Liquid-filled Intragastric Balloon Systems: Letter to Healthcare Providers - Potential Risks

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AUDIENCE: Surgery, Gastroenterology, Health Professional

ISSUE: FDA is issuing an update to alert health care providers of five reports of unanticipated deaths that occurred from 2016 to present in patients with liquid-filled intragastric balloon systems used to treat obesity. Four reports involve the Orbera Intragastric Balloon System, manufactured by Apollo Endo Surgery, and one report involves the ReShape Integrated Dual Balloon System, manufactured by ReShape Medical Inc.

All five reports indicate that patient deaths occurred within a month or less of balloon placement. In three reports, death occurred as soon as one to three days after balloon placement. At this time, we do not know the root cause or incidence rate of patient death, nor have we been able to definitively attribute the deaths to the devices or the insertion procedures for these devices (e.g., gastric and esophageal perforation, or intestinal obstruction). The Agency has also received two additional reports of deaths in the same time period related to potential complications associated with balloon treatment (one gastric perforation with the Orbera Intragastric Balloon System and one esophageal perforation with the ReShape Integrated Dual Balloon System).

The FDA continues to work with Apollo Endo-Surgery and ReShape Medical Inc. to better understand the issue of unanticipated death, and to monitor the potential complications of acute pancreatitis and spontaneous over-inflation. Additionally, as part of the ongoing, FDA-mandated post-approval studies for these devices, we will obtain more information to help assess the continued safety and effectiveness of these approved medical devices.

The FDA will keep the public informed as significant new information becomes available.

BACKGROUND: In February 2017, the FDA issued a letter to health care providers to recommend close monitoring of patients with liquid-filled intragastric balloon systems used to treat obesity for the potential risks of acute pancreatitis and spontaneous over-inflation. Since issuing this letter, both companies have revised their product labeling to address these risks.

RECOMMENDATION: FDA continues to recommend that health care providers closely monitor patients treated with these devices for complications and that you report any adverse events related to intragastric balloon systems through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to

1-800-FDA-0178

[08/10/2017 - **Letter to Healthcare Providers (/MedicalDevices/Safety/LetterstoHealthCare-Providers/ucm570707.htm)** - FDA]