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

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.
DESCRIPTION

LAP-BAND AP™ Adjustable Gastric Banding System is designed to induce weight loss in severely obese patients by limiting food consumption. The band's bypassing of portions of the stomach or intestines and connected by kink-resistant tubing to the Access Port, which of the calibration tube. The inner surface of the band is made of medical grade silicone, which is smooth and non-irritating to the stomach. The outer surface of the band is covered with a durable, slip-resistant material to prevent slippage. The band is adjusted postoperatively by the surgeon or an authorized Allergan distributor to achieve the desired stoma size. The Access Port is a small incision in the skin above the band that allows the patient to self-adjust the band pressure. The system is approved by the FDA and is indicated for use in patients with a body mass index (BMI) of at least 35 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.

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 telangiectasies.
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 experienced an intra-operative 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.
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.
15. Patients or family members with a known diagnosis or history of 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 by physician to be inappropriate for select patients.
6. Patients should be advised that the LAP-BAND AP™ System is a long-term implant. Explant 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 dilation has been reported to result from stoma obstruction from over-restriction by excessive band inflation. Patients should not expect to lose weight as fast as gastric bypass patients, and band inflation should proceed in small increments. Deflation of the band is recommended if esophageal dilation develops.
8. Some types of esophageal dysmotility may result in inadequate weight loss or in esophageal dilation 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.
9. Patients with Barrett's esophagus may have problems associated with their esophageal pathology that could compromise their post-surgical course. Use of the band in these patients should be considered on the basis of each patient's medical history and severity of symptoms.
10. Patient self-adjustment of superficially placed access ports has been reported. This can result in inappropriate band tightness, infection and other complications.

PRECAUTIONS

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

2. It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant.
3. As with 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. Revision procedures may require the existing staple line to be partially disrupted to avoid having a second point of obstruction below the band. As with any revision procedure, the possibility of complications such as erosion and infection is increased. Any damage to the...
stomach during the procedure may result in peritonitis and death or in late erosion of the device into the GI tract.

6. Care must be taken to place the Access Port in a stable position away from areas that may be affected by significant weight loss, physical activity or subsequent surgery. Failure to do so may result in the inability to perform percutaneous band adjustments.

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

8. Failure to create a stable, smooth path for the Access Port tubing, without sharp turns or bends, can result in tubing breaks and leakage. In order to avoid incorrect placement, the port should be placed lateral to the trocar opening. A pocket must be created for the port so that it is placed far enough from the trocar path to avoid abrupt kinking of the tubing. The tubing path should point in the direction of the Access Port connector so that the tubing will form a straight line with a gentle arching transition into the abdomen. (See Figure 1, Port Placement Options).

9. The LAP-BAND APR 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 these items 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 APR 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-shot 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 occur. Stomach perforation may result in peritonitis and death.

16. Over-distention of the stomach during placement may result in leakage of the port into the surrounding tissues.

17. 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.

18. 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 APR System Access Port Needles. Do not use standard hypodermic needles, as these may cause leaks.

19. When adjusting band volume never enter the Access Port with a “syringeless” needle. Fluid in the device is under pressure and will be released through the needle.

20. 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.

21. If fluid has been added, it is important to establish the stoma is not too small before discharge. Care must be taken to not add too much saline, thereby closing the 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.

22. 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.

23. Patients must be carefully counseled on the need for the appropriate nutritional (including caloric) needs and advised on the proper diet selection. The physician may choose to prescribe appropriate dietary supplements. The appropriate physical monitoring and dietary counseling should take place regularly.

24. Patients must be cautioned to chew their food thoroughly. Patients with dentures must 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.

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

26. Anti-inflammatory agents, that 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.

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

28. All patients should have their reproductive areas shielded during radiography.

30. Insufficient weight loss may be caused by pouch enlargement or, more frequently, 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 folicates 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.

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 bloating, dysphagia, dehydration, constipation, and weight regain have been reported after gastric restriction procedures. Band slippage and/or pouch dilatation can occur. Gastroesophageal reflux, nausea and/or vomiting with early or minor slippage may be successfully resolved by band deflation in some cases. More serious slippages may require band repositioning and/or removal. Immediate re-operation to remove the band is indicated if there is total stomach obstruction that does not respond to band deflation or if there is abdominal pain.

Gastric banding done as a revision procedure has a greater risk of complications. Prior abdominal surgery is commonly associated with adhesions involving the stomach. In the US study, 42% of the 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. Consultation with other experienced LAP-BAND® System surgeons is strongly advised in these cases.

