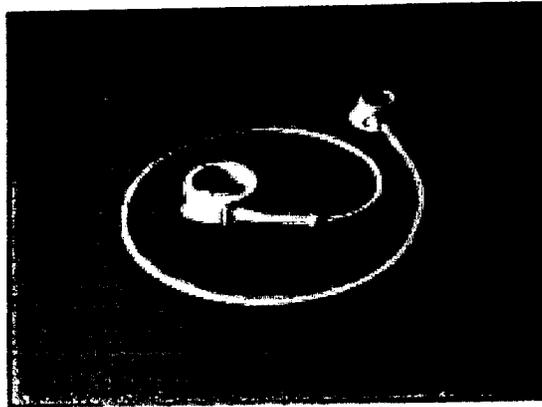




**BioEnterics**  
CORPORATION An **INAMED** Company

# LAP-BAND<sup>®</sup>

## Adjustable Gastric Banding System



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

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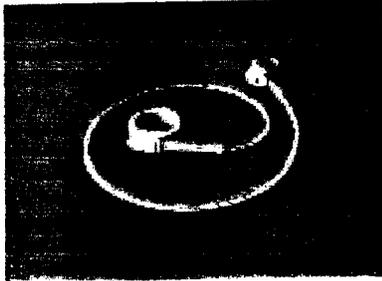


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## LAP-BAND® Adjustable Gastric Banding System



**Figure 1. The LAP-BAND Adjustable Gastric Banding System**

### 1. Description

9.75 cm size: Cat. No. B-2210  
10.0 cm size: Cat. No. B-2220

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

The initial pouch and stoma sizes are established through the use of the calibration tube. The inner surface of the band is inflatable and connected by kink-resistant tubing to the access port, which is included in the **LAP-BAND System**. This permits post-operative percutaneous stoma size adjustment. Dietary and behavior modification counseling and frequent and long-term follow-up are required for all patients after weight-loss surgery.

Surgeons planning laparoscopic placement must have extensive advanced laparoscopic experience, i.e., 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 of Bariatric Surgeons (ASBS) and the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) joint

"Guidelines for Surgical Treatment of Morbid Obesity" and the SAGES "Guidelines for Framework for Post-Residency Surgical Education and Training". Surgeon participation in a training program authorized by BioEnterics or by an authorized BioEnterics distributor is required prior to use of the **LAP-BAND System**. Please see the last page for directions on obtaining additional information.

### Brief Description of Procedure

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

Please refer to the Surgical Procedure section, page 11, for more information.

### 2. Intended Use / Indications

The **LAP-BAND System** is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.

### (3) Contraindications

The LAP-BAND System is contraindicated in:

1. Patients with inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease.
2. Patients with severe cardiopulmonary diseases or other serious organic disease which may make them poor surgical candidates.
3. Patients with potential upper 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 intraoperative gastric injury during the implantation procedure, such as a gastric perforation at or near the location of the intended band placement.
7. Patients with cirrhosis.
8. Patients with chronic pancreatitis.
9. Patients who are addicted to alcohol and/or drugs.
10. Non-adult patients (patients under 18 years of age).
11. Patients who have an infection anywhere in their body or where the possibility of contamination prior to or during the surgery exists.
12. Patients on chronic, long-term steroid treatment.
13. Patients who are unable or unwilling to comply with dietary restrictions, which are required by this procedure.

14. Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system or who have exhibited a pain intolerance to implanted devices.
15. Patients or family members with a known diagnosis or pre-existing symptoms of autoimmune connective tissue disease such as systemic lupus erythematosus or scleroderma.
16. **Pregnancy:** Placement of the LAP-BAND System is contraindicated for patients who currently are or may be pregnant. Patients who become pregnant after band placement may require deflation of their bands.

### 4. Warnings

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

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

**WARNING:** 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.

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

**WARNING:** 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.

**WARNING:** Patients should be advised that the LAP-BAND System is a long-term implant. Explant and replacement surgery may be indicated at any time. Medical management of adverse reactions may include explantation. Revision surgery for explantation and replacement may also be indicated to achieve patient satisfaction.

**WARNING:** 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.

**WARNING:** Some types of esophageal dysmotility may result in inadequate weight loss or may result in esophageal dilatation when the band is inflated and require removal of the band. On the basis of each patient's medical history and symptoms, surgeons should determine whether esophageal motility function studies are necessary. If these studies indicate that the patient has esophageal dysmotility, the increased risks associated with band placement must be considered.

**WARNING:** 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.

**WARNING:** Patient self-adjustment of superficially placed access ports has been reported. This can result in inappropriate band tightness, infection and other complications.

## 5. Precautions

**CAUTION:** Laparoscopic band placement is an advanced laparoscopic procedure. Surgeons planning laparoscopic placement must:

1. Have extensive advanced laparoscopic experience, i.e., funduplications.
2. 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.
3. Participate in a training program for the **LAP-BAND System** authorized by BioEnterics Corporation or an authorized BioEnterics distributor (this is a requirement for use).
4. Be observed by qualified personnel during their first band placements.

5. Have the equipment and experience necessary to complete the procedure via laparotomy if required.

6. Be willing to report the results of their experience to further improve the surgical treatment of severe obesity.

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

**CAUTION:** As with other gastroplasty surgeries, particular care must be taken during dissection and during implantation of the device to avoid damage to the gastrointestinal tract. Any damage to the stomach during the procedure may result in erosion of the device into the GI tract.

**CAUTION:** During insertion of the calibration tube, care must be taken to prevent perforation of the esophagus or stomach.

**CAUTION:** In revision procedures the existing staple line may need to be partially disrupted to avoid having a second point of obstruction below the band. As with any revision procedure, the possibility of complications such as erosion and infection is increased. Any damage to the stomach during the procedure may result in peritonitis and death, or in late erosion of the device into the GI tract.

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

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

**CAUTION:** The **LAP-BAND System** is for single use only. Do not use a band, access port, needle or calibration tube which appears damaged (cut, torn, etc.) in any way. Do not use one of them if the package has been opened or damaged, or if there is any evidence of tampering. If packaging has been damaged, the product may not be sterile and may cause an infection.

Do not attempt to clean, re-sterilize or re-use any part of the **LAP-BAND Adjustable Gastric Banding System**. The product may be damaged or distorted if re-sterilized.

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

**CAUTION:** Care must be taken to avoid damaging the band, its inflatable section or tubing, the access port or the calibration tube. Use only rubber-shod clamps to clamp tubing.

**CAUTION:** The band, access port and calibration tube may be damaged by sharp objects and manipulation with instruments. A damaged device must not be implanted. For this reason, a stand-by device should be available at the time of surgery.

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

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

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

**CAUTION:** Failure to use an appropriate atraumatic instrument such as the **LAP-BAND Closure Tool** to lock the band may result in damage to the band or injury to surrounding tissues.

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

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

**CAUTION:** When adjusting band volume use of an inappropriate needle may cause access

port leakage and require re-operation to replace the port. Use only **LAP-BAND System Access Port Needles**. Do not use standard hypodermic needles, as these may cause leaks.

**CAUTION:** When adjusting band volume never enter the access port with a "syringeless" needle. The fluid in the device is under pressure and will be released through the needle.

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

**CAUTION:** When adjusting band volume if fluid has been added to decrease the stoma size, it is important to establish, before discharge, that the stoma is not too small. Care must be taken during band adjustments not to add too much saline, thereby closing the gastric stoma. Check the adjustment by having the patient drink water. If the patient is unable to swallow, remove some fluid from the port, then 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.

**CAUTION:** It is the responsibility of the surgeon to advise the patient of the dietary restrictions which follow this procedure and to provide diet and behavior modification support. Failure to adhere to the dietary restrictions may result in obstruction and/or failure to lose weight.

**CAUTION:** Patients must be carefully counseled on the need for proper dietary habits. They should be evaluated for nutritional (including caloric) needs and advised on the proper diet selection. If necessary to avoid any nutritional deficiencies, the physician may choose to prescribe appropriate dietary supplements. The appropriate physical monitoring and dietary counseling should take place regularly.

**CAUTION:** Patients must be cautioned to chew their food thoroughly. Patients with dentures must be cautioned to be particularly careful to cut their food into small pieces. Failure to follow these precautions may result in vomiting, stomal irritation and edema, possibly even obstruction.

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

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

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

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

**CAUTION:** Insufficient weight loss may be caused by pouch enlargement or more infrequently band erosion, in which case further inflation of the band would not be appropriate.

**CAUTION:** Elevated homocysteine levels have been found in patients actively losing weight after obesity surgery. Supplemental folate and vitamin B12 may be necessary to maintain normal homocysteine levels. Elevated homocysteine levels may increase cardiovascular risk and the risk of neural tube abnormalities.

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

## 6. 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, major blood vessels, lung problems, thrombosis, and rupture of the wound.

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

Slippage of the band can occur. 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 stomal outlet obstruction that does not respond to band deflation, or if there is abdominal pain, then immediate re-operation to remove the band is indicated.

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

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

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

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

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

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

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

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

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

Rapid weight loss may result in development of cholelithiasis which may result in the need for a cholecystectomy.

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

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

All Serious Adverse Events* Recorded as of December 2000	(N=299) (% Pts)
Band Slippage, Pouch Dilatation	11%
Stoma Obstruction	8%
Gastroesophageal Reflux	3%
Esophageal Dilatation	2%
Cholelithiasis	2%
Incisional Infection	2%
Abdominal Pain	2%
Gastroenteritis	2%
Nausea and/or Vomiting	2%
Port Leak	2%
Delayed Esophageal Emptying	1%
GI Perforation	1%
Hernia	1%
Band Erosion	1%
Chest Pain	1%
Dysphagia	1%
Infection	1%
Asthma	1%
Atelectasis	1%
Dehydration	1%
Headache	1%
Abnormal Healing	1%
Hiatal Hernia	1%
Improper Band Placement	1%
Respiratory Disorder	1%
Thrombosis	1%
Thyroid Disorder	1%
Death	0%

The following table summarizes all adverse events that occurred at a rate of 5% or more.

