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## 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 450,000 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.<sup>1,2,3</sup> 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:***

#### *Less Invasive Surgical Option:*

- The LAP-BAND® System can be applied to the top portion of the stomach laparoscopically using minimally-invasive surgery, which reduces the length of hospital stay and recovery period<sup>1,2</sup>
- The LAP-BAND® System procedure has a 61 percent lower rate of total complications compared to gastric bypass, including one-tenth the rate of serious complications,<sup>4</sup> and a 10-times lower short-term mortality rate than standard gastric bypass<sup>5</sup>
- The LAP-BAND® System carries fewer risks of vitamin and mineral deficiencies than gastric bypass<sup>6</sup>
- 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:***

- The LAP-BAND® System was approved in the United States in 2001 on the basis of a nonrandomized, single-arm study (N=299) that showed significant improvement in percent of excess weight loss vs. baseline was achieved at 12 months (34.5 percent), 24 months (37.8 percent) and 36 months (36.2 percent)<sup>7</sup>
- More recently, weight loss with laparoscopic adjustable gastric banding (LAGB) has been shown to be comparable to weight loss with gastric bypass at 36 months and beyond, based on a meta-analysis of 43 peer-reviewed bariatric surgery studies<sup>8†</sup>
- A recent U.S. based single-center study showed that LAP-BAND® System patients achieved an average excess weight loss of 62 percent ( $\pm 20.9$  percent) by year three (follow-up data were available from 68 of the total 77 patients at three years)<sup>9†</sup>



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- In clinical studies of severely obese people, weight loss associated with the LAP-BAND® System has been shown to improve or resolve four common obesity-related co-morbidities, including type 2 diabetes, gastroesophageal reflux, asthma and sleep apnea<sup>10,11,12,13</sup>
- Adjustability 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](http://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.



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

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