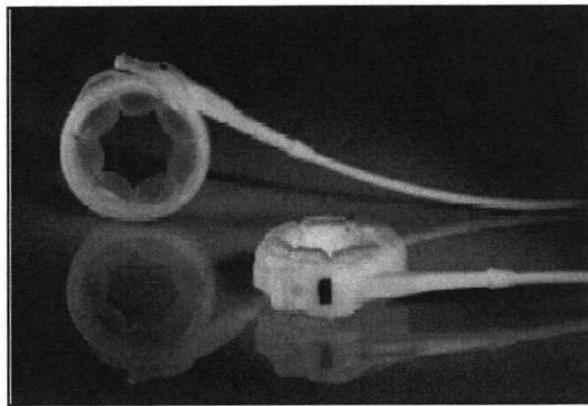


DRAFT



**LAP-BAND AP[®] System Adjustable Gastric Banding System with
OMNIFORM[®] Design**

DIRECTIONS FOR USE (DFU)



Rx Only

A detailed booklet called "The LAP-BAND System, Surgical Aid in the Treatment of Obesity, A decision guide for Adults" is available from Allergan. This booklet should be provided to all patients considering LAP-BAND[®] System surgery. The booklet includes a patient acknowledgment/consent form which should be completed prior to surgery.



Description	TBD
Intended Use / Indications	TBD
Contraindications	TBD
Warnings	TBD
Precautions	TBD
Adverse Events	TBD
Clinical Experience	TBD
Individualization of Treatment	TBD
Patient Counseling Information	TBD
How Supplied	TBD
Operator's Manual	TBD
LAP-BAND AP [®] System Surgical Procedure	TBD
Instructions for Use: Band Adjustment	TBD
Authorized Training Program and Product Ordering Information	TBD

DESCRIPTION

Cat. No. B-2240

LAP-BAND AP[®] System Standard w/Access Port I

Cat. No. B-2245

LAP-BAND AP[®] System Large w/Access Port I

Cat. No. B-2260

LAP-BAND AP[®] System Standard w/Access Port II

Cat. No. B-2265

LAP-BAND AP[®] System Large w/Access Port II

The LAP-BAND AP[®] Adjustable Gastric Banding System is designed to induce weight loss in severely obese patients by limiting food consumption. The band's slip-through buckle design makes laparoscopic placement around the stomach easier, allowing the formation of a small gastric pouch and stoma. No cutting or stapling of the stomach is required, and there is no bypassing of portions of the stomach or intestines.

The LAP-BAND AP[®] Adjustable Gastric Banding System with OMNIFORM[®] Design is the latest advance in laparoscopic adjustable gastric banding for the treatment of morbid obesity. The initial pouch and stoma sizes are established through the use of the calibration tube. The inner surface of the band is inflatable and connected by kink-resistant tubing to the Access Port, which is included in the LAP-BAND AP[®] System. This permits post-operative percutaneous, stoma size adjustment. Dietary and behavior modification counseling and frequent, long-term follow-up are required for all patients after weight-loss surgery.

Surgeons planning laparoscopic placement must have extensive advanced laparoscopic experience, i.e., funduplications as well as previous experience in treating obese patients, and have the staff and commitment to comply with the long-term follow-up requirements of obesity procedures. They should comply with the American Society for Metabolic & Bariatric Surgeons (ASMBS) and the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) joint "Guidelines for Surgical Treatment of Morbid Obesity" and the SAGES "Guidelines for Framework for Post-Residency Surgical Education and Training". Surgeon participation in a training program authorized by Allergan or by an authorized Allergan distributor is required prior to use of the LAP-BAND AP[®] System. Please see the last page for directions on obtaining additional information.

Brief Description of Procedure

During the surgical procedure, the inflatable band is flushed with sterile saline. The band is placed around the stomach and inflated with sterile saline to create the proper stoma diameter and pouch size using the calibration tube. The tubing is connected to the Access Port placed on the rectus muscle or fixed in an accessible subcutaneous space. Arrows pointing in the direction of the Access Port are printed on the tubing. These arrows assist the surgeon in identifying the correct tubing orientation. The tubing may be shortened to tailor the position of the port to the patient. The two components (calibration tube and Access Port) are joined with the stainless steel tubing connector. Ligatures may be placed on both tubing ends over the connector. The Access Port may then be sutured in place utilizing the suture holes in the port base. Postoperatively, the surgeon may adjust the stoma size percutaneously by injecting or aspirating saline with the Access Port needle.

Please refer to the Surgical Procedure section for more information.

INTENDED USE / INDICATIONS

The LAP-BAND® System is indicated for weight reduction for patients with obesity, with a Body Mass Index (BMI) of at least 40 kg/m² or a BMI of at least 30 kg/m² with one or more obesity related comorbid conditions.

It is indicated for use in 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 AP® System is contraindicated in:

1. Patients with inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease.
2. Patients with severe cardiopulmonary diseases or other serious organic disease which may make them poor surgical candidates.
3. Patients with potential upper gastrointestinal bleeding conditions such as esophageal or gastric varices or congenital or acquired intestinal telangiectases.
4. Patients with portal hypertension.
5. Patients with congenital or acquired anomalies of the GI tract such as atresias or stenoses.

6. Patients who have/experience an intra-operative gastric injury during the implantation procedure, such as a gastric perforation at or near the location of the intended band placement.
7. Patients with cirrhosis.
8. Patients with chronic pancreatitis.
9. Patients who are addicted to alcohol and/or drugs.
10. Non-adult patients (patients under 18 years of age).
11. Patients who have an infection anywhere in their body or where the possibility of contamination prior to or during the surgery exists.
12. Patients on chronic, long-term steroid treatment.
13. Patients who are unable or unwilling to comply with dietary restrictions that are required by this procedure.
14. Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system or who have exhibited pain intolerance to implanted devices.
15. Patients or family members with a known diagnosis or pre-existing symptoms of autoimmune connective-tissue disease such as systemic lupus erythematosus or scleroderma.
16. Pregnancy: Placement of the LAP-BAND AP[®] System is contraindicated for patients who currently are or may be pregnant. Patients who become pregnant after band placement may require deflation of their bands.

WARNINGS

1. Laparoscopic or laparotomic placement of the LAP-BAND AP[®] System is major surgery and death can occur.
2. Failure to secure the band properly may result in its subsequent displacement and necessitate a second operation.
3. A large hiatal hernia may prevent accurate positioning of the device. Placement of the band should be considered on a case-by-case basis depending on the severity of the hernia.
4. The band should not be sutured to the stomach. Suturing the band directly to the stomach may result in erosion.
5. Patients' emotional and psychological stability should be evaluated prior to surgery. Gastric banding may be determined by physician to be inappropriate for select patients.

6. Patients should be advised that the LAP-BAND AP[®] System is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Medical management of adverse reactions may include explantation. Revision surgery for explantation and replacement may also be indicated to achieve patient satisfaction.
7. Esophageal distension or dilatation has been reported to result from stoma obstruction from over-restriction by excessive band inflation. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should proceed in small increments. Deflation of the band is recommended if esophageal dilatation develops.
8. Some types of esophageal dysmotility may result in inadequate weight loss or may result in esophageal dilatation when the band is inflated and may require removal of the band. On the basis of each patient's medical history and symptoms, surgeons should determine whether esophageal motility function studies are necessary. If these studies indicate that the patient has esophageal dysmotility, the increased risks associated with band placement must be considered.
9. Patients with Barrett's esophagus may have problems associated with their esophageal pathology that could compromise their post-surgical course. Use of the band in these patients should be considered on the basis of each patient's medical history and severity of symptoms.
10. Patient self-adjustment of superficially placed access ports has been reported. This can result in inappropriate band tightness, infection and other complications.

PRECAUTIONS

1. Laparoscopic band placement is an advanced laparoscopic procedure. Surgeons planning laparoscopic placement must:
 - a. Have extensive advanced laparoscopic experience, i.e., funduplications.
 - b. Have previous experience in treating obese patients and have the staff and commitment to comply with the long-term follow-up requirements of obesity procedures.
 - c. Participate in a training program for the LAP-BAND[®] System authorized by Allergan or an authorized Allergan distributor (this is a requirement).
 - d. Be observed by qualified personnel during their first band placements.
 - e. Have the equipment and experience necessary to complete the procedure via laparotomy if required.
 - f. Be willing to report the results of their experience to further improve the surgical treatment of severe obesity.

2. It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant.
3. As with gastroplasty surgeries, particular care must be taken during dissection and during implantation of the device to avoid damage to the gastrointestinal tract. Any damage to the stomach during the procedure may result in erosion of the device into the GI tract.
4. During insertion of the calibration tube, care must be taken to prevent perforation of the esophagus or stomach.
5. Revision procedures may require the existing staple line to be partially disrupted to avoid having a second point of obstruction below the band. As with any revision procedure, the possibility of complications such as erosion and infection is increased. Any damage to the stomach during the procedure may result in peritonitis and death or in late erosion of the device into the GI tract.
6. Care must be taken to place the Access Port in a stable position away from areas that may be affected by significant weight loss, physical activity or subsequent surgery. Failure to do so may result in the inability to perform percutaneous band adjustments.
7. Care must be taken during band adjustment to avoid puncturing the tubing that connects the Access Port and band, as this will cause leakage and deflation of the inflatable section.
8. Failure to create a stable, smooth path for the Access Port tubing, without sharp turns or bends, can result in tubing breaks and leakage. In order to avoid incorrect placement, the port should be placed lateral to the trocar opening. A pocket must be created for the port so that it is placed far enough from the trocar path to avoid abrupt kinking of the tubing. The tubing path should point in the direction of the Access Port connector so that the tubing will form a straight line with a gentle arching transition into the abdomen. (See Figure 1. Port Placement Options)

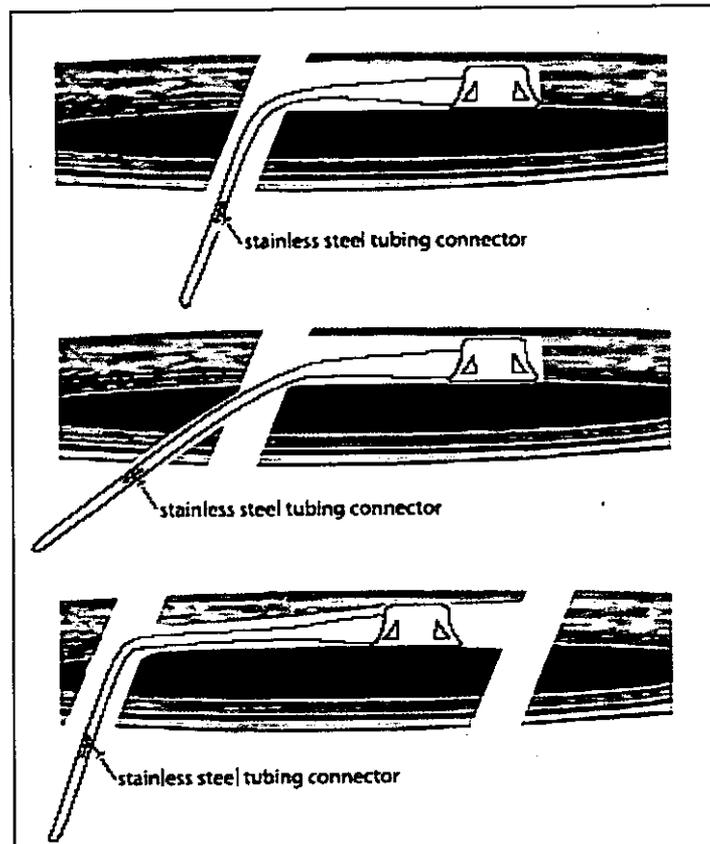


Figure 1. Port Placement Options

9. The LAP-BAND AP[®] System is for single use only. Do not use a band, Access Port, needle or calibration tube that appears damaged (cut, torn, etc.) in any way. Do not use any of the above components if the package has been opened or damaged or if there is any evidence of tampering. If packaging has been damaged, the product may not be sterile and may cause an infection.
10. Do not attempt to clean or re-sterilize any part of the LAP-BAND AP[®] System. The product may be damaged or distorted if re-sterilized.
11. Special care must be used when handling the device because contaminants such as lint, fingerprints and talc may lead to a foreign body reaction.
12. Care must be taken to avoid damaging the band, its inflatable section or tubing, the Access Port or the calibration tube. Use only rubber-shod clamps to clamp tubing.
13. The band, Access Port and calibration tube may be damaged by sharp objects and manipulation with instruments. A damaged device must not be implanted. For this reason, a stand-by device should be available at the time of surgery.
14. Failure to use the tubing end plug during placement of the band may result in damage to the band tubing during band placement.

15. Do not push the tip of any instrument against the stomach wall or use excessive electrocautery. Stomach perforation or damage may result in peritonitis and death.
16. Over-dissection of the stomach during placement may result in slippage or erosion of the band and require reoperation.
17. Failure to use an appropriate atraumatic instrument such as the LAP-BAND[®] System Closure Tool to lock the band may result in damage to the band or injury to surrounding tissues.
18. When adjusting band volume, take care to ensure the radiographic screen is perpendicular to the needle shaft (the needle will appear as a dot on the screen). This will facilitate adjustment of needle position as needed while moving through the tissue to the port.
19. When adjusting band volume, use of an inappropriate needle may cause Access Port leakage and require reoperation to replace the port. Use only LAP-BAND AP[®] System Access Port Needles. Do not use standard hypodermic needles, as these may cause leaks.
20. When adjusting band volume, the needle must be inserted perpendicular to the Access Port septum. Failure to do so may cause damage to the port and result in leaks.
21. When adjusting band volume never enter the Access Port with a “syringeless” needle. The fluid in the device is under pressure and will be released through the needle.
22. When adjusting band volume after the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.
23. If fluid has been added, it is important to establish that the stoma is not too small before discharge. Care must be taken to not add too much saline, thereby closing the gastric stoma. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then re-check. A physician familiar with the adjustment procedure must be available for several days post-adjustment to deflate the band in case of an obstruction.
24. It is the responsibility of the surgeon to advise the patient of the dietary restrictions that follow this procedure and to provide diet and behavior modification support. Failure to adhere to the dietary restrictions may result in obstruction and/or failure to lose weight.
25. Patients must be carefully counseled on the need for proper dietary habits. They should be evaluated for nutritional (including caloric) needs and advised on the proper diet selection. The physician may choose to prescribe appropriate dietary supplements. Appropriate physical monitoring and dietary counseling should take place regularly.
26. Patients must be cautioned to chew their food thoroughly. Patients with dentures must be cautioned to be particularly careful to cut their food into small pieces. Failure to follow these precautions may result in vomiting, stomal irritation and edema, possibly even obstruction.

27. Patients must be seen regularly during periods of rapid weight loss for signs of malnutrition, anemia or other related complications.
28. Anti-inflammatory agents, such as aspirin and non-steroidal anti-inflammatory drugs (NSAIDs), may irritate the stomach and should be used with caution. The use of such medications may be associated with an increased risk of erosion.
29. Patients who become pregnant, severely ill, or who require more extensive nutrition may require deflation of their bands.
30. All patients should have their reproductive areas shielded during radiography.
31. Insufficient weight loss may be caused by pouch enlargement or, more infrequently, band erosion in which case further inflation of the band would not be appropriate.
32. Elevated homocysteine levels have been found in patients actively losing weight after obesity surgery. Supplemental folate and vitamin B12 may be necessary to maintain normal homocysteine levels. Elevated homocysteine levels may increase cardiovascular risk and the risk of neural tube abnormalities.
33. Although there have been no reports of autoimmune disease with the use of the LAP-BAND[®] System, auto-immune diseases/connective tissue disorders (i.e., systemic lupus erythematosus, sclero-derma) have been reported following long-term implantation of other silicone implants. However, there is no conclusive evidence to substantiate a relationship between connective-tissue disorders and silicone implants.

ADVERSE EVENTS

It is important to discuss all possible complications and adverse events with your patient. Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical procedure, the risks associated with any surgical procedure and the patient's degree of intolerance to any foreign object implanted in the body.

Perforation of the stomach can occur. **Death can also occur.** Specific complications of laparoscopic surgery can include spleen damage (sometimes requiring splenectomy) or liver damage, bleeding from major blood vessels, lung problems, thrombosis, and rupture of the wound.

Ulceration, gastritis, gastroesophageal reflux, heartburn, gas bloat, dysphagia, dehydration, constipation, and weight regain have been reported after gastric restriction procedures.

Band slippage and/or pouch dilatation can occur. Gastroesophageal reflux, nausea and/or vomiting with early or minor slippage may be successfully resolved by band deflation in some cases. More serious slippages may require surgery to reposition and/or remove the band.

Immediate reoperation to remove the band is indicated if there is total stoma outlet obstruction that does not respond to band deflation or if there is abdominal pain.

Gastric banding done as a revision procedure has a greater risk of complications. Prior abdominal surgery is commonly associated with adhesions involving the stomach. In the US pivotal study of severely obese adults, 42% of the subjects undergoing revision surgery were reported to have adhesions involving the stomach. Care and time must be taken to adequately release the adhesions to provide access, exposure and mobilization of the stomach for a revision procedure.

There is a risk of band erosion into stomach tissue. Erosion of the band into stomach tissue has been associated with revision surgery after the use of gastric-irritating medications, after stomach damage and after extensive dissection or use of electrocautery, and during early experience. Symptoms of band erosion may include reduced weight loss, weight gain, Access Port infection, or abdominal pain. Reoperation to remove the device is required.

Reoperation for band erosions may result in a gastrectomy of the affected area. Eroded bands have been removed gastroscopically in a very few cases. Consultation with other experienced LAP-BAND® System surgeons is strongly advised in these cases.

Esophageal distension or dilatation has been infrequently reported. This is most likely a consequence of incorrect band placement, over-restriction or stoma obstruction. It can also be due to excessive vomiting or patient noncompliance, and may be more likely in cases of pre-existing esophageal dysmotility. Deflation of the band is recommended if esophageal dilatation develops. A revision procedure may be necessary to reposition or remove the band if deflation does not resolve the dilatation.

Obstruction of stomas has been reported as both an early and a late complication of this procedure. This can be caused by edema, food, improper initial calibration, band slippage, pouch torsion, or patient non-compliance regarding choice and chewing of food.

Infection can occur in the immediate post-operative period or years after insertion of the device. In the presence of infection or contamination, removal of the device is indicated.

Unplanned deflation of the band may occur due to leakage from the band, the port or the connecting tubing.

Nausea and vomiting may occur, particularly in the first few days after surgery and when the patient eats more than recommended. Nausea and vomiting may also be symptoms of stoma obstruction or a band/stomach slippage. Frequent, severe vomiting can result in pouch dilatation, stomach slippage or esophageal dilatation. Deflation of the band is immediately indicated in all of these situations. Deflation of the band may alleviate excessively rapid weight loss and nausea and vomiting. Reoperation to reposition or remove the device may be required.

Rapid weight loss may result in symptoms of malnutrition, anemia and related complications (i.e., polyneuropathies). Deflation of the band may alleviate excessively rapid weight loss.

Rapid weight loss may result in development of cholelithiasis which may require cholecystectomy.

The following table summarizes serious adverse events (SAEs) that were reported to have occurred during the 3-year US pivotal clinical trial in severely obese adults, initiated in 1995. A total of 299 subjects were studied with a total of 633 subject years.

Table 1: Serious Adverse Events Considered Related to the LAP-BAND® System for the US Pivotal Study in Severely Obese Adults

Adverse Event	% of 299 subjects
Band Slippage, Pouch Dilatation	11
Stoma Obstruction	8
Gastroesophageal Reflux	3
Esophageal Dilatation	2
Cholelithiasis	2
Incisional Infection	2
Abdominal Pain	2
Gastroenteritis	2
Nausea and/or Vomiting	2
Port Leak	2
Delayed Esophageal Emptying	1
GI Perforation	1
Hernia	1
Band Erosion	1
Chest Pain	1
Dysphagia	1
Infection	1
Asthma	1
Atelectasis	1
Dehydration	1
Headache	1
Abnormal Healing	1
Hiatal Hernia	1
Improper Band Placement	1
Respiratory Disorder	1
Thrombosis	1
Thyroid Disorder	1
Death	0

There were additional occurrences of these events that were considered to be non-serious.

Table 2 shows occurrences of all adverse events reported at a rate of 5% or more.

Table 2: All Adverse Events that Occurred at a Rate of 5% or More for the US Pivotal Study in Severely Obese Adults

Adverse Event	# of subjects	% of 299 subjects
Digestive		
Nausea and/or Vomiting	152	51
Gastroesophageal Reflux	103	34
Stoma Obstruction	41	14
Constipation	27	9
Dysphagia	26	9
Diarrhea	22	7
Abnormal Stools	18	6
Body as a Whole		
Abdominal Pain	80	27
Asthenia	25	8
Incisional Infection	21	7
Infection	20	7
Fever	18	6
Hernia	16	5
Pain	16	5
Chest Pain	15	5
Pain Incision	14	5
Band-Specific		
Band Slippage/Pouch Dilatation	72	24
Metabolic and Nutritional		
Healing Abnormal	23	8
Port-Specific		
Port Site Pain	26	9
Port Displacement	18	6
Skin and Appendages		
Alopecia	23	8

Other adverse events considered related to the LAP-BAND® System that occurred in fewer than 1% of subjects included: esophagitis, gastritis, hiatal hernia, pancreatitis, abdominal pain, hernia, incisional infection, infection, redundant skin, dehydration, GI perforation, diarrhea, abnormal stools, constipation, flatulence, dyspepsia, eructation, cardiospasm, hematemesis, asthenia, fever, chest pain, incision pain, contact dermatitis, abnormal healing, edema, paresthesia, dysmenorrhea, hypochromic anemia, band leak, cholecystitis, esophageal dysmotility, esophageal ulcer, esophagitis, port displacement, port site pain, spleen injury, and wound infection.

Twenty-six subjects (9%, 26/299) had a total of 27 reoperations. Thirteen of these 27 (48%)

revision procedures were completed laparoscopically. In 9 of the 27 procedures (33%), the band was removed and replaced with a new band in the same procedure. These were due to: 3 initially incorrect placements, 5 stoma obstructions or band slippage/pouch dilatation, and 1 band system leakage. Two subjects had new band replacements at separate interventions. Sixteen of 27 revision procedures (59%) did not require removal of bands. All of these revisions were performed to correct band slippage/pouch dilatation. Six of these (37.5%) were completed laparoscopically. There were no deaths associated with LAP-BAND® System revisions.

