Device Change Request

Application ID:	DV-2021-CR-12964-1
Status:	Under Review
Date Received:	02/07/2021

Sponsor Details

Agent Name:	
Sponsor Name:	Life Healthcare Pty Ltd
Contact Name:	s22 [redacted]
Email Address:	s22 [redacted] @lifehealthcare.com.au
Phone Number:	s22 [redacted]

Change Request

ARTG No: 177101

ChangeType:

- (●) Variation to ARTG Listed Entry
- ( ) Variation to ARTG Registered Entry (High Level)
- ( ) Variation to ARTG Registered Entry (IVDs and Disinfectants)
- ( ) Variation to ARTG Included Entry

Description: Request to link updated manufacturer's name as per approved manufacturer's evidence variations to DV-2016-MC-01540-1 and DV-2016-MC-01538-1.; Request to also update the ARTGs 177102, 287096, 275680, 275679, 275678, 275677, 275676, 275675

Medical Device Application

Class IIb
Status: Approved

Application Change history

Application Progress Date	
Date received:	12/10/2010
Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID:	177101
Product ID:	303745

Application Details	
Application identifier:	DV-2010-DA-14938-3
Submission identifier:	DA-2010-05775-7
Sponsor's own reference:	Spine - Spinal Kinetics - Cervical Disc
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	◯ Yes ◯ No
Will you be applying for listing of this product on the Prosthesis List?	◯ Yes ◯ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	◯ Yes ◯ No
Cancel ARTG - product:	
Is this application supported by EU MDR/IVDR certification?	

Sponsor Details	
Sponsor name:	Life Healthcare Pty Ltd

Contact details:	s22
Contact email:	s22@lifehealthcare.com.au

Class Details	
This application is to:	
Class:	Class IIb

Device Product Characteristics

Is the device, or any form of the device, supplied sterile:	Yes
Sterilisation Method:	
Is the device intended to be invasive:	Yes
s the device, or any form of the device, intended for single use:	Yes
Is the device an active device:	No
Does the device contain material or ingredients of microbial origin:	No
Does the device contain material or ingredients of recombinant origin:	No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:	No
Does the device contain material or ingredients of Human Origin:	No
Does the device contain Human Blood or its components:	
Does the device consist of:	Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable	No
Animal Species:	
Country of Origin:	
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable:	
Is the device medicated:	No
Is the device formulated:	No
Does the product contain a medicine that is supplied separately in the Australian Market:	No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device:	No
Does the device contain a metal on metal bearing:	
I declare that this device contains only components that are medical devices which have been individually certified.	No
Is this a Class IIb spinal fusion device:	
Is the device software:	

Manufacturer Details

Manufacturer evidence number:	DV-2010-MC-14207-3 :Spine-SpinalKinetics - Lumbar & cervical disc
Manufacturer name:	Spinal Kinetics Inc (United States Of America)[54912]
Manufacturer address as on evidence:	595 North Pastoria Avenue Sunnyvale CA 94085 United States Of America S [178057]

GMDNS Code and Description	
GMDNS code and description:	Cervical total disc replacement prosthesis[48164]

Device Category Terms	
Device category 1:	Non-active implantable devices
Device category 2:	
Device category 3:	

Product Details	
Unique Product Identifier (UPI):	
Total number of devices covered:	
Functional description:	

Variant List

#	Variant type	Variant range

Standard Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Non Standard Conditions

Note: A non standard conditions must not contain semi colons.

To remove, enter item #

Declaration

41FD Matters to be certified:

The applicant must certify that:
(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under subsection

41BD(2); and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) the applicant:
(i) has available sufficient information to substantiate that compliance with the essential principles; or
(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(f) either:
(i) an appropriate conformity assessment procedure has been applied to devices of that kind; or
(ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and
(g) the applicant:
(i) has available sufficient information to substantiate the application of the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f) (ii); or
(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(h) both of the following are complied with in relation to devices of that kind:
(i) the applicable provisions of the Therapeutic Goods Advertising Code;
(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and
(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
(j) the information included in or with the application is complete and correct.

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

41FDA Basis of certification of conformity assessment procedures

When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:
(a) on a conformity assessment certificate that is in force; or
(b) on an Australian conformity assessment body certificate that is in force; or
(c) on an overseas regulator conformity assessment document that is in force.

This is in accordance with Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion in the Register) Determination.

IMPORTANT - It is taken that the person, who is stated in this application as the contact person, has authorised and electronically signed the declaration under section 41FD of the Act, as provided above, on behalf of the sponsor.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:
A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:
……

History

28/10/2010 11:02:27 AM Approved.

Review Completed - Accepted, 28/10/2010)

Record		Date	
Fee	810	Date Paid	13/10/2010
		Date Decision	28/10/2010

Start Dates		Finish Dates		Working Days
Application Received	12/10/2010	Payment Received	13/10/2010	1
Payment Received	13/10/2010	Application Decision	28/10/2010	12
			Total Working Days	13

Response ID ANON-A5FQ-NE2S-5

Document 3

Submitted to Notification form: Reclassification of spinal implantable medical devices
Submitted on 2022-04-14 14:25:56

About the submitter

1 What is your name?

Name:
s22 [redacted]

2 What is your email address?

email:
s22 [redacted]@lifehealthcare.com.au

Please confirm your email address:
s22 [redacted]@lifehealthcare.com.au

3 Which of the following best describes your role in relation to the medical device for which this notification is being submitted?

