://www.tga.gov.au/safety/problem-device-report-industry.htm
Medical Device Healthcare Professionals/Users: http://www.tga.gov.au/safety/problem-device-report-user.htm

---

From: IRIS [mailto:IRIS@health.gov.au]
Sent: Thursday, 1 August 2019 1:12 PM
Subject: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]

Dear s22 ,

Please see the attached letter in relation to a Device Incident Report (DIR) that was submitted to the Therapeutic Goods Administration (TGA) by **a healthcare professional/user.**

Kind regards,

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 @fziomed.com

File Reference: E19-612208
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 58685 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

An incident report has been received by the Therapeutic Goods Administration from a healthcare professional/user for the above mentioned medical device and an investigation into the incident is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information. The Therapeutic Goods Administration is not requesting any action from you.

Should you have any further queries concerning this report please call s22 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

01/08/2019

DIR 58685 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Initial Report:
30/07/2019

ARTG #:
152224

Brand Name:
Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc [40334]

Sponsor:
Fziomed Australia Pty Ltd [49415]
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name: s22

Phone: s22

Fax:

Email: s22 @fziomed.com

Reporter:
s22
Paediatric Surgeon
Perth Children's Hospital

Confidential: No

Phone: s22
Fax:

Email: s22 @health.wa.gov.au

Date of Implant:
24/07/2019

Date of Explant:

Clinical Event Information:
We used the product Oxiplast laparoscopically after adhesiolysis for adhesive bowel obstruction as an anti adhesive barrier gel approx. one week prior.
A full blood count was taken yesterday and the blood film identified the presence of a foreign body. This was confirmed with a repeat blood film today.
It is currently suspected that this extracellular blood foreign body is the agent (oxyplast)
The reason for it being within the blood stream is unclear.
We have not found any documented case reports of this in humans. There is one case report in horses of the product being identified in blood.

Details of Similar Events: N/A

Number of Similar Events: N/A Rate of Similar Events:N/A

Countries Similar Events Also Occurred: N/A

Problem Observed (Level 1)
Agent found in blood sample

Investigation Findings (Level 1)
No Findings Available

Investigation Conclusion (Level 1)
Cause Not Established

Outcome of Investigation (L1)
Reviewed, for Trending Purposes Only

Summary of Investigation:
The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to):

- The commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc.

- The individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Date Completed:
01/08/2019

***** End of DIR 58685 *****

From: s22
To: IRIS
Subject: Read: DIR 58685 - Reporter Completion Letter [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Thursday, 1 August 2019 1:14:53 PM

Your message

To: s22

contained an option unknown to Outlook, therefore receipt generation failed.

From: IRIS
To: s22 @fziomed.com
Subject: DIR 58685 - Sponsor Completion Letter [SEC=OFFICIAL, ACCESS=Commercial]
Date: Thursday, 1 August 2019 1:12:03 PM
Attachments: DIR 58685 - Sponsor Completion Letter.pdf

Dear s22 ,

Please see the attached letter in relation to a Device Incident Report (DIR) that was submitted to the Therapeutic Goods Administration (TGA) by **a healthcare professional/user.**

Kind regards,

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 @fziomed.com

File Reference: E19-612208
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 58685 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

An incident report has been received by the Therapeutic Goods Administration from a healthcare professional/user for the above mentioned medical device and an investigation into the incident is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information. The Therapeutic Goods Administration is not requesting any action from you.

Should you have any further queries concerning this report please call s22 or send an email to: IRIS@health.gov.au.

Yours sincerely

Signed electronically by

Administration officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

01/08/2019

DIR 58685 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Initial Report:
30/07/2019

ARTG #:
152224

Brand Name:
Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc [40334]

Sponsor:
Fziomed Australia Pty Ltd [49415]
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name: s22

Phone: s22

Fax:

Email: s22 @fziomed.com

Reporter:
Dr s22
Paediatric Surgeon
Perth Children's Hospital

Confidential: No

Phone: s22
Fax:

Email: s22 @health.wa.gov.au

Date of Implant:
24/07/2019

Date of Explant:

Clinical Event Information:
We used the product Oxiplast laparoscopically after adhesiolysis for adhesive bowel obstruction as an anti adhesive barrier gel approx. one week prior.
A full blood count was taken yesterday and the blood film identified the presence of a foreign body. This was confirmed with a repeat blood film today.
It is currently suspected that this extracellular blood foreign body is the agent (oxyplast)
The reason for it being within the blood stream is unclear.
We have not found any documented case reports of this in humans. There is one case report in horses of the product being identified in blood.

Details of Similar Events: N/A

Number of Similar Events: N/A Rate of Similar Events:N/A

Countries Similar Events Also Occurred: N/A

Problem Observed (Level 1)
Agent found in blood sample

Investigation Findings (Level 1)
No Findings Available

Investigation Conclusion (Level 1)
Cause Not Established

Outcome of Investigation (L1)
Reviewed, for Trending Purposes Only

Summary of Investigation:
The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to):

- The commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc.

- The individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Date Completed:
01/08/2019

***** End of DIR 58685 *****

From: IRIS
To: s22 @health.wa.gov.au
Subject: DIR 58685 - Reporter Completion Letter [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Thursday, 1 August 2019 1:06:21 PM
Attachments: DIR 58685 - Reporter Completion Letter.pdf

Dear Dr s22

Please see the attached letter in relation to the Device Incident Report (DIR) that you submitted to the Therapeutic Goods Administration (TGA).

Kind regards,

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Branch
Therapeutic Goods Administration (TGA)

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website. MDIR Technical assistance is available via 1800 010 624 or email (eBS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please click on the following link - http://www.tga.gov.au/form/ebusiness-services-forms.

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx

For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

Document 7

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

Dr s22
Paediatric Surgeon
Perth Children's Hospital

Email: s22 @health.wa.gov.au

File Reference: E19-612208
Sent by email

Dear Dr s22

DEVICE INCIDENT REPORT DIR 58685 - Oxyplex/AP laparoscopic absorbable adhesion barrier gel

An investigation into the incident you reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any questions regarding this report please call s22 or send an email to: IRIS@health.gov.au.

Yours sincerely,

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Device Vigilance and Monitoring Section
Medical Devices Branch
Therapeutic Goods Administration

01/08/2019

DIR 58685 - Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Reporter Reference #:

Date of Adverse Event:
s22

Date of Report:
30/07/2019

ARTG #:
152224

Brand Name:
Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc

Sponsor:
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name:
s22

Phone:
s22

Reporter:
Dr s22
Paediatric Surgeon
Perth Children's Hospital

Confidential: No

Phone: s22
Fax:

Email: s22 @health.wa.gov.au

Date of Implant:
s22

Date of Explant:

Clinical Event Information:
We used the product Oxiplast laparoscopically after adhesiolysis for adhesive bowel obstruction as an anti adhesive barrier gel approx. one week prior.
A full blood count was taken yesterday and the blood film identified the presence of a foreign body. This was confirmed with a repeat blood film today.
It is currently suspected that this extracellular blood foreign body is the agent (oxyplast)
The reason for it being within the blood stream is unclear.
We have not found any documented case reports of this in humans. There is one case report in horses of the product being identified in blood.

Investigation Summary:
The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme.

The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to):

- The commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc.

- The individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device.

In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.

Date Completed:
01/08/2019

***** End of DIR 58685 *****

Document 8

30/07/2019
SIGNED

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 428385

Released by s22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
58685	E19-612208		Final

ARTG: 152224

Document Container URL:

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	30/07/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
30/07/2019	30/07/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
01/08/2019	Doctor		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Surgeon		Trend data only	

Event Description for Website Publication:

Blood film test revealed extracellular blood foreign body in patient which is suspected to be this product.

Clinical Event Information:

We used the product Oxiplast laparoscopically after adhesiolysis for adhesive bowel obstruction as an anti adhesive barrier gel approx. one week prior.
a full blood count was taken yesterday and the blood film identified the presence of a foreign body.
this was confirmed with a repeat blood film today.
It is currently suspected that this extracellular blood foreign body is the agent (oxyplast)
The reason for it being within the blood stream is unclear.
We have not found any documented case reports of this in humans. There is one case report in horses of the product being identified in blood.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1	Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Information

Sex:	Weight:	Age:
s22		[redacted]

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:
Blood film: :Signif cant extracellular precipitant present between and overlying red cells- this is blue-purple in appearance. No intracellular organisms seen.	Unknown		Procedure or Surgery

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:	Preferred Contact Method:
s22		Email
Reporter Title:	**First Name:**	**Surname:**
[redacted]	[redacted]	[redacted]
Position:		**Company/Institution:**

Document 8

Position:
Paediatric Surgeon

Company/Institution:
Perth Children's Hospital

Address 1:

Address2:

Town/Suburb:

State:

Counby:
Australia

Postcode:

Phone:
s22

Fax:

Mobile:

Email:
s22 @health.wa.gov.au

Are you happy for the device company to contact you about the incident?:

Last External Submission By:

Initial Reporter Section

As Above?:
Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:
No

Search Device ARTG:
152224

Device ARTG #:
152224

Therapeutic Licence Type:
Medical Device

Product Licence Category:
Included

Device Class:
Class III

GMDN / UMDN Code:
34212

GMDN / UMDN Text:
Barrier, absorbable, adhesion prevention

Brand Name:
Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Initial Device Description:
Oxyplex/AP laparoscopic absorbable adhesion barrier gel

Usage of Device:

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

Purchase Date:

Expiry Date:

Date of Implant:
24/07/2019

Date of Explant:

Place of Implantation:
Perth Childrens Hospital

Reported Device Location:
Insitu

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Access Contact Email:

Additional Devices Added:
0

Manufacturer Information Section

Manufacturer Name:
Fziomed Inc

Manufacturer Client Id:
40334

Address 1:

Address 2:

Town/Suburb:

State/Province:

Country:

			Australia
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Yes	30/07/2019		
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	Date of Initial TGA Action:	Report Status:		
08/05/2008	30/07/2019	Closed		
Problems Observed:				
Appropriate Term/Code Not Available; ;				

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Rate considered low at this stage	Unassigned
Report Priority:				
Not Investigated				

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
Team Meeting Notes:		

DPRC Review

Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:
Meeting Notes:		

Initial Risk Analysis

Date:	Assessor:	Licence Status:	Status Reason:	Status Effective Date:
31/07/2019	s22 [redacted]	Active		08/05/2008
Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
Patient	Serious Injury	No Injury	No	No
Sterile:	Invasive Device:	Single Use:	Human Origin:	Genetically Modified:

Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Further Review Needed:
Yes	Yes	Yes	No	No
No	Unlikely	Serious	Minor Risk	Team Review

Risk Assessment Notes:

QLK Consulted, no problems with IRIS, PMR or recalls.

Risk is agent found in blood test. Not enough information to determine that the foreign body in blood sample is agent.

First DIR since 2012.

Final Risk Assessment:

Yes

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client#:
49415	Fziomed Australia Pty Ltd		49415
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 339		CURRUMBIN WATERS
State:	**Postcode:**	**Phone:**	**Fax:**
QLD	4223	s22	
Email:			
[redacted]@fziomed.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	**CAPA# Reference:**

Risk Assessment

Frequency:	Severity:
Rating:	

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

01/08/2019 - DIR Closed

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details									
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		01/08/2019				
☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		01/08/2019				

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			agent found in blood sample	

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government. Thank you for submitting your adverse event report and contributing to the ongoing work of the IRIS scheme. The TGA conducts a review of all adverse event incidents reported to it. The outcome of the review may take a number of paths including (but not limited to): · The commencement of a formal investigation which could lead to regulatory action such as the recall of the product, advice to users on the safe use of the device, manufacturing improvements and/or design changes, etc. · The individual report may be closed but used for monitoring and trending analysis. This means that the information is incorporated into an ongoing body of evidence on the current real-world performance and safety profile of the device. In this instance, no further investigation of the reported event will occur. The TGA will continue to monitor the rate and pattern of occurrence of the reported adverse event and may re-open the file as appropriate.	

Document 8

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Document 8

Where did you get this device from?: Supplier

How reliant is the affected person on correct/safe operation of this device?: Partially

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 58685 - Original user report	239	Form	

Flow Details : DIR-REQ - Device Incident Request : 178457

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
178457	DIR-REQ		Closed	s22	OPR Administration User	01/08/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	01/08/2019 13:12:26	
Comment		

Document 9

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

09/08/2021
SIGNED

DIR : 45 - ID : 527372

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71615	E21-373395		Final

ARTG: 152224

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	09/08/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
09/08/2021	09/08/2021	21/09/2021	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
23/12/2021	Doctor		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Hospital Administrator		For Team Meeting	

Event Description for Website Publication:

Blood film test revealed, extracellular blood foreign body in patients which are suspected to be this product.

Clinical Event Information:

Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
5	Initial Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Others -> Insufficient Information ->

Health Impact

Recorded Health Impacts:

Insufficient Information -> ->

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Gender	Age	Primary Pathology	Complication descriptor
s22			Precipitant in blood film Precipitant in blood film Mild Precipitate Mild-Mod Precipitate Mild Precipitate

Patient Outcome/Consequences:

Additional Event Description:

Document 9

No Injury

Describe any test (lab, xray, etc.):	Injured - Extent of Injury:	Other medical devices currently using/implanted:	Medical Problem Device Used For:
	No Injury		

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			Email

Reporter Title:	First Name:	Surname:
	s22	s22

Position:	Company/Institution:
Administrative Coordinator	Perth Children's Hospital

Address 1:	Address 2:	Town/ Suburb:	State:
15 Hospital Avenue		Nedlands	WA

Country:	Postcode:	Phone:	Fax:
Australia	6009	s22	

Mobile:	Email:	Last External Submission By:
	officeofoperations@health.wa.gov.au	

Initial Reporter Section

As Above?:	*If No, fill out the following:*	Initial Reporter Confidential:
No		Yes

Search Reporter By Surname:	Initial Reporter #:	Preferred Contact Method:
[redacted]		

Title:	First Name:	Surname:
s22	[redacted]	[redacted]

Position:	Company/Institution:
Paediatric Surgeon	Perth Children's Hospital

Address 1:	Address 2:	Town/ Suburb:	State:
15 Hospital Avenue		Nedlands	WA

Postcode:	Country:	Phone:	Fax:
6009	Australia	s22	

Mobile:	Email:	Allow the device company to contact you about the incident:
	s22 [redacted]@health.wa.gov.au	☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic Licence Type:
No	152224	152224	Medical Device

Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class III	34212	Barrier, absorbable, adhesion prevention

Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention	Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention	Single Use	

Model #:	Serial #:	Batch #:	Lot #:

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:

Document 9

Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
29/08/2021		Place of use	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
	A	08/05/2008	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Fziomed Inc		40334	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Fziomed Australia Pty Ltd		PO Box 339	
Town/Suburb:	**State:**	**Country:**	**Postcode:**
CURRUMBIN WATERS	QLD	Australia	4223
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	12/07/2021		
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	Yes	More information is required	Team A (AIMD, III & Reg/Listed)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
21/09/2021	User report	Investigation (within DIR) is recommended

Notes for Team meeting:

Zero recalls, no PMR, no similar events. This is a HCP report. Please find attached a letter from Hospital Doctor sent to Sponsor for content. Not too sure if the Doctor wants a response from TGA. Should we request the IFU to see if "precipitant on post-operative blood films" is a known complication and maybe get rates?

Outcomes from Team Meeting:

Request current IFU

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:

09/08/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional		No	s22	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
	No	Level 1 Investigation (no complete screening)	Level 1 Investigation (to complete screening)	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
		Final; Low rates. No similar reports over the six months, last report is 30/7/2019. no batch or cluster issue identified.		No	No
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	Yes - some potential factors (up to 3)			No	0 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
	Compatibility of device - patient characteristics	Routine	Routine		No
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	Yes - some potential sensitivities (up to 3)	Final; Low rates. No similar reports over the six months, last report is 30/7/2019. no batch or cluster issue identified.			No
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
	Device used in high risk populations, Device used in high acuity clinical environments				No
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
	I undertook an internet search (e.g., Google)	Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	**Name:**		**Client#:**
49415	Fziomed Australia Pty Ltd		49415
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 339		CURRUMBIN WATERS
State:	**Postcode:**	**Phone:**	**Fax:**
QLD	4223	s22	
Email:			
[redacted]@fziomed.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:		**Details of Similar Events:**	
Additional Details (use for tables):		**CAPA# Reference:**	
		Risk Assessment	
		Frequency:	**Severity:**
		Rating:	
Type Cause and Outcome:	**Number of Similar Events:**	**Expected Rate:**	**Actual Rate:**
Countries Similar Events Also Occurred:			
Completed Actions:		**Planned Actions and Proposed Timelines:**	

Document 9

Additional Comments:

DIR closed 23/12/21

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigation	
Unknown Issues	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received
Information from Sponsors (e.g. 41JA, Questionnaires, Emails)		12/10/2021	

Evidence

Investigation Questions (Level 1 and Level 2):

Request for IFU

Potential Risks

Delays in response by product manufacturers: ☐

Delays in response by incident reporters: ☐

Delays in analysis within the TGA: ☐

Delays in reporting by other sources (e.g. clinical registries): ☐

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
☐		Reporter Routine Correspondence	Reporter Notification Letter		24/09/2021				D21-3133367
☐		Sponsor Routine Correspondence	Sponsor Request for Information – email or letter/informal		24/09/2021	22/10/2021	28/09/2021	D21-3144232	D21-3133392
☐		Sponsor Routine Correspondence	Questionnaire - non-regulatory		12/10/2021	08/11/2021	15/10/2021	D21-3217454	D21-3203270
☐					23/12/2021				
☐									

Document 9

☐		Sponsor Routine Correspondence	Sponsor DIR Closure Letter		23/12/2021					
☐		Reporter Routine Correspondence	Reporter DIR Closure Letter		23/12/2021					

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Appropriate Term/Code Not Available			extracellular blood foreign body	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Others	Insufficient Information		

Health Impact

Details			
Level 1	Level 2	Level 3	
Insufficient Information			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Usage Problem Identified				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to User	Cause Traced to Intentional Off-Label, Unapproved, or Contraindicated Use		

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, No Further Action Required			

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	
Investigator's Notes:		Summary Findings:		Recall Number:

A review of IFU state that Product "has not been evaluated in children" and "a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later" Therefore off label by using the product on children ages 2-7 years, and there will be a residual amount in blood test done in the post op period up to 10 weeks post op, given the absorption rate (6-10 weeks).	A review of the device instructions for use (IFU) states that "Oxiplex/AP has not been evaluated in children", the IFU also includes "a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later" Reviewed no further action required.; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	Document 9

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Document 9

Additional Device Information

Where did you get this device from?: Supplier

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1: 15

Address Line 2: Hospital Avenue

Town/Suburb: Nedlands

State: WA

Postcode: 6009

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		00206BAB01B2210712152749	69	Form Item	Report Information Section / Brand Name
FILE		Oxilpex_PCH_July2021	318	Form Item	Report Information Section / Brand Name
FILE		DIR 71615 - Original User Report	860	Form	
FILE		RE DIR 71615 - Request For Information Letter ...	1553	Form	
FILE		Reporter/user complete letter	156	Form	
FILE		Sponsor complete letter	159	Form	

Flow Details : DIR-REQ - Device Incident Request : 314737

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
314737	DIR-REQ		Closed	s22	OPR Administration User	23/12/2021	Normal	0

Document 9

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	23/12/2021 14:43:18	
Comment		

From: IRIS
To: officeofoperations@health.wa.gov.au
Subject: DIR 71615 - Reporter Notification Letter [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Friday, 24 September 2021 10:27:32 AM
Attachments: DIR 71615 - Reporter Notification Letter.pdf

Dear s22

Please see the attached letter in relation to the Device Incident Report (DIR) that has been submitted to the Therapeutic Goods Administration (TGA).

Kind regards,

-
s22
-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.


Australian Government
Department of Health
Celebrating
100
YEARS OF HEALTH
1921 - 2021

Document 10

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Administrative Coordinator
Perth Children's Hospital
15 Hospital Avenue
Nedlands WA 6009
Email: officeofoperations@health.wa.gov.au

File Reference: E21-373395
Sent by email

Dear s22,

DEVICE INCIDENT REPORT DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Medical Device Incident Report Investigation (IRIS) Database, where it will be evaluated against any previous incidents with the same or similar devices. This report is currently under investigation and a copy of the Device Incident Report (DIR) is attached for your reference.

Should you have any questions, please contact our team on s22 or email: IRIS@health.gov.au quoting the above DIR number. The TGA may contact you regarding this report.

Thank you for your support of the Medical Device Incident Report Investigation Scheme.

Yours sincerely
Signed electronically by

Administrative Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

24/09/2021

DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Final Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc

Sponsor:
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:

Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

Additional Event Description:

***** End of DIR 71615 *****

From: IRIS
To: s22 @fziomed.com
Subject: DIR 71615 - Request For Information Letter *Response due 22/10/2021* [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Friday, 24 September 2021 10:33:28 AM
Attachments: DIR 71615 - Request For Information Letter.pdf

Dear s22

Please see the attached **Request For Information Letter** for action. **Please note the due date for a response is 22 October 2021.**

Kind regards,

-
s22
-
Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Department of Health

Email: IRIS@health.gov.au
Phone: **DST** s22
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.


Australian Government
Department of Health
Celebrating
100
YEARS OF HEALTH
1921 - 2021

Document 11

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22

Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 @fziomed.com

File Reference: E21-373395
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the TGA database report is attached.

To assist in the evaluation and resolution of this report, could you please provide the information requested below referencing the above DIR number and return it to this office **within 20 working days of the date of this letter and no later than close of business 22/10/2021**.

- Please provide a copy of the Instructions For Use.

Electronic submission of all information is preferred. Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device(s) to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

If you do not respond with the requested information or with a request for a reasonable extension to this timeframe within the twenty days, you will receive a letter under Section 41JA of the Therapeutic Goods Act requesting the information and no further extension of time will be granted.

Thank you for your cooperation. If you require further information please contact our team on s22 [redacted]

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

24/09/2021

DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc

Sponsor:
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

***** End of DIR 71615 *****

From: s22
To: IRIS
Cc: s22 ; s22
Subject: RE: DIR 71615 - Request For Information Letter *Response due 22/10/2021* [SEC=OFFICIAL, ACCESS=Personal-Privacy]
Date: Tuesday, 28 September 2021 5:12:05 AM
Attachments: DIR 71615 - Request For Information Letter.pdf
02329(D)1 OxiplexAP IFU.pdf

Dear Ms. s22

See the attached file, 2329(D)1.pdf, that contains the Instructions for Use for Oxiplex/AP that is the subject of DIR 71615 – Request for Information Letter.

Please contact me if something more is needed.

~s22

s22
FzioMed, Inc.|231 Bonetti Drive, San Luis Obispo, CA 93401 US
T s22 | F +1 805 546 0571 s22 @fziomed.com

From: IRIS [mailto:IRIS@health.gov.au]
Sent: Thursday, September 23, 2021 5:34 PM
To: s22 @fziomed.com>
Subject: DIR 71615 - Request For Information Letter *Response due 22/10/2021* [SEC=OFFICIAL, ACCESS=Personal-Privacy]

Dear s22

Please see the attached **Request For Information Letter** for action. **Please note the due date for a response is 22 October 2021.**

Kind regards,

-
s22
-

Device Support Team
Medical Device Incident Report Investigation Scheme (IRIS)
Devices Post Market Monitoring | Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)

Department of Health

Email: IRIS@health.gov.au
Phone: **DST** s22 [redacted]
Phone: **IRIS** 1800 809 361
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Please Note: Medical device sponsors and manufacturers are encouraged to submit adverse events via the online Medical Device Incident Reporting (MDIR) system. The MDIR allows sponsors and manufacturers to submit initial, follow-up and final reports and review reports already submitted to the TGA. The MDIR can be accessed via https://apps.tga.gov.au/prod/mdir/MDIRSummary.aspx, using a TGA eBusiness Service (eBS) user name and password. MDIR guidance documents and FAQ are available from the 'Training' section of the TGA eBS portal, or from the TGA website.
MDIR Technical assistance is available via s22 [redacted] or email (IRIS@health.gov.au). If you are a sponsor or manufacturer requiring a new account to gain access to the MDIR system or need to update your details with TGA eBS, please contact TBS Helpdesk via 1800 010 624 or email (eBS@health.gov.au).

Online reporting forms for Medical Device Healthcare Professionals/Users can be accessed via:
https://apps.tga.gov.au/prod/mdir/udir03.aspx
For ongoing information and updates please subscribe to the TGA's Medical Devices Information and IVDs Information email subscription services.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22 [redacted]
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 [redacted]@fziomed.com

File Reference: E21-373395
Sent by email

Dear s22 [redacted],

DEVICE INCIDENT REPORT DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the TGA database report is attached.

To assist in the evaluation and resolution of this report, could you please provide the information requested below referencing the above DIR number and return it to this office **within 20 working days of the date of this letter and no later than close of business 22/10/2021**.

- Please provide a copy of the Instructions For Use.

Electronic submission of all information is preferred. Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device(s) to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user

If you do not respond with the requested information or with a request for a reasonable extension to this timeframe within the twenty days, you will receive a letter under Section 41JA of the Therapeutic Goods Act requesting the information and no further extension of time will be granted.

Thank you for your cooperation. If you require further information please contact our team on s22 .

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

24/09/2021

DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc

Sponsor:
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

***** End of DIR 71615 *****

Oxiplex/AP®

Absorbable Adhesion Barrier Gel

EN	ABSORBABLE ADHESION BARRIER GEL
AR	جل حاجز التصاق قابل للامتصاص
BG	РЕЗОРБИРУЕМ АНТИАДХЕЗИОНЕН БАРИЕРЕН ГЕЛ
CS	VSTŘEBATELNÝ GEL ZABRAŇUJÍCÍ VZNIKU SRŮSTŮ
DA	RESORBERBAR ADHÆRENCEBARRIERE GEL
DE	RESORBIERBARES ADHÄSIONSPROPHYLAXE-GEL
EL	ΑΠΟΡΡΟΦΗΣΙΜΗ ΓΕΛΗ ΠΑΡΕΜΠΟΔΙΣΗΣ ΔΗΜΙΟΥΡΓΙΑΣ ΣΥΜΦΥΣΕΩΝ
ES	GEL DE BARRERA ANTIADHERENTE ABSORBIBLE
FI	RESORBOITUVA KIINNIKKEENESTOGEELI
FR	GEL BARRIÈRE ANTI-ADHÉRENCE RÉSORBABLE
HU	FELSZÍVÓDÓ TAPADÁSGÁTLÓ GÉL
IT	BARRIERA ANTI-ADERENZE IN GEL ASSORBIBILE
NL	RESORBEERBARE GELBARRIÈRE TEGEN ADHESIES
NO	ABSORBERENDE, KLEBENDE BESKYTTENDE GEL
PL	WCHŁANIALNY ŻEL ZAPOBIEGAJĄCY POWSTAWANIU ZROSTÓW
PT	GEL DE BARREIRA ANTI-ADERÊNCIAS ABSORVÍVEL
RO	GEL RESORBABIL CA BARIERĂ ÎMPOTRIVA ADERENȚELOR
SK	VSTREBATEĽNÝ GÉL ZABRAŇUJÚCI VZNIKU ZRASTOV
SL	ABSORPTIVNA ADHEZIJSKA BARIERA V OBLIKI GELA
SR	RESORPTIVNI GEL ZA SPREČAVANJE ADHEZIJE TKIVA
SV	RESORBERBAR ADHERENSBARRIÄRGEL
TR	YAPIŞMA (ADEZYON) ÖNLEYİCİ EMİLEBİLİR JEL

This product is protected by one or more of the patents listed on patentees website (www.fziomed.com)

FzioMed

www.fziomed.com

FzioMed, Inc.
231 Bonetti Drive
San Luis Obispo, California 93401, USA

FzioMed Australia Pty Ltd
Suite E316
3 Oracle Boulevard
Broadbeach QLD 4218
Australia

EC REP OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels, Belgium
Tele: +32.2.732.59.54
www.obelis.net

STERILE

CE 0344

EN

DESCRIPTION
Oxiplex/AP is a clear, single use flowable gel. The gel is a sterile, absorbable combination of polyethylene oxide (PEO) and sodium carboxymethylcellulose (CMC). The gel is calcium stabilized, isotonic, and has been shown in preclinical studies to clear the peritoneal cavity within 30 days.

INTENDED USE
Oxiplex/AP is intended for use as a mechanical barrier to adhesion formation.

INDICATIONS
Oxiplex/AP is intended to be used as an adjunct to intrauterine or peritoneal surgery for reducing the incidence, extent, and severity of postoperative adhesions at the surgical site.

CONTRAINDICATIONS
Do not use Oxiplex/AP in the presence of infection.

WARNINGS
Do not inject intravenously.

PRECAUTIONS
Oxiplex/AP is supplied sterile. Do not use beyond the expiry date. Safety and efficacy of Oxiplex/AP have not been studied under conditions of reuse of device and/or applicator. Reuse may lead to immunological response and/or infection due to cross contamination, improper storage and/or handling. Oxiplex/AP has not been studied in combination with other adhesion prevention products, in the presence of intraperitoneal medicinal agents or hemostatic agents, or as a distention medium. Oxiplex/AP has not been evaluated in children or pregnant or nursing women. Therefore, patients should be advised to avoid conception during the first menstrual cycle after the application of Oxiplex/AP. Oxiplex/AP has not been evaluated in the presence of malignancies. Oxiplex/AP has not been evaluated following opening of the bowel, bladder, or other visceral organs. The gel has not been evaluated in the presence of bile. As with any implanted material, foreign body reactions may occur with Oxiplex/AP. Application of multiple layers of gel in the peritoneal cavity increases the risk of gel becoming dislodged from the intended site of application, and in some of these cases, a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later. Residual gel was not associated with clinical sequelae.[3,4]

STORAGE AND HANDLING: Store at room temperature (2 - 25 °C).

HOW SUPPLIED
Oxiplex/AP is supplied sterile in a thermoform tray. The thermoform tray contains two 20mL syringes of gel and one gel applicator. The exterior of the package and outer contents are not sterile. Self-adhesive labels are provided for documentation purposes. The labels identify the product and production lot.

INSTRUCTIONS FOR USE
PREPROCEDURE
Oxiplex/AP is to be used by physicians only. Use Oxiplex/AP according to the instructions for use. Risk is inherent in the use of all medical devices. To minimize residual risk associated with the use of this device, it is recommended that the information for use be read by the physician and discussed with the patient prior to use of the device. Patients known to have a history of hypersensitivity to Oxiplex/AP or its components should not be treated with Oxiplex/AP. The gel serves as a barrier between tissues to prevent adhesions from forming. Tissue must be separated by gel for effective adhesion prevention.

DEVICE PREPARATION AND DISPOSAL
Oxiplex/AP is for single use only. Do not reuse/re-sterilize.
1. Remove packaging containing the Oxiplex/AP filled syringe and applicator from box.
2. Inspect packaging for any damage. Do not use if damaged or open.
3. Using sterile technique, introduce syringes and applicator into the sterile operating field.
4. Remove cap from luer lock end of syringe. When using the applicator for peritoneal use, connect the gel applicator to the luer lock end of the syringe; rotate until firmly attached. (The same applicator is to be used for both syringes, if needed.)
5. After use, discard syringes, any remaining gel, and applicator. The used Oxiplex/AP device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

INTRAUTERINE SURGERY
1. Apply gel at the conclusion of the procedure after aspiration of all fluids and distention media.
2. Attach the syringe luer lock to the hysteroscope. Fill the hysteroscope with gel by compressing the syringe plunger until gel appears at the tip end of the hysteroscope.
3. Begin application of the gel at the fundus of the uterus. Gradually apply gel to completely fill the uterus and cervical canal by compressing the syringe plunger while slowly withdrawing the hysteroscope. See Figure 1.
4. Conclude the procedure according to the standard technique of the surgeon.

PELVIC GYNECOLOGICAL AND PERITONEAL SURGERIES
1. Apply gel at the conclusion of the procedure after aspiration of all irrigation fluid. It is recommended that the patient be placed in a reverse Trendelenburg position for the most efficient removal of residual irrigation fluid.
2. Cover all anatomical sites where adhesion prevention is desired with a single layer of Oxiplex/AP.* Applicator dispenses the gel in a "ribbon." Only a single-layer gel ribbon (about 2 mm in depth) should be used to coat the tissue surfaces for which adhesion prevention is intended. See Figure 2.
3. Use only enough gel to place a single layer of gel on the tissues as described. It is not necessary to use all 40mL of gel.
4. Do not reposition gel with probes or other instruments once it has been applied. If gel falls into a pool of irrigation fluid, its ability to adhere to peritoneal tissues may be compromised. Therefore, it should be removed from the peritoneal cavity and new gel should be applied to the site.
5. Conclude the procedure according to the standard technique of the surgeon.

*ADDITIONAL GEL APPLICATION INSTRUCTIONS: PELVIC GYNECOLOGICAL SURGERIES
1. Lift ovary away from pelvic sidewall and apply a single layer of gel to cover the ovarian fossa and posterior surface of the ovary.
2. Return ovary to normal anatomical position and apply a single layer of gel to cover the anterior portion of the ovary.
3. Apply a single layer of gel to cover the Fallopian tube, including the ampulla and the mesosalpinx.
4. Apply a single layer of gel to cover the lateral aspect of the uterus facing the adnexa.

Typically 15mL of gel is sufficient to cover a single adnexa and adjacent structures, including the ovarian fossa and lateral margin of the uterus.