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

Obstruction of stomach 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
Serious Adverse Events Considered Related to the LAP-BAND® System for the US Study
(Recorded as of December 2000, 299 Patients)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>% of patients</th>
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<tbody>
<tr>
<td>Band Slippage, Pouch Dilation</td>
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<tr>
<td>Stoma Obstruction</td>
<td>8</td>
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<tr>
<td>Gastroesophageal Reflux</td>
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<tr>
<td>Esophageal Dilatation</td>
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<tr>
<td>Cholelithiasis</td>
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<tr>
<td>Incisional Infection</td>
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<tr>
<td>Abdominal Pain</td>
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<tr>
<td>Gastroenteritis</td>
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<tr>
<td>Nausea and/or Vomiting</td>
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<td>Port Leak</td>
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<tr>
<td>Delayed Esophageal Emptying</td>
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<tr>
<td>GI Perforation</td>
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<tr>
<td>Hernia</td>
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<tr>
<td>Band Erosion</td>
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</tr>
<tr>
<td>Chest Pain</td>
<td>1</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>1</td>
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<tr>
<td>Infection</td>
<td>1</td>
</tr>
<tr>
<td>Asthma</td>
<td>1</td>
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<tr>
<td>Atelactasis</td>
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<tr>
<td>Dehydration</td>
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<tr>
<td>Headache</td>
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<tr>
<td>Abnormal Healing</td>
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<tr>
<td>Hiatal Hernia</td>
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<td>Improper Band Placement</td>
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<td>Respiratory Disorder</td>
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<td>Thrombosis</td>
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<td>Thyroid Disorder</td>
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<td>Death</td>
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</table>

All Adverse Events (Mild, Moderate, Severe) that Occurred at a Rate of 5% or More
(Recorded as of December 2000, 299 Patients)

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digestive</td>
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<tr>
<td>Nausea and/or Vomiting</td>
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<tr>
<td>Gastroesophageal Reflux</td>
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<tr>
<td>Stoma Obstruction</td>
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<tr>
<td>Constipation</td>
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<td>Dysphagia</td>
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<td>Diarrhea</td>
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<td>Abnormal Stools</td>
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<td>Abdominal Pain</td>
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<tr>
<td>Aspiration</td>
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<tr>
<td>Incisional Infection</td>
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<tr>
<td>Infection</td>
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<tr>
<td>Fever</td>
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<tr>
<td>Hernia</td>
<td>16</td>
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<tr>
<td>Pain</td>
<td>16</td>
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<tr>
<td>Chest Pain</td>
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<td>Pain Incision</td>
<td>14</td>
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<tr>
<td>Band-Specific</td>
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<tr>
<td>Band Slippage/Pouch Dilation</td>
<td>72</td>
</tr>
<tr>
<td>Metabolic and Nutritional</td>
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<tr>
<td>Healing Abnormal</td>
<td>23</td>
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<tr>
<td>Port-Specific</td>
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<tr>
<td>Port Site Pain</td>
<td>26</td>
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<td>Port Displacement</td>
<td>18</td>
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<tr>
<td>Skin and Appendages</td>
<td></td>
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<tr>
<td>Alopecia</td>
<td>23</td>
</tr>
</tbody>
</table>

Adverse Events:
- Infection, redundant skin, dehydration, GI perforation, diarrhea, abdominal stools, constipation, flatulence, dyspepsia, eructation, cardiohypertension, anemia, fever, chest pain, incision pain, contact dermatitis, abnormal healing, edema, parenchyma, 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 had new band replacements at separate interventions. Sixteen of 27 revision procedures (59%) did not require removal of bands. All of these revisions were performed to correct band slippage/pouch dilatation. Six of these (37.5%) were completed laparoscopically. There were no deaths associated with LAP-BAND® System revisions.
- Seventy-five subjects had their entire LAP-BAND® Systems explanted. Fifty-one of the 75 explants (68%) were counter measures to adverse events. Band slippage/pouch dilatation and/or stoma obstruction was the most common adverse event associated with these explants (32% - 24/75). Other events associated with these explants were erosion (5% - 3/75), 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 1 respiratory disorder. Insufficient weight loss was also reported as a contributor to the decision to explant in 24 of the 75 explants (32%).

