



LAP-BAND AP® Adjustable Gastric Banding System with OMNIFORM™ Design

DIRECTIONS FOR USE (DFU)

Rx Only



LAP-BAND AP® Adjustable Gastric Banding System

DESCRIPTION

Cat No. B-2260 LAP-BAND AP® System Standard
Cat No. B-2265 LAP-BAND AP® System Large

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 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 AP®, constructed 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 (ASBMS) 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 (sold separately). 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 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 secured in place utilizing the suture holes in the port base or the RapidPort tool (if using the RapidPort design). 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 AP® Systems is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 35 or a BMI of at least 30 with one or more severe comorbid conditions, or those who are 100 pounds 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.

Weight loss associated with the LAP-BAND® System has been shown to improve or lead to remission of type 2 diabetes in patients with BMI greater than or equal to 35.

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 reoperation.
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 to be inappropriate, in the opinion of the surgeon for select patients.

6. Patients should be advised that the LAP-BAND AP® 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.
7. 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.
8. Some types of esophageal dysmotility may result in inadequate weight loss or may result in esophageal dilatation when the band is inflated. Band removal may be required. 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. Patients self-adjustment of their bands has been reported. This can result in inappropriate band tightness, infection and other complications.
11. Patients must be carefully counseled on the need to report all vomiting, abdominal pain or other gastrointestinal or nutritional issues as these symptoms may indicate a condition not related to the LAP-BAND® System.

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 for use).
 - 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 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.
4. During insertion of the Calibration Tube, care must be taken to prevent perforation of the esophagus or stomach.
5. 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.

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).

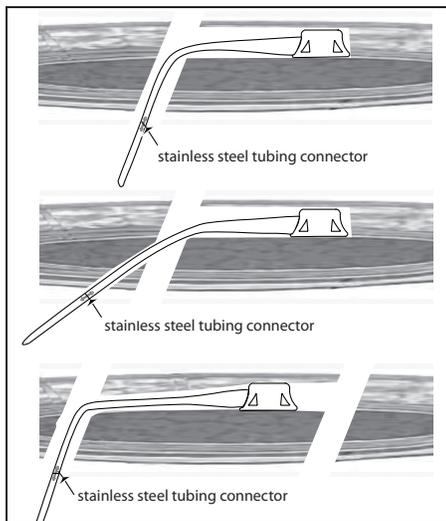


Figure 1. Port Placement Options

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 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.
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 instruments 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. Failure to enter the port with the needle perpendicular to the port may cause damage to the access port and result in leaks.
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 never enter the Access Port with a "syringeless" needle. The fluid in the device is under pressure and will be released through the needle.
21. 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.
22. 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.
23. 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.
24. 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.
25. 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.
26. Patients must be seen regularly during periods of rapid weight loss for signs of malnutrition, anemia or other related complications.
27. Anti-inflammatory agents, which may irritate the stomach, such as aspirin and non-steroidal anti-inflammatory drugs, should be used with caution. The use of such medications may be associated with an increased risk of erosion.
28. Patients who become pregnant, severely ill, or who require more extensive nutrition may require deflation of their bands.

29. All patients should have their reproductive, areas shielded during radiography.
30. 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.
31. 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.
32. 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 currently no conclusive clinical 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.

Slippage and/or pouch dilatation of the band can occur. Gastroesophageal 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 US adult study, 42% of the patients 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. Symptoms of band erosion may include reduced weight loss, weight gain, Access Port infection, or abdominal pain. Reoperation 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. 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.

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 result in the need for a cholecystectomy.

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 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 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.

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.

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.

The LAP-BAND AP® System (including accessories) is not intended to be re-sterilized or re-used. Cleaning and autoclaving processes can cause damage to the components resulting in improper function or band deflation. Such failures would require re-entry in order to resolve. Reuse of the device can cause risk of infection to the patient.