Seventy-five subjects had their entire LAP-BAND® Systems explanted. Fifty-one of the 75 explants (68%, 51/75) were counter measures to adverse events. Band slippage/pouch dilatation and/or stoma obstruction was the most common adverse event associated with these explants (32%, 24/75). Other events associated with these explants were erosion (5%, 4/75), infection (4%, 3/75), GI disorders such as gastroesophageal reflux and/or dysphagia (11%, 8/75), LAP-BAND® System leak (4%, 3/75); one needle damage to shell and 2 access port tubing leaks, esophageal disorders, such as dilatation and delayed emptying (7%, 5/75); gastric perforation (3%, 2/75); one abdominal pain; and one respiratory disorder. Insufficient weight loss was also reported as a contributor to the decision to explant in 24 of the 75 explants (32%, 24/75). Data from a post-approval study showed an estimated explant rate of 6.5% per year over the first five years following implantation.

One-year data are available for 149 obese subjects with BMI ≥ 30 and < 40 who underwent LAP-BAND® System placement surgery in a Lower BMI study, initiated in 2007. This study will continue to follow subjects for an additional 4 years (5 years in total). The following table summarizes the SAEs that were reported to have occurred in the US Lower BMI clinical trial.

Table 3: Serious Adverse Events Considered Related to the LAP-BAND® System for the US Lower BMI Study

Adverse Event	# of subjects	% of 149 subjects
Abdominal Pain	2	1.3
Shoulder Pain	1	0.7
Dysphagia	1	0.7
Medical Device Complication (Band Erosion)	1	0.7
Gastric Outlet Obstruction	1	0.7
Vomiting	1	0.7

These seven device-related SAEs occurred in three subjects (2%, 3/149). They were hospitalized for 7 days or less and discharged following band removal. There were no deaths in the Lower BMI Study.

There were additional occurrences of these events that were considered to be non-serious. Table 4 shows occurrences of all device-related events reported at a rate of 2% or more.

Table 4: Device-Related Adverse Events that Occurred in $\geq 2\%$ of Subjects in the US Lower BMI Study

Preferred Term	Subjects		Events		Mild	Moderate	Severe
	N	(%) ^a	N	(%) ^b	n (%)	n (%)	n (%)
Vomiting	43	28.9%	43	(20.0%)	29 (67.4%)	13 (30.2%)	1 (2.3%)
Dysphagia	33	22.1%	33	(15.3%)	20 (60.6%)	12 (36.4%)	1 (3.0%)
Post procedural pain	28	18.8%	28	(13.0%)	1 (3.6%)	27 (96.4%)	0 (0.0%)
Gastroesophageal reflux disease	22	14.8%	22	(10.2%)	15 (68.2%)	7 (31.8%)	0 (0.0%)
Abdominal pain	8	5.4%	8	(3.7%)	2 (25.0%)	6 (75.0%)	0 (0.0%)
Nausea	8	5.4%	8	(3.7%)	5 (62.5%)	3 (37.5%)	0 (0.0%)
Dyspepsia	7	4.7%	7	(3.3%)	4 (57.1%)	3 (42.9%)	0 (0.0%)
Implant Site Pain	7	4.7%	7	(3.3%)	6 (85.7%)	1 (14.3%)	0 (0.0%)
Abdominal pain upper	4	2.7%	4	(1.9%)	3 (75.0%)	1 (25.0%)	0 (0.0%)
Constipation	4	2.7%	4	(1.9%)	3 (75.0%)	1 (25.0%)	0 (0.0%)
Medical device complication ^c	4	2.7%	4	(1.9%)	2 (50.0%)	1 (25.0%)	1 (25.0%)
Dehydration	3	2.0%	3	(1.4%)	1 (33.3%)	2 (66.7%)	0 (0.0%)
Device malfunction ^d	3	2.0%	3	(1.4%)	0 (0.0%)	2 (66.7%)	1 (33.3%)
Shoulder pain	3	2.0%	3	(1.4%)	1 (33.3%)	2 (66.7%)	0 (0.0%)

^a Percentage is based on 149 subjects

^b Percentage is based on 215 device-related adverse events

^c Complications included band erosion, tubing palpated in umbilical hernia, and band slippage

^d Malfunctions included partial slip, flipped port, and band slippage.

Other adverse events considered related to the LAP-BAND[®] System that occurred in fewer than 2% of study patients included: diarrhea (n=2), gastric pouch dilatation (n=2), gastritis (n=2), esophageal dilatation (n=2), syncope (n=2), seroma (n=2). Other events reported to occur in only one patient per event included; abdominal discomfort, alopecia, anemia, arthralgia, decrease blood folate, flatulence, gastrointestinal motility disorder, bronchitis, chills, implant site infection, implant site irritation, implant site hemorrhage, night sweats, hypotrichosis, headache, nail infection, pyrexia, skin irritation, esophageal obstruction, esophageal spasm, postoperative infection, urinary tract infection, muscle spasms, depression, back pain, and hypertension.

Seven subjects (4.6%, 7/149) each required one reoperation, and there were no intraoperative complications. Four of these (57.1%, 4/7) were LAP-BAND[®] System explantations due to dysphagia (in 2 subjects), erosion of the band, or abdominal pain. Two reoperations were access port revisions due to port flip or port site pain; the original ports were retained. One reoperation was for repositioning of the original band to correct for band slippage.

CLINICAL EXPERIENCE

The LAP-BAND® System is indicated for use only in 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.

The effects of the LAP-BAND® System have been studied in severely obese subjects (BMI \geq 40 or those who are 100 lbs. or more over their estimated ideal weight) as well as in mild to moderately obese subjects (BMI \geq 30 and $<$ 40) in the US, in the pivotal study and Lower BMI study, respectively.

Clinical Experience in Severely Obese Adults (initiated in 1995)

Purpose of the Trial:

This study evaluated the safety and effectiveness of the device for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40, or those who are 100 lbs. or more over their estimated ideal weight, as determined using the 1983 Metropolitan Life Insurance Height and Weight Table (using the midpoint for medium frame).

Study Design:

A 3-year, single-arm, multi-center study was initiated in June 1995 with 299 subjects enrolled at 8 centers under the care of 12 surgeons. All procedures were completed utilizing a perigastric dissection technique with pouches of 25 ml or (later in the study) 15 ml, using the 9.75cm (B-2210) and 10.0cm (B-2220) LAP-BAND® Systems. Of the procedures, 259 were completed laparoscopically and 33 via laparotomy, including 13 intraoperative conversions (4.7% conversion rate).

The primary effectiveness measure was the percent Excess Weight Loss (%EWL) at 1, 2, and 3 years following the LAP-BAND® implantation. The secondary effectiveness measures used in the study determined the differences between the weight loss (at years 1, 2 and 3) and the weight loss/gain experienced by the subject in the year(s) prior to the placement of the LAP-BAND® System. In addition, changes in a subject's quality of life were also determined as part of the secondary effectiveness measure.

The %EWL is defined as weight loss (operative weight minus selected weight) divided by excess weight (operative weight minus ideal weight) multiplied by 100. Study subjects were weighed immediately before surgery, at 3 weeks postoperatively, and then again at regular intervals over the next 3 years (3, 6, 9, 12, 18, 24, 30, and 36 months). The 1983 Metropolitan Life Height and Weight Table was used to determine ideal weight.

The primary safety parameters included incidence and severity of complications. Safety measurements were based on subjects' reported adverse events before surgery ($<$ 3 weeks) and postoperatively ($>$ 3 weeks), either during scheduled visits or as called to the attention of the

study nurse or investigator to report urgent problems. Any noted complications were divided into device-related and non-device-related events.

Subjects Studied:

A total of 299 subjects participated in the U.S. study, with 85% of participants being female and 15% being male. Distribution by race was 81% Caucasian, 15% African-American and 4% Hispanic. The average age at which subjects became obese was 18.4 and the average age at the time of surgery was 38.8 years.

The mean weight at entry into the trial was 293 pounds, with mean excess weight of 156 pounds and mean BMI of 47.4. Thirty percent (30%) of subjects had BMI \geq 50 and were classified as “superobese.” During the five years prior to surgery, subjects on average gained 54 pounds, with the average BMI increasing from 39 to 47.4. These subjects had significant comorbidities which included: hypertension (42%), gallstone/gallbladder disease (25%), gastrointestinal diseases (24%), asthma (16%), non-insulin dependent diabetes (11%), and insulin dependent diabetes (5%).

Subject Inclusion Criteria:

- Age 18 to 55.
- BMI \geq 40, or at least 100 pounds above estimated ideal weight.
- Willingness to comply with the substantial lifelong dietary restrictions required by the procedure.
- History of obesity for at least 5 years.
- History of failure with non-surgical, weight loss methods.
- Willingness to follow protocol requirements, including signed informed consent, routine follow-up schedule, completing quality-of-life questionnaires, completing laboratory tests, completing diet and behavior modification counseling.
- Reside within a reasonable distance from the investigator’s office and be able to travel to the investigator to complete all routine follow-up visits.

Subject Exclusion Criteria:

- Surgery or treatment representing an unreasonable risk to the subject.
- Family or subject history of inflammatory disease of the gastrointestinal tract, including gastric ulceration, duodenal ulceration, Grade 2–4 esophagitis, or specific inflammation such as Crohn’s disease or ulcerative colitis.

- Severe cardiopulmonary disease or other serious organic diseases.
- Severe coagulopathy, upper gastrointestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasia.
- Congenital or acquired anomalies of the GI tract such as atresias or stenoses.
- Severe hiatal hernia.
- Pregnancy or the intention of becoming pregnant in the next 12 months.
- Alcohol or drug addiction.
- Mentally retarded, emotionally unstable, or exhibited psychological characteristics.
- Previous bariatric surgery (except Adjustable Silicone Gastric Band), intestinal obstruction or adhesive peritonitis.
- Infection anywhere in the body at the time of surgery.
- Family or subject history of a known diagnosis or pre-existing symptoms of systemic lupus erythematosus, scleroderma, or other autoimmune disease.
- Participating in another ongoing clinical trial in which concomitant diagnostic or therapeutic intervention would adversely affect the integrity of the LAP-BAND® System US Clinical Trial.

Effectiveness Results:

Study subjects achieved significant improvement in %EWL, weight loss, excess weight and BMI at 12, 24 and 36 months following placement of the LAP-BAND® System. Although most improvement was seen in the first 12 months, statistically significant improvement continued through month 36. The effectiveness of the LAP-BAND® System at month 36 (after surgery, endpoint data) is summarized in Table 5.

Table 5: Summary of weight loss results at 36 Months

	Baseline Mean (N=292 at surgery)	36-month Mean (N=178)
%EWL	N/A	36.20%
Weight (lbs)	293	240.6
Range	193-475	113-406
Mean Excess Wt (lbs)	156	104
Range	74-335	-15-263
Mean BMI (kg/m2)	47.4	38.7
Range	35.9-74.3	19.3-63.6

N=Number of Subjects

Primary Effectiveness Results

Percent Excess Weight Loss (%EWL): In the study, the mean EWL increased steadily from 9.9% at 3 weeks to 37.8% at 24 months following the placement of the LAP-BAND® System. Improvements in %EWL through 36 months were significant ($p<0.0001$) when compared to baseline. This level of improvement has been demonstrated in the medical literature to improve comorbidities.¹

Table 6: Mean %EWL by Visit

Visit	N	%EWL
6 months	233	26.5
12 months	233	34.5
18 months	190	36.4
24 months	189	37.8
30 months	148	37.9
36 months	178	36.2

N = number of Subjects

¹ National Institute of Health. "Summary of recommendations," Clinical guidelines on identification, evaluation, and treatment of overweight and obesity in adults. The evidence report. 1998

Secondary Effectiveness Results

Weight and Excess Weight Loss: The study showed that the subjects' mean weight decreased steadily from 293 pounds at baseline to 235 pounds at 30 months post-surgery. Weight loss through 36 months was significant when compared to baseline. The study also showed that mean excess weight was reduced from 156 pounds to 98.2 pounds. The weight changes from baseline were statistically significant at each visit (paired t-test $p < 0.0001$).

The observed level of weight loss at 12 months and beyond is equivalent to almost 20% total weight loss. This 20% total weight loss is substantially greater than the 10% weight loss that has been shown in the literature to improve or resolve comorbid conditions associated with obesity.¹

Table 7: Mean Weight by Visit

Visit	N	Weight (lbs)
Baseline	288	293.5
6 months	233	254.5
12 months	233	241.8
18 months	190	240.5
24 months	189	234.5
30 months	148	235.4
36 months	178	240.6

N = number of Subjects

Body Mass Index (BMI) Decrease: The study showed that mean BMI decreased steadily from 47.5 at baseline to 38.1 at 24 months post-surgery. The improvements in BMI from baseline were statistically significant at each visit (paired t-test $p < 0.0001$).

At baseline, 9% of subjects were not morbidly obese (they had a BMI < 40). By 12 months following the placement of the LAP-BAND® System, 60% of subjects were no longer morbidly obese, and one-third were no longer severely obese (they had a BMI < 35). At the start of the study, almost 30% of subjects were super obese (they had a BMI > 50); by 12 months post-surgery only 7% of the subjects were still super obese.

Table 8: Mean BMI by Visit

Visit	N	BMI
Baseline	288	47.5
6 months	233	41.2
12 months	233	39.0
18 months	190	38.7
24 months	189	38.1
30 months	148	38.1
36 months	178	38.7

N = number of Subjects

Quality of Life Improvement: Quality of life was evaluated using several validated assessments, including the Beck Depression Index, the MBSR Appearance Evaluation, the RAND SF-36 Mental Health Composite and the RAND SF-36 Physical Health Composite. There were significant ($p < 0.0001$) improvements in the subjects' physical functioning, social functioning, emotional well-being, and physical and mental health at 12 months and at 36 months following LAP-BAND® System placement, demonstrating a significant improvement in the subjects' quality of life.

Safety:

Safety endpoints are provided in the Adverse Events section.

Site-to-site variations:

Site-to-site variations were observed in both effectiveness and safety in the US pivotal clinical study. Experience with advanced laparoscopic procedures, attitudes regarding bariatric procedures, and patient management and support practices were factors found to be related to the variations. No center performed more than two to three procedures, on average, a month. This limited and infrequent experience with both laparoscopic placement and patient management was expected to affect, and did affect, the learning curve in each center.

Clinical Experience in Lower BMI Adults (initiated in 2007)

Purpose of the Trial:

This study evaluated the safety and effectiveness of the device for use in weight reduction for obese patients with a lower Body Mass Index, BMI ≥ 30 kg/m² and < 35 kg/m² with or without comorbid conditions or with a BMI ≥ 35 kg/m² and < 40 kg/m² without any severe comorbid conditions.

Study Design:

A single-arm, multi-center study was initiated in November 2007, and 160 subjects enrolled at 7 sites. Subjects completed one-year follow-up in July 2009. Of those enrolled, 149 received

LAP-BAND[®] implantation following screening. Some subjects were placed on pre-surgical liquid diets as advised by study investigators.

The primary effectiveness measure was percent of subjects who achieved clinically successful weight loss at one year following LAP-BAND[®] implantation, where success was defined as $\geq 30\%$ Excess Weight Loss (EWL). Secondary effectiveness measures included changes from baseline to 12 months in: percent total weight loss (%WL); comorbid conditions of type 2 diabetes, dyslipidemia, and hypertension; and health-related quality of life as measured by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire.

The %EWL is defined as weight loss (baseline weight minus follow-up weight) divided by excess weight (baseline weight minus ideal weight) multiplied by 100. The %WL is defined as weight loss divided by baseline weight. Ideal weight was determined based on a BMI of 25 kg/m². Study subjects were weighed prior to surgery (screening visit and 7 days before surgery), at surgery, at 1 week postoperatively, and at regular intervals over the next year (1, 2, 4, 6, 8, 10, 12 months). Baseline weight is the weight at screening for subjects placed on the pre-surgical diet and at surgery for subjects who were not placed on the diet. Post-surgical follow-up consists of 18 scheduled visits (Week 1 and Months 1, 2, 4, 6, 8, 10, 12, 15, 18, 21, 24, 30, 36, 42, 48, 54, and 60) plus additional unscheduled visits as needed.

The primary safety parameters included incidence and severity of adverse events related to treatment.

Subjects Studied:

A total of 160 subjects were enrolled in the US Lower BMI study. Following screening, 149 subjects received LAP-BAND[®] implantation, of which 91% were female and 9% were male. Distribution by race was 77% Caucasian, 9% African-American, 11% Hispanic, 1.3% Asian, and 1.3% other. The average age at the time of surgery was 39.3 years. All 149 procedures were completed utilizing a pars flaccida technique, using the LAP-BAND AP[®] (Standard and Large) Systems, and were completed laparoscopically.

The mean weight at baseline was 215 pounds, with mean excess weight of 63 pounds and mean BMI of 35.4. Fifty-seven percent (57%) of subjects had BMI ≥ 35 and < 40 , and the remainder had BMI < 35 . These subjects had significant obesity related comorbidities which included: osteoarthritis (38%), back pain (35%), gastroesophageal reflux (28%), depression (28%), respiratory abnormality (26%), dyslipidemia (20%), hypertension (18%), urinary incontinence (11%), venous stasis (7%), sleep apnea (7%), and type 2 diabetes (4%).

Key inclusion criteria:

- Age 18 to 55.
- BMI ≥ 30 kg/m² and < 35 kg/m² with or without obesity related comorbid conditions or BMI ≥ 35 kg/m² and < 40 kg/m² without any severe comorbid conditions.

- History of obesity for at least 2 years.
- History of failure with non-surgical and more conservative weight-reduction alternatives.
- Physically and mentally able to comply with the visit schedule and behavior modification required for the LAP-BAND®.
- Successful completion of pre-operative screening, educational programs and psychological assessment supporting that the subject is an appropriate bariatric surgical candidate.

Key exclusion criteria:

- History of congenital or acquired anomalies of the gastrointestinal (GI) tract, such as intestinal telangiectasia, intestinal malrotation, duodenal ulceration, previously diagnosed Grade 3-4 esophagitis, congenital abdominal wall defects, or inflammatory bowel disease (i.e. Crohn's disease).
- Severe cardiopulmonary or other serious or uncontrolled organic disease (e.g. thyroid disease).
- Severe coagulopathy, hepatic insufficiency or cirrhosis.
- History of bariatric, gastric, or esophageal surgery.
- History of intestinal obstruction or adhesive peritonitis.
- History of esophageal dysmotility disorders.
- Type I diabetes.
- Pregnancy or intention of becoming pregnant during the study (if female of childbearing potential).
- Uncontrolled psychiatric disorders (including untreated major depression, schizophrenia, substance abuse, bulimia nervosa), immaturity, or lack of family support which would potentially compromise the subject's ability to fully comprehend and/or cooperate with the study protocol.
- Chronic use of aspirin and/or non-steroidal anti-inflammatory medications and unwillingness to discontinue the use of these concomitant medications.
- Concurrent use of weight loss medications.

- Any condition that would be a contraindication in the LAP-BAND® System Directions for Use.

Effectiveness Results:

Study subjects achieved significant improvement in %EWL, excess weight, weight loss, %WL, BMI, waist circumference and hip circumference at 12 months after placement of the LAP-BAND® System. The effectiveness of the LAP-BAND® System at month 12 (after surgery) is summarized in Table 9:

Table 9: Summary of Weight, BMI, and Body Changes at 12 Months

Parameter	Baseline Mean (SD) n ^a = 149	Month 12 Mean (SD) n = 143 ^b	Mean Change from Baseline at Month 12	95% CI (Lower, Upper)	P-value ^c
Weight (lbs)	214.9 (24.3)	174.7 (24.5)	39.7	36.4, 43.0	<0.0001
%WL	N/A	18.3 (8.5)	18.3	16.9, 19.7	<0.0001
Excess Weight (lbs)	62.8 (16.1)	22.8 (19.4)	39.7	36.4, 43.0	<0.0001
%EWL	N/A	64.5 (30.3)	64.5	59.5, 69.5	<0.0001
BMI (kg/m ²)	35.4 (2.6)	28.8 (3.2)	6.5	6.0, 7.1	<0.0001
% BMI Loss	N/A	18.3 (8.5)	18.3	16.9, 19.7	<0.0001
Waist Circumference (inches)	41.5 (3.5)	35.4 (4.4)	5.9	5.4, 6.5	<0.0001
Hip Circumference (inches)	47.7 (3.0)	41.9 (3.5)	5.8	5.2, 6.4	<0.0001

^a n is the actual number of patients at visit

^b n=140 for waist circumference and hip circumference

^c P-value is for the evaluation of mean change from baseline by paired t -test or Wilcoxon signed-rank test based on P-value of normality test <0.05

Figure 2 shows the average %EWL over time in the first year.

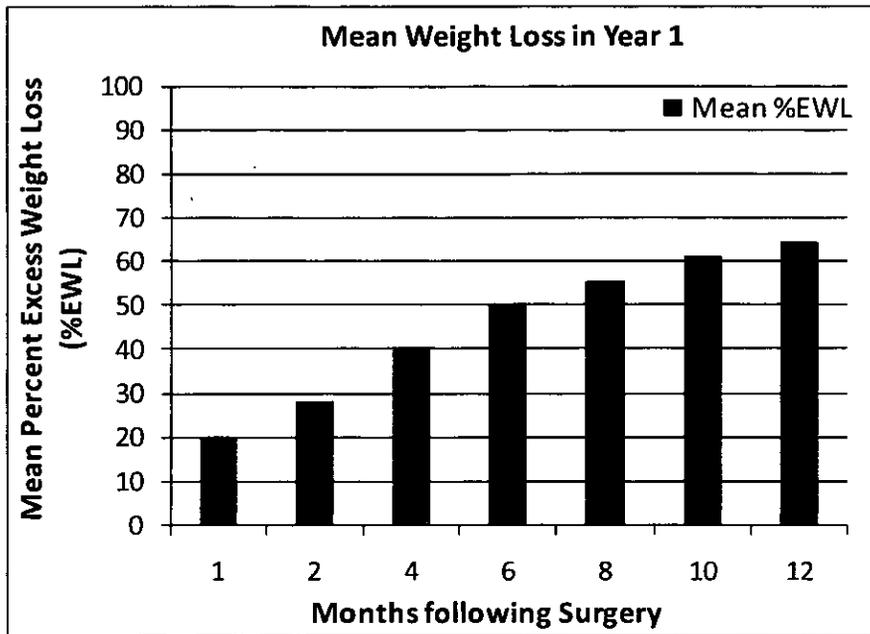


Figure 2: Mean Percent Excess Weight Loss (%EWL) over 12 Months

At baseline, over half (57.0%, 85/149) of subjects had BMI ≥ 35 . By 12 months, only two subjects (1.4%, 2/143) had BMI ≥ 35 . Over half of subjects (52.4%, 75/143) were no longer obese at 12 month. Furthermore, an additional 13.3% (19/143) of subjects were at normal weight (BMI < 25) at 12 months.

