

The HSA Medical Device Alert circular aims to highlight concerns relating to the use of medical devices to healthcare professionals. This issue highlights concerns related to labeling, software problems, manufacturing, quality assurance, electrical safety, and device wear for the period 2011 to 2012.

Abbott Medical Optics Recall for Sensor Opti-Edge Soft Acrylic IOLs

- **Concern:** Certain lots of intraocular lens (IOL) had mislabelled diopters.
- **Risk:** Mislabelled IOL could lead to potential unexpected postoperative refractive error and may result in a secondary surgical intervention to correct this error.
- **Action:** A recall was issued for all affected units on the market in December 2012. In addition, a Dear Healthcare Professional Letter* (DHCPL) was disseminated by the company in consultation with HSA in January 2013.

GE Healthcare Field Safety Corrective Action (FSCA) for CARESCAPE Monitor B850

- **Concern:** Use of the device may generate incorrectly calculated cardiac output values if the default catheter settings are used. Additionally the "Lead Off" error alarm will not function under specific workflow conditions.
- **Risk:** Patients could be in cardiogenic shock when cardiac output was reported as normal.
- **Action:** A software correction was provided as a permanent risk control measure. Supply of the corrected products was permitted after HSA's assessment that the concerns were addressed effectively.

Siemens Healthcare Diagnostics Recall for ADVIA ALPAMP & ALPDEA

- **Concern:** Affected units of ADVIA Chemistry Alkaline Phosphatase (ALPAMP) and Alkaline Phosphatase (ALPDEA) showed abnormal high absorbance exceeding the blank or sample limit, as well as, a calculation error that prevented the system from generating a report of the results.
- **Risk:** Although no health risks were noted, affected units of the device in the market were required to be disposed as a precautionary measure.
- **Action:** The concern was due to the exposure of the device to temperatures outside the recommended

range during manufacturing. Supply of the product was allowed only after the corrective and preventive actions were taken.

DePuy Mitek Recall for LUPINE BR Anchor System

- **Concern:** Device with incorrect suture configuration was supplied as a result of operator-related manufacturing assembly problems.
- **Risk:** Use of the affected LUPINE BR Anchor System can result in a loose repair of the injury (eg, bone fixation for shoulder, elbow, ankle and knee).
- **Action:** A recall was issued for all affected units on the market in November 2011. A DHCPL was disseminated by the company in November 2011. Before permitting supply of the product, 100% inspection checks during the manufacturing process and quality control checks on each batch of the final sealed device was implemented by the product owner.

Maquet Critical Care FSCA for MAQUET Servo-i Ventilator Systems

- **Concern:** Users might come in contact with the live parts of the device AC/DC converter when the front cover is removed without disconnecting the main power cable.
- **Risk:** Users may experience electric shock, burns and heart fibrillation.
- **Action:** The defect stemmed from a hardware design change that removed the original protective cover. FSCA required reinstating the protective cover and providing a warning label for users.

Philips Medical System FSCA for Multi Diagnost Eleva

- **Concern:** Cables of the device may become damaged due to the sharp edges of the cable guiding plate after more than a year of usage.
- **Risk:** Cable damage can result in loss of live imagery and unexpected movements of the device.
- **Action:** Before supply was allowed by HSA, corrective actions were taken to replace any damaged cables, and the cable guiding plate was replaced to prevent a recurrence.

For more information on the FSCAs outlined in this issue, please contact the Compliance Branch at HSA_Compliance@hsa.gov.sg.

*A copy of the DHCPL can be found on the MOH Alert database accessible via the professional council websites. All FSCAs were communicated to the affected consignees either through a DHCPL or a Field Safety Notice (FSN).

Please send your enquiries, comments and suggestions to:

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