Sponsor

4 What is the name of the sponsor of this medical device?

Sponsor name:
Life Healthcare Pty Ltd

ARTG 1

1 Please mention the ARTG number:

ARTG Number: 1:
177101

2 What is the GMDN code for this kind of medical device?

GMDN Code:
48164

3 What is the current classification of this kind of medical device?

Class IIb

4 What will be the new classification of this kind of medical device?

Class III

5 Please provide the following:

The number of UPIs that are supplied under this ARTG:
1

UPI-1 and variants:
M6-C Artificial Cervical Disc, Variants: Depth 12.5-16mm, Width 15-17mm, Height 6-7mm

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

6 Please specify the number of devices supplied in Australia, in 2019, for each UPI.

UPI-1 and variants:
626

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

7 Please specify the number of devices supplied in Australia, in 2020, for each UPI.

UPI-1 and variants:
486

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

8 Please select the most suitable option for each UPI.

UPIs planning to reclassify - UPI-1 and variants:
Planning to reclassify

UPIs planning to reclassify - UPI-2 and variants:

UPIs planning to reclassify - UPI-3 and variants:

UPIs planning to reclassify - UPI-4 and variants:

UPIs planning to reclassify - UPI-5 and variants:

UPIs planning to reclassify - UPI-6 and variants:

UPIs planning to reclassify - UPI-7 and variants:

UPIs planning to reclassify - UPI-8 and variants:

UPIs planning to reclassify - UPI-9 and variants:

UPIs planning to reclassify - UPI-10 and variants:

9 Please confirm if you will be submitting an application for your device to be included in the ARTG as a Class III medical device before 1 November 2024.

Document 6

Yes, will be submitting an application for inclusion

10 Will you require a TGA conformity assessment for your device(s) to be included in the ARTG as a Class III medical device?

No

Please specify the number of UPIs that will require TGA conformity assessment:

s22

s22

s22

s22

s22

s22

Declaration

1 I declare that all information provided in this form is true and correct at the time of submission. Important note: Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the Criminal Code Act 1995.

Yes

From: s22
To: mdconsent@health.gov.au
Cc: Devices Verification Section
Subject: Consent to Supply - Breach of EP"s – LifeHealthcare - ANON-T1PJ-PJMT-T [SEC=OFFICIAL]
Date: Monday, 29 November 2021 8:15:19 AM
Attachments: response-ANON-T1PJ-PJMT-T.pdf
Implementation Plan (1).docx
Spinal Kinetics M6-C Brochure.pdf

This is the attachment for Response ID ANON-T1PJ-PJMT-T In Form B – They have included an Implementation Plan and am Interim PIC. This is for 2 ARTG numbers.

This is for a PIC PIL consent

Australian Government
Department of Health
Therapeutic Goods Administration

File Reference: TRIM E21-418843
Sent by email

LifeHealthcare Pty Ltd
PO Box 646,
NORTH RYDE NSW 2113

Email: s22 @lifehealthcare.com.au

Dear s22

Request under sections 41MA and 41MAA for consent to import, supply, or export of medical devices that do not comply with the essential principles

ARTG and Device:	177101 - Cervical total disc replacement prosthesis 177102 - Lumbar total disc replacement prosthesis
Non Compliance:	Essential principle 13A.2 in relation to the patient implant cards.
Period for consent:	From 1 December 2021 until 25 May 2024.

I refer to your request dated 26 November 2021 for consent to import and supply medical devices that do not comply with the essential principles. Details of the devices of the kind specified in the application are provided in the table above (the Devices).

As a delegate to the Secretary of the Department of Health for the purposes of sections 41MA and 41MAA of the *Therapeutic Goods Act 1989* (the Act) I have made a decision to grant consent to import, export and supply the Devices that do not comply with Essential principle 13A.2 relating to patient implant cards being provided with the device of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Reasons for my decision
On 26 November 202, LifeHealthcare Pty Ltd (the sponsor) submitted an application to the TGA under sections 41MA and 41MAA of the Act requesting consent for importation, supply, or exportation of a medical devices that do not comply with the essential principles of Schedule 1 of the Regulations.

In the application, you explained that the current patient implant brochure does not contain the TGA details required to be compliant. The reason for the proposed duration is that this will be the maximum time as the manufacturer must transition to the MDR by this date. The actual transition time will be prior to this date but is not currently known due to transition procedures.

Essential principle 13A.2(1) of Schedule 1 of the Regulations in relation to Patient implant cards for implantable devices states that 'Patient implant cards and patient information leaflet for implantable medical devices must be provided with the medical device'.

Consequently, in order to ensure continuity of supply you are seeking consent to supply the Devices that do not comply with the requirements of the essential principles.

- In the application, you advised that the current patient brochure from Cerapedics will be provided electronically in place of the leaflet on LifeHealthcare website from 01-Dec-2021. Hard copy will not be provided with the device. A letter to each hospital and surgeon notifying them of the availability of patient information materials on LifeHealthcare webpage will be sent out by 01-Dec-2021. A QR code and a link to the exact location of patient information material is included in the letter. Additionally, we will also include a directional handout (containing the QR code and website link) with the surgeon's letter. Surgeons can instantly provide it to the patients at the time of consultation. Patients can take that piece of information with them to easily access the materials later. The support from the sponsor is to:
    - Educate sales representatives to assist surgeons/ healthcare facility to access patient materials and / or procure hard copies
    - Educate customer care team to answer customer queries related to PIL/ PIC. FAQ document has been prepared for their support.
    - provide directional handout containing a QR code and website link to the PIL/ PIC location to the surgeons. The surgeons may refer to LHC's website to capture the relevant PIL's name in this handout before giving it to the patient for their reference later.

You also stated that the fully compliant PILs are being prepared as part of the MDR process for the manufacturer. The implementation date is not currently known, but during the interim period an existing patient brochure covering most of the TGA requirements will be provided. Once the compliant PIL is signed off it will replace the brochure on the LHC website. Healthcare facilities and surgeons will be notified of the availability of compliant PILs through email communication as well as direct via LHC representatives. Internal Sales and Customer Care teams will also be informed of this update. The directional handout will not be impacted by this change. The surgeons would continue to refer to LHC's website to mention the relevant PIL's name in this handout before giving it to the patient.

Considering the above, and under the circumstances, the risks associated with the non-compliance of the product information with the essential principles do not appear to be high. I have made a decision to grant consent to import, supply or export the Devices that do not comply with the essential principles from 1 December 2021 until 25 May 2024.

