



American Society for Metabolic & Bariatric Surgery

FDA Approval of ORBERA™ Intra-gastric Balloon Offers New Weight Loss Option for Patients with Obesity

The U.S. Food and Drug Administration (FDA) today approved the ORBERA™ Intra-gastric Balloon, a new non-surgical intervention for the treatment of obesity. The device, which is approved for use in patients with a body mass index (BMI) of 30 to 40, was shown in a clinical trial to be more effective for weight loss than diet and exercise alone. The American Society for Metabolic and Bariatric Surgery (ASMBS) welcomes this expansion to the spectrum of treatment options for obesity.

“I am pleased to see the FDA approve the ORBERA Intra-Gastric Balloon. With this device, we can provide additional care to so many patients in need. Along with counseling, medications, other endoscopic procedures, and proven and effective bariatric surgery, patients with obesity now have hope and evidence to provide them successful support,” said John M. Morton, MD, MPH, president of the ASMBS.

“Like any other obesity intervention, the results of this intervention must be enhanced and safeguarded by ASMBS members who are skilled, experienced medical professionals working 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.”

ASMBS past president Jaime Ponce, MD, commented, “The bariatric surgery community is very excited to have one more endoscopic option to help patients with moderate obesity. It helps fill the gap between diet and exercise and bariatric surgery. The device has been used internationally for more than 15 years and we expect that it will now become an important treatment option for patients in the United States.”

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.asmb.org.

###