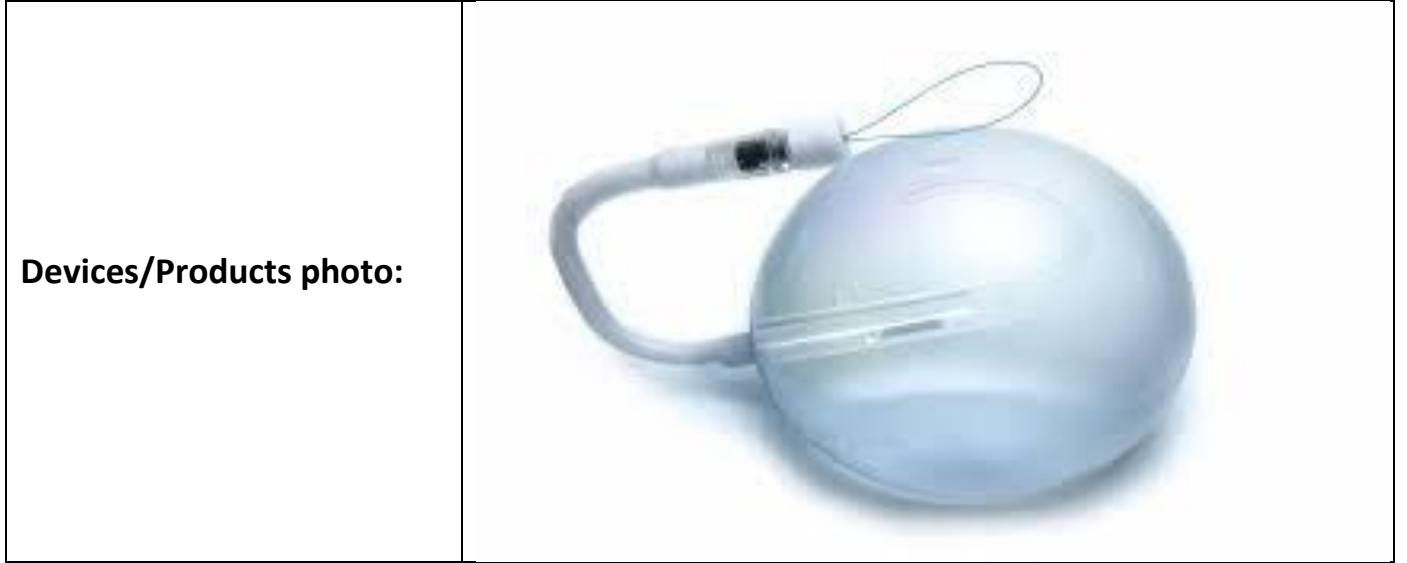


Safety Communication

Multiple Risks associated with Intra-gastric Balloons

Device/ Product Name:	Gastric Balloons, Appetite-Suppressing
Lot numbers/Serials:	Not Specified
Manufacturer:	Not Specified
Problem:	SFDA would like to bring your attention to the international reports of various complications, including some with a fatal outcome, associated with the use of the intra-gastric balloons for weight-loss therapy. These complications include gastric perforation, esophageal perforation, acute pancreatitis, and spontaneous balloon overinflation.
Recommendation/Actions:	<ul style="list-style-type: none"> • Implanting physicians should consider this information in the discussion of risks and benefits with prospective patients prior to balloon placement. • Patients need to be made aware that they should seek urgent medical care if they develop symptoms of severe abdominal pain, nausea and vomiting while the balloon is in place. • Physicians should monitor patients carefully for the entire time the intra-gastric balloon is used. • Healthcare professionals are advised to consider these possible complications during the diagnostic work-up of patients using intra-gastric balloons who present with significant upper gastrointestinal symptoms.



You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

[National Center for Medical Devices Reporting.](#)

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)

North Ring Road - Al Nafal Unit (1)

Riyadh 13312 - 6288

Tel: +966 (11) 2038222 Ext: 2406, 2479

Fax: +966 (11) 2757245

Or

[Saudi Vigilance](#)

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Sincerely,
NCMDR Team