ADVERSE REACTIONS
No device-related adverse reactions were reported in clinical studies.[1-4] Although not necessarily attributable to the use of Oxiplex/AP, the following adverse events have been reported: pain, fever, swelling, inflammation, foreign body reaction, and poor performance.

REFERENCES

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 46 29.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Contents: 2 - Syringe 20mL
1 - Applicator tip

AR

Document 12

الوصف

Oxiplex/AP هو جل شفاف، قابل للتدفق للاستخدام مرة واحدة فقط. الجل مزيج معقم قابل للامتصاص يتكون من أكسيد البولي إيثيلين (PEO) وكربوكسي ميثيل سليلوز الصوديوم (CMC). الجل مستقر الكالسيوم ومتساوي التوتر، وظهر في الدراسات قبل الإكلينيكية أنه يسمح التجويف البريتوني في غضون 30 يومًا.

الاستخدام المقصود

Oxiplex/APمخصص للاستخدام كحاجز ميكانيكي ضد تكوّن الالتصاقات.

دواعي الاستخدام

Oxiplex/AP مخصص للاستخدام كأداة مساعدة للجراحة داخل الرحم أو الغشاء البريتوني لتقليل وقائع الالتصاقات التي تقع بعد العمليات ومدى وقوعها وشدتها في موضع الجراحة.

موانع الاستخدام

لا تستخدم Oxiplex/AP عند وجود التهابات.

تحذيرات

لا تحقنه عن طريق الوريد.

الاحتياطات

يتم توريد Oxiplex/AP في حالة معقمة. امتنع عن الاستخدام بعد تاريخ انتهاء الصلاحية. لم يتم إجراء دراسات حول سلامة Oxiplex/AP وفعاليته في ظروف إعادة استخدام الجهاز و/أو أداة الاستخدام (للمطباق). قد تؤدي إعادة الاستخدام إلى حدوث ردة فعل مناعية و/أو إصابة بعدوى بسبب انتقال التلوث أو اتباع أساليب غير سليمة للتخزين و/أو المناولة. لم يخضع Oxiplex/AP للدراسة عند استخدامه مع غيره من منتجات منع الالتصاق، ولا في وجود العوامل الدوائية أو العوامل المانعة للنزيف المستخدمة داخل الغشاء البريتوني أو وسيط للاتفخ. لم يخضع Oxiplex/AP للتقييم عند استخدامه لدى الأطفال أو الأمهات الحوامل أو المرضعات. ولذلك ينبغي إرشاد المريضات لتجنب الحمل خلال دورة الحيض الأولى بعد استخدام Oxiplex/AP. لم يخضع Oxiplex/AP للتقييم عند استخدامه في وجود الأورام الخبيثة. لم يخضع Oxiplex/AP للتقييم عند استخدامه بعد فتح الأمعاء أو المثانة أو غيرها من الأعضاء الحشوية. لم يتم تقييم الجل عند وجود الصفراء. كما هو الحال مع أي مواد تتم زراعتها، قد تحدث ردود أفعال بفعل الأجسام الغريبة عند استخدام Oxiplex/AP. يؤدي وضع طبقات متعددة من الجل في التجويف البريتوني إلى زيادة خطر إزاحة الجل عن موضع الاستخدام المقصود، ولوحظ في بعض الأحيان وجود روابط من الجل خلال الجراحة المتابعة المتعلقة بالدراسة الإكلينيكية بعد مرور ٦ إلى ١٠ أسابيع. لم يرتبط الجل المترسب بظهور أي تبعات إكلينيكية.[3,4]

التخزين والمناولة: يتم التخزين في درجة حرارة الغرفة (2 - 25° مئوية).

طريقة توريد المنتج

يتم توريد Oxiplex/AP في حالة معقمة وفي صينية مشكّلة حرارية. تحتوي الصينية المشكّلة حرارياً من زوج من محاقن الجل بسعة ٢٠ مل وأداة استخدام (مطباق) للجل. لا يكون السطح الخارجي للعبوة والمحتويات الخارجية معقمًا. يتم تقديم ملصقات ذاتية الالتصاق لأغراض التوثيق. تقوم هذه الملصقات بتمييز المنتج ورقم تشغيلة الإنتاج.

إرشادات الاستعمال

التحضير للإجراء الطبي

يجب أن يقتصر استخدام Oxiplex/AP على الأطباء فقط. استخدم Oxiplex/AP وفقًا لإرشادات الاستخدام.

هناك عنصر خطورة يكمن في استخدام جميع الأجهزة الطبية. وللحد من المخاطر المتبقية المرتبطة باستخدام هذا الجهاز، يُنصح الطبيب بقراءة معلومات الاستخدام ومناقشتها مع المريض قبل استخدام الجهاز.

وفي حالة المرضى ذوي التاريخ المرضي المعروف للإصابة بفرط الحساسية تجاه Oxiplex/AP أو مكوناته، لا ينبغي إخضاعهم للعلاج باستخدام Oxiplex/AP.

يعمل الجل كحاجز ما بين الأنسجة لمنع تكوّن الالتصاقات. ويجب فصل الأنسجة باستخدام الجل للوقاية الفعالة من الالتصاق.

تحضير الجهاز والتخلص منه

Oxiplex/AP مخصص للاستخدام مرة واحدة فقط. امتنع عن إعادة استخدام المنتج أو إعادة تعقيمه.

1. قم بإزالة مواد التغليف المحتوية على محقن Oxiplex/AP المعبأ والمطباق من العلبة.
2. افحص مواد التغليف بحثًا عن أي تلف. وامتنع عن الاستخدام في حالة اكتشاف تلف في مواد التغليف أو انفتاحها.
3. استخدم أداة مُعقمًا لإدخال المحاقن والمطباق إلى حيز العملية الجراحية المعقم.
4. قم بإزالة الغطاء من طرف قفل لور الخاص بالمحقن، عند استخدام المطباق تحت الغشاء البريتوني، قم بتوصيل طرف قفل لور من المحقن، وقم بلفه حتى يتم توصيله بإحكام. (يجب استخدام نفس المطباق مع المحقن إذا لزم الأمر).
5. بعد الاستخدام، تخلص من المحاقن ومن أي جل متبقٍ ومن المطباق. ويجب مراعاة أن جهاز Oxiplex/AP قد يشكل خطرًا بيولوجيًا. اتبع الإرشادات العامة المطبقة على مستوى الدولة أو للمستوى المحلي أو المؤسسة الطبية للتخلص من المواد التي تشكل مخاطر بيولوجية.

الجراحة داخل الرحم

1. ضع الجل في ختام الإجراء الجراحي وذلك بعد تصريف كل السوائل ومسائط الانتفاخ.
2. قم بتوصيل قفل لور الخاص بالمحقن في منظار الرحم. املأ منظار الرحم بالجل بالضغط على مكبس المحقن حتى يظهر الجل في طرف منظار الرحم.
3. ابدأ استخدام الجل من قاعدة الرحم. ضع الجل بالتدريج بالرحم وقناة عنق الرحم بالكامل من طريق الضغط على مكبس المحقن مع سحب منظار الرحم. انظر شكل ١.
4. قم بتنفيذ الإجراء الطبي وفقًا للأسلوب القياسي الذي يتبعه الجراح.

جراحات طب النساء في الحوض وجراحات الغشاء البريتوني (الصفاق)

1. ضع الجل في ختام الإجراء الجراحي وذلك بعد تصريف كل سوائل الترويض. يُنصح بوضع المريضة في وضع ترندلنبورغ العكسي لإزالة سوائل التروية المتبقية بأكبر قدر من الفعالية.
2. قم بتغطية جميع المواقع التشريحية المطلوب وقايتها من الالتصاقات وذلك باستخدام طبقة واحدة من Oxiplex/AP*. يقوم المطباق بتوزيع الجل على شكل سرير يطوه. ينبغي استخدام حاقنة واحدة من الجل (بحجم يصل إلى ٢ مل) لتغطية أصغر الأنسجة المطلوب وقايتها من الالتصاقات. انظر شكل ٢.
3. استخدم قدرًا كافيًا من الجل فقط لوضع طبقة واحدة منه على الأنسجة كما هو موصوف. وليس من الضروري استخدام كل الجل البالغ حجمه ٤٠ مل.
4. امتنع عن تغيير وضع الجل بالمجسات أو غيرها من الأدوات نورضعه. في حالة دخول الجل في تجمع من سوائل الترويض قد تتأثر قدرته على الالتصاق بالأنسجة البريتونية، ولذلك ينبغي إزالته من التجويف البريتوني ووضع كمية جديدة من الجل على المرقع.
5. قم بتنفيذ الإجراء الطبي وفقًا للأسلوب القياسي الذي يتبعه الجراح.

* إرشادات إضافية لوضع الجل، جراحات طب النساء في الحوض

1. ارفع المبيض وابعده عن الجدار الجانبي للحوض وضع طبقة واحدة من الجل لتغطية تجويف الحوض والسطح الخلفي للمبيض.
2. قم بإرجاع المبيض إلى الوضع التشريحي العادي وضع طبقة واحدة من الجل لتغطية الجزء الأمامي من المبيض.
3. ضع طبقة واحدة من الجل لتغطية قناة فالوب، بما يشمل البوق ومسراق البوق.
4. ضع طبقة واحدة من الجل لتغطية جانب الرحم المواجه للملحقات.

وعادةً ما يكفي مقدار ١٥ مل من الجل لتغطية أحد الملحقات والتكوينات المجاورة لها، بما يشمل تجاويف المبيض والحافة الجانبية للرحم.

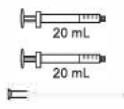
التفاعلات العكسية

لم ترد تقارير بوقوع أي تفاعلات عكسية ترتبط باستخدام الجهاز في الدراسات الإكلينيكية (السريرية).[1-4] وعلى الرغم من عدم ارتباط التفاعلات العكسية التالية بشكل مباشر باستخدام جهاز Oxiplex/AP، فقد وردت تقارير بحدوثها: الألم، والحمى، والتورم، والالتهاب، ورد الفعل ضد الأجسام الغريبة، وضعف الأداء.

مراجع

1. DiSpiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

المحتويات: 1 - حقنة سعة ٢٠ مل، 1 - سن أداة قابل للتثبيت



BG

ОПИСАНИЕ
Oxiplex/AP е прозрачен течен гел за еднократна употреба. Гелът е стерилна, резорбируема комбинация от полиетилен оксид (PEO) и натриева карбоксиметилцелулоза (CMC). Гелът е стабилизиран с калций и изотоничен и в предклинични проучвания е показано, че прочиства перитонеалната кухина в рамките на 30 дни.

ПРЕДНАЗНАЧЕНИЕ
Oxiplex/AP е предназначен за използване като механична бариера против образуването на адхезии.

ПОКАЗАНИЯ
Oxiplex/AP е показан за употреба като допълнение към интраутеринна или перитонеална хирургия за намаляване на появяването, степента и тежестта на постоперативни адхезии в хирургичната област.

ПРОТИВОПОКАЗАНИЯ
Не използвайте Oxiplex/AP при наличие на инфекция.

ПРЕДУПРЕЖДЕНИЯ
Да не се инжектира интравенозно.

ПРЕДПАЗНИ МЕРКИ
Oxiplex/AP се доставя стерилен. Да не се използва след датата на изтичане на срока на годност. Безопасността и ефикасността на Oxiplex/AP не са изследвани при условията на повторна употреба на изделието и/или апликатора. Повторното използване може да доведе до имунологична реакция и/или инфекция поради вторично замърсяване, неправилно съхранение и/или боравене. Oxiplex/AP не е проучван в съчетание с други продукти за предотвратяване на адхезии, при наличие на интраперитонеални медикаментозни или хемостатични активни вещества, или като средство за раздуване на кухината. Oxiplex/AP не е оценяван при деца или бременни/кърмещи жени. Поради тази причина, пациентите трябва да бъдат посъветвани да избягват зачатие по време на първия менструален цикъл след прилагането на Oxiplex/AP. Oxiplex/AP не е оценяван при наличие на злокачествени образувания. Oxiplex/AP не е оценяван след отваряне на червата, пилорния мехур или други вътрешни органи. Гелът не е оценяван при наличие на жлъчна течност. Като при всеки имплантиран материал, с Oxiplex/AP може да възникнат реакции към чуждото тяло. Нанасянето на повече от един слой от гела в перитонеалната кухина увеличава риска от отделяне на гела от целевата област на приложение, а в някои от тези случаи е наблюдавано малко количество остатъчен гел по време на процедурите за проследяване по клиничното проучване в период от 6 до 10 седмици по-късно. Остатъчният гел не е асоциран с клинични последици.[3,4]

СЪХРАНЕНИЕ И БОРАВЕНЕ
Да се съхранява на стайна температура (2 - 25 °C).

КАК СЕ ДОСТАВЯ
Oxiplex/AP се доставя стерилен в термоформована тава. Термоформованата тава съдържа две спринцовки по 20 ml с гел и един апликатор за гел. Външната част на опаковката и външното съдържание не са стерилни. Предоставени са самозалепващи се етикети за документационни цели. Етикетите идентифицират продукта и производствената партида.

ИНСТРУКЦИИ ЗА УПОТРЕБА
ПРЕДИ ПРОЦЕДУРАТА
Oxiplex/AP трябва да се използва само от лекари. Използвайте Oxiplex/AP в съответствие с инструкциите за употреба.
При използването на всички медицински изделия съществува известен риск. За да се сведе до минимум остатъчният риск, свързан с използването на това изделие, се препоръчва информацията за употреба да бъде прочетена от лекаря и обсъдена с пациента преди използване на изделието. Пациентите, които имат известна свръхчувствителност към Oxiplex/AP или неговите компоненти, не бива да бъдат третирани с Oxiplex/AP. Гелът служи като бариера между тъканите, за да предотврати образуването на адхезии. Тъканите трябва да бъдат разделени от гела за ефективна превенция на адхезии.

ПОДГОТОВКА НА ИЗДЕЛИЕТО И ИЗХВЪРЛЯНЕ
Oxiplex/AP е само за еднократна употреба. Да не се използва/стерилизира повторно.

1. Извадете опаковката, съдържаща спринцовката, пълна с Oxiplex/AP, и апликатора от кутията.
2. Отлепете опаковката за повреди. Не използвайте, ако е повредена или отворена.
3. Използвайки стерилна техника, въведете спринцовките и апликатора в стерилното оперативно поле.
4. Отстранете капачката от накрайника на спринцовката с луер-лок. При използване на апликатора за перитонеална употреба, свържете апликатора за гел с накрайника с луер-лок на спринцовката; завъртете, докато се фиксира добре. (При необходимост за двете спринцовки се използва същият апликатор.)
5. След употреба изхвърлете спринцовките, всякакъв остатъчен гел, и апликатора. Използваното изделие Oxiplex/AP може да представлява биологична опасност. Следвайте националните, местните или институционалните насоки за изхвърляне на биологично опасни материали.

ИНТРАУТЕРИННА ХИРУРГИЯ
1. Нанесете гел при завършване на процедурата, след като аспирирате всички течности и средства за раздуване.
2. Прикачете луер-лока на спринцовката към хистероскопа. Напълнете хистероскопа с гел, като натиснете буталото на спринцовката, докато на върха на хистероскопа се появи гел.
3. Започнете да нанасяте гела в дъното на матката. Постепенно нанасяйте гел, докато изцяло напълните матката и цервикалния канал, като натискате буталото на спринцовката и същевременно бавно изтегляте хистероскопа навън. Вижте Фигура 1.
4. Завършете процедурата според стандартната техника на хирурга.

ТАЗОВИ ГИНЕКОЛОГИЧНИ И ПЕРИТОНЕАЛНИ ХИРУРГИЧНИ ОПЕРАЦИИ
1. Нанесете гел при завършване на процедурата, след като аспирирате всичката ирригационна течност. Препоръчва се пациентът да бъде поставен в обърната позиция на Тренделенбург за най-ефикасно отстраняване на остатъчната ирригационна течност.
2. Покрийте всички анатомични области, където се желае превенция на адхезии, с единичен слой Oxiplex/AP.* Апликаторът нанася гела във формата на „панделка". Трябва да се използва само един слой панделка от гел (с дълбочина около 2 мм) за покриване на тъканните повърхности, при които се желае превенция на адхезии. Вижте Фигура 2.
3. Използвайте самотолкова гел, колкото е необходим за нанасяне на единичен слой гел върху тъканите, както е описано. Не е необходимо да използвате всичките 40 ml гел.
4. Не размесвайте гела със сонди или други инструменти, след като е бил нанесен. Ако гелът попадне в събрана ирригационна течност, неговата способност да прилепва към перитонеалните тъкани може да се влоши. Затова в такъв случай гелът трябва да се извади от перитонеалната кухина и в областта да се нанесе нов гел.
5. Завършете процедурата според стандартната техника на хирурга.

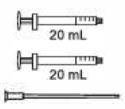
*ДОПЪЛНИТЕЛНИ ИНСТРУКЦИИ ЗА НАНАСЯНЕ НА ГЕЛ: ТАЗОВИ ГИНЕКОЛОГИЧНИ ХИРУРГИЧНИ ОПЕРАЦИИ
1. Повдигнете яйчника от тазовата страничната стена и нанесете единичен слой гел, който да покрие ямката на яйчника и постериорната повърхност на яйчника.
2. Върнете яйчника в нормалната анатомична позиция и нанесете единичен гел, за да покриете антериорната част на яйчника.
3. Нанесете единичен слой гел, за да покриете фалопиевата тръба, включително ампулата и мезосалпинкса.
4. Нанесете единичен слой гел, за да покриете латералната област на матката с лице към аднексите.
●Обикновено 15 ml гел са достатъчни да покрият един аднекс и непосредствените структури, включително ямките на яйчниците и латералната област на матката.

НЕБЛАГОПРИЯТНИ РЕАКЦИИ
В клиничните проучвания не са докладвани неблагоприятни реакции, свързани с изделието.[1-4] Макар и не непременно свързани с използването на Oxiplex/AP, са били докладвани следните неблагоприятни явления: болка, температура, подуване, възпаление, реакция към чуждо тяло и влошена ефективност.

Референции

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Съдържание:
2 – Спринцовка 20 ml
1 – Връх на апликатор



1a – Posizionare l'applicatore riempito di gel allineando l'apertura dell'applicatore su un margine della zona desiderata.
1b – Fare scorrere la punta dell'applicatore lateralmente sul sito premendo contemporaneamente il pistone della siringa per applicare un nastro di gel dello spessore di 2 mm.
1c – Dopo aver ricoperto completamente il sito una volta, non applicare ulteriore gel nello stesso sito.
2a,b,c – Se un singolo strato di gel non è sufficiente per ricoprire adeguatamente il sito, è possibile applicare ulteriori strati vicino al gel applicato in precedenza. Evitare di sovrapporre gli strati di gel aggiuntivi.

1a – Breng de met gel gevulde applicator in positie door de gleuf in de applicator te lijnen met een zijde van het gewenste gebied.
1b – Beweeg de tip van de applicator lateraal over het gebied terwijl u de stamper van de spuit ingedrukt houdt om een 2 mm dik gel-lint aan te brengen.
1c – Breng geen gel meer op het gebied aan nadat het gehele gebied met gel is bekleed.
2a,b,c – Als het gebied niet adequaat bekleed is met een enkele laag gel, kunnen er extra lagen worden aangebracht naast de eerder aangebrachte gel. Vermijd het aanbrengen van extra lagen boven op andere gel-lagen.

1a – Plasser den gel-fylte applikatoren ved å rette inn sporet på applikatoren over kanten på det ønskede stedet.
1b – Før applikatorspissen lateralt over stedet samtidig med at sprøytestempelet trykkes for å legge et 2 mm dypt bånd med gel.
1c – Etter at stedet er helt dekket en gang, skal det ikke legges mer gel på det stedet.
2a,b,c – Dersom stedet ikke er korrekt dekket av ett enkelt lag gel, kan nye lag påføres ved siden av den tidligere påførte gelen. Unngå å påføre ekstra lag med gel på toppen av et tannet.

1a – Ustawić napełniony żelem aplikator, umieszczając jego szczelinę nad krawędzią miejsca, gdzie będzie zastosowany żel.
1b – Przesunąć w poprzek końcówkę aplikatora nad miejscem zastosowania żelu, przyciskając tłok strzykawki w celu nałożenia wstęgi żelu o grubości 2 mm.
1c - Po całkowitym, jednokrotnym pokryciu miejsca, nie nakładać więcej żelu.
2a,b,c – Jeżeli miejsce nie zostanie właściwie pokryte przez jedną warstwę żelu, obok warstwy nałożonej poprzednio można nałożyć dodatkowe warstwy. Należy unikać nakładania na siebie dodatkowych warstw żelu.

1a – Posicionar o aplicador cheio de gel alinhando a ranhura do aplicador por cima de uma margem do local pretendido.
1b – Passar a ponta do aplicador lateralmente sobre o local, pressionando simultaneamente o êmbolo da seringa para aplicar uma fita de gel de 2 mm de espessura.
1c – Depois de cobrir totalmente o local uma vez, não aplicar gel adicional nesse local.
2a,b,c – Se o local não ficar adequadamente revestido com uma camada única de gel, podem aplicar-se camadas adicionais próximo do gel previamente aplicado. Evitar aplicar camadas adicionais de gel umas por cima das outras.

1a - Poziționați aplicatorul umplut cu gel prin alinierea canalului aplicatorului pe sau marginea locului dorit.
1b - Mișcați vârful aplicatorului în lateral peste locul respectiv în timp ce apăsați pistonul seringii, pentru a aplica o panglică de gel cu o adâncime de 2 mm.
1c - După ce ați acoperit o dată complet locul, nu mai aplicați gel suplimentar pe locul respectiv.
2a,b,c - Dacă locul nu este acoperit corespunzător printr-un singur strat de gel, straturile suplimentare pot fi aplicate lângă gelul aplicat anterior. Evitați aplicarea straturilor suplimentare de gel su prapuse.

1a – Aplikátor s gélom umiestnite tak, že štrbinu aplikátora zarovnajte s okrajom požadovaného miesta.
1b – 2 mm hrubú stužku gélu naneste potiahnutím aplikačnej špičky laterálne cez miesto a pritom stláčajte piest striekačky.
1c – Po jednom úplnom pokrytí miesta nenanášajte na to isté miesto ďalší gél.
2a,b,c – Ak miesto nie je dostatočne pokryté jednou vrstvou gélu, možno vedľa už naneseného gélu aplikovať ďalšie vrstvy. Nenanášajte viac vrstiev gélu na seba.

1a – Z gelom napolnjeni aplikator držite tako, da boreža aplikatorja poravnana z robom mesta nanosa.
1b – S konico aplikatorja bočno potegnite nad mestom nanosa in ob tem pritiskajte na bat brizgalke tako nanesite 2 mm debelo plast gela.
1c – Ko z enim slojem povsem prekrijete mesto nanosa, tja ne nanašajte več gela.
2a,b,c – Če mesto nanosa ni povsem prekrito s slojem gela, lahko dodatne sloje nanesete zraven že nanesenega gela. Izogibajte se nanašanju novih slojev gela enega na drugega.

1a - Postavite aplikator napunjen gelom tako što ćete poravnati otvor aplikatora preko ivice željene lokacije.
1b - Savijte vrh aplikatora bočno preko lokacije dok pritiskate klip šprica za nanošenje trake gela dubine od 2 mm.
1c - Posle potpunog pokrivanja lokacije jednim slojem, nemojte nanositi dodatni gel na to mesto.
2a,b,c - Ako lokacija nije adekvatno pokrivena jednim slojem gela, mogu se naneti dodatni slojevi pored prethodno nanetog gela. Izbegavajte nanošenje dodatnih slojeva gela jedan preko drugog.

1a – Placera den gelfyllda applikatorn genom att rikta in applikatoröppningen över kanten på det önskade området.
1b – För applikatorspetsen lateralt över området samtidigt som sprutkolven trycks in för att applicera en 2 mm tjock gelsträng.
1c – När väl området är helt täckt appliceras inget ytterligare gel.
2a,b,c – Om inte området täcks tillräckligt av ett enkelt gellager kan ytterligare lager appliceras intill tidigare applicerad gel. Undvik att applicera ytterligare gellager ovanpå de tidigare.

1a – Jeli le doldurulmuş aplikatörü, aplikatörün oyuğunu uygulama bölgesinin kenarına hizalayacak şekilde yerleştirin.
1b – 2 mm kalınlığında jel şeridi uygulamak için, bir yandan enjektörün pistonuna basınç uygulayarak, aynı anda aplikatörün ucunu uygulama bölgesi üzerinden yanlamasına geçirin.
1c – Uygulama bölgesini jel ile bir kez tamamen kapladıktan sonra, bu bölgeye daha fazla jel uygulamayın.
2a,b,c – Uygulama bölgesi tek tabaka jel ile yeterince kaplanmazsa, önceden uygulanan jelin yanına ilave tabakalar uygulanabilir. İlave jel tabakalarını birbiri üstüne gelecek şekilde uygulamaktan kaçının.

Figure 1 • شكل 1 • Фигура 1 • Obrázek 1 • Figur 1 • Abbildung 1 • Εικόνα 1 • Figura 1 • Kuva 1 • figure 1 • 1. ábra • Figua 1 • Afbeelding 1 • Figur 1 • Rysunek 1 • Figura 1 • Figua 1 • Obrázok 1 • Slika 1 • Slika 1 • Bild 1 • Şekil 1

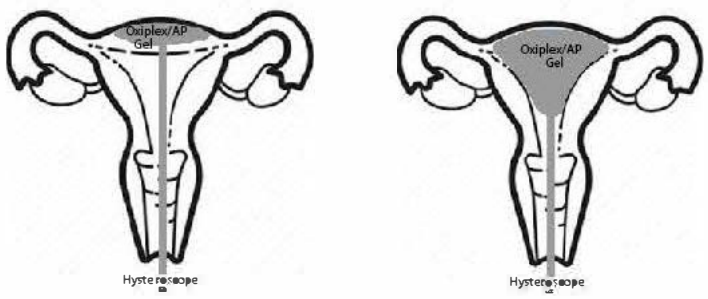
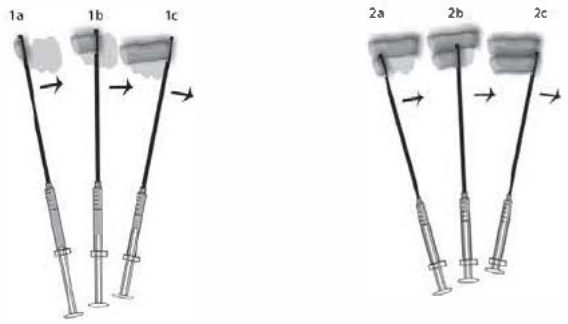


Figure 2 • شكل 2 • Фигура 2 • Obrázek 2 • figur 2 • Abbildung 2 • Εικόνα 2 • Figura 2 • Kuva 2 • figure 2 • 2. ábra • Figua 2 • 2. attēls • Afbeelding 2 • Figur 2 • Rysunek 2 • Figura 2 • Figura 2 • Obrázok 2 • Slika 2 • Slika 2 • Bild 2 • Şekil 2



1a – Position the gel-filled applicator by aligning the applicator slot over a margin of the desired site.
1b – Sweep the applicator tip laterally over the site while depressing the syringe plunger to apply a 2 mm deep ribbon of gel.
1c – After completely covering the site once, do not apply additional gel to that site.
2a, b, c – If the site is not adequately covered by a single layer of gel, additional layers can be applied next to previously applied gel. Avoid applying additional layers of gel on top of one another.

ضع أداة الوضع المليئة بالهلام بحذاة فتحة أداة الوضع على حافة الموضع المطلوب وتطلق طرف أداة الوضع أفقيًا فوق المكان أثناء الضغط على مكبس الحقنة لوضع شريط بعمق 2 ملم وسمك تغطية المكان بالكامل مرة واحدة، لا تضع هلام إضافي في هذا المكان. - 1a, b, c

وإذا لم يتم تغطية المكان بطريقة كافية بطبقة واحدة من الهلام، يمكن وضع طبقات إضافية بجانب الهلام الموضوع سابقًا. تجنب وضع طبقات من الهلام فوق بعضها البعض. - 2a, b, c

1a - Позиционирайте пълния с гел апликатор, като подравните отвора на апликатора над участък от желаната област.
1b - Плъзнете върха на апликатора латерално над областта, като същевременно натискате буталото на спринцовката, за да нанесете лентичка от гела с дълбочина 2 мм.
1c - След като покриете областта изцяло един път, не нанасяйте допълнителен гел в тази област.
2a, b, c - Ако областта не бъде адекватно покрита от един слой гел, може да се нанесат допълнителни слоеве гел до вече нанесения гел. Избягвайте нанасяне на допълнителни слоеве гел един върху друг.

1a – Aplikátor s gelem umístěte štěrbinou aplikátoru na okraj požadované oblasti.
1b – Nanášejte 2 mm silný proužek gelu tažením aplikačního hrotu laterálně přes požadované místo a současným stlačováním pístu stříkačky.
1c – Po pokrytí požadované oblasti nenanášejte na sebe další gel.
2a, b, c – Pokud místo není dostatečně pokryto jednou vrstvou gelu, je možné vedle dříve aplikovaného gelu nanést další vrstvy. Nenanášejte více vrstev gelu na sebe.

1a – Den gelfyldte applikator placeres ved at rette applikatoråbningen ind mod kanten af det ønskede område.
1b – Applikator spidsen stryges lateralt over området, mens injektionsprojektens stempel trykkes ned, så der påføres gel i et 2 mm tykt bånd.
1c – Når området er dækket helt én gang, skal der ikke påføres mere gel i det pågældende område.
2a, b, c – Hvis ét lag gel ikke er tilstrækkeligt til at dække hele området, kan der påføres yderligere lag gel ved siden af den allerede påførte gel. Undgå, at gelbåndene overlapper hinanden.

1a – Die Öffnung des mit Gel gefüllten Applikators mit einem Rand auf die ausgewählte Stelle ausrichten.
1b – Mit der Applikatorspitze lateral über den Situs streichen, dabei gleichzeitig den Spritzenkolben drücken, um einen 2 mm starken Streifen Gel aufzutragen.
1c – Sobald der gesamte Bereich einmal bedeckt ist, sollte an dieser Stelle kein weiteres Gel mehr aufgetragen werden.
2a, b, c – Falls die Oberfläche nicht ausreichend mit einer Gelschicht bedeckt ist, kann eine zusätzliche Schicht neben dem vorher aufgetragenen Gel appliziert werden. Dabei ist das Auftragen von einer Gelschicht auf eine andere zu vermeiden.

1a – Τοποθετήστε τον εφαρμογέα με τη γέλη, ευθυγραμμίζοντας τη σχισμή τ ου εφαρμογέα από νω από μια από τις πλευρές του επιθυμητού σημείου.
1b – Μετακινήστε πλευρικά το άκρο του εφαρμογέα πάνω από το σημείο, ενώ παράλληλα πιέζετε το έμβολο της σύριγγας, έτσι ώστε να εφαρμόσετε μια ταινία γέλης βάθους 2 mm.
1c – Αφού καλύψετε πλήρως το σημείο με μία στρώση, μην εφαρμόζετε άλλη ποσότητα γέλης στο σημείο αυτό.
2a, b, c – Εάν το σημείο δεν έχει καλυφθεί επαρκώς με μία στρώση γέλης, μπορείτε να εφαρμόσετε πρόσθετες στρώσεις δίπλα στην υπάρχουσα γέλη. Αποφύγετε την εφαρμογή πρόσθετων στρώσεων γέλης πάνω από τη ήδη υπάρχουσα.

1a – Acomode el aplicador lleno de gel alineándolo con la ranura del aplicador sobre un margen del sitio deseado.
1b – Pase la punta del aplicador lateralmente sobre el sitio mientras presiona el émbolo de la jeringa para aplicar una cinta de gel de 2 mm de espesor.
1c – Después de cubrir completamente el sitio una vez, no debe aplicarse más gel en ese lugar.
2a, b, c – Si el sitio no queda bien cubierto con una sola capa de gel, pueden aplicarse capas adicionales, junto al gel previamente aplicado. Evite aplicar capas adicionales sobre las ya aplicadas.

1a – Aseta geelillä täytetty aseti n paikalleen kohdista malla asettimen lovi kohdealueen reunan kanssa.
1b – Vedä asettimen kärkeä lateraalisesti kohdealueen päältä painaen samalla ruiskun mäntää, jolloin 2 mm paksu nauha geeliä levittyy kudoksen pintaan.
1c – Kun alue on peitetty kokonaan kerran, geeliä ei levitetä enempää samalle alueelle.
2a, b, c – Jos alue ei peity riittävästi yhdellä kerroksella geeliä, lisäkerroksia voidaan levittää aiemmin levitetyn geelin viereen. Vältä levittämästä lisäkerroksia jo levitetyn geelikerroksen päälle.

1a – Positionner l'applicateur rempli de gel en alignant la fente de l'applicateur sur une marge du site désiré.
1b – Passer l'embout de l'applicateur latéralement sur le site en appuyant sur le piston de la seringue pour appliquer un ruban de gel d'une épaisseur de 2 mm.
1c – Lorsque le site est complètement recouvert d'une couche de gel, il est inutile d'en ajouter.
2a, b, c – Si une couche unique de gel ne suffit pas pour bien recouvrir le site, il est possible d'ajouter du gel à côté de la couche existante. Les couches de gel ne doivent pas se chevaucher.

