



LAP-BAND® Adjustable Gastric Banding System

with the Access Port II

DIRECTIONS FOR USE (DFU)

Rx Only

A detailed booklet called "A Surgical Aid in the Treatment of Morbid Obesity" 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.



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DESCRIPTION

Cat. No. B-2215

LAP-BAND® System 9.75 with Access Port II

Cat. No. B-2225

LAP-BAND® System 10.0 with Access Port II

Cat. No. B-2255

LAP-BAND® VG System with Access Port II

The LAP-BAND® 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 eases laparoscopic placement around the stomach, 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® VG System is constructed with OMNIFORM® technology, which employs soft, pre-curved sections in the inflation area. 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® System. This enables post-operative percutaneous stoma size adjustment. Dietary and behavior modification counseling and frequent and 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., fundoplications 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 of Bariatric Surgeons (ASBS) 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".

Brief Description of Procedure

During the surgical procedure, the inflatable band is flushed with sterile saline. Using the Calibration Tube, 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 or in the rectus muscle or fixed in an accessible subcutaneous space. The tubing may be shortened to tailor the position of the port to the patient. 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 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 LAP-BAND® System Surgical Procedure section for more information.

INTENDED USE / INDICATIONS

The LAP-BAND® System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative

weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

CONTRAINDICATIONS

The LAP-BAND® System is 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 gastro-intestinal 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, which 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® 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

CAUTION: Laparoscopic or laparotomic placement of the LAP-BAND® System is major surgery and death can occur.

CAUTION: Failure to secure the band properly may result in its subsequent displacement and necessitate reoperation.

CAUTION: 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.

CAUTION: The band should not be sutured to the stomach. Suturing the band directly to the stomach may result in erosion.

CAUTION: Patients' emotional and psychological stability should be evaluated prior to surgery. Gastric banding may be determined to be inappropriate, in the opinion of the surgeon, for select patients.

CAUTION: Patients should be advised that the LAP-BAND® System is a long-term implant. Explant 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.

CAUTION: Esophageal distension or dilatation has been reported to result from stoma obstruction due to 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.

CAUTION: Some types of esophageal dysmotility may result in inadequate weight loss or may result in esophageal dilatation when the band is inflated and 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.

CAUTION: 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.

CAUTION: Patient self-adjustment of superficially placed Access Ports has been reported. This can result in inappropriate band tightness, infection and other complications.

PRECAUTIONS

CAUTION: Laparoscopic band placement is an advanced laparoscopic procedure. Surgeons planning laparoscopic placement must have extensive advanced laparoscopic experience, i.e., fundoplications, and:

1. 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
2. Participate in a training program for the LAP-BAND® System authorized by Allergan or an authorized Allergan distributor (this is a requirement for use)
3. Be observed by qualified personnel during their first band placements
4. Have the equipment and experience necessary to complete the procedure via laparotomy if required
5. Be willing to report the results of their experience to further improve the surgical treatment of severe obesity

CAUTION: It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant.

CAUTION: As with other 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.

CAUTION: During insertion of the Calibration Tube, care must be taken to prevent perforation of the esophagus or stomach.

CAUTION: In revision procedures the existing staple line may need 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.

CAUTION: 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.

CAUTION: Care must be taken during band adjustment to avoid puncturing the tubing which connects the Access Port and band, as this will cause leakage and deflation of the inflatable section.

CAUTION: 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 and 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)

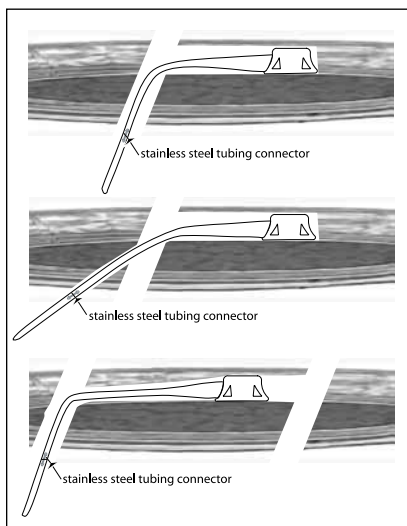


Figure 1. Port Placement Options

CAUTION: The LAP-BAND® System is for single use only. Do not use a band, Access Port, needle or Calibration Tube which appears damaged (cut, torn, etc.) in any way. Do not use one of them 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. Do not attempt to clean, re-sterilize or re-use any part of the LAP-BAND® Adjustable Gastric Banding System. The product may be damaged or distorted if re-sterilized.

CAUTION: It is important that special care be used when handling the device because contaminants such as lint, fingerprints and talc may lead to a foreign body reaction.

CAUTION: 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.

CAUTION: 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.

CAUTION: Failure to use the tubing end plug during placement of the band may result in damage to the band tubing during band placement.

CAUTION: 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.

CAUTION: Over-dissection of the stomach during placement may result in slippage or erosion of the band and require reoperation.

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

CAUTION: The band is not intended to be opened laparoscopically with surgical instruments. Unrecognized damage to the band may result in subsequent breakage or failure of the device.

CAUTION: When adjusting band volume 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.

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

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: 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.

CAUTION: When adjusting band volume once the septum is punctured, do not tilt or rock the needle, as this may cause fluid leakage or damage to the septum.

CAUTION: When adjusting band volume if fluid has been added to decrease the stoma size, it is important to establish, before discharge, that the stoma is not too small. Care must be taken during band adjustments not to 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.

CAUTION: It is the responsibility of the surgeon to advise the patient of the dietary restrictions which 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.

CAUTION: 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. If necessary to avoid any nutritional deficiencies, the physician may choose to prescribe appropriate dietary supplements. The appropriate physical monitoring and dietary counseling should take place regularly.

CAUTION: 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.

CAUTION: Patients must be seen regularly during periods of rapid weight loss for signs of malnutrition, anemia or other related complications.

CAUTION: Anti-inflammatory agents, which may irritate the stomach, such as aspirin and non-steroidal antiinflammatory drugs, should be used with caution. The use of such medications may be associated with an increased risk of erosion.

CAUTION: Patients who become pregnant or severely ill, or who require more extensive nutrition, may require deflation of their bands.

CAUTION: All patients should have their reproductive areas shielded during radiography.

CAUTION: 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.

CAUTION: 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.

CAUTION: Although there have been no reports of autoimmune disease with the use of the LAP-BAND® System, autoimmune diseases/connective tissue disorders (i.e., systemic lupus erythematosus, sclero-derma) have been reported following long-term implantation of other silicone devices. These conditions have primarily been hypothesized to be associated with silicone breast implants. There is currently no conclusive clinical evidence to substantiate a relationship between connective tissue disorders and silicone implants. Definitive long-term epidemiological studies to further evaluate this possible association are currently underway. However, the surgeon should be aware that if autoimmune symptoms develop following implantation, definitive treatment and/or band removal may be indicated. Likewise, patients who exhibit pre-existing autoimmune symptoms should be carefully evaluated prior to implantation of the LAP-BAND® System and may not be appropriate candidates (see Contraindications).

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.

Slippage of the band can occur. Gastro-esophageal reflux, nausea and/or vomiting with early or minor slippage may be in some cases successfully resolved by band deflation. More serious slippages may require band repositioning and/or removal. If there is total stoma outlet obstruction that does not respond to band deflation, or if there is abdominal pain, then immediate re-operation to remove the band is indicated.

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 U.S. study, 42% of the U.S. patients undergoing revisions were reported to have developed 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.

Re-operation to remove the device is required. Re-operation for band erosions may result in a gastrectomy of the affected area. Eroded bands have been removed gastroscopically in a very few cases, depending on the degree of erosion. Consultation with other experienced LAP-BAND® System surgeons is strongly advised in these cases.

Esophageal distension or dilatation has been reported infrequently. This is most likely a consequence of incorrect band placement, over-restriction, stoma obstruction, and 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 re-position 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.

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, or re-operation 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 result in the need for a cholecystectomy.

The following table summarizes serious adverse events that were reported to have occurred during the U.S. clinical trial. Two hundred and ninety-nine patients were studied with a total of 633 patient years.

