



Safety Notice 013/16

18 November 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Regulation and Compliance Unit, MOH

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Cardiology
- Directors of Cardiac Catheter Laboratories
- Directors of Cardiothoracic Surgery
- Directors of Intensive Care Units
- Directors of Emergency Departments

Expert Reference Group

Content reviewed by:

- ACI
- Clinical Excellence Commission

Clinical Excellence Commission

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Review date

November 2018

Implantable cardiac defibrillator and cardiac resynchronization therapy defibrillator devices

Background

A hazard alert was issued by St Jude Medical, in consultation with the Therapeutic Goods Administration [TGA] on 18 October 2016, for [various models](#) of implantable cardioverter defibrillators [ICDs] and cardiac resynchronisation therapy defibrillators [CRT-Ds] manufactured before 23 May 2015.

St Jude Medical is also recalling unused stock of the devices.

ICDs and CRT-Ds are implantable medical devices that deliver electrical impulses to treat abnormal heart rhythms.

It has been confirmed that a very small proportion of the devices (0.21%) has developed premature battery depletion after implantation due to shorting caused by lithium cluster formation in the battery.

If this occurs, defibrillation therapy is interrupted which can lead to serious health consequences. There are two overseas reports of deaths associated with loss of defibrillation therapy due to premature battery depletion and ten overseas reports of serious events [collapse] that may have been linked to premature battery depletion.

Battery depletion in these cases can occur within a day to a few weeks.

Premature battery depletion can be identified by health professionals through remote monitoring or during normal follow-up appointments through the elective replacement indicator or other signs of advanced battery depletion.

Patients will also receive a vibratory patient notifier alert if their device has reached elective replacement indicator.

Further information

Further information for health professionals and details of affected devices [including model numbers] at <http://www.tga.gov.au/alert/st-jude-icds-and-crt-ds-various-models>

TGA Recall can be accessed at <https://www.tga.gov.au/recall-actions>

Suggested actions by Local Health Districts/Networks

1. Forward this Safety Notice to appropriate areas for action.
2. Have a procedure in place to:
 - a. Contact patients with the devices to advise them of the above issue and the implications for them;
 - b. Check individual patient devices;
 - c. Regularly monitor patients with the devices;
 - d. Identify concerns with the devices as soon as possible; and
 - e. Replace affected devices immediately if elective replacement indicator reached.
3. Report adverse events related to the use of the devices into the NSW Incident Management System and the TGA.