The reasons for the start date of 1 December 2021 is that from this date all manufacturers of existing permanently implantable devices need to make available patient information cards with the devices. Together, patient information leaflets and patient implant cards will assist consumers and doctors in the informed consent process and enhance the traceability of medical devices in the health system.

Due to the number of applications for Consent to Supply re non-compliance with essential principle 13A your implementation plan will be reassessed post approval and if further clarification is required the TGA will be in contact with you.

You are reminded that the devices of the kind in relation to which this consent is given must comply with all other applicable provisions of the Act and Regulations.

Review rights

Should you wish to seek a review of my decision to give consent under sections 41MA and 41MAA of the Act your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Signed electronically by

s22 [redacted]

[redacted]

Medical Devices Surveillance Branch
Therapeutic Goods Administration

30 November 2021

Attachment A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation. Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Further information on Section 60 and the Reviewable Initial Decisions can be found at the following TGA webpages:

Section 60
https://www.tga.gov.au/publication/guidance-requesting-reconsideration-initial-decision

Reviewable Initial Decisions
https://www.tga.gov.au/publication/reviewable-initial-decisions-under-therapeutic-goods-act-regulations-0

From: s22 @health.gov.au
To: s22 @lifehealthcare.com.au
Subject: s41MA & 41MAA Notice consent to supply - ANON-T1PJ-PJMT-T - LifeHealthcare - ARTG 177101 & 177102 [SEC=OFFICIAL]
Date: Tuesday, 30 November 2021 3:26:12 PM
Attachments: s41MA & 41MAA Notice consent to supply - ANON-T1PJ-PJMT-T - LifeHealthcare - ARTG 177101 & 177102.pdf

---

Dear s22

Please see the attached notice under s41MA & 41MAA in regards to consent to supply - ANON-T1PJ-PJMT-T - LifeHealthcare - ARTG 177101 & 177102.

Kind regards,

s22

Devices Post Market Reform & Review Section | Medical Devices Surveillance Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Australian Government Department of Health
E: s22 @health.gov.au | s22 @health.gov.au
Location: 136 Narrabundah Lane Symonston, ACT 2609
PO Box 100, Woden ACT 2606, Australia

Australian Government
Department of Health
Therapeutic Goods Administration

File Reference: TRIM E21-418843
Sent by email

LifeHealthcare Pty Ltd
PO Box 646,
NORTH RYDE NSW 2113

Email: s22 @lifehealthcare.com.au

Dear s22

Request under sections 41MA and 41MAA for consent to import, supply, or export of medical devices that do not comply with the essential principles

ARTG and Device:	177101 - Cervical total disc replacement prosthesis 177102 - Lumbar total disc replacement prosthesis
Non Compliance:	Essential principle 13A.2 in relation to the patient implant cards.
Period for consent:	From 1 December 2021 until 25 May 2024.

I refer to your request dated 26 November 2021 for consent to import and supply medical devices that do not comply with the essential principles. Details of the devices of the kind specified in the application are provided in the table above (the Devices).

As a delegate to the Secretary of the Department of Health for the purposes of sections 41MA and 41MAA of the *Therapeutic Goods Act 1989* (the Act) I have made a decision to grant consent to import, export and supply the Devices that do not comply with Essential principle 13A.2 relating to patient implant cards being provided with the device of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Reasons for my decision
On 26 November 202, LifeHealthcare Pty Ltd (the sponsor) submitted an application to the TGA under sections 41MA and 41MAA of the Act requesting consent for importation, supply, or exportation of a medical devices that do not comply with the essential principles of Schedule 1 of the Regulations.

In the application, you explained that the current patient implant brochure does not contain the TGA details required to be compliant. The reason for the proposed duration is that this will be the maximum time as the manufacturer must transition to the MDR by this date. The actual transition time will be prior to this date but is not currently known due to transition procedures.

Essential principle 13A.2(1) of Schedule 1 of the Regulations in relation to Patient implant cards for implantable devices states that 'Patient implant cards and patient information leaflet for implantable medical devices must be provided with the medical device'.

Consequently, in order to ensure continuity of supply you are seeking consent to supply the Devices that do not comply with the requirements of the essential principles.

- In the application, you advised that the current patient brochure from Cerapedics will be provided electronically in place of the leaflet on LifeHealthcare website from 01-Dec-2021. Hard copy will not be provided with the device. A letter to each hospital and surgeon notifying them of the availability of patient information materials on LifeHealthcare webpage will be sent out by 01-Dec-2021. A QR code and a link to the exact location of patient information material is included in the letter. Additionally, we will also include a directional handout (containing the QR code and website link) with the surgeon's letter. Surgeons can instantly provide it to the patients at the time of consultation. Patients can take that piece of information with them to easily access the materials later. The support from the sponsor is to:
    - Educate sales representatives to assist surgeons/ healthcare facility to access patient materials and / or procure hard copies
    - Educate customer care team to answer customer queries related to PIL/ PIC. FAQ document has been prepared for their support.
    - provide directional handout containing a QR code and website link to the PIL/ PIC location to the surgeons. The surgeons may refer to LHC's website to capture the relevant PIL's name in this handout before giving it to the patient for their reference later.

You also stated that the fully compliant PILs are being prepared as part of the MDR process for the manufacturer. The implementation date is not currently known, but during the interim period an existing patient brochure covering most of the TGA requirements will be provided. Once the compliant PIL is signed off it will replace the brochure on the LHC website. Healthcare facilities and surgeons will be notified of the availability of compliant PILs through email communication as well as direct via LHC representatives. Internal Sales and Customer Care teams will also be informed of this update. The directional handout will not be impacted by this change. The surgeons would continue to refer to LHC's website to mention the relevant PIL's name in this handout before giving it to the patient.

Considering the above, and under the circumstances, the risks associated with the non-compliance of the product information with the essential principles do not appear to be high. I have made a decision to grant consent to import, supply or export the Devices that do not comply with the essential principles from 1 December 2021 until 25 May 2024.

The reasons for the start date of 1 December 2021 is that from this date all manufacturers of existing permanently implantable devices need to make available patient information cards with the devices. Together, patient information leaflets and patient implant cards will assist consumers and doctors in the informed consent process and enhance the traceability of medical devices in the health system.

