Australian Government

Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION; AND IMPLANT HAZARD ALERT*

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2020-RN-00478-1

DATE AGREED: 2/06/2020

PRODUCT: **M6-C Artificial Cervical Discs**

Item Codes:
CDM-625
CDM-635L
CDL-627
CDL-637L
CDM-725
CDM-735L
CDL-727
CDL-737L

ARTG 177101
(Life Healthcare Pty Ltd - Cervical total disc replacement prosthesis)

SPONSOR: Life Healthcare Pty Ltd

PHONE: 1800 060 168 - Life Healthcare Customer Service

REASON: After conducting a post-market review on the Spinal Kinetics M6-C implants, it was determined that the Instructions for Use (IFU) contains insufficient information regarding the potential consequences of peri-prosthetic osteolysis associated to the use of this device.

The new IFU contains updated precautions regarding the potential consequences of peri-prosthetic osteolysis as below:

"Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis. Peri-prosthetic osteolysis may result in neck pain and serious neurological sequelae including cervical spinal cord compression and quadriplegia."

PROPOSED CUSTOMER ACTIONS: **Product Defect Correction:**
Life Healthcare is advising customers to inspect all un-implanted stock on site and replace the outdated IFU with the updated version provided with the customer letter (distributed by the sponsor). The new IFU contains updated precautions regarding the potential consequences of peri-prosthetic osteolysis.

Implant Hazard Alert:
Customers are requested to bring the IFU update to the attention of relevant staff involved in the implantation of these devices and on-going patient management.
Routine long term clinical and radiographic monitoring of patients implanted with the M6-C is suggested to assess any changes in implant condition or surrounding anatomy. Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 95 hospitals nationally excluding NT, along with 149 surgeons.

Product export status: N/A

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm