Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling

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-01542-1
Product Name/Description[iii]	Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling Restorelle DirectFix Anterior Model/Catalogue Number: 501450 SKU Number: 5014501022 ARTG 190172 Restorelle DirectFix Posterior Model/Catalogue Number: 501460 SKU Number: 5014601022 ARTG 190172 Altis Single Incision Sling System Model/Catalogue Number: 519650 SKU Number: 5195601022 ARTG 190173
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	21/12/2017
Responsible Entity[vii]	Coloplast Pty Ltd
Reason / Issue[viii]	On November 28, 2017, the Therapeutic Goods Administration (TGA) notified Coloplast of TGA's decision to remove transvaginal mesh products used to treat Pelvic Organ Prolapse (POP), and single incision mini-slings from the Australian Register of Therapeutic Goods (ARTG), effective January 4, 2018. The TGA believes there is currently a lack of adequate scientific evidence for it to be satisfied that the risks to patients are outweighed by the benefits of these devices. Further information can be found on the TGA website. Following this direction from TGA, Coloplast is recalling all Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling products from the Australian market. No other Coloplast devices are affected by this recall.
Recall Action[ix]	Recall

Recall Action Instructions[x]	Coloplast is advising hospitals to quarantine any affected product for return to Coloplast. Instructions for product return are provided on the Customer Letter issued to affected customers.
Contact Information[xi]	03 9541 1146 - Coloplast

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.