All Adverse Events (Mild, Moderate, Severe) Recorded as of December 2000		
	(N=299)	(≥ 5%)
Digestive	N	%
Nausea and/or Vomiting	152	51
Gastroesophageal Reflux	103	34
Stoma Obstruction	41	14
Constipation	27	9
Dysphagia	26	9
Diarrhea	22	7
Abnormal Stools	18	6
<b>Body as a Whole</b>		
Abdominal Pain	80	27
Asthenia	25	8
Incisional Infection	21	7
Infection	20	7
Fever	18	6
Hernia	16	5
Pain	16	5
Chest Pain	15	5
Pain Incision	14	5
<b>Band-Specific</b>		
Band Slippage/Pouch Dilatation	72	24
<b>Metabolic and Nutritional</b>		
Healing Abnormal	23	8
<b>Port-Specific</b>		
Port Site Pain	26	9
Port Displacement	18	6
<b>Skin and Appendages</b>		
Alopecia	23	8

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

Twenty-seven revision procedures, involving 26 subjects (9%, 26/299) occurred. Thirteen of these 27 (48%) revision procedures were completed laparoscopically. In 9 of the 27 procedures (33%),

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

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

## 7. Clinical Experience

### Purpose of the Trial:

The purpose of the study was to support the safety and effectiveness of the device for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use of the mid-point for medium frame).

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

**Study Design:**

In June of 1995, BEC initiated a non-randomized, single-arm (non-comparative) study. The study consisted of a multi-center clinical evaluation with eight (8) participating sites and an enrollment of 299 subjects. The study was approved with patient follow-up at 3 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 30 months, and 36 months.

The primary efficacy measures included the percent excess weight loss (%EWL) at one, two, and three years following the procedure. The differences between these weight losses and the weight loss (gain) experienced by the subject in the year(s) prior to placement of the LAP-BAND were considered as secondary efficacy measures. In addition, secondary efficacy measures also included changes in quality of life.

The primary safety parameters included incidence and severity of complications. These complications were divided into device-related and non-device-related events.

**Patients Studied:**

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

The mean weight at entry was 293 pounds, and the mean excess weight was 156 pounds. The mean BMI was 47.4. Thirty percent were  $\geq 50$  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 (5%).

**Patient inclusion criteria:**

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

**Patient exclusion criteria:**

- Surgery or treatment represents an unreasonable risk to the subject.
- Family or patient history of inflammatory disease of the gastrointestinal tract, including gastric ulceration, duodenal ulceration, Grade 2-4 esophagitis, or specific inflammation such as Crohn's disease or ulcerative colitis.
- Severe cardiopulmonary disease or other serious organic diseases.
- Severe coagulopathy, upper gastro-intestinal bleeding conditions such as esophageal or gastric varices, congenital or acquired intestinal telangiectasia.

- Congenital or acquired anomalies of the GI tract such as atresias or stenoses.
- Severe hiatal hernia.
- Pregnant or has the intention of becoming pregnant in the next 12 months
- Alcohol or drug addiction.
- Mentally retarded, emotionally unstable, or exhibits 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 LAGB clinical trial.

**Clinical Study Methods:**

The primary effectiveness measure was the percent excess weight loss (%EWL), defined as weight loss divided by excess weight multiplied by 100. Weight loss was equal to operative weight minus selected weight. Study subjects were weighed immediately before surgery and postoperatively at 3 weeks, 3, 6, 9, 12, 18, 24, 30, and 36 months. The 1983 Metropolitan Life Height and Weight Table was the scale to determine ideal weight.

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

Enrollment began in June 1995 and was completed in June 1998. There were 8 centers and 12 surgeons. All procedures were completed utilizing a peri-gastric 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 intra-operative 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 after 36 months subsequent to surgery:

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

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.

**Primary Endpoint: %EWL**

**Mean %EWL by Visit**

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

The mean %EWL increased steadily from 9.9% at three weeks to 37.8% at 24 months. Improvements in %EWL through 36 months were significant ( $p < 0.0001$ ) when compared to baseline and at a level that has been demonstrated in the medical literature to improve comorbidities.<sup>1</sup>

**Secondary Endpoints: Weight and Excess Weight**

Mean Weight by Visit (in pounds)

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

Mean weight decreased steadily from 293 pounds at baseline to 235 pounds at 30 months. Weight loss through 36 months was significant when compared to baseline. Mean excess weight was reduced from 156 pounds to 98.2 pounds. The weight changes from baseline were statistically significant at each visit (paired t-test  $p < 0.0001$ ).

The observed level of weight loss at 12 months and beyond is equivalent to almost 20% total weight loss, substantially more than the 10% weight loss that has been reported in the literature to improve or resolve comorbid conditions associated with obesity.<sup>1</sup>

**Secondary Endpoint: Body Mass Index**

Mean BMI by Visit

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

Mean BMI decreased steadily from 47.5 at baseline to 38.1 at 24 months. The improvements in BMI from baseline were statistically significant at each visit (paired t-test  $p < 0.0001$ ). At baseline, 9% of subjects were not morbidly

obese (they had a BMI  $< 40$ ). By 12 months, 60% of subjects were no longer morbidly obese, and one-third were no longer severely obese (they had a BMI  $< 35$ ). Almost 30% of subjects were super obese (they had a BMI  $\geq 50$ ) when they entered the study. By 12 months, only 7% of the subjects were still super obese.

**Secondary Endpoint: Quality of Life**

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

**Safety**

Safety endpoints are provided in the Adverse Events section.

**Site-to-site variations**

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

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

## 8. Individualization of Treatment

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

International data suggests hyper-insulinemia, insulin resistance and disease associated with insulin resistance, poor physical activity, pain and poor general health responses to the SF-36 Health Survey are associated with a slower weight loss. Older, less physically able and insulin resistant patients are likely to lose weight at a slower rate than younger physically able persons.

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

## 9. Patient Counseling Information

A detailed booklet called "Information for Patients, A Surgical Aid in the Treatment of Morbid Obesity" is available from BioEnterics Corporation. 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.

## 10. How Supplied

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

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

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

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

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

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

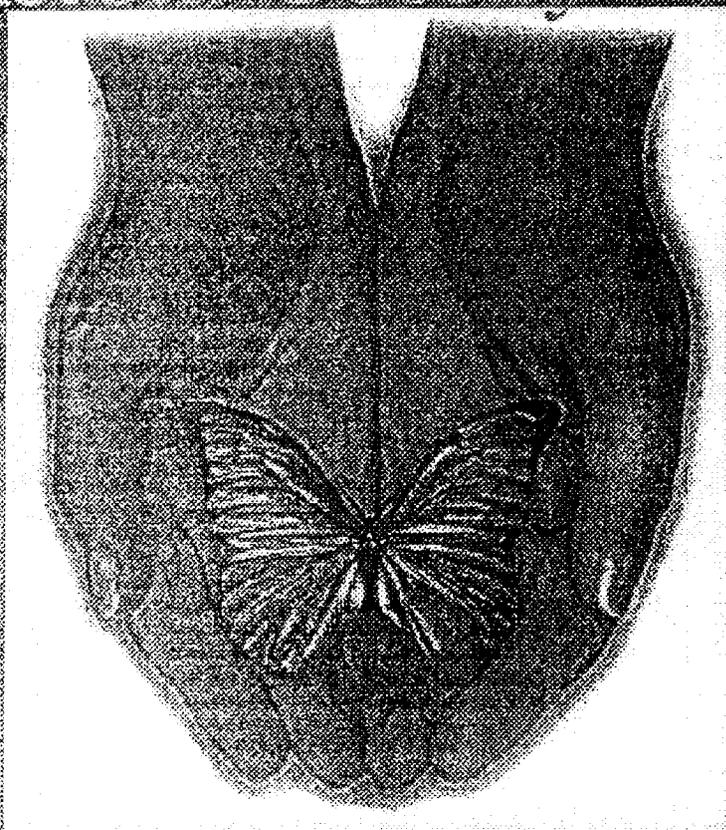
### Required Equipment and Materials (Included)

#### System Components:

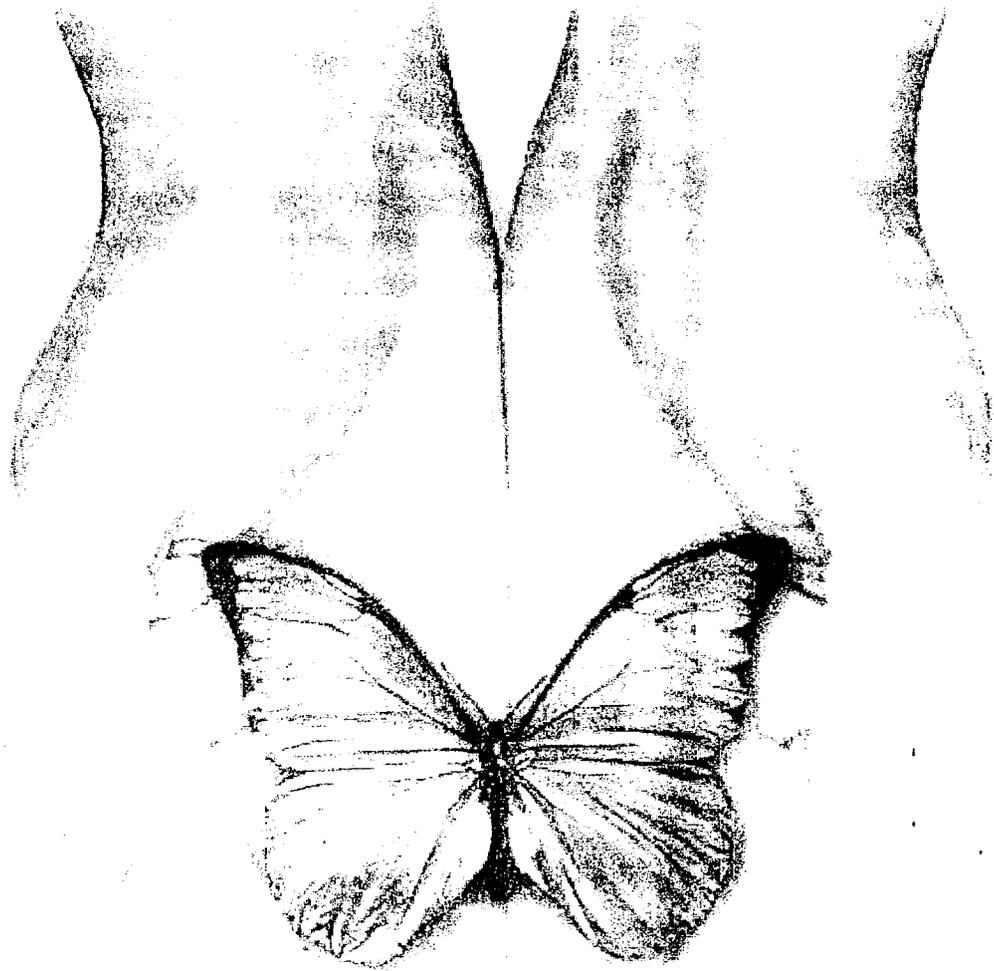
1. LAP-BAND Adjustable Gastric Band (sterile), one each
2. Access Port with Stainless Steel Connector (sterile), one each
3. Calibration Tube (non-sterile), one each
4. Access Port Needle, 89 mm (3.5 inch), (sterile), one each
5. Blunt flushing needle, 16 gauge, 40.5 mm (1.6 inch) (sterile), one each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

**Note:** The LAP-BAND System is available in two sizes, 9.75 cm and 10.0 cm. Both the 9.75 cm and 10.0 cm band may be used for most patients. The 10.0 cm provides a very slight additional range of adjustability. After resolution of postoperative edema, most patients with appropriately placed bands report minimal if any restriction until saline is added to the band, regardless of the size used. For reoperations (particularly conversion from other procedures) and the pars flacida dissection, the 10.0 cm band is normally used. It is recommended that surgeons evaluate the amount of tissue within the band prior to band locking. If it appears excessive (the band would not fit loosely), remove some omental tissue or move the dissection closer to the stomach wall or higher on the stomach. Additional information regarding size selection is provided in the training program.

