Safety Notice 015/23

Issue date
28 June 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:

- Cardiac Catheter Laboratories
- Intensive Care Units
- Coronary Care Units
- Perioperative Units
- Perfusion/Cardiac Surgeons

Expert Reference Group
Content reviewed by:
Cardiac Clinicians
Representatives from:
ACI Cardiac Network
State Preparedness & Response Unit
HealthShare NSW

Clinical Excellence Commission
Tel: 02 9269 5500
Email: CEC-recalls@health.nsw.gov.au
Internet
https://www.health.nsw.gov.au/sabs/Pages/default.aspx
Intranet
http://internal.health.nsw.gov.au/quality/sabs/index.html

Review date
June 2024

Getinge Intra-Aortic Balloon Pump catheter insertion

Situation

On 15 June 2023, the Therapeutic Goods Administration (TGA) issued a Class 1 Urgent Product Defect Correction (RC-2023-RN-00539-1) that impacted on the introducers that are used with Getinge Intra-Aortic Balloon (IAB) pump catheters.

Background

An Intra-Aortic Balloon (IAB) pump is a device used to increase myocardial oxygen perfusion and indirectly increase cardiac output by reducing afterload. IAB pumps are used in Cardiac Catheter Laboratories, Intensive Care Units, Coronary Care Units and in cardiothoracic surgery.

Insertion kits consist of a catheter, introducer and a sheath. There have been reports of the introducer dilator included with IAB insertion kits fracturing at the hub when attempting to remove the introducer dilator from the sheath, leaving the introducer dilator body housed within the sheath. This issue may impact patient safety when performing a sheathed IAB catheter insertion

Product codes affected are:

- Sensation Plus 50cc D684-00-0576-01
- Sensation Plus 40cc D684-00-0568-01
- Mega 30cc D684-00-0294-01
- Mega 40cc D684-00-0295-01
- Mega 50cc D684-00-0296-01

Assessment

Over a three-year period, there have been 10 complaints globally related to this issue. Of these, three were serious adverse events and one patient death. No incidents have been reported in NSW in ims+.

Balloon catheter insertion can be safely performed using either a sheathed insertion or sheathless insertion procedure.

Clinical Recommendations

- **DO NOT** use the sheath or introducer dilator included in the Getinge IAB insertions kits to perform a sheathed insertion
  - Where a sheathed insertion is required use an alternate 8 French femoral dilator and sheath
- The Getinge IAB catheter and insertion kit can continue to be used with a sheathless insertion technique
- Label all Getinge IAB kits to notify staff that the sheath or introducer dilator are not to be used
- Ensure that a standard 8 French femoral sheath is available where IAB catheters are inserted

Required actions for the Local Health Districts/Networks

For example:

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where IAB catheters are used
2. Include this Safety Notice in relevant handovers and safety huddles
3. Label all Getinge IAB kits to notify staff that the sheath or introducer dilator are not to be used
4. Ensure that an alternate 8 French femoral dilator and sheath is available where IAB catheters are inserted
5. Escalate any concerns to CEC-recalls@health.nsw.gov.au
6. Report any incidents associated with Getinge IAB pumps and consumables into ims+ and TGA.
7. Confirm receipt and distribution of this Safety Notice within [72] hours to CEC-recalls@health.nsw.gov.au