Due to the number of applications for Consent to Supply re non-compliance with essential principle 13A your implementation plan will be reassessed post approval and if further clarification is required the TGA will be in contact with you.

You are reminded that the devices of the kind in relation to which this consent is given must comply with all other applicable provisions of the Act and Regulations.

Review rights

Should you wish to seek a review of my decision to give consent under sections 41MA and 41MAA of the Act your rights of review are outlined in Attachment A to this letter.

Yours sincerely

Signed electronically by

s22 [redacted]

[redacted]

Medical Devices Surveillance Branch
Therapeutic Goods Administration

30 November 2021

Attachment A

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation. Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Further information on Section 60 and the Reviewable Initial Decisions can be found at the following TGA webpages:

Section 60
https://www.tga.gov.au/publication/guidance-requesting-reconsideration-initial-decision

Reviewable Initial Decisions
https://www.tga.gov.au/publication/reviewable-initial-decisions-under-therapeutic-goods-act-regulations-0

From: _Quality
To: Recalls
Cc: s22 ; _Regulatory; _Quality
Subject: Redlined draft IFU M6-C - ARTG 177101 [SEC=No Protective Marking]
Date: Wednesday, 20 May 2020 4:22:05 PM
Attachments: PK 0225 Rev 03 DRAFT M6-C IFU 2020.01.30 REDLINES.pdf

---

Good afternoon,

Please see draft proposed version of updated IFU and provide direction as to whether this update may be subject to recall action through the URPTG.

Kind regards,

s22

_Quality

LifeHealthcare
Not your typical multinational
F s22
E customerservice@lifehealthcare.com.au
Customer Service 1800 060 168

INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Spinal Kinetics LLC, an Orthofix Company
501 Mercury Drive
Sunnyvale, CA 94085 USA
+1 408-636-2500
www.orthofix.com
M6info@orthofix.com

Customer Service
+1 408-636-2515
CustomerService@spinalkinetics.com

Device System Name:

M6-C™ Artificial Cervical Disc

English EN	**X-XX**
German	**X-XX**
French	**X-XX**
Spanish	**X-XX**
Italian	**X-XX**
Dutch	**X-XX**
Greek	**X-XX**
Portuguese	**X-XX**
Turkish	**X-XX**
Czech	**X-XX**
Slovak	**X-XX**
Russian	**X-XX**
Slovak	**X-XX**

EC REP

European Authorized Representative:/Autorisierte Vertretung in Europa:/ Representant agree Europe:/Representante autorizado en Europa:/ Rappresentante autorizzato in Europa:/Erkend vertegenwoordiger in Europa:/Εξουσιοδοτημένος Αντιπρόσωπος στην Ευρώπη:/ Representante Autorizado na Europa:/Avrupa Yetkili Temsilcisi:/ Autorizovany evropsky zastupce:/Autorizovany zastupca pre Europu:/Уполномоченный представитель в Европе:/ Auktoriserad representant i Europa:

MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

Telephone: +49 6442 962073

INTENDED USE

The M6-C™ Artificial Cervical Disc is an intervertebral disc prosthesis intended to permit motion of a functional spinal unit in the cervical spine when the native disc is diseased.

DEVICE DESCRIPTION

The M6-C™ Artificial Cervical Disc is an intervertebral disc prosthesis designed to permit motion of a functional spinal unit in the cervical spine when replacing a degenerated native disc. The device is comprised of ultra-high molecular weight polyethylene (UHMWPE) fiber wound in a specific pattern, with multiple redundant layers, creating a fiber matrix (artificial annulus). The fiber is wound around a polycarbonate urethane polymer (PCU) core (artificial nucleus) and through the slots in two Ti6Al4V titanium alloy inner endplates (see **Figure 1**). The core is situated between and in contact with the two inner endplates, but not affixed to them. A PCU sheath surrounds the fiber matrix and is retained by two Ti6Al4V weld bands that are welded to the inner endplates. Two Ti6Al4V outer endplates are also welded to the inner endplates. The exterior surfaces of the outer endplates include low profile fins and are coated with titanium plasma spray (TPS).

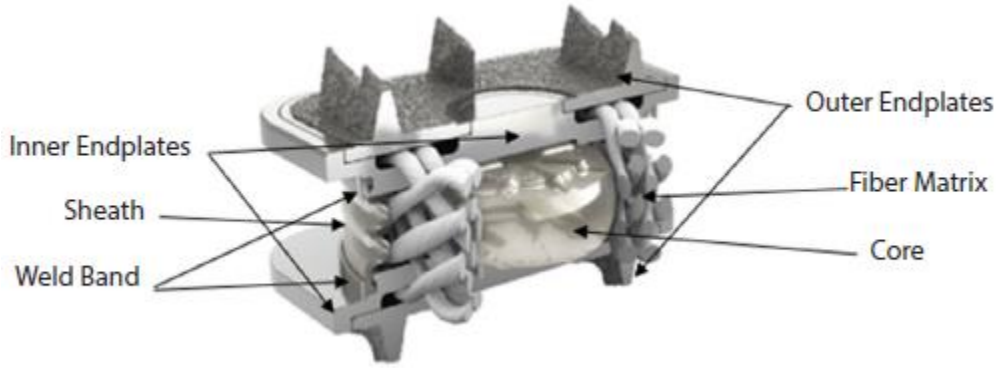


Figure 1: Cross-Section View of the M6-C™ Artificial Cervical Disc

The M6-C™ Artificial Cervical Disc is designed to maintain the natural behavior of a functional spinal unit by replicating the biomechanical characteristics of the native disc. This design enables the M6-C™ Artificial Cervical Disc to move in all six degrees of freedom, with independent angular rotations (flexion-extension, lateral bending and axial rotation) along with independent translational motions (anterior-posterior and lateral translations as well as axial compression). The device is intended to replicate the physiological phenomenon of progressive resistance to motion in all six degrees of freedom. The sheath is designed to minimize any tissue ingrowth as well as the migration of wear debris. The serrated fins provide acute fixation to the superior and inferior vertebral bodies. The TPS coating increases the bone contact surface area.