# *A Surgical Aid in the Treatment of Morbid Obesity*



*LAP-BAND® Adjustable Gastric  
Banding System Information for Patients*



P/N 94829 Rev: C  
06/13/01

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For more information on the LAP-BAND System, please call 1-800-437-3303



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## Introduction

Almost every day, you see reports in the media about an amazing new diet or some new pill for weight loss. Even so, the number of people with a serious weight problem keeps going up. If you are one of those people, you probably already know that weighing more than you should is bad for your health.

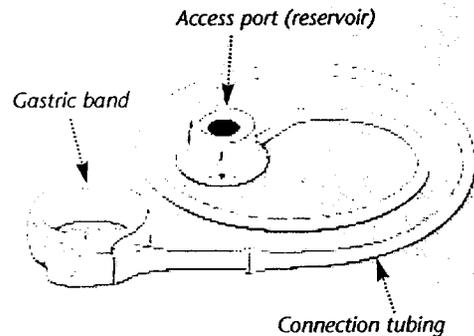
If you are severely obese, you have higher risk for problems such as heart disease and diabetes. Plus, weighing more than you should can affect the way you feel about yourself. It can give you a negative self-image. It also can cause you to become socially isolated.

The best remedy for being overweight is to exercise more while you eat less and eat sensibly. That way you can use up more energy than you take in and lose weight. A diet can help people lose weight. And some people can have success with drugs that make them feel less hungry. But over the long term, these methods don't work for everyone. Some people quickly regain the weight they lose on a diet. Some even end up weighing more. Drugs that make you feel less hungry do not usually produce weight loss that lasts.

If you've tried these methods and still have a problem with excess weight, you may want to consider surgery. Surgery can help some people lose weight and keep it off. This booklet gives you important information about one type of surgery used to treat severe obesity with the aid of the LAP-BAND® Adjustable Gastric Banding System.

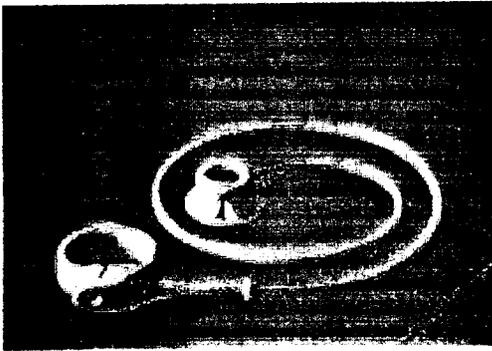
### What is the LAP-BAND® System?

The LAP-BAND System includes an adjustable silicone elastomer band that is surgically placed around the stomach. (This will be explained in more detail later in this booklet.) The band is designed to limit food intake. When you eat less food your body draws on its own fat reserves to get the energy it needs. The result is you lose weight.



*The LAP-BAND Adjustable Gastric Banding System*

Besides telling you about the LAP-BAND Adjustable Gastric Banding System, this booklet looks at obesity and the health risks it brings. It explains some treatment options, and gives you information you need to decide what is best for you. But please be sure you talk to your doctor about all your options. The LAP-BAND System is an aid to weight loss. It is not a miracle cure. Not everyone will lose weight or keep it off. You will still need to work to have long-lasting weight-loss results.



*The LAP-BAND Adjustable Gastric Banding System*

### *The concept of obesity*

Not everyone who has a weight problem should consider surgery. It depends on whether or not you are overweight, obese, or morbidly obese.

One way to tell is by your Body Mass Index (BMI). Your BMI depends on both your weight and your height. There is a chart on page 34 to help you find your own BMI.

### **Who should consider surgery?**

An ideal BMI is 19 to 25.<sup>1</sup> If your BMI is between 25 and 30, you are thought to be overweight. If it is higher than 30, you are obese. That means you are at risk for health problems.

If your BMI is 40 or more, you are said to have "morbid" obesity. A BMI higher than 40 suggests surgery might be a proper approach. For some people with a BMI between 35 and 40 ("severe" obesity), surgery might also be a good choice. These are people who have other conditions. For instance, if your BMI is 37 and you have severe sleep apnea, diabetes mellitus, or heart problems, your doctor might suggest surgery to help you lose weight.<sup>2,3</sup>

In the following pages, you will find out more about the causes of obesity and morbid obesity. You will also find out about problems connected with excess weight and learn about methods for treating it.

## *What causes obesity and morbid obesity?*

Many things can lead to obesity and morbid obesity. The five main causes are discussed below:

### Energy balance

To work right, your body needs the energy that comes from food. When you eat the same amount of food your body needs, your weight stays the same. If you get more energy from your food than you need, some is left over. Your body stores that extra energy as fatty tissue. If your body never uses the extra fat, you will gain weight. How much food you need depends on how fast your body uses energy. Some people with higher metabolism use energy faster than others. Some need more energy because they are more active.

### Heredity

If others in your family are obese, then you have a higher risk for obesity. A study in Canada looked at 12 sets of identical twins. Each twin consumed 1000 extra calories a day for three weeks. All of the subjects in the study gained weight. But not all subjects gained the same amount of weight. The interesting thing, though, was that in each set of twins, one twin gained the same amount as the other.<sup>4</sup>

In 1994, scientists found a gene in mice that was linked to obesity. This gene produces the protein leptin, which

contributes to feeling full. Mice with a defective gene eat large amounts of food. But when humans were studied, the results were not the same. So it seems unlikely that a single gene can explain severe obesity.

Genetic research does show that a number of processes don't work as well in obese people as they do in others. These include how fat is burned, metabolism, and feelings of hunger and fullness.

### Metabolic disorders

Metabolism refers to how your body gets energy from food. Lots of things can affect metabolism. For instance, trouble with your thyroid gland can change your metabolism and lead to obesity or morbid obesity.

### Eating and social habits

Your eating habits can affect your weight. Things like not eating a balanced diet or eating fast-food and fatty snacks between meals can all cause obesity. Another habit that can cause obesity is eating portions that are too large or too rich. Drinking too many high-calorie soft drinks can also cause it. Not getting enough exercise can make the effect of these habits worse.

### Psychological factors

Most people's eating habits are affected by their surroundings. For some people, smell and color will cause them to eat more. Some will eat to be social.

For instance, someone might say to you, "Don't be such a snob. Have a piece of cake."

Some people eat for comfort. They may eat in times of grief or stress. The "blow-out" is a common response after a diet fails. Then a person might say, "It never works." Thinking that way can lead to a vicious cycle of eating and dieting that will only make the person gain more weight.

*"It's really awful to have to go through life as someone who is obese. You feel worthless. Sometimes you are lonely and unhappy. You often want to apologize for being the way you are. You don't ever dare eat a single snack because you are afraid people will say, 'It's your own fault. It is all your doing.' There are practical problems you face, like seats that are too small on buses or in theaters, and not being able to find reasonably priced clothes in your size. You also have to fight all kinds of prejudices. You are seen as dirty, lazy, antisocial, and stupid. You also have to put up with all kinds of comments like 'cow,' 'elephant,' and 'pig.' Even from your closest associates! I also have a hard time finding work and having relationships. People go by what you look like. What I really find hardest is that people don't take you seriously. That means, in the end, you feel totally alone."*

*(Patient before the LAP-BAND System surgery)*

## *The risks of being severely obese*

If you are morbidly obese, you have major risks to your

- health
- psychological and social well being
- day to day living

### Health risks

Obese people have more risk for

- diabetes
- joint problems
- high blood pressure
- high cholesterol
- cancer
- gallbladder problems
- breathing difficulties
- coronary artery disease

If you already have some diseases, such as diabetes or heart disease, they can get worse. Plus, the more weight you gain, the more risk you have. As a result, your life expectancy is shorter. You also may be less able to do things to help your health improve. Exercise is important to good health. But severe obesity makes you less mobile. It is hard to exercise or take part in sports. Severe obesity can also affect fertility. That means you are less likely to become pregnant. On the other

hand, if you do become pregnant, you have more risk of problems during pregnancy and childbirth.

**Risks to your psychological and social well being**  
People with a weight problem often have a negative self-image. Their environment can make this worse. Obese children, for instance, may be teased at school and have few friends. You may find it hard to buy clothes that look good. Bus or train seats, telephone booths and cars may be too small. You are also likely to be left out of social functions that require exercise. People with severe obesity often find themselves socially isolated.

#### Risks in day to day living

Even normal tasks become harder when you are severely obese. You tend to tire more quickly. You may also have breathing problems. Not being able to move as well makes it hard for some people to maintain personal hygiene.

#### *What can be done for severe obesity?*

There are several options for treating severe obesity. Some treatments do not involve surgery and some do.

#### Non-surgical treatments

The most common approach for losing weight is to eat less, eat more sensibly, and exercise more. But if you are severely obese, this approach may not be

*"Obese people experience many problems in their immediate environment because obesity is directly visible to other people, which means that it affects social interaction. People not only have firm opinions on the outward appearance of someone suffering from obesity, but they also make judgements about his or her character. For example, obesity is often seen as a sign of weakness and laziness - that obese people have no control over how much they eat. Most of the patients I see in my practice have experienced this attitude from other people. You will also find this pattern repeated in studies on quality of life. According to one study (Rand and MacGregor, 1990, eds.), prior to surgery the majority of obese patients considered themselves unattractive and felt as if people were talking about them behind their backs. They also felt that they were discriminated against when it came to trying to get a job, and found that doctors frequently treated them with little respect. It is noticeable that around 18 months after a stomach operation this self-image changes completely. I see this change in my patients too, and it gives me enormous satisfaction every time."  
(LAP-BAND® System surgeon)*

enough. Sticking to a diet and exercise plan is hard and sometimes painful. Many who lose weight quickly gain it back when the diet ends. That leads to more diets, or taking special drinks that replace a meal, or using a so-called "wonder pill." The cycle of losing weight and gaining it back is called the yo-yo effect. While temporary weight loss can help, the yo-yo effect can also make it harder to lose weight in the future.

