Fax received: [redacted] **7 page(s)**

messagemanager to: iris 26/10/2012 11:31 AM

1 attachment

SM065938.pdf

7 page(s) received from 0249616722 on Friday, 26 October 2012 at 11:32 AM
(MSN 257418)

[redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

[redacted]

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Users Medical Device Incident Report *eg Doctors, Nurses, Patients, Public*

What should be reported? A medical device is any material instrument, apparatus, machine, implement, contrivance, implant etc (including any component, part or accessory) which is used in health care and includes in-vitro diagnostics.
Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What should you do with the device? **Please keep the device and its associated packaging until you are contacted by the TGA/Medsafe.** To send the device please follow the instructions in this link
http://www.tga.gov.au/problem/iris/devices-testing.htm

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, performance or quality.
2. Safety Alert – information relating to the correct use of the device to inform those responsible for the device, or affected by the problem.
3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical device manufacturers or suppliers should use form # MDIR03
http://www.tga.gov.au/docs/html/forms/iris_mdir.htm

A	**Product Identification**	*Please provide all available details*	Date of Report: 27/09/12.
1.	Brand/Trade Name	Eska	
2.	Device Description *(eg Urinary Catheter)*	Hip Prosthesis.	
3.	Device Identification	Model: Eska [redacted] Serial Number	Batch Number: 60510730 [redacted] Lot Number: HN80J.
4.	Relevant Dates	Purchase (Approximate):	Expiry: If Device is Implantable *(eg pacemaker, venous port etc)* Date of Implant: 6/4/2010. Date of Explant: 28/8/2012.
5.	Manufacturer's name address & telephone	[redacted] Eska - copy of details from hospital attached	
6.	Supplier's name address and telephone	?	
B	**Reporting the Problem**	*Please provide all available details*	
7.	Has the supplier been informed of the problem?	☐ YES ☐ NO Not to my knowledge.	If YES Date Contacted: / If YES add contact details Name: / Phone / Fax: ( )
8.	Where is the device now?	☐ Place of use ☑ With Reporter ☐ With Supplier ☑ With Patient	Please Do Not discard the device or related consumables & packaging. Contacts for access to device Name: [redacted] Phone / Fax: [redacted]
9.	Is this device supplied sterile?	☐ YES ☑ NO	Is this device reusable? ☐ YES ☑ NO / Is this device single use? ☑ YES ☐ NO

C Problem Description

Please provide all available details
If you do not have enough space please add information onto another sheet of paper or into the body of your email.

10. Add a brief description of the problem. Include what led to, or contributed to the problem.

Have had 4 hip operations over last 5 years - Details attached. As far as we know all were Extra brand (metal on metal) except last replacement on 28/8/12 which is xeflon. Approx. ~~Apr~~ May/June 2012 had blood

11. Add a brief description of the consequences or outcome of the problem.

Please add sketches and pictures if necessary and/or available

test done for cobalt. Test confirmed extremely high amts in blood - recommended same be replaced as soon as possible This was completed on 28/8/12 - By Dr Harbury. We strongly believe - the metal on metal hip was the main contributor to health deterioration. Have attached hospital paperwork from 6/4/2010 showing all this info I have been able to obtain -

D Reporter

Please provide all available details

12. Do you want your identity to remain confidential?

If YES your name & contact details will not be disclosed to manufacturers or suppliers without your permission. TGA will contact you if more information is needed.

A report without contact details cannot be processed.

[redacted]

Name	Position / Occupation
[redacted]	[redacted]
Department, Institution & Address	**Phone**
[redacted]	[redacted]
	Fax
	[redacted]
email	–

E Initial Reporter

Please provide all available details

13. Do they want their identity to remain confidential?

If YES their name & contact details will not be disclosed to manufacturers or suppliers without their permission. TGA will contact them if more information is needed.

