Safety Notice 009/18

Intragastric Balloon Systems

6 August 2018

Distributed to:

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

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Surgery
- Gastrointestinal Surgeons
- Gastroenterologists
- Operating Suite Managers
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Directors of Emergency Departments

Expert Reference Group

Content reviewed by:

- Agency of Clinical Innovation
- Surgical Services Taskforce

Clinical Excellence Commission

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Review date

August 2019

Background

Following a publication from the US Food and Drug Administration regarding the potential risks with liquid-filled intragastric balloons, the Therapeutic Goods Administration (TGA) conducted a product safety review of two intragastric balloon systems on the Australian Register of Therapeutic Goods (ARTG) and have issued an alert.

Intragastric balloons systems are fluid-filled balloons which are temporary devices which are inserted via endoscope to treat obesity by creating a feeling of fullness and delaying gastric emptying.

Since 2009, the TGA have received 19 adverse event reports, including three deaths, related to intragastric balloon systems which are in use in Australia.

In response to the product safety review, the TGA is working with sponsors and manufacturers to ensure that clinicians and patients are aware of the risks associated with intragastric balloon systems, including updated Instructions for Use.

Contraindications for use

Conditions where the use of intragastric balloons systems are contraindicated include (but are not limited to – see manufacturer Instructions for Use for full list):

- Under 18 years of age
- Previous upper gastrointestinal surgery
- Regularly take aspirin, non-steroidal anti-inflammatory agents, COX-2 inhibitors, anti-coagulants or anti-platelet agents
- Pregnancy
- Clinically significant hiatus hernia
- History of inflammatory disease of the gastrointestinal tract.

Adverse events associated with intragastric balloons systems

- Obstruction
- Ulceration
- Necrosis
- Ischaemia (gastric or intestinal)
- Spontaneous hyperinflation of the balloon
- Perforation (oesophageal, gastric or intestinal)
- Gastritis / gastric erosions
- Acute pancreatitis

Patients with intragastric balloons who experience complications are advised to seek advice from their Specialist, General Practitioner, or present to Emergency Departments with the patient card provided at the time of surgery.
For further information, please refer to the device Instructions for Use.

Suggested actions by Local Health Districts/Networks

1. Forward information to appropriate areas for action.
2. Report problems related to intragastric balloon systems to the TGA at: https://www.tga.gov.au/reporting-problems and via the Incident Information Management System (IIMS).
3. Document actions taken.