Serious Adverse Events Considered Related to the LAP-BAND® System for the US Study

(Recorded as of December 2000, 299 Patients)

Adverse Event	% of patients
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. 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-seven revision procedures, involving 26 subjects (9%, 26/299) occurred. 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 were revised with a new band at separate interventions. Sixteen of 27 revision procedures (59%) did not require removal of the band. All of these 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%) were countermeasures 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%). Data from a post-approval study showed an estimated explant rate of 6.5% per year over the first 5 years following implantation.

CLINICAL EXPERIENCE

Purpose of the Trial

The purpose of the study was to support 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 according to the 1983 Metropolitan Life Insurance Tables (use of the mid-point for medium frame). The product 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.

Study Design

In June of 1995, a nonrandomized, single-arm (non-comparative) study was initiated. The study consisted of a multi-center clinical evaluation with eight (8) participating sites and an enrollment of 299 subjects. The study was approved with patient follow-up at 3 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 30 months, and 36 months. The 9.75cm (B-2210) and 10.0cm (B-2220) LAP-BAND® Systems were used in the study. The primary efficacy measures included the percent excess weight loss (%EWL) at one, two, and three years following the procedure. The differences between these weight losses and the weight loss/gain experienced by the subjects in the year(s) prior to placement of the LAP-BAND® System were considered as secondary efficacy measures. In addition, secondary efficacy measures also included changes in quality of life. The primary safety parameters included incidence and severity of complications. These complications were divided into device-related and non-device-related events.

Patients Studied

There were 299 patients in the U.S. study. The patient gender breakdown was 85% female and 15% male, which is consistent with gender distribution among patients seeking surgical treatment for severe obesity. Patient race categories were 81% Caucasian, 15% African-American and 4% Hispanic. The average age that patients became obese was 18.4 years and the average age at the time of surgery was 38.8 years.

The mean weight at entry was 293 pounds, and the mean excess weight was 156 pounds. The mean BMI was 47.4. Thirty percent had a BMI ≥ 50 and thus classified as "superobese". During the five years prior to surgery, patients had gained an average of 54 pounds and the average BMI had increased from 39 to 47.4.

In these patients, significant comorbidities included: hypertension (42%), gallstone/gallbladder disease

All Adverse Events (Mild, Moderate, Severe) that Occurred at a Rate of 5% or More

(Recorded as of December 2000, 299 Patients)

	# of patients	% of patients
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 Dilation	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

(25%), gastrointestinal diseases (24%), asthma (16%), non-insulin dependent diabetes (11%), and insulin dependent diabetes (5%).

Patient inclusion criteria

- Age 18 to 55
- Male or female
- BMI of 40 or above, or 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

Patient exclusion criteria

- Surgery or treatment represents an unreasonable risk to the subject
- Family or patient 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
- Pregnant or has the intention of becoming pregnant in the next 12 months
- Alcohol or drug addiction
- Mentally retarded, emotionally unstable, or exhibits psychosocial 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 patient history of a known diagnosis or preexisting 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 clinical trial

Clinical Study Methods

The primary effectiveness measure was the percent excess weight loss (%EWL), defined as weight loss divided by excess weight multiplied by 100. Weight

loss was equal to operative weight minus selected weight. Study subjects were weighed immediately before surgery and postoperatively at 3 weeks, 3, 6, 9, 12, 18, 24, 30, and 36 months. The 1983 Metropolitan Life Height and Weight Table was the scale to determine ideal weight.

Safety measurements were based on the patients' reported adverse events perioperatively (< 3 weeks) and postoperatively (> 3 weeks), during scheduled visits or called to the attention of the study nurse or investigator to report urgent problems.

Enrollment began in June 1995 and was completed in June 1998. There were 8 centers and 12 surgeons. All procedures were completed utilizing a perigastric dissection technique with pouches of 25 ml or (later in the study) 15 ml. Two hundred and fifty-nine procedures were completed laparoscopically, and 33 via laparotomy, including 13 intraoperative conversions (4.7% conversion rate).