1a – Helyezze a géllel töltött adagolót a kívánt helyszínre úgy, hogy az adagoló horony beállításával.
1b – 2 mm vastag csík felvitelé hez a fecskendő dugattyúját folyamato san nyomva, oldal ról húzza el az adagoló hegyét az érintett terület felett.
1c – Az érintett terület egyszeri teljes befedése után ugyan arra a helyre több gélt ne vigyen fel.
2a, b, c – Ha a területet nem mindenhol borítja egy réteg gél, további rétegek vihetők fel közvetlenül a korábban felvitt gélréteg mellé. Kerülje a régi és újabb gélrétegek átfedését.

CS

POPIS
Oxiplex/AP je čirý tekutý gel na jednopoužití. Gel je sterilní vstřebatelná směs polyetylén oxidu (PEO) a sodné soli karboxymetyl-celulózy (CMC). Gel je stabilizován vápníkem, je izotonický a předklinické studie ukázaly, že je z dutiny břišní vstřebán do 30 dnů.

POUŽITÍ
Prostředek Oxiplex/AP je určen k použití jako mechanická překážka tvorby srůstů.

INDIKACE
Prostředek Oxiplex/AP je určen k použití jako doplněk nitroděložního nebo peritoneálního chirurgického zákroku za účelem snížení výskytu, rozsahu a závažnosti pooperačních srůstů v míst ě chirurgického zákroku.

KONTRAINDIKACE
Nepoužívejte gel Oxiplex/AP v přítomnosti infekce.

VAROVÁNÍ
Nezavádějte nitrožilně.

BEZPEČNOSTNÍ OPATŘENÍ
Prostředek Oxiplex/AP se dodává sterilní. Nepoužívejte po datu exspirace. Bezpečnost a účinnost prostředku Oxiplex/AP nebyla testována za podmínek nekopakovaného použití prostředku a/nebo aplikátoru. Opakované použití může vést k imunologické reakci a/nebo infekci způsobené křížovou kontaminací, nesprávným skladováním a/nebo manipulací. Prostředek Oxiplex/AP nebyl studován v kombinaci s jinými produkty pro prevenci srůstů, za přítomnosti intraperitoneálních léčivých látek či hemostatických látek a nejako distenčních médium. Při pravém Oxiplex/AP nebyl hodnocen u dětí ani u těhotných nebo kojících žen. Z toho důvodu je nutné pacientky poučit, aby se vyhnuly oplodnění během první menstruačního cyklu po aplikaci prostředku Oxiplex/AP. Prostředek Oxiplex/AP nebyl hodnocen v přítomnosti hroubných nádorů. Prostředek Oxiplex/AP nebyl hodnocen po otevření střeva, močového měchýře a jiných vnitřních orgánů. Gel nebyl hodnocen v přítomnosti žluči. Stejně jako u jiných implantovaných materiálů může u prostředku Oxiplex/AP dojít k odmítavé reakci organizmu. Aplikace více vrstev gelu v peritoneální dutině zvyšuje riziko uvolnění gelu z určeného místa aplikace a v některých případech bylo během klinické studie v rozmezí od zákroku po dobu následujících 6 až 10 týdnů pozorováno malé množství zbytkového gelu. Zbytkový gel nebyl spojen s klinickými následky.[3,4]

SKLADOVÁNÍ A MANIPULACE: Skladujte při pokojové teplotě (2–25 °C).

ZPŮSOB DODÁVÁNÍ
Prostředek Oxiplex/AP se dodává sterilní v tepelně tvarovaném podnosu. Tepelně tvarovaný podnos obsahuje dvě 20ml stříkačky s gelem a jeden aplikátor gelu. Vnější povrch balení a vnější obsah nejsou sterilní. Pro účely dokumentace jsou k dispozici samolepicí štítky. Štítky označují produkt a výrobní šarži.

NÁVOD K POUŽITÍ
PŘED ZPRACOVÁNÍ
Prostředek Oxiplex/AP mohou používat pouze lékaři. Prostředek Oxiplex/AP používejte dle pokynů v návodu k použití. S používáním veškerých zdravotnických prostředků je spojeno riziko. Za účelem minimalizace reziduálního rizika spojeného s používáním tohoto prostředku se doporučuje, aby si lékař před použitím prostředku přečetl informace o použití a projednal je s pacientkou.
Pacientky s anamnézou přecitlivělosti na prostředek Oxiplex/AP nebo jeho součásti nesmí být prostředkem Oxiplex/AP léčeny.
Gel slouží jako překážka mezi tkáněmi, aby se zabránilo tvorbě srůstů. Pro účinnou prevenci srůstů musí být tkáně odděleny gelem.

PŘÍPRAVA A LIKVIDACE PROSTŘEDKU
Prostředek Oxiplex/AP je určen k jednorázovému použití. Nepoužívejte opakovaně / neresterilizujte.
1. Vyjměte krabičky balení obsahující injekční stříkačku prostředku Oxiplex/AP a aplikátor.
2. Zkontrolujte, zda balení není poškozeno. Pokud je otevřené nebo poškozené, nepoužívejte ho.
3. Sterilní technikou zavěste jehly a aplikátor do sterilního operačního pole.
4. Sejměte uzávěr z konce stříkačky s hrotem Luer Lock. Pokud připerioneální použití používáte aplikátor, připojte aplikátor gelu ke koncistříkačky s hrotem Luer Lock; otáčejte, dokud nedojde k pevnému spojení. (V případě potřeby je nutné použít stejný aplikátor s obě ma stříkačkami.)
5. Po použití zlikvidujte stříkačky, zbývající gel a aplikátor. Použitý prostředek Oxiplex/AP může představovat biologicky nebezpečný materiál. Dodržujte národní, místní nebo nemocniční pokyny pro likvidaci biologických nebezpečných materiálů.

NITRODĚLOŽNÍ CHIRURGICKÉ ZÁKROKY
1. Gel aplikujte na závěr zákroku po odsátí veškerých tekutin a distenčního média.
2. Připojte hrot Luer Lock stříkačky k hysteroskopu. Naplňte hysteroskop gelem stlačováním pístu stříkačky, dokud se gel neobjeví na hrotu hysteroskopu.
3. Zahajte aplikaci gelu v místě fundu děložního. Postupně aplikujte gel, abyste zcela naplnili děložní a cervikální kanál stlačováním pístu stříkačky při pomalém vytahování hysteroskopu. Viz obrázek 1.
4. Zákrok dokončete standardní technikou podle zvyklostí daného chirurga.

PANEVNÍ GYNEKOLOGICKÉ A PERITONEÁLNÍ CHIRURGICKÉ ZÁKROKY
1. Gel aplikujte na závěr zákroku po odsátí veškerých tekutin použitých k proplachování. Pacientku se doporučuje umístit do reverzní Trendelenburgovy polohy, která zajistí co nejúčinnější odstraňování zbytkových tekutin použitých k proplachování.
2. Anatomické oblasti, ve kterých chcete zajistit prevenci srůstů, překryjte jednou vrstvou prostředku Oxiplex/AP.* Aplikátor dávkuje gel v „pásu". K pokrytí povrchu tkáně, na které chcete zajistit prevenci srůstů, je nutné použít pás gelu v jedné vrstvě (v hloubce přibližně 2 mm). Viz obrázek 2.
3. Použijte pouze množství gelu, které bude dostačovat ke umístění jedné vrstvy gelu na tkáně popsaným postupem. Není nutné použít všech 40 ml gelu.
4. Po aplikaci gel nepřemisťujte sondami ani žádnými dalšími nástroji. Pokud gel spadne do nahromaděné tekutiny použité k proplachování, může být schopnost přilnout k peritoneální tkáni m. Z toho důvodu je nutné ho z peritoneální dutiny odsát a na místo aplikovat nový gel.
5. Zákrok dokončete standardní technikou podle zvyklostí daného chirurga.

***DALŠÍ POKYNY K APLIKACI GELU: PANEVNÍ GYNEKOLOGICKÉ CHIRURGICKÉ ZÁKROKY**
1. Nadzvedněte vaječník mimo pánevní stěnu a aplikujte jednu vrstvu gelu, která pokryje vaječníkovou jamku a zadní povrch vaječníku.
2. Vraťte vaječník do normální anatomické polohy a aplikujte jednu vrstvu gelu, která pokryje přední část vaječníku.
3. Aplikujte jednu vrstvu gelu na pokrytí vejcovodu včetně ampule a mezosalpinxu.
4. Aplikujte jednu vrstvu gelu na pokrytí boční strany děložní směřující k adnexe.
15 ml gelu obvykle postačuje k pokrytí jedné adnexe a přilehlých struktur včetně vaječníkové jamky a posterior ního okraje děložní.

NEŽÁDOUCÍ ÚČINKY
V klinických studiích nebyly hlášeny žádné nežádoucí účinky související s prostředkem.[1-4] Přestože nebyly nutně přičítány použití prostředku Oxiplex/AP, byly hlášeny následující nežádoucí účinky: bolest, horečka, otok, zánět, odmítavá reakce organismu a špatný výkon.

LITERATURA

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20: 2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Obsah balení:
2 - 20 ml injekční stříkačka
1 - aplikátor

DA

BESKRIVELSE
Oxiplex/AP er en klar, flydende gel til engangsbrug. Gelen er en steril, resorberbar blanding af polyethylenoxid (PEO) og natrium carboxymethylcellulose (CMC). Gelen er calciumstabiliseret, isotonisk og har i prækliniske forsøg vist sig at resorberet fra peritonealkaviteten inden for 30 dage.

ANVENDELSE
Oxiplex/AP er beregnet til brug som en mekanisk barriere til adhæsionsdannelse.

INDIKATIONER

Oxiplex/AP er beregnet til brug som et hjælpemiddel i forbindelse med intrauterin eller peritoneal kirurgi til reduktion af incidens, udbredelse og sværhed af postoperative adhæsioner omkring operationsstedet.

KONTRAINDIKATIONER
Oxiplex/AP må ikke anvendes ved tilstedeværelsen af infektion.

ADVARSLER
Må ikke injiceres intravenøst.

FORHOLDSREGLER
Oxiplex/AP leveres sterilt. Må ikke anvendes efter udløbsdatoen. Sikkerheden ved og effektiviteten af Oxiplex/AP er ikke blevet undersøgt under forhold med genanvendelse af anordningen og/eller applikatoren. Genanvendelse kan medføre immunologisk respons og/eller infektion pga. krydskontaminering, ukorrekt opbevaring og/eller håndtering. Oxiplex/AP er ikke blevet undersøgt i kombination med andre adhæsionshæmmende produkter ved tilstedeværelse af intraperitoneale lægemidler eller hæmostatika eller som et udspilingsmiddel. Oxiplex/AP er ikke blevet evalueret hos børn eller gravide eller ammende kvinder. Patienter bør derfor rådes til at undgå graviditet under den første menstruationscyklus efter påføring af Oxiplex/AP. Oxiplex/AP er ikke blevet evalueret ved tilstedeværelse af maligniteter. Oxiplex/AP er ikke blevet evalueret efter åbning af tarmen, blæren eller andre indvoldsorganer. Gelen er ikke blevet evalueret ved tilstedeværelse af galde. Som ved ethvert implanteret materiale kan der opstå fremmedlegemereaktioner ved behandling med Oxiplex/AP. Påføring af flere lag med gel i den peritoneale legemshule øger risikoen for, at gelen løsner sig fra det tilsigtede påføringsområde, og i nogle af disse tilfælde, blev en lille smule resterende gel observeret i forbindelse med den kliniske undersøgelse, som blev udført som opfølgning til indgrebet 6 til 10 uger senere. Resterende gel blev ikke associeret med kliniske følgesygdomme.[3,4]

OPBEVARING OG HÅNDTERING: Opbevares ved stuetemperatur (2 - 25 °C).

LEVERING
Oxiplex/AP leveres sterilt i en termoformet bakke. Den termoformede bakke indeholder to 20 ml-sprøjter med gel og en gelapplikator. Pakningens udvendige overflade og indhold er ikke sterile. Der medfølger selvklæbende mærkater til dokumentationsformål. Mærkaterne identificerer produktet og det tilhørende batchnummer.

BRUGSANVISNING
FØR PROCEDUREN
Oxiplex/AP må kun anvendes af læger. Oxiplex/AP skal anvendes i henhold til brugsanvisningen.
Brugen af alle medicinske anordninger medfører en risiko. For at minimere restrisici associeret med denne anordning anbefales det, at brugsanvisningen læses af lægen og diskuteres med patienten, inden anordningen tages i brug.
Patienter, som har en sygehistorie med overfølsomhed over for Oxiplex/AP eller anordningens komponenter, bør ikke behandles med Oxiplex/AP.
Gelen fungerer som en barriere mellem vævsstrukturer for at forhindre adhæsionsdannelse. Vævet skal deles ved hjælp af gelen for at opnå en effektiv, adhæsionshæmmende virkning.

KLARGØRING OG BORTSKAFFELSE AF ANORDNINGEN
Oxiplex/AP er kun beregnet til engangsbrug. Må ikke genbruges/resteriliseres.
1. Fjern emballagen med den fyldte Oxiplex/AP-sprøjte og applikator fra æsken.
2. Efterse emballagen for beskadigelse. Tag ikke produktet i brug, hvis emballagen er beskadiget eller brudt.
3. Overfør sprøjtern e og applikatoren til det sterile operationsfelt vha. en steril teknik.
4. Fjern hætten fra sprøjtens luer-lås. Ved peritoneal brug skal gelapplikatoren kobles til sprøjtens luer-lås; drej den, indtil den er sikkert fastkoblet. (Den samme applikator skal anvendes til begge sprøjter, om nødvendigt).
5. Efter brug skal sprøjterne, evt. resterende gel og applikatoren kasseres. Den brugte Oxiplex/AP-anordning kan udgøre en miljøfare. Følg nationale, lokale og institutionelle retningslinjer vedr. bortskaffelse af miljøfarligt affald.

INTRAUTERIN KIRURGI
1. Påfør gelen ved indgrebets afslutning og efter aspiration af alle væsker og udspilingsmidler.
2. Kobl sprøjtens luer-lås til hysteroskopet. Fyld hysteroskopet med gel ved at trykke ned på sprøjtestemplet, indtil gelen kommer til syne i spidsen af hysteroskopet.
3. Start påføring af gelen ved fundus uteri. Påfør gelen gradvis: for at fylde uterus og livmoderkanalen fuldstændigt ved at trykke ned på sprøjtestemplet, mens hysteroskopet langsomt udtrækkes. Se figur 1.
4. Afslut indgrebet i henhold til kirurgens standardteknik.

BÆKKENGYNÆKOLOGISK OG PERITONEAL KIRURGI
1. Påfør gelen ved indgrebets afslutning og efter aspiration af alle skyllevæske. Det anbefales, at patienten placeres i omvendt Trendelenburgs leje for at opnå den mest effektive fjernelse af resterende skyllevæske.
2. Dæk alle anatomiske områder, hvor der ønskes en adhæsionshæmmende virkning, med et enkelt lag Oxiplex/AP.* Applikatoren dispenserer gelen i et "bånd". Kun et enkelt lag gelbånd (ca. 2 mm dybt) skal anvendes til at dække vævsoverflader, hvor der ønskes en adhæsionshæmmende virkning. Se figur 2.
3. Anvend kun nok gel til at placere et enkelt lag gel på vævsstrukturerne iht. ovenstående anvisninger. Det er ikke nødvendigt at anvende al gelen (40 ml).
4. Undlad at repositionere gelen ved hjælp af sonder eller andre instrumenter efter påføring. Hvis der falder gel ned i skyllevæske, kan gelens evne til at adhærere til peritoneale vævsstrukturer blive kompromiteret. Gelen bør derfor fjernes fra den peritoneale legemshule, hvorefter en ny portion gel skal påføres området.
5. Afslut indgrebet i henhold til kirurgens standardteknik.

***YDERLIGERE GELPÅFØRINGSANVISNINGER: BÆKKENGYNÆKOLOGISK KIRURGI**
1. Løft ovariet væk fra bækkensidevæggen, og påfør et enkelt lag gel for at dække fossa ovarica og ovariets posteriore overflade.
2. Returnér ovariet til organets normale, anatomiske placering, og påfør et enkelt lag gel for at dække ovariets anteriore del.
3. Påfør et enkelt lag gel for at dække tuba uterina, herunder ampulla og mesosalpinx.
4. Påfør et enkelt lag gel for at dække den laterale flade af uterus, der vender mod adnexa.

Normalt er 15 ml gel tilstrækkeligt til at dække en enkelt adnexa og tilstødende strukturer, herunder fossa ovarica og den laterale margen af uterus.

KOMPLIKATIONER
Der er ikke blevet rapporteret nogen anordningsrelaterede komplikationer i forbindelse med kliniske undersøgelser.[1,4] Selvom de ikke nødvendigvis kan forbindes med brugen af Oxiplex/AP, er følgende komplikationer blevet rapporteret: Smerte, feber, hævelse, inflammation, fremmedlegemereaktion og svækket præstationsevne.

KILDEHENVISNINGER

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Indhold: 2 - Injektionssprøjte 20 ml
1 - Applikatorspids

TR

ÜRÜN TANIMI
Oxiplex/AP, şeffaf, tek kullanımlık, akışkan bir jeldir. Jel, polietilen oksit (PEO) ve sodyum karboksimetilselülozun (CMC) steril, emilebilir bir bileşimidir. Jel, kalsiyum ile stabilize edilmiş olup, izotoniktir ve klinik öncesi çalışmalarda peritoneal boşluktan 30 gün içinde temizlendiği gösterilmiştir.

KULLANIM ALANI
Oxiplex/AP adezyon oluşumuna karşı mekanik bir bariyer olarak kullanılmak üzere tasarlanmıştır.

ENDİKASYONLARI
Oxiplex/AP cerrahi bölgede ameliyat sonrası adezyon sıklığını, derecesini ve şiddetini azaltmak için intrauterin veya peritoneal cerrahide yardımcı olarak kullanılmak üzere tasarlanmıştır.

KONTRAENDİKASYONLARI
Oxiplex/AP jeli enfeksiyon varlığında kullanmayın.

UYARILAR
Damar içine enjekte etmeyin.

ÖNLEMLER
Oxiplex/AP steril tedarik edilir. Son kullanma tarihinden sonra kullanmayın. Cihazın ve/veya aplikatörün tekrar kullanıldığı koşullar altında Oxiplex/AP güvenliği ve etkililiği araştırılmamıştır. Tekrar kullanım çapraz kontaminasyon, uygunsuz saklama ve/veya kullanımdan dolayı immünolojik tepkiye neden olabilir. Oxiplex/AP, diğer adezyon önleme ürünleriyle birlikte, intraperitoneal tıbbi ajanlar veya hemostatik ajanların varlığında veya bir distansiyon medyası olarak incelenmemiştir. Oxiplex/AP çocuklarda veya hamile ya da emziren kadınlarda değerlendirilmemiştir. Dolayısıyla, Oxiplex/AP uygulandıktan sonra ilk adet döngüsü sırasında hastalara gebelikten kaçınmaları tavsiye edilmelidir. Oxiplex/AP maligniteler varlığında değerlendirilmemiştir. Oxiplex/AP bağırsak, mesane veya diğer organların açılmasının ardından değerlendirilmemiştir. Jel, safra varlığında değerlendirilmemiştir. Herhangi bir implant materyalinde olduğu gibi, Oxiplex/AP ile yabancı madde reaksiyonları meydana gelebilir. Peritoneal boşluğa birden fazla jel tabakası uygulanması jelin istenen uygulama alanından kayma riskini artırır ve bu vakaların bir kısmında, 6 ila 10 hafta sonraki klinik takip çalışmaları sırasında küçük miktarda jel kalıntısı gözlenmiştir. Jel kalıntısı klinik sekellerle ilişkilendirilmemiştir.[3,4]

SAKLAMA VE KULLANIM: Oda sıcaklığında (2 - 25 °C) saklayın.

TEDARİK ŞEKLİ
Oxiplex/AP termoform bir tepside steril olarak sunulur. Termoform tepsi, iki adet 20 ml jel şırıngası ve bir jel aplikatörü içerir. Ambalajın dış kısmı ve dış içerikler steril değildir. Dokümantasyon amaçlı olarak kendinden yapışkanlı etiketler sunulur. Etiket, ürünü ve üretim partisini tanımlar.

KULLANMA TALİMATLARI
PROSEDÜR ÖNCESİ
Oxiplex/AP yalnızca doktorlar tarafından kullanılmak içindir. Oxiplex/AP kullanım talimatlarına göre kullanılmalıdır.
Tüm tıbbi cihaz kullanımlarında risk mevcuttur. Bu cihazın kullanımıyla bağlantılı kalıntı riskini minimuma indirmek için, kullanım bilgilerinin doktor tarafından okunması ve kullanımdan önce hasta ile görüşülmesi gerekir. Oxiplex/AP ürününe veya bileşenlerine aşırı hassasiyeti olan hastalara Oxiplex/AP uygulanmamalıdır. Jel adezyon oluşumunu önlemek için dokular arası bir bariyer görevi görür. Etkin adezyon önleme için doku jel ile ayrılmalıdır.

CİHAZ IN HAZIRLANMASI VE İMHASI
Oxiplex/AP yalnızca tek kullanımlıktır. Tekrar kullanmayın / tekrar sterilize etmeyin.
1. Oxiplex/AP ile dolu şırıngayı ve aplikatörü içeren ambalajı kutudan çıkarın.
2. Ambalajda herhangi bir hasar olup olmadığını kontrol edin. Ambalaj hasarlı veya açıksa kullanmayın.
3. Steril bir teknik kullanarak şırıngaları ve aplikatörü steril operasyon alanına uygulayın.
4. Şırınganın luer kilit ucundaki kapağı çıkarın. Aplikatörü peritoneal kullanıma dönük olarak kullanırken, jel aplikatörünü şırınganın luer kilit ucuna bağlayın; sıkıca bağlanana kadar döndürün. (Gerekirse aynı aplikatör her iki şırınga için kullanılacaktır.)
5. Kullanım sonrası şırıngaları, kalan tüm jeli ve aplikatörü atın. Kullanılmış Oxiplex/AP cihazı biyolojik tehlike oluşturabilir. Biyolojik tehlike oluşturan ürünün imhası için ulusal, yerel veya kurumsal kılavuzlerı takip edin.

INTRAUTERİN CERRAHİSİ
1. Tüm sıvıların ve distansiyon medyasının aspirasyonunun ardından prosedür sonunda jeli uygulayın.
2. Şırınga luer kilidini histeroskopa takın. Histeroskopun ucunda jel belirene kadar, şırınga pistonunu iterek histeroskopu jel ile doldurun.
3. Jeli uygulamaya uterus fundusundan başlayın. Uterusu ve servikal kanalı tamamen doldurmak için, bir yandan şırınga pistonunu iterken bir yandan da yavaşça histeroskopu geri çekerek jeli kademeli olarak uygulayın. Şekil 1'e bakın.
4. Prosedürü cerrahın standart tekniğine göre tamamlayın.

PELVİKİNEKOLOJİK VE PERİTONEAL CERRAHİLERİ
1. Tüm yıkama sıvısının aspirasyonunun ardından prosedür sonunda jeli uygulayın. Kalıntı yıkama sıvısının en verimli şekilde giderilmesi için hastanın ters Trendelenburg konumuna yerleştirilmesi önerilir.
2. Adezyon önlemenin gerekli olduğu tüm anatomik bölgelere tek bir Oxiplex/AP tabakasıyla kaplayın.* Aplikatör, jeli "şerit" halinde dağıtır. Adezyon önlemenin gerekli olduğu dokuları kaplamak için yalnızca tek bir katman jel şeridi (yaklaşık 2 mm derinliğinde) kullanılmalıdır. Şekil 2'ye bakın.
3. Dokulara, açıklanan şekilde yalnızca tek bir tabaka uygulamak için gerekecek miktarda jel kullanın. 40 ml jelin tamamının kullanılması zorunlu değildir.
4. Jel uygulandıktan sonra problarla veya diğer cihazlarla yerini değiştirmeyin. Jel, yıkama sıvısı havuzunun içine düşerse, peritoneal dokulara yapışma beceresi azalabilir. Bu yüzden, peritoneal boşluktaki jel giderilmeli ve bölgeye yeni jel uygulanmalıdır.
5. Prosedürü cerrahın standart tekniğine göre tamamlayın.

***EK JEL UYGULAMA TALİMATLARI: PELVİKİNEKOLOJİK CERRAHİLERİ**
1. Yumurtalığı pelvik yan duvardan kaldırarak uzaklaştırın ve yumurtalık fossasını ve yumurtalık arka yüzeyini kaplayacak şekilde tek bir jel tabakası uygulayın.
2. Yumurtalığı normal anatomik konumuna geri getirin ve yumurtalığın ön kısmını kaplayacak şekilde tek bir jel tabakası uygulayın.
3. Ampulla ve mezosalpinks de dahil olmak üzere fallop tüpünü kaplayacak şekilde tek bir jel tabakası uygulayın.
4. Uterusun adnekse bakan lateral bölgesini kaplayacak şekilde tek bir jel tabakası uygulayın.

Genellikle, yumurtalık fossası ve uterusun lateral kenarı dahil tek bir adneks ve komşu yapıları kaplamak için 15 ml jel yeterlidir.

ADVERS REAKSİYONLAR

Klinik çalışmalarda cihazla ilgili advers reaksiyon bildirilmemiştir.[1,4] Her ne kadar tam olarak Oxiplex/AP kullanımıyla ilişkilendirilemeyecek olsa da, şu advers reaksiyonlar bildirilmiştir: ağrı, ateş, şişme, enflamasyon, yabancı madde reaksiyonu ve kötü performans.

REFERANSLAR

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

İçindekiler: 2 - Şırınga 20 mL
1 - Aplikatör ucu

SV

BESKRIVNING
Oxiplex/AP är en klar, flytande gel för engångsbruk. Gelen är en steril, resorberbar kombination av polyetenoxid (PEO) och natriumkarboxymetylcellulosa (CMC). Gelen är kalciumstabiliserad, isoton och har i prekliniska studier visat sig försvinna från bukhålan inom 30 dagar.

AVSEDD ANVÄNDNING
Oxiplex/AP är avsedd för användning som mekaninsk barriär som prevention mot adherenser.

INDIKATIONER
Oxiplex/AP är avsedd att användas som komplement till intrauterin eller peritoneal kirurgi för att: minska incidensen, omfattningen och svårighetsgraden av postoperativa adherenser vid operationsplatsen.

KONTRAINDIKATIONER
Använd inte Oxiplex/AP då infektion föreligger.

VARNINGAR
Får inte ges som intravenös injektion.

FÖRSIKTIGHETSÅTGÄRDER
Oxiplex/AP levereras sterilt. Använd inte efter utgångsdatum. Oxiplex/AP säkerhet och effektivitet har inte studerats under återanvändning av produkt och/eller applikator. Återanvändning kan leda till infektion och/eller immunologisk reaktion på grund av korskontaminering, olämplig förvaring och/eller hantering. Oxiplex/AP har inte utvärderats för användning med andra produkter för adherensprevention, i samband med intraperitoneala läkemedel eller hemostatiska medel eller som vävexpanderande medium. Oxiplex/AP har inte utvärderats för användning hos barn eller gravida eller ammande kvinnor. Därför bör patienter rekommenderas att undvika befruktning under den första menstruationscykeln efter applicering av Oxiplex/AP. Oxiplex/AP har inte utvärderats för användning i samband med malignitet. Oxiplex/AP har inte utvärderats efter öppning av tarmen, urinblåsan eller andra viscerala organ. Gelen har inte utvärderats för användning i närvaro av galla. Som vid alla implanterade material kan kroppen reagera på de främmande föremålen. Flera lager gel i bukhålan ökar risken för att gel förflyttas från den avsedda användningsstället, och i några av dessa fall observerades en liten mängd resgel under det kliniska studieuppföljningsförfarandet 6 till 10 veckor senare. Återstående gel var inte associerad med följdsjukdomar.[3,4]

FÖRVARING OCH HANTERING: Förvara i rumstemperatur (2 – 25 °C).

LEVERANSSÄTT
Oxiplex/AP levereras sterilt i en termoformbricka. Termoformbrickan innehåller två 20 ml sprutor med gel och en gelapplikator. Utvändigt är förpackningen inte steril. Självhäftande etiketter till handhålls för dokumentation. Etiketterna identifierar produkten och produktionspartiet.

BRUKSANVISNING
FÖRE INGREPPET
Oxiplex/AP ska endas: användas av läkare. Använd Oxiplex/AP enligt bruksanvisningen. Risken är densamma som vid användningen av all medicinsk utrustning. För att: minimera de kvarstående risker som är förknippade med användningen av denna enhet rekommenderas att informationen för användning läses av läkaren och diskuteras med patienten innan du använder enheten. Patienter som är kända för att: vara överkänsliga mot Oxiplex/AP eller dess komponenter bör inte behandlas med Oxiplex/AP. Gelen fungerar som en barriär mellan vävnader för att: förhindra adhesionerfrån att: bildas. Vävnaden måste separeras med gel för effektivt adherensförebyggande.

ANVÄNDNING OCH BORTSKAFFNING AV ENHETEN
Oxiplex/AP är endast avsedd för engångsbruk. Återanvänd/omsterilisera inte.
1. Ta bort förpackningen innehållande Oxiplex/AP fylld spruta och applikator från boxen.
2. kontrollera att: förpackningen inte är skadad. Använd inte om den är skadad eller öppen.
3. För in sprutor och applikator i det sterila operationsområdet med steril teknik.
4. Ta bort locket från luerlåsänden på sprutan. När applikatorn används för peritoneal användning skall du ansluta gelapplikatorn till luerlåsänden på sprutan och rotera tills den är ordentligt fastsatt (Samma applikator ska användas för båda sprutorna, om det behövs).
5. Kassera sprutor, eventuell kvarvarande gel och applikator efter användning. Den använda Oxiplex/AP-enheten kan utgöra en biologisk risk. Följ nationella, lokala eller institutionella riktlinjer för bortskaffande av biohazard material.

INTRAUTERIN KIRURGI
1. Applicera gelen i slutet av proceduren efter du har sugit bort alla vätskor och avnadsexpanderande medel.
2. Fäst sprutens luerlås på hysteroskopet. Fyll hysteroskopet med gel genom att: komprimera sprutkolven tills gel blir synlig i hysteroskopets spetsände.
3. Börja applicera gelen vid livmoderns fundus. Applicera gelen gradvis tills hela livmodern och livmoderhalsen fylls genom att: komprimera sprutkolven samtidigt som hysteroskopet långsamt dras ut. Se bild 1.
4. Slutför det kirurgiska ingreppet enligt standardteknik av kirurgen.

PELVISK GINEKOLOGISK OCH PERITONEAL KIRURGI
1. Applicera gelen i slutet av proceduren efter du har sugit bort hela spolningsvätskan. Det rekommenderas att: patienten placeras i omvänd Trendelenburg-position för det mest effektiva avlägsnandet av kvarvarande spolningsvätskan.
2. Täck alla anatomiska platser där prevention av adhesion är önskvärt med ett enda lager Oxiplex/AP.* Applikatören fördelar gelen i ett" band". En dastett enda lager gel (ca 2 mm i djup) bör användas för att: belägga vävnadsytorna för vilka prevention av adhesion är avsedd. Se bild 2.
3. Använd endas: tillräcklig med gel för att: applicera ett enda lager gel på vävnaderna på det sätt: som beskrivs. Det är inte nödvändigt att: använda alla 40 ml av gel.
4. Flytta inte gelen med sonder eller andra instrument när den har applicerats. Om gel kommer i kontakt med en stor mängd av spolningsvätskan, kan dess förmåga att: sitta fast: vid peritoneala vävnader även tyras. Därför ska den avlägsnas från bukhålan och ny gel appliceras på platser i.
5. Slutför det kirurgiska ingreppet enligt standardteknik av kirurgen.

*** YTTERLIGARE INSTRUKTIONER FÖR GELAPPLIKATIONEN: PELVISK GYNEKOLOGISK KIRURGI**
1. Lyft bort äggstockarna från bäckenets sidovägg och applicera ett enda lager gel så att: det täcker äggstockarnas fossa och äggstockarnas bakre yta.
2. Sätt: tillbaka äggstockarna i normal anatomisk position och applicera ett enda lager gel så att: det täcker äggstockarnas främre del.
3. Applicera ett enda enda lager gel så att: det täcker äggledaren, inklusive ampulla och mesosalpinx.
4. Applicera ett enda lager gel så att: det täcker livmoderns laterala del mot adnexa.

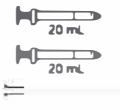
Vanligtvis är 15 ml gel tillräcklig för att: täcka en enda adnexa och intilliggande strukturer, innefattande äggstockarnas fossa och livmoderns sidomarginal.

KOMPLIKATIONER
Inga enhetrelaterade biverkningar har rapporterats i kliniska studier.[1-4] Även om det inte nödvändigtvis hänför sig till användningen av Oxiplex/AP har följande biverkningar rapporterats: smärta, feber, svullnad, inflammation, främmandekroppsreaktion och dåliga prestanda.

