



Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Notification

HeartMate 3 Left Ventricular Assist System and Outflow Graft Clip

© Commonwealth of Australia 2018.

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the Copyright Act 1968 or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

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. Copyright restrictions apply to the System of Australian Recall actions (SARA) <<http://tga.gov.au/about/website-copyright.htm>>.

Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2018-RN-01527-1
Product Name/Descriptionⁱⁱⁱ	<p>HeartMate 3 Left Ventricular Assist System and Outflow Graft Clip</p> <p>HeartMate 3 Left Ventricular Assist System Catalogue Number: 106524INT LVAS KIT, HM3</p> <p>Outflow Graft Clip Catalogue Number: 10012390GBL</p> <p>ARTG Number: 300895 (Abbott Medical Australia - HeartMate 3 LVAS Implant Kit Model 106524INT - Implantable ventricular circulatory assist system)</p>
Recall Action Level^{iv}	Hospital
Recall Action Classification^v	Class I
Recall Action Commencement Date^{vi}	4/12/2018
Responsible Entity^{vii}	Abbott Medical Australia Pty Ltd
Reason / Issue^{viii}	<p>Further to the May 2018 Hazard Alert communication (RC-2018-RN-00668-1) sent to surgeons in regards to HeartMate 3 (HM3) Outflow Graft twist occlusions, Abbott is now informing physicians that the new Outflow Graft Clip will be available upon local regulatory approval.</p> <p>The regulatory review of the design improvement is ongoing and Abbott expects to receive CE approval for the Outflow Graft Clip within the coming weeks.</p> <p>The Outflow Graft Clip has been designed to prevent any rotation of the outflow graft, thus eliminating the safety concern reported in the May 2018 notice. The Outflow Graft Clip is intended to be used with all new patient implants and may be used on patient cases where an Outflow Graft twist is confirmed and surgical intervention is required.</p>
Recall Action^{ix}	Hazard Alert

Recall Action Instructions^x	<p>New Patients</p> <ul style="list-style-type: none"> During implant, when attaching the Outflow Graft to the Pump Cover, a clicking sound will be heard as the Screw Ring is tightened. Continue turning the Screw Ring clockwise until it comes to a complete stop and stops clicking. To avoid damaging the assembly, do not use tools to tighten the screw ring. Once the screw ring is tightened, apply the Outflow Graft Clip according to the Instructions For Use, as provided. <p>Ongoing Patients</p> <ul style="list-style-type: none"> For patients not experiencing any evidence of an outflow graft obstruction, Abbott recommends standard of follow-up as previously outlined in the May 2018 notice without performing a surgical intervention to apply the Outflow Graft Clip. For patients previously implanted with the HM3 who are experiencing an outflow graft obstruction and require a surgical intervention to repair the obstruction, Abbott recommends applying the clip at the time of surgical intervention according to the Outflow Graft Instructions for Use.
Contact Information^{xi}	Abbott MCS Clinical Specialist via 1 800 839 259

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.