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MEDICAL DEVICE Alert

Retention of Medical Device Fragments

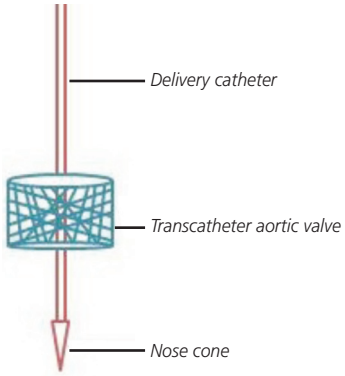
The use of medical devices not according to the Instructions for Use (IFU) or the use of defective medical devices may result in unintended device fragmentation or dislodgement of device parts. These device fragments may potentially pose a risk to patient health as there is a possibility of their retention in the patient's body. Such risks may include delays in surgical procedures as physicians attempt to retrieve the device parts, and complications resulting from infections, blood vessel occlusion or tissue damage due to bio-incompatibilities between tissues and device material.

Background information

The US FDA receives nearly 1,000 adverse event (AE) reports related to unretrieved device fragments in patients from unintentional device separation each year.[1] In Singapore, between 2011 and 2013, HSA had received 115 of such similar reports locally from our medical device dealers. Based on the investigational results of reported AEs, as well as the severity and probability of occurrence of potential health hazards arising from device fragment retention, medical device manufacturers may initiate the necessary Field Safety Corrective Actions (FSCAs). FSCAs may involve the recall of defective devices or the reinforcement of correct usage methods through improved training programmes and/or amendments to the device's IFU.

Examples of recent FSCAs addressing medical device fragmentation and retention

Case #1: FSCA for Medtronic CoreValve AccuTrak Delivery Catheter System (DCS)



Schematic diagram of a transcatheter aortic valve and delivery catheter

In November 2013, Medtronic International Limited ('Medtronic') initiated an update to the IFU for its CoreValve AccuTrak DCS. The CoreValve AccuTrak DCS is used to deliver the CoreValve Percutaneous Transcatheter Aortic Valve to the implant site where the native aortic valve is to be replaced.

Medtronic had initiated this IFU update, as it had received 38 global reports of the DCS nose cone separating from the catheter, potentially remaining in patients and leading to risks such as embolism and additional surgical interventions to retrieve the nose cone. There have been no local complaints or incidents of AEs related to this issue.

Based on their investigations, Medtronic had attributed most of the incidents of nose cone separation to the way the device was used. In some incidents, the device was used in ways cautioned against in the IFU. As such, Medtronic initiated the IFU update to reinforce that (1) the guidewire should not be removed from the catheter while the catheter is inserted in the patient, (2) the retrieval or removal of the Aortic Valve bioprosthesis from the patient is not recommended once deployment is initiated, (3) the capsule should be closed before removal of the DCS, and (4) the DCS should not be manipulated forcefully during removal from the introducer sheath when resistance is encountered.

The relevant physicians using this device locally were informed of this safety issue by Medtronic via a Dear Healthcare Professional Letter (DHCPL)[2] issued in December 2013.

Case #2: FSCA for Olympus ThunderBeat Series of Hand Instruments

Olympus Thunderbeat Hand Instrument's probe tip and PTFE pad

Source: Olympus Technology website, http://www.olympus-global.com/en/technology/technology/thunderbeat/

In December 2013, Olympus Singapore Pte Ltd ('Olympus') initiated an update to the label and IFU for its ThunderBeat Series of Hand Instruments. The ThunderBeat is used in open, laparoscopic and endoscopic surgical procedures, in which cutting, vessel ligation and coagulation are performed.

Olympus had initiated this label and IFU update, as it had received from the US and Canada, 35 reports of breakage of the probe tips. These may result in device fragments falling into and being retained in the patient's body cavity. In Singapore, one event of probe tip breakage and four events of separation of the PTFE (also known as Teflon) pads were reported to HSA. None of the events resulted in user or patient adverse effects.

Olympus had attributed such reports to the use of the device in a manner not in accordance to the IFU. As such, Olympus initiated the label and IFU update to reinforce that (1) users should not grasp metal or hard objects or tissue (e.g., bone or calcified tissue) with the probe tips, (2) there should not be body fluids present around the probe tips, (3) ultrasonic energy should not be activated when tissue is not present in the grasping section, (4) device should not be activated while grasping thick tissue or twisting the device shaft, and (5) sharp devices (e.g., scalpels) should not be used to clean the grasping section of probe tips.

All affected healthcare facilities were informed of this safety issue and the IFU and label update, through the dissemination of a field safety notice in December 2013.

Advisory to healthcare professionals and call for reporting

HSA would like to reinforce the importance of performing visual inspections of all surgical instruments prior to any surgical procedure, in order to identify potential device faults or parts that could potentially dislodge. This is especially so for reusable instruments that may have undergone some degree of wear and tear. Surgical instruments should also be used according to the IFU or the Surgical Technique Guide that is enclosed with the instruments. Usage contrary to a device's indications or instructions may weaken the device or subject it to undue stress, causing breakage and unintended retention.

Healthcare professionals are also encouraged to report any adverse events related to retention of device fragments to *HSA_productsafety@hsa.gov.sg*. Prompt reporting of such events will trigger investigations into their root cause. This will in turn expedite corrective actions, whether in the form of changes in manufacturing processes or strengthened IFU, to safeguard patients' health.

References

1 *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062015.htm (last accessed 28 March 2014)*

2 *http://www.hsa.gov.sg/DHCPL*

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