



American Society for Metabolic & Bariatric Surgery

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AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY VIEWS NEW BALLOON DEVICE FOR OBESITY AS BRIDGE BETWEEN MEDICATIONS AND BARIATRIC SURGERY

GAINESVILLE, FL – July 29, 2015 – The U.S. Food and Drug Administration (FDA) yesterday approved a new balloon device called the ReShape Integrated Dual Balloon System, that may help fill a treatment gap between medications and surgery for people with obesity and one or more obesity-related conditions, according to the American Society for Metabolic and Bariatric Surgery (ASMBS), the nation’s largest organization for bariatric surgeons.

“I am pleased and gratified that after careful review the FDA has approved this new device for the treatment of patients with obesity or body mass index (BMI) of 30 to 40. We are at the dawn of a new age in obesity treatment with the addition of this safe and effective treatment option,” said John M. Morton, MD, MPH, president of the ASMBS and director of the Bariatric and Metabolic Inter-Disciplinary (BMI) Clinic at Stanford Health in California. “Much like cardiac disease, we are seeing demonstration of the full continuum of care for obesity from primary prevention and FDA-approved medications to the endoscopic ReShape Dual Balloon to established, effective bariatric surgery procedures. The ReShape Dual Balloon offers a bridge between medications and surgery similar to a cardiac stent in cardiac disease.”

The dual balloon is delivered into the stomach via the mouth through a minimally invasive endoscopic outpatient procedure. Once implanted, it is inflated to occupy space in the stomach, which may trigger feelings of fullness and lead to weight loss. The device does not change or alter the stomach’s natural anatomy. According to an [FDA news release](#), “patients are advised to follow a medically supervised diet and exercise plan to augment their weight loss efforts while using the ReShape Dual Balloon and to maintain their weight loss following its removal. It is meant to be temporary and should be removed six months after it is inserted.”

“In the right patients and in the right hands, this new device will provide hope to patients who may not have sought care before this approval. Like any other obesity intervention, the results of this intervention must be enhanced and safeguarded within a proven, multi-disciplinary program that provides the critical support to ensure success,” added Dr. Morton. “The ASMBS looks forward to fulfilling its mission of lessening the burden of obesity by providing medical education, assuring patient safety and securing optimal outcomes with this new device.”

Jaime Ponce, MD, medical director for Hamilton Medical Center Bariatric Surgery program and principal investigator of the REDUCE Pivotal Trial commented, “Patients suffering with moderate obesity that are struggling with poor success with diets, and are not candidates for surgery, now with the ReShape Dual Balloon have a new option that allows them to lose more weight than with just simple diet and exercise. It will be one more tool, performed endoscopically in an outpatient setting, that will be available at centers treating obesity.”

The Centers for Disease Control and Prevention (CDC) reports more than 72 million Americans have obesity and, according to the ASMBS, about 24 million have severe obesity. Individuals with a body mass index (BMI) greater

than 30 have a 50 to 100 percent increased risk of premature death compared to healthy weight individuals, as well as an increased risk of developing more than 30 obesity-related diseases and conditions including Type 2 diabetes, heart disease and certain cancers. In 2013, the American Medical Association (AMA) declared obesity a disease.

About the ASMBS

The ASMBS is the largest organization for bariatric surgeons in the nation. It is a non-profit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in obesity, while maintaining a steady exchange of experiences and ideas that may lead to improved outcomes for morbidly obese patients. For more information, visit www.asmbs.org.

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