Primary Effectiveness Results

Percent of subjects with $\geq 30\%$ EWL at one year following LAP-BAND[®] System surgery:

At one year following LAP-BAND[®] surgery, 83.9% of subjects ($p < 0.0001$) achieved EWL of at least 30%. The percentages of subjects achieving different levels of %EWL are shown in the Tables 10 and 11.

Table 10: Percent of Subjects Achieving at Least 30%EWL by Visit

Follow-up Visit	N	% of Subjects with $\geq 30\%$ EWL (without imputation) ^a	% of Subjects with $\geq 30\%$ EWL (with imputation) ^b
Month 1	149	16.1%	16.1%
Month 2	148	41.2%	40.9%
Month 4	146	70.5%	69.1%
Month 6	149	83.2%	83.2%
Month 8	147	86.4%	85.2%
Month 10	142	85.9%	81.9%
Month 12	143	83.9%	80.5%

N = Number of subjects at follow-up visit

^a Percentage based on observed cases

^b Percentage with unobserved cases imputed as %EWL < 30%

Table 11: Distribution of Subjects by %EWL at 12 Months

%EWL	N	% of Subjects*
$\geq 10\%$	141	98.6%
$\geq 30\%$	120	83.9%
$\geq 50\%$	98	68.5%
$\geq 70\%$	62	43.4%
$\geq 90\%$	29	20.3%

N = 143 subjects at 12 months.

*Rows are cumulative frequencies

Secondary Effectiveness Results

Percent Total Weight Loss (%WL): The study showed that mean weight decreased steadily from 214.9 pounds at baseline to 174.7 pounds, resulting in an average 18.3%WL at 12 months. Percent total weight loss through 12 months was significant when compared to baseline ($p < 0.0001$). The percentage of subjects achieving various levels of %WL is shown in Table 12.

Table 12: Distribution of Subjects by %WL at 12 Months

%WL	N	% of Subjects*
≥5%	135	94.4%
≥10%	115	80.4%
≥15%	94	65.7%
≥20%	64	44.8%
≥25%	29	20.3%

N = 143 subjects at 12 months.

*Rows are cumulative frequencies

Change in Comorbid Conditions (Type 2 Diabetes, Dyslipidemia, and Hypertension): In the study, changes in obesity related comorbid conditions were based on Investigator assessments of the severity of the conditions at each timepoint. At 12 months post-surgery, improvement was noted in type 2 diabetes, dyslipidemia, and hypertension. The number of subjects with each comorbid condition is small; therefore, it is difficult to make definitive statements regarding improvement in the conditions. Table 13 shows the change in these three comorbidities at 12 months following LAP-BAND® placement. These reported changes in comorbid conditions were consistent with changes in associated laboratory values, as shown in Tables 14-16.

Table 13: Change in Comorbid Conditions at 12 Months

Comorbid Conditions	Surgery Status N (%)*	Resolved n (%)**	Improved n (%)**	No Change n (%)**	Worsened n (%)**
Diabetes Type II	6 (4.0%)	2 (33.3%)	0 (0.0%)	4 (66.7%)	0 (0.0%)
Dyslipidemia	29 (19.5%)	8 (27.6%)	0 (0.0%)	21 (72.4%)	0 (0.0%)
Hypertension	27 (18.1%)	6 (22.2%)	2 (7.4%)	19 (70.4%)	0 (0.0%)

N is number of subjects having comorbid condition at surgery.

*% is of total population (149).

**% is of N for each comorbid condition.

Table 14: Changes in Fasting Plasma Glucose and Glycosylated Hemoglobin (HbA1c)

Lab Test	Subject group	n ^a	Screening		Month 12 Change from Screening (Month 12-Screening)		
			Mean	SD	Mean	95% CI	P-value ^b
Fasting Plasma Glucose (mg/dL)	All Subjects	145	93.4	14.1	-3.6	-5.6, -1.6	0.0006
	Subjects with Abnormal baseline values ^c	5	149.2	15.4	-40.4	-74.1, -6.7	0.0625
HbA1c (%)	All subjects	145	5.4	0.5	-0.1	-0.1, -0.03	0.0053
	Subjects with Abnormal baseline values ^d	2	7.5	0.5	-0.8	-13.5, 11.9	1.0000

^a n is the number of patients with values at Screening and Month 12

^b P-value is from Wilcoxon signed-rank test, testing against a difference of 0

^c n Abnormal Fasting Plasma Glucose is defined as ≥ 126 mg/dL

^d Abnormal HbA1c is defined as $\geq 7\%$

Table 15: Changes in Lipids [Total Cholesterol, High Density Lipoproteins (HDL), Low Density Lipoproteins (LDL), and Triglycerides]

Lab Test	Subject group	n ^a	Screening		Month 12 Change from Screening (Month 12-Screening)		
			Mean	SD	Mean	95% CI	P-value ^b
Cholesterol (mg/dL)	All Subjects	143	204.5	38.1	-13.7	-18.6, -8.9	<0.0001
	Subjects with Abnormal baseline values ^c	24	258.9	20.7	-39.4	-52.8, -26.0	<0.0001
HDL (mg/dL)	All subjects	143	55.7	13.7	5.8	4.0, 7.6	<0.0001
	Subjects with Abnormal baseline values ^d	15	36.7	2.5	7.7	4.2, 11.3	0.0012
LDL (mg/dL)	All subjects	143	121.3	30.4	-13.4	-17.6, -9.1	<0.0001
	Subjects with Abnormal baseline values ^e	16	171.3	14.8	-46.8	-58.3, -35.3	<0.0001
Triglycerides (mg/dL)	All subjects	143	137.2	67.5	-30.7	-40.0, -21.3	<0.0001
	Subjects with Abnormal baseline values ^f	22	261.4	61.5	-98.7	-135.9, -61.5	<0.0001

^a n is the number of patients with values at Screening and Month 12

^b P-value is from Wilcoxon signed-rank test, testing against a difference of 0

^c n Abnormal Cholesterol is defined as ≥ 240 mg/dL

^d Abnormal HDL is defined as < 40 mg/dL

^e n Abnormal LDL is defined as ≥ 160 mg/dL

^f Abnormal Triglycerides are defined as ≥ 200 mg/dL

Table 16: Changes in Blood Pressure [Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)]

Lab Test	Subject group	n ^a	Screening		Month 12 Change from Screening (Month 12-Screening)		
			Mean	SD	Mean	95% CI	P-value ^b
SBP (mm Hg)	All Subjects	142	127.6	14.8	-8.1	-10.9, -5.3	<0.0001
	Subjects with Abnormal baseline values ^c	27	150.9	10.0	-21.0	-28.2, -13.9	<0.0001
DBP (mm Hg)	All subjects	142	79.1	9.3	-3.1	-4.8, -1.3	0.0004
	Subjects with Abnormal baseline values ^d	16	94.3	4.9	-9.4	-15.2, -3.7	0.0027

^a n is the number of patients with values at Screening and Month 12

^b P-value is from Wilcoxon signed-rank test, testing against a difference of 0

^c n Abnormal SBP is defined as ≥ 140 mm Hg

^d Abnormal DBP is defined as ≥ 90 mm Hg

IWQOL-Lite: Quality of life significantly improved as measured by the Impact of Weighton Quality of Life-Lite assessment. The mean IWQOL-Lite score was 62.8 at baseline, and improved to 90.6 at 12 months ($p < 0.0001$). Significant improvements were observed in all five scale domains ($p < 0.0001$).

Table 17: Change in IWQOL-Lite Score at 12 Months

Domains	N	Baseline Mean	Month 12 Mean	Mean Change	p-value
Physical Function	142	60.9	92.7	31.8	<0.0001
Self-Esteem	141	43.6	80.4	36.8	<0.0001
Sexual Life	139	66.3	89.0	22.7	<0.0001
Public Distress	143	79.0	96.6	17.6	<0.0001
Work	143	75.8	95.7	19.9	<0.0001
Total Score	142	62.5	90.5	28.0	<0.0001

N = Number of Subjects with scores at both baseline and 12 months

Additional Effectiveness Results

Changes in Other Obesity Related Comorbid Conditions: In addition to the comorbidities of dyslipidemia, Type 2 diabetes, and hypertension, additional comorbidities were assessed by the Investigator for severity at baseline and Month 12. All comorbid conditions demonstrated improvement or resolution at Month 12 with the LAP-BAND[®] System, as shown in Table 18.

Table 18: Month 12 Change in Status of Other Comorbid Conditions

Comorbid Condition	Present at Baseline n (%) ^a	Resolved ^b n (%) ^c	Improved ^c n (%) ^c	Unchanged n (%) ^c	Worsened ^d n (%) ^c
Back Pain	52 (34.9%)	18 (34.6%)	2 (3.8%)	31 (59.6%)	1 (1.9%)
Depression	41 (27.5%)	9 (22.0%)	1 (2.4%)	30 (73.2%)	0 (0.0%)
Gastroesophageal Reflux	42 (28.2%)	30 (71.4%)	0 (0.0%)	9 (21.4%)	0 (0.0%)
Metabolic Syndrome	1 (0.7%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Osteoarthritis	57 (38.3%)	18 (31.6%)	0 (0.0%)	38 (66.7%)	1 (1.8%)
Respiratory Abnormality	38 (25.5%)	18 (47.4%)	1 (2.6%)	19 (50.0%)	0 (0.0%)
Sleep Apnea	11 (7.4%)	4 (36.4%)	1 (9.1%)	6 (54.5%)	0 (0.0%)
Urinary Incontinence	16 (10.7%)	8 (50.0%)	0 (0.0%)	8 (50.0%)	0 (0.0%)
Venous Stasis	11 (7.4%)	6 (54.5%)	0 (0.0%)	5 (45.5%)	0 (0.0%)

^a n is the number of patients having comorbid conditions at Surgery; percent is of total population;

^b Resolved is defined as patients moving to the None category

^c Improved is defined as patients improving by at least one category but not Resolved

^d Worsened is defined as patients worsening by at least one category

^e n is the number of patients with status Resolved/Improved/Unchanged/Worsened at Month 12; percent is of patients who had condition at Surgery; sum of change in status (Resolved + Improved + Unchanged + Worsened) may not equal Baseline status due to missing data at Month 12.

Other Patient Reported Outcomes: Consistent with improvements seen in IWQOL-Lite, significant improvements from baseline were seen at Month 12 in other patient reported outcomes including the SF-36, Beck Depression Inventory-II, Three Factor Eating Questionnaire, and Questionnaire on Eating and Weight Patterns – Revised.

Safety:

Safety endpoints are provided in the Adverse Events section.

Site-to-site variations:

All sites in the study had the majority (76%-100%) of subjects achieving $\geq 30\%$ EWL.

INDIVIDUALIZATION OF TREATMENT

Placement of the LAP-BAND[®] System is contraindicated for patients who currently are or may be pregnant. Patients who become pregnant or severely ill after implantation of the LAP-BAND[®] System, or who require more extensive nutrition, may require deflation of their bands. In rare cases, removal may be needed.

International data suggests that hyper-insulinemia, insulin resistance and disease(s) associated with insulin resistance, poor physical activity, pain and poor general health responses to the SF-36 Health Survey are associated with a slower weight loss.

Older, less physically able and insulin resistant patients are likely to lose weight at a slower rate than younger physically able persons.

Patients who are super-obese can achieve weight reduction sufficient to improve health and quality of life with the LAP-BAND® System but may remain severely obese. They may lose more weight with a malabsorptive procedure or a procedure with a malabsorptive component. The patient's weight loss needs and expectations should be considered when selecting an obesity procedure.

PATIENT COUNSELING INFORMATION

A detailed booklet called "The LAP-BAND System, Surgical Aid in the Treatment of Obesity, A decision guide for Adults" is available from Allergan. This booklet should be provided to all patients considering LAP-BAND® System surgery. This booklet includes a patient acknowledgment/consent form which should be completed prior to surgery.

HOW SUPPLIED

All components of the LAP-BAND AP® Adjustable Gastric Banding System are for single use only.

The band, Access Port, and stainless steel connector are provided sterile in double packaging with a protective outer container. The Access Port needle is provided sterile in separate packaging.

CAUTION: If the package has been damaged or if the inner package is opened outside the sterile field, the product must be considered non-sterile and may cause infection of the patient.

The calibration tube is provided clean and non-sterile and does not require sterilization.

LAP-BAND® System boxes should be stored in a clean, dry location (standard hospital supply storage).

The LAP-BAND® System has a two-year shelf life.

Required Equipment and Materials (Included)

System Components:

1. LAP-BAND AP® Adjustable Gastric Banding System (sterile), one each
2. Access Port with Stainless Steel Connector (sterile), one each
3. Calibration Tube (non-sterile), one each

4. Access Port Needle, 89 mm (3.5 inch), (sterile), one each
5. Blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile), one each
6. Blunt flushing needle, 22 gauge, 127 mm (5 inch) (sterile), one each
7. End plug with Stainless Steel Connector (sterile), one each

The LAP-BAND AP[®] System is available in two sizes, Standard and Large. The physician should choose the appropriate size depending upon the patient's individual anatomy. Most patients with correctly fitted bands report minimal, if any, restriction following resolution of post-operative edema until saline is added to the band, regardless of band size. The Large band is normally used for reoperations (particularly conversion from other procedures) and the pars flaccida dissection. Surgeons are advised to evaluate the amount of tissue within the band prior to band locking and suturing in place, and, if it appears excessive, to remove some omental tissue or move the dissection closer to the stomach wall or higher on the stomach. Additional information regarding size selection is provided in the training program.

LAP-BAND AP[®] Adjustable Gastric Banding System Features:

The LAP-BAND AP[®] System is made of silicone elastomer that forms a ring around the proximal stomach when fastened. The band transitions to a radiopaque 50 cm-long silicone tube. Its kink-resistance and arrows printed on top aid the surgeon in placing it toward the Access Port. An end plug seals the system while the band is passed around the stomach.

Access Port:

The Access Port (Figures 3 and 4) is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port needle.

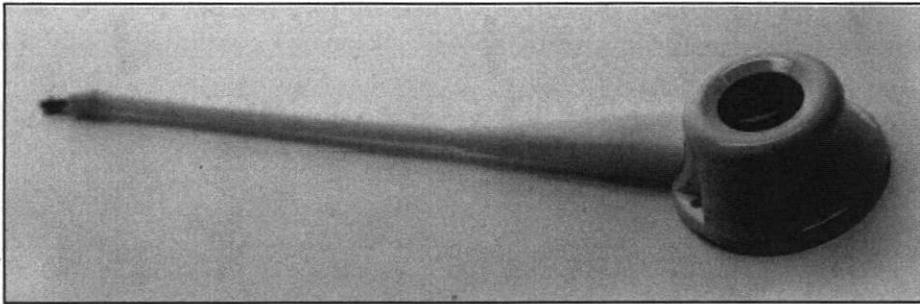


Figure 3. Access Port I

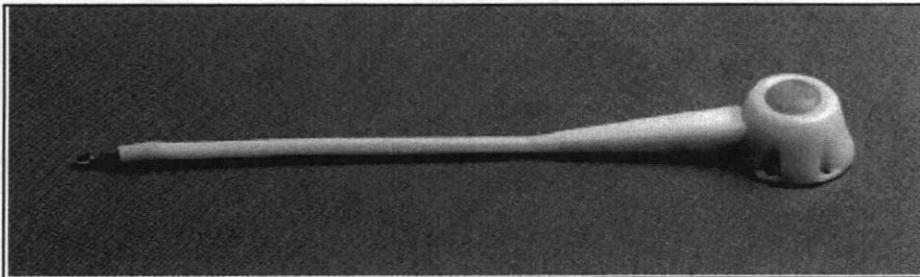


Figure 4. Access Port II

Features Include:

1. High-compression septum; tested to over 200 punctures with a 20 gauge non-coring needle.
2. Port reservoir with positive tactile feedback designed for long-term durability; resists gouging and retains integrity throughout repeated needle contact.
3. Radiopaque and compatible with diagnostic imaging; including MRI and CT scanning, although a minimal “halo” effect has been reported due to the stainless steel tubing connector.
4. Contoured polysulfone housing; light-weight smooth and rounded.
5. A stainless steel connector which is used with ligatures to join the tubing of the band to the access port.

Access Port Needle Features:

The Access Port needle is a 20 gauge, 89 mm (3.5 inch) long non-coring, deflected-tip (“Huber tip”) needle designed to penetrate the Access Port during post-operative adjustment of the LAP-BAND AP[®] System (see Instructions for Use). Access port needles are available in boxes of 10

(B-20301-10).

Calibration Tube:

The calibration tube (Figure 5) is a dual-lumen translucent silicone tube, 157 cm long with a 13 mm diameter sensor tip at its distal end. A 15 cc to 25 cc balloon for controlled sizing and positioning of the gastric pouch is located 3.5 cm from the distal end of the catheter. The balloon is inflated via an inflation port that remains external during the procedure. The calibration tube is for single use only.

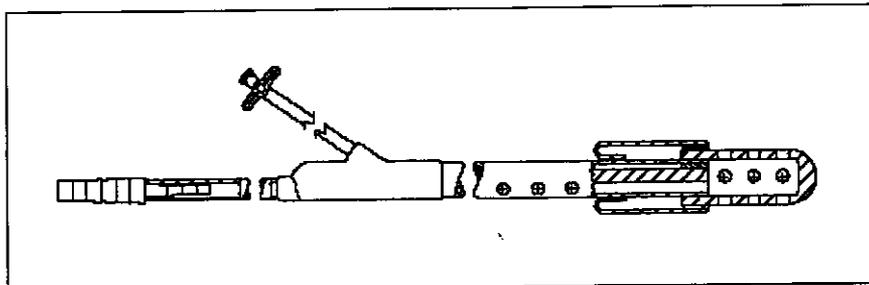


Figure 5. Calibration Tube

Features Include:

1. Integral inflatable gastric pouch sizer balloon
2. Inflation tubing and stopcock attached for ease in filling the calibration balloon
3. Drainage, suction and irrigation

Required Equipment and Materials (Not Included):

- Atraumatic Graspers
- Sterile Saline (non-pyrogenic, isotonic, 0.9% NaCl)
- Syringe, 5 or 10 cc
- 2-0 Ethibond, intestinal needle
- 2-0 Dexon, cutting needle
- Rubber-shod clamps (mosquito with tubing sleeves)

Additional Equipment Recommended for Laparoscopic Placement:

- Articulating dissector (long shaft) or Reticulating grasper (long shaft)

- 15 mm or 18 mm trocar
- 5.5 mm reducer for 15 or 18 mm trocar
- 0° and 30° laparoscopes
- Trocars; extra-long trocars sometimes needed
- Extra-long cautery hook and suction irrigation
- A set of long laparoscopic atraumatic graspers, dissectors, scissors, clip appliers, Babcock grasper and fan-type liver retractor

Additional Equipment Recommended for Placement via Laparotomy:

Surgeons electing laparoscopic placement should also be prepared with the equipment necessary for placement via laparotomy.

- Penrose Drain
- Abdominal Retractor System for Obesity
- Liver Retractor for Obesity
- Standard set of abdominal surgical retractor instruments as required for laparotomy in the open placement of the LAP-BAND AP[®] System

Special Equipment and Materials Required for Band Adjustment:

- X-ray equipment with monitor
- Local anesthetic with a 1 cc syringe and 30 gauge needle
- Sterile 20 gauge 89 mm (3.5 in.) Access Port needle (supplied with LAP-BAND[®] System and available separately) or a sterile 20 gauge 51 mm (2 in.) Access Port needle (available as 10 pack: B-20302-10) or other 20 or 22 gauge non-coring, deflected tip (“Huber tip”) needle ONLY.
- Sterile, non-pyrogenic isotonic saline solution in a 1 cc syringe for normal adjustments or a larger syringe when the total amount of band fluid is being measured.
- A washer or coin for localizing the port.

OPERATOR'S MANUAL

Prophylactic Antibiotics

The perioperative administration of prophylactic antibiotics, which would cover the skin and gut flora is recommended.

Pre-operative Upper GI

All LAP-BAND® System patients should have a pre-operative upper GI.

Access Port Preparation

1. Remove Access Port along with the 22 gauge blunt flushing needle from the sterile container
2. The blunt flushing needle fits loosely inside the fill tubing of the Access Port. Do not attempt to insert it into the port
3. Hold the Access Port with the fill tubing in an upright position with the port on the bottom
4. Attach a 5 cc saline-filled syringe to the blunt flushing needle
5. Inject sterile saline to irrigate the Access Port. As it fills, all air and excess fluid will be forced out of the tubing past the blunt flushing needle
6. Keep the port tubing upright until it is attached to the band fill tubing
7. The Access Port and tubing are now full of saline, mostly free of air, and ready to be attached to the implanted band tubing

Band Preparation

For the Circulator

1. Give Scrub Tech/RN 15 cc of sterile, nonpyrogenic isotonic 0.9% NaCl saline solution and a 10 cc syringe (w/o needle).
2. Prior to opening the box, confirm the size and type of LAP-BAND® System with the surgeon.
3. Do not open or throw away the sterile Access Port Needle unless it is requested by the surgeon. If the needle is not used, label with patient's name and give to the surgeon for future LAP-BAND® System adjustments.

4. Give anesthesiologist the Calibration Tube (packaged separately).

For the Anesthesiologist

1. The Calibration Tube is an oral suction tube which requires a lubricant and 30 cc syringe for inflation.
2. Surgeon will instruct anesthesiologist to remove patient's N/G tube (if one has been inserted). Insert the Calibration Tube orally until it passes below the gastro-esophageal (GE) junction.
3. Surgeon will ask anesthesiologist to inflate balloon with 25 cc of air (or saline) and to pull back on tube until resistance is met – this determines precisely where the GE junction is located.
4. Once the junction is clearly marked, the surgeon will then instruct anesthesiologist to deflate the Calibration Tube and either retract it into the esophagus or remove it entirely.
5. Discard the Calibration Tube after use only when surgeon has completed surgery. During insertion of the calibration balloon, care must be taken to prevent perforation of the esophagus or stomach.

