

**Australian Government**

Department of Health
Therapeutic Goods Administration

**Australian Medical Device
Incident Report Investigation Scheme**

File Reference: 2012/022344

Dear [REDACTED],

DEVICE INCIDENT REPORT DIR 29032 - Eska Hip Prosthesis

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

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

Should you have any questions or further information, please contact me on (02) 6232 8695 or iris@tga.gov.au quoting the above DIR number. The TGA may contact you regarding this report.

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

Yours sincerely

Signed electronically by

[REDACTED]

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

22/10/2014

DIR 29032 - Eska Hip Prosthesis

Reporter Reference #:

Date of Adverse Event:

Date of Final 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

Sponsor:
Eska Australia
72 South Street
RYDALMERE NSW 2116

Contact Name:

[REDACTED]

Phone:

[REDACTED]

Reporter:

[REDACTED]

Confidential: No

Phone:

[REDACTED]

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:

End of DIR 29032