Product Effectiveness

The following tables present data from the clinical trial that demonstrates the effectiveness of the LAP-BAND® System as it compares baseline data (collected before surgery) to data collected 36 months subsequent to surgery:

Significant improvement in %EWL, weight loss, excess weight and BMI when compared to baseline was achieved at 12, 24 and 36 months. Although most improvement was seen in the first 12 months, statistically significant improvement continued through month 36.

	Baseline Data (N=292)	36-month End Point Data (N=178)
%EWL	N/A	36.2%
Mean Wt (lbs)	293	240.6
Range	193-475	113-406
Mean Excess Wt (lbs) at Surgery	156	104
Range	74-335	-15-263
Mean BMI (kg/M ²) at surgery	47.4	38.7
Range	35.9-74.3	19.3-63.6

N = Number of Patients

Primary Endpoint: %EWL

The mean %EWL increased steadily from 9.9% at three weeks to 37.8% at 24 months. Improvements in %EWL through 36 months were significant (p<0.0001) when compared to baseline and at a level that has been demonstrated in the medical literature to improve comorbidities.

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 Patients

Secondary Endpoint: Weight and Excess Weight

Mean weight decreased steadily from 293 pounds at baseline to 235 pounds at 30 months. Weight loss through 36 months was significant when compared to baseline. 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, substantially more than the 10% weight loss that has been reported in the literature to improve or resolve comorbid conditions associated with obesity.¹

Mean Weight by Visit (in pounds)

Visit	N	Weight
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 Patients

Secondary Endpoint: Body Mass Index

Mean BMI decreased steadily from 47.5 at baseline to 38.1 at 24 months. 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, 60% of subjects were no longer morbidly obese, and one-third were no longer severely obese (they had a BMI < 35). Almost 30% of subjects were super obese (they had a BMI > 50) when they entered the study. By 12 months, only 7% of the subjects were still super obese.

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 Patients

Secondary Endpoint: Quality of Life

Quality of life was evaluated using several validated instruments, 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 in efficacy and safety were observed in the U.S. Clinical Study. Experience with advanced laparoscopic procedures, attitudes regarding bariatric procedures, and patient management and support practices were factors. No centers performed more than an average of two to three procedures a month. This limited and infrequent experience would be expected to cause and did cause a protracted learning curve in both laparoscopic placement and patient management.

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 hyper-insulinemia, insulin resistance and disease 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 still be severely obese. They will probably lose more weight with a malabsorptive procedure or a procedure with a malabsorptive component. Patient weight loss needs and expectations should be considered when selecting an obesity procedure.

PATIENT COUNSELING INFORMATION

A detailed booklet called "A Surgical Aid in the Treatment of Morbid Obesity" 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.

Required Equipment and Materials (Included)

System Components:

1. LAP-BAND® System (sterile), one each
2. Access Port II 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

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

Note: The LAP-BAND® System 9.75 cm and 10.0 cm may be used for most patients. The LAP-BAND® VG System provides a very slight additional range of adjustability. After resolution of postoperative edema, most patients with appropriately placed bands report minimal if any restriction until saline is added to the band, regardless of the size used. For re-operations (particularly conversion from other procedures) and the pars flaccida dissection, the 10.0 cm band is normally used. It is recommended that surgeons evaluate the amount of tissue within the band prior to band locking. If it appears excessive (the band would not fit loosely), 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® Adjustable Gastric Banding System Features:

The LAP-BAND® System is a gastric band which, when properly placed through the retrogastric tunnel, forms a circular ring around the proximal stomach. All bands transition to a silicone tube which is 50 cm long. The band is made of silicone elastomer. The inner surface of the band is inflatable. The radiopaque, kink-resistant tubing is used to connect the inflatable section to the Access Port. An end plug is provided to seal the system while the band is being passed around the stomach.

Access Port II Features: The Access Port II (Figure 2) is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port needle.



Figure 2. Access Port II

Features Include:

1. High-compression septum; tested to over 200 punctures with a 20 gauge non-coring needle.
2. Port reservoir; positive tactile feedback, designed for long-term durability when the Access Port needle makes contact, resists gouging from repeated needle contact for long-term reservoir integrity.
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.

