Safety Notice 15/18

PARIETEX COMPOSITE PARASTOMAL MESH HAZARD ALERT AND RECALL

9 November 2018

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Surgery
- Gastroenterologists
- Gastrointestinal Surgeons
- Directors of Nursing
- NUM Operating Theatres
- Directors of Emergency Department

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Director Patient Safety

Clinical Excellence Commission

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Review date

November 2019

Background

The Therapeutic Goods Administration (TGA) has issued an urgent hazard alert and medical device recall for Medtronic's Parietex Composite Parastomal Mesh 15cm and 20cm (ARTG Number 176136).

This mesh product is used to repair hernias that have arisen through the abdominal wall defect created during stoma formation for a colostomy or ileostomy. They are the most common complication of ostomy surgery.

The hazard alert and recall were issued following multiple reports of parastomal mesh failure identified several years following parastomal hernia repair with the Parietex Composite Parastomal Mesh using the modified Sugarbaker repair technique. The mesh failure has led to hernia recurrence requiring additional surgical treatment.

Medtronic has advised that this mesh product was supplied to a number of public and private health facilities in NSW.

Recommendations for NSW Health facilities

Medical device recall

Facilities should identify and quarantine any Parietex mesh product affected by the device recall in accordance with the device recall notice. The recall notice can be sourced at: https://apps.tga.gov.au/PROD/SARA/arn-report.aspx

If a facility has identified and quarantines affected Parietex mesh product but has not received a recall letter they should contact Medtronic directly to arrange return.

Medical device hazard alert

Patients who received a Parietex Composite Parastomal Mesh repair for the treatment of a parastomal hernia without symptoms or signs of hernia recurrence need no additional follow up or surveillance beyond standard post-surgical care.

Patients with parastomal mesh repair that exhibit symptoms of parastomal hernia recurrence should be referred to a surgeon for evaluation. Recurrence of hernia may occur months to years after implantation.

Symptoms of hernia recurrence may include discomfort, localised pain-free or painful bulging, and possible changes in the overlying skin.

Mesh-related complications

Complications after hernia repair are relatively common. There are complications specific to mesh implantation that patients should be informed of when consenting to hernia repair with mesh. These include infection or migration of the medical device, and erosion into surrounding tissues.

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant staff.
2. Identify and quarantine any unused product subject to medical device recall.
3. Refer any patients exhibiting symptoms or signs of parastomal hernia recurrence to a surgeon for clinical assessment and review.
4. Report problems related to any Parietex mesh to the TGA at: https://www.tga.gov.au/reporting-problems and via the Incident Information Management System (IIMS).
5. Document any actions taken.

Made Obsolete September 2022
TGA Recall Action Completed. Ref: https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2018-RN-01373-1