For The Scrub Tech/RN

1. After the Circulator opens outer LAP-BAND AP[®] System package, pick up inner sterile container by the tab and put on back table in a secure location.
2. Peel outer wrapping at the yellow indicator on the bottom side of the Tyvek and remove LAP-BAND AP[®] System and priming needle.
3. Connect priming needle to the LAP-BAND AP[®] System tubing end.
4. Fill a 20 cc syringe with at least 15 cc of saline and connect syringe to the priming needle. Flush the band and inflatable shell area several times, each time drawing out air bubbles. A residual amount of saline will stay in the LAP-BAND AP[®] System.
5. View the inflatable portion of the band for leaks or uneven inflation.
6. Inject about 5 cc saline and disconnect the syringe. The excess saline will be forced out of the band, leaving about 4 cc of saline in the LAP-BAND AP[®] System Standard and 5 cc in the LAP-BAND AP[®] System Large.
7. At this point, you have replaced most of the air in the LAP-BAND AP[®] System with saline.
8. Insert the end plug into the tubing end until the stainless steel tubing connector disappears

into the open end of the band fill tube – this will facilitate pulling the tube around the stomach (Figure 6). The tubing can be slippery. Using 4x4 gauze sponges will help grasp the tubing.

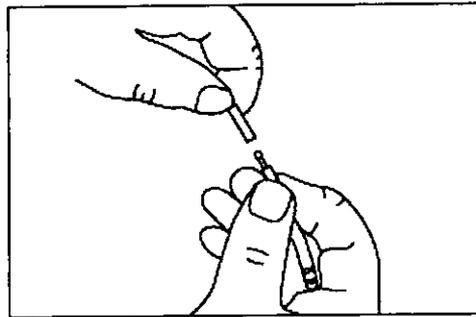


Figure 6. Insertion of Band Tubing End Plug

9. Place the band in saline bowl or set aside until ready for insertion – it is now ready for implantation.
10. If your patient's anatomy requires a larger initial circumference, the LAP-BAND AP[®] System's perimeter can be made larger by removing saline from the band via the Access Port. It is important to remove any additional saline via the Access Port so no air will enter the LAP-BAND[®] System, compromising later adjustments.

MAXIMUM FILL CAPACITY VOLUMES

LAP-BAND AP [™] System Standard	10 cc
LAP-BAND AP [™] System Large	14 cc

Procedure Basics

As with other surgical decisions, it is the surgeon's responsibility to judge his or her skill and experience as well as the procedure best suited to the patient's needs. Detailed presentations of specific procedures have been published. These publications and additional information regarding procedures are provided in Allergan authorized LAP-BAND® System Programs.

It has been reported that a liquid diet prior to surgery may reduce the patient's liver size, providing a clearer view and easier access to the stomach when placing the LAP-BAND® System.

The following information regarding the surgical procedure, adjustments and band removal is intended to supplement, not replace, information provided in these workshops.

LAP-BAND AP® SYSTEM SURGICAL PROCEDURE

Anesthesia: The anesthesiologist typically avoids mask ventilation prior to intubation in order to prevent aspiration of gastric contents into the respiratory tract. Crash induction of anesthesia (injection of anesthetic drugs followed immediately by intubation under cricoid compression) is common in obesity surgery. A nasogastric tube is typically placed after intubation in order to empty the stomach.

Position of the Patient and the Surgeon: The patient is most commonly placed in a lithotomy position, in a moderate anti-Trendelenburg tilt. The hips and the knees are slightly flexed in order to prevent the patient from slipping down the table. This position helps displace the intra-abdominal viscera and the fatty omentum downward so that the upper part of the stomach may be better visualized. The surgeon stands between the patient's legs, the first assistant on the patient's left side and the second assistant on the patient's right.

Pneumoperitoneum: The laparoscopic procedure is performed under carbon dioxide pneumoperitoneum. Pressure is monitored constantly.

Position of the Trocars: Four, five, or six trocars are initially placed for this procedure. The trocars need to be positioned high on the patient's abdomen, and they must be inserted so that they angle towards the gastric hiatus. This is important for better instrument access in the severely obese abdomen. A trocar is needed for introduction of the atraumatic graspers, usually in the right upper quadrant or below the right costal margin. A 15 or 18 mm port is required for introduction of the gastric band, usually in the left paramedial position or on the left anterior axillary line below the costal margin (Access Port site).

Exposure of the Subcardial Area: A liver retractor is placed to hold the left lobe of the liver anteriorly and to the patient's right to expose the esophageal hiatus, the anterior stomach and lesser omentum.

Measurement of the Pouch: The anesthesiologist passes the calibration tube down into the

stomach and inflates its balloon with 25 cc of air (some surgeons prefer saline). The balloon is withdrawn upwards until it is against the gastroesophageal junction (Figure 7).

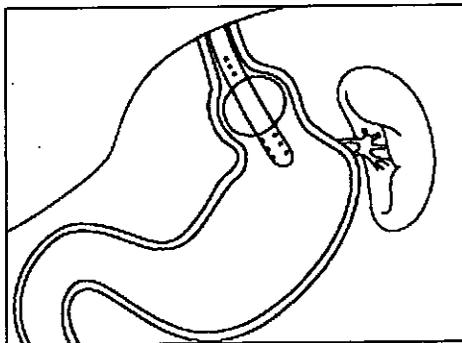


Figure 7. Calibration Tube balloon withdrawn upwards against the gastroesophageal junction.

This permits correct selection of the location along the lesser curvature and into the phrenogastric ligament to perform the blunt dissection (Figure 8).

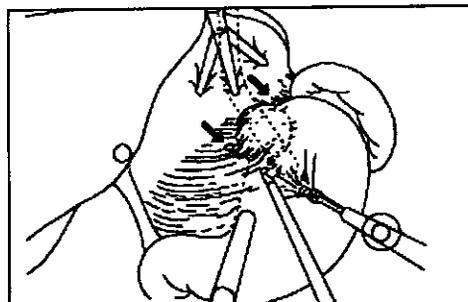


Figure 8. Calibration Tube balloon and dissection point selected

Lesser Curve Dissection Options

Recommended Technique

PARS FLACCIDA: Dissection begins directly lateral to the equator of the calibration balloon in the avascular space of the Pars Flaccida. After seeing the caudate lobe of the liver, blunt dissection is continued under direct visualization until the right crus is seen, followed immediately by the left crus over to the angle of His.

The PARS FLACCIDA technique is recommended as it is the most widely used method for laparoscopic adjustable gastric banding and results in a reduced incidence of gastric prolapse and pouch dilatation compared to the PERI-GASTRIC technique (described below).

Alternate techniques

PERI-GASTRIC: Dissection starts directly on the lesser curve at the mid-point (equator) of the calibration balloon. Dissection is completed behind the stomach toward the angle of His under direct visualization, taking care to avoid the lesser sac. Retro-gastric suturing is an option (Figure 9).

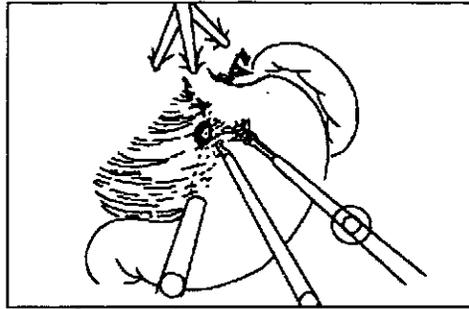


Figure 9. Dissection of the lesser curvature:

PARS FLACCIDA TO PERI-GASTRIC: Dissection begins with the Pars Flaccida technique (above). A second dissection is made at the mid-point (equator) of the balloon near the stomach until the peri-gastric dissection intercepts the Pars Flaccida dissection. The band is then placed from the angle of His through to the peri-gastric opening.

Under direct vision, the full thickness of the hepatogastric ligament is dissected from the gastric wall to make a narrow opening. The posterior gastric wall should be clearly recognizable. The dissection should be the same size as the band or even smaller to reduce the possibility of band and/or stomach slippage.

Dissection of the Greater Curvature: A very small opening is created in the avascular phrenogastric ligament, close to the gastric wall at the Angle of His.

Retrogastric Tunnel: Always under direct vision, blunt dissection is continued towards the Angle of His until the passage is completed (Figure 10).

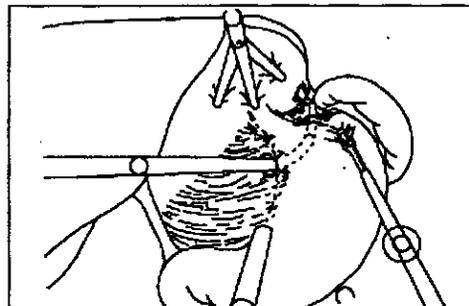


Figure 10. Posterior instrument passage.

WARNING: Do not push the tip of any instrument against the stomach wall or use excessive electrocautery. Stomach perforation or damage may result. Stomach perforation may result in peritonitis and death.

WARNING: Any damage to the stomach during the procedure may result in erosion of the device into the GI tract.

CAUTION: Do not over-dissect the opening. Excessive dissection may result in movement or erosion of the band. A blunt instrument is gently passed through the retrogastric tunnel.

Introduction and Placement of the Band: The inflatable band and Access Port are flushed with sterile saline (see “Band Preparation” and “Access Port Preparation”). The band is introduced into the abdomen via a 15 mm or 18 mm trocar. The band is pulled, end plug first, into place around the stomach with the instrument previously placed through the retrogastric tunnel (Figure 11).

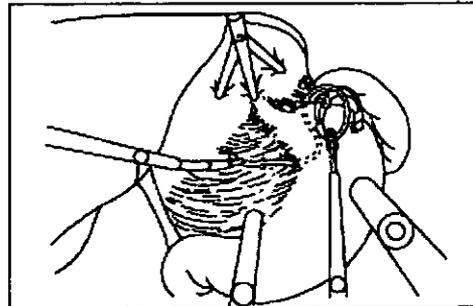


Figure 11. Placement of the band.

The tubing is inserted into the band’s buckle. The band is locked in place using atraumatic graspers.

CAUTION: Failure to use an appropriate atraumatic instrument to lock the band may result in damage to the band or injury to surrounding tissues.

Opening or Unlocking the LAP-BAND AP® System: The LAP-BAND AP® System provides for the re-opening of the band in the case of slippage or malposition. With atraumatic graspers, stabilize the band by grasping the ridge on the back of the band. With the other grasper, pull the buckle tab up (see Figure 12) and slide the tubing through the buckle until there is ample area to adjust the position of the band.

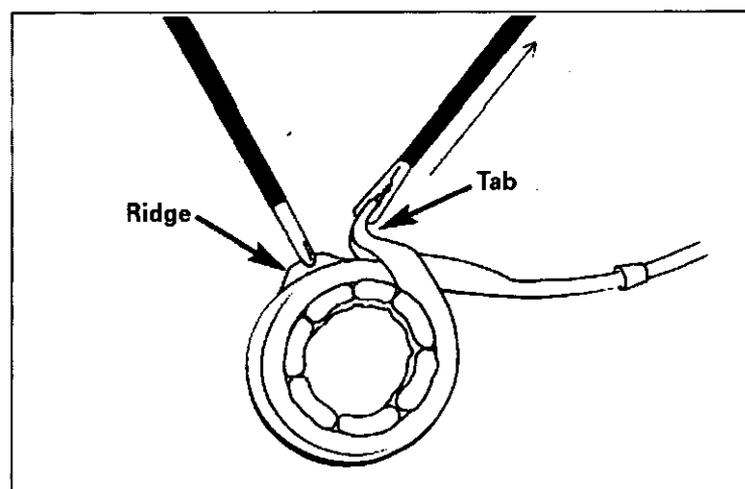


Figure 12. Unlocking the LAP-BAND AP® System.

CAUTION: Failure to create a new tunnel for the band during repositioning may lead to further slipping.

Retention Gastro-gastric Sutures: Multiple non-absorbable sutures are placed between the seromuscular layer of the stomach just proximal and distal to the band. Sutures should be placed from below the band to above the band, pulling the stomach up over the band until the smooth surface of the band is almost completely covered. The tubing and buckle area should not be included in the gastro-gastric imbrication (Figure 13).

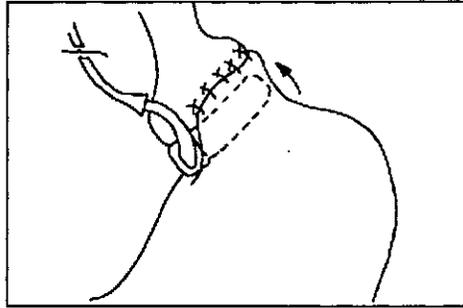


Figure 13. Suturing the greater curvature over the LAP-BAND® System and pouch.

Access Port Placement and Closure: The band tubing is brought outside the abdomen and is connected to the Access Port. The port is then placed on the rectus muscle or in an accessible subcutaneous site. The tubing may be shortened to tailor the position of the port to the patient while avoiding tension between the port and the band. The two components are joined with the stainless steel tubing connector. Ligatures may be placed on both tubing ends over the connector. The Access Port is then fixed in place, using suturing or other fixation method. The trocar holes are closed.

INSTRUCTIONS FOR USE: BAND ADJUSTMENT

The following are general guidelines for LAP-BAND® System adjustments:

1. The initial postoperative adjustment should occur at six weeks or more after placement, when usually 3-4 cc of normal saline would be added.
2. The patient should be reviewed regularly (every 4-6 weeks), depending on patient need, with weight and clinical status measured. If the weight loss has averaged less than 1 lb per week over the period and the patient indicates there is no excessive restriction to eating, a further increment of fluid should be added.
3. Normally, additional fluid would not be added if average weight loss has been greater than 2 lbs per week between visits.
4. If the weight loss averaged between 1 and 2 lbs per week, additional fluid would be indicated if the patient felt he/she could eat too freely or found it difficult to comply with the dietary rules.
5. Fluid would be removed from the system if there were symptoms of excessive restriction or obstruction, including excessive sense of fullness, heartburn, regurgitation and vomiting. If symptoms are not relieved by removal of the fluid, barium meal should be used to evaluate the anatomy.

Prior to doing an adjustment to decrease the stoma, review the patient's chart for total band volume and recent adjustments. If recent adjustments have not been effective in increasing restriction and the patient has been compliant with nutritional guidelines, the patient may have a leaking band system, pouch enlargement or esophageal dilatation due to stomal obstruction, band slippage or over-restriction.

LAP-BAND® System patency can be confirmed by injecting saline into the band system, then immediately withdrawing it. An absence or decrease in fluid volume indicates that a leak in the system may exist. The band may be evaluated for a leak using a radiopaque solution, such as Hypaque or Conray-43, flushing it from the band system after the evaluation. If pouch enlargement or band/stomach slippage is suspected, a limited upper GI with a small amount of barium or gastrografin can be used to evaluate the size of the pouch, the gastric stoma and the position of the band.

CAUTION: Insufficient weight loss may be a symptom of inadequate restriction (band too loose), or pouch or esophageal enlargement, and may be accompanied by other symptoms, such as heartburn, regurgitation or vomiting. If this is the case, inflation of the band would not be appropriate.

Excessive restriction may result in a closed stoma. Because of the possible complications that can occur with excessive restriction, a doctor familiar with the adjustment procedure must be available for several days post-adjustment to adjust the stoma in case of an emergency. (See

CAUTION after step 10).

Deflation (an increase in stoma size) is considered if the patient experiences frequent episodes of vomiting, is unable to swallow liquids or appropriate foods, or if there are medical indications for increasing nutrient intake. Elective deflation of the band is advisable in the following situations:

- Pregnancy
- Significant concurrent illness
- General anaesthesia
- Remote Travel
- Travel to areas where food or water contamination is endemic

WARNING: Esophageal distension or dilatation has been reported and may be associated with stoma obstruction due to incorrect band placement or over-restriction, due to excessive band inflation. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should proceed in small increments. Deflation of the band is recommended if esophageal dilatation develops.

If esophageal dilatation is present, then steps should be taken to identify and resolve the cause(s). Deflation of the band may resolve dilatations that are entirely due to over-restriction. Dietary evaluation and appropriate nutritional counseling regarding correct eating behavior should follow band deflation and precede subsequent gradual re-inflations. Re-inflation of the band should be conducted gradually in small increments over several months. Dietary counseling should be ongoing, and repeat upper GI exams should be done at each band adjustment.

Band deflation may not resolve the dilatation if the stoma obstruction is due to a significant gastric slippage or if the band is incorrectly placed around the esophagus. Band repositioning or removal may be necessary if band deflation does not resolve the dilatation.

Adjustment of Port Located Within Rectus Sheath and/or Deep Below Adipose Tissue

Access Port Radiographic Profile: The Access Port's white plastic housing is not radiopaque. An ideal overhead view (0°) of the access port shows two concentric rings. The Access Port for the LAP-BAND AP® System Standard is identified by a single radiopaque marker, which signifies a fill range of 0-10 cc (Figure 14).

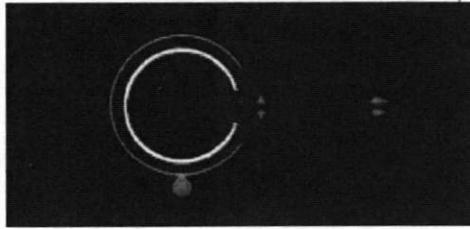


Figure 14. Top or bottom view x-ray image of the LAP-BAND AP[®] System Standard Access Port II

The Access Port for the LAP-BAND AP[®] System Large is identified by two radiopaque markers which signifies a fill range of 0-14 cc (Figure 15).

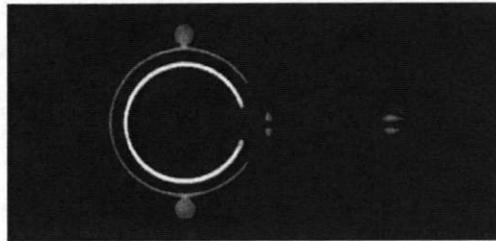


Figure 15. Top or bottom view x-ray image of the LAP-BAND AP[®] System Large Access Port II

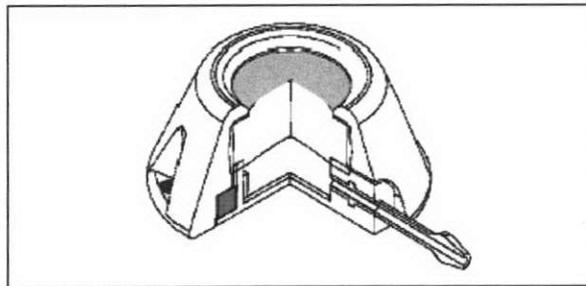


Figure 16. Cross-Section view of the Access Port II

Access ports have been reported to be “flipped” or inverted. If you initially see an oblique or side view on x-ray, then either reposition the patient or the x-ray equipment until you obtain a perpendicular, overhead (0°) view. Targeting the port for needle penetration can be difficult if this orientation is not controlled. Be aware that an upside down (180°) port shows the same image.

Steps for Performing an Adjustment

1. Shield the reproductive organs of all patients if using radiology to locate the Access Port.
2. Wash your hands with a germicidal solution. Sterile gloves are advised. Always penetrate the Access Port using aseptic technique.
3. Complete a skin prep with an antiseptic solution.

4. Locate the Access Port radiologically or by manual palpation.
5. Local anesthesia may be used to eliminate pain during injection.
6. Position the needle perpendicularly to the septum of the Access Port (Figure 17)

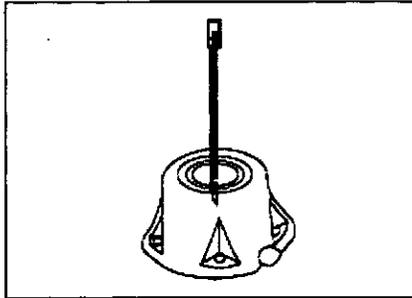


Figure 17. Needle and Access Port II

CAUTION: When adjusting band volume, the needle must be inserted perpendicular to the Access Port septum. Failure to do so may cause damage to the port and result in leaks.

CAUTION: Use of an inappropriate needle may cause Access Port leakage and require reoperation to replace the port. Do not use standard hypodermic needles as these may cause leaks. Use only LAP-BAND® System Access Port Needles.

CAUTION: Take care to ensure that the radiographic screen is perpendicular to the needle shaft (the needle will appear as a dot on the screen). This will facilitate adjustment of needle position as needed while moving through the tissue to the port.

7. When the Access Port is felt, and just prior to penetrating it, you may confirm radiographically that the needle is properly positioned. Attach a syringe to the needle before penetrating the port. A one-way stopcock can be connected to the needle to prevent fluid loss.

CAUTION: Never enter the Access Port with a “syringeless” needle. The fluid in the device is under pressure and will be released through the needle.

8. Penetrate the Access Port. The port must be penetrated until the needle is stopped by the bottom of the portal chamber. Withdraw some saline to confirm that the bevel of the needle is within the port. If, after penetration, the saline solution cannot be withdrawn or injected, the bevel of the needle may be occluded by the port septum. Try to advance the needle further into the port to the bottom of the portal chamber. If you cannot advance, then re-enter the port with another sterile needle.

CAUTION: Once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.

9. To increase stoma size: Taking into account any fluid withdrawn to confirm port

penetration, remove fluid to deflate the band and increase the stoma size. Take care to remove only enough fluid to deflate the band; avoid creating a vacuum.

10. To decrease stoma size: Taking into account any fluid withdrawn to confirm port penetration, inject additional saline to further inflate the band and decrease the stoma size.

CAUTION: Important: If fluid has been added to decrease the stoma size, it is important to establish that the stoma is not too small, before discharge. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then recheck. A physician familiar with the adjustment procedure must be available for several days post-adjustment to deflate the band in case of an obstruction.

Adjustment Following Significant Weight Loss

Once significant weight has been lost it may become possible to palpate and locate the Access Port without the use of x-ray. If this is the case, complete all the other steps, skin prep, aseptic technique, etc. An evaluation of the stoma and pouch size is recommended via a gastrografin or limited barium swallow prior to and following adjustments. This is important to avoid inadvertent overinflation of the band and possible stoma obstruction.

Band Removal/Repositioning

The band can be unlocked, removed and/or repositioned if necessary. The band is usually surrounded by a thin, clear capsule. After entering the abdomen via laparotomy or a laparoscopic approach, cut open the capsule and unlock the band as described previously, reposition the band, and complete the band placement as previously described.

Medical Imaging

The LAP-BAND[®] System has been proven to be MRI safe per testing conducted by Allergan when exposed to 3T or lower MRI scans. (Please refer to MRISafety.com for more information).