The M6-C™ Artificial Cervical Disc is currently offered in four different footprint sizes and two heights, as shown in Figure 1~~Figure 1~~~~Figure 1~~ and Table 1~~Table 1~~~~Table 1~~.

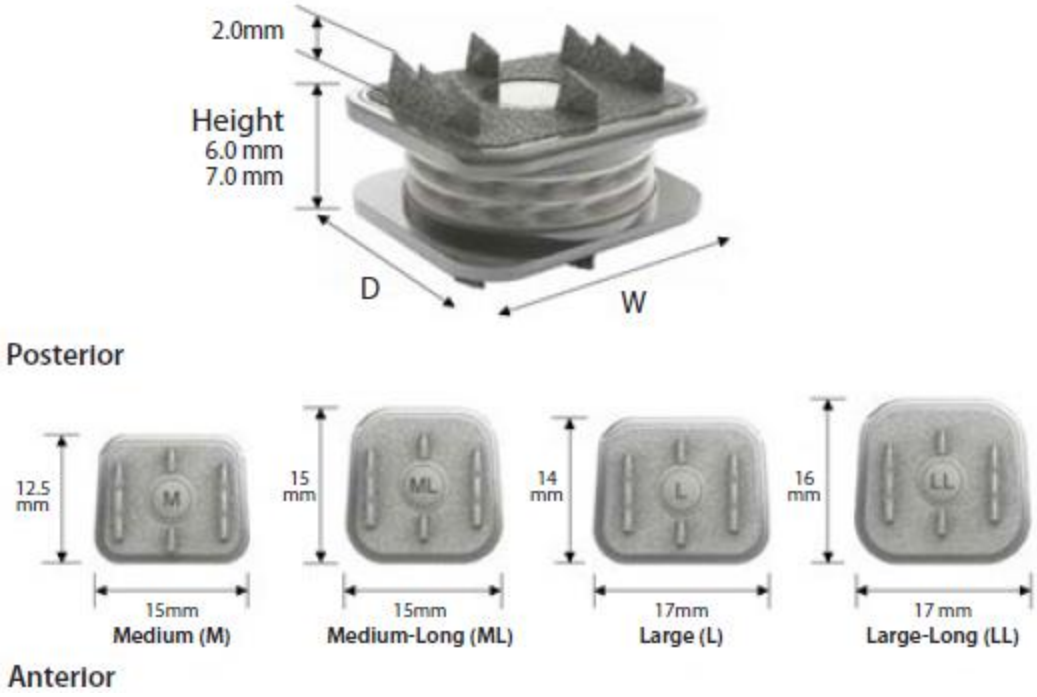


Figure 1: M6-C™ Artificial Cervical Disc Heights and Footprint Sizes

Table 1: M6-C™ Artificial Cervical Disc Catalog Number and Size

REF	Description	Provided Sterile
CDM-625	Cervical Disc – 6 Medium (15mm W x 12.5mm D x 6mm H)	Yes
CDM-725	Cervical Disc – 7 Medium (15mm W x 12.5mm D x 7mm H)	Yes
CDL-627	Cervical Disc – 6 Large (17mm W x 14mm D x 6mm H)	Yes
CDL-727	Cervical Disc – 7 Large (17mm W x 14mm D x 7mm H)	Yes
CDM-635L	Cervical Disc – 6 Medium-Long (15mm W x 15mm D x 6mm H)	Yes
CDM-735L	Cervical Disc – 7 Medium-Long (15mm W x 15mm D x 7mm H)	Yes
CDL-637L	Cervical Disc – 6 Large-Long (17mm W x 16mm D x 6mm H)	Yes
CDL-737L	Cervical Disc – 7 Large-Long (17mm W x 16mm D x 7mm H)	Yes

INDICATIONS FOR USE

The M6-C™ Artificial Cervical Disc System is intended for use in skeletally mature patients undergoing primary surgery for treatment of symptomatic disc diseases of the cervical spine at any one level or multiple levels between C3 through C7, who have not responded to non-operative conservative

management.* The disease state is demonstrated by signs and/or symptoms of disc herniation, osteophyte formation, or loss of disc height.
** The non-operative conservative management requirement may be waived in the cases of myelopathy requiring immediate treatment and/or cervical radiculopathy with worsening neurological functions (i.e. motor weakness).*

CONTRAINDICATIONS

The M6-C™ Artificial Cervical Disc should not be implanted in patients with the following conditions:

- Be ≥70 years of age.
- Have a bone mineral density with T-score ≤-1.5 as determined by spine DXA if male ≥60 years of age or female ≥50 years of age.
- Have an active systemic infection or infection at the operative site.
- Have sustained an osteoporotic fracture of the spine, hip or wrist.
- Have received medications (e.g., methotrexate, alendronate) that interfere with bone and mineral metabolism within 2 weeks of the planned date of the index surgery.
- Have any medical or surgical condition precluding the potential benefit of spinal surgery.
- Have a history of endocrine or metabolic disorders (e.g., Paget's disease) known to affect bone and mineral metabolism.
- Have rheumatoid arthritis or other autoimmune disease or a systemic disorder such as HIV or active hepatitis.
- Have spinal metastases.
- Have a known allergy to titanium, polyurethane, polyethylene or ethylene oxide residuals.
- Have type 1 or type 2 diabetes requiring daily insulin management.
- Be pregnant.
- Have axial neck pain as the solitary symptom.
- Have severe cervical myelopathy as evidenced by any sign of gait disturbance, unilateral or bilateral leg weakness, and/or uncontrollable bowel/bladder symptoms related to cervical spine disease.
- Require a treatment (e.g., posterior element decompression) that destabilizes the spine.
- Have advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative site.
- Have advanced degenerative changes (e.g., spondylosis) at the index vertebral level as evidenced by:
  - Bridging osteophytes;
  - Average ROM <4°;
  - Disc height <25% of the AP width of the inferior vertebral body; as measured in a lateral radiograph in neutral position;
  - Subluxation >3mm;
  - Kyphotic deformity at >20° on neutral radiographs.

