



Operative Permit for Lap-Band® Placement

Lap-Band® Placement Operation

The planned operation involves placement of a silicone elastomer band or “belt” around the uppermost part of your stomach. The section of your stomach above the Band, called the “stomach pouch” is intended to have a size of one ounce or less, so that the procedures should help you become full with very small meals. The Band is adjustable by means of a balloon lining its internal circumferences – this feature is intended to allow the outlet of the stomach pouch to be narrowed over time so that you will become full easily, or opened somewhat if you cannot eat appropriate foods.

Expected Outcomes and Patient Commitments

The operation does not guarantee weight loss, and does not cure the underlying cause of obesity. The procedure only works well when coupled with an active effort on the part of the patients to adapt their eating habits toward infrequent small volume meals in concert with the surgical changes – the Lap-Band® is best viewed as a “tool” to assist in the reduction of calorie intake and it cannot serve as a substitute for the patient’s mental effort in dieting and exercise. It is particularly important for Lap-Band® patients to avoid high-calorie liquids or other “soft” calories, because these foods will not promote satiety (sense of fullness). The amount of weight lost depends on

- the patient’s starting weight (heavier patients tend to lose more weight, but end up further above ideal body weight),
- the patient’s age (younger patients tend to get closer to ideal body weight), and
- motivation.

Thus there is no guaranteed amount of weight loss, though it is reasonable to expect that the overwhelming majority of surgical patients will lose enough weight to have a significant positive impact on their medical condition.

Diet

For the first two weeks after surgery, you should consume only liquids. Over the next several weeks you should gradually progress to eating small amounts of soft but healthy food. The Band will be calibrated over time, with the goal of helping you achieve weight loss of 1 to 2 pounds each week.

Removal of Lap-Band®

It is reported by surgeons experience with the Lap-Band® that it can be removed with minimal residual effects on the stomach. However, you must clearly understand that such removal would only be planned if medical complications arise. We will not offer Band removal if the patient is simply tired of having the volume of eating restricted. In this context, you must understand that if the Band is removed and the intestinal anatomy is not modified in some other way (such as conversion to Gastric Bypass) then substantial weight regain is guaranteed.

Operative Permit for Lap-Band® Placement (Continued)

Potential Nutritional Problems

Patient who have undergone Weight Loss Surgery may develop deficiency of Iron (may result in anemia), Vitamin B12, or Calcium (may result in osteoporosis, “weak bones”). No other major nutritional problems have been identified to commonly occur – however it is required for patients to have screening blood work checked on a periodic basis for life. Patients should also take basic mineral supplements as instructed by the surgeon (usually vitamins with Iron, and supplemental Calcium) for life.

Risks of the Operation

Risk of the Lap-Band® operation include risks that are

1. Physically related to the surgical procedures, and
2. The risks caused by the stress that any major surgical procedure would impose on your body and vital signs.
3. Financial risk. If your procedure is not covered by insurance you will be responsible for any complications if they should they occur.

One or more of the following adverse events can occur in any patient, and some patients die as a result of undergoing the weight loss operation. The risk of death from this procedure ranges from a low of 1 in 1,000 for the best risk patients, up to 1 in 4 or worse for patients who are severely ill before surgery. Another way to describe the risk of death is as a percentage: from 0.1% chance of death (“low risk”) up to or greater than 25% chance of death.

Physical Risks

Physical risks that are related to the surgical procedure include:

- Injury to the stomach (causes Band erosion or stomach leak)
- Injury to other nearby structures such as the spleen (may require removal of the spleen), liver, esophagus, other bowel/intestine, blood vessels, nerves, or muscles of the abdominal wall
- Shifting or slippage of the Band
- Kinking/breakage or other malfunction of the Band or associate tubing, bleeding, infection, or reaction to the Band or tubing material.
- The Band may erode through the wall of the stomach.
- Patients may also have wound healing problems that lead to wound infection or wound weakness (hernia).
- Some reports have described functional problems or dilation of the esophagus that may be caused by the pouch outlet restriction – esophageal or stomach functional problems might persist even after Band removal. The stomach pouch outlet may become blocked by food, tissue swelling, or over-inflation of the Band.

Most of the problems outlined above would require later procedures to diagnose, repair, or revise a part of the surgery that is not working correctly. These procedures may include IV fluids, Upper GI X-Rays, CT scans, endoscopic procedures, or repeat operation(s).



