LAP-BAND® System Fact Sheet

The LAP-BAND® Adjustable Gastric Banding System is the first U.S. Food and Drug Administration (FDA) approved adjustable gastric band for use in weight reduction. Used in more than 300,000 procedures worldwide, this simple reversible surgically implanted device has safely helped severely obese adults successfully achieve and maintain long-term weight loss. The LAP-BAND® System was approved by the FDA in June 2001 for severely obese adults with a Body Mass Index (BMI) of 40 or more or for adults with a BMI of at least 35 plus at least one severe obesity-related health condition, such as Type 2 diabetes, hypertension and asthma.

How the LAP-BAND® Adjustable Gastric Banding System Works:

The LAP-BAND® System was developed to facilitate long-term weight loss and reduce the health risks associated with severe and morbid obesity. Unlike gastric bypass, it does not involve stomach cutting, stapling or intestinal re-routing.[1,2,3] Using laparoscopic surgical techniques, the device is placed around the top portion of the patient's stomach, creating a small pouch. By reducing stomach capacity, the LAP-BAND® System can help achieve long-term weight loss by creating an earlier feeling of satiety. The LAP-BAND® System is adjustable, which means that the inflatable band can be tightened or loosened to help the patient achieve a level of satiety while maintaining a healthy diet. It is also reversible and can be removed at any time.

Key Benefits of the LAP-BAND®System over Gastric Bypass:

Safer, Less Invasive Surgical Option:

- The LAP-BAND® System can be applied to the top portion of the stomach laparoscopically using "keyhole" surgery, which offers the advantages of reduced pain, length of hospital stay and recovery period[1,2]
- The LAP-BAND® System procedure has a lower severe complication rate perioperatively (less than 1 percent) and lower mean short-term mortality rate (0.05 percent, approximately 1/10 the mortality rate of gastric bypass)[3]
- The LAP-BAND® System carries fewer risks of vitamin and mineral deficiencies than gastric bypass[4]
- The LAP-BAND® System has non-surgical adjustments that help the patient attain and maintain a healthy satiety level and minimize the potential for weight regain
- The LAP-BAND® System is reversible and it can be removed at any time

LAP-BAND®System Effectiveness:

- In clinical studies of severely obese patients, the LAP-BAND® System has been demonstrated to be an effective surgical method for weight loss, improving co-morbid conditions such as Type 2 diabetes and hypertension and reducing the use of medication to treat those conditions[5]
- Adjustibility helps patients sustain long-term weight loss benefits

LAP-BAND®System Reimbursement:

The LAP-BAND® System is covered by most health plans and Medicare.

For more information about the LAP-BAND® System, please visit www.lapband.com.

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IMPORTANT: THIS IS A BRIEF INTRODUCTION. PLEASE CONTACT YOUR PHYSICIAN OR SURGEON REGARDING THE POSSIBLE RISKS AND BENEFITS OF OBESITY SURGERY.

Indications: The LAP-BAND® System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight.

Contraindications: The LAP-BAND® System is not recommended for non-adult patients, patients with conditions that may make them poor surgical candidates or increase the risk of poor results, who are unwilling or unable to comply with the required dietary restrictions, or who currently are or may become pregnant.

Warnings: The LAP-BAND® System is a long-term implant. Explant and replacement surgery may be required at some time. Patients who become pregnant or severely ill, or who require more extensive nutrition may require deflation of their bands. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should proceed in small increments. Anti-inflammatory agents, such as aspirin, should be used with caution and may contribute to an increased risk of band erosion.

Adverse Events: Placement of the LAP-BAND® System is major surgery and, as with any surgery, death can occur. Possible complications include the risks associated with the medications and methods used during surgery, the risks associated with any surgical procedure, and the patient's ability to tolerate a foreign object implanted in the body.

Band slippage, erosion and deflation, obstruction of the stomach, dilation of the esophagus, infection, or nausea and vomiting may occur. Reoperation may be required.

Rapid weight loss may result in complications that may require additional surgery. Deflation of the band may alleviate excessively rapid weight loss or esophageal dilation.

Not all contraindications, warnings, or adverse events are included in this brief description. More detailed risk information is available at www.lapband.com or 1-877-LAP-BAND.

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1 Chapman A, Game P, O'Brien P, Maddern G, Kiroff G, Foster B, Ham J. Executive summary: Laparoscopic adjustable gastric banding for the treatment of obesity: Update and re-appraisal. Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) Report No. 31, Second Edition. Adelaide, South Australia: ASERNIP-S, June 2002. (Laparoscopic adjustable gastric banding surgery, like the LAP-BAND® surgery, is associated with a mean short-term mortality rate of around 0.05% compared to 0.50% for Gastric Bypass and 0.31% for Vertical Banded Gastroplasty.)

2 Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ. Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. Obes Surg. 2005 Jun-Jul;15(6):858-63.

3 Chapman AE, Kiroff G, Game P, Foster B, O'Brien P, Ham J, Maddern GJ. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. Surgery 2004;135:326-351.

4 Fisher BL, Schauer P.Medical and surgical options in the treatment of severe obesity. Am J Surg 2002;184:9S-16S.

5 Ahroni JH, Montgomery KF, Watkins BM. Laparoscopic Adjustable Gastric Banding: Weight Loss, Co-morbidities, Medication Usage and Quality of Life at One Year," Obesity Surgery 2005; 15:641-647.