PRECAUTIONS

- Read and understand the M6-C™ Artificial Cervical Disc System Instructions for Use prior to use.
- The M6-C™ Artificial Cervical Disc is intended to be used with the M6-C™ Manual Surgical Instruments.
- Refer to the M6-C™ Artificial Cervical Disc Operative Technique Manual for implantation instructions.
- The M6-C™ Artificial Cervical Disc System is intended to be used only by surgeons with training in cervical spine surgery and related surgical techniques, and biomechanical principles of the spine and spine arthroplasty.
- Prior to use, the surgeon must be trained in the surgical procedure as outlined in the M6-C™ Artificial Cervical Disc Operative Technique Manual and thoroughly familiar with the implant and instruments.
- Improper surgical use and technique may lead to suboptimal clinical outcomes.
- Do not use the M6-C™ Artificial Cervical Disc after the last day of the month of the "Use by date" on the label.

- Inspect the device package before opening. Do not use if package is damaged or shows any evidence of breached packaging, compromised device sterility, or storage above 60˚C (140˚F). The temperature recorder label on the box turns black if the product has reached 60˚C (140˚F).
- Use sterile technique to carefully remove the Disc from the packaging. Inspect the M6-C™ Artificial Cervical Disc to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- The M6-C™ Artificial Cervical Disc must be implanted using the M6-C™ Manual Surgical Instruments. The use of the Spinal Kinetics Instruments for purposes other than those for which they are intended may result in damaged or broken instruments. Do not use any other implant components or instrumentation. Detailed instructions on the use and limitations of the M6-C™ Artificial Cervical Disc must be given to the patient. Postoperative rehabilitation and restrictions must be reviewed with the patient prior to discharge from the hospital.
- The M6-C™ Artificial Cervical Disc serial number and the size must be documented for each patient record.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect M6-C™ Artificial Cervical Disc, incorrect surgical techniques, including improper use of instruments, the limitations of treatment methods, or inadequate asepsis.
- The surgeon should instruct the patient on postoperative rehabilitation and limitations. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful osseointegration of the implant. The patient must be made aware of the limitations of the implant and that early strenuous physical activity and high load bearing have been implicated in premature loosening of fixation prior to proper integration. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
- Instructions for postoperative care should be according to the surgeon's discretion and may consist of a physician-managed, individual post-operative rehabilitation program. Certain activities should be limited or avoided for two weeks postoperative. It is recommended that the surgeon discuss with the patient the following limitations:
    - Excessive neck movements: Short term use of a soft neck collar to stabilize the neck and reduce excess movement is an option. Instruct patient to avoid excessive flexion/extension for two weeks postoperative.
    - Heavy lifting: Avoid lifting anything heavier than about 3.5-4.5 kilograms (8-10 pounds) for two weeks postoperative.
    - Returning to work: In general, return to light work, such as a desk job or school, approximately one week after surgery. Returning to a more physical job, such as construction, may take six weeks or longer.
    - Resuming sports and other physical activities: The timeline for returning to sports and other recreational activities can vary. The weight permitted for lifting may gradually increase starting after two weeks. Some light sport activities may be permitted at about 4 weeks, such as jogging, biking, or swimming. A return to competitive sports may take 6 weeks or longer, depending on the integration of the device and the ability to perform the sport's movements pain-free. There is currently a lack of data regarding cervical artificial discs and contact or extreme sports.
- Physicians should instruct patients to contact surgeon in the event of significant increase in pain which may indicate a device performance issue.
- Routine long term clinical and radiographic monitoring of patients implanted with the M6-C is suggested to assess any changes in implant condition or surrounding anatomy. s47G(1)(a) [redacted]
-

WARNINGS

- Correct placement of the M6-C™ Artificial Cervical Disc is essential to optimal performance.
- The M6-C™ Artificial Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with this device. A lack of adequate

experience and/or training may lead to a higher incidence of adverse events, such as vascular or neurological complications.

- The M6-C™ Artificial Cervical Disc is single use only. Do not re-sterilize or reuse the M6-C™ Artificial Cervical Disc. Re-sterilizing and/or reusing the M6-C™ Artificial Cervical Disc may result in impaired performance and could cause patient injury and/or the communication of infectious diseases between patients.
- The M6-C™ Manual Surgical Instruments are reusable, supplied non-sterile and must be sterilized in accordance with the recommended cleaning and sterilization procedures contained within the individual instrument Instructions for Use booklet.
- During implantation, the surgeon should ensure that none of the surgical instruments or the M6-C™ Artificial Cervical Disc progress beyond the posterior border of the vertebral bodies. Due to the proximity of vascular and neurological structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage with the use of this device and allowing the instruments or the M6-C™ Artificial Cervical Disc to progress beyond the posterior border of the vertebrae may result in injury to these structures.
- Fluoroscopic confirmation of positioning of certain instruments and the implant should be performed during the surgical procedure. Failure to confirm position of instruments and the implant during the surgical implantation procedure may result in patient injury.
- Ensure that the appropriate size M6-C™ Artificial Cervical Disc is chosen. Using an inappropriately sized M6-C™ Artificial Cervical Disc may result in less than optimal clinical outcomes. Proper sizing should be determined in accordance with the M6-C™ Artificial Cervical Disc Operative Technique Manual.