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. Access Port Needle, (sterile), one each
4. Blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile), one each
5. Blunt flushing needle, 22 gauge, 127 mm (5 inch) (sterile), one each
6. 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. 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 Large band is normally used. It is recommended that surgeons evaluate the amount of tissue within the band prior to band locking and suturing in place. 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 AP® Adjustable Gastric Banding System Features:

The LAP-BAND AP® system is constructed with OmniForm™ Design, which employs soft, pre-curved sections in the inflation bladder. When fastened, the LAPBAND AP® system forms a circular ring around the proximal stomach. All bands transition to a silicone tube which is approximately 50 cm long. The band is made of silicone elastomer. The radiopaque, kink-resistant tubing is used to connect the inflatable section to the Access Port. Arrows printed on the tubing aid the surgeon in placing it toward the Access Port. An end plug is provided to seal the system while the band is being passed around the stomach.

Access Port:

The Access Port (one example shown in Figure 2) is for percutaneous adjustment of the stoma diameter and is self-sealing when penetrated by the Access Port needle.

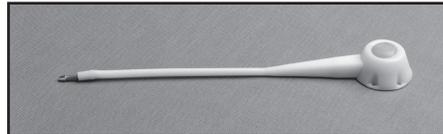


Figure 2. Access Port II with tapered transition

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. 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 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 (3.5 inch), B-20302-10 (2 inch) and B-20311-10 (1.5 inch)).

Additional Equipment and Materials (Not Included):

- Calibration Tube (non-sterile)
- 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)

Calibration Tube (B-2017)

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

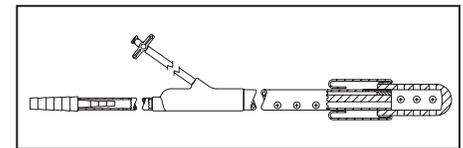


Figure 3. Calibration Tube

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

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
- Use a 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 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 (sold 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 16 gauge 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 4). The tubing can be slippery. Using 4x4 gauze sponges will help grasp the tubing.

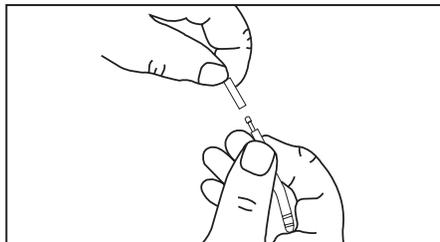


Figure 4. Insertion of Band Tubing End Plug

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 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 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 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 5).

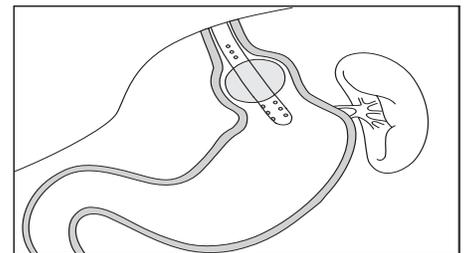


Figure 5. Calibration Tube balloon withdrawn upwards against the gastroesophageal junction.

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

Lesser Curve Dissection Options

Three techniques have been used to dissect on the lesser curve.

Preferred Technique:

NOTE: 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).

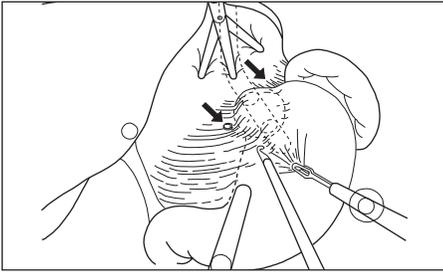


Figure 6. Calibration Tube balloon and dissection point selected.

PARS FLACCIDA TECHNIQUE: 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.

Other Techniques:

PERI-GASTRIC TECHNIQUE: Dissection 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).

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.

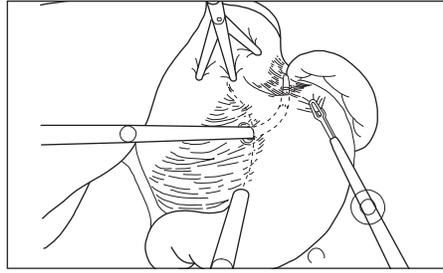


Figure 8. Posterior instrument passage.

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 9).

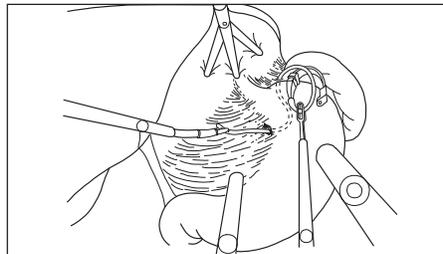


Figure 9. Placement of the band.