Asking professionals can help. A physician or a dietitian can help you change your lifestyle. A program of improved eating habits and exercise will be important over time. A doctor may even prescribe drugs to reduce your appetite for a while. But studies show that diets and weight-loss aids rarely work in helping severely obese people reach the goal of long-lasting weight loss. Nor do other options that don't use surgery. Those options include jaw wiring, hypnosis, or counseling, for example.

#### Surgery as an option

If non-surgical methods have not helped you lose weight and keep it off, you still have another option. Surgery to reduce how much your stomach holds may work for you. But keep in mind that a positive attitude is key to the success of the surgery. Surgery can help you achieve your long-term goal only if you are ready for and committed to losing weight and keeping it off.

#### Surgery options

There are two types of surgery for obesity. One is called malabsorptive. This surgery shortens the digestive tract. The other kind is called restrictive. This surgery reduces how much food the stomach can hold. Some surgeries are combinations of the two types. The two most common obesity surgeries in the United States are the Gastric Bypass and the Vertical Banded Gastroplasty.

#### The Gastric Bypass

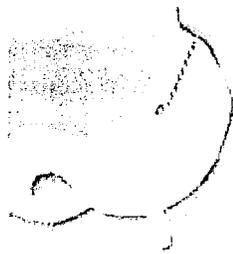
The Gastric Bypass is both a restrictive and a malabsorptive procedure. With this surgery, most of the stomach and part of the intestines are bypassed. With the Gastric Bypass, the stomach is stapled to make a smaller pouch. Then a part of the intestines is attached (usually stapled) to the small stomach pouch. The result is that you cannot eat as much and you absorb less nutrients and calories from your food.



*Gastric Bypass*

### Vertical Banded Gastroplasty (VBG)

The VBG is a restrictive surgery. The surgeon uses staples to make a small stomach pouch. This reduces how much food your stomach can hold. When the amount of food the stomach can hold is reduced, you feel full sooner. But at the same time, the stomach digests nutrients and calories in a normal way.



*Stomach Stapling/VBG*

There is more than one way to reduce how much food the stomach can hold. VBG is one. Another is to use the LAP-BAND Adjustable Gastric Banding System.

### LAP-BAND Adjustable Gastric Banding System

This option restricts how much the stomach can hold by placing an adjustable band around the upper part of the stomach. There is no cutting or stapling needed to divide the upper stomach pouch from the lower stomach. The result is you take in less food. But unlike stomach stapling, the

LAP-BAND can be adjusted to suit your situation, and can be removed if necessary.



*The LAP-BAND System*

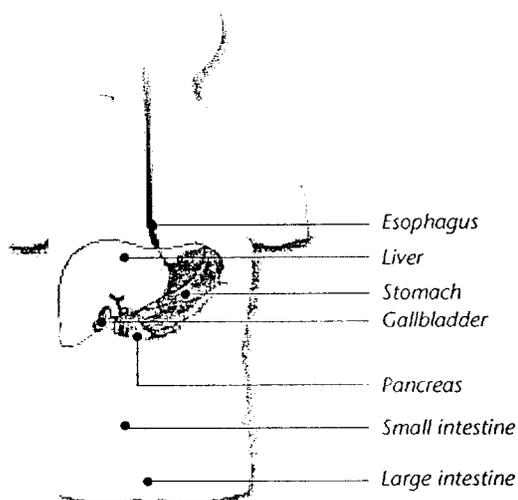
The LAP-BAND System uses new surgical technology to help you lose weight by reducing how much your stomach can hold and lengthening the feeling of being full. The success of this process, however, also depends on how motivated you are and how committed you are to your goal of long-lasting weight loss.

### *The LAP-BAND System*

The LAP-BAND System was designed to help you lose excess body weight. It uses a process called laparoscopic banding. This process is the least invasive way to use surgery to reduce the amount of food your stomach can hold. The name "LAP-BAND" comes from the surgical technique used (laparoscopic) and the name of the product used (gastric band).

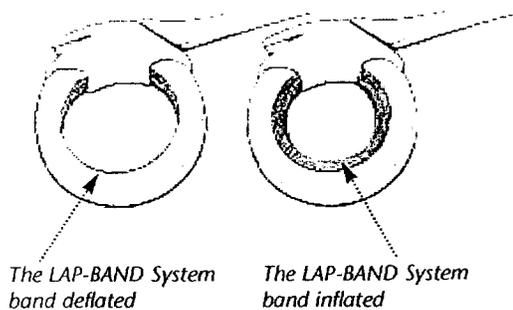
One big advantage of the LAP-BAND System is that the band's size can be changed to meet your needs. This is not possible with other techniques.

How does the LAP-BAND System work? Your body gets energy from food while it passes through the alimentary canal. This consists of the mouth, the esophagus, the stomach, and the small and large intestines. Digestion starts in the mouth with chewing and the addition of saliva. After the food passes through the esophagus, this process continues in the stomach. The stomach then provides temporary storage for food. Gastric juices, which contain enzymes, break down the food. This way, energy can be carried through the body by the blood.



The LAP-BAND System's adjustable band is a silicone elastomer hollow ring filled with saline and placed around the upper part of the stomach. This creates a new small stomach pouch, with the larger part of the stomach below the band. This way, the food storage area in the stomach is reduced. The pouch above the band can hold only a small amount of food. The band also controls the stoma (stomach outlet) between the two parts of the stomach. The size of the opening between the two parts of the stomach controls the flow rate of the food from the upper to the lower part of the stomach. This lets you feel full sooner. The feeling also lasts longer.

To change the size of the stoma, the inner surface of the band can be adjusted by adding or removing saline. This process is called inflating or deflating. Saline is a salty solution like other fluids in your body.



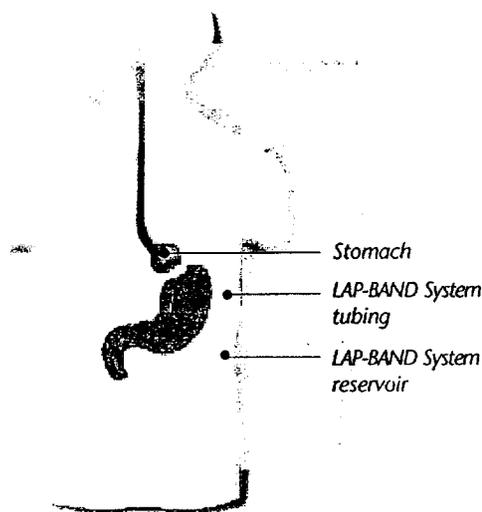
The band is connected by a tube to a reservoir placed **beneath** the skin during surgery. Later, the surgeon can control the amount of saline in the band by piercing the reservoir through the skin with a fine needle. If the band is too loose and weight loss too small, adding more saline can reduce the size of the stoma. If the band is too tight, the surgeon will remove some saline. This too can be done without more surgery. Being able to adjust the band is a unique feature of the LAP-BAND System and is a normal part of the follow-up. If adjusting the band does not help you lose weight the way you and your doctor want it to, or if the band is still too tight, another surgery may be needed. The band position on the stomach can be changed or the size of the upper stomach pouch can be reduced.

How is the LAP-BAND System placed around the stomach?

The LAP-BAND System is usually placed laparoscopically. Laparoscopic surgery requires general anesthesia. First the surgeon makes a few small incisions in the abdominal wall and inserts narrow, hollow tubes. Thin surgical instruments are then passed through the tubes. The surgeon can see inside the abdomen by using a small camera that also goes through the tubes. The picture the camera takes is shown on a monitor that is like a TV screen. This technique is called "laparoscopy" and is considered "minimally invasive."

A small tunnel is made behind the top of the stomach. Then the band is pulled around the stomach to form a ring. The band has a locking part which securely holds the band in a circle around the stomach.

There are clear advantages to this kind of surgery. In an "open" surgery, a larger incision is made. After a laparoscopic surgery, most people feel much less pain. There are fewer wound complications. Patients also recover faster and are able to resume normal activities sooner.



Sometimes, for a variety of reasons, the surgeon may need to make the larger incision to place the LAP-BAND System. The surgeon may need to decide this

during the operation. Both techniques are discussed in this booklet. You and your surgeon should decide together what plan is best for you.

How is the LAP-BAND System used?

The LAP-BAND System is an aid to help you achieve longer-lasting weight loss. It does this by limiting how much you can eat, reducing your appetite, and slowing digestion. You should still remember, though, that the LAP-BAND System by itself will not solve your problem of severe obesity. Nor will it ensure that you reach your goal weight or even lose weight. The amount of weight you lose depends

both on the band and on your motivation and commitment to a new lifestyle and eating habits.

How much weight will I lose with the LAP-BAND System?

The average weight loss in the United States clinical study was approximately 36-38% of excess weight, 2 and 3 years after surgery. A few people lost up to 100% of their excess weight, some did not lose any weight, and a few got heavier. The following table includes information about how much weight patients lost in the U.S. study. Weight loss is described in terms of the percent of the excess weight a person lost (EWL = Weight Loss/Excess Weight X 100).

Excess Weight Loss at 3 Years	All Patients		Diabetic Patients		Super Obese Patients (BMI of at least 50)	
	%	# patients	%	# patients	%	# patients
Gained over 5% EWL	2%	4	4%	1	0	0
No change ± 5% EWL	5%	9	0	0	9%	5
Lost at least 25% EWL	62%	110	50%	12	58%	32
Lost at least 33% EWL	52%	93	46%	11	53%	29
Lost at least 50% EWL	22%	39	13%	3	15%	8
Lost at least 75% EWL	10%	18	8%	2	4%	2
Total number of patients		178		24		55

EWL = Excess Weight Loss

57

Assume that you weigh 330 pounds. Also assume that for your height your ideal weight is 155 pounds. That means you weigh 175 pounds more than your ideal weight. 38% of 175 pounds is 66.5 pounds.

Some people lose more than others. You may never reach your ideal weight. At the same time, chances are good that your health will improve, along with your self-image.

What if the LAP-BAND System needs to be removed?

If there is a problem with the band, or if you can't lose enough weight or adjust to the new eating habits, your surgeon may decide to remove the band. That decision will come after your surgeon consults with you. Removing the LAP-BAND System will most likely restore your stomach to its original form. Also, the digestive tract will again function normally. Please keep in mind, though, that when the band is removed, your weight will likely increase.