REFERENSER

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick. Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005 Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456

Innehåll: 2 - spruta 20 ml
1 - appliceringsspets



DE

Document 12

BESCHREIBUNG
Oxiplex/AP ist ein transparentes, fließfähiges Gel zum Einmalgebrauch. Es besteht aus einer sterilen, resorbierbaren Mischung aus Polyethylenoxid (PEO) und Natrium-Carboxymethylcellulose (CMC). Das Gel ist mit Kalzium stabilisiert und isotonisch. In vorklinischen Studien hat sich gezeigt, dass es in der Peritonealhöhle innerhalb von 30 Tagen abgebaut wird.

VERWENDUNGSZWECK
Oxiplex/AP ist als mechanische Barriere gegen Adhäsionsbildung indiziert.

INDIKATIONEN
Oxiplex/AP wird ergänzend zur intrauterinen oder peritonealen Chirurgie verwendet, um die Inzidenz, das Ausmaß und die Schwere postoperativer Adhäsionen an der OP-Stelle zu reduzieren.

KONTRAINDIKATIONEN
Oxiplex/AP darf nicht bei akuten Infektionen eingesetzt werden.

WARNHINWEISE
Nicht intravenös injizieren.

VORSICHTSMASSNAHMEN
Oxiplex/AP wird steril geliefert. Nicht nach Ablauf des Verfallsdatums verwenden. Die Sicherheit und Wirksamkeit von Oxiplex/AP wurden nicht unter Bedingungen einer Wiederverwendung des Produkts und/oder des Applikators untersucht. Die Wiederverwendung kann zu einer Immunreaktion und/oder Infektion infolge einer Kreuzkontamination, unsachgemäßer Lagerung und/oder Handhabung führen. Oxiplex/AP wurde nicht in Kombination mit anderen Produkten zur Adhäsionsvorbeugung bei Vorliegen intraperitonealer medizinischer oder hämostatischer Wirkstoffe oder als Dehnungsmittel untersucht. Oxiplex/AP wurde nicht an Kindern oder schwangeren Frauen oder stillenden Frauen evaluiert. Deshalb sollten die Patientinnen dazu angewiesen werden, während des ersten Menstruationszyklus nach der Anwendung von Oxiplex/AP eine Empfängnis zu verhüten. Oxiplex/AP wurde nicht bei Vorliegen von Malignitäten evaluiert. Oxiplex/AP wurde nicht nach einer Öffnung des Darms, der Blase oder anderer Eingeweide evaluiert. Das Gel wurde nicht bei Vorliegen von Gallenflüssigkeit evaluiert. Wie bei allen implantierten Materialien kann es bei Oxiplex/AP zu Fremdkörperreaktionen kommen. Das Auftragen von mehreren Gelschichten in der Peritonealhöhle erhöht das Risiko, dass das Gel sich von der geplanten Anbringungsstelle löst, und in manchen dieser Fälle wurde während der Nachuntersuchung im Rahmen der klinischen Studie 6 bis 10 Wochen später immer noch eine kleine Menge restlichen Gels beobachtet. Restliches Gel wurde nicht mit klinischen Spätfolgen assoziiert.[3,4]

LAGERUNG UND HANDHABUNG: Bei Raumtemperatur (2 - 25 °C) lagern.

LIEFERFORM
Oxiplex/AP wird steril in einer Thermoformschale geliefert. Die Thermoformschale enthält zwei mit Gel gefüllte 20-ml-Spritzen und einen Gelapplikator. Das Äußere der Verpackung und der äußere Inhalt sind nicht steril. Zu Dokumentationszwecken werden selbsthaftende Etiketten geliefert. Die Etiketten dienen der Identifizierung des Produkts und der Produktionscharge.

GEBRAUCHSANWEISUNG
VOR DEM VERFAHREN
Oxiplex/AP darf nur von Ärzten verwendet werden. Verwenden Sie Oxiplex/AP gemäß der Gebrauchsanweisung. Die Verwendung aller medizinischen Produkte birgt ein Risiko. Um das Restrisiko im Zusammenhang mit der Verwendung dieses Produkts zu minimieren, wird empfohlen, dass der Arzt die Gebrauchsinformationen liest und vor der Verwendung des Produkts mit dem Patienten bespricht. Patienten, deren Anamnese eine Überempfindlichkeit gegenüber Oxiplex/AP oder seinen Komponenten aufweist, sollten nicht mit Oxiplex/AP behandelt werden. Das Gel fungiert als Barriere zwischen Geweben, um die Bildung von Adhäsionen zu vermeiden. Gewebe muss durch Gel getrennt werden, um einer Adhäsion effektiv vorzubeugen.

VORBEREITUNG UND ENTSORGUNG DES PRODUKTS
Oxiplex/AP ist nur für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden/erneut sterilisieren.
1. Nehmen Sie die Verpackung, welche die mit Oxiplex/AP gefüllte Spritze und den Applikator enthält, aus dem Karton.
2. Überprüfen Sie die Verpackung auf Beschädigungen. Nicht verwenden, falls sie beschädigt oder geöffnet ist.
3. Überführen Sie die Spritzen und den Applikator unter Anwendung einer sterilen Technik in den sterilen Operationsbereich.
4. Nehmen Sie die Kappe vom Spritzende mit Luer-Anschluss. Bei der peritonealen Verwendung des Applikators verbinden Sie den Gelapplikator mit dem Spritzenende mit Luer-Anschluss; drehen Sie ihn solange, bis er fest sitzt. (Derselbe Applikator wird bei Bedarf für beide Spritzen verwendet.)
5. Spritzen, übriges Gel und den Applikator nach Gebrauch entsorgen. Das gebrauchte Oxiplex/AP kann eine biologische Gefahr darstellen. Befolgen Sie die nationalen, lokalen oder die Richtlinien Ihrer Einrichtung zur Entsorgung von biologischem Gefahrenmaterial.

INTRAUTERINE CHIRURGIE
1. Tragen Sie bei Abschluss des Verfahrens und nach Absaugung jeglicher Flüssigkeiten und Dehnungsmittel Gel auf.
2. Befestigen Sie den Luer-Anschluss der Spritze am Hysteroskop. Füllen Sie das Hysteroskop mit Gel, indem Sie den Spritzenkolben hinunterdrücken, bis Gel am Spitzenende des Hysteroskops erscheint.
3. Beginnen Sie mit dem Auftragen des Gels am Gebärmutterfundus. Tragen Sie das Gel schrittweise auf, um den Uterus und den Zervixkanal vollständig zu füllen, indem Sie den Spritzenkolben hinunterdrücken, während Sie das Hysteroskop langsam zurückziehen. Siehe Abbildung 1.
4. Schließen Sie das Verfahren gemäß der Standardtechnik des Chirurgen ab.

GYNÄKOLOGISCHE UND PERITONEALE OPERATIONEN IM BECKENBEREICH
1. Tragen Sie bei Abschluss des Verfahrens und nach Absaugung jeglicher Spülflüssigkeit Gel auf. Es wird empfohlen, die Patientin in eine umgekehrte Trendelenburg-Position zu bringen, um übrige Spülflüssigkeit am effektivsten zu entfernen.
2. Bedecken Sie alle anatomischen Stellen, wo einer Adhäsion vorgebeugt werden soll, mit einer einzelnen Schicht Oxiplex/AP.* Der Applikator gibt das Gel als „Band" ab. Es sollte nur eine einzelne Schicht des Gelbandes (etwa 2 mm tief) verwendet werden, um die Gewebeoberflächen zu bedecken, auf denen der Bildung einer Adhäsion vorgebeugt werden soll. Siehe Abbildung 2.
3. Verwenden Sie nur so viel Gel wie notwendig ist, um gemäß Beschreibung eine einzelne Gelschicht auf die Gewebe aufzubringen. Es ist nicht erforderlich, die gesamten 40 ml des Gels zu verwenden.
4. Positionieren Sie das Gel nicht neu mit Sonden oder anderen Instrumenten, sobald es aufgebracht ist. Wenn das Gel in eine Ansammlung von Spülflüssigkeit gerät, kann seine Haftfähigkeit an peritonealen Geweben beeinträchtigt sein. Deshalb sollte es aus der Peritonealhöhle entfernt und neues Gel sollte an der Stelle aufgetragen werden.
5. Schließen Sie das Verfahren gemäß der Standardtechnik des Chirurgen ab.

***WEITERE ANWEISUNGEN ZUM AUFBRINGEN DES GELS: GYNÄKOLOGISCHE OPERATIONEN IM BECKENBEREICH**
1. Heben Sie den Eierstock von der Seitenwand des Beckens an und tragen Sie eine einzelne Schicht des Gels auf, um die Fossa ovarica und die hintere Oberfläche des Eierstocks zu bedecken.
2. Bringen Sie den Eierstock wieder in die normale anatomische Position zurück und tragen Sie eine einzelne Schicht des Gels auf, um den vorderen Bereich des Eierstocks zu bedecken.
3. Bringen Sie eine einzelne Schicht des Gels auf, um den Eileiter zu bedecken, einschließlich der Ampulla und der Mesosalpinx.
4. Bringen Sie eine einzelne Schicht des Gels auf, um den lateralen zu den Adnexa zeigenden Aspekt des Uterus zu bedecken.

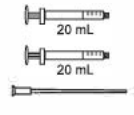
Gewöhnlich sind 15 ml des Gels ausreichend, um ein einzelnes Adnexum und angrenzende Strukturen zu bedecken, einschließlich der Fossa ovarica und des lateralen Randes des Uterus.

NEBENWIRKUNGEN
Es wurden keine mit dem Produkt in Verbindung stehenden Nebenwirkungen in klinischen Studien berichtet.[1-4] Obwohl sie nicht notwendigerweise der Verwendung von Oxiplex/AP zuzuschreiben sind, wurden die folgenden unerwünschten Ereignisse berichtet: Schmerzen, Fieber, Schwellung, Entzündung, Fremdkörperreaktion und schlechte Funktionsfähigkeit.

REFERENZEN

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick. Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005 Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Inhalt: 2 - Spritze 20 ml
1 - Applikatorspitze



EL

ΠΕΡΙΓΡΑΦΗ
Η γέλη Oxiplex/APείναι μια διαφανής, ρευστή γέλη μίας χρήσης. Η γέλη αποτελείται από ένα σύστεμα, απορροφήσιμο μίγμα από πολυαιθυλενοξείδιο (PEO) και νατριούχο καρβοξυμεθυλοκυτταρίνη (CMC). Η γέλη σταθεροποιείται με αυτόματο τρόπο, είναι ισότονη και, όπως έχει αποδειχθεί σε προκλινικές μελέτες, αποβάλλεται από την περιτοναϊκή κοιλότητα εντός 30 ημερών.

ΧΡΗΣΗ ΓΙΑ ΤΗΝ ΟΠΟΙΑ ΠΡΟΟΡΙΖΕΤΑΙ
Το Oxiplex/AP προορίζεται για χρήση ως μηχανικός φραγμός στον αχηματισμό συμφύσεων.

ΕΝΔΕΙΞΕΙΣ
Το Oxiplex/AP προορίζεται για χρήση ως βοήθημα σε ενδομητριακές ή περιτοναϊκές χειρουργικές επεμβάσεις με σκοπό τη μείωση της επίπτωσης, της έκτασης και της σοβαρότητας των μετεγχειρητικών συμφύσεων στη χειρουργική τοιχοθεσία.

ΑΝΤΕΝΔΕΙΞΕΙΣ
Μη χρησιμοποιείτε τη γέλη Oxiplex/APπαρουσία λοίμωξης.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ
Να μη χορηγείται με ενδοαρτηριακή ένεση.

ΠΡΟΦΥΛΑΞΕΙΣ
Το Oxiplex/AP παρέχεται αποστειρωμένο. Να μην χρησιμοποιείται πέραν της ημερομηνίας λήξης. Η ασφάλεια και η αποτελεσματικότητα του Oxiplex/AP δεν έχουν μελετηθεί από συνθήκες επαναληπτικής χρήσης του ιατροτεχνολογικού προϊόντος ή/και του εφαρμογέα. Η επαναληπτική χρήση μπορεί να οδηγήσει σε ανοσολογική απόκριση ή/και λοίμωξη λόγω διαταραγμένης ισόλυσης, σκλήρυνσης φλάγκης ή/και χειρισμού. Το Oxiplex/APδεν έχει μελετηθεί σε συνδυασμό με άλλα προϊόντα αποφυγής των συμφύσεων, παρουσία ενδοπεριτοναϊκών φαρμακευτικών ουσιών ή αμοσταγμάτων ή ως μεσοδιαστολής. Το Oxiplex/AP δεν έχει αξιολογηθεί σε παιδιά ή σε γυναίκες που είναι έγκυοι ή θηλάζουν. Επομένως, πρέπει να συνιστάται οι ασθενείς να αποφεύγουν τη σύλληψη κατά τον πρώτο κύκλο της εμμηνόρροιας μετά την εφαρμογή του Oxiplex/AP. Το Oxiplex/AP δεν έχει αξιολογηθεί παρουσία νεκρωθείων. Το Oxiplex/APδεν έχει αξιολογηθεί δια τα από διάνοιξη του εντέρου, της κύστης ή άλλων σπλαχνικών οργάνων. Η γέλη δεν έχει αξιολογηθεί παρουσία χολής. Όπως και με κάθε άλλο εμφυτευμένο υλικό, ενδέχεται να προκύψουν παράσειτες σε ξένο σώμα με το Oxiplex/AP. Η εφαρμογή πολλαπλών στρώσεων γέλης στην περιτοναϊκή κοιλότητα αυξάνει τον κίνδυνο αποκόλλησης της γέλης από την τοποθεσία εφαρμογής για την οποία προορίζεται και, σε ορισμένες από αυτές τις περιπτώσεις, μια μικρή ποσότητα υπολειμματικής γέλης παρατηρήθηκε κατά την διάρκεια παρακολούθησης στα πλαίσια της κλινικής μελέτης 6 με 10 εβδομάδες αργότερα. Η υπολειμματική γέλη δεν σχετιζόταν με κλινικά επακόλουθα.[3,4]

ΦΥΛΑΞΗ ΚΑΙ ΧΕΙΡΙΣΜΟΣ: Φυλάσσετε σε θερμοκρασία δωματίου (2 - 25 °C).

ΤΡΟΠΟΣ ΠΑΡΟΧΗΣ
Το Oxiplex/AP παρέχεται αποστειρωμένο σε θερμοφορμοσφραγισμένο δίσκο. Ο θερμοφορμοσφραγισμένος δίσκος περιέχει δυο σύριγγες γέλης των 20 mL και έναν εφαρμογέα γέλης. Το εξωτερικό τμήμα της συσκευασίας και τα εξωτερικά περιεχόμενα δεν είναι αποστειρωμένα. Οι αυτοκόλλητες ετικέτες παρέχονται για σκοπούς τεκμηρίωσης. Οι ετικέτες λειτουργούν αναγνωριστικά για το προϊόν και την παρτίδα του προϊόντος.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
ΠΡΙΝ ΑΠΟ ΤΗΝ ΕΠΕΜΒΑΣΗ
Το Oxiplex/AP πρέπει να χρησιμοποιείται μόνο από γιατρούς. Χρησιμοποιείτε το Oxiplex/AP σύμφωνα με τις οδηγίες χρήσης. Η χρήση άλλων των ιατροτεχνολογικών προϊόντων ενέχει κινδύνους. Για να ελαχιστοποιηθούν οι υπολειμματικοί κίνδυνοι που σχετίζονται με τη χρήση αυτού του ιατροτεχνολογικού προϊόντος, συνιστάται στον/στην ιατρό να διαβάζει τις πληροφορίες σχετικά με τη χρήση και να τις συζητάει με τον/την ασθενή πριν από τη χρήση του ιατροτεχνολογικού προϊόντος. Το Oxiplex/AP δεν πρέπει να χρησιμοποιείται σε ασθενείς που έχουν ιστορικό υπερευαισθησίας στο Oxiplex/AP ή τα συστατικά του. Η γέλη λειτουργεί ως φραγμός μεταξύ των ιστών με σκοπό την αποφυγή του σχηματισμού συμφύσεων. Για αποτελεσματική αποφυγή των συμφύσεων, οι ιστοί πρέπει να διαχωρίζονται με τέτοιους με γέλη.

ΠΡΟΕΤΟΙΜΑΣΙΑ ΚΑΙ ΑΠΟΡΡΙΨΗ ΤΟΥ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟΥ ΠΡΟΪΟΝΤΟΣ
Το Oxiplex/AP προορίζεται για μια χρήση μόνο. Μην χρησιμοποιείτε ξανά/μην επαναποστειρώνετε.
1. Αφαιρέστε τη συσκευασία που περιέχει τη σύριγγα που είναι πληρωμένη με το Oxiplex/AP και τον εφαρμογέα από το κουτί.
2. Επιθεωρήστε τη συσκευασία για τυχόν ζημιές. Μη χρησιμοποιείτε εάν διαπιστωθούν ζημιές ή ότι η συσκευασία είναι ανοιχτή.
3. Με αποστειρωμένη τεχνική, εισάγετε τις σύριγγες και τον εφαρμογέα στο στείρο χειρουργικό πεδίο.
4. Αφαιρέστε το πώμα από το άκρο της σύριγγας με τη θήκη luer lock. Όταν χρησιμοποιείτε τον εφαρμογέα για περιτοναϊκή χρήση, συνδέστε τον εφαρμογέα της γέλης με το άκρο της σύριγγας με τη θήκη luer lock. Περιστρέψτε μέχρι να συνδεθεί σταθερά. (Ο ίδιος εφαρμογέας μπορεί να χρησιμοποιηθεί και για τις δύο σύριγγες, εάν χρειαστεί.)
5. Μετά τη χρήση, απορρίψτε τις σύριγγες, τυχόν υπολειμματική γέλη και τον εφαρμογέα. Το ιατροτεχνολογικό προϊόν Oxiplex/AP που χρησιμοποιήθηκε ενδέχεται να αποτελεί βιολογικό κίνδυνο. Ακολουθείτε τις εθνικές, τοπικές ή ιδρυματικές κατευθυντήριες οδηγίες για την απόρριψη του βιοεπικίνδυνου υλικού.

ΕΝΔΟΜΗΤΡΙΑΚΗ ΧΕΙΡΟΥΡΓΙΚΗ ΕΠΕΜΒΑΣΗ
1. Εφαρμόστε γέλη κατά την ολοκλήρωση της επέμβασης, αφού έχει γίνει αναρρόφηση όλων των υγρών και των υλικών διαστολής.
2. Συνδέστε τη θήκη luerlock της σύριγγας με το μητροσκόπιο. Γεμίστε το μητροσκόπιο με γέλη, πιέζοντας το έμβολο της σύριγγας, έως ότου εμφανιστεί γέλη στο άκρο του μητροσκοπίου.
3. Ξεκινήστε την εφαρμογή της γέλης στον θόλο της μήτρας. Εφαρμόστε σταδιακά τη γέλη μέχρι να γεμίσει τελείως η μήτρα και η κοιλότητα της πυέλου, πιέζοντας το έμβολο της σύριγγας ενώ αποσύρετε αργά το μητροσκόπιο. Δείτε την Εικόνα 1.
4. Ολοκληρώστε τη χειρουργική επέμβαση σύμφωνα με την πρότυπη τεχνική του/της χειρουργού.

ΠΥΕΛΙΚΕΣ ΓΥΝΑΙΚΟΛΟΓΙΚΕΣ ΚΑΙ ΠΕΡΙΤΟΝΑΪΚΕΣ ΧΕΙΡΟΥΡΓΙΚΕΣ ΕΠΕΜΒΑΣΕΙΣ
1. Εφαρμόστε γέλη κατά την ολοκλήρωση της επέμβασης, αφού έχει γίνει αναρρόφηση όλου του υγρού καταιονισμού. Συνιστάται να τοποθετείται η/η ασθενής σε ανάστροφη θέση Trendelenburg, με την οποία επιτυγχάνεται η πιο αποτελεσματική αφαίρεση του υπολειμματικού υγρού καταιονισμού.
2. Καλύψτε όλες τις ανατομικές τοποθεσίες όπου επιθυμείτε να αποφύγετε τον σχηματισμό συμφύσεων με μια στρώση Oxiplex/AP.* Ο εφαρμογέας χορηγεί τη γέλη σε μορφή "καρδέλας". Καλύψτε τις επιφάνειες των ιστών εκείνων όπου θέλετε να αποφύγετε τον σχηματισμό συμφύσεων με μια μόνο στρώση γέλης (βάθους 2 mm περίπου). Δείτε την Εικόνα 2.
3. Χρησιμοποιήστε μόνο όση γέλη χρειάζεται για να καλύψετε τους ιστούς με μια μονή στρώση γέλης όπως περιγράφεται. Δεν είναι απαραίτητο να χρησιμοποιήσετε και τα 40 mL της γέλης.
4. Μην επανατοποθετείτε τη γέλη με μηλεί ή άλλα όργανα αφού έχει ήδη γίνει εφαρμογή της. Εάν πέσει γέλη σε ένα σημείο όπου έχει συσσωρευθεί υγρό καταιονισμού, η ικανότητά της να επικολληθεί σε περιτοναϊκούς ιστούς μπορεί να διακυβευτεί. Επομένως πρέπει να την αφαιρέσετε από την περιτοναϊκή κοιλότητα και να εφαρμόσετε εκ νέου γέλη στην τοποθεσία.
5. Ολοκληρώστε τη χειρουργική επέμβαση σύμφωνα με την πρότυπη τεχνική του/της χειρουργού.

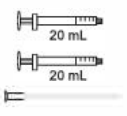
***ΕΠΙΠΡΟΣΘΕΤΕΣ ΟΔΗΓΙΕΣ ΓΙΑ ΤΗΝ ΕΦΑΡΜΟΓΗ ΓΕΛΗΣ: ΠΥΕΛΙΚΕΣ ΓΥΝΑΙΚΟΛΟΓΙΚΕΣ ΧΕΙΡΟΥΡΓΙΚΕΣ ΕΠΕΜΒΑΣΕΙΣ**
1. Ανασηκώστε και απομακρύνετε την ωοθήκη από το πλευρικό τοίχωμα της πυέλου και εφαρμόστε μια μονή στρώση γέλης για να καλύψετε τον ωοθηκικό βόθρο και την οπίσθια επιφάνεια της ωοθήκης.
2. Επαναφέρετε την ωοθήκη στην κανονική ανατομική της θέση και εφαρμόστε μια μονή στρώση γέλης για να καλύψετε το πρόσθιο τμήμα της ωοθήκης.
3. Εφαρμόστε μια μονή στρώση γέλης γύρω από τη σάλπιγγα, συμπεριλαμβανομένης της ληκύθου και της μεσοσάλπιγγας.
4. Εφαρμόστε μια μονή στρώση γέλης γύρω από την πλάγια όψη της μήτρας που βλέπει προς τα εξαρτήματα. Συνήθως, 15 mL γέλης επαρκούν για την κάλυψη ενός εξαρτήματος και των παρακείμενων δομών του, συμπεριλαμβανομένου του ωοθηκικού βόθρου και του πλάγιου περιβωλίου της μήτρας.

ΑΝΕΠΙΘΥΜΗΤΕΣ ΑΝΤΙΔΡΑΣΕΙΣ
Κατά τις κλινικές μελέτες δεν αναφέρθηκαν ανεπιθύμητες αντιδράσεις που σχετίζονται με το ιατροτεχνολογικό προϊόν.[1-4] Αν και δεν σχετίζονται απαραιτήτως με τη χρήση του Oxiplex/AP, οι ακόλουθες ανεπιθύμητες αντιδράσεις έχουν αναφερθεί: άλγος, πυρετός, οίδημα, φλεγμονή, αντίδραση σε ξένο σώμα και κακή απόδοση.

ΒΙΒΛΙΟΓΡΑΦΙΑ

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no.4:462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, A J Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Περιεχόμενα: 2 - Σύριγγα του 20 mL
1 - Άκρο απλικατέρ



SR

Document 12

OPIS
Oxiplex/AP je prozirni tečni gel za jednokratnu upotrebu. Ovaj gel je sterilna, resorptivna kombinacija polietilen oksida (PEO) i natrijum karboksimetilceluloze (CMC). Gel je stabilizovan kalcijumom, izotoničan, i dokazano je u preliminarnim studijama da čisti peritonealnu šupljinu u roku od 30 dana.

NAMENA
Oxiplex/AP je namenjen za upotrebu kao mehanička barijera za formiranje adhezije.

INDIKACIJE
Oxiplex/AP je namenjen da se koristi kao dodatak intrauterinarnoj ili peritoneumskoj hirurgiji radi smanjenja pojave, stepena i težine postoperativnih adhezija na operativnom mestu.

KONTRAINDIKACIJE
Nemojte koristiti Oxiplex/AP ukoliko postoji infekcija.

UPOZORENJA
Nemojte doziratiintravenozno.

MERE PREDOSTROŽNOSTI
Oxiplex/AP se isporučuje sterilan. Nemojte ga koristiti posle isteka roka upotrebe. Nije izvršena provera bezbednosti i efikasnosti Oxiplex/AP u uslovima ponovnog korišćenja sredstva i/ili aplikatora. Ponovna upotreba možedovesti do imunološkog odgovora i/ili infekcije zbog unakrsne kontaminacije, nepravilnog skladištenja i/ili rukovanja. Oxiplex/AP nije ispitivan u kombinaciji sa drugim preparatima za sprečavanje adhezije, u prisustvu intraperitonealnih lekovitih sredstava ili hemostatskih sredstava ili kao sredstvo za distenziju (nadimanje). Oxiplex/AP nije ispitivan kod dece ili trudnica, niti kod žena dojilja. Stoga pacijentima treba savetovati da izbegavaju začeće tokom prvog menstrualnog ciklusa nakon primene Oxiplex/AP. Oxiplex/AP nije procenjen u prisustvu maligniteta. Oxiplex/AP nije procenjen nakon otvaranja creva, bešike ili drugih visceralnih organa. Ovaj gel nije procenjen u prisustvu žučiKao i kod drugih materijala za implantaciju, reakcije na strana tela mogu se pojaviti i kod Oxiplex/AP. Primena višestrukih slojeva gela u peritonealnoj šupljini povećava rizik da se gel odvoji od predviđene lokacije primene, a u nekim od ovih slučajeva zabeležena je mala količina zaostalog gela tokom postupka praćenja kliničke studije 6 do 10 nedelja kasnije. Zaostali gel nije povezan sa kliničkim posledicama.[3,4]

SKLADIŠTENJE I RUKOVANJE
Čuvati na sobnoj temperaturi (2 - 25 °C).

NAČIN ISPORUKE
Oxiplex/AP se isporučuje sterilan u termički zaptivenom pakovanju. Termički zaptiveno pakovanje sadrži dva šprica od 20 ml gela i jedan aplikator gela. Spoljašnji deo pakovanja i spoljni sadržaj nisu sterilni. Samolepljive nalepnice su namenjene za korišćenje u dokumentaciji. Etikete pokazuju proizvod i proizvodnu seriju.

UPUTSTVO ZA UPOTREBU
PREDPROCEDURA
Oxiplex/AP smeju da koriste samo lekari. Koristite Oxiplex/AP u skladu sa uputstvima za upotrebu. Rizik postoji kod upotrebe svih medicinskih sredstava. Da bi se smanjio rezidualni rizik povezan sa upotrebom ovog sredstva, preporučuje se da lekar pročita informacije o upotrebi i razgovara sa pacijentom pre upotrebe sredstva. Kod pacijenata za koje je poznato da su preosetljivi na Oxiplex/AP ili njegove komponente ne treba koristiti Oxiplex/AP. Gel služi kao barijera između tkiva koja služi za sprečavanje pojave adhezije. Tkiva se moraju odvojiti gelom da bi se efikasno sprečila adhezija.

PRIPREMA SREDSTVA I ODLAGANJE
Oxiplex/AP je samo za jednokratnu upotrebu. Nemojte ponovo koristiti/ponovo sterilisati.
1. Uklonite ambalažu sa kutije u kojoj se nalazi špric napunjen Oxiplex/AP i aplikator.
2. Proverite da pakovanje nije oštećeno. Nemojte koristitiako je pakovanje oštećeno ili otvoreno.
3. Vodeći računa o sterilnosti, unesite špriceve i aplikatore u sterilno polje rada.
4. Uklonite poklopac sa kraja šprica gde se nalazi „luer lock" navoj. Kada koristite aplikator za peritonealnu upotrebu, priključite aplikator gela na deo šprica gde se nalazi „luer lock" navoj; okrećite dok potpuno ne pričvrstite. (Isti aplikator se koristi za oba šprica, ako je potrebno.)
5. Nakon upotrebe, odložite špriceve, preostali gel i aplikator u otpad. Iskorišćeno sredstvo Oxiplex/AP može biti biološki opasan otpad. Pridržavajte se nacionalnih, lokalnih ili institucionalnih smernica za odlaganje bioloških opasnih materija.

INTRAUTERINARNA HIRURGIJA
1. Nanesite gel po završetku procedure aspiracije svih tečnosti i sredstava za nadimanje.
2. Postavite „luer lock" navoj na histeroskop. Histeroskop napunite gelom pritiskajući klip šprica dok se ne pojavi gel na vrhu histeroskopa.
3. Započnite aplikaciju gela na fundusu materice. Postepeno aplicirajte gel za potpuno punjenje materice i cervikalnog kanala pritiskanjem klipa šprica dok polako povlačite histeroskop. Pogledajte sliku 1.
4. Završite proceduru standardnom tehnikom hirurga.

PELVIČNE GINEKOLOŠKE I PERITONEALNE OPERACIJE
1. Nanesite gel po završetku procedure nakon aspiracije sve tečnosti za irigaciju. Preporučuje se da se pacijent postavi u obrnuti Trendelenburgov položaj za najefikasnije uklanjanje ostatka tečnosti za irigaciju.
2. Pokrijte sve anatomske lokacije gde je poželjno sprečavanje adhezije jednim slojem Oxiplex/AP.* Aplikator nanosi gel u vidu „trake". Za nanošenje na površinu tkiva gde je potrebno sprečavanje adhezije, treba koristiti samo jednoslojnu gel traku (dubine oko 2 mm). Pogledajte sliku 2.
3. Koristite samo onoliko gela koliko je potrebno za jedan sloj gela na tkivu kako je opisano. Nije neophodno koristiti celokupnu količinu od 40 ml gela.
4. Nemojte ponovo nanositi gel sondama ili drugim instrumentima nakon jednog nanošenja. Ako gel upadne u posudu sa tečnošću za irigaciju, može se umanjiti njegova sposobnost prijanjanja za peritonealna tkiva. Zato ga treba ukloniti iz peritonealne šupljine, a novi gel treba naneti na to mesto.
5. Završite proceduru standardnom tehnikom hirurga.

***DODATNA UPUTSTVA ZA PRIMENU GELA: PELVIČNE GINEKOLOŠKE OPERACIJE**
1. Podignite jajnik od zida karlice i nanesite jedan sloj gela kako biste pokrili jamicu jajnika i površinu zadnje strane jajnika.
2. Vratite jajnik u normalni anatomski položaj i nanesite jedan sloj gela na prednji deo jajnika.
3. Nanesite jedan sloj gela na jajovod, uključujući i ampulu i mezosalpinks.
4. Nanesite jedan sloj gela na lateralni deo materice okrenut ka jajnicima i jajovodima (adneksa). Obično je 15 ml gela dovoljno da pokrije jednu adneksu i susedne strukture, uključujući jamicu jajnika i bočnu ivicu materice.

NEŽELJENE REAKCIJE
U kliničkim studijama nisu zabeležene nikakve neželjene reakcije vezane za ovo sredstvo.[1-4] Iako se nužno ne pripisuju upotrebi sredstva Oxiplex/AP, prijavljeni su sledeći neželjeni događaji: bol, temperatura, otok, upala, reakcija na strano telo i loše performanse.

REFERENCE

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, A J Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Sadržaj:
2 – Špric 20ml
1 –Vrh aplikatora

SL

OPIS
Oxiplex®/AP je prozoren, tekoč gel za enkratno uporabo. Je sterilna, absorptivna kombinacija polietilen oksida (PEO) in natrijeve karboksimetilceluloze (CMC). Gel je stabiliziran s kalcijem in izotoničen, predklinične raziskave pa so pokazale, da se iz trebušne votline izloči v 30 dneh.

UPORABA
Oxiplex/AP se uporablja kot mehanska pregrada za nastanek adhezij.

INDIKACIJE
Oxiplex/AP se uporablja kot pripomoček pri intrauterinih ali peritonealnih kirurških posegih za zmanjšanje pojavnosti, obsega in stopnje pooperativnih adhezij na mestu operacije.

KONTRAINDIKACIJE
Gela Oxiplex®/AP ne uporabljajte v prisotnosti okužbe.

OPOZORILA
Ni primerno za intravenozno vbrizganje.