Returned Goods Policy

Authorization must be received from customer service at Allergan prior to return of the merchandise. Merchandise returned must have all the manufacturer's seals intact to be eligible for credit or replacement. Products returned may be subject to restocking charges.

No credit will be issued on marked or damaged boxes with stickers.

Special Notice

The manufacturer of the LAP-BAND AP[®] Adjustable Gastric Banding System has designed, tested and manufactured it to be reasonably fit for its intended use. However, the LAP-BAND AP[®] System is not a lifetime product and it may break or fail, in whole or in part, at any time after implantation and notwithstanding the absence of any defect. Causes of partial or complete failure include, without limitation, expected or unexpected bodily reactions to the presence and position of the implanted device, rare or atypical medical complications, component failure and normal wear and tear. In addition, the LAP-BAND AP[®] System may be easily damaged by improper handling or use. Please refer to the adverse events section in this document and to the

Information for Patients booklet for a presentation of the warnings, precautions, and the possible adverse events associated with the use of the LAP-BAND AP[®] Adjustable Gastric Banding System.

Reporting and Return of Explanted Devices

The reason for explantation should be reported and the explanted device returned to Allergan. In the event of such an explantation, please contact Product Support at 800.624.4261 for an explant kit and explant return instructions.

AUTHORIZED TRAINING PROGRAM AND PRODUCT ORDERING INFORMATION

LAP-BAND[®] System Placement is an advanced laparoscopic procedure. Surgeons planning LAP-BAND[®] System placement must participate in a LAP-BAND[®] System training program authorized by Allergan or an authorized Allergan distributor. This required training program is specific to the Allergan LAP-BAND[®] System and does not qualify for use with other gastric bands.

For additional information please contact:

Manufacturer
Allergan
Santa Barbara, CA 93111, USA
Tel: (805) 683-6761
Fax: (805) 681-5765

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

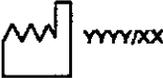
The LAP-BAND AP[®] Adjustable Gastric Banding System contains no latex or natural rubber materials.

US Patents: 5,601,604; 5,658,298.

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www.allergan.com

HM0613 L013-xx x/xx

STYLE	Device Style
	Sterile, Dry Heat Sterilized, Date of Sterilization, Year & Month
	Attention! See instructions for use.
	Single Use Only. Do Not Reuse.
	Lot Number
	Use By Year & Month
	Manufacturer
	Date of Manufacture, Year & Month
SN	Serial Number
REF	Catalog Number
	Authorized Representative in the European Community

References:

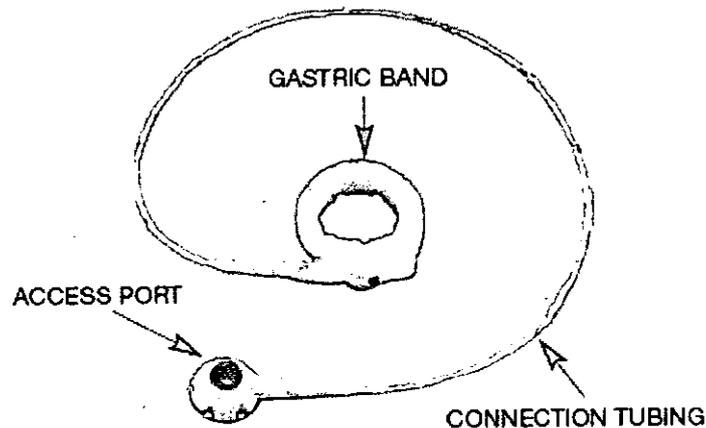
1. NIH, *Summary of recommendations, in Clinical guidelines on identification, evaluation, and treatment of overweight and obesity in adults. The evidence report.* 1998.

The LAP-BAND[®] System
SURGICAL AID IN THE TREATMENT OF OBESITY
A decision guide for adults

Caution: Federal law restricts this device to sale by or on
the order of a licensed healthcare practitioner

XXXX 2011

Image: Full size LAP-BAND® System



THE LAP-BAND® SYSTEM

Caption: The LAP-BAND® System is medical device made of soft silicone placed around the upper part of your stomach by a qualified surgeon in order to treat obesity and the health problems related to obesity. Because it restricts how much solid food you can eat at once, it helps reduce feelings of hunger and make you feel full more quickly and for a longer time.

If you are a person with obesity, your extra weight is affecting your health, and you are ready to make a serious commitment to change, the LAP-BAND® Adjustable Gastric Banding System could be the right choice for you. It's not a miracle cure—to succeed with it you have got to make a lifetime commitment to drastically change your lifestyle. Your surgeon will explain to you how truly challenging making that change will be, as well as the chances for success. But if you do your part, the LAP-BAND® System can help you control your hunger and lose weight. Before you make your decision, it's important to understand what the LAP-BAND® System involves and what it requires you to do. That's what this booklet is about.

Allergan (the maker of the LAP-BAND® System) has prepared this information to help you understand the LAP-BAND® and help you to make an informed decision. This booklet may help you answer some of the questions you have about the LAP-BAND® and about surgery in general. It will also provide you with specific information about the risk and benefits of the LAP-BAND® System.

This information cannot and should not replace discussions with your surgeon. Your decision about whether or not to get the LAP-BAND® should

be based on realistic expectations of the outcome. There is no guarantee that your results will match other individuals. Your results will depend on many factors that are specific to you, such as your overall health, age, specific illnesses you may have, as well as your commitment to a new lifestyle. Speak to your surgeon about your expectations for surgery and afterwards, and about any risks and potential complications.

What's in this booklet

Here's what this booklet can tell you before you make your decision about the LAP BAND® System:

1. Are you eligible? Page X

2. Understanding Obesity Page X

Why is obesity dangerous and why is losing weight such a struggle for some people?

3. Understanding the LAP-BAND® System Page X

What exactly does the LAP BAND® System do, and how does it work?

4. Understanding the Process Page X

If you decide to use the LAP BAND® System, what happens and what will be expected of you?

5. Making your decision Page X

6. Frequently asked questions Page X

1. Are you eligible?

The LAP-BAND® System is not right for everyone. Achieving success with the LAP-BAND® requires a lifetime commitment to changing your eating habits, a commitment which is very hard to make and at which not everyone succeeds. Here are the guidelines your surgeon will use to determine if you are eligible for it.

Indications (things that make you a good candidate for the LAP-BAND® System):

These are the factors your surgeon will consider when deciding if you are a good candidate for the LAP-BAND® System. Even if you meet all of these criteria, your surgeon may still recommend a different treatment option.:

- ✓ You are at least 18 years old.
- ✓ Your body mass index (BMI) is 30 or higher and you have a health problem related to your weight. Or if your BMI is 40 or higher. (See the explanation of BMI on page X).
- ✓ You have tried hard to lose weight but have only had short-term success.
- ✓ You do not have a disease that may have caused you to be overweight.
- ✓ You are prepared to set a lifetime goal to make drastic, challenging permanent changes to your eating habits and lifestyle.
- ✓ You are willing and able to return to your doctor for follow-up visits and band adjustments.
- ✓ You understand the information in this booklet and other information shared by your surgeon.

You must talk to your surgeon about all of these factors, especially if there are any that you do not understand fully.

Contraindications (Factors that make you a poor candidate for the LAP-BAND®)

Many factors can make you a poor candidate for the LAP-BAND® System, and your surgeon will know how to assess them. Your surgeon may decide the LAP-BAND® System is not right for you if:

You have a disease or condition, such as severe heart or lung disease, that your surgeon decides makes you a poor candidate for surgery. Any surgery involves some amount of risk. Risks can be from the surgery itself and from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions. Your risks will vary depending on your weight, age, and medical history. Your surgeon will assess if you are healthy enough for surgery.

Your throat (esophagus), stomach or intestine is not normal. For instance, you might have a narrowed opening. Because the LAP-BAND® works by controlling the amount of food that can move from the throat into the stomach, an abnormal or narrowed opening could cause a blockage of your throat. This could cause stretching (dilatation) of the esophagus. Very rarely, this can cause damage to the throat that would require the LAP-BAND® to be removed. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.

You are pregnant. For now, you should focus on being healthy during your pregnancy. Healthy eating, not weight loss, should be your main concern. Any abdominal surgery involves some amount of risk, and LAP-BAND® surgery is not recommended while you are pregnant.

If you have a LAP-BAND®, it will not interfere with you becoming pregnant or with your pregnancy if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because your period may become more regular. If you need to eat more while you are pregnant, the band can be loosened. After the pregnancy it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

You are addicted to alcohol or drugs. If you are addicted to alcohol or drugs, it may be hard for you to make major, lifelong changes to your eating habits. The LAP-BAND® will not work without these changes and you should not have this procedure. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

Also, any surgery involves some amount of risk. Risks can be from the surgery itself and from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions, including drug or alcohol addiction. Your risks will vary depending on your weight, age, and medical history. Your surgeon will assess if you are healthy enough for surgery.

You are under 18 years of age. The LAP-BAND® is currently not approved for use in people under the age of 18 years old by the US Food and Drug Administration (FDA).

You don't understand how the LAP-BAND® System works. If you don't understand how the LAP-BAND® works, it may be hard for you to make major, lifelong changes to your eating habits. The LAP-BAND® will not work without these changes and you should not have this procedure until you understand how the LAP-BAND® works. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

You are not prepared to set a lifetime weight goal and make major, lifelong changes to your eating habits required to meet that goal. You must be willing and able to make major, lifelong changes to your eating habits. The LAP-BAND® will not work without these changes and you should not have this procedure if you are not prepared to make these changes. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

Caution **You have an inflammatory disease or problem of the digestive tract, such as stomach ulcers or Crohn's disease.** If you have these problems, or take certain medicines to treat these problems, you may bleed during surgery or have trouble healing. Tell your doctor about your health problems and any medicines you are taking. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.

Caution **You have a medical problem that could cause bleeding in the throat (esophagus) or stomach. These could be problems developed over time that cause veins and/or blood vessels to get bigger such as esophageal or gastric varicies (a dilated vein). This could also include conditions you may have been born with, such as congenital or acquired intestinal telangiectasia (dilation of a small blood vessel).** These problems are rare but can cause bleeding during surgery. You may not know if you have a problem before you have surgery. Your surgeon will decide if they can continue with surgery if they find you have any of these problems.

- Caution** *You have portal hypertension (high blood pressure in your veins).* Any surgery involves some amount of risk. Risks can be from the surgery itself and from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions. Your risks will vary depending on your weight, age, and medical history. Your surgeon will assess if you are healthy enough for surgery.
- Caution** *You have experienced an injury, such as a tear at or near the location of the intended band placement.* Any damage to where the LAP-BAND® will be placed should be fully healed before surgery. Do not get a LAP-BAND® if you have any damage because it could slow healing and increase bleeding. It could also cause the LAP-BAND® to eat into the stomach and you would need an additional surgery to remove the LAP-BAND®. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.
- Caution** *You have cirrhosis, other types of liver disease or chronic pancreatitis (a swollen or inflamed pancreas that lasts for a long time).* These problems may indicate that you are not healthy enough for surgery, or could cause bleeding. These problems are rare but can cause bleeding during surgery. You may not know if you have a problem before you have surgery. Your surgeon will decide if they can continue with surgery if they find you have any of these problems.
- Caution** *You have an infection anywhere in your body or one that could affect the surgical area.* An infection could increase the risk of surgery and potentially lead to problems with the LAP-BAND®.
- Caution** *You are on constant, long-term steroid treatment.* If you have used steroid medicines for a long time, it may be harder to heal after the LAP-BAND® surgery. This could cause an increased risk of problems. Tell your doctor about any medicines you are taking. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.
- Caution** *You are allergic to materials in the device.* Allergies to the materials in the LAP-BAND® device are rare. Tell your surgeon if you have an allergy to silicone, nickel or titanium. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.

Caution *You think you will not be able to stand the post-operative pain or have a history of not being able to stand pain in general.* Pain from LAP-BAND® surgery is usually felt in the areas around the cuts (incisions) made during surgery. Most people find the pain to be mild to medium. Pain is often treated with over-the-counter medicines such as non-steroidal anti-inflammatory drugs (like Advil) or acetaminophen (like Tylenol). Tell your surgeon if you have concerns about pain. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.

Caution *You have an autoimmune connective tissue disease, which might be a disease such as systemic lupus erythematosus or scleroderma. The same is true if you have symptoms of one of these diseases.* If you have these problems, or take certain medicines to treat these problems, you may bleed during surgery or have trouble healing. Tell your doctor about your health problems and any medicines you are taking. Your surgeon can assess your specific risks and determine if the LAP-BAND® is right for you.

You must talk to your surgeon about all of these factors, especially if there are some you do not understand fully.

What are the risks?

Before you decide on surgery to treat obesity, you should know what the risks of the surgery are. Talk with your surgeon in detail about all the possible risks and complications. This information will help you make an informed decision.

Risks and Warnings:

Warning: Any type of surgery involves some degree of risk, including abdominal surgery and bariatric surgery. Surgical risks are even greater when the patient is obese or has other underlying medical conditions. Specific risks will vary depending on a person's weight, age, and medical history.

The LAP-BAND® System placement includes the same risks as all major surgeries. Risks of general surgery can include:

- Damage to the spleen or liver that can sometimes cause the removal of the spleen
- Damage to major blood vessels
- Lung problems
- Blood clots (thrombosis)
- Tearing or infection of the wound
- Tearing of the stomach or esophagus during surgery

Death is one of the risks of surgery. It can occur any time during the operation or as a result of complications from the operation, despite all the precautions that are taken by your surgeon. In over 15 years of use of the LAP-BAND[®], deaths have occurred in 0.006 percent of patients (about one in 17,000).

In addition to the risks of general surgery, the following risks and complications are possible following surgery to place the LAP-BAND[®] System:

What adverse events could happen if I get a LAP-BAND [®] System?	How likely is it that this adverse event would happen to me? In the first year after placement of the LAP-BAND [®] System...	What could happen if I experience this adverse event?	What should I do if I experience this adverse event?
You may throw up (vomit) or cough up food that you just ate (regurgitation)	51 percent of patients with a BMI of 40 or greater experienced vomiting and/or nausea in the clinical trial. 29 percent of patients with a BMI between 30 and 40 experienced vomiting or regurgitation in the clinical trial.	Throwing up is unpleasant and may cause dehydration.	After your surgery, you must allow the new stomach structure to heal completely and in the right position. It may take a month or more for this to happen. It is very important to follow your eating and drinking instructions after the operation.
You may have difficulty swallowing (dysphagia)	9 percent of patients with a BMI 40 or greater had difficulty swallowing in the clinical trial. 22 percent of patients with a BMI between 30 and 40 had difficulty swallowing in the clinical trial.	If you have difficulty swallowing, it may be hard for you to take in enough food and fluids to get enough nutrients.	To help prevent adverse events, you must choose the right foods, eat small meals, eat slowly and chew food thoroughly. If you cannot eat or drink for more than 12 hours, you should call your doctor.
You could experience gastroesophageal reflux disease (GERD)	34 percent of patients with a BMI of 40 or greater reported GERD in the clinical trial. 15 percent of patients with a BMI between 30 and 40 reported GERD in the clinical trial.	GERD can damage the throat (esophagus) from stomach acid backing up (refluxing). This can make swallowing difficult.	
You may feel nausea	51 percent of patients with a BMI of 40 or greater experienced nausea and/or vomiting in the clinical trial. 5 percent of patients with a BMI between 30 and 40 experienced nausea in the clinical trial.	Nausea is unpleasant and can make it difficult to eat or drink. If this happens over a long time, you could become dehydrated.	
You may experience indigestion or upset stomach (dyspepsia)	0.7 percent of patients with a BMI of 40 or greater experienced indigestion or upset stomach in the clinical trial. 5 percent of patients with a BMI between 30 and 40 experienced indigestion or upset stomach in the clinical trial.	Indigestion and upset stomach can be unpleasant. This can make it difficult to eat or drink. If this happens over a long time, you could become dehydrated.	

What adverse events could happen if I get a LAP-BAND® System?	How likely is it that this adverse event would happen to me? In the first year after placement of the LAP-BAND® System...	What could happen if I experience this adverse event?	What should I do if I experience this adverse event?
You feel pain in your abdomen	27 percent of patients with a BMI of 40 or greater reported pain in their abdomen in the clinical trial. 5 percent of patients with a BMI between 30 and 40 reported pain in their abdomen in the clinical trial.	Pain from LAP-BAND® surgery is usually felt in the area around the cut (incision). Most people find the pain to be mild to medium.	Pain is often treated with over-the-counter medicines such as non-steroidal anti-inflammatory drugs or acetaminophen. Tell your surgeon if you have concerns about pain.
You experience pain following the surgical procedure to implant the LAP-BAND®	5 percent of patients with a BMI of 40 or greater reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial. 19 percent of patients with a BMI between 30 and 40 reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial.		
You have pain at the site where the LAP-BAND® was implanted	5 percent of patients with a BMI of 40 or greater reported pain at the incision site following the surgical procedure to place the LAP-BAND® System in the clinical trial. 5 percent of patients with a BMI between 30 and 40 reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial.		
You have a leak in the LAP-BAND® device	In over 15 years of use of the LAP-BAND®, leaks have occurred in 0.850 percent of patients.	A leak in the LAP-BAND® will not allow the device to work properly and will need to be corrected surgically.	A leak in your LAP-BAND® will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device.
Your new stomach pouch stretches (pouch dilatation) after surgery	24 percent of patients with a BMI of 40 or greater experienced a pouch dilatation and/or band slip in the clinical trial. 1 percent of patients with a BMI between 30 and 40 experienced a pouch dilatation in the clinical trial. In over 15 years of use of the LAP-BAND®, pouch dilatations have occurred in 0.03 percent of patients.	A slip in the placement of the LAP-BAND® will not allow the device to work properly and will need to be corrected.	A slip in your LAP-BAND® will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device.

What adverse events could happen if I get a LAP-BAND [®] System?	How likely is it that this adverse event would happen to me? In the first year after placement of the LAP-BAND [®] System...	What could happen if I experience this adverse event?	What should I do if I experience this adverse event?
Your LAP-BAND [®] slips (moves from its original position) after surgery	<p>24 percent of patients with a BMI of 40 or greater experienced a LAP-BAND[®] slip and/or pouch dilatation in the clinical trial.</p> <p>1 percent of patients with a BMI between 30 and 40 experienced a LAP-BAND[®] slip in the clinical trial.</p> <p>In over 15 years of use of the LAP-BAND[®], slips have occurred in 0.13 percent of patients.</p>	A slip in the placement of the LAP-BAND [®] will not allow the device to work properly and will need to be corrected.	A slip in your LAP-BAND [®] will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND [®] device.
Your LAP-BAND [®] erodes into the lining of the stomach	<p>1 percent of patients with a BMI of 40 or greater experienced a LAP-BAND[®] erosion in the clinical trial.</p> <p>0.7 percent of patients with a BMI between 30 and 40 experienced a LAP-BAND[®] erosion in the clinical trial</p> <p>In over 15 years of use of the LAP-BAND[®], erosion has occurred in 0.046 percent of patients.</p>	Erosion of the LAP-BAND [®] may cause pain and will not allow the device to work properly. This will need to be corrected surgically.	If your LAP-BAND [®] erodes into the stomach, it will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND [®] device.
You experience stretching of the esophagus (esophageal dilatation)	<p>2 percent of patients with a BMI of 40 or greater experienced esophageal dilatation in the clinical trial.</p> <p>1 percent of patients with a BMI between 30 and 40 experienced esophageal dilatation in the clinical trial.</p> <p>In over 15 years of use of the LAP-BAND[®], stretching of the esophagus has occurred 0.021 percent of patients.</p>	Stretching of the esophagus may cause pain and will not allow the LAP-BAND [®] to work properly. This will need to be corrected.	<p>If your LAP-BAND[®] causes stretching of the esophagus, the band will need to be deflated. An additional surgical procedure may be necessary to reposition or remove the band.</p> <p>To help prevent esophageal dilatation eat small meals, eat slowly and chew food thoroughly.</p>

Other adverse events that were considered to be related to the LAP-BAND® System, and which occurred in less than 1% of the patients with a BMI of 40 or greater during the first three years, included: esophagitis (inflammation of the esophagus), gastritis (inflammation of the stomach), hiatal hernia (stomach protruding into the chest), pancreatitis (inflammation of the pancreas), abdominal pain, hernia, incisional infection, infection, redundant skin, dehydration, gastrointestinal perforation (tear of the stomach), diarrhea, abnormal stools, constipation, flatulence (gas), dyspepsia (upset stomach), eructation (belching), cardiospasm (disorder of the muscles used in swallowing), hematemesis (vomiting blood), asthenia (fatigue), fever, chest pain, incision pain, contact dermatitis (inflammation of the skin due to contact with a substance), abnormal healing, edema (accumulation of fluid in the skin, paresthesia (numbness or tingling), dysmenorrhea (abnormal periods), hypochromic anemia, band leak, cholecystitis (inflammation of the gallbladder), esophageal dysmotility (disorder of the muscles used to transport food to the stomach), esophageal ulcer (sore), port displacement, port site pain, spleen injury, and wound infection.

Other adverse events that were considered to be related to the LAP-BAND® System, and which occurred in less than 5% of the patients with a BMI between 30 and 40 during the first year, included: medical device complication (band too tight, tubing migrated into a hernia), device malfunction (flipped port), dehydration, diarrhea, gastritis (inflammation of the stomach), syncope (fainting), seroma (pocket of clear fluid), abdominal discomfort, flatulence (gas), gastrointestinal motility disorder (disorder of the muscles used to transport food to the stomach), esophageal obstruction, esophageal spasm, bronchitis, implant site infection, nail infection, postoperative infection, urinary tract infection, chills, implant site hemorrhage (bleeding), implant site irritation, pyrexia (fever), alopecia (hair loss), hypotrichosis (abnormal hair growth), night sweats, skin irritation, arthralgia (joint pain), back pain, muscle spasms, headache, anemia, blood folate decrease, depression, and hypertension (high blood pressure).

The importance of your body mass index

Knowing your body mass index (BMI) can help you understand whether you might qualify for the LAP-BAND® System.

Your body mass index is the number you get if you divide your weight in kilograms by your height (in meters) squared. It is essentially a way to combine your height and weight into a single measure. It helps determine how much excess weight you carry.

To find out your BMI, see **What's your BMI?**, at right.

