NSW GOVERNMENT Health

Safety Alert 001/16

Product Recall Catheters with Beacon Tip Technology

06 May 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- HealthShare Product Manager
- NSW Health Private Hospital Branch

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Cardiothoracic and Cardiac Catheter Laboratories
- Directors Cardiology
- Directors Surgery
- Directors of Radiology

Clinical Heads of

- Cardiothoracic Surgery
- Cardiology
- Intensive Care Units
- Operating Theatres
- Radiology Departments
- Emergency Departments

Deadline for completion of action

10 May 2016

Expert Reference Group

Content reviewed by:

- Clinical Excellence Commission
- HealthShare
- Office of Chief Health Officer

Clinical Excellence Commission

Tel. 02 9269 5500
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Email:
CEC-PatientSafety@health.nsw.gov.au
Internet Website:
http://www.health.nsw.gov.au/quality/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date
May 2017

Background

On 22 April, 2016 the Therapeutics Goods Administration (TGA) issued an urgent medical device recall for Cook Catheters with Beacon Tip Technology due to an increase in reports of polymer degradation of the catheter tip resulting in tip fracture and/or separation.

Potential adverse events that may occur as a result of catheter polymer degradation could include loss of device function, separation of a device segment leading to medical intervention, or complications resulting from a separated segment such as device fragments lodging in the vascular system. Fragments within the vascular system could result in embolization to the heart or lungs, or occluding blood flow to end organs.

Beacon Tip catheters are used in several different procedures, including the peripheral, coronary hepatic and genitourinary system. In the absence of availability of these catheters, patient procedures may be delayed or some patients requiring immediate intervention will need open surgery which would not otherwise be necessary. This has an obvious impact on the patients by increasing procedural complication risk, length of stay and recovery.

Cook Medical has notified its customers and distributors by recall notification letters. The letters requested that all customers and distributors quarantine and discontinue use of all potentially affected units and return the affected product to Cook as soon as possible.

The TGA Urgent recall notice Reference RC-2016-RN-00483-1 Catheter with Beacon Tip Technology, a list of Cook Medical products affected and an a list of alternate products will be circulated to Chief Executives of NSW Health Local Health Districts/Networks and to the NSW Health Private Hospital Branch for circulation to relevant interventional units within the LHD such as operating theatres, cardiac catheter laboratories and radiology departments and other relevant interventional units as locally identified. It is important to note that these alternate products are not identical to Cook products and there may be variations in shape and handling characteristics. The companies identified that have alternate products include

- Boston Scientific
- Johnson & Johnson
- Terumo
- Merit Medical
- Medical Specilties

Local Health Districts/Networks/Relevant Service Providers should:

- Distribute this Safety Alert 001-16 and the TGA recall notice to all relevant clinical departments.
- Assess the current supply status and potential patient impact for each facility and provide feedback to the CEC by close of business Thursday 12 May 2016
- Develop a local plan to manage the supply shortage and contact the Clinical Product

Actions required by Local Health Districts/Networks/Relevant Service Providers

1. Ensure circulation of the Cook Medical product recall for Cook Catheters with Beacon Tip Technology is circulated to all interventional units within the LHD
2. Health Services immediately quarantine and discontinue use of all potentially affected units and return to Cook Medical and a report that this has occurred
3. Report adverse events or side effects related to the use of these products into the NSW Incident Management System
4. Develop a local plan to manage the supply shortage and contact the Clinical Product Manger if there are problems managing the supply shortage locally.
5. Assess the current supply status and potential patient impact for each facility, confirm affected products are removed from circulation and provide feedback summary report to CEC-PatientSafety@health.nsw.gov.au by close of business Tuesday 10 May 2016

Made Obsolete October 2021
TGA Recall completed