VARNOSTNI UKREPI
Oxiplex/AP je dobavi sterilen. Ne uporabljajte po poteku roka uporabnosti. Varnost in učinkovitost gela Oxiplex/AP nista bili preučeni pri ponovni uporabi pripomočka in/ali aplikatorja. Ponovna uporaba lahko privede do imunološkega odziva in/ali okužbe zaradi navzkrižne kontaminacije, nepravilnega shranjevanja in/ali navnanja. Oxiplex/AP ni bil preučen v kombinaciji z drugimi sredstvi za preprečevanje adhezij, o bi prisotnosti intraperitonealnih medicinskih sredstev ali hemostatskih sredstev ali kot sredstvo za distenzijo. Oxiplex/AP ni bil analiziran pri otrocih, nosečnicah ali doječih materah. Zato je bolnicam treba svetovati, da preprečijo zanositev v prvem menstrualnem ciklusu po nanosu gela Oxiplex/AP. Oxiplex/AP ni bil analiziran v prisotnosti malignih tvorb. Oxiplex/AP ni bil analiziran po odprtju črevesja, mehurja ali drugih notranjih organov. Gel ni bil analiziran v prisotnosti žolča. Kot pri vsakem drugem vsajenem materialu se lahko pri Oxiplex/AP pojavijo reakcije zaradi tujka. Nanos več plasti gela v peritonealno votlino povečuje tveganje premika gela s predvidenega mesta nanosa, v nekaterih primerih pa so majhno količino ostanka gela opazili pri kontrolnem posegu v okviru klinične študije 6 do 10 tednov pozneje. Ostanek gela ni bil povezan s kliničnimi posledicami.[3,4]

SHRANJEVANJE IN RAVNANJE Shranjujte na sobni temperaturi (2-25 °C).

NAČIN DOBAVE
Oxiplex/AP je dobavljen sterilen na toplotno oblikovanem pladnju. Toplotno oblikovan pladenj vsebuje dve 20-mililitrski brizgali z gelom in en aplikator gela. Zunanji sterilni bralec in zunanja vsebina nista sterilni. Samolepilne etikete so priložene za dokumentacijske namene. Z etiketami je zagotovljena identifikacija proizvoda in proizvodne serije.

NAVODILA ZA UPORABO
PRED POSEGOM
Oxiplex/AP lahko uporabljajo samo zdravniki. Oxiplex/AP uporabljajte v skladu z navodili za uporabo. Pri uporabi vseh medicinskih pripomočkov obstaja določeno tveganje. Za zmanjšanje preostalega tveganja, povezanega z uporabo tega pripomočka, je priporočljivo, da zdravnik pred uporabo pripomočka prebere informacije za uporabo in se o njih pogovori z bolnikom. Bolnikov znano anamnezo preobčutljivosti za Oxiplex/AP ali njegove sestavne dele ne smete zdraviti z gelom Oxiplex/AP. Gel služi kot pregrada med tkivi za preprečevanje nastanka adhezij. Za učinkovito preprečevanje adhezij je treba tkivo ločiti z gelom.

PRIPRAVA IN ODLAGANJE PRIPOMOČKA
Oxiplex/AP je namenjen samo enkratni uporabi. Ni za ponovno uporabo/ponovno sterilizacijo.
1. Iz škatle vzemite ovojnino, ki vsebuje brizgalko, napolnjeno z gelom Oxiplex/AP, in aplikator.
2. Ovojnino preglejte in preverite, ali je kakor koli poškodovana. Če je poškodovana ali odprta, pripomočka ne uporabite.
3. Z uporabo sterilne tehnike vnesite brizgalki in aplikator v sterilno kirurško polje.
4. Snemite kapico s konca brizgalke z nastavkom luer lock. Pri uporabi aplikatorja za peritonealne posege povežite aplikator gela s koncem brizgalke z nastavkom luer lock: vrtite ga, dokler ni trdno pritrjen. (Po potrebi uporabite isti aplikator za obe brizgalki.)
5. Brizgalki, morebitni preostanek gela in aplikator po uporabi zavrzite. Uporabljeni pripomoček Oxiplex/AP lahko predstavlja biološko nevarnost. Upoštevajte nacionalne, lokalne oziroma institucionalne smernice za odlaganje biološko nevarnega materiala.

INTRAUTERINI POSEG
1. Gel nanesite na koncu posega po aspiraciji vseh tekočin in sredstva za distenzijo.
2. Brizgalko z nastavkom luer lock pritrdite na histeroskop. Histeroskop napolnite z gelom tako, da stiskate bat brizgalke, dokler se gel ne pojavi na koničnem histeroskopa.
3. Nanos gela začnite pri maternični svodu. Postopoma nanašajte gel, da popolnoma napolnite maternico in cervikalni kanal, in sicer tako, da stiskate bat brizgalke, pri tem pa histeroskop počasi izvlečete. Glejte sliko 1.
4. Posto pek zaključite v skladu s standardno tehniko kirurga.

MEDENIČNI GINEKOLOŠKI IN PERITONEALNI POSEGI
1. Gel nanesite na koncu posega po aspiraciji vse tekočine za izpiranje. Za najučinkovitejšo aspiracijo preostale tekočine za izpiranje je priporočljivo, da bolnika namestite v obratni Trendelenburgov položaj.
2. Vsa anatomska mesta, na katerih želite preprečiti adhezije, prekrijte z eno plastjo gela Oxiplex/AP.* Aplikator dovede gel v obliki »traku«. Na površine tkiv, na katerih je predvideno preprečevanje adhezij, lahko nanesete samo eno plast traku v obliki gela (približno 2 mm na debelo). Glejte sliko 2.
3. V skladu z navodili na tkivu uporabite samo toliko gela, da bo zadostovalo za nanos ene plasti gela. Nit eba, da porabite vseh 40 ml gela.
4. Po nanosu gela pazite, da ga ne premaknete s sondami ali drugimi instrumenti. Če gel zaide v nakopičeno tekočino za izpiranje, je lahko ogrožena njegova sposobnost spremljanja peritonealnih tkiv. Zatoga je treba odstraniti iz peritonealne votline in na zadevno mesto nanesti nov gel.
5. Posto pek zaključite v skladu s standardno tehniko kirurga.

***DODATNA NAVODILA ZA NANOS GELA: MEDENIČNI GINEKOLOŠKI POSEGI**
1. Jajčnik privadignite od stranske stene medenice in nanesite eno plast gela, da prekrijete ložo jajčnika in posteriorno površino jajčnika.
2. Jajčnik namestite nazaj v običajen anatomski položaj, nato pa nanesite eno plast gela, da prekrijete anteriorni del jajčnika.
3. Nanesite eno plast gela, da prekrijete jajcevod, vključno z ampulo in mezosalpinksom.
4. Nanesite eno plast gela, da prekrijete stransko del maternice, obrnjen proti adneksom.

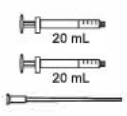
Običajno 15 ml gela zadostuje za prekrivanje posameznih adneksov in okolnih strukturi, vključno z ložo jajčnika in stranskim robom maternice.

STRANSKI UČINKI
Pri kliničnih študijah ni bilo v zvezi s pripomočkom zabeleženih nobenih stranskih učinkov.[1-4] Navajajo naslednje neželene dogodke, ki pa jih ni mogoče nujno pripisati uporabi gela Oxiplex/AP: bolečine, vročina, otekanje, vnetje, reakcija na tujek in slabša učinkovitost.

REFERENCE

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceed (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplew AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456

Vsebina: 2 - brizga 20 ml
1 - konica aplikatorja



ES

Document 12

DESCRIPCION
Oxiplex/AP es un gel fluido transparente para un solo uso. Es una combinación absorbible estéril de óxido de polietileno (POE) y carboximetilcelulosa sódica (CMC). Se encuentra estabilizado con calcio, es isotónico y se ha comprobado en estudios preclínicos que desaparece de la cavidad peritoneal antes de transcurridos 30 días.

USO INDICADO
Oxiplex/AP está diseñado para utilizarse como barrera mecánica ante la formación de adhesiones.

INDICACIONES
Oxiplex/AP está diseñado para utilizarse como accesorio en cirugía intrauterina o peritoneal para reducir la incidencia, extensión y gravedad de adhesiones posoperatorias en el sitio quirúrgico.

CONTRAINDICACIONES
No utilice Oxiplex/AP en presencia de infección.

ADVERTENCIAS
No inyectar por vía intravenosa.

PRECAUCIONES
Oxiplex/AP se suministra estéril. No lo utilice después de la fecha de caducidad. No se ha estudiado la seguridad ni la eficacia de Oxiplex/AP en condiciones de reutilización del dispositivo o del aplicador. La reutilización puede provocar una respuesta inmunológica o una infección debido a la contaminación cruzada o a la manipulación o al almacenamiento inadecuados. Oxiplex/AP no se ha estudiado en combinación con otros productos de prevención de adhesiones, en presencia de agentes medicinales intraperitoneales ni agentes hemostáticos, ni como medio de distensión. Oxiplex/AP no se ha evaluado en niños ni mujeres embarazadas o lactantes. Por lo tanto, debe aconsejarse a las pacientes que eviten el embarazo durante el primer ciclo menstrual tras aplicar Oxiplex/AP. Oxiplex/AP no se ha evaluado en presencia de cánceres. Oxiplex/AP no se ha evaluado tras la apertura del intestino, vejiga u otros órganos viscerales. No se ha evaluado el gel en presencia de bilis. Al igual que sucede con cualquier material implantado, puede haber reacciones a cuerpos extraños con Oxiplex/AP. La aplicación de varias capas de gel en la cavidad peritoneal aumenta el riesgo de que se desprenda el gel del sitio de aplicación deseado, y en algunos casos, se observó una pequeña cantidad de gel residual durante el procedimiento de seguimiento del estudio clínico de 6 a 10 semanas después. El gel residual no se asoció con secuelas clínicas.[3,4]

ALMACENAMIENTO Y MANIPULACION: Guárdelo a temperatura ambiente (2 - 25 °C).

PRESENTACION
Oxiplex/AP se suministra estéril en una bandeja termoformada. La bandeja termoformada contiene dos jeringas de 20 ml de gel y un aplicador de gel. El exterior del paquete y el contenido exterior no son estériles. Se suministran etiquetas autoadhesivas a efectos de documentación. Las etiquetas identifican el producto y el lote del producto.

INSTRUCCIONES DE USO
ANTES DEL PROCEDIMIENTO
Solo los médicos utilizarán Oxiplex/AP. Use Oxiplex/AP conforme a las instrucciones de uso.
El riesgo es inherente al uso de todo dispositivo médico. Para minimizar el riesgo residual asociado al uso de este dispositivo, se recomienda que el médico lea la información de uso y la discuta con el paciente antes de utilizar el dispositivo.
Los pacientes que se sabe que tienen una historia de hipersensibilidad a Oxiplex/AP o a sus componentes no deben recibir tratamiento con Oxiplex/AP.
El gel sirve de barrera entre los tejidos para prevenir la formación de adhesiones. El tejido debe separarse con gel para prevenir la formación efectiva de adhesiones.

PREPARACION Y ELIMINACION DEL DISPOSITIVO
Oxiplex/AP es de un solo uso. No lo reutilice ni reesterilice.
1. Extraiga el paquete que contiene la jeringa cargada de Oxiplex/AP y el aplicador de la caja.
2. Inspeccione el paquete por si presentara daños. No lo utilice si está dañado o abierto.
3. Con una técnica estéril, introduzca las jeringas y el aplicador en el campo de operación estéril.
4. Retire el tapón del extremo luer lock de la jeringa. Cuando utilice el aplicador para uso peritoneal, conecte el aplicador de gel al extremo luer lock de la jeringa; gire hasta que esté bien acoplado. (El mismo aplicador se utilizará para ambas jeringas, si es necesario.)
5. Deseche las jeringas, el gel sobrante y el aplicador, después de su uso. El dispositivo Oxiplex/AP usado puede ser un peligro biológico. Siga las directrices nacionales, locales o institucionales para desechar material biopeligroso.

CIRUGIA INTRAUTERINA
1. Aplique gel al concluir el procedimiento después de aspirar todos los líquidos y los medios de distensión.
2. Acople el luer lock de la jeringa al histeroscopio. Rellene el histeroscopio con gel comprimiendo el émbolo de la jeringa hasta que aparezca gel en el extremo de la punta del histeroscopio.
3. Empiece a aplicar el gel en el fondo uterino. Aplique gradualmente el gel hasta rellenar por completo el útero y el endocérvix comprimiendo el émbolo de la jeringa mientras retira lentamente el histeroscopio. Consulte la figura 1.
4. La intervención quirúrgica concluye conforme a la técnica estándar del cirujano.

CIRUGIAS PERITONEALES Y GINECOLOGICAS PELVICAS
1. Aplique gel al concluir el procedimiento después de aspirar todos los líquidos de irrigación. Se recomienda colocar al paciente en una posición antiTrendelenburg para eliminar mejor el líquido de irrigación residual.
2. Cubra todos los sitios anatómicos donde se desea prevenir la adhesión con una sola capa de Oxiplex/AP.* El aplicador dispensa el gel en una "franja". Solo debe utilizarse una sola franja de gel de una capa (de unos 2 mm de espesor) para revestir las superficies de tejido de los que se desea prevenir la adhesión. Consulte la figura 2.
3. Use solo el gel suficiente para colocar una sola capa de gel sobre los tejidos descritos. No es necesario utilizar los 40 ml de gel.
4. No vuelva a colocar gel con sondas u otros instrumentos una vez que se haya aplicado. Si cae gel en un charco de líquido de irrigación, su capacidad de adherirse a tejidos peritoneales puede verse comprometida. Por lo tanto, debe retirarse de la cavidad peritoneal y debe aplicarse gel nuevo en el sitio.
5. La intervención quirúrgica concluye conforme a la técnica estándar del cirujano.

***INSTRUCCIONES ADICIONALES PARA LA APLICACION DE GEL: CIRUGIAS GINECOLOGICAS PELVICAS**
1. Levante el ovario de la pared pélvica y aplique una sola capa de gel para cubrir la fosa ovárica y la superficie posterior del ovario.
2. Vuelva a colocar el ovario a la posición anatómica normal y aplique una sola capa de gel para cubrir la parte anterior del ovario.
3. Aplique una sola capa de gel para cubrir la trompa de Falopio, incluido la ampolla y el mesosálpinx.
4. Aplique una sola capa de gel para cubrir la cara lateral del útero frente a los anexos.

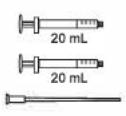
Normalmente 15 ml de gel son suficientes para cubrir un solo anexo y las estructuras adyacentes, incluida la fosa ovárica y el margen lateral del útero.

REACCIONES ADVERSAS
No se ha informado de reacciones adversas relativas al dispositivo en estudios clínicos.[1-4] Se ha informado de los siguientes acontecimientos adversos, aunque no se atribuyen necesariamente al uso de Oxiplex/AP: dolor, fiebre, inflamación, reacción a cuerpos extraños y mal funcionamiento.

REFERENCIAS

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceed (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplew AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456

Contenido: 2 - Jeringa de 20 ml
1 - Aplicador



FI

KUVAUS
Oxiplex/AP-geeli on kirkas:a, kertakäyttöistä nes:emäistä geeliä. Geeli on steriiliä resorboituva yhdistelmä polyetyleenioksidia (PEO) ja natriumkarboksimetyyliselluloosaa (CMC). Geeli on kalsiumstabiloitu, isotoninen ja sen on todettu esikliinisissä tutkimuksissa puhdistavan vatsaontelon 30 päivän sisällä.

KÄYTTOTARKOITUS
Oxiplex/AP on tarkoitettu käytet:äväksi mekaanisena es:eenä adheesion muodostumiselle.

INDIKAATIOT
Oxiplex/AP on tarkoitettu käytet:äväksi apuvälineenä kohdunsisäisissä tai vatsakalvon leikkauksissa leikkauksen jälkeisten adheesioiden esiintymis:iheyden, laajuuden ja vakavuuden vähentämisessä leikkausalueella.

KONTRAINDIKAATIOT
Oxiplex/AP-geeliä ei saa käyttää infektion esiintyessä.

VAROITUKSET
Ei saa injisoida suonensisäses:i.

VAROTOIMET
Oxiplex/AP toimitetaan steriilinä. Älä käytä viimeisen käyttöpäivän jälkeen. Oxiplex/AP-tuotteen turvallisuutta ja tehokkuut:a ei ole tutkit:u olosuhteissa, joissa laitetta ja/tai applikaat:oria käytetään uudelleen. Uudelleenkäytöstä voi seurata immunologinen reaktio ja/tai infektio ris:ikontaminaation, väärän laisen varastoinnin ja/tai käsit:elyn johdos:a. Oxiplex/AP-tuotetta ei ole tutkit:u yhdessä muiden adheesioinehkäisytuot:eiden, vatsakalvonsisäis:en lääkeaineiden tai hemos:aat:is:en aineiden kanssa tai laajentumaaineena. Oxiplex/AP-tuotet:a ei ole arvioitu lapsilla tai imettävillä naisilla. Sen vuoksi potilaita tulisi ohjeis:aa vält:ämään hedelmöittymis:ä ensimmäisen kuukautiskierron aikana Oxiplex/AP-tuotteen käyttämisen jälkeen. Oxiplex/AP-tuotet:a ei ole arvioitu pahanlaatuisuuksien läsnä ollessa. Oxiplex/AP-tuotetta ei ole arvioitu suolen, virtsarakon tai muun sisäelimen avaamisen jälkeen. Geeliä ei ole arvioitu sappinesteen läsnäollessa. Kuten kaikkien implantoitujen materiaalien kanssa, vierasesinereaktioita voi esiintyä Oxiplex/AP-tuotteen kanssa. Usean geelikerroksen levittäminen vatsankalvononteloon kasvattaa geelin irtoamisen riskiä sen levit:ämisen kohdassa, ja joissakin tapauksissa pieniä määriä geelinjäämiä on havait:u kliinisten tutkimus:en seurantamenetteły ssä 6 – 10 vuoden kulut:ua. Geelinjäämäteivät liittyneet kliinisiin jälkitauteihin.[3,4]

SÄILYTYS JA KÄSITTELY: Säilytä huoneenlämmössä (2-25 °C).

TOIMITUS TAPA
Oxiplex/AP toimitetaan s:erillinä lämpömuovaillussa tarjotinpakkauksessa. Lämpömuovailtu tarjotinpakkaus sisältä kaksi 20 ml:n geeliruiskua ja yhden geeliapplikaattorin. Pakkauksen ulkopinta ja ulommat sisällöt eivätole steriilejä. Tarraetiketit sisältyvät pakkaukseen dokumentaatiota rkoituksia varten. Tarra sisältää tuotteen ja tuote-erän tiedot.

KÄYTTÖOHJEET
ESIVALMISTELU
Oxiplex/AP on tarkoitettu vain lääkärien käytettäväksi. Käytä Oxiplex/AP -tuotetta käyttöohjeiden mukaisesti. Kaikkien lääkelait:eiden käyttöön liittyy luonnost aanriskejä. Lait:een käyttöön liittyvien jäännösriskien minimoimiseksi suosit:elemme, että lääkäri lukee käyttöön liittyvät tiedot ja keskustelee potilaan kanssa ennen lait:een käyttöä. Potilaat, joilla tiedetään olevan yliherkkyysanamneesi Oxiplex/AP-tuotteelle tai sen komponenteille ei tulisi hoitaa Oxiplex/AP-tuotteella.
Geeli toimii kudosten välisenä esteenä es:äen adheesioiden muodostumista. Kudokset on erotettava geelillä tehokkaan adheesionsuojan saavuttamiseksi.

LAITTEEN VALMISTELU JA HÄVITTÄMINEN
Oxiplex/AP on tarkoitettu vain kertakäyttöön. Älä käytä/steriloi tuotetta uudelleen.
1. Pois:a Oxiplex/AP-tuot:eella täytetyn ruiskun ja applikaattorin sisältävä pakkaus laatikosta.
2. Tarkis:a pakkaus vaurioiden varalta. Älä käytä, mikäli pakkaus on vahingoit:unut tai avat:u.
3. Vie ruiskut ja applikaat:oristeriiliille leikkausalueelle steriilillä tekniikkaan käyttäen.
4. Pois:a ruiskun pään luer-liit:imen hattu. Käyttäessäsi applikaat:oria vatsakalvonontelossa, liitä geelin applikaat:ori ruiskun luer-liit:imen puoleiseen päähän. Kiinnitä lujasti kiertämällä. (Sama applikaattori on tarkoitettu käytettäväksi tarvittaessa molemmilla ruiskuilla.)
5. Käytön jälkeen hävitä ruiskut, yli jäänyt geeli ja applikaat:ori. Käytetty Oxiplex/AP voi muodostaa biologisen vaaran. Noudata biologises:i vaarallisen materiaalin hävittämisessä kansallisia, paikallisia tai organisaation omia ohjeita.

KOHDUNSISÄINEN KIRURGIA
1. Levitä geeliä toimenpiteen päät:eeksi kaikkien nes:eiden ja laajentumakalvojen tyhjentämisen jälkeen.
2. Kiinnitä ruiskun luer-liitin hysteroskooppiin. Täytä hysteroskooppi geelillä painamalla ruiskun mäntää, kunnes geeliä tulee esiin hysteroskoopin kärjestä.
3. Aloita geelin levit:äminen kohdunpohjaan. Levitä geeliä as:eit:ain ja täytä kohdun ja kohdunkaulan kanavat täysin painamalla ruiskun mäntää ja vetämällä hysteroskooppia samalla ulospäin. Katso Kuva 1.
4. Päätä leikkaus:oimenpide kirurgin normaalin tekniikan mukaises:i.

LANTION GYNEKOLOGISET JA VATSANKALVON LEIKKAUKSET
1. Levitä geeliä toimenpiteen päät:eeksi kaikkien huuhtelunes:eiden tyhjentämisen jälkeen. Suosit:elemme potilaan asentamista kääntei seen Trendelenburgin asentoon ylimääräisen huuhtelunes:een mahdollisimman tehokkaan tyhjentämisen vuoksi.
2. Peitä kaikki neanatomiset alueet, joissa adheesion ehkäiseminen on toivottua, yhdellä kerroksella Oxiplex/AP-tuotetta.* Applikaat:ori annostelee geeliä nauhamaisena muodostelmana. Kudospinnat, joissa adheesion ehkäiseminen on tarkoitettu, tulee peittää vain yhdellä geelinauhakerroksella (noin 2 mm:n paksuudelta). Katso Kuva 2.
3. Käytä ainoastaan riittävä määrä geeliä yhden geelikerroksen levit:äm iseen kudokselle kuvauksen mukaises:i. Koko 40 ml:n geelimäärän käyttäminen ei ole tarpeen.
4. Älä siirrä kerran levitettyä geeliä koet:imien tai muiden ins:rumenttien avulla. Jos geeli putoaa huuhtelunes:eeseen, sen tarttumiskyky vatsankalvon kudokseen voi olla heikentynyt. Siksi se tulisi poistaa vatsankalvonontelos:a ja uusi geeli tulisi levit:ää alueelle.
5. Päätä leikkaus:oimenpide kirurgin normaalin tekniikan mukaises:i.

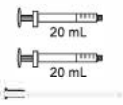
***LISÄTYN GEELIN LEVITYSOHJEET: LANTION GYNEKOLOGISET LEIKKAUKSET**
1. Nos:a munasarjoja pois lantion sivuseinästä ja levitä kohdun kannat:imen takana sijaitsevan kuopan ja munasarjan takapinnan peit:ävä yksit:äinen kerros geeliä.
2. Palauta munasarja normaaliin anatomiseen asentoon ja levitä yksit:äinen munasarjan etuosan peit:ävä kerros geeliä.
3. Levitä munajohtimen ja munajohtimen avartuman ja liepeen peittävä yksittäinen kerros geeliä.
4. Levitä kohdun sivuelimien puoleisen lateraalipuolen peittävä yksittäinen kerros geeliä.
Tyypillisesti 15 ml geeliä riittää yksit:äisen sivuelimen ja sen vereisten rakenteiden, mukaan luk en kohdun takana sijaitsevan kuopanja kohdun lateraalireunan peit:äm iseen.

HAITTAVAIKUTUKSET
Kliinisissä tutkimuksissa ei ole raportoitu laitteeseen liittyviä haittavaikutuksia.[1-4] Seuraavia haitavaikutuksia, jotka eivät vält:ämät:ä liity Oxiplex/AP-tuot:een käyttöön, on raportoitu: kipu, kuume, turvotus, tulehdus, vierasesinereaktio ja huono suorituskyky.

VIITTEET

1. Di Spiezio Sardo, At:illo, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick. Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceptoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Sisältö: 2 - Ruisku 20 mL
1 - Applikaattorikärki



SK

Document 12

POPIS
Oxiplex/AP je číry, tekutý gél na jednorazové použitie. Gél je sterilnou vstrebateľnou kombináciou polyetylén oxidu (PEO) a sodnej soli karboxymetyl-celulózy (CMC). Gél má stabilizovanú hladinu vápnika, je izotonický a v predklinických štúdiách sa preukázalo, že sa od neho peritoneálna dutina vyčistí do 30 dní.

URČENE POUŽITIE
Gél Oxiplex/AP je určený na použitie ako mechanická bariéra proti tvorbe adhézií.

INDIKACIE
Gél Oxiplex/AP je určený na použitie ako pomocná látka pri intrauterinných alebo peritoneálnych operáciách na zníženie výskytu, rozsahu a závažnosti pooperačných adhézií v operovanej oblasti.

KONTRAINDIKACIE
Gél Oxiplex/AP nepoužívajte v prítomnosti infekcie.

VAROVANIA
Nepodávajte intravenózne.

BEZPEČNOSTNE OPATRENIA
Gél Oxiplex/AP sa dodáva sterilný. Nepoužívajte ho po uplynutí dátumu exspirácie. Bezpečnosť a účinnosť gélu Oxiplex/AP nebola v podmienkach opakovaného použitia prípravku a/alebo aplikátora skúmaná. Opakované použitie môže viesť k imunologickej reakcii a/alebo infekcii z dôvodu krížovej kontaminácie, nevhodného skladovania a/alebo manipulácie. Gél Oxiplex/AP nebol skúmaný v kombinácii s inými prostriedkami proti adhéziám, v prítomnosti intraperitoneálnych liečiv či hemostatických činidiel, ani ako diseminačné médium. Gél Oxiplex/AP nebol hodnotený u detí ani u tehotných či dojčiacich žien. Preto je potrebné, aby boli pacientky pou čené o vyhýbaní sa oteh otnému počas prvého menštruačného cyklu po aplikácii gélu Oxiplex/AP. Gél Oxiplex/AP nebol hodnotený v podmienkach prítomnosti malignít. Gél Oxiplex/AP nebol hodnotený v podmienkach po otvorení čreva, mechúra, ani iných viscerálnych orgánov. Gél nebol hodnotený v podmienkach prítomnosti žlče. Rovnako ako pri všetkých implantovaných materiáloch, aj pri géli Oxiplex/AP sa môžu vyskytnúť reakcie na cudzorodé teleso. Aplikácia viacer ých vrstiev gélu v peritoneálnej dutine zvyšuje riziko uvoľnenia gélu zo želaného mies:a aplikácie, a v niektorých z týchto prípadov bolo počas kontrolného zákroku v rámci klinickej štúdie o 6 až 10 týždňov neskôr pozorované malé množstvo reziduálneho gélu. Prítomnosť reziduálneho gélu nebola spojená s klinickými následkami.[3,4]

SKLADOVANIE A MANIPULACIA: Skladujte pri izbovej teplote (2 – 25 °C).

SPOSOB DODAVKY
Gél Oxiplex/AP sa dodáva sterilný v tepelne formovanom podnose. Tepelne formovaný podnos obsahuje dve 20 ml striekačky s gélom a jeden aplikátor gélu. Vonkajšia strana balenia a vonkajší obsah nie sú sterilné. Samolepiace štítky sa dodávajú pre dokumentačné účely. Štítky identifikujú výrobok a výrobnú šaržu.

NAVOD NA POUŽITIE
PRED ZAKROKOM
Gél Oxiplex/AP je určený len na použitie lekármi. Gél Oxiplex/AP používajte podľa návodu na použitie. Riziko je prítomné pri použití všetkých zdravotníckych pomôcok. Pre minimalizáciu reziduálneho rizika spojeného s použitím tejto zdravotníckej pomôcky sa odporúča, aby si lekár pred použitím tejto pomôcky prečítal informácie o použití a prediskutoval ich spolu s pacientom. Pacienti so známou hypersenzitivitou na gél Oxiplex/AP alebo jeho zložky v anamnéze nesmú byť ošetrovaní gélom Oxiplex/AP. Gél slúži ako bariéra medzi tkanivami pre zabránenie tvorbe adhézií. Pre účinné zabránenie vytvoreniu adhézií musia byť tkanivá oddelené gélom.

PRÍPRAVA POMOCKY A LIKVIDACIA
Gél Oxiplex/AP je určený len na jednorazové použitie. Nepoužívajte/nes:erilizujte ho opakovane.
1. Vyberte balenie obsahujúce striekačku naplnenú gélom Oxiplex/AP a aplikátor zo škatule.
2. Skontrolujte balenie z hľadiska akýchkoľvek poškodení. Ak je poškodené alebo otvorené, výrobok nepoužívajte.
3. Použitím s:erilnej techniky preneste striekačky a aplikátor do s:erilného operačného poľa.
4. Odstráňte uzáver z konca striekačky typu luer lock. Keď sa aplikátor používa na peritoneálne použitie, aplikátor gélu nasaďte na koniec striekačky typu luer lock a zatočte ho až pokým sa pevne nepripojí. (Tenký aplikátor sa používa pre obe striekačky, ak je to potrebné.)
5. Po použití zlikvidujte striekačky, všetok zvyšný gél a aplikátor. Použitá pomôcka Oxiplex/AP môže predstavovať biologické riziko. Dodržujte národné, mies:ne alebo nemocničné usmernenia týkajúce sa nakladania s biologicky nebezpečným materiálom.

INTRAUTERINNE OPERACIE
1. Gél aplikujte na záver zákroku po aspirovaní všetkých tekutín a distenčných médií.
2. Pripojte striekačku koncom typu luer lock k hysteroskopu. Naplňte hysteroskop gélom stlačením piestu striekačky, až kým sa gél neobjaví na konci špičky hysteroskopu.
3. Začnite aplikáciu gélu do fundu uteru. Postupnou aplikáciou gélu vyplňte celý uterus aj cervikálny kanál tak, že budete stláčať piest striekačky a zároveň pomaly vytiahovať hysteroskop. Pozrite obrázok 1.
4. Ukončite zákrok štandardnou technikou podľa uváženia chirurga.

GYNEKOLOGICKE A PERITONEALNE OPERACIE V OBLASTI PANVY
1. Gél aplikujte na záver zákroku po aspirovaní všetkých irigačných tekutín. Odporúča sa, aby s pacient nachádzal v opačnej Trendelenburgovej polohe s cieľom čo najúčinnejšieho odstránenia zvyšnej irigačnej tekutiny.
2. Všetky anatomické miesta, kde je potrebné zabrániť adhéziám, pokryte jednou vrstvou gélu Oxiplex/AP.* Aplikátor aplikuje gél v podobe „pásika". Na pokrytie povrchov tkanív, kde je potrebné zabrániť adhéziám, sa má použiť iba jedna vrstva pásika gélu (približne 2 mm hrubá). Pozrite obrázok 2.
3. Použite iba toľko gélu, aby bola na tkanivá nanesená iba jedna vrstva gélu, ako je to opísané. Nie je nevyhnutné použiť všetkých 40 ml gélu.
4. Keď bol gél raz aplikovaný, už ho nepremiestňujte pomocou sond ani iných nás:rojov. Keď gél skĺzne do nahromadenej irigačnej tekutiny, jeho schopnosť priľnúť k peritoneálnym tkanivám môže byť narušená. Preto je v takom prípade potrebné ho vybrať z peritoneálnej dutiny a aplikovať na miesto nový gél.
5. Ukončite zákrok štandardnou technikou podľa uváženia chirurga.

***DODATOČNE POKYNY K APLIKACII GELU: PANVOVE GYNEKOLOGICKE OPERACIE**
1. Nadvihnite ovárium smerom od bočnej steny panvy a aplikujte jednu vrstvu gélu tak, aby ste pokryli fossa ovarii a posteriórny povrch ovária.
2. Vráťte ovárium do normálnej anatomickej polohy a aplikujte jednu vrstvu gélu tak, aby ste pokryli anteriórnu časť ovária.
3. Aplikujte jednu vrstvu gélu tak, aby s:e pokryli vajíčkovod vrátane ampuly a jej mezosalpinx.
4. Aplikujte jednu vrstvu gélu tak, aby s:e pokryli laterálnu časť uteru smerujúcu k adnexám.
Obyčajne stačí 15 ml gélu na pokrytie jedného adnex a priľahlých štruktúr vrátane fossa ovarii a laterálneho okraja uteru.

NEŽIADUCE REAKCIE
V klinických štúdiách neboli hlásené žiadne nežiaduce reakcie súvisiace s pomôckou.[1-4] Boli hlásené nasledovné nežiaduce udalosti, ktoré však nemusia súvisieť s použitím gélu Oxiplex/AP: bolesť, horúčka, opuch, zápal, reakcia na cudzorodé teleso a slabý účinok.

REFERENCIE

1. Di Spiezio Sardo, At:illo, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick. Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceptoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorff P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Obsah: 2 – 20 ml striekačka
1 – aplikátor

RO

DESCRIERE
Oxiplex/AP este un gel fluid, incolor, pentru o singură utilizare. Gelul este o combinaţie sterilă, resorbabilă de oxid de polietilenă (PEO) şi carboximetilceluloză de sodiu (CMC). Gelul este stabilizat prin calciu, izotonic, iar în studiile preclinice a prezentat curăţarea cavităţii peritoneale în termen de 30 de zile.

UTILIZAREA PREVAZUTA
Oxiplex/AP este destinat utilizării ca barieră mecanică împotriva formării aderenţelor.

INDICAŢII
Oxiplex/AP este destinat utilizării ca adjuvant în operaţia chirurgicală intrauterină sau peritoneală, pentru reducerea incidenţei, extinderii şi gravităţii aderenţelor post-operatorii la locul operaţiei chirurgicale.