## *Advantages of the LAP-BAND System*

The LAP-BAND System has the following advantages:

- It is less invasive than other surgical techniques.
- The band can be adjusted.
- The process can be reversed.
- It may require less hospital time than other surgical techniques.
- Recovery may be quicker.

*"The advantage of LAP-BAND is that it goes around the outside of the stomach, and the procedure can be reversed. I wouldn't have other surgeries. Having my stomach stapled is so final. Obviously, the LAP-BAND is also final, because you have to 'wear' it for the rest of your life. But it's good to know you can have it removed if there is a problem. With the LAP-BAND method, your new small stomach won't let you eat much. This means you can lose a lot of weight in a short time. It also means the weight loss is long lasting. With a diet, you always put the weight back on or even put on more. I've won the battle with my body and my mind. I'm going to make sure it stays that way."  
(LAP-BAND System patient)*

The process is less invasive:

Of the surgeries used to treat obesity, the one used to place the LAP-BAND System causes the least trauma. There is no need for cutting or stapling the stomach. Also, the LAP-BAND System can usually be placed laparoscopically. The main benefits of that kind of surgery are

- fewer operative complications
- less pain
- faster recovery

With this surgery, it's possible to avoid large incisions and scars.

The band is adjustable:

Normally, you don't need more surgery to adjust the size of the stoma. Band adjustment is a regular part of follow-up for this procedure. It's also a feature that may become more important as you lose weight. There are reasons you might need to change how much food you can eat. These can include your weight-loss progress, pregnancy, and illness. With the LAP-BAND System, the amount of food you can eat at one time can often be changed without more surgery. This can be done simply by inflating or deflating the band.

Changes can be reversed:

If it needs to be, the LAP-BAND System can be removed. When it is, the stomach generally returns to its original form. In general, it's easier to remove the LAP-BAND System than it is to reverse other procedures. Reversing other procedures typically leaves staples and more traumatized tissue.

You need less hospital time:

Patients normally leave the hospital one to three days after laparoscopic surgery. If a large incision is required or if there are complications, more days in the hospital may be needed.

You may recover more quickly:

After the procedure, patients usually get back to their normal activities in a week or two. It may take four weeks or more if the procedure is not done laparoscopically or if there are complications.

### *Who can use the LAP-BAND System?*

The LAP-BAND System is not right for everyone. You and your surgeon should work together to decide if this is the right treatment for you. Here are some of the things your surgeon will consider.

## Indications<sup>s</sup> !

The LAP-BAND System may be right for you if

- 1) You are between 18 and 56 years old.
- 2) Your BMI is 40 or higher or you weigh at least twice your ideal weight or you weigh at least 100 pounds (45 kilos) more than your ideal weight.
- 3) You have been overweight for more than 5 years.
- 4) Your serious attempts to lose weight have had only short-term success.
- 5) You do not have any other disease that may have caused you to be overweight.
- 6) You are prepared to make major changes in your eating habits and lifestyle.
- 7) You are willing to continue working with the specialist who is treating you.
- 8) You do not drink alcohol in excess.

If your BMI is less than 40, the LAP-BAND System may not be right for you. On the other hand, your surgeon may consider it if you have health problems that are related to obesity. Your surgeon may also have other criteria he or she uses. Ask him or her to discuss the criteria with you.

## Contraindications !

The LAP-BAND System is not right for you if

- 1) You have an inflammatory disease or condition of the gastrointestinal tract, such as ulcers, severe esophagitis, or Crohn's disease.
- 2) You have severe heart or lung disease that makes you a poor candidate for surgery.
- 3) You have some other disease that makes you a poor candidate for surgery.
- 4) You have a problem that could cause bleeding in the esophagus or stomach. That might include esophageal or gastric varices (a dilated vein). It might also be something such as congenital or acquired intestinal telangiectasia (dilation of a small blood vessel).
- 5) You have portal hypertension.
- 6) Your esophagus, stomach, or intestine is not normal (congenital or acquired). For instance you might have a narrowed opening.
- 7) You have/experience an intra-operative gastric injury, such as a gastric perforation at or near the location of the intended band placement.
- 8) You have cirrhosis.
- 9) You have chronic pancreatitis.
- 10) You are pregnant. (If you become pregnant after the LAP-BAND System has been placed, the band may need to be deflated. The same is true if you need more nutrition for any other reason, such as becoming seriously ill. In rare cases, removal may be needed.)
- 11) You are addicted to alcohol or drugs.
- 12) You are under 18 years of age.
- 13) You have an infection anywhere in your body or one that could contaminate the surgical area.

- 14) You are on chronic, long-term steroid treatment.
- 15) You cannot or do not want to follow the dietary rules that come with this procedure.
- 16) You might be allergic to materials in the device.
- 17) You cannot tolerate pain from an implanted device.
- 18) You or someone in you family has an autoimmune connective tissue disease. That might be a disease such as systemic lupus erythematosus or scleroderma. The same is true if you have symptoms of one of these diseases.

Some surgeons say patients with a "sweet tooth" will not do well with the LAP-BAND System. If you eat a lot of sweet foods, your surgeon may decide not to do the procedure. The same is true if you often drink milkshakes or other high-calorie liquids.

Your motivation is key

Your surgeon will not do the operation unless he or she knows you understand the problems your excess weight is causing. Also, your surgeon will make sure you know you have responsibilities. These include new eating patterns and a new lifestyle. If you are ready to take an active part in reducing your weight, your surgeon will consider the treatment. First, though, your surgeon will want to make sure you know about the advantages, disadvantages, and risks involved.

### *Risks, complications, and adverse events you need to know about*

All surgical procedures have risks. When you decide on a procedure, you should know what the risks are. Talk with your surgeon in detail about all the risks and complications that might arise. Then you will have the information you need to make a decision.

What are the general risks? **!**

Using the LAP-BAND System includes the same risks that come with all major surgeries. There are also added risks in any operation for patients who are seriously overweight. You should know that death is one of the risks. It can occur any time during the operation. It can also occur as a result of the operation. Death can occur despite all the precautions that are taken. There is a risk of gastric perforation (a tear in the stomach wall) during or after the procedure that might lead to the need for another surgery. In the U.S. clinical study this happened in 1% of the patients. There were no deaths during or immediately after surgery in the U.S. study. Your age can increase your risk from surgery. So can excess weight. Certain diseases, whether they were caused by obesity or not, can increase your risk from surgery. There are also risks that come with the medications and the methods used in the surgical procedure. You also have risks that come from how your body responds to any foreign object implanted in it.

Published results from past surgeries, however, do show that LAP-BAND System surgery may have fewer risks than other surgical treatments for obesity.

Patients can experience complications after surgery. Most complications are not serious but some may require hospitalization and/or re-operation. In the United States clinical study, with 3-year follow-up reported, 88% of the 299 patients had one or more adverse events, ranging from mild, moderate, to severe. Nausea and vomiting (51%), gastroesophageal reflux (regurgitation) (34%), band slippage/pouch dilatation (24%) and stoma obstruction (stomach-band outlet blockage) (14%) were the most common post-operative complications. In the study, 25% of the patients had their band systems removed, two-thirds of which were following adverse events. Esophageal dilatation or dysmotility (poor esophageal function) occurred in 11% of patients, the long-term effects of which are currently unknown. Constipation, diarrhea and dysphagia (difficulty swallowing) occurred in 9% of the patients. In 9% of the patients, a second surgery was needed to fix a problem with the band or initial surgery. In 9% of the patients, there was an additional procedure to fix a leaking or twisted access port. The access port design has been improved. Four out of 299 patients (1.3%) had their bands erode into their stomachs. These bands needed to be removed in a second

operation. Surgical techniques have evolved to reduce slippage. Surgeons with more laparoscopic experience and more experience with these procedures report fewer complications.

Adverse events that were considered to be non-serious, and which occurred in less than 1% of the patients, included: esophagitis (inflammation of the esophagus), gastritis (inflammation of the stomach), hiatal hernia (some stomach above the diaphragm), pancreatitis (inflammation of the pancreas), abdominal pain, hernia, incisional hernia, infection, redundant skin, dehydration, diarrhea (frequent semi-solid bowel movements), abnormal stools, constipation, flatulence (gas), dyspepsia (upset stomach), eructation (belching), cardiospasm (an obstruction of passage of food through the bottom of the esophagus), hematemesis (vomiting of blood), asthenia (fatigue), fever, chest pain, incision pain, contact dermatitis (rash), abnormal healing, edema (swelling), paresthesia (abnormal sensation of burning, prickly, or tingling), dysmenorrhea (difficult periods), hypochromic anemia (low oxygen carrying part of blood), band system leak, cholecystitis (gall stones), esophageal ulcer (sore), port displacement, port site pain, spleen injury, and wound infection. Be sure to ask your surgeon about these possible complications and any of these medical terms that you don't understand.

Is there a chance the device will need to be removed?

The LAP-BAND System is a long-term implant, but it may have to be removed or replaced at any time. For instance, the device may need to be removed to manage any adverse reactions you might have. The device may also need to be removed, repositioned or replaced if you aren't losing as much weight as you and your doctor feel you should be losing.

What are the specific risks and possible complications? !

Talk to your doctor about all of the following risks and complications:

- ulceration
- gastritis (irritated stomach tissue)
- gastroesophageal reflux (regurgitation)
- heartburn
- gas bloat
- dysphagia (difficulty swallowing)
- dehydration
- constipation
- weight regain
- death

Laparoscopic surgery has its own set of possible problems. They include:

- spleen or liver damage (sometimes requiring spleen removal)
- damage to major blood vessels
- lung problems
- thrombosis (blood clots)
- rupture of the wound
- perforation of the stomach or esophagus during surgery

Laparoscopic surgery is not always possible. The surgeon may need to switch to an "open" method due to some of the reasons mentioned here. This happened in about 5% of the cases in the U.S. Clinical Study.

There are also problems that can occur that are directly related to the LAP-BAND System.

- The band can spontaneously deflate because of leakage. That leakage can come from the band, the reservoir, or the tubing that connects them.
- The band can slip.
- There can be stomach slippage.
- The stomach pouch can enlarge.
- The stoma (stomach outlet) can be blocked.
- The band can erode into the stomach.