CAUTIONS

- Perform a complete discectomy of the disc space between the uncinates and up to the posterior ligament. Take care to release / decompress the foramen bilaterally.
- It is important to remove all anterior and posterior osteophytes on the superior and inferior vertebral endplates. To prevent weakening of the endplates, use of a burr/drill is discouraged during endplate preparation. Use the Cervical Retainer as needed to maintain distraction. Take care not to over-distract the disc space. Ensure proper alignment and placement of the device as misalignment may cause excessive wear and/or early failure of the device.
- Excessive removal of subchondral bone during the preparation of the vertebral endplates may lead to less than optimal clinical outcomes and is not recommended.
- Once removed from the package, keep the M6-C™ Artificial Cervical Disc from coming into contact with any cloth, sponges or other foreign material that may become attached to the Titanium Plasma Spray Coating of the endplates. The Packaging Clip may be used to safely store the loaded M6-C™ Artificial Cervical Disc.
- The M6-C™ Artificial Cervical Disc is designed to be implanted with the endplates parallel to each other. Excessive endplate lordosis or kyphosis can lead to less than optimal M6-C™ Artificial Cervical Disc performance.
- The M6-C™ Artificial Cervical Disc cannot be re-positioned in an anterior direction without complete removal. Take care not to place the M6-C™ Artificial Cervical Disc too posterior.
- Surgical implants must never be re-used or re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

POTENTIAL ADVERSE EFFECTS

Below is a list of the potential adverse effects (e.g., complications) identified for: (1) those associated with any general surgical procedure; (2) those associated with anterior cervical spine surgery; and (3) those associated with a cervical artificial disc device, including the M6-C™ Artificial Cervical Disc. In addition to the risks listed below, there is also the risk that surgery may not be effective in relieving symptoms, or may cause worsening of symptoms. Additional surgery may be required to correct some of the adverse effects.

General Surgery Risks

General surgical risks are, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Blood clots, including pulmonary emboli
- Medication and anesthesia reactions
- Phlebitis
- Pneumonia
- Atelectasis
- Soft tissue damage
- Septicemia
- Hemorrhage possibly requiring a blood transfusion, with possible transfusion reaction
- Myocardial infarction
- Paralysis
- Poor tissue healing
- Cerebrovascular accident (CVA)
- Death

Anterior Cervical Surgery Risks

Anterior cervical surgical risks are, but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Injury or damage to the trachea, esophagus, nerves or blood vessels
- Dysphagia
- Hoarseness
- Vocal cord paralysis
- Paresis
- Recurrent laryngeal nerve palsy
- Soft tissue damage
- Spinal cord damage
- Dural tear with cerebrospinal fluid leakage
- Arm weakness or numbness
- Death
- Bowel, bladder or sexual dysfunction
- Nerve root injury
- Airway obstruction
- Epidural hematoma or bleeding
- Epidural fibrosis
- Vertebral body fracture
- Dysesthesia or numbness
- Paresthesia
- Unresolved pain
- Surgical intervention at incorrect level
- Need for supplemental fixation
- Spinal instability

Cervical Artificial Disc Risks

Risks specific to cervical artificial discs, including the M6-C™ Artificial Cervical Disc, are but may not be limited to:

- Infection/abscess/cyst, localized or systemic
- Allergic reaction to the implant materials
- Implant failure
- Device migration
- s47G(1)(a) [redacted]
- Device subsidence
- Device fatigue or fracture or breakage
- Device instability
- Separation of device components
- Placement difficulties, device malposition
- Improper device sizing
- Excessive device height loss
- Wear debris (manifested as osteolysis and/or device damage/breakage/failure)
- Disc space collapse
- Material degradation (manifested as osteolysis and/or device damage/breakage/failure)
- Excessive facet loading
- Dural tear with cerebrospinal fluid leakage
- Soft tissue damage
- Epidural fibrosis
- Nerve injury, paralysis or weakness that is temporary or permanent
- Injury or damage to the trachea, esophagus, or blood vessels
- Epidural hematoma or bleeding
- Dysesthesia or numbness
- Paresthesia
- Failure to relieve symptoms including unresolved pain
- Additional surgery due to loss of fixation, infection or injury
- Heterotopic ossification (Grades 1-4); Spontaneous fusion due to heterotopic ossification, development of bridging bone or osteophytes
- Periarticular calcification and/or fusion

- Kyphosis or hyper-extension
- Loss of flexibility
- Asymmetric range of motion
- Vertebral body fracture
- Spinal cord damage, s47G(1)(a) [redacted]
- Development of spinal conditions, including but not limited to spinal stenosis, spondylolisthesis, or retrolisthesis
- Removal, revision, reoperation or supplemental fixation of the disc
- s47G(1)(a) [redacted] osteolysis, bone loss, or bone resorption
- Death

These conditions do not include all potential adverse effects that may occur, but are important considerations in relation to the use of the M6-C™ Artificial Cervical Disc.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the M6-C™ Artificial Cervical Disc is MR Conditional. A patient with the M6-C™ Artificial Cervical Disc can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-T or 3.0-T, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the M6-C™ Artificial Cervical Disc is expected to produce a maximum temperature rise of 2.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the M6-C™ Artificial Cervical Disc extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3.0-Tesla MR system.

HOW SUPPLIED

- The M6-C™ Artificial Cervical Disc is supplied sterile and is single use only. Do not re-sterilize or reuse the M6-C™ Artificial Cervical Disc. Re-sterilizing and/or reusing the M6-C™ Artificial Cervical Disc may result in impaired performance and could cause patient injury and/or the communication of infectious diseases between patients.
- Do not use the M6-C™ Artificial Cervical Disc after the last day of the month of the “Use by date” on the label.
- Inspect the device package before opening. Do not use if package is damaged or shows any evidence of breached packaging, compromised device sterility, or storage above 60˚C (140˚F). The temperature recorder label on the box turns black if the product has reached 60˚C (140˚F).
- Use sterile technique to carefully remove the Disc from the packaging. Inspect the M6-C™ Artificial Cervical Disc to ensure it exhibits no signs of damage (e.g., metal and plastic damage).
- Once removed from the package, keep the M6-C™ Artificial Cervical Disc from coming into contact with any cloth, sponges or other foreign material that may become attached to the Titanium Plasma Spray Coating of the endplates.
- The M6-C™ Artificial Cervical Disc serial number and the size must be documented for each patient record.