The stainless steel connector 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® System (see Instructions for Use). Access Port needles are available in boxes of 10 as well as an Adjustment Kit to help facilitate proper adjustments (proper needle and saline solution).

Calibration Tube Features: The Calibration Tube (Figure 3) 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 3. The 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):

1. Atraumatic Graspers
2. Sterile Saline (non-pyrogenic, isotonic, 0.9% NaCL)
3. Syringe, 5 cc
4. 2-0 Ethibond, intestinal needle
5. 2-0 Dexon, cutting needle
6. Rubber-shod clamps (mosquito with tubing sleeves)

Additional Equipment Recommended for Laparoscopic Placement:

1. Articulating dissector (long shaft) or Roticulator grasper (long shaft)
2. 15 mm or 18 mm trocar
3. 5.5 mm reducer for 15 or 18 mm trocar
4. 0° and 30° laparoscopes
5. Trocars; extra-long trocars sometimes needed
6. Extra-long cautery hook and suction irrigation
7. A set of long laparoscopic atraumatic graspers, dissectors, scissors, clip appliers, Babcock grasper and fan retractor

Additional Equipment Recommended for Placement via Laparotomy:

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

1. Penrose Drain

2. Abdominal Retractor System for Obesity
3. Liver Retractor for Obesity

Use a standard set of abdominal surgical retractor instruments as required for laparotomy in the open placement of the LAP-BAND® System.

Special Equipment and Materials Required for Band Adjustment:

1. X-ray equipment with monitor
2. Local anesthetic with a 1 cc syringe and 30 gauge needle
3. Sterile 20 gauge 50 or 89 mm 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.
4. 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
5. 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 II Preparation

1. Remove the Access Port II 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

LAP-BAND® SYSTEM 9.75/10.0 PREPARATION

For the Circulator

1. Give Scrub Tech/RN 15 cc of sterile, non-pyrogenic isotonic 0.9% NaCl saline solution and a 10 cc syringe (without 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 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 gastroesophageal (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® 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® System and priming needle
3. Connect priming needle to the LAP-BAND® System tubing end
4. Fill a syringe with 5 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
5. View the inflatable portion of the band for weaknesses, leaks or uneven inflation
6. 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 4).
7. Place the band in saline bowl or set aside until ready for insertion – It is now ready for implantation.

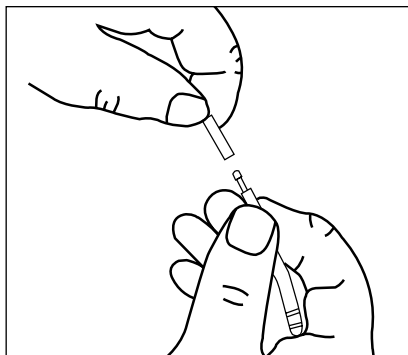


Figure 4. Insertion of Band Tubing End Plug

LAP-BAND® VG SYSTEM PREPARATION

1. Fill a 10 cc syringe with 10cc 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 band.
2. View the inflatable portion of the band for weaknesses, leaks or uneven inflation.
3. 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 band.
4. At this point, you have replaced most of the air in the band with saline.
5. 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. The tubing can be slippery. Using 4x4 gauze sponges will help grasp the tubing. (Figure 4)
6. Place the band in saline bowl or set aside until ready for insertion – It is now ready for implantation
7. If your patient's anatomy requires a larger initial perimeter, the band'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.

Procedure Basics

As with other surgical decisions, it is the responsibility of the surgeon to use his or her own judgment in utilizing the procedures best suited to the needs of the patient and the skill and experience of the surgeon. Detailed presentations of specific procedures have been published. These publications and additional information regarding procedures are provided in Allergan authorized LAP-BAND® System training programs.

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

LAP-BAND® 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 downwards 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 grasper, 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 para-medial 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 5).