Obstruction of the stoma can be caused by

- food
- swelling
- improper placement of the band

- the band being over-inflated
- band or stomach slippage
- stomach pouch twisting
- stomach pouch enlargement

There have been some reports that the esophagus has stretched or dilated in some patients. This could be caused by

- improper placement of the band
- the band being tightened too much
- stoma obstruction
- binge eating
- excessive vomiting

Patients who have a weaker esophagus may be more likely to have this problem. A weaker esophagus is one that is not good at pushing food through. Tell your surgeon if you have difficulty swallowing. Then your surgeon can evaluate this.

Weight loss with the LAP-BAND System is typically slower and more gradual than with some other weight-loss surgeries. Tightening the band too fast or too much to try to speed up weight loss should be avoided. The stomach pouch and/or esophagus can become enlarged as a result. You need to learn how to use your band as a tool that can help you reduce the amount you eat.

Infection is possible. Also, the band can erode into the stomach. This can happen right after surgery or years later, although this rarely happens.

Complications can cause reduced weight loss. They can also cause weight gain. Other complications can result that require more surgery to remove, reposition, or replace the band.

Some patients have more nausea and vomiting than others. You should see your physician at once if vomiting persists. Rapid weight loss may lead to symptoms of

- malnutrition
- anemia
- related complications

It is possible you may not lose much weight or any weight at all. You could also have complications related to obesity.

If any complications occur, you may need to stay in the hospital longer. You may also need to return to the hospital later. A number of less serious complications can also occur. These may have little effect on how long it takes you to recover from surgery.

If you have existing problems, such as diabetes, a large hiatal hernia (part of the stomach in the chest cavity), Barrett's esophagus (severe, chronic inflammation of the lower esophagus), or emotional or psychological problems, you may have more complications. Your surgeon will consider how bad your symptoms are, and if you are a good candidate for the LAP-BAND System surgery. You also have more risk of complications if you've had a surgery before in the same area. If the procedure is not done laparoscopically by an experienced surgeon, you may have more risk of complications.

Anti-inflammatory drugs that may irritate the stomach, such as aspirin and NSAIDs, should be used with caution.

Some people need folate and vitamin B12 supplements to maintain normal homocysteine levels. Elevated homocysteine levels can increase risks to your heart and the risk of spinal birth defects.

You can develop gallstones after a rapid weight loss. This can make it necessary to remove your gallbladder.

There have been no reports of autoimmune disease with the use of the LAP-BAND System. Autoimmune diseases and connective tissue disorders, though, have

been reported after long-term implantation of other silicone devices. These problems can include systemic lupus erythematosus and scleroderma. At this time, there is no conclusive clinical evidence that supports a relationship between connective-tissue disorders and silicone implants. Long-term studies to further evaluate this possibility are still being done. You should know, though, that if autoimmune symptoms develop after the band is in place, you may need treatment. The band may also need to be removed. Talk with your surgeon about this possibility. Also, if you have symptoms of autoimmune disease now, the LAP-BAND System may not be right for you.

#### Removing the band

If the LAP-BAND System has been placed laparoscopically, it may be possible to remove it the same way. This is an advantage of the LAP-BAND System. However, an "open" procedure may be necessary to remove a band. In the U.S. Clinical Study, 60% of the bands that were removed were done laparoscopically. Surgeons report that after the band is removed, the stomach returns to essentially a normal state.

At this time, there are no known reasons to suggest that the band should be replaced or removed at some point unless a complication occurs or you do not lose weight. It is difficult, though, to say whether

the band will stay in place for the rest of your life. It may need to be removed or replaced at some point. Removing the device requires a surgical procedure. That procedure will have all the related risks and possible complications that come with surgery. The risk of some complications, such as erosions and infection, increase with any added procedure.

## *The operation*

The more you know about the LAP-BAND System procedure, the easier the process should be for you.

### Getting ready for surgery

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

- a dietitian
- a physiotherapist
- a psychologist
- other specialists

You will also need to have a number of tests before your surgery. These are to evaluate your health. When it is time for the surgery, you will be admitted to the hospital either the day before or on the morning of your surgery.

*"A number of examinations have to be carried out before a patient can undergo surgery. The patient also needs to visit a dietitian. The dietitian may give him or her a food diary in order to obtain a comprehensive picture. The aim is that the patient should keep a detailed diary of what he or she eats for a week. This diary is used to assess whether surgery will be helpful. We can only decide to carry out the operation involving a band around the stomach once we have the green light from all quarters. The patient is usually admitted the day before the operation. The results of all the examinations are checked again. Then I again explain to the patient what the operation involves, and the anesthesiologist talks to him or her about the anesthesia and the form of pain relief that will be used after the operation. When the patient has been admitted, he or she is also seen by a physiotherapist, with the emphasis being on respiratory therapy. After the operation, the patient may find it less easy to breathe deeply, and it may be painful to cough up mucus. So before the operation, the physiotherapist gives the patient instructions on the correct way to breathe and cough, so that post-operative treatment can be carried out efficiently and well."*  
(LAP-BAND System surgeon)

### The surgery

When it is time for the operation, you will receive a general anesthesia. If your case is typical, the operation will be done laparoscopically. During the

operation, the band part of the LAP-BAND System will be fastened around the upper part of your stomach. This will create a small stomach pouch. Part of the lower stomach will then be sutured over the band. The rest of the lower stomach will stay in its normal position. The reservoir for adjusting the band will be placed under your skin. To do this, the surgeon will slightly enlarge one of the incisions that he or she made for the laparoscopic tubes.

#### Open operation

Sometimes laparoscopic surgery can't be done. Or sometimes, even after the laparoscopic surgery has started, the surgeon may switch to the "open" method. There could be a number of reasons for this. For instance, bleeding or problems placing the band could make the open method with the larger incision necessary. If this is the case, you will not be aware of it while you are under the anesthesia. The surgeon will make a larger incision in the abdomen to perform the operation. After this "open" surgery, you will most likely need to stay in the hospital longer. That's because there could be more complications. It also may take more time for you to get back to your normal routine. In the U.S. study about 5% of the patients were converted to open procedures.

#### After the surgery

Once the anesthesia has worn off, you may feel some pain. This pain can usually be relieved with ordinary painkillers. The hospital staff will help you get out of bed and start moving as soon as possible. This will help prevent blood clots, respiratory problems, and bedsores.

On the day after the surgery, you will likely be given an X-ray. This is so your health team can see that the LAP-BAND System is in the right place. It is also to see that the new stomach outlet is open. You may be asked to swallow a liquid that can be seen on X-ray.

After a laparoscopic surgery, you will normally stay in the hospital for 1 to 3 days. The hospital stay may be longer after the open procedure or if there are complications. If there are no complications, you should be able to resume normal activities within a week or two after the surgery.

## *Eating and drinking after the operation*

After your surgery, you will need a new diet. You should discuss this in detail with your surgeon and/or dietitian. They can help you learn and get used to the changes in lifestyle and eating habits you need to make.

Note: The following information is meant to be an overview. Your surgeon may give you specific instructions just for you. Be sure you know the instructions your doctor wants you to follow.

It is very important to follow the eating and drinking instructions right from the start after the operation. That's because you must allow the new stomach structure to heal completely and in the right position. It may take a month or more for this to happen. It is important, especially in the early weeks, not to stretch the small stomach pouch above the band. Vomiting can do this, so it is important not to vomit. Vomiting can increase the chance of stomach tissue slipping up through the band.

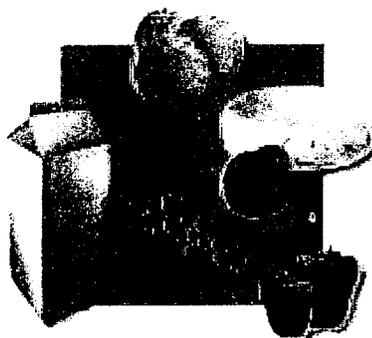
The first few days after the operation  
Right after the operation, you can have an occasional sip of water or suck on an ice cube. You shouldn't drink more than this. The day after the operation, you can take a little more fluid. But you

should take only a small amount at a time. Besides water, you should also choose liquids that have an adequate number of calories. To prevent nausea and vomiting, do not drink too much.

### **The first one to four weeks**

These drinks and very soft foods are recommended for the first four weeks after the operation:

- clear broth or soup (with no vegetables or meat and not creamy)
- low-fat yogurt
- milk (preferably skim)
- jello
- fruit juice or pureed soft fruit.



As time goes on, you will slowly move to solid food based on your surgeon's and/or dietitian's advice.

In the first few weeks, you may be able to eat foods that may not be allowed in your diet later because these foods may contain too many calories. It is more important in the first few weeks to let your stomach adjust to the LAP-BAND System than it is to lose weight. In general, you should follow the advice of your dietitian about these foods.

#### Four to six weeks

At this time, you may start having slightly thicker, creamier soups. This will help you switch gradually to more solid foods later. Some products like bread, red meat, and rice may still cause you problems. So it is better to eat softer foods that are easier to digest. These might include foods such as moist white meat (chicken, veal) and fish.

Chew all your food well. If you have dentures be sure to cut your food into small pieces and to chew it thoroughly. If you don't follow these precautions, you may have vomiting, stomach irritation, and swelling. You could also have stomach obstruction. If you have problems with solid foods and suffer from nausea or vomiting, go back to the liquid diet you had earlier. Then slowly add soft foods to help you transition to solid foods later. Always ask for advice that is specific to your situation from your doctor or dietitian. Vomiting may increase the

incidence of band slippage, stomach slippage, or stretching of the small stomach pouch above the band.

#### Band adjustments

With the LAP-BAND System, the band can be adjusted to meet your specific needs. That is one of its more attractive aspects. This feature allows you and your surgeon to find the right level of restriction for YOU!

When first placing it, your surgeon usually leaves the band empty or only partially inflated. This lets you get acquainted with your band during the first few weeks after surgery. It also lets healing occur around the new band site.

These first few weeks are a critical time. You need to avoid vomiting. You also need to avoid putting pressure on your new small stomach above the band. The first time the band is adjusted is usually 4 to 6 weeks after your surgery. The exact time will vary. You and your surgeon will decide when the right time is for your band adjustment. To determine how ready you are for a band adjustment, your surgeon will consider:

- your weight loss
- the amount of food you can comfortably eat
- your exercise routine
- how much fluid is already in your band

Being able to adjust the LAP-BAND System gives you and your surgeon control. If the band is too tight, your surgeon can "loosen" it by taking out some of the fluid. If the band is too loose, your surgeon can tighten it. Your surgeon does this by injecting fluid. Only a clinician trained and authorized by BioEnterics can adjust your band. Never let an untrained clinician do it. Never let a non-medical person do it. And never try to adjust your own band. You could cause adverse reactions for you. You could also damage your band.

