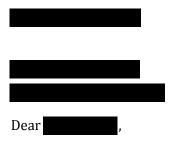
File Reference: 2012/022344

Australian Medical Device Incident Report Investigation Scheme



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

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 Final Report: Date of Adverse Event: 26/10/2012 ARTG #: **Brand Name:** 118430 Eska Hip Prosthesis **Device Class:** Model #: Serial #: Class IIb **Software Version:** Batch #: Lot #: 605107303 MHN80I Manufacturer: Eska Implants GmbH and Co Sponsor: Contact Name: Eska Australia 72 South Street **RYDALMERE NSW 2116** Phone: Confidential: No Reporter: Phone: Fax: Email: Date of Implant: Date of Explant: 28/08/2012 06/04/2010

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 colbalt. Test confirmed extremely high amounts in blood. Recomended 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