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 the mid point for medium frame).
The product is indicated for use only in patients who have failed more conservative weight-reduction approaches, 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 1996, a non-randomized, single-armed (non-comparative) study was initiated. The study consisted of a multi-center clinical evaluation with 8 participating sites and an enrollment of 299 subjects. The study was approved with patient follow-up at 3 weeks, 3, 6, 9, 12, 18, 24, 30, and 36 months. The 9.75 cm (B-2110) and 10.0 cm (B-2220) LAP-BAND® Systems were used in the study.

The primary effectiveness 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 subject in the year(s) prior to placement of the LAP-BAND® System were considered as secondary effectiveness measures. In addition, secondary effectiveness 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 US study. The patient gender breakdown was 80% female and 19% 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 at which 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 were 350 BMI and thus classified as "super-obese." 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 (25%), gastrointestinal diseases (24%), asthma (16%), non-insulin dependent diabetes (11%), and insulin dependent diabetes (8%).

Patient inclusion criteria:
- Age 18 to 55.
- Male or female.
- BMI of 40 or above, or at least 100 pounds above estimated ideal weight.
- Willingness to comply with the substantial lifelong dietary restrictions required by the procedure.
- History of obesity for at least 5 years.
- History of failure with non-surgical, weight-loss methods.
- Willingness to follow protocol requirements, including signed informed consent, routine follow-up schedule, completing quality-of-life questionnaires, completing...
laboratory tests, completing diet and behavior modification counseling.

• Reside within a reasonable distance from the investigator’s office and be able to travel to the office 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, or angiodysplasia.
• Congenital or acquired anomalies of the GI tract such as stenosis or malrotation.
• Severe hiatal hernia.
• Pregnancy or the intention of becoming pregnant in the next 12 months.
• Alcohol or drug addiction.
• Mentally retarded; emotionally unstable or exhibits psychological characteristics.
• Previous bariatric surgery (except Adjustable Silicone Gastric Band), intestinal obstruction or adhesive peritonitis.
• Infection anywhere in the body at the time of surgery.
• Family or patient history of a known diagnosis or pre-existing symptoms of systemic lupus erythematosus, scleroderma or other autoimmune disease.
• Participating in another ongoing clinical trial in which concomitant diagnostic or therapeutic intervention would adversely affect the integrity of the LAP-BAND® System U.S. 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 per operatively (< 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 perioperative dissection technique with pouches of 25 ml or later in the study) 15 ml. 259 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.

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<thead>
<tr>
<th>Visit</th>
<th>N</th>
<th>%EWL</th>
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<tr>
<td>6 months</td>
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<tr>
<td>12 months</td>
<td>233</td>
<td>34.5</td>
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<tr>
<td>18 months</td>
<td>190</td>
<td>36.4</td>
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<td>24 months</td>
<td>169</td>
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<td>30 months</td>
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<td>36 months</td>
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Mean %EWL by Visit

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<tr>
<th>Visit</th>
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<th>%EWL</th>
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<td>Baseline</td>
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<tr>
<td>6 months</td>
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<td>36 months</td>
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Mean Weight by Visit (in pounds)

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Mean BMI by Visit

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HOW SUPPLIED

All components of the LAP-BAND® AP™ Adjustable Gastric Banding System are for single use only. The band, Access Port, and stainless steel connector are provided sterile in double packaging with a protective outer container. The Access Port needle is provided sterile in separate packaging.

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

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

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

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

Required Equipment and Materials (Included)

System Components:
1. LAP-BAND® AP™ Adjustable Gastric Banding System (sterile), one each
2. Access Port with Stainless Steel Connector (sterile), one each
3. Calibration Tube (non-sterile), one each
4. Access Port Needle, 89 mm (3.5 inch), (sterile), one each
5. Blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile), one each
6. Blunt flushing needle, 22 gauge, 127 mm (5 inch) (sterile), one each
7. End plug with Stainless Steel Connector (sterile), one each

The LAP-BAND® AP™ System is available in two sizes, Standard and Large. The physician should choose the appropriate size depending upon the patient’s individual anatomy. Most patients with correctly fitted bands report minimal, and the physician may consider non-sterile and may cause infection of the patient.

The Access Port Needle used to join the tubing of the band to the Access Port.

Access Port Needle Features:
The Access Port needle is a 20 gauge, 89 mm (3.5 inch) long non-coring, deflected-tip (“Huber tip”) needle designed to penetrate the Access Port during post-operative adjustment of the LAP-BAND® AP™ System (see Instructions for Use). Access port needles are available in boxes of 10 (B-20301-10).