DEVICE RETRIEVAL

Please contact Spinal Kinetics to receive specific instructions regarding the preferred method for explant handling and transport as well as data collection, including histopathological, mechanical, patient, and adverse event information. Please refer to M6-C™ Artificial Cervical Disc Operative Technique Manual for

step-by-step instructions on the required surgical technique for device removal. All explanted devices must be returned to Spinal Kinetics for analysis.

It is preferred that no cleaning, decontamination or sterilization be performed at the hospital. Some surgical centers may require that the device be decontaminated or sterilized prior to leaving the facility. Note that many sterilization methods will damage the device (e.g., autoclaving, immersion in alcohol), and the effects of other methods are unknown. Rinsing with water or saline is acceptable. If decontamination and sterilization are required, 10% neutral buffered formalin is best. If cleaning, decontamination or sterilization is performed, note what cleaning methods and materials were used.

It is preferred that the explanted device is packed “dry” (no fluid) or wrapped in formalin-soaked gauze. The device can be gently rinsed with water or saline to remove excess blood and fluids.

Send explant in a leak-proof container, with the date of removal, explanting surgeon, and any known information regarding initial implantation, reasons for removal, and adverse event information. Please note that the explanted M6-C™ Artificial Cervical Disc should be removed as carefully as possible in order to keep the implant and surrounding tissue intact if possible. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, i.e., intact or in pieces. Spinal Kinetics will request additional information regarding the reason for removal, patient information and associated clinical outcomes.

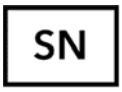
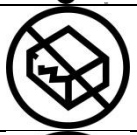
NOTE: All implant removals must be reported immediately to Spinal Kinetics.

CONTACT INFORMATION **Manufactured by:/Hergestellt von:/Fabrique par :/Fabricado por:/ Prodotto da:/Vervaardigd door:/Κατασκευαστής:/Fabricado por:/Uretici:/ Vyrobce:/Vyrobene:/Произведено:/Tillverkas av:**

Spinal Kinetics LLC, an Orthofix Company
501 Mercury Drive
Sunnyvale, CA 94085, USA
408-636-2500
M6info@orthofix.com

Customer Service
Phone: +1-408-636-2515
CustomerService@spinalkinetics.com

Definitions of symbols on device label

	Catalog Number
	Lot Number
	Serial Number
	Use by Date
	Sterile with Ethylene Oxide Gas
	Single Use Only / Do Not Reuse
	Read Instructions Prior to Use: www.orthofix.com/IFU
	Manufacturer
	Transient temperature limitation; Store at room temperature
	Do not use if package is damaged
	Do not resterilize
	Authorized Representative in the European Community
	MR Conditional

PK 0225 Rev 03

CE 0050

CE Mark 0050
Applicable to
Implant Only

From:	Recalls
To:	Recalls
Bcc:	DL Recalls_Devices Group; s22 s22 @health.govt.nz; s22 @aoa.org.au; s22 @aoanjrr.org.au; s22 @aoa.org.au
Subject:	Hospital Level Product Defect Correction & Implant Hazard Alert - Life Healthcare - M6-C Artificial Cervical Discs [SEC=OFFICIAL]
Date:	Friday, 5 June 2020 8:40:37 AM
Attachments:	TGA Recall Notice & Implant Hazard Alert - RC-2020-RN-00478-1.pdf TGA Distribution List - RC-2020-RN-00478-1.pdf

Dear All,

Please find attached a notice of a recall action due for distribution at 9:00am today.

Recipients should note that all future notices will be scheduled for delivery as a single tranche of emails at 9:00am on the relevant business day, which will avoid the sending recall notices later in the day.

This email and attached notice may be further distributed as required, however, **please do not pass on customer information/distribution lists to third parties.**

The sponsor of the product is contacting the attached customers.

Other relevant information: None

The attached information is being made available to you in accordance with section 61(7) of the *Therapeutic Goods Act 1989* for the purpose of alerting you to recall and other market actions conducted under the *Uniform Recall Procedure for Therapeutic Goods*. As the information may contain personal and commercially sensitive and confidential information, please safeguard the information and do not distribute this email to third parties.

Kind Regards,

Recalls Section
Manufacturing Quality Branch

Phone: 02 6289 4613
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

Do you know all Recall Actions undertaken in Australia are on the System for Australian Recall Actions (SARA)? For further information, please refer to the TGA Website http://tga.gov.au/safety/sara.htm

s22

Document 8

s22

Document 8

s22

Document 8

Australian Government

Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION; AND IMPLANT HAZARD ALERT*

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2020-RN-00478-1

DATE AGREED: 2/06/2020

PRODUCT: **M6-C Artificial Cervical Discs**

Item Codes:
CDM-625
CDM-635L
CDL-627
CDL-637L
CDM-725
CDM-735L
CDL-727
CDL-737L

ARTG 177101
(Life Healthcare Pty Ltd - Cervical total disc replacement prosthesis)

SPONSOR: Life Healthcare Pty Ltd

PHONE: 1800 060 168 - Life Healthcare Customer Service

REASON: After conducting a post-market review on the Spinal Kinetics M6-C implants, it was determined that the Instructions for Use (IFU) contains insufficient information regarding the potential consequences of peri-prosthetic osteolysis associated to the use of this device.

The new IFU contains updated precautions regarding the potential consequences of peri-prosthetic osteolysis as below:

"Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis. Peri-prosthetic osteolysis may result in neck pain and serious neurological sequelae including cervical spinal cord compression and quadriplegia."

PROPOSED CUSTOMER ACTIONS: **<u>Product Defect Correction:</u>**
Life Healthcare is advising customers to inspect all un-implanted stock on site and replace the outdated IFU with the updated version provided with the customer letter (distributed by the sponsor). The new IFU contains updated precautions regarding the potential consequences of peri-prosthetic osteolysis.

Implant Hazard Alert:
Customers are requested to bring the IFU update to the attention of relevant staff involved in the implantation of these devices and on-going patient management.
Routine long term clinical and radiographic monitoring of patients implanted with the M6-C is suggested to assess any changes in implant condition or surrounding anatomy. Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 95 hospitals nationally excluding NT, along with 149 surgeons.

Product export status: N/A

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm