

LAP-BAND PROCEDURE

Approved by the FDA in June 2001, the BioEnterics® LAP-BAND Adjustable Gastric Banding System is the newest and the only adjustable surgical treatment for morbid obesity in the United States. The lap-band helps you to lose weight by reducing how much your stomach can hold and lengthening the feeling of being full. The success of the lap-band process, however, also depends on how motivated you are and how committed you are to your goal of long-lasting weight loss. Since its clinical introduction in 1993, more than 100,000 LAP-BAND procedures have been performed around the world.

How does the Lap-Band work?

Your body gets energy from food while it passes through your mouth, esophagus, stomach and then 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 is how energy can be carried through the body by the blood.

During the procedure, the surgeon uses laparoscopic techniques (using small incisions and long-shafted instruments), to implant an inflatable silicone band into the patient's abdomen. Like a wristwatch, the band is fastened around the upper stomach to create a new, tiny stomach pouch that limits and controls the amount of food you eat. It also creates a small outlet that slows the emptying process into the stomach and the intestines. As a result, patients experience an earlier sensation of fullness and are satisfied with smaller amounts of food. In turn, this results in weight loss.

Least Traumatic Procedure

Since there is no cutting, stapling or stomach re-routing involved in the LAP-BAND System procedure, it is considered the least traumatic of all weight loss surgeries. The laparoscopic approach to the surgery also offers the advantages of reduced post-operative pain, fewer wound complications and quicker recovery so that you may resume your normal activities sooner. If for any reason the LAP-BAND System needs to be removed, the stomach generally returns to its original form.

Adjustable Treatment

The LAP-BAND System is also the only adjustable weight loss surgery. The diameter of the band is adjustable for a customized weight-loss rate. Your individual needs can change as you lose weight. For example, pregnant patients can expand their band to accommodate a

growing fetus, while patients who aren't experiencing significant weight loss can have their band tightened.

To modify the size of the band, its inner surface can be inflated or deflated with a saline solution. The band is connected by tubing to an access port, which is placed well below the skin during surgery. After the operation, the practitioner can control the amount of saline in the band by entering the port with a fine needle through the skin.

The Lap-Band System

The LAP-BAND System is the least invasive of the surgical procedures to treat morbid obesity. It works by limiting how much you can eat, reducing your appetite, and slowing digestion. It will not, however, solve the problem of morbid obesity by itself and without patient motivation and commitment to improved eating habits and regular exercise. The average weight loss in the United States clinical study was approximately 36-38% of excess weight, 2 to 3 years after surgery. A few people lost up to 100% of their excess weight, and a few got heavier. Some people lose more than others. You may never reach your ideal weight but chances are good that your health will improve, along with your self-image.

Indications

It is major surgery, and it is not without risk of complications. The Lap-Band System is reversible. The Lap-Band can be removed completely, usually restoring your stomach to its original form. (Weight will likely be regained when the band is removed).

You may be a candidate for a Lap-Band placement if:

- You are at least 18-63 years old
- You have a BMI of greater than 40 for at least 5 years
- You have a BMI of 35-40 and have other medical problems
- You have been unable to maintain weight-loss with serious efforts at dietary methods
- You are prepared to make major changes in your eating habits and lifestyle
- You have no serious mental health condition or other health condition that may have caused you to be overweight
- You are not chemically dependent or drink alcohol in excess
- You have never had surgery on your stomach before
- You have a normal esophagus and do not have severe reflux disease

Advantages:

Lowest mortality rate compared to other obesity surgeries

Least invasive surgical approach

No stomach stapling or cutting, or intestinal re-routing

Adjustable
Reversible
Lowest operative complication rate
Lower risk of nutritional deficiencies

Disadvantages:

Slower initial weight loss than Gastric Bypass
Regular follow-up critical for optimal results
Requires an implanted medical device
In some cases, effectiveness can be reduced due to band slippage
In some cases, the access port may leak and require minor revisional surgery

Complications

All surgical procedures have the risk of complications. The risk of serious complications from the placement of a Lap-Band is quite low, but the risks are real. Some may require hospitalization and /or re-operation. The risk of complications following the placement of the Lap-Band is similar to the risk of complications following any major surgery on your digestive tract. Morbidly obese patients face added risks because of their body size.