If your BMI is 30 or more, you are said to be obese. Although it depends on height, usually people who are obese (BMI of 30) are at least 30 pounds overweight. That means you are at risk for health problems. If your BMI is 40 or more, you are said to be morbidly obese, with a high risk of health problems. Surgery is a good approach for people with a BMI of 30 or more whose weight is impacting their health.

Sidebar: What's your BMI?

Here's how to find out. On the left, find the row that's closest to your weight. Then, find the column that's closest to your height. In the square where your row and column cross, you'll see your BMI. See what color that square is. Then, look below the table to see what the color means.

Ideal weight to overweight: You are not eligible for the LAP-BAND® System.

Obesity: You may be eligible for the LAP-BAND® System.

Image: BMI chart

Removing the LAP-BAND® System

The LAP-BAND® System is an implanted device intended for long-term use, but it may need to be removed, repositioned or replaced to manage complications or adverse events or if you aren't losing as much weight as your surgeon feels you should be losing.

If the LAP-BAND® System has been placed laparoscopically, it may be possible to remove it the same way. However, an open procedure may be necessary to remove it. In the U.S. clinical study of morbidly obese adults (BMI of 40 or greater), the majority of the LAP-BAND® Systems that were removed were done laparoscopically. In the U.S. clinical study of obese adults, all were removed laparoscopically. After the LAP-BAND® System is removed, the stomach normally returns to the size it was before surgery. It is common for people to regain weight after having their LAP-BAND® System removed.

The LAP-BAND® System is intended to stay in place for the rest of your life. If your LAP-BAND® System is removed, readjusted, or replaced, the surgery will have the same risks as with any other surgery. The risk of some problems increase with any added procedure. Your surgeon will be able to explain this to you fully. You may also find out more about surgery and its risks at <http://www.nlm.nih.gov/medlineplus/surgery.html>, a site of the National Institutes of Health.

Benefits

The benefit of this device is weight loss, which in turn can lead to improvements in other health conditions. The device will not work or will not work well if you are not willing to make a major, lifelong change to your eating habits. If you do not make the major, lifelong changes required, you will have endured the risks of surgery and of having an implanted LAP-BAND[®] for the rest of your life without getting the benefits of the device.

Your first step is committing to a goal.

[INSERT PLEDGE CARD HERE]

I am willing to set a goal of making major, lifelong changes to my eating habits. These changes will be very challenging and not all patients succeed.

My long-term weight loss goal is _____

Signed _____ Date _____

Continue reading to determine if the LAP-BAND[®] System is the right choice for you.

An important decision

Should you have surgery for weight loss? That's a decision you'll have to make after a careful discussion with your doctor and a surgeon who is certified to perform the LAP-BAND[®] System surgery.

In the end, your surgeon is the best person to decide if you are eligible for the LAP-BAND[®] System, and if the system is appropriate for you.. It may also be worthwhile for you to read the rest of this booklet and learn more about what's involved.

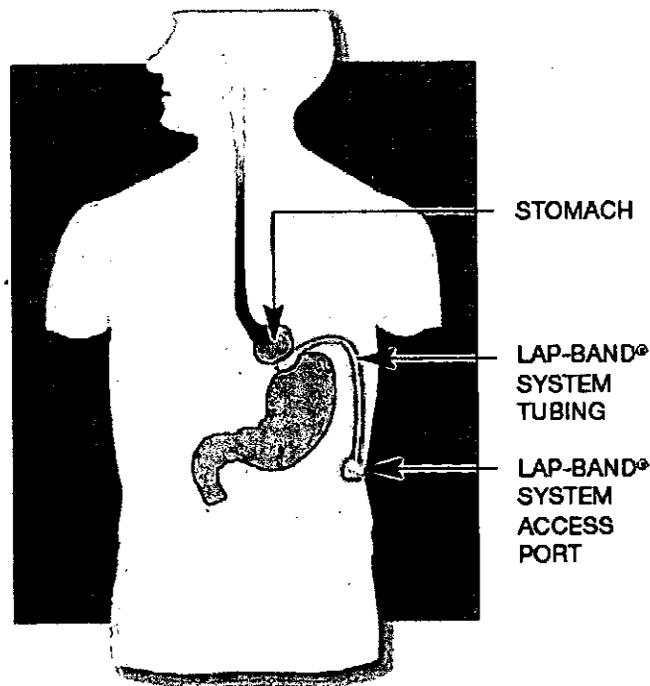
Sidebar: What is the LAP-BAND® System?

The LAP-BAND® System is an implanted soft adjustable band made of silicone that your surgeon places around the upper part of your stomach. The band creates a small stomach pouch above where it sits, with the rest of your stomach below. With the band, you need less food to feel full and you feel full for a longer time. This, combined with a major, lifelong change to your eating habits, helps you lose weight.

The band is hollow, almost like an inner tube, and is filled with a saline solution. The band is connected by a thin tube to a “port” that sits under your skin, to one side of your belly button.

To make the band tighter or looser, a trained health professional uses a fine needle to inject or remove saline solution through the port. This can be done during a routine office visit.

Image: Stomach with LAP-BAND® System



Caption: The LAP-BAND® System creates a small upper stomach pouch.

Forms you might have to sign

Your surgeon can play an important part in helping you to decide whether to get the LAP-BAND® System. If your surgeon gave you this booklet, he may ask you to sign these forms in the back.

- **My Surgeon Gave Me this Booklet** shows that you received this booklet from your surgeon.
- **I Read and Understood What's in this Booklet** shows that you have read the booklet, understood its contents and received counseling from your surgeon.

2. Understanding Obesity

What is obesity?

The LAP-BAND® System is designed to treat obesity. But what exactly is obesity, anyway?

Obesity is a medical condition in which a person has much more body fat than is healthy. In fact, there may be enough extra fat to hurt a person's health, and even reduce the number of years they are expected to live.

Obesity is measured by the body mass index (BMI). The body mass index is a number that compares your weight to your height. This number tells how much excess weight you have. A healthy BMI is no more than 25. A person who is considered obese may have a BMI of 30, or even higher. To find out what your BMI is, look at page 0.

You may hear doctors talk about different degrees of obesity. Obesity starts when a person has a BMI of 30. A BMI of 40 or more is considered morbid obesity. "Morbid" might sound like an odd word to describe someone's weight. It means that the excess weight can cause diseases—which doctors sometimes call "morbidity."

What causes obesity?

If you are a person with obesity you may wonder, "What caused me to be obese? Is it my fault?" First, read about the five main causes of obesity below—and then we'll ask these questions again.

Cause 1 • Energy imbalance

To work properly, your body needs the energy that comes from food.

When your food gives you the same amount of energy your body needs, your weight stays the same. If your food gives you more energy than you need, some energy is left over. Your body stores that leftover energy as fat. If your body does not burn that extra fat, you gain weight.

The amount of energy you need from food depends on how fast your body uses energy. Some people use energy faster than others. We say they have a high metabolism. Other people use energy slower than others. We say they have a low metabolism.

A low metabolism makes it harder to keep weight at a healthy level and can contribute to obesity.

Cause 2 • Metabolic disorders

Some people have metabolic disorders—medical conditions that keep certain body organs from functioning normally and which affect metabolism. One common example of a metabolic disorder is diabetes. Trouble with the thyroid gland can also affect metabolism.

People with metabolic disorders often have extra difficulty controlling their weight and may struggle with obesity.

Cause 3 • Heredity

Your heredity is the traits you inherit from your parents. If your parents are tall, blue-eyed, or dark-haired, chances are greater that you will be, too. Obesity works the same way. If members of your family are obese—like your parents or brothers and sisters, for example—then chances are greater that you will be.

A study done in Canada showed that this is true. The study looked at twelve pairs of identical twins—people with identical heredity. In the study, all of the twins ate more calories than their bodies needed, and gained different amounts of weight. But within each pair, both twins gained the same amount of weight. That suggests their heredity has a lot to do with weight gain. Everyone inherits a certain chance of having obesity, and everyone's chance is different.

In addition, research shows that some weight-related body processes don't work as well in people with obesity as in others. These processes include how the body burns fat, how much energy it needs (metabolism), and how hunger and fullness are felt.

What does all this mean? It means that if someone inherits a tendency to gain weight, or inherits weight-related body processes that don't work well, this heredity may help cause them to become obese.

Cause 4 • Eating and activity habits

We all have habits. For example, you might be in the habit of watching TV after work. Often, we form our habits without thinking much about them. Once they are formed, habits can become strong.

Some habits have to do with eating, and some eating habits can lead to obesity if they become too frequent. Here are some examples:

- eating fast food
- eating high-calorie snacks
- eating large portions
- eating food that's full of fat or sugar
- drinking high-calorie soft drinks or coffee drinks

How much physical activity you get can become a habit, too. If you get in the habit of always taking a car instead of walking, or always using an elevator instead of stairs, your body burns fewer calories and turns more of your food into fat. That can contribute to obesity. In short, if you take in more calories than you burn, you will gain weight.

Cause 5 • Psychological factors

Sometimes we eat because we are hungry. But sometimes we eat because of thoughts and feelings—psychological factors.

For example, we may eat to ease stress, such as before a presentation or a big family event. We may eat for comfort when we are sad. Sometimes we eat to be social, like at a party where snacks are served. For some people, the smell or color of food triggers them to eat. For others, certain situations trigger them to eat, like being out with friends or watching TV.

These psychological factors can be very powerful. By leading us to eat when our bodies don't really need the extra food, they can contribute to obesity.

So, now let's ask our questions again. What causes someone to be obese? Is it his or her fault?

As you've seen, many powerful causes of obesity are out of our control.

People cannot control their heredity, their metabolism or the medical conditions that may affect how their bodies use food energy. But they *can* work on their habits, thoughts and feelings. It is not easy, and it won't happen overnight, but choosing to do something about obesity is a decision every person can make.

Why is obesity a problem worth solving?

Why is obesity considered to be such a problem? Why is it so important to do something about it? What are the benefits of losing the weight?

Risks to your health

If you are a person with obesity, you probably already know that weighing more than you should is bad for your health. There's no way to sugarcoat it: people who are obese are much more likely to get serious illnesses. Once you have an illness, obesity can make it much worse. The more weight you gain, the more risks you face. As a result of all this, your life expectancy is shorter.

There is a long list of illnesses associated with obesity. Here are some important ones:

- High blood pressure
- Heart disease
- High cholesterol
- Coronary artery disease
- Gallbladder problems
- Type 2 diabetes (a disease in which the body doesn't produce enough insulin)
- Breathing problems such as asthma
- Certain types of cancer
- Sleep apnea (a sleeping disorder that causes pauses in breathing during sleep)
- Osteoarthritis
- Gastroesophageal reflux disease (acid reflux)
- Joint problems

As if all that wasn't enough, if you are a women, obesity can also affect your ability to get pregnant and raise your risk of health problems during pregnancy and childbirth. It even makes it harder for you to get the exercise that could help your health improve.

You are at a crossroads. If you are obese now, the odds are high that, without effective action, you'll be obese for the rest of your life—facing all of the health risks we've discussed. But if you *do* take action, you can change the course of your health for the better.

Weight loss can help improve asthma, sleep apnea, diabetes and other weight-related conditions. And it can reduce the chance that many serious illnesses will strike you later in life. Losing your excess weight makes it easier for you to maintain a healthy, active lifestyle.

Risks to your mental and social well-being

All of us deserve to have fun and friends. But for some adults, obesity affects the way they feel about themselves and hurts their social life.

There can be many reasons for this. Some obese people are excluded from social groups. Some find it harder to make friends or to date. Some feel uncomfortable participating in sports or wearing swimsuits. If these kinds of experiences go on long enough, some people may find themselves isolated from other people and feeling depressed.

Not everybody with obesity faces all of these difficulties. Even so, if you are obese you might know what it's like to feel that you're treated differently than people of average weight, or that people don't see you for who you really are.

Inconveniences of everyday life

If you are a person with obesity, it can be harder to do many of the normal, day-to-day things that many people take for granted.

For example, if you have to walk a few blocks or climb stairs, you may get tired quickly or have breathing problems. You may have to spend extra time shopping to find clothes that you feel comfortable in and look good in. Bus or plane seats, restaurant booths, and cars may be too small and uncomfortable to sit in. It may be hard to tie your shoes or scratch an itch.

All in all, obesity can be a hassle.

What are your options for dealing with obesity?

There are several options to treat obesity. Some treatments do not involve surgery and some do.

Non-surgical treatments for obesity

The most common approach for losing weight is to exercise more, eat less and eat healthier food. When you do these things, you burn more calories than you eat, which is the key to losing weight. But if you are a person with obesity, this approach may not be enough. Sticking to a diet and maintaining an appropriate activity level is hard to do.

Some people work with a doctor or a dietician to help them change their lifestyle. A program focused on better eating habits and greater activity levels can help you lose weight. Some people use prescription or over-the-counter drugs to try to lose weight. People who use drugs to lose weight often regain the weight over time and sometimes end up weighing even more.

Some people replace meals with special drinks/shakes. Many people who lose weight this way quickly gain it back when the diet ends. This yo-yo effect can lead to additional weight gain and make it harder to lose weight in the future.

Some people use other options such as going under hypnosis, or seeking behavior therapy or counseling.

However, studies show that diets, drugs, weight loss aids and other temporary measures usually don't help people with obesity to maintain permanent weight loss and a healthy lifestyle over the long run.

Surgical treatments for obesity

If you have tried diet and exercise and other methods, but they have not helped you to lose weight and keep it off, surgery may be another option to consider. Weight loss surgeries are meant for people who are suffering from obesity.

If you are considering surgery to treat obesity, it is important to understand your options. No matter which kind of surgery you may choose, remember that to succeed you must change your habits for the rest of your life. While the surgery will help, you must commit to eating less food and eating healthier food, changes which can be very challenging.

Comparing surgical treatment options

Surgery to treat obesity works in one or more ways. Restrictive surgery reduces how much food the stomach can hold. Malabsorptive surgery shortens the digestive tract. In both cases, your body doesn't get as many food calories as before.

Below is a short overview of the two most common types of surgery for obesity. For more information, visit <http://www.nlm.nih.gov/medlineplus/weightlossurgery.html>, a website of the National Institutes of Health, or visit the Obesity Action Coalition website (obesityaction.org.) Both surgeries carry risks. Only your surgeon will be able to tell you which surgery, if any, makes sense for you.

1. Gastric Bypass

In this procedure, the surgeon makes the stomach smaller, usually by stapling off a part of it from the rest, and then attaches a part of the intestines to it. Because the stomach is smaller, patients cannot eat as much food as before. Since the bypassed section of their intestines no longer digests food, patients absorb fewer nutrients and calories from food. Gastric bypass surgery is a restrictive and malabsorptive type of surgery. This surgery can be reversed, if necessary.

2. The LAP-BAND® System

During LAP-BAND® System surgery, the surgeon makes the stomach smaller by placing an adjustable silicone band around the upper part of the stomach. This reduces how much food the stomach can hold and makes patients feel fuller sooner so they eat less. LAP-BAND® surgery is a restrictive type of surgery.

The LAP-BAND® System requires no cutting or stapling of your stomach. The LAP-BAND® System can be tightened or loosened to fit the needs of your changing body in the months and years following surgery. The LAP-BAND® System can also be removed, if necessary.

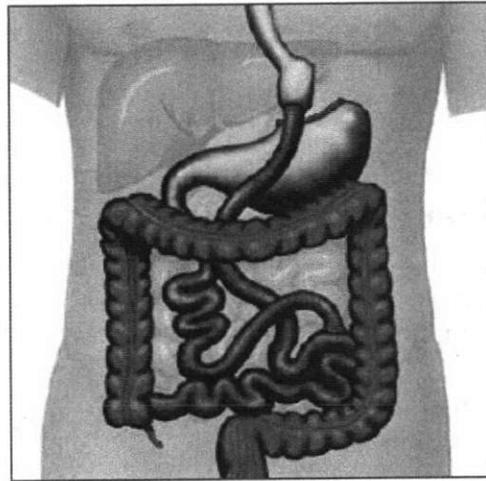
Sidebar: Two common types of surgery for obesity

Gastric bypass and the LAP-BAND® System are two surgical ways to treat obesity.

Gastric bypass: The stomach is made smaller, usually with staples, and attached to a lower part of the intestines, shortening the digestive tract.

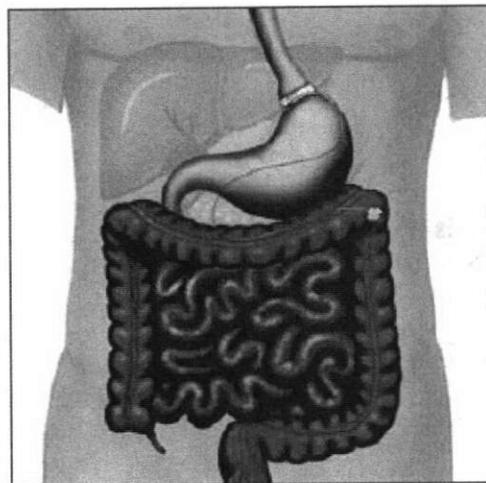
The LAP-BAND® System: The stomach is wrapped with an adjustable silicone band that creates a small upper pouch. The band can be tightened or loosened without surgery.

Image: Gastric bypass stomach



GASTRIC BYPASS

Image: LAP-BAND® System stomach



THE LAP-BAND® SYSTEM

Call outs in Section 2

- People cannot control their heredity, but choosing to do something about their obesity is a decision every person can make.
- Weighing more than you should is bad for your health.
- Losing your excess weight makes it easier for you to maintain a healthy, active lifestyle.
- If you have tried diet and exercise and other methods, but they have not helped you to lose weight and keep it off, surgery may be another option to consider.
- To find a LAP-BAND® System certified surgeon in your area, use the surgeon locator at lapband.com

3. Understanding the LAP-BAND® System

What is the LAP-BAND® System?

The LAP-BAND® System includes a special device (the band) that restricts the capacity of your stomach.

The device is a silicone band that's placed around your stomach and divides it into two sections—a small upper pouch and a larger lower pouch. The band is about the size of a small napkin ring. It opens up to go around your stomach, then fastens shut.

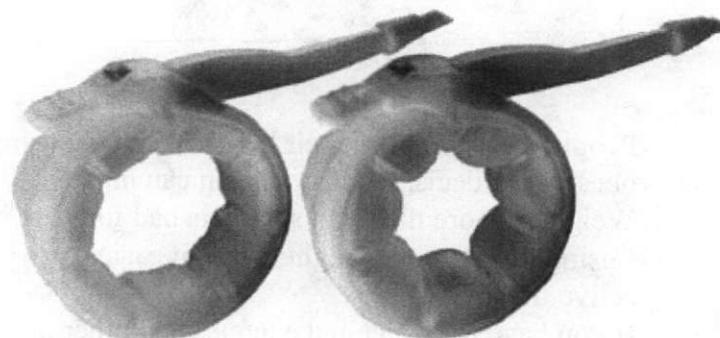
The band is adjustable. The inside part of the band is hollow, almost like an inner tube, and it holds a saline solution (salty water). This inside part is connected by a thin, flexible tube to an access port that sits under your skin on one side of your belly button. To make the band tighter or looser, your surgeon can use a fine needle to inject or remove saline solution through the access port.

The system is not visible from the outside. The gastric band itself is not visible anywhere on your body. You may be able to feel the access port under your skin, but usually no one will be able to see it.

Sidebar: Why is it called LAP-BAND®?

The name "LAP-BAND®" combines the surgical technique (**laparoscopic**) with the product name (**gastric band**)

Image: LAP-BAND® System



LAP-BAND® SYSTEM
DEFLATED

LAP-BAND® SYSTEM
INFLATED

How is the band placed?

Your surgeon places the band around the upper part of your stomach through a surgical procedure. The procedure is done under general anesthesia, meaning that you are put to sleep. It's usually done as laparoscopic surgery, meaning that it is done through several small incisions (cuts.) This is different from an open procedure, which is done through one large cut.

Sidebar: What happens in the surgery

Here is what will happen during a typical surgery using the laparoscopic procedure:

The surgeon makes a few small cuts between one-half inch and one inch long on your torso and inserts narrow tubes to guide the surgical tools. A special camera in one tube shows the surgeon what is happening.

Using long, thin tools, the surgeon places the band around the top part of your stomach, creating a small upper stomach pouch.

The surgeon then sutures (sews) part of the lower stomach over the band to hold it in place. The rest of the lower stomach stays in its normal position.

The surgeon places the access port under your skin and connects it to the band's tubing. The port is sutured to part of your abdominal muscle.

Benefits of laparoscopic procedures

Because surgery can usually be completed through a laparoscopic procedure, most people who receive the LAP-BAND® System can enjoy the benefits of this less invasive method. These benefits include:

- Fewer complications: studies show laparoscopic surgery is less risky than open surgery.
- Less pain: after a laparoscopic surgery, most people feel much less pain compared to open surgery.
- Faster recovery: patients heal more quickly and can return to their normal routine in less time.
- No large scars: If the procedure is completed laparoscopically, there are usually only several small scars, each about half an inch to an inch long. The scar on the access port may be one to three inches long.

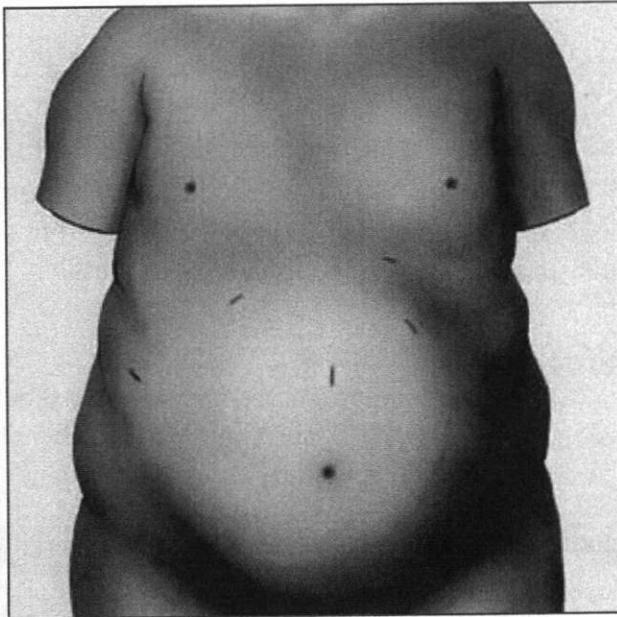
If you need an open procedure

Sometimes laparoscopic surgery can't be done, or the surgeon may need to change to an open surgery during the operation. There could be a number of reasons for this. For instance, bleeding or problems placing the LAP-BAND® System could make an open procedure necessary.

