HSA Health Sciences Authority

Medical Device ALERT

Vol. 1 Issue 1 (Dec 2012)

The HSA Medical Device Alert circular aims to highlight concerns relating to the use of medical devices to healthcare professionals. Where the implant is designed to enhance or support a damaged or missing physiological structure, it remains an important issue with regard to the safety of its use on patients. This issue covers topics including Stryker Orthopaedic Limerick's Recall of the Howmedica Modular Resection System (HMRS), Cochlear Limited's Recall of the Nucleus CI500 implants, and Zimmer Inc.'s Field Safety Corrective Actions (FSCA) for Hip Prosthesis.

Did you know?
With the gazetting of the Health Products (Medical Devices) Regulations in 2010, manufacturers, importers, suppliers or registrants of medical devices have to report *FSCAs to HSA as part of their postmarketing commitments.

Stryker Orthopaedics Limerick's Recall of the HMRS and HMRS Distal Femur

- The HMRS is a modular prosthesis intended for the treatment of primary and secondary bone tumours or for revision hip and knee arthroplasty.
- Presence of excessive material at the base of the slot feature in the distal femoral component was identified.
- Use of the affected device may lead to an extended surgery time.
- A recall was issued by Stryker Orthopaedics Limerick in August 2011.

What is a *FSCA?
FSCA means any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device.

Examples of actions taken may include:

- Product recall
- Product replacement
- Destruction, modification or retrofitting of the medical device
- Software upgrades
- Clinical management of the patient using the medical device
- Changes to the labels or Instructions For Use (IFU)

Cochlear Limited's Recall of the Nucleus CI512 and Nucleus CI513 Cochlear Implant

- Although less than 1% of the implant had failed since its launch, a spike (3-fold increase) in the global average weekly rate of reports was observed in 2011.
- A total of 168 global reports of Nucleus CI500 implant failures were received by Cochlear Limited. Of these 168 reports, 96.4% involved the user experiencing intermittency of sound that finally led to implant failure.
- A recall was initiated by Cochlear Limited in September 2011.
- All unimplanted units were recalled in September 2011.

Report Medical Device FSCA & Adverse Events (AEs)
You can report:

- All FSCAs to the Compliance Branch at Fax: 6478 9028
- All suspected Medical Device AEs to the Vigilance Branch at
  Tel: 6866 3538; Fax: 6478 9069;
  Email: HSA_productsafety@hsa.gov.sg

All reporting forms are available at www.hsa.gov.sg

For further information on Medical Device FSCA and AE reporting, please contact the Compliance Branch at HSA_Compliance@hsa.gov.sg

Zimmer Inc.'s FSCA for Zimmer ZMR Porous Revision Hip Prosthesis and ZMR Revision Taper Hip Prosthesis

- In November 2011, a revision to the IFU and Surgical Technique to change the product indication from "revision total hip athroplasty" and limited to "cementless revision hip arthroplasty" was submitted to HSA.
- Revision was due to the unanticipated ambiguity in the warning in the IFU.
- Under a lack of proximal femoral support, use of the affected implant based on the published indication may result in a premature fracture and, eventually, vascular and neural damage.

Please send your enquiries, comments and suggestions to:
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