[redacted] If YES or NO add contact details below

Name	Position / Occupation
Department, Institution & Address	**Phone** ( )
	Fax ( )
email	

F TGA Feedback

Please provide all available details

14. Who can TGA or Medsafe contact for more information regarding this incident?

☑ Reporter	☐ Initial Reporter	☑ Other Appropriate Person	Phone & Fax
Name [redacted]	*Name*	*Name* [redacted]	[redacted]

G How to submit

Post, Fax or email your completed form to:

	✉ Post to		🖱 email / internet	🖷 Fax to	☎ Phone
Australian Reporters **TGA**	**Reply Paid 100** Medical Device IRIS TGA, PO Box 100 Woden ACT 2606 AUSTRALIA	**Courier delivery:** TGA 136 Narrabundah Ln, Symonston ACT 2609, AUSTRALIA	iris@tga.gov.au www.tga.gov.au/docs/html/forms/iris_udir.htm	(02) 6232 8555	FREE HOTLINE 1800 809 361
	✉ Post to		🖱 email / internet	🖷 Fax to	☎ Phone
New Zealand Reporters **MEDSAFE**	Robert Jelas Senior Advisor Compliance Management MEDSAFE Ministry of Health Deloitte House 10 Brandon Street PO Box 5013 Wellington NEW ZEALAND		Robert_Jelas@moh.govt.nz www.medsafe.govt.nz www.moh.govt.nz	(04) 819 6806	(04) 819 6881

[redacted]

[redacted]

8TH OCTOBER, 2007

RIGHT HIP RESURFACED – BRAND – ESKA

SPECIALIST; [redacted]

[redacted]

17TH MARCH, 2008

LEFT HIP RESURFACED – BRAND – ESKA

SPECIALIST; [redacted]

[redacted]

6TH APRIL, 2010

RIGHT HIP – TOTAL HIP REPLACEMENT – BRAND ESKA

SPECIALIST; [redacted]

[redacted]

[redacted]

[redacted]

NSW GOVERNMENT Health

[redacted]

Local Health District

[redacted]

Our ref: 8798643/09102012

[redacted]

Dear [redacted]

I apologise for delay in forwarding this information to you. I have tried to phone you on a couple of occasions, without success. I have attached a copy of the operation report from 6 April 2010 and information from the "procedure case report" (which is not part of the medical record) on the same day. Information recorded includes brand, implant description, and batch number.

I trust this information will be of use to you.

Yours sincerely,

[redacted]

Medical Record Manager

[redacted]

Revision Right Total Hip Replacement...

Unplanned Return to OR

No.

Procedure Information

Operation performed

Revision Right Total Hip Replacement

Operation description: .
GA. IVAB. L Lateral position.
posterior approach. capsulotomy. cervical osteotomy. removal of implant. multiple swabs. femur prepared to accept (Stryker) Securefit 7/132 implant. surfaced with 44 mm medium length ESKA head. stable construct. posterior repair through transosseous holes. close in layers, monocryl to skin.
Wound Class: Clean.

Prosthesis details

Prosthetic Details.

[redacted] [redacted]

[redacted] - [Finalized] Implants / Prosthetics

Task Edit View Patient Chart Links Notifications Document Pick List Help

Perioperative Tracking | Case Tracking | Case Selection | Dynamic View | Message Centre | Patient List | SurgiNet Intranet | SEALS Test Manual | GuidanceMS | Links

Change | Exit | Calculator | AdHoc | Explorer Menu | DB Pricing Tool Application | Charge Review | Scheduling Appointment Book | Preference Card Maintenance

[redacted] Recent | MRN

[redacted] Age [redacted] Sex [redacted] Location: Surgical SDM; -; 0... [redacted]

MRN:8798643 DOB: [redacted] Inpatient; Admit/Reg Date: 02/04/2010 09:44; Discharge Date: 10/04/2010 14:21

Menu | Surgical Case Data | Print | ago

- Patient Information
- Flowsheet
- Allergies
- Diagnosis, Alerts & Prob.
- Alerts View
- Orders
- Documentation
- Forms
- Patient Schedule
- Clinical Notes View
- IView
- Nursing Operative View
- Surgical Case Data
- Postoperative Summary..
- Inpatient Summary MPag

Procedure Case Report SDM

Documentation | Pick List

Procedure Case Report SDM
- ✓ Case Times
- ✓ Procedure TimeOut
- ✓ Surgical Procedures
- ✓ General Case Data
- ✓ Case Attendance
- ✓ Implants / Prosthetics
- ✓ Delays

1 2 >

Implant Description	Quantity Used	Lot/Batch Number	Brand/Manufacturers
605107305 SECUR-FIT MAX HA 132 DEG #7	1	MHN80J	Stryker

Implant Description:

Quantity Used:

Lot/Batch Number:

Brand/Manufacturer:

Add | Modify | Remove | Clear | << Prev | Next>>

B I U | Microsoft Sans Serif | 10

Segment Text
Pre Care Activity

SERRD WATERSLE 29 August 2012 15:26 AEST

Operation Report

[redacted]

Result type:Operation Report
Result date:06 April 2010 11:37
Result status:Auth (Verified)
Result title:Operation Report
Verified by:[redacted] on 06 April 2010 11:43
Visit Info:[redacted] Inpatient, 02/04/2010 -

Operation Report

Patient:[redacted] MRN - 8798643 - SDMH MRN
Age:[redacted] Sex:[redacted] DOB:[redacted]
Author:[redacted]

Operative Information

Date of Operation
06-APR-2010
Facility/Surgical Area/Operating Room
[redacted]
Medical staff: Medical Staff involved in this procedure.
Proceduralist - Principal:[redacted]
Anaesthetist - Senior: Procedure attendee, Other
Proceduralist - Assisting:[redacted]
Procedural Consultant:[redacted]
Type of anaesthetic
General
Procedure type
Emergency

Operative Note

Planned procedure
Revision Right Total Hip Replacement
Unplanned Return to OR
No.
Procedure Information
Operation performed

Revision Right Total Hip Replacement

Operation description: .
GA. IVAB. L Lateral position.
posterior approach. capsulotomy. cervical osteotomy. removal of implant. multiple swabs. femur prepared to accept (Stryker) Securefit 7/132 implant. surfaced with 44 mm medium length ESKA head. stable construct. posterior repair through transosseous holes. close in layers, monocryl to skin.
Wound Class: Clean.
Prosthesis details
Prosthetic Details.

Lot MHN80J
N/o
60510730S

Surgical Pathology

Specimens sent to pathology
Specimens documented.
Description: swab right hip joint
Quantity: 1
Time Taken: 06/04/2010 10:22
Destination: Microbiology

Operation Report [redacted]

Result type:Operation Report
Result date:06 April 2010 11:37
Result status:Auth (Verified)
Result title:Operation Report
Verified by: [redacted] on 06 April 2010 11:43
Visit Info: [redacted] Inpatient, 02/04/2010 -

Operation Report

Patient: [redacted] **MRN - 8798643 - SDMH MRN**
Age: [redacted] Sex: [redacted] DOB: [redacted]
Author: [redacted]

Operative Information
Date of Operation
06-APR-2010
Facility/Surgical Area/Operating Room
[redacted]
Medical staff: Medical Staff involved in this procedure.
Proceduralist - Principal: [redacted]
Anaesthetist - Senior: Procedure attendee, Other
Proceduralist - Assisting: [redacted]
Procedural Consultant: [redacted]
Type of anaesthetic
General
Procedure type
Emergency

Operative Note
Planned procedure
Revision Right Total Hip Replacement
Unplanned Return to OR
No.
Procedure Information
Operation performed

Revision Right Total Hip Replacement

Operation description: .
GA. IVAB. L Lateral position.
posterior approach. capsulotomy. cervical osteotomy. removal of implant. multiple swabs. femur prepared to accept (Stryker) Securefit 7/132 implant. surfaced with 44 mm medium length ESKA head. stable construct. posterior repair through transosseous holes. close in layers, monocryl to skin.
Wound Class: Clean.
Prosthesis details
Prosthetic Details.

Lot No MHN80J
6051073OS

Surgical Pathology
Specimens sent to pathology
Specimens documented.
Description: swab right hip joint
Quantity: 1
Time Taken: 06/04/2010 10:22
Destination: Microbiology