Calibration Tube:
The calibration tube (Figure 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 inflated 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.

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

Additional 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 89 mm (3.5 inch) Access Port needle (supplied with LAP-BAND® System and available separately) or a sterile 20 gauge 51 mm (2 inch) Access Port needle (available as 10 pack: B-20302-10) or other 20 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 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 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 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 to Scrub Tech/RN approximately 15 cc of sterile, non-pyrogenic isotonic 0.9% NaCl 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
For the Anesthesiologist:

1. The Calibration Tube is an oral suction tube that requires a lubricant and 30 cc syringe for inflation.

2. Surgeon will instruct anesthesiologist to remove patient's NG 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 one 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 Technol:

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.


4. Fill a 20 cc syringe with at least 15 cc of saline and connect syringe to the priming needle. Flush the band and inflatable shell area several times, each time drawing out air bubbles. A residual amount of saline will stay in the LAP-BAND Ap™ System.

5. View the inflatable portion of the band for leaks or uneven inflation.

6. Inject about 5 cc saline and disconnect the syringe. The excess saline will be forced out of the band, leaving about 4 cc of saline in the LAP-BAND Ap™ System Standard and 5 cc in the LAP-BAND Ap™ System Large.

7. At this point, you have replaced most of the air in the LAP-BAND Ap™ System with saline.

8. Insert the end plug into the tubing end until the stainless steel tubing connector disappears into the open end of the band fill tube - this will facilitate pulling the tube around the stomach (see Figure 5). The tubing can be slippery. Using 4x4 gauze sponges will help grasp the tubing.

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's 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 workshops.

LAP-BAND Ap™ SYSTEM SURGICAL PROCEDURE

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

Position of the Patient and the Surgeon: The patient is most commonly placed in a lithotomy position, in a moderate anti-Trendelenburg tilt. The surgeon stands between the patient's legs, the first assistant on the patient's right, and to 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 in the patient's abdomen, and they must be inserted so that they are clearly recognizable.

Lesser Curve Dissection Options

Lesser curve is seen, followed immediately by the left crus over to the angle of His. PARS FLACCIDA TO PARI-GASTRIC TECHNIQUE: Dissection begins with the pars flaccida technique (above). A second dissection is made at the midpoint (equator) of the balloon near the stomach until the pari-gastric dissection intercepts the pars flaccida dissection. The band is then placed from the angle of His through to the pari-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.

Retrogastrectomy: Always use blunt dissection until the opening is large enough to insert the band system. Through this opening, use blunt dissection to create a tunnel of sufficient size to accommodate the band system. The tubing is inserted into the band's space. The tubing may be shortened to tailor the position of the band.

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.

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

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 sutured in place utilizing the four suture holes in the port base. 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. Normally, additional fluid would not be added if average weight loss has been greater than 1 kilo (or 2 lbs) per week without vomiting.

4. If the weight loss averaged between 0.5 and 1 kilo per week, additional fluid would be indicated if the patient felt hungry but 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 fluid 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 slipage 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 possibility of a leak in the system. The band may be evaluated for a leak using a radiopaque solution, such as Hyopaque or Conray-43, flushing it from the band system after the evaluation. If pouch enlargement or band/stomach slipage 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), 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 anesthesia
- 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 from 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 dilation 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 dilation.

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

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

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

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

Figure 15. Top or bottom view x-ray image of the LAP-BAND AP™ System 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 preferably antiseptic 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 radiographically or by manual palpation.
5. Local anesthesia may be used to eliminate pain during injection.
6. Position the needle perpendicularly to the septum of the Access Port (Figure 17).

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 "springless" needle. The fluid in the device is under pressure and could be released through the needle.

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

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

9. To increase stoma size: Taking into account any fluid withdrawn to confirm port penetration, remove fluid to deflate the band and increase the stoma size. Take care to remove only enough fluid to deflate the band; avoid creating a vacuum.

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

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

Adjustment Following Significant Weight Loss

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

Band Removal/Repositioning

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

Medical Imaging

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

Returned Goods Policy

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

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

Special Notice

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

Reporting and Return of Explanted Devices

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

AUTHORIZED TRAINING PROGRAM AND PRODUCT ORDERING INFORMATION

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

For additional information please contact:

Manufacturer

Allergan

5540 Ewilk Street
Santa Barbara, California 93111, U.S.A.

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.

U.S. Patents: 5,601,604; 6,558,298.
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