



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Medical Device
Incident Report Investigation Scheme

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR

Date: 20/05/2011

DIR: 23483

Manufacturer Name:

Prosthesis, internal, joint, hip, femoral component/Eska
 Implants GmbH and Co

Question / Requirement

- 1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number
- | |
|---------------------------|
| ARTG: |
| 118426 – Acetabular liner |
| 118428 – Femoral head |
-
- 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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| b) For Export | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
-
- 3) How many devices of this model have been supplied:
- | | | |
|--|--------------|--|
| | In Australia | 656 femoral heads
600 acetabular liners |
| | Worldwide | |
-
- 4) How many devices of this batch (if applicable) have been supplied:
- | | | |
|--|--------------|--|
| | In Australia | 8 femoral heads
3 acetabular liners |
| | 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? ☒ ☐
- 17 revisions have been recorded in the NJRR up to the end of 2009
 4 revisions have been reported to Orthodynamics from Eska Australia since 1st April 2010 (including this incident)
- If YES please how many: _____
- If YES please give details: Revisions due to high cobalt ion levels
- 8 JUN 2011
-
- 8) If you are not the manufacturer, has the manufacturer been contacted for any other reports of similar problems with this product? ☒ ☐

If YES please how many: Please see attachment for manufacturer status

If YES please give details: Please see attachment for manufacturer status

Question / Requirement (continued)

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

A previous investigation revealed potential problem with earlier designs of Biosurf femoral head. These were immediately removed from the market by Orthodynamics GmbH at the end of February 2011 (see attached extract of original TGA report – submitted to Jorge Garcia 28th February 2011).

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

Date:

Investigation revealed that the Biosurf femoral head that was revised was to the former design which could have resulted in increased wear at the head-cup interface as described in earlier report to TGA. Hip simulator wear testing demonstrates a significantly lower wear rate with the latest design of device which is currently available on the market.

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

- | | |
|--|---|
| <input type="checkbox"/> Sample of the product/device | <input type="checkbox"/> Operator's manual |
| <input type="checkbox"/> Product Specifications | <input type="checkbox"/> Technical Service Manual |
| <input type="checkbox"/> Descriptive product promotional documentation | <input type="checkbox"/> Clinical training manual in printed or video form |
| <input type="checkbox"/> Instructions for use, as supplied with the device | <input type="checkbox"/> In-house training documentation |
| <input type="checkbox"/> Device Packaging with printed instructions | <input type="checkbox"/> Evidence of compliance with the Essential Principles |
| <input type="checkbox"/> A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:200 | |

- 12) Additional Information required:

1. Please provide the current rate of metallosis for this device

Of the 832 femoral heads supplied that could be used with a metal-on-metal bearing, we know of 21 revisions (2.5%). However, the metal-on-metal usage is believed to be almost exclusive to Australia which means there have been 21 revisions of a possible 656 femoral head couplings (3.2%).

Information Supplied by:

13) Name	<div></div>	Phone	<div></div>
Signature	<div></div>	Fax	<div></div>

Position

email

This questionnaire and any appended documents should be returned to the TGA within **5 working days**.



Attach your completed form to an **email** and send to: iris@tga.gov.au



Fax your completed form to: (02) 62 03 1713

Supporting documentation following by normal mail

Please do not send more than one copy of your response to the TGA

Postal Address:



Medical Device Incident Report Investigation Scheme, Market Vigilance & Monitoring Section,
Therapeutic Goods Administration, **PO Box 100**, WODEN ACT 2606, Australia

Courier Address:



Medical Device Incident Report Investigation Scheme, Market Vigilance & Monitoring Section,
Therapeutic Goods Administration, 136 Narrabundah Lane, SYMONSTON ACT 2606, Australia

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, regulatory history in another country, or any other matter prescribed by the regulations in relation to the product.

DIR/23483 Prosthesis, internal, joint, hip, femoral
component/Eska Implants GmbH and Co

Reporter#

Exempt/Not on Artg: N
Syst/Artg No:ARTG/118441
Ecri Code: 35666 Prosthesis, internal, joint, hip,
femoral component

Device: Hip prosthesis
Model No:
Batch No:
Serial No:
Manufacturer:Eska Implants GmbH and Co 45325
DDR

Sponsor: Eska Australia 45270
Unit 4 4-6 Chaplin Drive
LANE COVE NSW 2066 AU

Contact: [REDACTED]
Phone: [REDACTED] Fax: [REDACTED]

Description: My mother had a hip replacement on the
31/8/09. The prosthesis used was a ESKA Metal
on Metal prostheses.
Dr requested a blood test be done for Mums'
annual examination, on the 4/10/10, Mums
cobalt level was 733 nanamol/litre, it was
tested again and on the 18/2/11 the level had
risen to 2,004 nanamol/litre. Mum was
experiencing pain in her hip, headaches, fluid
around the joint and a general feeling of
being unwell.
After these high readings Dr recommended
revision surgery which was carried out on the
29/3/11. He said once the metal was replaced
with a ceramic ball it would stop the friction
caused by metal on metal and stop the cobalt
leaching and stop the cobalt level increasing
further. He had no information as to what
affects the high level of cobalt has done to
mums system and vital organs or what it will
continue to do, as it could take a long time
to get out of her system.

After reading information regarding the re-
call world wide of Johnson on Johnson (DePuy)
due to the health risks caused by metal on
metal prostheses causing cobalt poisoning. I
contacted ESKA Australia, they have not taken
these prostheses off the market and are still
available for surgeons to choose. They were
sorry for mums ill health and having to
undergo major surgery again to remove the
metal prostheses, but were not saying that the
prostheses was at fault or that any
compensation was available.
Dr told us he had stopped using these

prostheses and 1 out of 10 patients had been adversely affected and required revision surgery.

Surely there needs to be an investigation on the use of the metal on metal prostheses, no matter what Company produces them. The metal on metal prostheses appears to be having the same affect on a large number people that undertake this surgery.

Report sourced from carer

Dates

Received: 16/05/2011

***** End Of DIR/ 23483 *****

Manufacturer status – Orthodynamics GmbH and ESKA Implants AG

On the 31st March 2010, The Summit Medical Group acquired the assets of the insolvent ESKA Implants AG. The Summit Medical Group then set up a new business called Orthodynamics GmbH. Orthodynamics GmbH continues to supply medical devices to the Australian market via the sponsor ESKA Australia.

The implants involved in this case were manufactured by ESKA Implants AG as they were implanted on the 31st August 2009. Since the formation of Orthodynamics GmbH, six of the Biosurf femoral heads have been supplied to the Australian market and no metal liners. All of the femoral heads supplied have been to the latest design, and Orthodynamics GmbH has also requested the return of all previous designs of femoral heads from our sponsor in Australia.

The legal manufacturer of the device relating to this complaint is therefore ESKA Implants AG. Whilst Orthodynamics GmbH is happy to assist the TGA wherever possible with the investigation, it is important to state that we do not have manufacturer responsibility for the device in question. Any queries relating directly to ESKA Implants AG should be addressed to the insolvency administrator, [REDACTED]

Finally, due to the terms of the asset acquisition, Orthodynamics GmbH does not have access to the complaints records prior to 1st April 2010. However, from previous correspondence with the TGA and the NJRR we know of 17 revisions prior to January 2010 that involved this combination of devices. Since 31st March 2010, four further revisions of ESKA Implants metal-on-metal prostheses have occurred due to concerns regarding high cobalt levels and metallosis.



Extract of report submitted to TGA:

**Investigation into Australian Orthopaedic Association National Joint Replacement Registry Data
for the ESKA Adapter (cementless) Femoral Stem Prosthesis and the ESKA Bionik Resurfacing
Femoral Head**

However, there is also reason to believe that there may be design factors associated with the Bionik femoral head which could account for a higher than expected revision rate. In July 2007, the external geometry of the Bionik femoral head was modified upon feedback from the Australian surgeons to avoid irritation of the iliopsoas tendon¹. This was followed by a further design change of the Biosurf surface in September 2008 to improve wear results (this is discussed further in the Bionik resurfacing head section).

Bionik Resurfacing Head

Following design changes to the external geometry of the Biosurf surface, a further wear test was commissioned in 2007². This test was performed using three conventional femoral heads. The results identified a higher mean wear rate of 10.83mg/million cycles which equates to 1.31mm³/year. These wear results are in the middle range of the reported values in the literature. The results were also inconsistent with a large standard deviation.

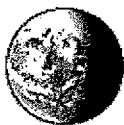
Concern about these results led to an improvement in polishing of the Biosurf components and a further test of four components³. This testing demonstrated a significantly higher wear rate again, and a wider range of results. The wear rate varied from 2.2mg/million cycles to 52.2mg/million cycles. Conversion of these results gives a mean volumetric wear rate of 3.29mm³/year which is beyond the levels reported in the published literature²².

The devices were left on the market by ESKA Implants AG until a design change was approved in September 2008. This remains the latest design iteration, and it was approved on the basis of achieving three consistently low results from the wear simulator testing for both surfaces^{4,5}. These latest wear results of 1.51mg/million cycles for the Biosurf and 1.81mg/million cycles (0.18mm³/year and 0.39mm³/year) for the conventional surface were lower than those seen in the original testing, and are at the low end of reported results in the literature.

The design was improved by moving the region of the dimples closer to the equator and reducing the number and depth of the dimples⁶. Following the successful wear results, the latest design of device replaced all previous issue stock in the ESKA Implants warehouse and all previous issue consigned European stock. It is understood that Australian stock was not replaced by the then owners of ESKA Implants AG and/or ESKA Australia. It should be stressed that this action was performed long before the change of ownership, and is in no way condoned by Orthodynamics GmbH. A review of stock currently held by the Australian distributor, ESKA Australia, and their customers, confirmed that there were still previous issue femoral heads in stock at their facility. Arrangements have now been put in place to ensure that this previous issue stock is returned to Orthodynamics GmbH to prevent its usage in the Australian market.



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- ¹ Change report 16-07 for Bionik femoral heads
 - ² Endolab test report 05.070904.10.963, June 2008
 - ³ Endolab test report 05.071113.10.981, July 2008
 - ⁴ Endolab test report 05.080109.10.1000, May 2008
 - ⁵ Endolab test report 05.070731.10.944, January 2008 (Non-Biosurf surface)
 - ⁶ Change report 05-08 for Bionik femoral head



08/06/2011 06:51 AM

To <iris@tga.gov.au>, <sharon.hughes@tga.gov.au>

cc

bcc

Subject: Device incident report DIR 23483 - Prosthesis, internal joint, hip, femoral and Co

FULL HEADER

3 attachments



Device Incident Report 23483.pdf DIR 23483 Manufacturer status.pdf DIR 23483 Extract of TGA report.pdf

DOCUMENT NOT YET CLASSIFIED

Dear Sharon,

Please find attached the completed incident report form, and associated documents, in response to the above incident (DIR 23483).

Should you require any further information, please do not hesitate to contact me.

Many thanks,
Steve.

Steven Meakins
Quality Management and Regulatory Affairs Manager - Implants

O R T H O D Y N A M I C S

Innovation in Total Hip Replacement



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