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 such as the LAP-BAND® System Closure Tool 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 10) and slide the tubing through the buckle until there is ample area to adjust the position of the band.

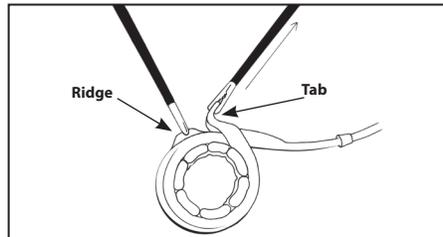


Figure 10. Unlocking the LAP-BAND AP® System.

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 11).

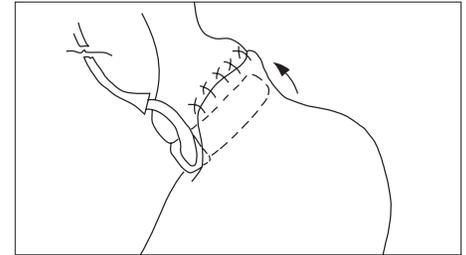


Figure 11. Suturing the greater curvature over the LAP-BAND AP® System and pouch.

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 the Rapid Port Application tool. 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, and 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, and weight and clinical status measured. If the weight loss has averaged less than 0.5 kilos per week over the period 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 1 kilo per week, normally no additional fluid would be added
4. If the weight loss averaged between 0.5 and 1 kilo 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, 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, 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 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.

Locating the Access Port with x-ray

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 12).

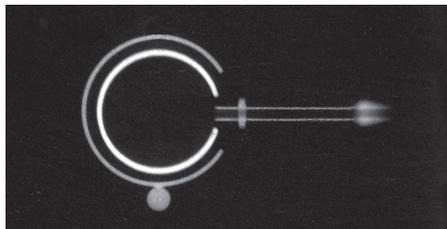


Figure 12. Top or bottom view x-ray image of the LAP-BAND AP® System Standard Access Port II

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 13).

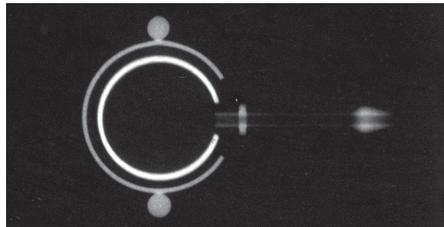


Figure 13. Top or bottom view x-ray image of the LAP-BAND AP® System Large Access Port II

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. Place a small metal object (coin, washer or use the access port needle as a pointer) and move it as necessary to position it exactly over the centre of the port. Make a circle around the object to mark the injection site. Alternatively, the access port can also be located by manual palpation.
5. Local anesthesia may be used to eliminate pain during injection.
6. When adjusting band volume, the needle must be inserted perpendicular to the access port septum (Figure 14). Failure to do so may cause damage to the access port and result in leaks.

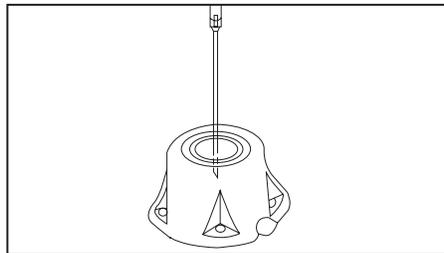


Figure 14. Needle and Access Port II

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 stoma 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.

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.

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:

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

The LAP-BAND AP® Adjustable Gastric Banding System and accessories are covered by the following US Patents:
5,601,604; 5,658,298.

	<p>Sterile, Dry Heat Sterilized, Date of Sterilization, Year & Month</p>
	<p>Attention! See instructions for use.</p>
	<p>Manufacturer</p>
	<p>Authorized Representative In the European Community</p>
<p>REF</p>	<p>Catalog Number</p>
	<p>Contains no latex</p>
<p>SN</p>	<p>Serial Number</p>
	<p>This device restricted to sale by or on the order of a physician.</p>
	<p>Use By Year & Month</p>
	<p>Single Use Only. Do Not Reuse.</p>



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