CONTRAINDICAŢII
Nu utilizaţi Oxiplex/AP în prezenţa infecţiilor.

AVERTISMENTE
Nu injectaţi intravenos.

PRECAUŢII
Oxiplex/AP este furnizat steril. Nu utilizaţi după data de expirare. Siguranţa şi eficacitatea Oxiplex/AP nu au fost studiate în condiţii de reutilizare a dispozitivului şi/sau aplicatorului. Reutilizarea poate duce la reacţii şi/sau infecţii imunologice din cauza contaminării încrucişate, depozitării şi/sau manipulării necorespunzătoare. Oxiplex/AP nu a fost studiat în combinaţie cu alte produse pentru prevenirea aderenţelor, în prezenţa agenţilor medicinali intraperitoneali sau hemostatici sau a mediului de dilatare. Oxiplex/AP nu a fost evaluat la copii sau la femei însărcinate sau care alăptează. Prin urmare, pacienţii trebuie sfătuiţi să evite concepţia în timpul primului ciclu menstrual de după aplicarea Oxiplex/AP. Oxiplex/AP nu a fost evaluat în prezenţa afecţiunilor maligne. Oxiplex/AP nu a fost evaluat în urma deschiderii intestinului, vezicii urinare sau a altor organe viscerale. Gelul nu a fost evaluat în prezenţa bilei. Ca în cazul oricărui material implantat, şi cu Oxiplex/AP pot să apară reacţii la corpuri străine. Aplicarea unor straturi multiple de gel în cavitatea peritoneală creşte riscul dislocării gelului de la locul intenţionat al aplicării, iar în unele dintre aceste cazuri s-a observat o cantitate mică de gel rezidual în timpul procedurii de urmărire a studiului clinic, de la 6 la 10 săptămâni mai târziu. Gelul rezidual nu a fost asociat cu sechele clinice.[3,4]

DEPOZITARE ŞI MANIPULARE
Depozitaţi la temperatura camerei (2 - 25 °C).

MOD DE LIVRARE
Oxiplex/AP este furnizat steril, într-o tavă termoformată. Tava termoformată conţine două seringi de câte 20 ml de gel şi un aplicator pentru gel. Exteriorul ambalajului şi conţinutul exterior nu sunt sterile. În scopuri de documentare sunt furnizate etichete autocolante. Etichetele identifică produsul şi lotul de fabricaţie.

INSTRUCŢIUNI DE UTILIZARE
PRE-PROCEDURA
Oxiplex/AP trebuie utilizat numai de către medici. Utilizaţi Oxiplex/AP conform instrucţiunilor de utilizare.
Riscul este inerent la utilizarea tuturor dispozitivelor medicale. Pentru a minimiza riscurile reziduale asociate utilizării acestui dispozitiv, se recomandă ca informaţiile pentru utilizare să fie citite de medic şi să fie discutate cu pacientul înainte de utilizarea dispozitivului. Pacienţii care au prezentat anterior hipersensibilitate la Oxiplex/AP sau la componentele acestuia, nu trebuie trataţi cu Oxiplex/AP. Gelul serveşte ca barieră între ţesuturi, pentru a preveni formarea aderenţelor. Ţesutul trebuie separat prin gel pentru prevenirea eficientă a aderenţei.

PREGATIREA ŞI ELIMINAREA DISPOZITIVULUI
Oxiplex/AP este destinat doar pentru o singură utilizare. Nu reutilizaţi/resterilizaţi.
1. Scoateţi din cutie ambalajele care conţin seringa umplută cu Oxiplex/AP şi aplicatorul.
2. Verificaţi ca ambalajul să nu prezinte deteriorări. Nu utilizaţi dacă este deteriorat sau deschis.
3. Utilizând o tehnică sterilă, introduceţi seringile şi aplicatorul în câmpul de operare steril.
4. Scoateţi capacul de pe capătul luer lock al seringii. Atunci când utilizaţi aplicatorul peritoneal, conectaţi aplicatorul pentru gel la capătul luer lock al seringii; rotiţi până când este ataşat ferm. (Se va utiliza acelaşi aplicator pentru ambele seringi, dacă este nevoie.)
5. După utilizare, aruncaţi seringile, orice resturi de gel şi aplicatorul. Dispozitivul Oxiplex/AP folosit poate prezenta risc biologic. Urmaţi instrucţiunile naţionale, locale sau instituţionale pentru eliminarea materialelor cu risc biologic.

OPERAŢIA CHIRURGICALA INTRAUTERINA
1. Aplicaţi gelul la finalul procedurii, după aspirarea completă a fluidului de irigare. Se recomandă ca pacientul să fie aşezat în poziţia Trendelenburg inversată, pentru îndepărtarea cea mai eficientă a fluidului de irigare rezidual.
2. Acoperiţi cu un singur strat de Oxiplex/AP toate locurile anatomice în care se doreşte prevenirea aderenţelor.* Aplicatorul eliberează gelul sub formă de „panglică". Se va utiliza un singur strat de gel eliberat în formă de panglică (aproximativ 2 mm în adâncime) pentru a acoperi suprafeţele de ţesut pentru care se intenţionează prevenirea formării aderenţelor. A se vedea figura 2.
3. Utilizaţi numai atât gel cât este suficient pentru a aplica un singur strat de gel pe ţesuturi, aşa cum este descris. Nu este necesar să utilizaţi întreaga cantitate de 40 ml de gel.
4. Nu repoziţionaţi gelul cu ajutorul sondelor sau a altor instrumente odată ce a fost aplicat. Dacă gelul cade într-un bazin de fluid de irigare, capacitatea sa de aderenţă la ţesuturile peritoneale poate fi compromisă. Prin urmare, trebuie îndepărtat din cavitatea peritoneală şi în acel loc trebuie aplicat un nou gel.
5. Încheiaţi procedura chirurgicală conform tehnicii standard a chirurgului.

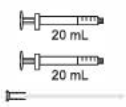
***INSTRUCŢIUNI SUPLIMENTARE PENTRU APLICAREA GELULUI: OPERAŢII CHIRURGICALE PELVIENE GINECOLOGICE**
1. Ridicaţi ovarul de pe peretele pelvian lateral şi aplicaţi un singur strat de gel pentru a acoperi fosa ovariană şi suprafaţa posterioară a ovarului.
2. Readuceţi ovarul în poziţia sa anatomică normală şi aplicaţi un singur strat de gel pentru a acoperi zona anterioară a ovarului.
3. Aplicaţi un singur strat de gel pentru a acoperi trompa lui Fallope, incluzând ampula şi mezosalpinxul.
4. Aplicaţi un singur strat de gel pentru a acoperi partea laterală a uterului, dinspre anexa uterină.
În mod tipic, o cantitate de 15 ml de gel este suficientă pentru a acoperi o singură anexă şi structurile adiacente, incluzând fosa ovariană şi marginea laterală a uterului.

REACŢII ADVERSE
În studiile clinice nu au fost raportate reacţii adverse legate de dispozitiv.[1-4] Totuşi, fără a fi neapărat atribuite utilizării Oxiplex/AP, au fost raportate următoarele efecte adverse: durere, febră, umflare, inflamaţie, reacţie la corpuri străine şi performanţă slabă.

REFERINŢE

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceed (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility: Vol. 84:5, pp. 1450-1456.

Conţinut:
2 – Seringă de 20 ml
1 – Vârf aplicator



FR

Document 12

DESCRIPTION
Le gel Oxiplex/AP est un gel liquide incolore à usage unique. Le gel est une combinaison d'oxyde de polyéthylène (PEO) et de carboxyméthylcellulose sodique (CMC), stérile et résorbable. Le gel est isotonique et stabilisé au calcium, et il a été démontré dans des études précliniques qu'il se résorbe de la cavité péritonéale en 30 jours

USAGE PRECONISE
Oxiplex/AP est prévu pour être utilisé comme barrière mécanique à la formation d'adhésion.

INDICATIONS
Oxiplex/AP est prévu pour être utilisé comme complément à la chirurgie intra-utérine ou péritonéale pour réduire l'incidence, l'étendue et la sévérité d'adhésions postopératoires sur le site chirurgical.

CONTRE-INDICATIONS
Ne pas utiliser le gel Oxiplex/AP en présence d'une infection.

MISES EN GARDE
Ne pas injecter par voie intraveineuse.

PRECAUTIONS D'EMPLOI
Oxiplex/AP est livré stérile. Ne pas utiliser au-delà de la date de péremption. La sécurité et l'efficacité de Oxiplex/AP n'ont pas été étudiées en cas de réutilisation du dispositif et/ou de l'applicateur. La réutilisation pourrait entraîner une réponse immunologique et/ou une infection due à la contamination croisée, à l'entreposage et/ou à une manipulation inadéquats. Oxiplex/AP n'a pas été évalué en association avec d'autres produits de prévention de l'adhésion, en présence d'agent médicaux ou hémostatiques intrapéritonéaux, ni comme milieu de distension. L'utilisation d'Oxiplex/AP chez les femmes enceintes, les femmes qui allaitent ou les enfants n'a pas été évaluée. En conséquence, il convient de conseiller aux patients d'éviter la conception pendant le premier cycle menstruel après l'application d'Oxiplex/AP. Oxiplex/AP n'a pas été évalué en présence d'une tumeur maligne. Oxiplex/AP n'a pas été évalué à la suite d'ouverture de l'intestin, de la vessie ou d'autres organes viscéraux. Le gel n'a pas été évalué en présence de bile. Comme avec tout produit implanté, des réactions aux corps étrangers peuvent se produire avec Oxiplex/AP. L'application de couches multiples de gel dans la cavité péritonéale augmente le risque que le gel soit délogé du site prévu d'application et, dans certains cas, une petite quantité de gel résiduel a été observée pendant la procédure de suivi de l'étude clinique 6 à 10 semaines plus tard. Le gel résiduel n'a pas été associé à des séquelles cliniques.[3,4]

ENTREPOSAGE ET MANIPULATION: Conserver à température ambiante (2 à 25 °C).

PRESENTATION
Oxiplex/AP est livré stérile dans un plateau thermoformé. Le plateau thermoformé contient deux seringues de 20 ml de gel et un applicateur de gel. L'extérieur de l'emballage et les contenus externes ne sont pas stériles. Des étiquettes adhésives sont fournies aux fins de documentation. Les étiquettes identifient le produit et le lot de fabrication.

MODE D'EMPLOI
PREPROCEDURE
Oxiplex/AP est strictement réservé à l'usage des médecins. Utiliser Oxiplex/AP selon le mode d'emploi.
Le risque est inhérent à l'utilisation de tout dispositif médical. Pour réduire les risques résiduels associés à l'utilisation de ce dispositif, il est recommandé au praticien de lire les informations d'utilisation et d'en discuter avec le patient avant l'utilisation du dispositif.
Les patients qui ont des antécédents connus d'hypersensibilité à Oxiplex/AP ou à l'un de ses composants ne doivent pas être traités avec Oxiplex/AP.
Le gel est utilisé comme barrière entre les tissus pour prévenir la formation d'adhésions. Les tissus doivent être séparés par le gel pour une prévention efficace de l'adhésion.

PREPARATION DU DISPOSITIF ET ELIMINATION
Oxiplex/AP est destiné à un usage unique. Ne pas réutiliser/stériliser de nouveau.
1. Retirer l'emballage contenant la seringue remplie d'Oxiplex/AP et l'applicateur de la boîte.
2. Vérifier l'intégrité de l'emballage. Ne pas utiliser si l'emballage est endommagé ou ouvert.
3. Introduire les seringues et l'applicateur dans le champ opératoire stérile en utilisant les techniques de maintien de la stérilité.
4. Retirer le capuchon de l'embout Luer de la seringue. Lors de l'utilisation de l'applicateur en usage péritonéal, raccorder l'applicateur de gel sur l'embout Luer de la seringue ; tourner jusqu'à obtenir une fixation solide. (Le même applicateur est prévu pour être utilisé avec les deux seringues si nécessaire)
5. Après usage, éliminer les seringues, tous restes de gel et l'applicateur. L'utilisation du dispositif Oxiplex/AP peut constituer un risque biologique. Se conformer aux recommandations locales ou institutionnelles pour l'élimination des DASRI.

CHIRURGIE INTRAUTERINE
1. Appliquer le gel à la fin de l'intervention chirurgicale, après aspiration de tous les fluides et media de distension.
2. Fixer l'embout Luer de la seringue sur l'hystéroscope. Remplir l'hystéroscope avec du gel en comprimant le piston de la seringue jusqu'à ce que le gel apparaisse à l'extrémité de l'hystéroscope.
3. Commencer l'application du gel sur le fundus de l'utérus. Appliquer graduellement le gel pour remplir complètement l'utérus et le canal cervical en comprimant le piston de la seringue tout en retirant doucement l'hystéroscope. Voir figure 1.
4. Terminer l'intervention chirurgicale conformément à la technique standard utilisée par le chirurgien.

CHIRURGIE PELVIENNE GYNECOLOGIQUE ET PERITONEALE
1. Appliquer le gel à la fin de l'intervention chirurgicale, après aspiration de tous les fluides d'irrigation. Il est recommandé de placer le patient en position de Trendelenburg inversée pour un retrait plus efficace des fluides d'irrigation.
2. Couvrir tous les sites anatomiques où la prévention de l'adhésion est souhaitée avec une seule couche d'Oxiplex/AP.* L'applicateur dépose le gel en « ruban ». Utiliser un ruban d'une seule couche (environ 2 mm d'épaisseur) pour couvrir les surfaces de tissus pour lesquelles la prévention de l'adhésion est nécessaire. Voir figure 2.
3. Utiliser seulement la quantité de gel nécessaire pour déposer une seule couche de gel sur les tissus comme décrit ici. Il n'est pas nécessaire d'utiliser l'intégralité des 40 ml de gel.
4. Ne pas repositionner le gel avec des sondes ou autres instruments une fois qu'il a été appliqué. Si du gel tombe dans une flaque de fluide d'irrigation, sa capacité à adhérer aux tissus péritonéaux peut être compromise. En conséquence, il doit être retiré de la cavité péritonéale et du gel neuf doit être appliqué sur le site.
5. Terminer l'intervention chirurgicale conformément à la technique standard utilisée par le chirurgien.

***INSTRUCTIONS SUPPLEMENTAIRES POUR L'APPLICATION DU GEL CHIRURGIE PELVIENNE GYNECOLOGIQUE**
1. Soulever l'ovaire pour l'écarter de la paroi pelvienne et appliquer une seule couche de gel pour couvrir la fosse ovarienne et la surface postérieure de l'ovaire.
2. Remettre l'ovaire en position anatomique normale et appliquer une seule couche de gel pour couvrir la portion antérieure de l'ovaire.
3. Appliquer une seule couche de gel pour couvrir la trompe de Fallope, y compris l'ampule et le mésosalpinx.
4. Appliquer une seule couche de gel pour couvrir la partie latérale de l'utérus en face de l'annexe.
En principe 15 ml de gel sont suffisants pour couvrir l'annexe et les structures adjacentes y compris la fosse ovarienne et le bord latéral de l'utérus.

EFFECTS SECONDAIRES INDESIRABLES
Aucun effet secondaire indésirable lié au dispositif n'a été rapporté durant les essais cliniques.[1-4] Même s'ils ne sont pas attribuables l'utilisation de l'Oxiplex/AP, les effets indésirables suivants ont été rapportés : douleur, fièvre, gonflement, inflammation, réaction a un corps étranger et manque d'efficacité.

REFERENCES

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceed (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility: Vol. 84:5, pp. 1450-1456.

Contenu: 2 - Seringue de 20 ml
1 - Embout applicateur

HU

LEIRAS
Az Oxiplex/AP átlátszó, egyszer használatos, folyékony gél. A gél polietilén-oxid (PEO) és nátrium-karboxi-metil-cellulóz (CMC) steril, felszívódó keveréke. A gél kalcium mal stabilizált és izotónikus, valamint a preklinikai vizsgálatok szerint 30 napon belül megtisztítja a hasüreget.

HASZNALAT
Az Oxiplex/AP rendeltetésszerint mechanikus gátként alkalmazható az adhesio kialakulása ellen.

JAVALLATOK
Az Oxiplex/AP rendeltetésénél fogva méhen belüli vagy perito nealis műtétek kiegészítő eszközeként, a műtéti területen kialakuló posztoperatív adhesiók előfordulásának, mértékének és súlyosságának csökkentésére használható.

ELLENJAVALLATOK
Fertőzések esetén az Oxiplex/AP használata tilos.

FIGYELMEZTETESEK
A gél intravénás befecskendezése tilos.

OVINTEZKEDESEK
A(z) Oxiplex/AP sterilen kerül forgalomba. A szavatossági idő lejárata után tilos felhasználni. A(z) Oxiplex/AP biztonságosságát és hatásosságát az eszköz és/vagy az applikátor újrafelhasználása esetén nem vizsgálták. Az újrafelhasználás keresztszennyeződést, nem megfelelő tisztítás és/vagy kezelés miatt immunológiai reakciót hoz és/vagy fertőzést okozhat. Az Optiplex/AP terméket nem vizsgálták az adhesiót megelőző más termékekkel együttes felhasználás esetén, intraperitoneális gyógyszerek vagy vérzéscsillapító szerek jelenlétében, valamint distensiós közegként sem. Az Optiplex/AP terméket nem értékelték gyermekben, sem várandós vagy szoptató nőkben. Emiatt a páciens eknek tanácsolni kell a fogamzás kerülését az Optiplex/AP alkalmazása utáni első menstruációs ciklus idején. Az Optiplex/AP malignus daganatokjelenlétében történő alkalmazását nem vizsgálták. Az Optiplex/AP-t nem értékelték a belek a hüvelyhólyag vagy más zsigerszervek felnyitása után. A gél epe jelenlétében történő alkalmazását nem vizsgálták. Bármilyen egyéb beültetett anyag hoz hasonlóan az Oxiplex/AP esetén is idegentest-reakciók fordulhatnak elő. A perito nealis üregben a gél több rétegben történő felvitele fokozza annak kockázatát, hogy a gélmozdulat tervezett alkalmazási helyéről, és néhány ilyen esetben 6-10 hétnél később kis mennyiségű gélmaradványt figyeltek meg a klinikai vizsgálat utólagos nyomon követési eljárása során. A gélmaradványt nem hozták összefüggésbe klinikai szövődményekkel.[3,4]

TAROLAS ES KEZELES: Szobahőmérsékleten tárolandó (2–25 °C).

KISZERELES
Az Oxiplex/AP steril állapotban, hőformázott tálcán kerül forgalomba. A hőformázott tálca 2 db 20 ml gélle l feltöltött fecskendőt és 1 db gélapplikátort tartalmaz. A csomagolás külső felülete és külső tartalma nem steril. Dokumentációs célokra öntapadó címkéket biztosítunk. A címkéka terméket és a gyártási tételt azonosítják.

HASZNALATI UTASITAS
A BEAVATKOZAS ELŐTT
Az Oxiplex/AP kizárólag orvosok által használható. Az Oxiplex/AP terméket a használati utasítás szerint kell használni. Minden orvostechnikai eszköz alkalmazása inherens kockázatokkal jár. Az eszköz használatával összefüggő maradványkockázatok minimalizálása érdekében az eszköz használata előtt az orvosnak ajánlatos elolvasni a használati utasítást, valamint meg kell beszélnie azt a páciens sel. Nem szabad az Oxiplex/AP terméket kezelni olyan pácienseket, akinek korábban allergiás reakciója volt az Oxiplex/AP termékkel vagy hasonló összetevőivel szemben ismert hiperérzékenysége van.
A gél a szövetek közötti adhesiók kialakulásának megelőzése céljából gátként működik. Az adhesio hatékony megelőzése érdekében a szövetet a gélle l kell szétválasztani.

AZ ESZKOZ ELOKESZITESE ES ARTALMATLANITASA
Az Oxiplex/AP kizárólag egyszer használatos. Újrafelhasználása vagy újrasterilizálása tilos.
1. Vegye ki az Oxiplex/AP termékkel feltöltött fecskendőt és az applikátort a dobozból.
2. Vizsgálja meg, hogy a csomagolás ép-e és sérülésmentes. Tilos felhasználni, ha sérült vagy felnyitva.
3. A fecskendőket és applikátort steril technika használatával kell a steril műtéti területre bevezetni.
4. Vegye le a kupakot a fecskendő Luer-záras végéről. Az applikátor perito nealis alkalmazásakor a fecskendő Luer-záras végéhez csatlakoztassa a gélapplikátort: forgassa el addig, ameddig fixen nem rögzül. (Szükség esetén mindkét fecskendőhöz ugyanazt az applikátort kell használni.)
5. A fecskendőket, az esetleg megmaradt gélt és az applikátort használat után selejtezni kell. A használt Oxiplex/AP eszköz biológiai veszélyforrás lehet. A bioló giailag veszélyes anyagok ártalmatlanítása akkor a nemzeti, helyi vagy intézményi irányelvek et kell követni.

MEHEN BELÜLI MŰTETEK
1. A gélt a beavatkozás végén, az összes folyadék és disztenziós anyag elszívása után kell felvinni.
2. Erőltesse a fecskendő Luer-zárát a hiszteroszkóp ra. A fecskendő dugattyúját lenyomva töltse fel géllel a hiszteroszkópot addig, ameddig a gél meg nem jelenik a hiszteroszkóp végén lévő hegynél.
3. A gél felvitelét a méh fundusánál kell elkezdeni. A fecskendő dugattyújának lenyomásával és a hiszteroszkóp lassú kihúzásával fokozatosan vigye fel a gélt, hogy az teljesen kitöltse a méhet és a méhnyakcsatornát. Lásd **1.** ábra.
4. A beavatkozást a sebészi megszokott technikája szerint kell befejezni.

NOGYOGYASZATI MEDENCE- ES PERITONEALIS MÜTETEK
1. A gélt a beavatkozás végén, az irrigáláshoz használt összes folyadék elszívása után kell felvinni. A megmaradt irrigálófolyadék leghatékonyabb eltávolításához ajánlott a páciens: fordított Trendelenburg pozícióba helyezni.
2. Minden anatómiai területet, ahol az adhesio megelőzése kívánatos, egyetlen réteg Oxiplex/AP-vel kell lefedni.* Az applikátor „szalagszerűen” adagolja a gélt. Az adhesio megelőzésére tervezett szövetfelületek befedéséhez csak egyetlen réteg en szabad felvinni a gélszalagot (kb. 2 mm vastagon). Lásd **2.** ábra.
3. Csak annyi gélt használjon, amennyi elegendő a gél egy rétegben, az ismertetett módon történő felvitelére a szövetekre. Nem szükséges mind a 40 ml gélt felhasználni.
4. Felvitel után a gélt tilos áthelyezni szondákvagy más eszközök segítségével. Ha a gél felgyülemlett irrigálófolyadékba esik, elveszítheti a képességét, hogy rátapadjon a perito nealis szövetekre. Ilyen esetben tehát el kell távolítani a perito nealis üregből, és új gélt kell felvinni a területre.
5. A beavatkozást a sebészi megszokott technikája szerint kell befejezni.

***AGEL FELVITELERE VONATKOZÓ KIEGESZITŐ UTASITASOK: NOGYOGYASZATI MEDENCEMŰTETEK**
1. Emelje el a petefészket a medence oldalfalától, és vigye fel egy réteg gélt a fossa ovarica és a petefészek hátsó felületének lefedéséhez.
2. Helyezze vissza a petefészket normál anatómiai helyzetébe, és vigyen fel egy réteg gélt a petefészek elülső részének lefedéséhez.
3. Vigyen fel egy réteg gélt a petevezeték, valamint az ampulla és a mesosalpinx lefedéséhez.
4. Vigyen fel egy réteg gélt a méh oldalsó, az adnexával szemben lévő részének lefedéséhez.
Jellemzően 15 ml gél elegendő egyetlen adnexa és a vele szomszédos képletek, mint a fossa ovarica, valamint a méh oldalsó szélének lefedéséhez.

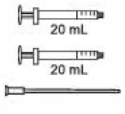
KEDVEZOTLEN REAKCIOK

Klinikai vizsgálatokban nem számoltak be semmilyen kedvezőtlen reakcióról.[1-4] Habár nem feltétlenül az Oxiplex/AP használatának betudható an, de a következő nemkívánatos események et számoltak be: fájdalom, láz, duzzadás, gyulladás, idegentest-reakció és rossz teljesítmény.

HIVATKOZASOK

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arri, ZviVaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20: 2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Tartalom: 2 db 20 ml-es fecskendő
1 db - végáródás segédeszközzel



PT

Document 12

DESCRIÇAO
O Oxiplex/AP é um gel fluido transparente, destinado a uma única utilização. O gel consiste numa combinação absorvível, esterilizada, de óxido de polietileno (OPE) e carboximetilcelulose de sódio (CMC). O gel é estabilizado por cálcio, isotónico e mostrou, em estudos pré-clínicos, desaparecer da cavidade peritoneal no prazo de 30 dias.

FINALIDADE
Oxiplex/AP destina-se a ser usado como barreira mecânica contra a formação de adesões.

INDICAÇÕES
Oxiplex/AP destina-se a ser usado como adjuvante na cirurgia intrauterina ou peritoneal para reduzir a incidência, a extensão e a gravidade de adesões pós-operatórias no local da cirurgia.

CONTRA-INDICAÇÕES
Não utilizar o Oxiplex/AP na presença de infecção.

ADVERTENCIAS
Não injectar por via intravenosa.

PRECAUÇÕES
Oxiplex/AP é fornecido estéril. Não utilize depois da data de validade. A segurança e a eficácia de Oxiplex/AP não foram estudadas em condições de reutilização do dispositivo e/ou aplicador. A reutilização poderá originar uma resposta imunitária e/ou infeção devido a contaminação cruzada, manipulação e/ou armazenamento impróprios. Oxiplex/AP não foi estudado em combinação com outros produtos de prevenção de adesões, na presença de agentes hemostáticos ou agentes medicamentosos intraperitoneais, nem como meio de distensão. Oxiplex/AP não foi avaliado em crianças, grávidas ou lactantes. Portanto, as doentes devem ser avisadas para evitarem conceber durante o primeiro ciclo menstrual após a aplicação de Oxiplex/AP. Oxiplex/AP não foi avaliado na presença de malignidades. Oxiplex/AP não foi avaliado após abertura do intestino, bexiga ou outros órgãos viscerais. O gel não foi avaliado na presença de bílis. Tal como acontece com qualquer material implantado, poderão ocorrer reações corpo estranhos com Oxiplex/AP. A aplicação de várias camadas de gel na cavidade peritoneal aumenta o risco de o gel se deslocar do local de aplicação pretendido e, em alguns casos, observou-se uma pequena quantidade de gel residual durante o procedimento de seguimento do estudo clínico 6 a 10 semanas mais tarde. O gel residual não foi associado a sequelas clínicas.[3,4]

ARMAZENAMENTO E MANIPULAÇAO: Armazene à temperatura ambiente (2– 25 °C).

APRESENTAÇAO
Oxiplex/AP é fornecido estéril numa bandeja termomoldada. A bandeja termomoldada contém duas seringas de 20 mL de gel e um aplicador. O exterior da embalagem e os conteúdos externos não são estéreis. São fornecidos rótulos autoadesivos para fins de documentação. Os rótulos identificam o produto e o lote de produção.

INSTRUÇÕES DE UTILIZAÇÃO
PRE-PROCEDIMENTO
Oxiplex/AP destina-se a ser utilizado apenas por médicos. Use Oxiplex/AP de acordo com as instruções de utilização. Há riscos inerentes à utilização de todos os dispositivos médicos. Para minimizar o risco residual associado à utilização deste dispositivo, recomenda-se que as instruções de utilização sejam lidas pelo médico e discutidas com o doente antes da utilização do mesmo.
Os doentes com história conhecida de hipersensibilidade a Oxiplex/AP ou aos seus componentes não devem ser tratados com Oxiplex/AP.
O gel atua como uma barreira entre tecidos para prevenir a formação de adesões. O tecido tem de estar separado por gel para uma prevenção de adesões eficaz.

PREPARAÇAO E ELIMINAÇAO DO DISPOSITIVO
Oxiplex/AP destina-se a ser utilizado uma única vez. Não reutilize/reesterilize.
1. Retire da caixa a embalagem que contém a seringa carregada com Oxiplex/AP e o aplicador.
2. Inspecione a embalagem quanto a danos. Não utilize se estiver danificada ou aberta.
3. Utilizando técnica asséptica, coloque as seringas e o aplicador no campo cirúrgico estéril.
4. Retire a tampa da extremidade luer lock da seringa. Ao utilizar o aplicador para uso peritoneal, encaixe o aplicador do gel na extremidade luer lock da seringa; rode até ficar firmemente encaixado. (Pode ser usado o mesmo aplicador para ambas as seringas, se necessário.)
5. Após a utilização, elimine as seringas, os restos de gel e o aplicador. Oxiplex/AP utilizado pode constituir um risco biológico. Siga as orientações nacionais, locais ou institucionais de eliminação de materiais com risco biológico.

CIRURGIA INTRAUTERINA
1. Aplique gel ao terminar o procedimento, após a aspiração de todos os fluidos e meios de distensão.
2. Encaixe a extremidade luer lock da seringa ao histeroscópio. Encha o histeroscópio com gel pressionando o êmbolo da seringa até aparecer gel na ponta do histeroscópio.
3. Inicie a aplicação do gel no fundus do útero. Aplique gradualmente gel até encher completamente o útero e o canal cervical pressionando o êmbolo da seringa enquanto retira lentamente o histeroscópio. Ver a figura **1.**
4. Termine o procedimento de acordo com a técnica padrão do cirurgião.

CIRURGIA PERITONEAL E GINECOLOGICA PELVICA
1. Aplique gel ao terminar o procedimento, após a aspiração de todos os fluidos de irrigação. Recomenda-se que o doente seja colocado numa posição de Trendelenburg reversa para obter a remoção mais eficaz do fluido de irrigação residual.
2. Cubra com uma única camada de Oxiplex/AP todos os locais anatómicos nos quais se pretende prevenir adesões.* O aplicador dispensa o gel em forma de «fita». Deve-se usar apenas uma única camada de fita de gel (cerca de 2 mm de profundidade) para revestir as superfícies dos tecidos nos quais se pretende prevenir adesões. Ver a figura 2.
3. Use apenas o gel suficiente para colocar uma única camada de gel nos tecidos conforme descrito. Não é necessário utilizar os 40 mL de gel.
4. Não reposicione o gel com sondas ou outros instrumentos depois de aplicado. Se o gel cair numa acumulação de fluido de irrigação, a sua capacidade de aderir aos tecidos peritoneais poderá ficar comprometida. Portanto, deve ser removido da cavidade peritoneal e deve-se aplicar novo gel no local.
5. Termine o procedimento de acordo com a técnica padrão do cirurgião.

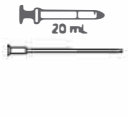
***INSTRUÇÕES ADICIONAIS DE APLICAÇÃO DO GEL: CIRURGIA GINECOLOGICA PELVICA**
1. Afaste o ovário da parede pélvica lateral e aplique uma única camada de gel para cobrir a fossa ovárica e a superfície posterior do ovário.
2. Volte a colocar o ovário na posição anatómica normal e aplique uma única camada de gel para cobrir a parte anterior do ovário.
3. Aplique uma única camada de gel para cobrir a trompa de Falópio, incluindo a ampulla e o mesosalpinx.
4. Aplique uma única camada de gel para cobrir o aspeto lateral do útero virado para as adnexa.
Normalmente, 15 mL de gel são suficientes para cobrir uma única adnexa ou estruturas adjacentes, incluindo a fossa ovárica e as margens laterais do útero.

REAÇÕES ADVERSAS
Não foram reportadas reações adversas relacionadas com o dispositivo em estudos clínicos.[1-4] Embora não sejam necessariamente atribuíveis ao uso de Oxiplex/AP, foram reportados os seguintes acontecimentos adversos: dor, febre, inchaço, inflamação, reação a corpo estranho e desempenho desfavorável.

REFERENCIAS

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arri, ZviVaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20: 2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Conteúdo: 2 - Seringa 20 mL
1 - Ponta aplicadora



PL

OPIS
Oxiplex/AP to przezroczysty, płynny żel przeznaczony do jednorazowego zastosowania. Stanowi on sterylną, absorbowalną kombinację tlenku polietylenu (PEO) i karboksymetylocelulozy sodu (CMC). Żel jest stabilizowany wapniem i jest izotoniczny. Na podstawie badań przedklinicznych wykazano, że oczyszcza on jamę otrzewnową w ciągu 30 dni.

ZASTOSOWANIE
Oxiplex/AP jest przeznaczony do stosowania jako mechaniczna bariera przed tworzeniem się zrostu.

WSKAZANIA
Oxiplex/AP przeznaczony jest do stosowania jako dodatek do chirurgii wewnątrzmacicznej lub otrzewnej w celu zmniejszenia częstości występowania, stopnia i nasilenia zrostów pooperacyjnych w operowanym miejscu.

PRZECIWWSKAZANIA
Żelu Oxiplex/AP nie należy stosować w obecności infekcji.

OSTRZEŻENIA
Nie wprowadzać dożylnie.

