

For Immediate Release

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New endoscopic, non-surgical bariatric options show promise for treating obesity

DOWNERS GROVE, Ill, August 7, 2015 –The FDA recently approved two new endoscopic bariatric therapies (EBT) for the treatment of obesity. According to the American Society for Gastrointestinal Endoscopy (ASGE), this development provides important new, minimally invasive tools for combatting the obesity epidemic and offers many patients an alternative to surgery.

The ReShape™ Integrated Dual Balloon System (ReShape™ Dual Balloon) was approved by the FDA on July 29. The ORBERA™ Intra gastric Balloon was approved by the FDA on August 6. Many new and emerging treatments can be performed endoscopically, providing an effective and minimally invasive approach that fills a gap in the management of obesity and related conditions. Despite the positive impact of bariatric surgery on individual patients, only about 1 percent of qualified candidates undergo these surgical procedures.

“Endoscopic bariatric therapies offer a viable, safe alternative for patients who have been unsuccessful at weight loss with diet and exercise. They may also be appropriate for patients who are not suitable for, or are unwilling to undergo, a more invasive surgical procedure,” said Christopher C. Thompson, MD, MHES, FASGE, chair of the ASGE Bariatric Endoscopy Task Force.

A new [meta-analysis](#) from ASGE concluded that endoscopic bariatric therapies can be effective options and are most beneficial when used as part of a comprehensive, multidisciplinary treatment program.

The ASGE systematic review and meta-analysis assessed EBTs using diagnostic/therapeutic [thresholds](#) established in 2012 as part of its Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) initiative. The PIVI program was initiated to identify important clinical questions related to endoscopy and to establish reasoned diagnostic and/or therapeutic thresholds for endoscopic technologies designed to resolve these questions.

This review and analysis, written by members of the ASGE Bariatric Endoscopy Task Force and the ASGE Technology Committee, is available on the web at [http://www.giejournal.org/article/S0016-5107\(15\)02271-3/fulltext](http://www.giejournal.org/article/S0016-5107(15)02271-3/fulltext). It analyzed all of the currently available literature for endoscopic bariatric therapies and identified devices that had been extensively studied. The task force concluded that endoscopic IGB therapy with the ORBERA™ device meets or exceeds the following predetermined efficacy threshold:

- EBT intended as a primary obesity intervention in Class II/III obese individuals (body mass index 35 kg/m^2) should achieve a mean minimum threshold of 25 percent excess weight loss (%EWL) measured at 12 months

Intragastric balloons intended for weight loss consist of one or more balloons that are placed into the stomach through the mouth using a minimally invasive endoscopic procedure while the patient is under mild sedation. As long as the balloons (filled with saline) are in place, they help patients to feel full so they eat smaller amounts. When it is time to remove the balloons, they are first deflated then removed using another endoscopic procedure. Balloons are typically removed after six months, with patients remaining in a lifestyle support program for one year to maintain weight loss. The intragastric balloon can be placed in an outpatient setting.

EBT should be performed in the context of a comprehensive, multidisciplinary treatment program including nutritional support, nursing care, behavioral medicine and other components of obesity management. Both didactic and hands-on endoscopic training and skill acquisition with EBT techniques, technologies and clinical management of obese patients will be needed before performing EBT procedures.

“The ASGE is pleased that the FDA has approved these new devices and looks forward to providing the support and education that will allow our members to use these devices as part of a multidisciplinary weight management program in patients with obesity,” said ASGE President Douglas O. Faigel, MD FASGE. “Gastrointestinal endoscopists will have an important role to play in combatting this difficult and growing epidemic.”

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About the American Society for Gastrointestinal Endoscopy

Since its founding in 1941, the American Society for Gastrointestinal Endoscopy (ASGE) has been dedicated to advancing patient care and digestive health by promoting excellence and innovation in gastrointestinal endoscopy. ASGE, with more than 13,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education. Visit www.asge.org and www.screen4coloncancer.org for more information and to find a qualified doctor in your area.