

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Wednesday, 3 December 2014 1:33 PM  
**Subject:** RE: DIR 29032 [SEC=UNCLASSIFIED]  
**Attachments:** DIR 29032 Sponsors Completion Letter.pdf

Dear [REDACTED]

Please find attached the Sponsors Completion Letter for DIR 29032.

Many Thanks

[REDACTED]  
Departmental Officer  
Device Vigilance and Monitoring  
Office of Product Review

[REDACTED]  
**Therapeutic Goods Administration**  
Department of Health  
PO Box 100  
Woden ACT 2606 Australia  
[www.tga.gov.au](http://www.tga.gov.au)



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

**Australian Medical Device  
Incident Report Investigation Scheme**

File Reference: 2012/022344

[REDACTED]  
Eska Australia  
72 South Street  
RYDALMERE NSW 2116

Attention: [REDACTED]

**DEVICE INCIDENT REPORT DIR 29032 - ARTG # 118430 - Prosthesis, internal, joint, hip,  
resurfacing**

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 me on (02) 6232 8477.

Yours sincerely

Electronically signed by

[REDACTED]  
Incident Report and Investigation Scheme  
Device Vigilance and Monitoring  
Office of Product Review  
Therapeutic Goods Administration

03/12/2014

DIR 29032 - ARTG # 118430 - Prosthesis, internal, joint, hip, resurfacing

Reporter Reference #:

Date of Adverse Event:

Date of Initial Report:  
26/10/2012

ARTG #:  
118430

Brand Name:  
Eska Hip Prosthesis

Device Class:  
Class IIb

Model #:

Serial #:

Software Version:

Batch #:  
605107303

Lot #:  
MHN80J

Manufacturer:  
Eska Implants GmbH and Co [45325]

Sponsor:  
Eska Australia [45270]  
72 South Street

Contact Name:

RYDALMERE NSW 2116

Phone:

Fax:

Email:

Reporter:

Confidential: No

Phone:

Fax:

Email:

Date of Implant:  
06/04/2010

Date of Explant:  
28/08/2012

**Clinical Event Information:**

Have had 4 hip operations over last 5 years. Details attached, as far as we know all were Eska brand (metal on metal) except last replacement on 28/8/12 which is teflon. Approx May/June 2012 had blood test done for cobalt. Test confirmed extremely high amounts in blood. Recommended some be replaced as soon as possible. This was completed on 28/8/12. We strongly believe the metal on metal hip was the main contributor to health deterioration. Have attached hospital paperwork from 6/4/2012 showing all the info I have been able to obtain.

**Patient Outcome/Consequences:**

**Device Analysis Results:**

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

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Type of Problem (Level 1)

Type of Problem (Level 2)

Other

Other

patient factors

Cause of Problem (Level 1)

Cause of Problem (Level 2)

Known Complication

Known Complication

Outcome of Investigation

Reviewed, No Further Action Required

Summary of Investigation:

The TGA is acutely aware of the problems that can arise from the wear of Metal on Metal (MoM) hip implants and even though ASR has had the highest rates of revision (repeat) surgery, that the problems are not restricted to that implant.

In April 2014, published two statements on the TGA Website on the matter. One of the statements was aimed at patients who have a MoM implant and the other is aimed at surgeons and other health professionals who may be caring for those patients. The TGA statements advise that patients with MoM implants will benefit from regular follow up including blood tests for Cobalt and Chromium in the blood and soft tissue imaging using MRI. It appears that the surgeon followed the advice of the TGA webstatement regarding follow up and ongoing care via blood tests for cobalt and chromium. The TGA statement for patients can be found on the TGA website at:  
<https://www.tga.gov.au/metal-metal-hip-implants-information-patients>

In spite of the problems with MoM hip implants, and the fact that MoM implants have been abandoned in total conventional hip replacement surgery, the Australian Orthopaedics Association and a group of experts that advise the TGA advised against a blanket ban on all MoM hip replacements as such a ban would mean that several implants that have good safety and performance would be removed from the market. The experts further advised that an implant by implant analysis of the safety and performance using National Joint Replacement Registry (NJRR) data that the TGA had already established remained the most appropriate way to deal with implants that have higher than expected revision rates, including those implants that are of the MoM type. The TGA has accepted that advice.

The Eska hip prosthesis (subject of this Device Incident Report) was cancelled from the Australian Register of Therapeutic Goods (ARTG) in June 2012 and unavailable for supply. Since the implant is no longer supplied on the market, no further investigation or regulatory action is indicated.

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Date Completed:  
28/11/2014

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End of DIR 29032

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