Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

Nitinol RF Reusable Electrodes

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2017-RN-00846-1
Product Name/Description[iii]	Nitinol RF Reusable Electrodes Product Codes: TCN-5, TCN-5-3M, TCN-10, TCN-10-3M, TCN-15, TCN-15-3M, TCN-20, TCN-20-3M, TCNK-5, TCNK-5-C, TCNK-5-R, TCNK-10, TCNK-10-C, TCNK-10-R, TCNK-15, TCNK-15-C, TCNK-15-R, TCNK-20, TCNK-20-C, TCNK-20-R All Lot Numbers ARTG Number: 158235
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	11/07/2017
Responsible Entity[vii]	Life Healthcare Pty Ltd
Reason / Issue[viii]	The manufacturer, Cosman Medical, has received complaints regarding Nitinol RF (Model TCN) Reusable electrodes. After multiple reprocessing cycles, the epoxy resin which holds the TCN Electrode in the hub can exhibit signs of damage. This damage may result in the inability to fully remove blood and/or tissue residuals prior to cleaning and re-sterilising the device. The failure to completely remove any blood and/or tissue from the TCN Electrodes prior to re-sterilisation creates a potential risk of infection and spread of blood borne pathogens to patients. Cosman Medical is implementing an action for Nitinol RF (TCN) reusable electrodes to convert them to single patient use electrodes (re-usable for one patient only). After single patient use, the used TCN Electrode should be disposed of in accordance with the individual institution's infectious material/biohazard waste control procedures. To date, Cosman have not received any reports of patient injury related to this issue.
Recall Action[ix]	Recall for Product Correction

Recall Action Instructions[x]	Action to be taken by users: Cosman Medical is implementing an action for Nitinol RF (TCN) reusable electrodes to convert them to single patient use electrodes. After single patient use, the used TCN Electrode should be disposed of in accordance with the individual institution's infectious material/biohazard waste control procedures. Unopened TCN Electrodes need to be identified as single patient use only (re-usable for one patient only). These devices are supplied non-sterile which require cleaning and sterilisation prior to use. These TCN electrodes may be used once the cleaning and sterilisation steps are completed. Isolate any used affected items. A LifeHealthcare Representative will arrange collection and replacement. Return the Reply Form provided by LifeHealthcare so they can validate that all customers have been advised of this action.
Contact Information[xi]	02 8114 1533 - LifeHealthcare

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

[x] Recall Action Instructions: What the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.