Operative Permit for Lap-Band® Placement (Continued)

Systemic Stress

Risks that arise from the systemic stress effects of major surgery include:

- lung failure
- heart failure or heart attack
- kidney failure
- pneumonia, and
- Deep Venous Thrombosis with possible Pulmonary Embolus (blood clot forms in legs and floats into the vessels of lungs).

Your significant obesity increases the risk of all these problems, and unfortunately also makes diagnosis and treatment of most problems more difficult (obviously), the obesity is the reason you are considering this surgery, so there is no way out of this dilemma).

Other Undesirable Outcomes

Your surgeon may encounter a situation in the operating room that requires a change in the operative plan. Findings such as unexpected tumor or massive enlargement of the liver, or cirrhosis of the liver, might make it medically sensible to stop the operation without placing the Band.

Not all patients lose all the weight they hope to. Inadequate weight loss may arise from a surgically correctable problem, but more commonly weight loss fails when patients fail to work with the surgery to dramatically reduce their calorie intake and establish a regular exercise program. The latter problem cannot be altered surgically.

Most patients will be left with excess skin on abdomen, arms, legs, or other areas. This skin may be unattractive, and may cause pain or hygiene problems. Unfortunately, the excess skin usually does not “snap back” with exercise or time – if it is to be treated it must be removed by additional surgery. Most patients find they have tremendously improved energy after recovering from surgery. Some minerals or other nutrients may be required. As a result of weight loss, patients may experience internal or external psychological distress – divorce, depression and/or need for counseling are commonly seen.

Possible Removal of the Gallbladder

Many patients who undergo Weight Loss Surgery have previously had their gallbladders removed. Of patients who still have their gallbladders at the time of surgery, some will have gallstones or gallbladder inflammation identified at the time of surgery. If a diseased gallbladder is identified before or during surgery, your surgeon may need to change the operative plan to account this finding. It may be appropriate to remove the gallbladder, and the appearance of the gallbladder (especially if there is apparent infection) might make it appropriate to place the Band at the same time. Your surgeon will need to make an assessment regarding the risk that the diseased gallbladder will progress to cause clinically significant problems as a result of the rapid weight loss, versus the possibility that manipulation of the gallbladder would increase the risk of a Band infection.



Operative Permit for Lap-Band® Placement (Continued)

If the gallbladder is normal, the surgeon will leave it alone because of the small but real risks of gallbladder removal (injury to the main bile duct or liver, leak from bile duct closure, or stones retained in main bile duct).

Conversion to Open Procedure

The Lap-Band® is designed to be placed laparoscopically, and this approach is almost always planned for our patients. Nevertheless, your surgeon's primary goal is to accomplish your weight loss operation so that, at the end of the procedure, the surgeon is satisfied that you have undergone an operation that gives you a very low chance of complications and an excellent chance of successful weight loss. Keeping this goal in mind, your surgeon requires your permission to make a judgment (if necessary) during the operation that is appropriate to convert to an open approach during the operation.

Fee For Lap-Band® Fills

Lap-Band® Fills are included for the first three months following surgery. After the three months, Lap-Band® Fills are charged at \$300 per fill and there will be no exceptions.

Fee for Revision or Complications for Self-Pay Patients

Should you be a self-pay patient and you need a revision or have a complication, this surgery will not be covered by your insurance.

Summary

You are being offered the Lap-Band® procedure because your surgeon believes it is a medically reasonable option in your case. Your part of the decision to undergo surgery is more complex and more important. Before choosing to undergo Lap-Band® Placement, you must:

1. Believe that your weight is a medically significant problem
2. Believe that you have exhausted all non-surgical options for weight loss
3. Understand the expected outcomes and the risks of the Lap-Band®, including reading the Patient Information Booklet published by the manufacturers of the Lap-Band®
4. Believe that the tradeoffs and risks associates with Lap-Band® are worth the risks of surgery for you
5. Pledge to comply with recommended follow-up visits with your surgeon, or to work with your surgeon to make other arrangements in you move, and
6. Pledge to keep Dr. Small or future associates of your personal address and telephone numbers.

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Patient Responsibility

If all of the above are true, please sign below:

Patient's Name (Please Print): _____

Patient's Signature: _____

Today's Date: _____

Thank you for choosing Surgical Associates of West Florida to provide your surgical care.



Dedicated To Delivering Quality Surgical Care

2

Visit Our Web Site at www.WestFloridaWeightLoss.com