Complications (reported from the U.S. Clinical study)

- Death
- Gastric/ Esophageal Perforation
- Nausea and vomiting
- Gastroesophageal reflux
- Band slippage
- Ulceration
- Heartburn
- Pouch dilatation
- Stoma obstruction
- Esophageal dilatation or dysmotility
- Dysphagia (difficulty swallowing)
- Required follow-up surgery for band problem or to fix leak or flipped port
- Erosion resulting in removal of the band
- Esophagitis
- Gastritis
- Blood Clots/ Pulmonary embolism
- Pneumonia
- Infection
- Injury to stomach or spleen
- Gallstones

Weight regain

Surgery

Placement of the Lap-band system will take about 1 hour or less under general anesthesia. This is an outpatient procedure. During the operation, the band will be fastened around the upper part of your 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 access port for adjusting the band will be placed under your skin. To do this, the surgeon will slightly enlarge one of the incisions that he made for the laparoscopic instruments. Once you are fully awake and able to drink fluids well, you will be allowed to go home. The Lap-Band will be placed without any saline in the band initially. Once the edema from the procedure has subsided, usually 6-8 weeks after surgery, the first adjustment can be done if needed.

Changes in Your Ability to Eat

It will be very important to follow the eating and drinking instructions starting right after the operation to allow the new stomach structure to heal completely and in the right position. This may take a month or more. It will also be important, especially in the early weeks, not to stretch the small stomach pouch above the band. Vomiting can stretch it, so it is important not to vomit. Vomiting can also increase the chance of stomach tissue slipping through the band.

The first few days post-op: Right after the operation you can take an occasional sip of water or suck on an ice cube. You shouldn't drink more than this. The day after surgery, you can take a little more fluid. You should only 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.

Dietary Guidelines

You will be given guidelines to follow for the first few weeks after surgery and thereafter. Generally, you will start with clear fluids, progress to full liquids, then slowly to soft foods as you tolerate without nausea or vomiting. It is very important in the first few weeks to let your stomach adjust to the lap-band rather than to lose weight.

As you progress into a regular diet, you will find some products like bread, red meat, rice and pasta may be difficult if not impossible for you to tolerate. It is better to eat softer foods that easier to tolerate such as moist white meat (chicken and pork) and fish. Chew all of your food well. If you do not follow these precautions, you may have

vomiting, stomach irritation, and swelling. You could also have stomach obstruction.

If you ever have problems with solid foods and suffer from nausea and vomiting, go back to the liquid diet you had earlier. Then slowly add soft foods to help you transition to solid foods later. Caution is always advised with vomiting as it may increase the incidence of band slippage, stomach slippage, or stretching of the small stomach pouch above the band.

Lap-Band Adjustments

The band can be adjusted to meet your specific needs. This is one of the more attractive aspects of the lap-band. This feature allows you and your practitioner to find the right level of restriction for you.

When first placing the lap-band, it is left empty so that you can get used to having it in place. It also allows for the necessary healing to occur around the new band site. These first few weeks are a very critical time. You need to avoid vomiting! You also need to avoid putting any pressure on your new small stomach above the band. The first time the band will be adjusted will usually be 6-8 weeks after surgery; however, this time will vary depending on your needs. To determine if it is time for an adjustment, your practitioner will consider:

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

Only a clinician trained and authorized by INAMED Health 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 yourself adverse reactions. You could also damage your band.

To adjust your band, the practitioner injects saline into the self-sealing port. This port is located under your skin. The band can also be adjusted by removing saline from the port. The adjustment is done with a special fine needle. You may feel a pricking sensation when it is done. The feeling is similar to when you give blood. Adjustments are usually done in the office; however, sometimes it may need to be done under fluoroscopy.

To get the best results, you may need several adjustments. Each one will range from 0.5cc to 2cc of fluid. The exact amount 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. Don't be in a hurry to have an adjustment before you are ready. To work, the band needs your participation along with a partnership with your clinicians.

Nutrition - 10 Important Rules

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

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. 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.

Motivation is the Key!

To work, the band needs your participation. Your success will depend on you and the partnership between you and your medical team. We will not perform the operation unless we are sure that you understand the problems your excess weight is causing. We will also make sure you understand your responsibilities, including adopting and maintaining new eating patterns and a new lifestyle.

Surgery is the first step to successful and sustained weight loss; however, you must adopt a lifelong program that will help you meet your goals. This multi-faceted program will include routine check-ups with your medical team and ongoing band adjustments if necessary. We also recommend that you attend a support group meeting when able.

If you are ready to take control of your obesity and your life with the Lap-Band, talk to us about the advantages, disadvantages and possible risks of this treatment.