To adjust your band, the clinician injects saline into the self-sealing access port. This port is located just under your skin. The band can also be adjusted by removing saline from the port. This is done with a special fine needle. You may feel a pricking sensation when this is done. The feeling is similar to when you give blood.

Adjustments are done either in the hospital or in a doctor's office that has x-ray equipment (fluoroscopy). The clinician may use fluoroscopy to assist in locating the access port. The surgeon may also use it to guide the needle into the port and to view inserting the needle. It is also used after the band has been adjusted to evaluate your pouch size and stoma size.

To get the best results, you may need more than one adjustment. Each one will range from 1/2 cc to 2 cc of fluid. The most the band can hold is 4 cc. The exact amount of fluid required to make the stoma the right size is unique for each person. An ideal "fill" should be just tight enough to let you gradually lose weight. That means you should still be able to eat enough to get the nutrients that you need while still reducing the over-all amount you can eat.

The LAP-BAND System is meant to offer you a way to obtain steady and safe weight loss. Don't be in a hurry to have an adjustment before you're ready. To work, the band needs your participation. Your success will depend on YOU and on the partnership between you and your clinicians.

#### Your new diet

When you can eat solid foods without problems, you will need to pay close attention to your diet. Liquids will pass through the reduced stomach pouch quickly and will not make you feel full. You should avoid high-calorie drinks from this point on. Drink water, broth, tea, and coffee (without sugar).

Too much food or big chunks of food can block the stomach pouch outlet. You can avoid this problem by chewing food well and eating small bits at a time. Eat

only three small meals a day. Make sure that these meals contain adequate nutrients. A healthy meal has vegetables, fruit, meat, bread, and/or dairy products.

A general guide on page 31 of this booklet can help you create good and healthy meals that contain adequate nutrients but little sugar and fat. Also, ask your surgeon and/or dietitian about your food choices.

### 10 important rules

Here are ten rules for eating, drinking, and exercise that will help you get the best results you can with the LAP-BAND System. How willing you are to follow a new way of eating is key to making the operation a success.

- 1) Eat only three small meals a day.
- 2) Eat slowly and chew thoroughly (approximately 15 to 20 times a bite).
- 3) Stop eating as soon as you feel full.
- 4) Do not drink while you are eating.
- 5) Do not eat between meals.
- 6) Eat only good quality foods.
- 7) Avoid fibrous food.
- 8) Drink enough fluids during the day.
- 9) Drink only low-calorie liquids.
- 10) Exercise at least 30 minutes a day.

### Why the rules are important and how to make them work

Rule 1: Eat only three small meals a day

The LAP-BAND System creates a small stomach pouch that can hold only about half a cup (3 to 4 ounces) of food. If you try to eat more than this at one time you may become nauseous. You may also vomit. **If you routinely eat too much, the small stomach pouch may stretch.** That will cancel the effect of the operation. Frequent vomiting can also cause certain complications, such as stomach slippage. You need to learn how much your stomach pouch can hold comfortably and then not exceed this amount.

Rule 2: Eat slowly and chew thoroughly

Food can pass through the new stoma only if it has been "chopped" into very small pieces. **Always remember to take more time for your meals and chew your food very well.**

Rule 3: Stop eating as soon as you feel full

Once your stomach is full, your body receives a signal that you have eaten enough. It takes time, though, for you to become aware of this signal. **If you hurry your meal, you may eat more than you need.** This can lead to nausea and vomiting. Take time over your meal. Try to recognize the feeling of fullness. **Then stop eating at once.**

Rule 4: Do not drink while you are eating. This operation can work only if you eat solid food. If you drink at mealtimes, the food you have eaten becomes liquid. Then the effectiveness of the LAP-BAND System is greatly reduced. **You should not drink anything for one to two hours after a meal.** That way you can keep the feeling of fullness as long as possible.

Rule 5: Do not eat between meals. **After a meal, do not eat anything else until the next meal.** Eating snacks between meals is one of the major reasons for weight-loss failure. It is very important to break this habit.

Rule 6: Eat only good quality foods. **With the LAP-BAND System in place, you should be able to eat only a small amount. So the food you eat should be as healthy as possible. Do not fill your small stomach pouch with "junk" food that lacks vitamins and other important nutrients.** Your meals should be high in protein and vitamins. Fresh vegetables, fruit, meat, and cereals are good foods to choose. Foods high in fat and sugar are not. You may eat apples and oranges, but try to avoid orange juice and apple juice. **Ask your doctor or dietitian before you take any vitamin supplements.**

Note: Solid food is more important than liquid food. **The LAP-BAND System will have little or no effect if you eat only liquid food.** Liquid food passes through the stomach outlet very quickly and does not make you feel full.

Rule 7: Avoid fibrous food. Food such as asparagus that contains many fibers can block the stoma. That's because you can't chew this food well enough to break it up into small pieces and your saliva can't break it down. **Fibrous food should be avoided.** If you would like to eat asparagus or other fibrous foods once in a while, then you must be sure to cook them well, cut them into very small pieces first and then chew thoroughly.

Rule 8: Drink enough fluids during the day. If you lose weight, your fat content will drop. That results in waste products. You will need to drink large amounts of liquid every day in order to urinate more and excrete these waste products from your body. Individual needs will vary, but you should drink at least 6-8 glasses of water a day. Remember: **you should only drink water, tea, or coffee (without milk or cream and sugar).** Also, **keep your food and drinks completely separate during the day.**

Rule 9: Drink only low-calorie liquids

Drinks, including those containing calories, simply run through the narrow outlet created by the band. If you drink liquids high in calories, you will lose little weight, even if you otherwise follow your diet.

Rule 10: Exercise at least 30 minutes a day

This rule is just as important as the other nine rules. Since physical exercise consumes energy and burns calories, it is very important to successful weight loss.



Exercise can help improve your general health. Your size may make it hard for you to exercise as much as you should. But get started, even if it is a little at first. The more weight you lose, the easier it should get. Start with simple exercises, such as walking and swimming. Gradually expand your program to include more vigorous forms of exercise such as cycling, jogging, and aerobics.

Increase your activity level in the course of daily living. For example: stand rather than sit, walk rather than stand, be outside rather than inside, walk rather than drive, climb the stairs rather than use the elevator, etc.

Important: Always check with your doctor about the amount and type of exercise that is best for you.

Note: Although these rules restrict your food intake and the types of food you are able to eat, make sure to keep your diet as varied and balanced as possible.

The rules described above are based on recommendations from Prof. P. O'Brien, Melbourne, Australia; Dr. R. Weiner, Frankfurt, Germany; and J. Gabrielle Rabner, MS RD, New York, United States.

## *Frequently asked questions*

**Q: Will I be sick a lot after the operation?**

**A:** The LAP-BAND System limits food intake. If you feel nauseous or sick on a regular basis, it may mean you are not chewing your food well. It could also mean you are not following the diet rules properly. Another reason you would feel sick may be that there is a problem with the placement of the band. So you should contact your doctor. Vomiting should be avoided as much as possible. It can cause the small stomach pouch to stretch. It can also lead to slippage of part of the stomach through the band. That would reduce the success of the operation. In some cases, it would also require another operation.

**Q: Will I suffer from constipation?**

**A:** There may be some reduction in the volume of your stools. That's normal after a decrease in food intake, because you eat less fiber. This should not cause severe problems. If difficulties do arise, check with your doctor. He or she may suggest you take a mild laxative and drink plenty of water for a while. Drinking plenty of water is a good idea, anyway. Your needs will vary, but you should drink at least 6-8 glasses of water a day.

**Q: Will I need to take vitamin supplements?**

**A:** You may. It's possible you may not get enough vitamins from three small meals a day. At your regular check-ups, your specialist will evaluate whether you are getting enough vitamin B12, folic acid, and iron. Your surgeon may advise you to take supplements.

**Q: What about other medication?**

**A:** You should be able to take prescribed medication. You may need to use capsules or break big tablets in half or dissolve them in water so they do not get stuck in the stoma and make you sick. You should always ask the doctor who prescribes the drugs about this. Your surgeon may tell you to avoid taking aspirin or other non-steroidal anti-inflammatory pain relievers. That's because they may irritate the stomach. The problems these drugs may cause could mean the band would need to be removed.

**Q: What about pregnancy?**

**A:** Becoming pregnant can be easier as you lose weight. Your menstrual cycle may become more regular. If you need to eat more while you are pregnant, the band can be loosened. After the pregnancy, the band may be made tighter again. Then you can go back to losing weight.

**Q: Can the band be removed?**

**A:** Although the LAP-BAND System is not meant to be removed, it can be. In some cases this can be done laparoscopically. Surgeons report that the stomach generally returns to its original shape once the band is removed. After the removal, though, you may soon go back up to your original weight. You may also gain more.

**Q: What if I go out to eat?**

**A:** Order only a small amount of food, such as an appetizer. Eat slowly. Finish at the same time as your table companions. You might want to let your host or hostess know in advance that you cannot eat very much.

**Q: What about alcohol?**

**A:** Alcohol has a high number of calories. It also breaks down vitamins. An occasional glass of wine or other alcoholic beverage, though, is not considered harmful to weight loss.

**Q: Will I need plastic surgery for the surplus skin when I have lost a lot of weight?**

**A:** That is not always the case. As a rule, plastic surgery will not be considered for at least a year or two after the operation. Sometimes the skin will mold itself around the new body tissue. You should give the skin the time it needs to adjust before you decide to have more surgery.

**Q: What will happen if I become ill?**

**A:** One of the major advantages of the LAP-BAND System is that it can be adjusted. If your illness requires you to eat more, the band can be loosened. This can be done by removing saline from it. When you have recovered from your illness and want to lose weight again, the band can be tightened. This can be done by increasing the amount of saline. If the band cannot be loosened enough, it may have to be removed.

**Q: How is the band adjusted?**

**A:** Adjustments are often carried out in the X-ray department. They are done there so the reservoir can be clearly seen. When X-rays are used, your reproductive organs should be shielded. Sometimes adjustments can be done in an outpatient clinic or office. Local anesthesia may or may not be needed. A fine needle is passed through the skin into the reservoir to add or subtract saline. This process most often takes only a few minutes. Most patients say it is nearly painless.

**Q: How much weight will I lose?**

**A:** The amount of weight you may lose depends on several things. The band needs to be in the right position. And you need to be committed to

your new lifestyle and eating habits. In the U.S. clinical trial, 2% of patients gained some weight. 5% neither gained, nor lost weight ( $\pm 5\%$ ). 61% of the patients lost at least 25% of their excess weight. 52% of the patients lost at least 33% of their excess weight. 22% lost at least 50% of their excess weight, and 10% lost at least 75% of their excess weight.

