Vol. 2 Issue 3 (Dec 2013)

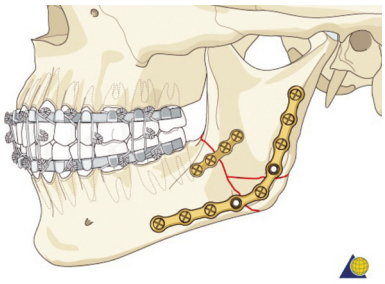
MEDICAL DEVICE Alert

Mislabelling of the Primary Packaging of Surgical Implants

Accurate labelling is crucial for the clear identification of a medical device. Mislabelling of a medical device can have serious consequences if the wrong or inappropriate device is used for a patient. The consequences are more serious if surgical implants are mislabelled. If such an error is discovered preoperatively, a delay in surgical procedure may result due to time spent obtaining the correct replacement implant for the patient. If such erroneous labelling is not detected before the surgical procedure and eventually leads to the implantation of a wrong device, a patient's health may be put at risk due to possible device failure or incompatibilities between the patient's tissue and the implant. These physical or biological incompatibilities can result in adverse reactions, implant failure and a need for revision surgery.

The number of reports received by HSA from locally authorised dealers due to mislabelled medical devices supplied in Singapore has increased from 17 in 2012, to 40 in the first nine months of 2013. This may be partly contributed by the full implementation of HSA's medical device regulatory framework, which includes mandatory regulatory reporting of medical device post-market issues, as well as closer vigilance efforts by HSA in the detection of these medical device issues. Of the reports received in 2013 regarding mislabelling of medical devices, half of these involved surgical implants. Below are two examples of such mislabelling cases received by HSA.

CASE #1: RECALL OF SYNTHES CMF MATRIX SCREWS IN CLIPS



Copyright by AO Foundation, Switzerland
Source: AO Surgery Reference, www.aosurgery.org

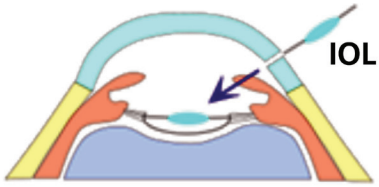
In April 2013, Synthes Singapore Pte Ltd ('Synthes') initiated a recall of its CMF Matrix Screws in Clips. These screws are part of various implant systems meant for orthognathic, maxillofacial and craniofacial surgeries.

Each screw is packaged in a clip that has a laser etch corresponding to the length of the screw. Synthes had initiated the recall as it was reported that the screw lengths etched on the clips did not correspond with the actual lengths of the screws. This error led to the possibility of an incorrect screw length being used during surgery which may result in serious or life-threatening adverse events occurring in the patient.

Between 2011 and the time of the recall, 12 discoveries of non-conformance took place during restocking, which prevented implantation of these incorrect screws. To date, there have not been any local adverse event reports received due to the use of these screws. The relevant physicians were informed of this safety issue and recall by Synthes via a Dear Healthcare Professional Letter (DHCPL) issued in April 2013. All screws with the erroneous laser etch have since been replaced by Synthes. The necessary corrective and preventive actions have also been carried out by Synthes and HSA has deemed these actions completed.

CASE #2: RECALL OF AMO SENSAR OPTI-EDGE SOFT ACRYLIC INTRAOCULAR LENS

In December 2012, Abbott Medical Optics Singapore Pte Ltd ('AMO') initiated a recall of its AMO Sensar Opti-Edge Soft Acrylic Intraocular Lens (IOL). These IOLs are intended for visual correction of aphakia in adult patients whose cataractous lenses have been removed. The recall was initiated as two production lots of IOLs were mislabelled with the incorrect diopter power. A patient implanted with an affected IOL may experience unexpected postoperative refractive error. Three local patients were found to be implanted with the wrong lens and needed follow-ups to determine the degree of refractive errors. Corrective measures (e.g. use of spectacles) had to be taken subsequently.



Copyright by Takuma-sa / Wikimedia Commons / CC-BY-SA-3.0 / GFDL
Source: Overview of phacoemulsification and replacement with intraocular lens

The relevant physicians were informed of this safety issue and the recall by AMO via a DHCPL issued in January 2013. To date, all mislabelled IOLs have been returned to AMO. The necessary corrective and preventive actions have since been carried out by AMO and HSA has deemed these actions completed.

Preoperative Precautions and Call for Reporting

In view of the risks involved for mislabelled surgical implants, HSA would like to reinforce the importance of preoperative planning and checks prior to all surgical implant procedures. These include checking that the correct specifications (i.e. dimension, orientation and material type) of the implants are selected, and that the implants match the descriptions on the package labels. Healthcare professionals are also advised to review the list of DHCPLs published on the MOH Health Professionals Portal (HPP), to determine if there are any current advisories on the use of medical devices.

As healthcare professionals play a vital role in ensuring patient safety and the continued safe use of medical devices, you are highly encouraged to report any discoveries of such erroneous labels and their associated adverse events to HSA and the local dealers. This will allow faster identification and rectification of any safety issues and facilitate delivery of safe healthcare to the patients.

Healthcare professionals are encouraged to report any adverse events related to mislabelled surgical implants to *HSA_productsafety@hsa.gov.sg*.

Editor-in-Chief:
A/Prof Chan Cheng Leng

Editorial team:
Chin Ching Siang, Joanna Koh, Adena Lim, Peck Li Fung, S Kumar Sanjay, Melody Tay

Please send your enquiries, comments and suggestions to:
Vigilance Branch, Health Products Regulation Group, Health Sciences Authority
11 Biopolis Way, #11-01, Helios, Singapore 138667
Tel: ***(65) 6866 3538*** Fax: ***(65) 6478 9069***
Website: ***http://www.hsa.gov.sg***
Email: ***HSA_productsafety@hsa.gov.sg***