SRODKI OSTROZNOSCI
Oxiplex/AP jest dostarczany sterylny. Nie stosować po upływie daty ważności. Bezpieczeństwo i skuteczność Oxiplex/AP nie zostały przebadane w warunkach ponownego użycia urządzenia i/lub aplikatora. Ponowne użycie może prowadzić do odpowiedzi immunologicznej i/lub zakażenia wskutek zanieczyszczenia krzyżowego, niewłaściwego przechowywania i/lub manipulacji. Oxiplex/AP nie poddano badaniu w połączeniu z innymi produktami zapobiegającymi zrostowi, w obecności otrzewnowych środków leczniczych lub środków hemostatycznych, lub jako ośrodek rozrzedzający Oxiplex/AP nie został poddany ocenie u dzieci, kobiet ciężarnych i karmiących matek. Dlatego pacjentom należy zalecić unikanie początku przedwszystkim cyklu menstruacyjnego po zastosowaniu Oxiplex/AP. Oxiplex/AP nie zostało poddane ocenie w obecności złośliwości. Oxiplex/AP nie poddano ocenie po otwarciu jelita, pęcherza moczowego lub innych organów trzewnych. Żel nie został poddany ocenie w obecności zżółci. Podobnie jak w przypadku dowolnego implementowanego materiału, przy stosowaniu Oxiplex/AP wystąpić mogą reakcje na ciało obce. Zastosowanie wielu warstw żelu w jamie otrzewnej zwiększa ryzyko wycieku żelu z planowanego miejsca użycia, w niektórych przypadkach zaobserwowano nawet niewielką ilość pozostałości żelu podczas badania klinicznego przeprowadzanego od 6 do 10 dni po dniu pierwszej operacji. Poza stałością żelu nie niosły za sobą naszpęstwa klinicznych.[3,4]

PRZECHOWYWANIE I OBSŁUGA: Przechowywać w temperaturze pokojowej (2-25°C).

SPOSOB DOSTAWY
Oxiplex/AP jest dostarczany sterylny w tacy termicznej. Taca termiczna zawiera dwie strzykawki z 20ml żelu oraz jeden aplikator żelu. Zewnętrzna strona opakowania ani zawartość nie są sterylne. Etykiety samoprzylepne są dostarczane w celach dokumentacyjnych. Etykiety umożliwiają identyfikację produktu i partii produkcyjnej.

INSTRUKCJA UZYTKOWANIA
ZABIEG WSTĘPNY
Oxiplex/AP przeznaczony jest do stosowania wyłącznie przez lekarzy. Stosować Oxiplex/AP zgodnie z instrukcją użytkowania. Ryzyko występuje w trakcie stosowania wszystkich urządzeń medycznych. W celu zminimalizowania ryzyka rezydualnego związanego z użytkowaniem tego urządzenia, zaleca się, aby przed użyciem urządzenia lekarz przeczytał informacje na temat jego stosowania i przedyskutował je z pacjentem. Pacjenci świadomi swej nadwrażliwości na przeszłości na Oxiplex/AP lub jego składnik nie powinni być leczeni Oxiplex/AP. Żel służy jako bariera pomiędzy tkankami, zapobiegając ochronę przed tworzeniem się zrostów. Aby skutecznie zapobiegać zrostom, należy oddzielić tkankę żelem.

PRZYGOTOWANIE I UTYLIZACJA URZĄDZENIA
Oxiplex/AP przeznaczony jest do jednorazowego użytku. Nie używać/nie sterylizować ponownie.
1. Rozpakuj opakowanie zawierające strzykawkę napełnioną Oxiplex/AP i aplikator.
2. Sprawdź opakowanie pod kątem wszelkich uszkodzeń. Nie używaj, jeśli jest uszkodzone lub otwarte.
3. Stosując sterylną technikę, wprowadź strzykawki i aplikator do sterylnego pola roboczego.
4. Zdejmij nasadkę z końcówki strzykawki typu luer. W trakcie dootrzewnowego stosowania aplikatora, podłącz aplikator żelowy do końca blokującego luer strzykawki; obracaj do momentu całkowitego zamocowania. (W tym celu należy użyć tego samego aplikatora w obu strzykawkach).
5. Po użyciu wyrzucić strzykawki, pozostały żel i aplikator. Użyty Oxiplex/AP może stanowić zagrożenie biologiczne. Należy postępować zgodnie z krajowymi, lokalnymi lub instytucjonalnymi wytycznymi dotyczącymi usuwania materiałów niebezpiecznych dla zdrowia.

ZABIEG WEWNĄTRZMACICZNY
1. Nałożyć żel po zakończeniu zabiegu, po aspiracji wszystkich płynów i środków rozrzedzających.
2. Zamocować blokadę końcówki typu luer strzykawki do histeroskopu. Wciskając tłok strzykawki napełniać histeroskop żelem, aż żel ukazuje się na samym końcu końcówki histeroskopu.
3. Rozpocząć aplikację żelu na dnie macicy. Stopniowo nakładać żel aż do całkowitego wypełnienia macicy i kanału szyjki macicy, wciskając tłok strzykawki podczas powolnego wycofywania histeroskopu. Patrz Rysunek 1.
4. Zabieg powinien być przeprowadzony przez chirurga, z zastosowaniem standardowo stosowanej przez niego techniki.

GINEKOLOGICZNE I DOTRZEWNOWE ZABIEGI PRZYMIEDNICY
1. Nałożyć żel po zakończeniu zabiegu, po aspiracji wszystkich płynów nawadniających. W celu jak najlepszego usunięcia pozostałości płynów nawadniających zaleca się umieszczenie pacjenta w pozycji odwrotnej do pozycji Trendelenburga.
2. Pokryć pojedynczą warstwą Oxiplex/AP wszystkie miejsca anatomiczne, w których wymagane jest przeciwdziałanie przed zrostem. *Aplikator dozuje żel w formie „wstążki". Do powlekania powierzchni tkanki, dla której przewidziane jest przeciwdziałanie przed zrostem, należy stosować jedynie jednowarstwową wstążkę żelową (około 2 mm głębokości). Patrz Rysunek 2.
3. Użyć jedynie tyle żelu, ile konieczne jest do umieszczenia pojedynczej warstwy żelu na tkankach, zgodnie z opisanym sposobem. Nie ma konieczności zastosowania całych 40 ml żelu.
4. Po nałożeniu żelu nie należy gorepozycjonować sondami ani innymi przyrządami. Jeśli żel dostanie się do płynu nawadniającego, jego zdolność do przylegania do tkanek otrzewnej może być zagrożona. Dlatego należy usunąć go z jamy otrzewnej i zaaplikować w to miejsce nowy żel.
5. Zabieg powinien być przeprowadzony przez chirurga, z zastosowaniem standardowo stosowanej przez niego techniki.

***INSTRUKCJE DOTYCZĄCE DODATKOWEJ APLIKACJI ZELU: GINEKOLOGICZNE I ZABIEGI PRZY MIEDNICY**
1. Unieść jajnik ze ściany bocznej miednicy i zaaplikować jedną warstwę żelu, aby pokryć dół jajnikowy i tylną powierzchnię jajnika.
2. Przywrócić jajnik do normalnej pozycji anatomicznej i zaaplikować pojedynczą warstwę żelu, aby pokryć przednią część jajnika.
3. Nałożyć pojedynczą warstwę żelu, aby pokryć rurkę jajowodu wraz z bańką i krezką jajowodu.
4. Nałożyć pojedynczą warstwę żelu w celu pokrycia bocznej strony macicy, w kierunku przydatki skóry.

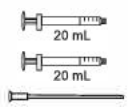
Zwykle 15 ml żelu wystarcza na pokrycie pojedynczego przydatku skóry i przylegających struktur, w tym jajowodu i bocznego brzegu macicy.

DZIAŁANIA NIEPOŻĄDANE
Podczas badań klinicznych nie zgłoszono żadnych działań niepożądanych związanych z urządzeniem[1-4]. Zgłoszono nasze pujące zdarzenia niepożądane, niekoniecznie związane z zastosowaniem Oxiplex/AP: ból, gorączka, obrzęk, zapalenie, reakcja na ciało obce, słabe wyniki.

REFERENCJE

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceed (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Zawartość: 2 – strzykawka 20 ml
1 – końcówka aplikatora



IT

DESCRIZIONE
Oxiplex/AP è un gel fluido, trasparente, monouso. Il gel è composto da una miscela sterile e assorbibile di ossido di polietilene (PEO) e carbossimetilcellulosa sodica (CMC). Il gel è stabilizzato al calcio, isotonico e studi preclinici hanno dimostrato che entro 30 giorni il prodotto non è più presente nella cavità peritoneale.

USO PREVISTO
Oxiplex/AP è destinato a essere utilizzato come barriera meccanica alla formazione di adesioni.

INDICAZIONI
Oxiplex/AP è destinato all'uso complementare in chirurgia intrauterina o peritoneale per ridurre l'incidenza, la portata, e la gravità di aderenze postoperatorie al sito chirurgico.

CONTROINDICAZIONI
Non utilizzare Oxiplex/AP in presenza di infezioni.

AVVERTENZE
Non iniettare per via endovenosa.

PRECAUZIONI
Oxiplex/AP viene fornito sterile. Non utilizzare dopo la data di scadenza. La sicurezza e l'efficacia di Oxiplex/AP non sono state studiate in condizioni di riutilizzo del dispositivo e/o dell'applicatore. Il riutilizzo può indurre risposte immunitarie e/o infezioni imputabili a contaminazione crociata o conservazione e/o trattamento impropri. L'uso di Oxiplex/AP non è stato studiato in combinazione con quello di altri prodotti di prevenzione delle aderenze, in concomitanza con l'uso di medicinali intraperitoneali o di agenti emostatici, né come mezzo di distensione. L'uso di Oxiplex/AP non è stato valutato nei bambini, né nelle donne in gravidanza o in allattamento. Pertanto, le pazienti devono essere messe in guardia rispetto al comportamento durante il primo ciclo mestruale successivo all'applicazione di Oxiplex/AP. L'uso di Oxiplex/AP non è stato valutato in presenza di neoplasie. L'uso di Oxiplex/AP non è stato valutato a seguito dell'apertura dell'intestino, della vescica, o di altri organi viscerali. L'applicazione del gel non è stata valutata in presenza di bile. Come per qualsiasi materiale di impianto, Oxiplex/AP può indurre reazioni da corpo estraneo. L'applicazione di strati multipli di gel nella cavità peritoneale aumenta il rischio di spostamento del gel dal previsto luogo di applicazione e, in alcuni di tali casi, durante lo studio clinico di follow up, è stata osservata una piccola quantità residua di gel a distanza di 6/10 settimane dopo la procedura. Il gel residuo non è stato associato a postumi clinici.[3,4]

CONSERVAZIONE E MANIPOLAZIONE: Conservare a temperatura ambiente (2 - 25 °C).

FORNITURA
Oxiplex/AP viene fornita sterile in vassoio termoformato. Il vassoio termoformato contiene due siringhe da 20 mL piene di gel e un applicatore per gel. L'esterno della confezione e gli elementi non contenuti all'interno non sono sterili. Vengono fornite etichette autoadesive di documentazione. Le etichette identificano il prodotto e il lotto di produzione.

ISTRUZIONI PER L'USO
PROCEDURA PRELIMINARE
Oxiplex/AP deve essere utilizzato esclusivamente da medici. Utilizzare Oxiplex/AP conformemente alle istruzioni per l'uso. L'uso di qualsiasi dispositivo medico pone dei rischi. Per ridurre al minimo ogni residuo rischio associato all'utilizzo di questo dispositivo, è consigliabile che il medico legga le informazioni per l'uso e che discuta con il paziente prima di utilizzare il dispositivo. I pazienti con storia clinica nota di ipersensibilità a Oxiplex/AP o ai suoi componenti non devono essere trattati con Oxiplex/AP. Il gel serve come barriera frapposta tra i tessuti al fine di impedire il formarsi di aderenze. Per una prevenzione efficace delle aderenze, il tessuto deve essere separato per mezzo del gel.

PREPARAZIONE DEL DISPOSITIVO E SMALTIMENTO
Oxiplex/AP è esclusivamente monouso. Non riutilizzare/risterilizzare.
1. Estrarre dalla scatola la confezione contenente la siringa pre riempita con Oxiplex/AP e il relativo applicatore.
2. Ispezionare la confezione per verificare se è danneggiata. Non utilizzare il prodotto se la confezione è danneggiata o aperta.
3. Con tecnica sterile, introdurre le siringhe e l'applicatore nel campo operatorio sterile.
4. Rimuovere il cappuccio dall'estremità del connettore luer lock della siringa. Quando l'applicatore viene utilizzato in procedure peritoneali, rimuovere il cappuccio dall'estremità del connettore luer lock della siringa e collegarvi l'applicatore del gel; ruotarlo finché è saldamente fissato. (Ove necessario, utilizzare il medesimo applicatore per entrambe le siringhe.)
5. Dopo l'uso, gettare le siringhe, ogni residuo di gel e l'applicatore. Il dispositivo Oxiplex/AP usato può essere a rischio biologico. Per lo smaltimento dei materiali biologici, attenersi alle linee guida nazionali, locali, o della struttura sanitaria.

CHIRURGIA INTRAUTERINA
1. Applicare il gel al termine della procedura, dopo aver aspirato ogni fluido e mezzo di distensione presente.
2. Collegare il connettore luer lock della siringa all'isteroscopio. Riempire l'isteroscopio con il gel comprimendolo con lo stantuffo della siringa finché il gel raggiunge l'estremità della punta dell'isteroscopio.
3. Avviare l'applicazione del gel sul fondo dell'utero. Applicare gradualmente il gel fino a riempire completamente l'utero e il canale cervicale agendo sullo stantuffo della siringa e ritraendo contemporaneamente e lentamente l'isteroscopio. Vedere Figura 1.
4. Terminare la procedura in base alla tecnica standard del chirurgo.

PROCEDURE CHIRURGICHE PELVICHE GINECOLOGICHE E PERITONEALI
1. Applicare il gel al termine della procedura, dopo aver aspirato ogni fluido di irrigazione. Per rendere più efficace la rimozione del fluido di irrigazione, disporre il paziente in posizione di Trendelenburg inversa.
2. Coprire tutti i siti anatomici in cui si desidera prevenire la formazione di aderenze con un singolo strato di Oxiplex/AP.* L'applicatore dispensa il gel in forma di "nastro". Per rivestire le superfici del tessuto che si desidera preservare dalla formazione di aderenze, deporre un nastro monostrato di gel (circa 2 mm di profondità). Vedere Figura 2.
3. Utilizzare solo la quantità di gel sufficiente a deporre un singolo strato di gel sui tessuti, come descritto. Non occorre usare interamente i 40 mL di gel disponibili.
4. Una volta applicato, non ridistribuire il gel servendosi di sonde o di altri strumenti. Se il gel cade in una raccolta di fluido di irrigazione, la sua capacità di aderire ai tessuti peritoneali può risultare compromessa. In tale circostanza, rimuoverlo dalla cavità peritoneale e applicare nuovo gel nel sito.
5. Terminare la procedura in base alla tecnica standard del chirurgo.

***ISTRUZIONI PER L'APPLICAZIONE ADDIZIONALE DI GEL: PROCEDURE CHIRURGICHE PELVICHE GINECOLOGICHE**
1. Sollevare l'ovaio dalla parete pelvica laterale e ricoprire la fossa ovarica e la superficie posteriore dell'ovaio con un singolo strato di gel.
2. Ripristinare la normale posizione anatomica dell'ovaio e ricoprirne la porzione anteriore con un singolo strato di gel.
3. Ricoprire la tuba di Faloppio, comprese l'ampolla e la mesosalpinge, con un singolo strato di gel.
4. Applicare un singolo strato di gel a coprire l'aspetto laterale dell'utero, prospiciente gli annessi.

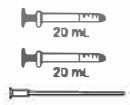
In genere, 15 mL di gel sono sufficienti per ricoprire un singolo annesso e le strutture anatomiche adiacenti, tra cui la fossa ovarica e il margine laterale dell'utero.

REAZIONI AVVERSE
Non sono state riportate reazioni avverse correlate all'uso del dispositivo in studi clinici.[1-4] Benché non necessariamente attribuibili all'uso di Oxiplex/AP, sono stati riportati i seguenti eventi avversi: dolore, febbre, gonfiore, infiammazione, reazione da corpo estraneo e scarsa performance.

RIFERIMENTI

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethykellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopk Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgkk, Ido Ben Ami, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Interceoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Contenuto: 2 - Siringa da 20 ml
1 - Punta dell'applicatore



NL

BESCHRIJVING
Oxiplex/AP is een doorzichtige vloeibare gel voor eenmalig gebruik. De gel is een steriele resorbeerbare combinatie van polyethyleenoxide (PEO) en natriumcarboxymethylcellulose (CMC). De gel is met calcium gestabiliseerd en is isotoon. Door preklinisch onderzoek is aangetoond dat de gel de peritoneale holte binnen 30 dagen zuivert.

BEOOGD GEBRUIK
Oxiplex/AP is bedoeld voor gebruik als mechanische barrière tegen adhesievorming.

INDICATIES
Oxiplex/AP is bedoeld om te worden gebruikt als aanvulling op een intra- uteriene of peritoneale operatie voor het verminderen van de incidentie, mate en ernst van postoperatieve adhesies op de operatielocatie.

CONTRA-INDICATIES
Gebruik Oxiplex/AP niet in de nabijheid van infecties.

WAARSCHUWINGEN
Niet intraveneus injecteren.

VOORZORGSMAATREGELEN
Oxiplex/AP wordt steriel geleverd. Niet gebruiken na de uiterste gebruiksdatum. De veiligheid en werkzaamheid van Oxiplex/AP bij hergebruik van het instrument en/of de applicator zijn niet beoordeeld. Hergebruik kan in immuunreacties en/of infectie resulteren, als gevolg van kruisbesmetting, onjuiste opslag en/of hantering. Er is geen onderzoek gedaan naar het gebruik van Oxiplex/AP in combinatie met andere producten voor adhesiepreventie, in de aanwezigheid van intraperitoneale geneesmiddelen of hemostatische middelen, of als dispersiemedium. Het gebruik van Oxiplex/AP bij kinderen of tijdens de zwangerschap of borstvoeding is niet geëvalueerd. Daarom moeten patiënten worden geadviseerd niet zwanger te worden tijdens de eerste menstruatiecyclus na toepassing van Oxiplex/AP. Oxiplex/AP is niet geëvalueerd in aanwezigheid van maligniteiten. Oxiplex/AP is niet geëvalueerd na opening van de darm, blaas of andere viscerale organen. De gel is niet geëvalueerd in aanwezigheid van gal. Zoals bij elk geïmplanteerd materiaal kunnen met Oxiplex/AP vreemd-lichaamreacties optreden. Het aanbrengen van meerdere lagen gel in de peritoneale holte verhoogt het risico van losraken van de gel van de beoogde toepassingsplaats en in sommige van deze gevallen werd bij een klinische studie een kleine hoeveelheid resterende gel waargenomen tijdens de follow-upprocedure 6 tot 10 weken later. Resterende gel werd niet in verband gebracht met klinische gevolgen.[3,4]

OPSLAGEN HANTERING: Bewaren bij kamertemperatuur (2 - 25 °C).

WIJZE VAN LEVERING
Oxiplex/AP wordt steriel geleverd in een thermoform bakje. Het thermoform bakje bevat twee 20 ml spuiten met gel en één gelapplicator. De buitenkant van de verpakking en de andere inhoud zijn niet steriel. Er worden zelfklevende etiketten meegeleverd voor documentatiedoeleinden. De etiketten identificeren het product en de productiepartij.

GEBRUIKSAANWIJZING
PREPROCEDURE
Oxiplex/AP mag uitsluitend worden gebruikt door artsen. Gebruik Oxiplex/AP volgens de gebruiksinstructies. Aan het gebruik van alle medische hulpmiddelen zijn risico's verbonden. Om risico's verbonden aan het gebruik van dit instrument te beperken, verdient het aanbeveling dat de gebruiksinformatie wordt gelezen door de arts en besproken met de patiënt vóór gebruik van het instrument. Patiënten met een bekende voorgeschiedenis van overgevoeligheid voor Oxiplex/AP of de bestanddelen ervan, mogen niet met Oxiplex/AP worden behandeld. De gel dient als barrière tussen weefsel om adhesievorming te voorkomen. Weefsel moet door de gel worden gescheiden voor een doeltreffende adhesiepreventie.

VOORBEREIDING VAN HET INSTRUMENT EN AFVOER
Oxiplex/AP is uitsluitend bedoeld voor eenmalig gebruik. Niet opnieuw gebruiken of opnieuw steriliseren.
1. Haal de verpakking met de met Oxiplex/AP gevulde spuiten applicator uit de doos.
2. Controleer de verpakking op beschadigingen. Gebruik het product niet als de verpakking beschadigd of geopend is.
3. Plaats de spuiten en applicator met behulp van steriele techniek in het steriele operatieveld.
4. Verwijder de dop van het luerlockuiteinde van de spuit. Bij gebruik van de applicator voor peritoneaal gebruik, koppel tude gelapplicator aan het luerlock-uiteinde van de spuit; draai stevig vast. (Indien nodig kan dezelfde applicator voor beide spuiten worden gebruikt).
5. Gooi de spuiten, eventueel resterende gel en de applicator weg na gebruik. Oxiplex/AP is na gebruik een potentieel biologisch gevaarlijk product. Volg de nationale, lokale of in de instelling geldende voorschriften voor de afvoer van biologisch gevaarlijk materiaal.

INTRA-UTERIENE CHIRURGIE
1. Breng de gel aan aan het einde van de procedure, na aspiratie van alle vloeistoffen en distentiemedia.
2. Bevestig de luerlock van de spuit op de hysteroscoop. Vul de hysteroscoop met gel door de spuitplunjer in te drukken totdat er gel aan het uiteinde van de hysteroscoop verschijnt.
3. Begin met het aanbrengen van de gel aan de bovenkant van de baarmoeder. Ga geleidelijk door met het aanbrengen van de gel totdat de baarmoeder en het cervixkanaal geheel gevuld zijn, door de spuitplunjer in te drukken terwijl u de hysteroscoop langzaam terugtrekt. Zie afbeelding 1.
4. Sluit de chirurgische procedure af volgens de standaardtechniek van de chirurg.

BEKKEN-, GYNAECOLOGISCHE EN PERITONEALE OPERATIES
1. Breng de gel aan aan het einde van de procedure, na aspiratie van alle irrigatievloeistoffen. Aanbevolen wordt om de patiënt in een omgekeerde Trendelenburgligging te plaatsen voor de meest efficiënte verwijdering van resterende irrigatievloeistof.
2. Bedek alle anatomische locaties waar adhesiepreventie gewenst is met een enkele laag Oxiplex/AP*. De applicator brengt de gel aan in een "lint". Er dient slechts een enkele laag gelint (van ongeveer 2 mm diep) te worden gebruikt om het weefseloppervlak waarvoor de adhesiepreventie is bedoeld, te bedekken. Zie afbeelding 2.
3. Gebruik net voldoende gel om een enkele laag gel op het weefsel aan te brengen zoals beschreven. Het is niet nodig om de volledige 40 ml gel te gebruiken.
4. Verplaats de gel niet met sondes of andere instrumenten als deze eenmaal is aangebracht. Als de gel in een plas irrigatievloeistof valt, kan het vermogen om te hechten aan peritoneaal weefsel zijn aangetast. In dat geval moet de gel uit de peritoneale holte worden verwijderd en moeten nieuwe gel worden aangebracht op de betreffende locatie.
5. Sluit de chirurgische procedure af volgens de standaardtechniek van de chirurg.

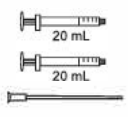
***AANVULLENDE INSTRUCTIES VOOR HET AANBRENGEN VAN DE GEL: BEKKEN/GYNAECOLOGISCHE OPERATIES**
1. Til de eierstok weg van de bekkenwand en breng een enkele laag gel aan om de eierstokholte en het posterieure oppervlak van de eierstok te bedekken.
2. Breng de eierstok terug in de normale anatomische positie en breng een enkele laag gel aan om het anterieure deel van de eierstok te bedekken.
3. Breng een enkele laag gel aan om de eileider inclusief de ampulla en de mesosalpinx te bedekken.
4. Breng een enkele laag gel aan om het laterale deel van de uterus te bedekken dat naar de adnexa is gericht. Normaal gesproken is 15 ml gel voldoende om één adnexa en aangrenzende structuren, inclusief de eierstokholte en de laterale grens van de uterus, te bedekken.

BIJWERKINGEN
Er zijn geen instrumentgerelateerde bijwerkingen gemeld in klinische studies.[1-4] Hoewel ze niet noodzakelijkerwijs te wijten zijn aan het gebruik van Oxiplex/AP, zijn de volgende bijwerkingen gemeld: pijn, koorts, zwelling, ontsteking, vreemdlichaamreacties en slechte wondgenezing.

REFERENTIES

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Inhoud: 2 - Spuit 20 ml.
1 - Applicatorpunt



NO

BESKRIVELSE
Oxiplex/AP er en klar, flytende gel til engangsbruk. Gelen er en steril, absorberbar kombinasjon av polyetylenoksid (PEO) og natriumkarboksymetylcellulose (CMC). Gelen er kalsiumstabilisert og isotonisk, og prekliniske studier har vist at den forsvinner fra peritonealhulen innen 30 dager.

TILTENKT BRUK
Oxiplex/AP er tiltenkt for bruk som en mekanisk barriere mot adhesjonsdannelse.

INDIKASJONER
Oxiplex/AP er tiltenkt for bruk som et supplement i intrauterin eller peritoneal kirurgi for å redusere forekomsten, omfanget av og alvorlighetsgraden av postoperative adhesjoner ved det kirurgiske stedet.

KONTRAINDIKASJONER
Oxiplex/AP skal ikke anvendes i nærheten av infeksjoner.

ADVARSLER
Skal ikke injiseres intravenøst.

FORHOLDSREGLER
Oxiplex/AP leveres steril. Må ikke brukes etter utløpsdatoen. Sikkerhet og effekt av Oxiplex/AP har ikke blitt studert i forbindelse med gjenbruk av anordningen og/eller applikatoren. Gjenbruk kan føre til immunologisk respons og/eller infeksjon på grunn av krysskontaminasjon, feilaktig oppbevaring og/eller håndtering. Oxiplex/AP har ikke blitt studert sammen med andre antiadhesjonsprodukter, i nærvær av intraperitoneale medisinske midler eller hemostasemidler eller som et dispersjonsmiddel. Oxiplex/AP har ikke blitt evaluert hos barn eller gravide eller ammende kvinner. Pasienter bør derfor rådes til å unngå å unnfange i løpet av den første menstruasjonssyklusen etter påføring av Oxiplex/AP. Oxiplex/AP har ikke blitt evaluert i nærvær av ondartede svulster. Oxiplex/AP har ikke blitt evaluert etter åpning av tarmen, blæren eller andre viscerale organer. (Product) har ikke blitt evaluert i nærvær av ondartete svulster. Ulikhet med annet implantert materiale, kan det forekomme reaksjoner over for fremmedlegemer med Oxiplex/AP. Påføring av flere lag med gel i peritonealhulen øker risikoen for at gel løsner fra det tiltenkte påføringsstedet, og i noen av disse tilfellene, har en liten mengde gjenværende gel blitt observert i oppfølgingsprosedyren for den kliniske studien 6 til 10 uker senere. Gjenværende gel ble ikke assosiert med klinisk sekvele.[3,4]

OPPBEVARING OG HÅNDTERING: Oppbevares ved romtemperatur (2–25 °C).

LEVERINGSMÅTE
Oxiplex/AP leveres sterilt i et termoformbrett. Termoformbrettet inneholder to sprøyter med 20 ml gel og én gelapplikator. Utsiden av emballasjen og det ytre innholdet er ikke sterilt. Det følger med klistremerketiketter for dokumentasjon. Etikettene identifiserer produktet og produksjonsløpet.

BRUKSANVISNING
FORHÅNDSPROSEDYRE
Oxiplex/AP skal kun brukes av leger. Bruk Oxiplex/AP i henhold til bruksanvisningen. Det er alltid en risiko ved bruk av medisinske anordninger. For å redusere den gjenværende risikoen forbundet med bruken av denne anordningen til et minimum anbefales det at legen leser informasjonen for bruk og drøfter det med pasienten før bruk av anordningen. Pasienter som har en kjent historikk av overfølsomhet overfor Oxiplex/AP eller dens komponenter, skal ikke behandles med Oxiplex/AP. Gelen fungerer som en barriere mellom vev for å forhindre adhesjon fra å dannes. Vev må skylles med gel for effektiv forhindring av adhesjon.

KLARGJØRING AV ANORDNINGEN OG KASSERING
Oxiplex/AP er kun til engangsbruk. Må ikke brukes/steriliseres på nytt.
1. Ta Oxiplex/AP ferdigfylte sprøyte og applikator ut av emballasjen og esken.
2. Kontroller emballasjen for eventuell skade. Må ikke brukes hvis skade teller åpnet.
3. Legg sprøytene og applikatorene i det sterile operasjonsfeltet ved bruk av steril teknikk.
4. Ta hetten av enden av sprøyten med luerlås. Ta hetten av enden av sprøyten med luerlås, og koble gelapplikatoren til enden av sprøyten med luerlås. Vri til den sitter godt fast. (Om nødvendig kan den samme applikatoren brukes for begge sprøytene.)
5. Kast sprøyter, eventuell resterende gel og applikatorene etter bruk. Den brukte Oxiplex/AP-anordningen kan være en biologisk risiko. Overhold nasjonale, lokale eller institusjonelle retningslinjer for kassering av materiale som er en biologisk risiko.

INTRAUTERIN KIRURGI
1. Påfør gelen på slutten av prosedyren etter å ha aspirert alle væsker og distensjonsmidler.
2. Fest sprøytens luerlås på hysteroskopet. Fyll hysteroskopet med gel ved å trykke ned sprøytestempelet til det kommer gel ut av tuppen på hysteroskopet.
3. Begynn påføringen av gel øverst i livmoren. Påfør gel gradvis slik at den fyller livmoren og livmorhalsen ved langsomt å trykke ned sprøytestempelet mens du langsomt trekker hysteroskopet tilbake. Se figur 1.
4. Avslutt prosedyren i henhold til kirurgens standardteknikk.

GYNEKOLOGISK OG PERITONEAL BEKKENKIRURGI
1. Påfør gelen på slutten av prosedyren etter å ha aspirert all irrigasjonsvæske. Det anbefales at pasienten plasseres i et revers Trendelenburg-leie for mest effektiv fjerning av gjenværende irrigasjonsvæske.
2. Dekk alle anatomiske steder der forhindring av adhesjoner ønskelig, med et lag Oxiplex/AP.* Applikatoren dispenserer gelen i et «bånd». Det skal bare brukes gel bånd i ett lag (dybde på ca. 2 mm) for å dekke vevsoverflatene som forhindring av adhesjoner tiltenkt for. Se figur 2.
3. Bruk bare nok gel til å plassere et enkelt lag med gel på vevene, som beskrevet. Det er ikke nødvendig å bruke hele mengden med 40 ml gel.
4. Ikke flytt gelen med sonder eller andre instrumenter når den har blitt påført. Hvis gelen faller i en oppsamling av irrigasjonsvæske, kan det hende at den ikke kan feste seg til peritonealt vev. Det må derfor fjernes fra peritonealhulen, og ny gel må påføres på stedet.
5. Avslutt prosedyren i henhold til kirurgens standardteknikk.

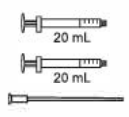
***INSTRUKSJONER VED PÅFØRING AV ENSTRA GEL: GYNEKOLOGISK BEKKENKIRURGI**
1. Løft eggstokken vekk fra sideveggen av bekkenet, og påfør et enkelt lag med gel for å dekke gropene i eggstokkene og den bakre overflaten av eggstokken.
2. Legg eggstokken tilbake i normal, anatomisk posisjon, og påfør et enkelt lag med gel for å dekke den fremre delen av eggstokken.
3. Påfør et enkelt lag med gel for å dekke eggleder en, inkludert mesosalpinx ampullen.
4. Påfør et enkelt lag med gel for å dekke den laterale delen av livmoren som er vendt mot livmortilbehøret. 15 ml gel holder som regel til å dekke et: enkelt tilbehør og tilstøtende strukturer, inkludert eggstokkgropene og den laterale kanten av livmoren.

BIVIRKNINGER
Det ble ikke rapportert om noen bivirkninger relatert til anordningen i kliniske studier.[1-4] Selv om det ikke nødvendigvis kan tilskrives bruken av Oxiplex/AP, har de følgende bivirkningene blitt rapportert: smerter, feber, hevelse, inflammasjon, reaksjon overfor fremmedlegemer og dårlig ytelse.

REFERANSER

1. Di Spiezio Sardo, Attilio, Marialuigia Spinelli, Silvia Bramante, Marianna Scognamiglio, Elena Greco, Maurizio Guida, Vito Cela and Carmine Nappi. "Efficacy of a Polyethylene Oxide-Sodium Carboxymethylcellulose Gel in Prevention of Intrauterine Adhesions after Hysteroscopic Surgery." J Minim Invasive Gynecol 2011, 18, no. 4: 462-9.
2. Fuchs, Noga, Noam Smorgick, Ido Ben Arni, Zvi Vaknin, Yoseph Tovbin, Reuvit Halperin and Moty Pansky. "Intercoat (Oxiplex/AP Gel) for Preventing Intrauterine Adhesions after Operative Hysteroscopy for Suspected Retained Products of Conception: Double-Blind, Prospective, Randomized Pilot Study." J. Minimally Invasive Gynecol. 2014, 21, no. 1.
3. Lundorf P, J Donnez, M Korell, AJ Audeburt, K Block and GS diZerega. 2005. Clinical evaluation of a viscoelastic gel for reduction of adhesions following gynecological surgery by laparoscopy in Europe. Human Reproduction. Vol. 20:2, pp. 514-520.
4. Young P, A Johns, C Templeman, C Witz, B Webster, R Ferland, M Diamond, K Block and GS diZerega. 2005. Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel: A Pilot Study. Fertility and Sterility. Vol. 84:5, pp. 1450-1456.

Innhold: 2 - sprøyte 20 ml.
1 - Applikatorspiss



From: s22
To: s22 @fziomed.com"
Subject: Questionnaire re DIR 71615 [SEC=OFFICIAL]
Date: Tuesday, 12 October 2021 8:49:00 AM
Attachments: DIR 71615 Request for Information .doc.rtf
image001.png

Please find the attached Questionnaire with regard to DIR 71615

Thankyou

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 E: s22 @health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 @fziomed.com

File Reference: E21-373395
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 71615 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

The Therapeutic Goods Administration has been advised of an incident involving the above product. A copy of the Device Incident Report (DIR) is attached.

To assist in the evaluation and resolution of this report, please provide the information requested in the attached questionnaire and return it to this office **within 20 working days of the date of this letter,** and no later than COB 08/11/2021.

Please send responses via email to s22 @health.gov.au, referencing the DIR number.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on

s22 or email: s22 @health.gov.au .

Yours sincerely

Signed electronically by

s22

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

11/10/2021

Document 13

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 11/10/2021

DIR: 71615 Manufacturer Name: Fziomed Inc [40334]

Question/Requirement		
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number	**ARTG:**	
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:	**YES**	**NO**
a) To the Australian Market	☐	☐
b) For Export	☐	☐
3) How many of this model have been supplied	In Australia:	
	Worldwide:	
4) How many of this batch (if applicable) have been supplied:	In Australia:	
	Worldwide:	
5) Are you aware of this problem, as reported?	☐	☐
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?	☐	☐
7) Have you had any other reports of similar* problems with this product in Australia?	☐	☐

If **YES**, how many:

If **YES**, please give details:

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? ☐ ☐

If **YES**, how many:

If **YES**, please give details:

9) Please provide details of any action you have taken, or intend to take, regarding this problem

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date:

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- ☐ Service History, and Safety and Performance Test Results
- ☐ Configuration Information and Documentation
- ☐ HHE (Health Hazard Evaluation)

12) Additional Information required: Document 13

- IFU states.
  "Oxiplex/AP has not been evaluated in children"

This incident was in children, has this changed, do you recommend its use in Children?

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name		Phone	
Signature		Fax	
		Email	
Position			

This questionnaire and any appended documents should be returned to the TGA within **20 working days or as specified on page 1 of this letter.**

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

Document 13

Reporter Reference #:

Date of Adverse Event:
s22

Date of Final Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc [40334]

Sponsor:
Fziomed Australia Pty Ltd [49415]
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name: s22

Phone: s22

Email: s22 @fziomed.com

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

Additional Event Description:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

From: s22
To: s22
Cc: s22 ; s22 ; IRIS
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]
Date: Thursday, 14 October 2021 4:11:35 AM
Attachments: image004.png
AU_DIR 71615 Request for Information_101321.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Mr. s22

See the attached file that contains the completed Questionnaire with regard to DIR 71615.

Please contact me with any questions or if something more is needed.

~s22

s22
FzioMed, Inc.|231 Bonetti Drive, San Luis Obispo, CA 93401 US
T s22 | F +1 805 546 0571 s22 @fziomed.com

From: s22 [mailto:s22 @health.gov.au]
Sent: Monday, October 11, 2021 2:49 PM
To: s22 @fziomed.com>
Subject: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Please find the attached Questionnaire with regard to DIR 71615

Thankyou

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 E: s22 @health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100

Woden ACT 2606
www.tga.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Document 14

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR **Date:** 11/10/2021

DIR: 71615 Manufacturer Name: FzioMed Inc [40334]

Question/Requirement			YES	NO
1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number		**ARTG: 15224**		
2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers:				
a) To the Australian Market			X	
b) For Export				X
3) How many of this model have been supplied	In Australia:	14, 274		
	Worldwide:	82,595		
4) How many of this batch (if applicable) have been supplied:	In Australia:	121		
	Worldwide:	141		
5) Are you aware of this problem, as reported?			X	
6) If deemed necessary, is a sample of the mentioned device available for review and/or testing?			X	
7) Have you had any other reports of similar* problems with this product in Australia?				X

If **YES**, how many: n/a

If **YES**, please give details:

n/a

* Similar events are based on the clinical event description and not the cause of an event. Both the confirmed and unconfirmed rates for similar events are often required and beneficial to show the full outlook of the device and its use.

8) Is the manufacturer aware of reports of similar problems with this product? ☐ ☒ X

If **YES**, how many: n/a

If **YES**, please give details:

n/a

9) Please provide details of any action you have taken, or intend to take, regarding this problem

After receiving the initial report in July 2019, FzioMed spoke with the surgeon via telephone and requested all relevant clinical information including: 1) Product code (reorder) number of product used in surgery (received); 2) lot number of product used (received) and approximate volume applied; 3) copy of haematology report (received); 4) copy of haematology slides (received); 5) copy of operative notes. The surgeon was informed that Oxiplex/AP is an inert physical barrier. It is a temporary implant and is excreted through the urine and faeces. FPC-09012, Oxiplex/AP, Lot 64996, was identified as being used. FzioMed responded to the additional information stating they had not seen this type of blood response to Oxiplex/AP and reiterated that use of the gel has not been evaluated in children.
On 14 July 2021, FzioMed received a report of additional cases whereby a precipitant was identified on blood films in the post-operative period after the product was used at surgery in children following a retrospective audit of Oxiplex AP in their facility. Again, relevant clinical information was requested. A copy of the Oxiplex AP IFU, noting that the product is to be used in adults only and precautions that Oxiplex/AP has not been evaluated in children or pregnant or nursing women, nor following opening of the bowel, bladder, or other visceral organs, or in the presence of bile, was provided to the distributor for the surgeon(s). The 14 July 2021 information was combined with the file of the initial report. No additional information was received by FzioMed.

10) Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

Date: 11 Feb 2020

An evaluation of the lot history records for lot 64996 showed no issue with the product which passed all QC requirements upon release. The product lot had been shipped to a single distributor in Australia twice and another distributor in Israel in the Dec 2018-Jan 2019 timeframe. No other complaint reports have been received for this product lot.

11) When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if checked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☐ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☐ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☐ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:2007.
- ☐ Service History, and Safety and Performance Test Results
- ☐ Configuration Information and Documentation
- ☐ HHE (Health Hazard Evaluation)

12) Additional Information required:

- IFU states.
  "Oxiplex/AP has not been evaluated in children"

This incident was in children, has this changed, do you recommend its use in Children?

The statement under PRECAUTIONS in FzioMed's Oxiplex/AP Instructions for Use, "Oxiplex/AP has not been evaluated in children..." has not changed. FzioMed does not recommend the use of Oxiplex/AP in children.

13) If your device is an implantable pacemaker/defibrillator and/or associated lead you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.
3. What material has been used to insulate, both internally and externally, the lead? (applicable to leads only)

Information Supplied By:

14)

Name s22 [redacted]
Signature s22 [redacted]
Position s22 [redacted]
Phone s22 [redacted]
Fax +1.805.546.0571
Email s22 [redacted]@fziomed.com

This questionnaire and any appended documents should be returned to the TGA within 20 working days or as specified on page 1 of this letter.

Electronic submission of all information is preferred.
Please send the requested information to email address: IRIS@health.gov.au

For large size documents, please post a universal serial bus (USB), compact disc (CD), or digital versatile disc (DVD) via postal address:

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

If you are sending a device/s to the TGA please follow the instructions via link:

https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-use

---

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act,

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Final Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
FzioMed Inc [40334]

Sponsor:
FzioMed Australia Pty Ltd [49415]
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Email: s22 [redacted]@fziomed.com

Fax:

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

Additional Event Description:

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

From: s22
To: s22
Subject: Completed DIR 71615 letter [SEC=OFFICIAL]
Date: Thursday, 23 December 2021 2:23:03 PM
Attachments: image001.png
Sponsor_Complete_Letter~Oxiplex DIR71615.pdf

Good afternoon s22

Please find attached the complete letter for DIR 71615

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 E: s22 @health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

s22
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223
Email: s22 @fziomed.com

File Reference: E21-373395
Sent by email

Dear s22

DEVICE INCIDENT REPORT DIR 71615 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

An investigation into the incident reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Medical Device Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please contact our team on s22 or send an email to: IRIS@health.gov.au

Yours sincerely

Signed electronically by

Administration Officer

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

23/12/2021

DIR 71615 - ARTG # 152224 - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22 [redacted]

Date of Initial Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc [40334]

Sponsor:
Fziomed Australia Pty Ltd [49415]
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name: s22 [redacted]

Phone: s22 [redacted]

Fax:

Email: s22 [redacted]@fziomed.com

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Clinical Signs (Level 1)
Others

Clinical Signs (Level 2)
Insufficient Information

Health Impacts (Level 1)
Insufficient Information

Health Impacts (Level 2)

Type of Problem (Level 1)
Appropriate Term/Code Not Available

Type of Problem (Level 2)

Cause of Problem (Level 1)
Usage Problem Identified

Cause of Problem (Level 2)

Outcome of Investigation

Reviewed, No Further Action Required

Summary of Investigation:
A review of the device instructions for use (IFU) states that “Oxiplex/AP has not been evaluated in children”, the IFU also includes “a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later”

Reviewed no further action required.; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:
23/12/2021

***** End of DIR 71615 *****

From: s22
To: s22 @health.wa.gov.au
Subject: DIR 71615 Oxiplex [SEC=OFFICIAL]
Date: Thursday, 23 December 2021 2:14:41 PM
Attachments: Reporter_Complete_Letter~STANDARD~Oxiplex DIR 71615.pdf

---

Good afternoon

Please find attached the completed investigation for DIR 71615

Regards s22

Medical Device Incident Report Investigation Scheme (IRIS)
Medical Devices Surveillance Branch
Therapeutic Goods Administration (TGA)
Email: iris@health.gov.au
Fax: 02 6232 1713
Post: PO Box 100, Woden, ACT 2606
Courier: 136 Narrabundah Lane, Symonston, ACT 2609

Document 16

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

Dr s22
Paediatric Surgeon
Perth Children's Hospital
15 Hospital Avenue
Nedlands WA 6009
Email: s22 @health.wa.gov.au

File Reference: E21-373395
Sent by email

Dear Dr s22

DEVICE INCIDENT REPORT DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

An investigation into the incident you reported to the Therapeutic Goods Administration concerning the above device is now complete.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, including the investigation summary is attached for your information.

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any questions regarding this report please contact our team on s22 or send an email to: IRIS@health.gov.au

Yours sincerely,
Signed electronically by

s22

Incident Report Investigation Scheme
Devices Post Market Monitoring Section
Therapeutic Goods Administration

23/12/2021

DIR 71615 - Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Reporter Reference #:

Date of Adverse Event:
s22

Date of Report:
09/08/2021

ARTG #:
152224

Brand Name:
Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Device Class:
Class III

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Fziomed Inc

Sponsor:
Fziomed Australia Pty Ltd
PO Box 339
CURRUMBIN WATERS QLD 4223

Contact Name:
s22

Phone:
s22

Reporter:

Confidential: Yes

Clinical Event Information:
Initially reported on [Redacted]; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in [Redacted], we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Patient Outcome/Consequences:
No Injury

Investigation Summary:
A review of the device instructions for use (IFU) states that “Oxiplex/AP has not been evaluated in children”, the IFU also includes “a small amount of residual gel was observed during the clinical study follow up procedure 6 to 10 weeks later”

Reviewed no further action required.; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Date Completed:
23/12/2021

***** End of DIR 71615 *****

Document 17

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DPMMS FORM 1.2.a	Request for Advice or Assessment of DIRs under investigation		
Comes under	DPMMS WI 1.2 – Risk assessment and triage of MD incident reports		
Applicable to	Devices Post Market Monitoring Section	Authorised by	s22 s22 DPMMS
Date issued	21 Mar 2021	Version #	1.0

Device(s):	Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention
Sponsor:	Fziomed Australia Pty Ltd
Manufacturer:	Fziomed Inc
Device Incident Report No:	DIR 71615
TRIM folder:	E21-373395
ARTG Number(s):	ARTG 152224

Area advice sought	☒ Clinical ☐ Laboratories ☐ Advertising ☐ Recalls ☐ Other:
Questions for assessment:	Review the IFU and determine if the IFU: • Is sufficient and meets the EP's for its intended use?. • Does the IFU require updating?
Additional Information:	Sponsor Questionnaire - D21-3217454

Include anything (via a TRIM number) that may assist the assessor to provide a comprehensive answer	Devices IFU - D21-3144232. Attached: • Copy of DIR 71615 • Documents that are attached to the DIR in Infoleader. (x 3 documents)
Time frame to complete *30 days unless otherwise negotiated with the section required to do the assessment*	

Comments and Rationale

Australian Register of Therapeutic Goods Inclusion Details

The Sponsor, Fziomed Australia Pty Ltd, has the device, “Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention” included under the Australian Register of Therapeutic Goods (ARTG) entry 152224. The ARTG entry describes the device under the category description of “Medical Device Class III”.

The intended use in TGA eBS and the ARTG public summary for ARTG 152224 is:

> “Oxiplex/AP is intended for use as a mechanical barrier to adhesion formation. It is intended to be used as an adjunct to intrauterine or peritoneal surgery for reducing the incidence, extent, and severity of postoperative adhesions at the surgical site.”

Background

The TGA received a DIR from a Hospital in Perth, for the Oxiplex/AP Gel, the report indicates that the product was used in children. The TGA requested the IFU from the sponsor, review of the IFU has been found to lack crucial information and is not clear regarding its use.

Electronically Signed by:
Requestor: s22 [redacted]
Date: 29/11/2021

Conclusion

Clinical assessor – s22 [redacted]

A DIR was received from Perth Children’s Hospital on 19 August 2021. According to the DIR, a precipitant was identified in the post-operative blood film of a paediatric patient in July 2019. The Director of Surgery at Perth Children’s Hospital contacted the distributor LifeHealthcare in August

2019 and initiated a retrospective audit in all patients treated with Oxiplex/ AP. According to the DIR, the audit identified the precipitant in the post-operative blood film of four more paediatric patients. However, no further information is provided about the audit. Both the distributor LifeHealthcare and the manufacturer FzioMed Inc were informed in July 2021.

No harms were identified in all 5 paediatric patients.

There was no information provided on the precipitant other than it was identified in post-operative blood films. It would be useful to know the name of the precipitant and how it was identified as a result of Oxiplex/AP use.

Whilst the intended purpose does not explicitly state adults only, the IFU does state under precautions that 'Oxiplex/AP has not been evaluated in children'. The IFU does not state that use in children is a contraindication. The IFU could be strengthened by making this statement.

Amending the IFU to limit the use to adults only or placing children in contraindications sections would strengthen the IFU, though its impact on overall risk may be modest, since the use in the paediatric age group seems low.

This appears to be an isolated cluster of cases involving a single institution. The sponsor has confirmed no other reports of this nature has been reported globally. FzioMed has sold 14,274 units in Australia from 8 May 2018 to 11 October 2021 and 82,595 units globally since 2002 . Hence, this type of use does not appear to be common.

Questions

1. Is IFU sufficient and meets the EP's for its intended use?

   A full assessment of device EP compliance is outside the scope of this request, since comprehensive clinical evidence has not been provided. EP compliance cannot be assessed from the IFU.

   However, the IFU is satisfactory and consistent with the clinical evidence available, hence complies with EP 13. There is no evidence to indicate non-compliance with the EPs due to this isolated case report, considering the extensive product history. Compliance with EP 2 could be enhanced by a more explicit IFU warning about use in the paediatric age group, which would further mitigate this risk. Whilst it could be suggested to the sponsor, the clinical assessor does not consider that continuing with the existing IFU would mean non-compliance with EP 2, because the impact of this change cannot be determined and would likely be modest.

   This advice is based on the available information that this is not a widespread phenomenon and that there have been no further case reports. If further instances of paediatric use were to be identified this may change this advice – hence DCS would be happy to review.

2. Does the IFU require updating?

   It cannot be determined if the clinician considered the precautions or not from the information provided but the IFU does not cite paediatric use as a contraindication or restrict the intended purpose to adults.

   The IFU did provide relevant information to guide clinical decision making.

   An IFU amendment could improve the IFU but the impact on risk is uncertain. Given the modest impact on risk and the lack of any identified harms at this stage, the clinical assessor considers an IFU amendment to be desirable but not essential. However, this advice could change if further reports are received or more information comes to light in the future.

   Hence, an update to the IFU should be considered by the sponsor but is not required at this stage.

Further information:

- The clinical assessor would be interested to know the likely identity of the precipitant, and to view a copy of the audit from Perth Children's Hospital, if these can be obtained from Perth Children's Hospital or the sponsor.

Assessor

Name	s22 [redacted]		
Position	Choose an item.		
Comments			
Signature	*Signed electronically in TRIM.*	Date	17 December 2021

Save this completed form into the relevant TRIM folder.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3558467	Previously DVMS TEMP 1.2.n version 1.0 (D18-11138355) Reissued as a FORM (DPMMS FORM 1.2.a version 1.0)	s22 [redacted] s22 [redacted]	21 Mar 2021

From: s22
To: s22
Subject: DIR 71615 Request for Clinical advice- TRIM E21-373395 [SEC=OFFICIAL]
Date: Tuesday, 30 November 2021 9:43:42 AM
Attachments: image001.png
00206BAB01B2210712152749.pdf
DIR 71615 - Original User Report.pdf
Oxilpex_PCH_July2021.pdf

Hi Clinical

Please find attached Request for clinical advice doe DIR 71615 D21-3383159

Included in this email are documents provided by the user with this report in infoleader.

All relevant information can be found in TRIM container. E21-373395

Regards

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 E: s22 @health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

LifeHealthcare
> Not your typical multinational

s22
s22
s22
Perth Children's Hospital

cc: s22
s22

26 July 2021

Dear Dr s22

Oxiplex AP Anti-Adhesive Barrier Gel

Thank you for your recent letter advising of the progress of your retrospective audit of Oxiplex AP and communication of findings to the Therapeutic Goods Administration (TGA).

We can confirm that since your August 2019 correspondence with LifeHealthcare we have not received any subsequent reports from customers regarding the performance of this product. Our monitoring of the TGA Database of Adverse Event Notifications also confirms no other parties have submitted adverse events related to this product.

To help address your request for further information we have also contacted the manufacturer of this product, Fziomed Inc. FzioMed confirm they have received no reports of this issue from anywhere other than the single July 2019 report from s22, and is not aware of any relevant publications. The manufacturer will also conduct an investigation pending provision of further information on the additional four cases you have identified.

If you wish to share below details directly we can provide this to Fziomed for investigation. Alternatively, as this will be submitted to the TGA the investigation will also be initiated through the TGA's Medical Device Incident Reporting framework.

"To facilitate further investigation, please provide the following for the 4 children mentioned in s22 s22 *letter:*

- *Date of surgery and operative notes*
- *Lot number(s) of gel used in each case*
- *Status /detail of outcome for each child*

Australian Head Office
LifeHealthcare Distribution Pty Ltd
Level 8, 15 Talavera Rd, North Ryde, NSW, 2113, Australia
ABN - 30 117 449 911 • **T** 1800 060 168

New Zealand Head Office
LifeHealthcare Ltd
Suite 1.5, 72 Dominion Road, Mount Eden Auckland, 1024, New Zealand
NZBN 9429033477831 • **T** 0800 880 448

info@lifehealthcare.com.au | www.lifehealthcare.com.au

LifeHealthcare
> Not your typical multinational

For each instance, kindly provide the laboratory name, location, and technician name, images of blood films and date of analysis (including the July 2019 report), along with detailed information of children who received the gel and whose blood smears showed no unexpected result/post-operative precipitant."

Please contact the undersigned at regulatory@lifehealthcare.com.au, s22 s22 s22 if you require further information. We thank you for keeping us informed of this review and collaborating with LifeHealthcare on the care of your patients and their families.

Regards,

s22

LifeHealthcare Pty Ltd

s22

LifeHealthcare Pty Ltd

Document 18

Government of **Western Australia**
Child and Adolescent Health Service

s22
LifeHealthcare
Level 2, 327 Cambridge Street
WEMBLEY WA 6014
s22 @lifehealthcare.com.au

Dear s22

In August 2019 s22 at Perth Children's Hospital (PCH) wrote to s22 of LifeHealthcare regarding the use of Oxiplex AP Anti-Adhesive Barrier Gel. Following on from this initial correspondence, the Department of General Surgery at PCH have undertaken a retrospective audit of the use of Oxiplex AP Anti-Adhesive Barrier Gel.

The audit identified further instances of precipitant on post-operative blood films of four children who received the Oxiplex AP Anti-Adhesive Barrier Gel at PCH. As such, PCH is currently in the process of reporting these cases to the Therapeutic Goods Administration.

I would appreciate if you can please provide any additional information that LifeHealthcare may have in regard to issues pertaining to the use of Oxiplex AP Anti-Adhesive Barrier Gel, since the last correspondence between PCH and LifeHealthcare in 2019. This information will assist PCH in providing advice and ongoing care to the affected patients and families.

s22

07 July 2021

cc: s22 PCH
s22 PCH

Document 18

09/08/2021
UNSIGNED

Device Incident Report : Medical Devices Branch - Device Vigilance and Monitoring

DIR : 44 - ID : 527372

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
71615			Final

ARTG:

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Triage		s22	09/08/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
09/08/2021	09/08/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
	Doctor		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Hospital Administrator			

Event Description for Website Publication:

Initially reported on 30/07/2019; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in 2018, we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Clinical Event Information:

Initially reported on 30/07/2019; Report number 58685: Blood Film Test revealed, extracellular blood foreign body in patient which is suspected to be this product.

After an index case in 2018, we retrospectively reviewed all cases that this product was used and have identified additional cases whereby a precipitant was identified on blood films in the post operative period after the product was used at surgery. The presence of this precipitant is not explained by the companies documentation as a potential outcome after using the product.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
5	Initial Reporter		
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Health Impact

Recorded Health Impacts:

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

Patient History:

Gender	Age	Primary Pathology	Complication descriptor
s22			Precipitant in blood film
			Precipitant in blood film
			Mild Precipitate

Document 18

s22 Mild-Mod Precipitate
Mild Precipitate

Patient Outcome/Consequences: No Injury

Additional Event Description:

Describe any test (Lab, xray, etc.):

Injured - Extent of Injury: No Injury

Other medical devices currently using/implanted:

Medical Problem Device Used For:

Additional Patients Added: 0

Submitting Reporter Section

Search Reporter By Surname: s22

Reporter #:

Preferred Contact Method: Email

Reporter Title:

First Name: s22

Surname: s22

Position: Administrative Coordinator

Company/Institution: Perth Children's Hospital

Address 1: 15

Address 2: Hospital Avenue

Town/Suburb: Nedlands

State: WA

Country: Australia

Postcode: 6009

Phone: +s22

Fax:

Mobile:

Email: officeofoperations@health.wa.gov.au

Last External Submission By:

Initial Reporter Section

As Above?: No

If No, fill out the following:

Initial Reporter Confidential: No

Search Reporter By Surname: s22

Initial Reporter #:

Preferred Contact Method:

Title: s22

First Name: s22

Surname: s22

Position: Paediatric Surgeon

Company/Institution: Perth Children's Hospital

Address 1: 15

Address 2: Hospital Avenue

Town/Suburb: Nedlands

State: WA

Postcode: 6009

Country: Australia

Phone: s22

Fax:

Mobile:

Email: s22 @health.wa.gov.au

Allow the device company to contact you about the incident: ☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*: No

Search Device ARTG:

Device ARTG #:

Therapeutic Licence Type:

Product Licence Category:

Device Class:

GMDN / UMDN Code:

GMDN / UMDN Text:

Brand Name: Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention

Initial Device Description: Barrier, absorbable, adhesion prevention

Usage of Device:

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

Document 18

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
29/08/2021		Place of use	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**
			0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Fziomed Australia Pty Ltd			
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Fziomed Australia Pty Ltd		PO Box 339	
Town/Suburb:	**State:**	**Country:**	**Postcode:**
CURRUMBIN WATERS	QLD	Australia	4223
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	12/07/2021		
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
	No			Unassigned	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:

Notes for Team meeting:

Outcomes from Team Meeting:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentation:**
09/08/2021					

Document 18

Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only			
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No				
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sensitivities identified:				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:			
		Yes			

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
Attention To:	Address 1:	Address 2:	Town/Suburb:
State:	Postcode:	Phone:	Fax:
Email:			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:		
Additional Details (use for tables):	CAPA# Reference:		
			
	Risk Assessment		
	Frequency:		Severity:
	Rating:		
Type Cause and Outcome:	Number of Similar Events:	Expected Rate:	Actual Rate:
Countries Similar Events Also Occurred:			
Completed Actions:	Planned Actions and Proposed Timelines:		
Additional Comments:			

Reason for Level 1 Investigation

Details of Reasons	

Document 18

Reason for Level 1 Investigation	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Evidence	If 'Others' please specify here	Expected Sourcing Date	Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

Click **[N]** to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details										
Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes	

List of Problem Observed Codes - Click **[N]** to begin entering information.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	

Document 18

Health Impact

Details			
Level 1	Level 2	Level 3	

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
Investigator's Notes:		**Summary Findings:**		**Recall Number:**

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter information manually.

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

Related DIR Information - Click **New** to begin entering information.

Document 18

Rec No
1

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details				
	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	
1									

Additional Patients

Click **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:		Patient History:	
Injured - Extent of Injury:	Was device directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Additional Event Description:	Medical Problem Device Used For:

Additional Device Information

Where did you get this device from?: Supplier

How reliant is the affected person on correct/safe operation of this device?:

Any other relevant information to aid assessing/investigating the incident?:

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes		15	Hospital Avenue

Document 18

Town/Suburb:	State:	Postcode:
Nedlands	WA	6009

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		00206BAB01B2210712152749	69	Form Item	Report Information Section / Brand Name
FILE		Oxilpex_PCH_July2021	318	Form Item	Report Information Section / Brand Name

Flow Details : DIR-REQ - Device Incident Request : 314737

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
314737	DIR-REQ		Triage	s22	IRIS Coordinator	09/08/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User		
Signed At		
Comment		

Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Program

Internal Form			
DPMMS FORM 1.2.a	Request for Advice or Assessment of DIRs under investigation		
Comes under	DPMMS WI 1.2 – Risk assessment and triage of MD incident reports		
Applicable to	Devices Post Market Monitoring Section	Authorised by	s22 s22 DPMMS
Date issued	21 Mar 2021	Version #	1.0

Device(s):	Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention
Sponsor:	Fziomed Australia Pty Ltd
Manufacturer:	Fziomed Inc
Device Incident Report No:	DIR 71615
TRIM folder:	E21-373395
ARTG Number(s):	ARTG 152224

Area advice sought	☒ Clinical ☐ Laboratories ☐ Advertising ☐ Recalls ☐ Other:
Questions for assessment:	Review the IFU and determine if the IFU: • Is sufficient and meets the EP's for its intended use?. • Does the IFU require updating?
Additional Information:	Sponsor Questionnaire - D21-3217454 Devices IFU - D21-3144232.

Include anything (via a TRIM number) that may assist the assessor to provide a comprehensive answer	Attached: • Copy of DIR 71615 • Documents that are attached to the DIR in Infoleader. (x 3 documents)
Time frame to complete *30 days unless otherwise negotiated with the section required to do the assessment*	

Comments and Rationale

Australian Register of Therapeutic Goods Inclusion Details

The Sponsor, Fziomed Australia Pty Ltd, has the device, “Oxiplex/AP Gel - Barrier, absorbable, adhesion prevention” included under the Australian Register of Therapeutic Goods (ARTG) entry 152224. The ARTG entry describes the device under the category description of “Medical Device Class III”.

The intended use in TGA eBS and the ARTG public summary for ARTG 152224 is:

> “Oxiplex/AP is intended for use as a mechanical barrier to adhesion formation. It is intended to be used as an adjunct to intrauterine or peritoneal surgery for reducing the incidence, extent, and severity of postoperative adhesions at the surgical site.”

Background

The TGA received a DIR from a Hospital in Perth, for the Oxiplex/AP Gel, the report indicates that the product was used in children. The TGA requested the IFU from the sponsor, review of the IFU has been found to lack crucial information and is not clear regarding its use.

Electronically Signed by:
Requestor: s22 [redacted]
Date: 29/11/2021

Conclusion

Provide a summary of the overall findings of the assessment.
This may be used to cut and paste into further correspondence and so is intended to prevent any incorrect translation of technical information.

Assessor

Name			
Position	Choose an item.		
Comments			
Signature	*Signed electronically in TRIM.*	Date	Click or tap to enter a date.

Save this completed form into the relevant TRIM folder.

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D20-3558467	Previously DVMS TEMP 1.2.n version 1.0 (D18-11138355) Reissued as a FORM (DPMMS FORM 1.2.a version 1.0)	s22 [redacted] s22 [redacted]	21 Mar 2021

From: s22
To: s22
Cc: s22 ; s22
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]
Date: Friday, 22 October 2021 9:42:40 AM
Attachments: image006.png
Importance: High

Dear s22 :

See the response to your two questions below.

Thank you.

~s22

s22
FzioMed, Inc.|231 Bonetti Drive, San Luis Obispo, CA 93401 US
T s22 | F +1 805 546 0571 s22 @fziomed.com

From: s22 [mailto:s22 @health.gov.au]
Sent: Wednesday, October 20, 2021 8:30 PM
To: s22 @fziomed.com>
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Dear s22

Thank you for your email. Review of your response to the questionnaire has raised further questions:

- In your response to question 9 you state *'A copy of the IFU, noting that the product is to be used in Adults only'*. Review of the IFU provided by you indicates that there is no such statement in it, can you please show where in the IFU the statement is?

FzioMed Response

FzioMed responded to the initial report in July 2019 that that use of the gel has not been evaluated in children. After receiving the additional report from the distributor, a copy of the Oxiplex AP IFU, noting that the product is to be used in adults only and precautions that Oxiplex/AP has not been evaluated in children or pregnant or nursing women, nor following opening of the bowel, bladder, or other visceral organs, or in the presence of bile, was provided to the distributor for the surgeon(s). The notation for use in adults was intended as clarification to the distributor.

- Please confirm the ARTG number as the one you have provided in your response is incorrect.

FzioMed Response

The ARTG number for FzioMed's Oxiplex/AP is 152224.

Please provide a response by COB 28 Oct 2021

Regards
s22

From: s22 @fziomed.com>
Sent: Thursday, 14 October 2021 4:12 AM
To: s22 @Health.gov.au>
Cc: s22 @fziomed.com>; s22 @advantagempc.com.au>; IRIS <IRIS@health.gov.au>
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Dear Mr. s22

See the attached file that contains the completed Questionnaire with regard to DIR 71615.

Please contact me with any questions or if something more is needed.

~s22

s22
FzioMed, Inc.|231 Bonetti Drive, San Luis Obispo, CA 93401 US
T +s22 | F +1 805 546 0571 s22 @fziomed.com

From: s22 [mailto:s22 @health.gov.au]
Sent: Monday, October 11, 2021 2:49 PM
To: s22 @fziomed.com>
Subject: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Please find the attached Questionnaire with regard to DIR 71615

Thankyou

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 [redacted] E: s22 [redacted]@health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: s22
To: s22
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]
Date: Thursday, 21 October 2021 2:30:11 PM
Attachments: image002.png

Dear s22

Thank you for your email. Review of your response to the questionnaire has raised further questions:

- In your response to question 9 you state *'A copy of the IFU, noting that the product is to be used in Adults only'*. Review of the IFU provided by you indicates that there is no such statement in it, can you please show where in the IFU the statement is?
- Please confirm the ARTG number as the one you have provided in your response is incorrect.

Please provide a response by COB 28 Oct 2021

Regards
s22

From: s22 @fziomed.com>
Sent: Thursday, 14 October 2021 4:12 AM
To: s22 @Health.gov.au>
Cc: s22 @fziomed.com>; s22 @advantagempc.com.au>; IRIS <IRIS@health.gov.au>
Subject: RE: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Dear s22 :

See the attached file that contains the completed Questionnaire with regard to DIR 71615.

Please contact me with any questions or if something more is needed.

~s22

s22
FzioMed, Inc.|231 Bonetti Drive, San Luis Obispo, CA 93401 US
T s22 | F +1 805 546 0571 s22 @fziomed.com

From: s22 [mailto:s22 @health.gov.au]
Sent: Monday, October 11, 2021 2:49 PM
To: s22 @fziomed.com>
Subject: Questionnaire re DIR 71615 [SEC=OFFICIAL]

Please find the attached Questionnaire with regard to DIR 71615

Thankyou

s22

Departmental Officer
Devices Post Market Monitoring Section

Medical Device and Product Quality Division | Health Products Regulation Group
Medical Devices Surveillance Branch
Australian Government Department of Health
P: s22 E: s22 @health.gov.au
Location: Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au
The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.