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FDA APPROVES REALIZE™ ADJUSTABLE GASTRIC BAND FOR MORBID OBESITY

Ethicon Endo-Surgery, Inc. Provides New Option To Treat Morbid Obesity

CINCINNATI, OH – DATE – Ethicon Endo-Surgery, Inc. announced today the U.S. Food and Drug Administration (FDA) approved for marketing the REALIZE™ Adjustable Gastric Band, a surgical implant for weight reduction and improvement in obesity-related health conditions, such as type-2 diabetes, in individuals suffering from morbid obesity.

The REALIZE Band is an innovative device intended for use in weight reduction for patients with morbid obesity and is indicated for individuals with a Body Mass Index (BMI) of at least 40 kg/m², or a BMI of at least 35 kg/m² with one or more co-morbid conditions. It is for use in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.

In the multi-center U.S. clinical trial of 276 patients with the REALIZE Band, patients who completed the three-year U.S. clinical trial (n=228) lost an average of 42.8 percent of their excess body weight. Thirty-five percent of patients who completed the three-year trial lost 50 percent or more of excess body weight and 10.5 percent lost 75 percent or more of excess body weight. The most commonly reported adverse events after surgery during the U.S. clinical trial were nausea, vomiting, constipation and gastroesophageal reflux (GERD). Only nine (3.3 percent) patients experienced a serious adverse event that was considered unanticipated and related to the REALIZE Band.

“This rigorous clinical trial showed patients using the REALIZE Band experienced significant weight loss within the first year, which remained steady over three years,” said Ed Phillips, MD, FACS, principal investigator in the REALIZE Band clinical trial and Director of the Center for Minimally Invasive and Bariatric Surgery at Cedars-Sinai Medical Center in Los Angeles. “This procedure, combined with the proper support system and a commitment to dietary and lifestyle changes after surgery, helped these patients achieve long-term weight loss and improvement in many obesity-related conditions.”

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In the REALIZE Band clinical trial, patients reported improvements in various aspects of their quality of life including better general health one year after surgery. Significant improvement in vitality, mental health and social functioning was reported at three years after surgery, and reduction in bodily pain and increased ability to complete daily and work activities three years after surgery were also reported.

“Obesity is a serious disease, and as a company we’re committed to providing more than products to address this worldwide epidemic; we provide bariatric solutions that can help people realize their health goals and live longer and healthier lives regardless of which surgical option may be right for them,” said Kevin Lobo, president, Ethicon Endo-Surgery, U.S. “With the approval of the REALIZE Band, Ethicon Endo-Surgery is the only global healthcare company to provide a complete range of bariatric surgical solutions to surgeons and their patients.”

About The REALIZE Band

The REALIZE Band, which is marketed under the name Swedish Adjustable Gastric Band (SAGB) outside the U.S., has been commercially available outside the U.S. since 1996 and has been used by more than 100,000 patients worldwide to help manage their weight.

In a gastric band procedure with the REALIZE Band, a soft, adjustable silicone band is wrapped around the stomach to create two chambers – a small upper stomach with a narrow opening to the lower stomach. After the procedure, the upper stomach can only hold about four ounces of food, which limits food intake, makes patients feel full faster and longer, and slows digestion.

Once the band is in place, surgeons attach the REALIZE Injection Port to the abdominal wall underneath the skin. Using the REALIZE Injection Port Applier, this can be completed in less than a minute, thereby decreasing time under anesthesia. The REALIZE Injection Port allows doctors to inject or remove saline to tighten or loosen the band. The tighter the band, the more quickly the upper stomach fills up and the less food a person can eat. Adjustments are made periodically based on the patient’s individual needs.

About Bariatric Surgery

According to the American Society for Metabolic & Bariatric Surgery (ASMBS), more than 15 million people in the U.S. suffer from morbid obesity and about 205,000 people are expected to have some form of bariatric surgery this year. The two most common procedures are gastric bypass and gastric banding. Most of these procedures are

performed laparoscopically using small incisions, which typically results in less pain, fewer complications and quicker recovery from surgery compared to traditional open surgery. Laparoscopic adjustable gastric banding (LAGB) is reversible, if necessary.

According to two recent landmark studies published in the *New England Journal of Medicine* in August 2007, patients with morbid obesity who have bariatric surgery (including gastric banding, gastric bypass, and vertical banded gastroplasty) lost significant weight over the long-term and are less likely to die from heart disease, diabetes and cancer seven to 10 years following the procedure than those who did not have the operation¹⁻². Another study published in the *Annals of Surgery* in 2004 showed the mortality rate from morbid obesity was reduced by 89 percent after bariatric surgery³.

As with any surgery, there are immediate and long-term complications and risks. Patients should consult with their doctors to discuss these risks and their surgical outcomes. Individual patient results may vary and are not indicative of all outcomes.

About Ethicon Endo-Surgery, Inc.

Ethicon Endo-Surgery, Inc., an operating company of Johnson & Johnson, is a global leader in minimally invasive and traditional surgical devices for bariatric surgery and many other areas of surgery. The company develops and markets advanced medical devices for minimally invasive and open surgical procedures. The company focuses on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, plastic surgery, orthopedics, gynecology and surgical oncology. More information on the company can be found at www.ethiconendo.com. For more information about the REALIZE Band visit www.realizeband.com.

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¹ Sjöström L, Narbro K, Sjöström CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med* 2007; 357:741-52.

² Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. *N Engl J Med* 2007;357:753-61.

³ Christou NV, Sampalis JS, Liberman M, et al. Surgery Decreases Long-term Mortality, Morbidity, and Health Care Use in Morbidly Obese Patients. *Ann Surg* 2004;240(3):416-424.