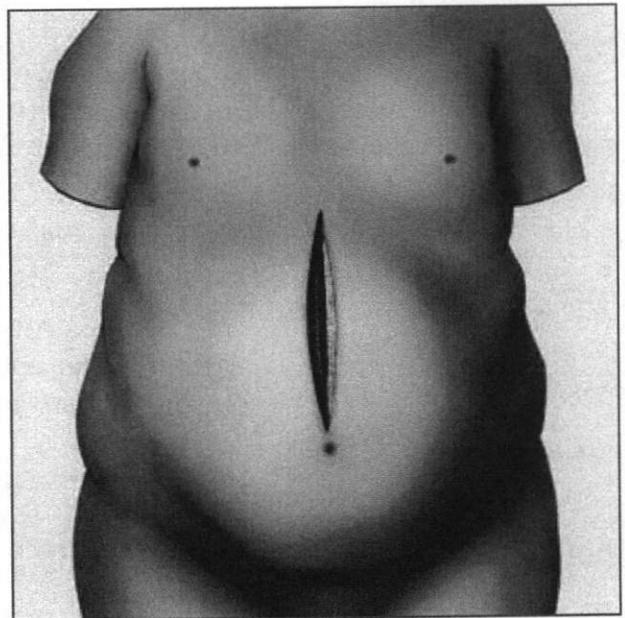
If the surgeon needs to switch to an open procedure during surgery, you will not be aware of it because you are already under anesthesia. In an open procedure, the surgeon will make a larger incision (cut) in the abdomen to perform the operation.

In the U.S. clinical study of adults with a BMI of 40 or greater, about 5% of the patients were switched to an open procedure after laparoscopic surgery started. In the second U.S. clinical study of obese adults with BMI between 30 and 40, none of the patients were switched to an open procedure after laparoscopic surgery started.

Image: Incisions for laparoscopic surgery vs. for open surgery



LAPAROSCOPIC PROCEDURE



OPEN PROCEDURE

How does the LAP-BAND® System work?

Once the LAP-BAND® System is in place, how does it work to help you lose weight?

With the band in place, the small pouch above the band can hold only a small amount of food. In order to be digested, the food has to pass through the opening between the upper pouch and lower pouch. The band controls the size of the opening, called the stoma, which controls how quickly food can pass from the upper to the lower pouch. The smaller the stoma, the longer it takes for food to pass from the upper to lower pouch.

With the band in place, you are less hungry, it takes less food for you to feel full, and you feel full for a longer time. You eat less food, which means your body draws on its fat reserves to get the energy it needs, and you lose weight.

How does the LAP-BAND® System help you lose weight?

The LAP-BAND® System helps you lose weight in three ways:

- *Reducing* your hunger
- *Reducing* how much your stomach can hold
- *Increasing* the amount of time that you feel full

As a result, your body absorbs fewer calories from food and burns fat to replace the missing calories. You lose weight.

Your role

Being successful with the LAP-BAND® System depends on you making a major, lifelong change to your eating habits a change which is very hard to make. You have to set a goal and stick to it. If you don't, you may lose no weight or very little. In addition, you will have undergone the risks of surgery and of living with an implanted LAP-BAND® System without taking full advantage of the benefits. The LAP-BAND® System has the potential to change your life, but the change has to start with you.

Adjustable based on your progress

One of the benefits of the LAP-BAND® System is that it can be adjusted to give you and your surgeon control of your progress. If the band is too loose and you are not losing weight (or not losing enough,) your surgeon can add more saline to your band to make the opening smaller. If the band is too tight, the surgeon can remove some saline.

Follow-up visits for adjustments are a critical step for a successful LAP-BAND® System patient. Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight. Adjustments are a part of the follow-up for the procedure and are usually done during a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be performed in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few minutes. Most patients say it is nearly painless.

If for any reason you need to loosen the band's restriction—for example, if you become pregnant or ill—your surgeon can deflate the band partially or completely.

Except in an emergency, only a surgeon or clinician trained and authorized by Allergan, Inc. (the company that makes the LAP-BAND® System) should adjust your band. In an emergency, someone familiar with the handling of ports and Huber needles can deflate the band then call a LAP-BAND® surgeon. Never try to adjust your own band. You could injure yourself and damage the LAP-BAND® System. If you move or are traveling, you should work with your surgeon to understand the best places to receive ongoing or emergency care.

To get the best results, you will likely need several adjustments over time. During each adjustment, only a very small amount of saline will be added to or removed from the band. The exact amount of fluid required to make the stoma the right size is different for each person. An ideal “fill” should be just tight enough to let you lose weight steadily over time. That means you should still be able to eat enough to get the nutrients you need while still reducing the overall amount you can eat.

Weight loss with the LAP-BAND® System is typically slow and steady, compared to other surgical methods of weight loss. The band should not be tightened too quickly or too tightly to try to speed up weight loss. This could cause the stomach pouch and/or esophagus (the tube that connects your mouth to your stomach) to become enlarged. You should be able to eat most foods, just smaller portions.

LAP-BAND® and pregnancy

The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because your menstrual cycle may become more regular. If you need to eat more while you are pregnant, the band can be loosened. After the pregnancy it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

Sidebar: Band adjusts as your needs change

With the LAP-BAND® System, your band can be adjusted by adding or removing saline solution. Your surgeon can tighten it to help you keep losing weight, or loosen it for a better fit. It can also be loosened in case of illness.

Day of surgery:

The band is at its widest opening, with very little saline inside.

Four to six weeks after surgery:

Saline may be added to tighten the band and help you lose weight.

Adjustments as needed:

Saline is added to or removed from the band to fit your needs.

Designed for long-term use

The LAP-BAND® System is designed to stay in your body long-term. It does not need to be removed, but if a problem occurs or you do not lose weight, your surgeon may reposition, remove or replace it.

If the LAP-BAND® System was placed laparoscopically, it may be possible to reposition, remove or replace it in the same way. This is an advantage of the LAP-BAND® System. Rarely, an open procedure is needed to remove it.

If you are considering having your LAP-BAND® System removed, you should discuss your concerns with your surgeon. Removing the band will allow your stomach to return to the size it was before your surgery and your digestive tract to the way it normally functions, which means your weight will likely increase.

Benefits of the LAP-BAND® System

There is no way to predict how much weight you will lose with the LAP-BAND® System. Some people lose more weight with the LAP-BAND® System than others. Getting the LAP-BAND® System doesn't guarantee that you will reach your goal weight or even lose weight.

The LAP-BAND® System will not solve your weight problem by itself--you have to set a goal to make major, lifelong changes to your eating habits. That means eating less food and eating healthier food, changes which are very challenging. How much weight you lose depends on how committed you are to doing your part. It is possible to lose two to three pounds a week in the first year after the operation, but one pound a week is more likely. It is also possible to lose less or none at all. Individual results vary. Twelve to 18 months after the operation, weekly weight loss usually slows or stops.

How much weight have other people lost?

In a clinical study of morbidly obese adult patients (BMI 40 or greater) from 1995 to 2001, the average patient lost approximately 36% of his or her excess weight three years after surgery. In a different clinical study of obese adult patients (BMI between 30 and 40) from 2007 to 2009, the average patient lost approximately 65% of his or her excess weight one year after surgery.

Excess weight means the extra pounds you carry above your ideal weight. For example, if your ideal weight is 155 pounds and you weigh 255 pounds, then you are 100 pounds overweight. This is your excess weight. If you lose 33% of your excess weight, then you lose 33 pounds.

The table below shows how much excess weight different adult patients lost in the two studies.

Results with the LAP-BAND® System

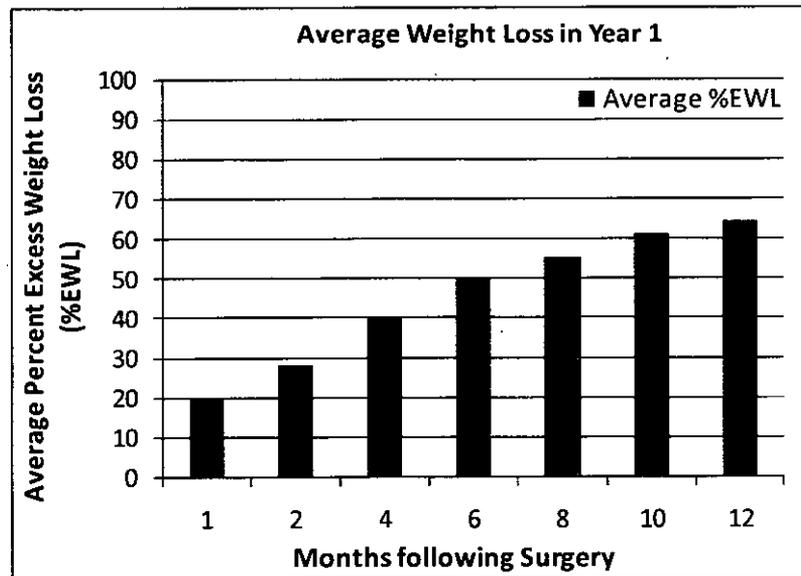
In the first study (from 1995 to 2001) of morbidly obese adults using the LAP-BAND® System, here are the results after three years.

In these patient groups:	Here's how many got these results:					
	Gained more than 5% of excess weight	Had no change in excess weight	Lost more than 25% of excess weight	Lost more than 33% of excess weight	Lost more than 50% of excess weight	Lost more than 75% of excess weight
All 178 patients	2% 4 patients	5% 9 patients	62% 110 patients	52% 93 patients	22% 39 patients	10% 18 patients
The 24 diabetic patients	4% 1 patients	0% 0 patient	50% 12 patients	46% 11 patients	13% 3 patients	8% 2 patients
The 55 super obese patients (BMI 50+)	0% 0 patients	9% 5 patients	58% 32 patients	53% 29 patients	15% 8 patients	4% 2 patients

In the second study (from 2007 to 2009) that looked at obese adults with BMI between 30 and 40, using the LAP-BAND® System, here are the results after one year.

In these patient groups:	Here's how many got these results:					
	Gained more than 5% of excess weight	Had no change in excess weight	Lost more than 25% of excess weight	Lost more than 33% of excess weight	Lost more than 50% of excess weight	Lost more than 75% of excess weight
All 143 patients	0% 0 patients	1% 2 patients	89% 127 patients	83% 119 patients	69% 98 patients	38% 55 patients

The average weight loss over the first year of the study is shown below.



In the clinical studies, patients who weren't considered good candidates for surgery were excluded as were patients who weren't healthy, had the presence of infection, had an underlying condition, had undergone a previous surgery in their stomach area, or for whom surgery was to be their first attempt at weight loss.

Success factors:

Many factors contribute to the success or the failure of a LAP-BAND® patient, and individual results vary. Patients who have had the LAP-BAND® placed well are more likely to experience success than those who don't. In the clinical study, one out of ten patients needed to have their LAP-BAND® fixed or readjusted. Patients who are committed to making major, lifelong changes to their eating habits are likely to do better with the LAP-BAND® System than those who don't. Patients who attend at least six follow-up sessions with their surgeon have significantly better results than those who attend less.

What are the advantages of the LAP-BAND® System?

The LAP-BAND® System is adjustable, and it is easier to remove the LAP-BAND® than it is to reverse other weight-loss surgeries. Also, the surgery for a LAP-BAND® is less invasive. Here are its five biggest advantages.

The LAP-BAND® System process is less invasive

Compared to other surgeries used to treat obesity, LAP-BAND® System placement causes the least amount of trauma to the body. There is no need for cutting or stapling the stomach. Also, the LAP-BAND® System can usually be placed laparoscopically. A completed laparoscopic procedure results in fewer complications, less pain, faster recovery and smaller scars.

The LAP-BAND® System is adjustable

Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight. Adjustments are a part of the follow-up for the procedure and are usually done in a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be carried out in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few minutes. Most patients say it is nearly painless.

The LAP-BAND® System can be removed

If the LAP-BAND® System is removed, the stomach generally returns to the size it was before the LAP-BAND® was implanted. It's easier to remove the LAP-BAND® System than it is to reverse other weight loss procedures. Reversing other procedures typically leaves your stomach with staples and more traumatized tissue.

The LAP-BAND® System may require less hospital time

After the LAP-BAND® System is placed laparoscopically, patients normally leave the hospital or surgical center within a day. If a large incision is required or if there are complications, more time in the hospital or surgical center may be needed.

Recovery with the LAP-BAND® System may be quicker

After the procedure, patients usually get back to their normal activities in a week or two. It may take longer if there are complications.

Who is eligible for the LAP-BAND® System?

As mentioned at the beginning of this booklet, the decision to have surgery for weight loss is a decision you'll want to make together with your doctor and your certified LAP-BAND® System surgeon. In the end, your surgeon is the best person to decide if you're eligible for and will benefit from the LAP-BAND® System.

Call outs in Section 3

- Why is it called LAP-BAND®? The name “LAP-BAND®” combines the surgical technique (laparoscopic) with the product name (gastric band).
- The LAP-BAND® System has the potential to change your life, but the change has to start with you.
- If for any reason you need to loosen the band’s restriction—your surgeon can deflate the band partially or completely.
- You must be willing to make major, lifelong changes to your eating habits for the LAP-BAND® System to work. These changes are very challenging.
- With the LAP-BAND® System, there is no need for cutting or stapling the stomach.
- Any surgery poses risks. It is important for you to consider these as you make your decision.
- Ask your surgeon about the risks and complications involved with having this procedure.

4. Understanding the Process

The more you know about getting a LAP-BAND® System, the better prepared you’ll be. This section will take you through a general overview of what happens and what you can expect. Your experience might be different, and your surgeon is the only person who will be able to fully describe the process you’ll follow.

If you have questions about the process as you are reading, jot them down on the checklist on page 0. Bring your checklist when you meet with your surgeon and ask your surgeon all of your questions.

Sidebar: Here’s what happens

Here is an overview of the steps you’ll follow with the LAP-BAND® System. For more details, see page X.

Find a surgeon

Find a LAP-BAND® System certified surgeon you’re comfortable with. Your surgeon is your guide throughout the process.

Meet with the experts

Meet with your surgeon and other experts to help you understand the procedure and how to plan for it.

Get ready for surgery

You’ll have some medical tests to make sure you are ready. Your surgeon may have you exercise and start a special diet.

Have the surgery

The surgery usually takes less than an hour and many patients are able to return home the same day. Some patients stay in the hospital or surgical center for a day or more afterward.

Recover from surgery

You'll need to take it easy for a while after surgery. Most patients get back to normal activities within a week or two.

Get used to the LAP-BAND® System

For six weeks, you'll follow a special diet, moving gradually from liquids to soft foods.

Get adjusted

Your LAP-BAND® System is loose when you first get it. The surgeon will tighten it, usually within four to six weeks. More adjustments will likely be needed.

Work on your new habits

To succeed with the LAP-BAND® System, you must stick to your goal of making major, lifelong changes to your eating habits.

Finding a surgeon

Your first step is to find a certified LAP-BAND® System surgeon. It's a good idea to speak with more than one surgeon and find the one you feel comfortable with. You can find a surgeon who has been trained to implant the LAP-BAND® System at lapband.com. Chances are, there is one close to you no matter where you live in the United States.

Before your surgery

Initial meetings with surgeon and other experts

Before your surgery, you should talk about the procedure in detail with your surgeon. Your surgeon may also want you to meet with other experts. They can help you understand what will happen during and after the operation.

These experts might include:

- A dietician (someone who specializes in diet and nutrition)
- A physical therapist (someone who specializes in helping the body move and function well)
- A psychologist (someone who specializes in evaluating and improving emotional well-being)
- Other specialists

Pre-surgical meeting with surgeon and anesthetist

You will discuss your entire medical history with your surgeon and anesthetist. This includes current and past medical conditions, illnesses or injuries as well as allergies to medications. You will also have the chance to get answers to all of your specific questions regarding the LAP-BAND® System and your surgery. It is important for you to disclose all of your health conditions and to answer all the surgeon's questions thoroughly and to the best of your ability. Your surgeon can make the best decisions for you when he knows your complete health profile.

Getting ready for your surgery

Medical tests

You will need to have many tests before your surgery. These are to make sure you are healthy enough for the surgery. These tests may include a chest X-ray, blood pressure and blood and other tests.

Get the things you'll need

As your surgery date gets near, you'll want to collect some of the things you'll need after the surgery. Your surgeon will provide you with a complete list. Some things you'll want with you include:

- Comfortable, loose-fitting clothes such as a sweat suit, slip-on shoes, pajamas/nightgown, robe, slippers and toiletries if staying over in the hospital or surgical center
- A small, soft pillow to cushion your lap from the car seatbelt on the ride home
- A complete list of your current medications and two days' supply of each one
- Some magazines and books
- Your insurance and other key information together in an envelope

Things you'll want at home include:

- Supply of ice chips for sipping
- Consommé (beef, chicken or vegetable broth with no added vegetables or meat)
- Skim milk
- Sugar-free popsicles and fruit juice

Having your surgery

The day before your surgery

Your surgeon will provide a complete list of instructions to help you get ready. For example, he or she might tell you that you shouldn't eat or drink anything starting at midnight before the morning of your surgery.

Arriving at the hospital or surgical center

You'll go to the hospital or surgical center either the day before your surgery or the morning of your surgery. Most surgeons ask you to arrive well in advance of the time of your procedure. The surgeon or someone from the surgeon's team will meet with you, and nurses will help you to get ready.

You should also bring an adult who will stay with you until the surgery is completed.

Having the surgery

When it is time for the surgery, you will receive general anesthesia. This will relax your muscles and make you become unconscious so that you will not feel any pain during your surgery. You may be in the operating room for two or three hours, but the actual procedure typically takes about half an hour to an hour.

Most surgeries are completed using the laparoscopic procedure explained on page 0. Sometimes, however, the surgeon may need to change to an open procedure during the surgery. In an open procedure, the surgeon will make a larger incision in the abdomen to perform the operation.

If you have an open procedure, you will need to stay in the hospital or surgical center longer because there could be more problems. It will also take more time for you to get back to your normal routine.

In the U.S. clinical study of morbidly obese adults in 1998-2001, about 5% of the patients were switched to an open procedure after laparoscopic surgery started. No patients in the U.S. clinical study of obese adults in 2007-2009 were switched to an open procedure.

After your surgery

When you wake up

Once the anesthesia has worn off and you are awake, you may feel some pain around where the surgeon made cuts. Many patients report a dull ache around the larger cut on their torso where the access port is. This pain can usually be relieved with normal painkillers such as acetaminophen (like Tylenol[®]) and usually goes away in a day or two.

The staff will also help you get out of bed and start moving as soon as possible. This will help prevent blood clots, breathing problems and bedsores.

The next day (or before leaving the same day)

On the day after the surgery, your health team may check to make sure your LAP-BAND® System is in the right place and that the new stomach outlet is open. They may use a fluoroscope (X-ray) to see inside you. You may be asked to swallow a liquid that can be seen on the X-ray.

How long you'll stay

After a laparoscopic surgery, you will normally leave the hospital or surgical center within one day. The hospital or surgical stay may be longer after an open procedure or if there are problems. If there are no problems, you should be able to get back to normal activities within a week or two after the surgery.

Recovering from the surgery**Follow your surgeon's guidelines**

After your surgery, your surgeon and his or her team of experts will give you specific instructions designed just for you. Be sure you know and understand these instructions. Discuss your diet with your surgeon and dietician, and follow their advice. They can help you learn and get used to the changes in lifestyle and eating habits you need to make.

The following information is based on the instructions patients generally follow. The time periods are true for most patients. And the time you spend in each phase may be different.

While you're recovering, it's important to eat and drink the right way

It will take a month or more for your new stomach structure to heal completely. It is very important to follow your eating and drinking instructions after the operation.

Your surgeon or dietician will provide you with a detailed eating plan that includes portion sizes and explains what foods to choose and how to chew them, but, in general, eating or drinking too much or too fast, not chewing foods properly or eating the wrong foods can cause you to vomit. It is important to avoid vomiting because vomiting can stretch the small stomach pouch above the band. Vomiting can also increase the chance of stomach tissue slipping up through the band or lead to other problems.

Sidebar: Eating during recovery

To allow your stomach to heal correctly, you'll ease your way back to solid foods. Here's a general overview on how it will be done. Your surgeon or dietician will provide you with a detailed eating plan designed just for you that may differ from this plan.

First two days after surgery

Drink water or clear liquids and suck on ice chips.

Day 3 through Day 7

Keep a liquid diet of chicken, beef or vegetable broth (none with cream), skim milk, no-sugar added fruit juice, sugar-free frozen fruit juice on a stick and water.

Day 8 through Day 21

Eat smooth pureed protein such as fish or chicken, pureed vegetables, fruit smoothies, hummus, egg salad, cottage cheese, pureed soup, gelatin, baby food, mashed potatoes, apple sauce, and low-fat yogurt or pudding. Drink liquids, but not with meals.

Day 22 through Day 42

Add soft foods like fish or ground turkey. Your surgeon or dietician will provide a complete list of the foods that will be appropriate. Drink liquids, but not with meals.

Once you begin to add foods that require chewing, your surgeon or dietician will explain to you how to cut your food into small pieces and chew foods well enough for your new stomach opening to accommodate.

If you don't follow this advice, you may experience stomach irritation and vomiting. These can cause the stomach pouch to expand, increase the chance of stomach tissue slipping up through the band or increase the chance of the band slipping out of place. You could also get blockage of the stoma.

If solid foods cause nausea and vomiting, your surgeon may advise you to go back to the liquid diet you had earlier and stay with that for a longer time.

Having your LAP-BAND® System adjusted

The LAP-BAND® System can be adjusted to meet your specific needs. That is one of the benefits of the system. This feature allows you and your surgeon to find the level of tightness that's right for you.

Getting used to the band

When your surgeon first places the band, it is usually empty or partially filled. This lets you get used to it during the first few weeks after surgery. It also allows for healing to occur around the new band site.

Having your first adjustment

Usually, the first adjustment is four to six weeks after surgery, but the timing and amount of adjustments will be different for each person. The first adjustment typically makes the band a little tighter to help you lose weight.

To determine if you are ready for an adjustment, your surgeon will consider:

- Your hunger
- Your weight loss
- The amount of food you can comfortably eat
- Your exercise routine
- How much fluid is already in your band

Don't rush it

Don't be in a hurry to have this adjustment before you are ready. Your surgeon's goal is for you to experience steady, safe weight loss, not weight loss in a hurry. Your surgeon will know the best time for an adjustment.