You should lose weight gradually. Losing weight too fast creates a health risk and can lead to a number of problems. Nausea and vomiting are only the most minor examples. A weight loss of 2 to 3 pounds a week in the first year after the operation is possible, but one pound a week is more likely. Twelve to 18 months after the operation, weekly weight loss is usually less. Remember that your main goal is to have a weight loss that prevents, improves, or resolves health problems connected with severe obesity.

**One final point:**

It is important that you ask your surgeon all the questions you may have about obesity surgery and the LAP-BAND Adjustable Gastric Banding System. It is also essential that you follow his or her advice.

## *Your food*

Use this section to help you plan what you eat. You may choose what you would like from each of the these food groups each day:

### 1. Fruit and vegetables

- 2 to 3 servings of fresh vegetables daily
- 1 to 2 servings of fresh fruit daily



### 2. Bread and cereals

- 1 small portion of corn flakes for breakfast
- 1 to 2 slices of whole wheat or rye bread each day  
(If you want, you can spread just a little margarine or butter on the bread)

### 3. Meat, fish, poultry, eggs

- 1 oz. to 2 oz. of meat, fish, or poultry or one egg each day

(Remove all visible fat from the meat. Remove the skin from poultry. Prepare the meat in ways that need very little fat. Grilling, steaming, microwaving, or boiling are all good ways to do that.)

### 4. Dairy products

Milk and yogurt are calories in liquid form. In theory, then, they should be avoided. But these types of food have calcium. That makes them an important part of a healthy daily diet. Choose a maximum of 2 cups of skimmed milk or low-fat yogurt and 1 oz. of cheese a day.

### 5. Fats

Restrict the use of fat to 3 to 4 teaspoons of margarine, butter, or oil per day. You can have low-fat salad dressings and mayonnaise in moderation.

### 6. Drinks

Drink as many calorie-free liquids per day as you wish. Suitable drinks are:

- tea or coffee
- water

- non-carbonated beverages containing few or no calories
- clear soup

Some doctors have reported that carbonated beverages may contribute to enlargement of the small pouch and should be avoided.

### Foods that must be avoided

These foods have a concentrated supply of calories with little nutritional value. These empty-calorie foods should be left out of your healthy diet.

Sugar and foodstuffs containing large quantities of sugar, such as

- high-calorie soft drinks
- syrups
- cakes
- biscuits
- sweets
- jam
- marmalade
- honey

### High-fat foods including

- chocolate
- chips
- pies
- pastries

Alcoholic drinks should also be avoided as much as possible. These are drinks such as

- beer
- wine
- liquors
- port
- sherry
- cocktails
- champagne
- other high-calorie drinks.

**BMI Chart (lbs/in)** BMI = lbs./inches<sup>2</sup> x 704.5

Weight (lbs.)	Height (ft)									
	4'9"	4'11"	5'1"	5'3"	5'5"	5'7"	5'9"	5'11"	6'1"	6'3"
154	33	31	29	27	26	24	23	22	20	19
165	36	33	31	29	28	26	24	23	22	21
176	38	36	33	31	29	28	26	25	23	22
187	40	38	35	33	31	29	28	26	25	24
198	43	40	37	35	33	31	29	28	26	25
209	45	42	40	37	35	33	31	29	28	26
220	48	44	42	39	37	35	33	31	29	28
231	50	47	44	41	39	36	34	32	31	29
243	52	49	46	43	40	38	36	34	32	30
254	55	51	48	45	42	40	38	35	34	32
265	57	53	50	47	44	42	39	37	35	33
276	59	56	52	49	46	43	41	39	37	35
287	62	58	54	51	48	45	42	40	38	36
298	64	60	56	53	50	47	44	42	39	37
309	67	62	58	55	51	48	46	43	41	39
320	69	64	60	57	53	50	47	45	42	40
331	71	67	62	59	55	52	49	46	44	42
342	74	69	65	61	57	54	51	48	45	43
353	76	71	67	63	59	55	52	49	47	44
364	78	73	69	64	61	57	54	51	48	46
375	81	76	71	66	62	59	56	52	50	47
386	83	78	73	68	64	61	57	54	51	48
397	86	80	75	70	66	62	59	56	53	50
408	88	82	77	72	68	64	60	57	54	51
419	90	84	79	74	70	66	62	59	56	53
430	93	87	81	76	72	67	64	60	57	54
441	95	89	83	78	73	69	65	62	58	55
452	98	91	85	80	75	71	67	63	60	57
463	100	93	87	82	77	73	69	65	61	58

<i>Body Mass Index Classification</i>						
Underweight	Ideal BMI	Overweight	Obesity	Severe Obesity	Morbid Obesity	Super Obesity
<19	19-25	25-30	>30	>35	>40	>50

Please note that the BMI does not distinguish between fat and muscle. It is possible for a heavily muscled individual to have a BMI in excess of 25 without increased health risks.

**BMI Chart (kg/m) BMI = kg/m<sup>2</sup>**

	Height (m)									
	1.45	1.5	1.55	1.6	1.65	1.7	1.75	1.8	1.85	1.9
70	33	31	29	27	26	24	23	22	20	19
75	36	33	31	29	28	26	24	23	22	21
80	38	36	33	31	29	28	26	25	23	22
85	40	38	35	33	31	29	28	26	25	24
90	43	40	37	35	33	31	29	28	26	25
95	45	42	40	37	35	33	31	29	28	26
100	48	44	42	39	37	35	33	31	29	28
105	50	47	44	41	39	36	34	32	31	29
110	52	49	46	43	40	38	36	34	32	30
115	55	51	48	45	42	40	38	35	34	32
120	57	53	50	47	44	42	39	37	35	33
125	59	56	52	49	46	43	41	39	37	35
130	62	58	54	51	48	45	42	40	38	36
135	64	60	56	53	50	47	44	42	39	37
140	67	62	58	55	51	48	46	43	41	39
145	69	64	60	57	53	50	47	45	42	40
150	71	67	62	59	55	52	49	46	44	42
155	74	69	65	61	57	54	51	48	45	43
160	76	71	67	63	59	55	52	49	47	44
165	78	73	69	64	61	57	54	51	48	46
170	81	76	71	66	62	59	56	52	50	47
175	83	78	73	68	64	61	57	54	51	48
180	86	80	75	70	66	62	59	56	53	50
185	88	82	77	72	68	64	60	57	54	51
190	90	84	79	74	70	66	62	59	56	53
195	93	87	81	76	72	67	64	60	57	54
200	95	89	83	78	73	69	65	62	58	55
205	98	91	85	80	75	71	67	63	60	57
210	100	93	87	82	77	73	69	65	61	58

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### *More about obesity and the LAP-BAND System...*

In America, obesity is a leading cause of preventable death. As such, it is a major public health challenge. Millions of adults are overweight or obese. Because they are, they have a greater risk for health problems.

Those problems include

- high blood pressure
- heart disease
- type 2 diabetes
- sleep apnea
- respiratory problems

The BioEnterics LAP-BAND Adjustable Gastric Banding System can help. Combined with diet and a program of behavior modification, it offers you a chance to reduce your weight. When you do that, you can also minimize the risks to your health.

The LAP-BAND System is not a miracle cure. It is an aid to losing weight. Not everyone will lose weight or keep the weight off. To get the long-lasting weight-loss results you want, you will need to work at it.

The purpose of this booklet is to give you the following information about the LAP-BAND System:

- how it works
- what its benefits are
- what its potential risks and complications might be

This booklet also covers topics such as

- obesity
- related health risks
- surgical and non-surgical options to treat obesity
- eating habits
- frequently asked questions about the LAP-BAND System.

On the opposite page is an Informed Consent form. Please sign and date this form. When you do, you are saying you have read this booklet. You are also saying you understand what it says. That means you understand the benefits that can result from this surgical procedure. It also means you understand the risks and potential complications associated with it. We strongly urge you to talk in detail with your surgeon about this procedure before you have it done.

<sup>1</sup> Ideal body weight is associated with the lowest death rate in insured populations and is taken from the 1983 Metropolitan Life Insurance Company tables.

<sup>2</sup> National Heart, Lung and Blood Institute, National Institutes of Health, *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*, 1998, p. X.

<sup>3</sup> American Society for Bariatric Surgery, Web site 10/99.

<sup>4</sup> Bouchard, C., et al., *The Response to Long-Term Feeding in Identical Twins*. *New England Journal of Medicine*, 1990, 322 (21): 1477-82.

<sup>5</sup> American Society for Bariatric Surgery, National Institutes of Health, and the International Federation for the Surgery of Obesity Guidelines.

## **Informed Consent: Information for Patients Considering LAP-BAND® Adjustable Gastric Banding System Surgery**

Before your surgery, you should know the risks connected with the LAP-BAND Adjustable Gastric Banding System. You should also know what the possible complications are. To learn about these, talk with your surgeon. When you do, ask about all the risks. Ask about all possible complications. Also ask about symptoms and conditions that might suggest this surgery is not right for you. To help with that talk, BioEnterics Corporation has prepared this booklet: "Information for Patients, A Surgical Aid in the Treatment of Morbid Obesity." Read it. Discuss what it says with your surgeon. Be sure you ask about terms you do not understand. You have to decide how willing you are to accept the risks and possible complications.

### **Additional Information**

You should also have other information. Talk with your surgeon about:

- alternatives to LAP-BAND System surgery
- the information in our package inserts
- risks and benefits this procedure poses for you

### **Special Notice**

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

**Patient Consent**

I have read the booklet "Information for Patients, A Surgical Aid in the Treatment of Morbid Obesity." I understand the risks it describes. I understand the potential complications it describes. I understand what it says about symptoms and conditions that might suggest this product is not right for me. I have discussed risks with my surgeon. I have discussed potential complications. I have talked with my surgeon about symptoms and conditions that might suggest this product is not right for me. I know not all risks connected with this product can be predicted. I also know those risks can be serious. They can be serious even with the best medical manufacturing. They can be serious with the best technology. They can be serious with the best surgical care. I accept all the risks. I accept the possible complications. I believe the benefits I will get from the LAP-BAND Adjustable Gastric Banding System surgery outweigh the risks. I take full responsibility for my choice. I choose to proceed with the surgery.

Signed by: \_\_\_\_\_ Date \_\_\_\_\_

Print or type patient name \_\_\_\_\_

Signed by: \_\_\_\_\_ Date \_\_\_\_\_

Print or type witness name \_\_\_\_\_

Original: Surgeon  
Copy: Patient



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For more information about the LAP-BAND® System, please call  
1-800-432-8803.

**CAUTION: This device is 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.



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