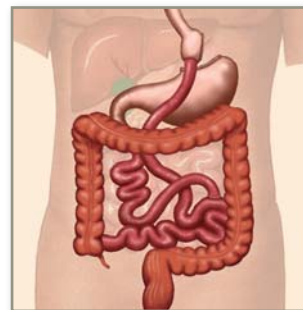
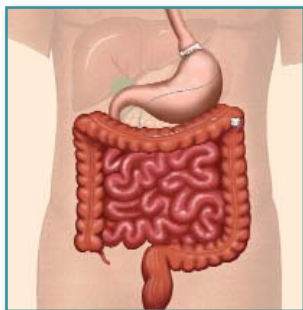


THE LAP-BAND® SYSTEM—A COMPARISON OF FEATURES AND OUTCOMES WITH ROUX-EN-Y GASTRIC BYPASS AND LAPAROSCOPIC SLEEVE GASTRECTOMY



	Laparoscopic Adjustable Gastric Banding (LAGB)	Roux-en-Y Gastric Bypass (RYGB)	Laparoscopic Sleeve Gastrectomy
Procedure	<ul style="list-style-type: none"> No change in the anatomy or stomach stapling is required Regular follow-ups allow for optimal results 	<ul style="list-style-type: none"> Requires cutting and stapling of stomach and bowel 	<ul style="list-style-type: none"> Requires cutting and stapling of stomach
Short-term (1 year) excess weight loss	<ul style="list-style-type: none"> 42% average excess weight loss 1 year after surgery¹ 	<ul style="list-style-type: none"> 67% average excess weight loss 1 year after surgery¹ 	<ul style="list-style-type: none"> 46% to 83% excess weight loss 1 year after surgery²
Long-term (>5 years) excess weight loss	<ul style="list-style-type: none"> 55% average excess weight loss 5 years after surgery¹ 	<ul style="list-style-type: none"> 58% average excess weight loss 5 years after surgery¹ 	<ul style="list-style-type: none"> No follow-up reported >3 years² May require second surgery
Postsurgical mortality (short-term)	<ul style="list-style-type: none"> 0.05%³ 	<ul style="list-style-type: none"> 0.50%³ 	<ul style="list-style-type: none"> 0.39%²
Early complications	<ul style="list-style-type: none"> 1.5%⁴ 	<ul style="list-style-type: none"> Up to 25.5% reported⁵ 	<ul style="list-style-type: none"> Rate equivalent to RYGB⁶
Postsurgical complications (long-term)	<ul style="list-style-type: none"> Band slippage⁷ Stoma obstruction⁷ Gastroesophageal reflux⁷ Nausea and vomiting⁷ 	<ul style="list-style-type: none"> Hernia⁵ Marginal ulcer⁵ Bowel obstruction⁵ Iron, vitamin B₁₂, folic acid, and calcium deficiencies⁸ Dumping syndrome³ 	<ul style="list-style-type: none"> Gastric remnant dilatation⁹ Suture line bleeding and leakage⁹ Gastric strictures⁹ May require second surgery⁹
Adjustability	<ul style="list-style-type: none"> Adjustable Reversible 	<ul style="list-style-type: none"> Nonadjustable Permanent 	<ul style="list-style-type: none"> Nonadjustable Permanent May require second surgery, doubling the risks associated with surgery and anesthesia

SEPARATING FACT FROM FICTION

1

“LAP-BAND® SYSTEM IS NOT FOR SWEET-EATERS”

FALSE

There are no data to suggest that the LAP-BAND® System does not work for sweet-eaters. Studies confirm that sweet-eating behavior is not a contraindication for the LAP-BAND® System.¹⁰

2

“FOLLOW-UP IS NOT NEEDED WITH GASTRIC BYPASS OR SLEEVE GASTRECTOMY”

FALSE

All bariatric procedures require constant follow-up to achieve satisfactory weight loss. Gastric bypass patients require regular follow-up due to the potential risk of malabsorption. It is known that nutritional deficiencies increase with time for gastric bypass patients.^{11,12}

3

“LAP-BAND® SYSTEM PROVIDES LESS RESOLUTION OF COMORBIDITIES”

FALSE

The LAP-BAND® System improves or resolves major obesity-related comorbidities including asthma, diabetes, hypertension, gastroesophageal reflux, and sleep apnea.¹³⁻¹⁶ No long-term (>5 years) comorbidity resolution data are yet available for sleeve gastrectomy.² Improvement of medical comorbidities has been reported as inadequate, with the recommendation that most patients undergo a second-stage procedure.⁹

4

“LAP-BAND® SYSTEM IS NOT FOR THE SUPER OBESE”

FALSE

Super obese (BMI >50) patients experience significant weight loss and comorbidity resolution with the LAP-BAND® System.^{17,18} Weight loss with the LAP-BAND® System is comparable to other bariatric procedures after the first year of follow-up. Even sleeve gastrectomy can be a difficult first procedure in the super obese.⁹ Higher-BMI patients (BMI >55) getting sleeve gastrectomy will most likely need to have a second-stage procedure later to help lose the rest of the weight.¹⁹

5

“LAP-BAND® SYSTEM LIMITS QUALITY OF LIFE COMPARED TO GASTRIC BYPASS”

FALSE

Studies show that the LAP-BAND® System provides a dramatic and sustained improvement in quality of life by reducing comorbidities, improving body image, and achieving overall better health associated with weight loss.²⁰⁻²²

A BRIEF DESCRIPTION OF RELEVANT INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS, AND ADVERSE EVENTS FOR THE LAP-BAND® SYSTEM.

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. The LAP-BAND® is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

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, (e.g., inflammatory or cardiopulmonary diseases, GI conditions, symptoms or family history of autoimmune disease, cirrhosis), who are unwilling or unable to comply with the required dietary restrictions, who have alcohol or drug addictions, or who currently are or may be 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, reflux, 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 malnutrition, anemia, or other complications that may require additional surgery. Deflation of the band may alleviate excessively rapid weight loss or esophageal dilation.

Important: For full safety information, please visit www.lapband.com or call Allergan Product Support at 1-800-624-4261.

CAUTION: This device is restricted to sale by or on the order of a physician.

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