Second adjustment

After the first adjustment and living with the band for a while, most people need another adjustment. If you have no weight loss for more than three weeks, have an increased appetite or feel hungry again less than four hours after a meal, it could be a sign that your band is too loose. If you regurgitate food, experience discomfort while eating or have a night cough, it could be a sign that your band is too tight. Let your surgeon know so that he or she can decide.

Maintenance

After the second adjustment, your surgeon will monitor your weight loss progress and adjust the band when needed. Everyone requires a different restriction level and adjustment schedule for optimal results. In the first year, you may need anywhere from one to ten adjustments. After the first year, it could be months or years until your next adjustment. If you are several years post-op, you may still require an adjustment. Long-term follow-up is the key to success.

Will I need plastic surgery for removal of the extra skin from weight loss?

Your surgeon will talk to you about what makes sense for you. In general, you should not consider plastic surgery for at least a year or two after the LAP-BAND® System operation. Sometimes the skin will mold itself around your new smaller body shape. You should give your skin time to adjust before you consider having more surgery.

Troubleshooting

If any of the following conditions occur, please contact your surgeon immediately. It could be the sign of band slippage, a serious condition:

- Nausea or vomiting that continues
- Night cough or night reflux (bringing up stomach juices)
- Asthma or worsening of asthma
- Being able to eat less
- Being suddenly able to eat more, then vomiting a few hours later
- Severe pain
- Difficulty swallowing or inability to swallow

In an emergency, contact your surgeon. Your surgeon may temporarily deflate your band to fix the slippage. If necessary, your surgeon will reposition or replace the band through surgery. If you can't reach your surgeon, you should proceed to the nearest hospital emergency room. Any clinician trained in the handling of ports and Huber needles will be able to deflate your band if necessary. Your surgeon should be notified as soon as possible.

Other reasons to talk to your surgeon:

- Becoming pregnant
- Being diagnosed with a serious illness
- Feelings of hunger return less than four hours after a meal
- Discomfort

Your new habits

Once you and your body have gotten used to the LAP-BAND® System, you will embark on a new life. You have set a goal to make a major lifelong change to your eating habits, and this change is a critical part of you succeeding in your weight loss.

A healthy, balanced diet

An important part of these new habits is your diet. From now on, you'll eat less food than you were used to before surgery and eat a healthier, more balanced diet. Because the band limits how much you can eat, it helps you to follow this plan. But in the end, your commitment to your new eating habits will determine how much weight you lose.

Your surgeon or dietician will work with you to create an eating and activity plan that meets your needs. Here are some guidelines for the diets you follow beginning in Week 4 after surgery, as you add soft foods and then foods that require chewing.

10 important guidelines and how to make them work

Rule 1: Eat smaller meals

Your surgeon or dietician will talk to you about portion size and how to chew your food thoroughly. The LAP-BAND® System creates a small stomach pouch that can hold only about a quarter cup of food at a time. If you try to eat more than this at one time, you may feel nauseated or vomit. If you routinely eat too much, the small stomach pouch may stretch. That will cancel the effect of the LAP-BAND® System.

Frequent vomiting can also cause certain problems, such as stomach slippage. Work with your surgeon or dietician to understand how much your stomach pouch can hold comfortably and don't exceed that amount.

Rule 2: Eat only when you're hungry

Eating when you're not hungry is a big reason that many people fail to lose weight. Your surgeon or dietician will work with you to create a diet that will include enough food to give you the nutrients you need and may include smaller meals scheduled at shorter intervals in order to keep you from feeling hungry.

With the LAP-BAND® System, you shouldn't feel hungry again less than four hours after a meal. If you do, let your surgeon know as your band may need to be adjusted.

Rule 3: Eat good quality foods

With the LAP-BAND® System in place, you can eat only a small amount at one time, so the food you eat should be as healthy as possible. Your surgeon or dietician will work with you to create a diet that includes healthy foods and avoids junk food, which is food with high calories or fat and low nutritional value. Your meals will include many fresh vegetables, fruit, meats, proteins and cereals. Foods high in fat and sugar will not be included. Your surgeon or dietician may ask you to take a vitamin supplement as well.

Rule 4: Approach problem foods carefully.

Some foods have difficulty passing through the new stomach and may cause blockage. That is because you can't chew this food well enough to break it up into small pieces, and your saliva can't break it down. Remember: your new stomach opening is about the diameter of a pencil eraser. Your surgeon or dietician will give you a complete list of foods which may give you trouble and teach you how to prepare them for the greatest chances of success if you still want to attempt them.

Foods that may cause problems include:

- Dry meat
- Shrimp
- Untoasted or doughy bread
- Pasta
- Rice
- Peanut butter
- Dried fruit
- Tough, stringy vegetables like corn, asparagus and celery
- Nuts
- Coconut
- Popcorn
- Greasy or fried food
- Seeds and skins of fruits and vegetables
- Membrane of citrus fruits such as oranges, lemons and grapefruit

Rule 5: Follow your surgeon or dietician's advice regarding chewing and swallowing

Remember: your new stomach opening is about the diameter of a pencil eraser, so you need to chew your food until it is smaller than that in order for it to go down after swallowing. Your surgeon or dietician will work with you so that you understand how to gauge that while you're eating. Cut your food into appropriate sizes, chew until the food is the right size to be swallowed and put down your silverware between bites. You will find yourself eating more slowly and you may enjoy it more.

Rule 6: Try to learn to recognize when you start to feel full

Once your stomach is full, your body receives a signal that you have eaten enough. It takes time, though, for you to become aware of this signal and if you have a history of overeating, you may not have learned to recognize it. If you hurry your meal, you may eat more than you need, which can lead to nausea and vomiting. Eat slowly and try to pay attention to the feelings of fullness.

Rule 7: Drink plenty of water or other liquids during the day

If you lose weight, your fat content will drop. This results in waste products. You will need to drink large amounts of liquid every day in order to urinate more and rid your body of these waste products. If you don't, you may become dehydrated. Your surgeon or dietician will let you know the amount of water you should drink each day, but in general patients should drink six to eight 8-oz glasses of liquid.

Rule 8: Do not drink while you are eating or following a meal.

If you drink with your meal, the food you have eaten passes through your stomach more quickly, so you no longer feel full. This greatly reduces the effectiveness of the LAP-BAND® System. You should not drink anything for one to two hours after a meal. That way, you feel full for as long as possible. Your surgeon or dietician will work with you to create a drinking plan that is right for you.

Rule 9: Drink only water, tea or coffee (no milk, cream or sugar)

You will reduce your ability to lose weight if you drink liquids containing calories, like sugared soda, fruit juice or coffee drinks. Liquids pass through the stomach outlet very quickly and do not make you feel full.

Rule 10: Be more physically active

Your surgeon or dietician will talk to you about an activity plan and provide instructions on how to follow it. Physical activity helps increase weight loss because it burns calories. Exercise can also help improve your general health.

Your size may make it hard for you to be active, but get started, even if it is a little at first. The more weight you lose, the easier it should get.

A convenient reminder

Cut out this reminder card, write your surgeon's phone number on the other side, and keep it in your wallet.

Sidebar: 10 important guidelines and how to make them work [Wallet card]

Here are 10 guidelines that will help you get the best results from the LAP-BAND® System. Your motivation to follow a healthier new lifestyle is key to success.

1. **Eat smaller meals**—about a quarter cup of food at a time, about the size of a small egg.
2. **Eat only when you're hungry**—and don't eat when you're not.
3. **Eat good quality foods.** Follow the plan your surgeon or dietician created for you.
4. **Avoid food with tough or stringy fibers.** Asparagus, corn, oranges and celery can be hard to digest. Follow the food plan created for you.
5. **Follow your surgeon or dietician's advice regarding chewing and swallowing.** Remember: your new stomach opening is the diameter of a pencil eraser.
6. **Try to learn to recognize when you start to feel full.** Pay closer attention and try to feel for this signal. Stop eating when you feel it.
7. **Drink plenty of water and other liquids during the day** to help rid your body of waste products.
8. **Do not drink while you are eating or following a meal.** This helps you keep the feeling of fullness.
9. **Drink only water, tea and coffee (no milk, cream or sugar).** Liquids do not make you feel full, so high calorie liquids like sugared soda or fruit juice reduce your weight loss.
10. **Be more physically active.** Follow the plan laid out for you by your surgeon or dietician.

Telephone numbers for your surgeon and medical team:

Cut out this card, fold it in half, and keep it in your wallet.

Sidebar: Making good choices

To succeed with the LAP-BAND® System, you'll need to make good food choices every day. Here's an example of what one day's worth of good choices might look like. Your surgeon or dietician will work with you to design a meal plan that's right for you.

Breakfast

Plain tea or coffee • Small bowl of hot cereal • Cup of low-fat yogurt

Lunch

Iced tea • Wheat toast with cheese • Fresh pear

Dinner

Fruit smoothie • Grilled chicken • Salad, low-fat dressing

Customized Support Program

Setting a goal to make a major, lifelong change to your eating habits is a big commitment, and the LAP-BAND® System offers a special support program to help you called My LAP-BAND® Journey®. Your customized My LAP-BAND® Journey® program lets you track your goals, monitor your changing body measurements, activities and even your moods as often as you like. With My LAP-BAND® Journey® you choose how to track your progress and achievements.

For example, My LAP-BAND® Journey® features checklists and reminders so you can mark all the steps you've taken on your journey. Use the Preparation Checklist to get ready for surgery, manage important milestones with the Appointment and Weight Trackers, keep yourself motivated by writing a Letter to Yourself, and eat healthy with the LAP-BAND® System recipe library. You will also receive timely tips and reminders to help you stay on track.

The My LAP-BAND® Journey® program will also provide access to a Personalized LAP-BAND® System Patient ID Card—a card to keep with you at all times and use when you're dining out, traveling or visiting the surgeon. It can also be helpful in case of a medical emergency or situations where others should know that you have been implanted with a surgical device.

You can access and begin using your custom My LAP-BAND® Journey® after you register at www.lapband.com/my_lapband/about.

5. Making your decision

A life change

Congratulations. Deciding to tackle your obesity is a big decision and one that can have positive impact on your future. We hope reading this booklet has helped you understand how the LAP-BAND® System works as well as the journey you'll take if you end up getting the LAP-BAND® System. Your surgeon is the only person who can fully answer all the questions you may have.

As you've learned, the LAP-BAND® System is not a miracle cure. Not everyone will lose weight or keep it off. Individual results vary. To achieve long-lasting weight loss, you will need to commit to making a major, lifelong change to your eating habits.

Finding a surgeon

Your first step towards successful surgical weight loss involves finding a surgeon qualified to perform LAP-BAND® System surgery. An experienced LAP-BAND® System surgeon will not just determine if this procedure is right for you and perform your surgery but will also help you with your payment options and pre-and post surgical education. You can find a list of qualified LAP-BAND® System surgeons near you at www.lapband.com/get_informed/consult/find/.

Sidebar: Questions to ask surgeons

You can use the following checklist to help you remember the things you want to discuss with the surgeons you consider. Once you've filled it out, just tear it out and take it with you to your appointment.

The surgeon's experience

- What procedures do you offer?
- How many weight-loss surgeries have you done?
- How many LAP-BAND® System procedures have you done?

Other questions

- May I see a sample of the LAP-BAND® System?
- What is the average excess weight loss experienced by your LAP-BAND® System patients? How about for other options?
- What are the most common complications you see with the LAP-BAND® System procedure? How does that compare to other options?

- Will I experience improvement with my weight-related health conditions?
What have your patients experienced?
- How will I know if I'm a good candidate for surgery?

Cost, support and follow-up care

- What is the cost of this procedure? Do you accept my insurance?
- Can your office help me with insurance approval or financing?
- How do adjustments work and how often will I need adjustments during the first year? Ongoing?
- How will you work with my primary care/family physician or other doctors I'm currently seeing for treatment?
- Do you have a team to address weight-related health conditions, dietary instruction, exercise training, nursing care and psychological counseling if I need it?
- Do you offer support groups for post surgery patients?
- What help can you give me to help educate my family and friends so that they can help me with this process?

Other concerns

- Write your own questions in the space below.

A careful decision

A decision to get the LAP-BAND® System should be made carefully after talking to your surgeon. We hope this booklet has helped you determine the questions and issues you want to discuss with him. It's very important that you and your surgeon have an in-depth discussion about the potential risks and rewards of choosing the LAP-BAND® System before you make your decision.

Good luck to you!

6. Frequently asked questions

Q: How much weight will I lose?

A: There is no way to predict how much weight you will lose with the LAP-BAND® System. Some people lose more weight with the LAP-BAND® System than others. Getting the LAP-BAND® System doesn't guarantee that you will reach your goal weight or even lose weight.

The LAP-BAND® System will not solve your weight problem by itself. You have to set a goal to make major, lifelong changes to your eating habits. That means eating less food and eating healthier food, changes which are very challenging. How much weight you lose depends on how committed you are to doing your part. It's possible to lose two to three pounds a week in the first year after the operation, but one pound a week is more likely. It's also possible to lose less or none at all. Individual results vary. Twelve to 18 months after the operation, weekly weight loss usually slows or stops.

Q: How much weight have other people lost?

A: In a clinical study of morbidly obese adult patients (BMI 40 or greater) from 1995 to 2001, the average patient lost approximately 36% of his or her excess weight three years after surgery. In a different clinical study of obese adult patients (BMI between 30 and 40) from 2007 to 2009, the average patient lost approximately 65% of his or her excess weight one year after surgery.

Excess weight means the extra pounds you carry above your ideal weight. For example, if your ideal weight is 155 pounds and you weigh 255 pounds, then you are 100 pounds overweight. This is your excess weight. If you lose 33% of your excess weight, then you lose 33 pounds.

The table below shows how much excess weight different adult patients lost in the two studies.

Results with the LAP-BAND® System

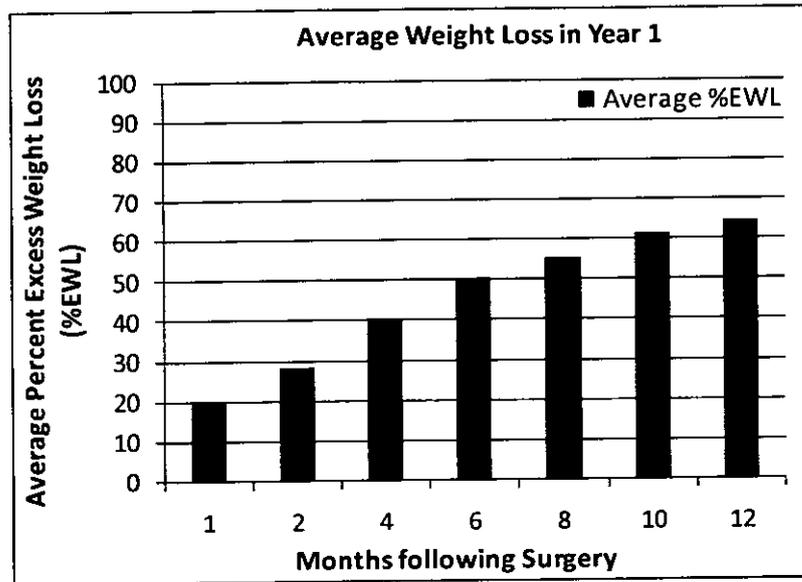
In the first study (from 1995 to 2001) of morbidly obese adults using the LAP-BAND® System, here are the results after three years.

In these patient groups:	Here's how many got these results:					
	Gained more than 5% of excess weight	Had no change in excess weight	Lost more than 25% of excess weight	Lost more than 33% of excess weight	Lost more than 50% of excess weight	Lost more than 75% of excess weight
All 178 patients	2% 4 patients	5% 9 patients	62% 110 patients	52% 93 patients	22% 39 patients	10% 18 patients
The 24 diabetic patients	4% 1 patients	0% 0 patient	50% 12 patients	46% 11 patients	13% 3 patients	8% 2 patients
The 55 super obese patients (BMI 50+)	0% 0 patients	9% 5 patients	58% 32 patients	53% 29 patients	15% 8 patients	4% 2 patients

In the second study (from 2007 to 2009) that looked at obese adults with BMI between 30 and 40, using the LAP-BAND® System, here are the results after one year.

In these patient groups:	Here's how many got these results:					
	Gained more than 5% of excess weight	Had no change in excess weight	Lost more than 25% of excess weight	Lost more than 33% of excess weight	Lost more than 50% of excess weight	Lost more than 75% of excess weight
All 143 patients	0% 0 patients	1% 2 patients	89% 127 patients	83% 119 patients	69% 98 patients	38% 55 patients

The average weight loss over the first year of the study is shown below.



In the clinical studies, patients who weren't considered good candidates for surgery were excluded as were patients who weren't healthy, had the presence of infection, had an underlying condition, had undergone a previous surgery in their stomach area or for whom surgery was to be their first attempt at weight loss.

Q: What factors contribute to success?

A: Many factors contribute to the success or the failure of a patient who has had the LAP-BAND® system implanted, and individual results vary. Patients who have had the LAP-BAND® placed well are more likely to experience success than those who don't. In the clinical study of morbidly obese adults, one out of ten patients needed to have their LAP-BAND® fixed or readjusted. Patients who are committed to making major, lifelong changes to their eating habits are likely to do better with the LAP-BAND® System than those who don't. Follow-up visits for adjustments are a critical step for a successful LAP-BAND® System patient. Patients who attend at least six follow-up sessions with their surgeon have significantly better results than those who attend less.

Q: When will I need an adjustment?

A: Usually, the first adjustment is four to six weeks after surgery, but the timing and amount of adjustments will be different for each person. The first adjustment typically makes the band a little tighter to help you lose weight.

To determine if you are ready for an adjustment, your surgeon will consider:

- Your hunger
- Your weight loss
- The amount of food you can comfortably eat
- Your exercise routine
- How much fluid is already in your band

Don't be in a hurry to have this adjustment before you are ready. Your surgeon's goal is for you to experience steady, safe weight loss, not weight loss in a hurry. Your surgeon will know the best time for an adjustment.

Q: How is the LAP-BAND® System adjusted?

A: Follow-up visits for adjustments are a critical step for a successful LAP-BAND® System patient. Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight. Adjustments are a part of the follow-up for the procedure and are usually done during a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be carried out in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few minutes. Most patients say it is nearly painless.

If for any reason you need to loosen the band's restriction—for example, if you become pregnant or ill—your surgeon can deflate the band partially or completely.

Q: What will happen if I become pregnant?

A: The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because your menstrual cycle may become more regular. If you need to eat more while you are pregnant, the band can be loosened. After the pregnancy it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

Q: Can the LAP-BAND® System be removed?

A: The LAP-BAND® System is designed to stay in your body long-term. It does not need to be removed, but if a problem occurs or you do not lose weight, your surgeon may reposition, remove or replace it.

If the LAP-BAND® System was placed laparoscopically, it may be possible to reposition, remove or replace it in the same way. This is an advantage of the LAP-BAND® System. Rarely, an open procedure is needed to remove it.

If you're considering having your LAP-BAND® System removed, you should discuss your concerns with your surgeon. Removing the band will allow your stomach to return to the size it was before your surgery and your digestive tract to the way it normally functions, which means your weight will likely increase.

Q: Will I need plastic surgery for removal of the extra skin from weight loss?

A: Your surgeon will talk to you about what makes sense for you. In general, you should not consider plastic surgery for at least a year or two after the LAP-BAND® System operation. Sometimes the skin will mold itself around your new smaller body shape. You should give your skin time to adjust before you consider having more surgery.

Resources/To Find Out More

National Institutes of Health Medline Site --

<http://www.nlm.nih.gov/medlineplus/weightlossurgery.html>

Obesity Action Coalition -- www.obesityaction.org

LAP-BAND® System Website -- www.lapband.com

Special notice

The manufacturer of the LAP-BAND® System has designed, tested and manufactured it to be reasonably fit for its intended use. However, the LAP-BAND® System is not a lifetime product and part or all of it may break or fail at any time after implantation. Some causes of partial or complete failure of the System may include expected or unexpected bodily reactions to the presence and position of the implanted device, rare or uncommon medical complications, failure of one of the parts of the LAP-BAND® System, and normal wear and tear. In addition, the LAP-BAND® System may be easily damaged by improper handling or use of the device. Please refer to the risk section at the beginning of the booklet for a presentation of the general and specific risks and possible complications associated with the use of the LAP-BAND® System.

Call outs in Section 6:

- The more you know about getting a LAP-BAND® System, the more prepared you'll be.
- Your surgeon or dietician will create an eating and drinking plan that is specific to your needs.
- Your goal to make major, lifelong changes to your eating habits is critical to your success.
- Follow the exercise plan your surgeon or dietician provides you.
- You can access and begin using your custom My LAP-BAND® Journey® after you register at www.lapband.com/my_lapband/about.
- The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant.

MY SURGEON GAVE ME THIS BOOKLET

(TO BE SIGNED BY PATIENT UPON RECEIPT OF THIS BOOKLET AND STORED IN THE PATIENT FILE)

My surgeon has given me the booklet "The LAP-BAND[®] System, Surgical Aid in the Treatment of Obesity, A decision guide for adults" for my use before my surgery.

Patient Signature

Date

Patient Name Printed

Surgeon Signature

Date

Surgeon Name Printed



I READ AND UNDERSTOOD WHAT'S IN THIS BOOKLET

(TO BE SIGNED BY PATIENT AFTER HE OR SHE HAS READ THIS BOOKLET AND STORED IN THE PATIENT FILE)

I have read the booklet, "The LAP-BAND[®] System, Surgical Aid in the Treatment of Obesity, A decision guide for adults" and understand the risks that it describes. I understand the potential problems described and the symptoms and conditions that may not make the LAP-BAND[®] System right for me. I have discussed the risks with my surgeon, and I know and understand that not all risks connected with this product can be predicted. I acknowledge that there can be serious risks even with the best medical manufacturing, technology and surgical care. I fully accept the risks and possible problems associated with the LAP-BAND[®] System procedure and believe that the benefits of the device and procedure outweigh the risks. I take full responsibility for my choice and choose to proceed with the LAP-BAND[®] System surgery.

Patient Signature

Date

Patient Name Printed

Surgeon Signature

Date

Surgeon Name Printed



**FOR MORE INFORMATION ABOUT OBESITY AND
THE LAP-BAND® SYSTEM PLEASE VISIT**

www.lapband.com

OR CALL

**1-800-LAP-BAND
527-2263**

**Please be certain to consult your surgeon
before starting any weight loss program.**

**CAUTION: THIS DEVICE IS RESTRICTED TO SALE
BY OR ON THE ORDER OF A DOCTOR.**

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