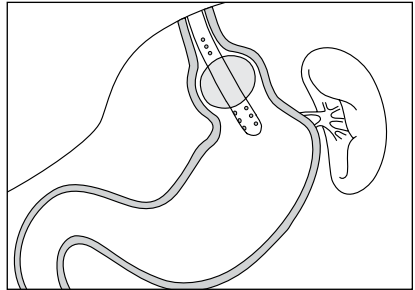


Figure 5. Calibration Tube balloon withdrawn upwards against the gastroesophageal junction.

This permits correct selection of the location along the lesser curvature and into the phrenogastric ligament to perform the blunt dissection (Figure 6).

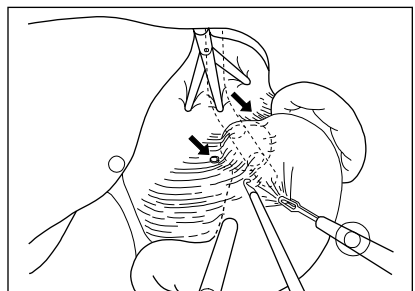


Figure 6. Calibration Tube balloon and dissection point selected.

Maximum Fill Capacity Volumes

Cat.No.	LAP-BAND® System	Max. Volume
B-2215	9.75 cm w/Access Port II	4 cc
B-2225	10.0 cm w/Access Port II	4 cc
B-2255	VG w/Access Port II	10 cc

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 TECHNIQUE: 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 7).

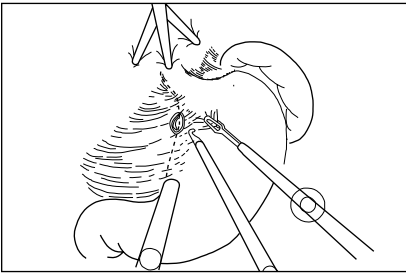


Figure 7. Dissection of the lesser curvature.

PARS FLACCIDA TO PERI-GASTRIC TECHNIQUE: 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 8).

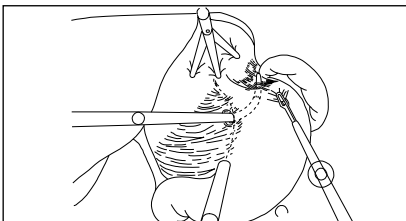


Figure 8. Posterior instrument passage.

CAUTION: 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.

CAUTION: 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 II 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 9).

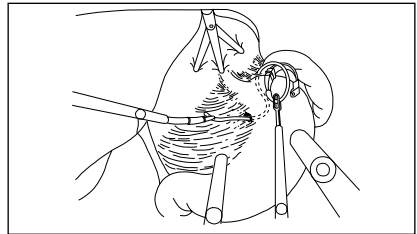


Figure 9. Placement of the band.

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.

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 10).

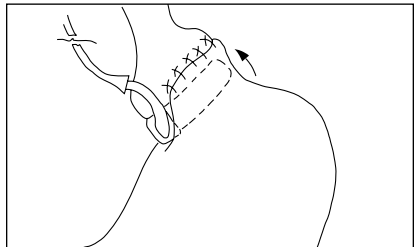


Figure 10. Suturing the greater curvature over the band and pouch.

Access Port II 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

Post-operatively, the surgeon may adjust the stoma size percutaneously by injecting or aspirating saline with the Access Port needle via the self-sealing Access Port.

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

1. The initial adjustment postoperatively should occur at six weeks or more after operation and usually 1-2 cc of sterile saline would be added for the 9.75 and 10.0 cm bands. Between 1-3 cc of sterile saline would be added for the VG band.
2. The patient should be reviewed regularly, (every 4-6 weeks) depending on patient need, and weight and clinical status measured. If the weight loss has averaged less than 1lb per week and the patient indicates there is not excessive restriction to eating, a further increment of fluid should be added.
3. Where the average weight loss between visits has been greater than 2 lbs per week, normally no additional fluid would be added.
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 difficulty in complying 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, a 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, or may have 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 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, it may be a symptom of 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. The internal diameter of the band can be increased approximately 0.5mm by withdrawing 0.4 cc of the fluid.

Elective deflation of the band is advisable in the following situations:

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

CAUTION: 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 dilatation which are entirely due to overrestriction. Dietary evaluation and appropriate nutritional counseling regarding correct eating behavior should follow band deflation and precede subsequent gradual reinflations. 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 inflation to evaluate the esophagus.

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.

Locating the Access Port with X-ray

Access Port II 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 II for the LAP-BAND® VG System is identified by a single radiopaque marker, which signifies a fill range of 0-10 cc (Figure 11).

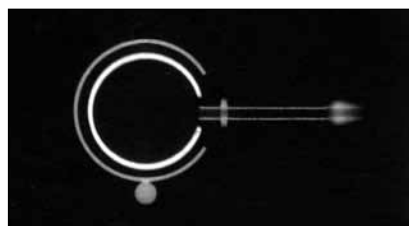


Figure 11. Top or bottom view x-ray image of the LAP-BAND® VG System Access Port II

The Access Port II for the LAP-BAND® System 9.75/10.0 has no radiopaque markers which, signifies a fill range of 0-4 cc (Figure 12).

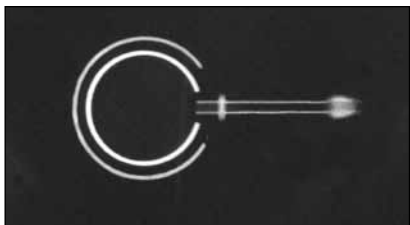


Figure 12. Top or bottom view x-ray image of the LAP-BAND® System 9.75/10.0 Access Port II

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.

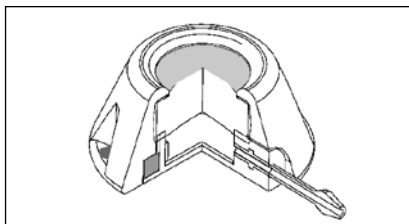


Figure 13. Cross-section view of the Access Port II

Steps for Performing an Adjustment

1. If using radiology to locate the Access Port II, shield the reproductive organs of all patients
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: place a small metal object (coin, washer, or use an Access Port needle as a pointer) on the abdomen and move it as necessary to position it exactly over the center of the port. Make a circle around the object to mark the injection site
5. Local anesthesia may be used to eliminate pain during injection
6. Position the needle perpendicularly to the septum of the Access Port (Figure 14)

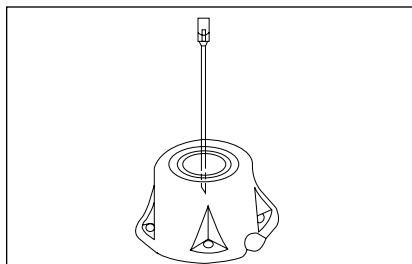


Figure 14. Needle and Access Port II

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, 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, before discharge, that the stoma is not too small. 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 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 gastrografen 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

The band can be removed 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 cut the buckle portion of the band under and behind the locking head. Cut the tubing where it attaches to the band and pull the band out buckle first, to avoid pulling the buckle behind the stomach. Remove the Access Port and remaining tubing. Close the wounds.

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.

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.

HOW SUPPLIED

All components of the LAP-BAND® 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).

Medical Imaging

The LAP-BAND® System is 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).

Special Notice

The manufacturer of the LAP-BAND® Adjustable Gastric Banding 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 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® System may be easily damaged by improper handling or use. Please refer to the adverse events section in this document and to the booklet, "A Surgical Aid in the Treatment of Morbid Obesity," for a presentation of the warnings, precautions, and the possible adverse events associated with the use of the LAP-BAND® Adjustable Gastric Banding System.

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
5540 Ekwil Street
Santa Barbara, CA 93111
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® Adjustable Gastric Banding System contains no latex or natural rubber materials.

The LAP-BAND® System and accessories are covered by the following U.S. Patents: 5,601,604; 5,658,298.

 STERILE	YYYY/XX Sterile, Dry Heat Sterilized, Date of Sterilization, Year & Month
	Attention! See instructions for use.
	Single Use Only. Do Not Reuse.
 YYYY/XX	Use By Year & Month
	Manufacturer
 YYYY/XX	Date of Manufacture, Year & Month
SN	Serial Number
REF	Catalog Number
	Contains no latex
	This device restricted to sale by or on the order of a physician.



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