



you *fit* here

lap.bandTM
S Y S T E M

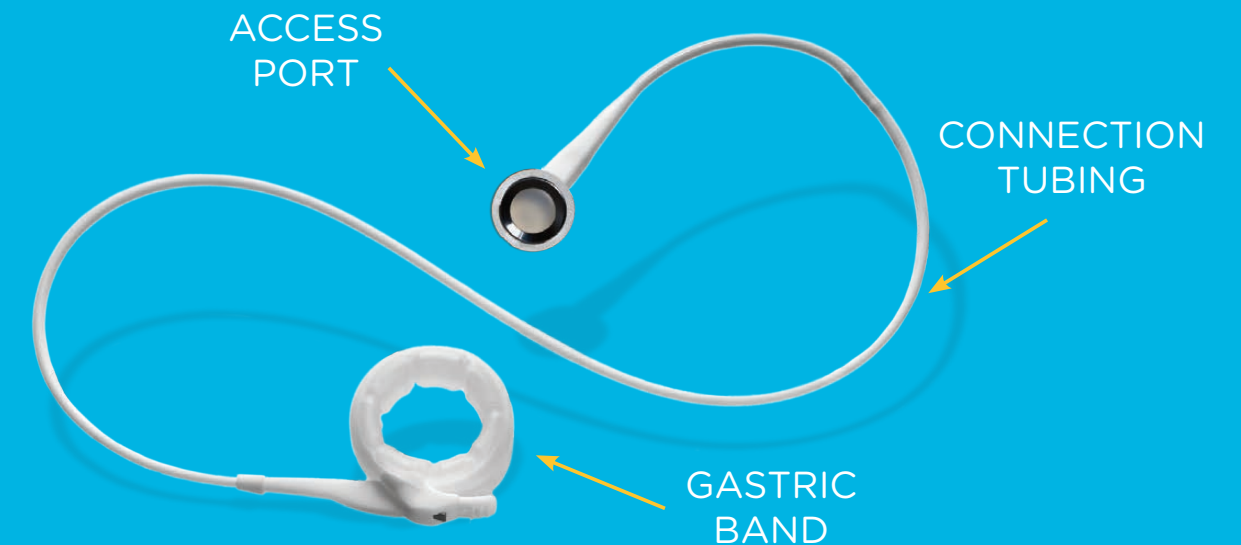
SURGICAL AID IN THE TREATMENT OF OBESITY
A Decision Guide For Adults

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

What's in this brochure

Here's what this brochure can tell you before you make your decision about the LAP-BAND® System:

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Why is obesity dangerous and why is losing weight such a struggle for some people?
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Introduction

If you have at least 30 lb to lose, your health is affected by your weight, and you are ready to make a serious commitment to change, the LAP-BAND® System may be the right choice for you.

The LAP-BAND® System is a medical device made of soft silicone. The band is placed around the upper part of your stomach by a qualified specialist in order to help bring your weight down and treat the health issues related to your weight. Because it restricts how much solid food you can eat at once, it helps you feel fuller more quickly and for a longer period of time.

It is not a miracle cure: to succeed, you have to make a commitment to drastically change your lifestyle. Your specialist will explain how truly challenging making that change may be for you and your chances for success. If you do your part, the LAP-BAND® System can help you control your hunger and lose weight.

Before you make a decision, it is important for you to understand what the LAP-BAND® System involves and what it requires you to do.

This brochure is designed to help answer some of the questions you may have about the LAP-BAND® System and weight-reduction surgery in general, so you can make an informed decision. It includes specific information about the benefits and the risks of the LAP-BAND® System.

This information cannot and should not replace discussions with your specialist.

Your decision about whether or not the LAP-BAND® System can help you should be based on realistic expectations of the outcome. Your results will depend on many factors that are specific to you, including your age, the specific health issues you may have, and your commitment to a new lifestyle.

Speak to your specialist about your expectations and any risks and potential complications.

1. Are you a good candidate for the LAP-BAND® System?

The LAP-BAND® System is not right for everyone. (Achieving success with the LAP-BAND® System requires a lifetime commitment to changing your eating habits; this is a difficult decision to make and not everyone succeeds.) Highlighted in the box below are the guidelines your specialist will use to determine if you are eligible.

What makes you a good candidate for the LAP-BAND® System

- You are at least 18 years old.
- Your body mass index (BMI) is 30 or higher AND you have a health problem related to your weight. Or your BMI is 40 or higher. (See the explanation of BMI on pages 11-13).
- You have tried hard to lose weight but have only had short-term success.
- You do not have a disease that may have caused you to be overweight.
- You are prepared to set a lifetime goal to make drastic, challenging, permanent changes to your eating habits and lifestyle.
- You are willing and able to return to your doctor for follow-up visits and band adjustments.
- You understand the information in this brochure and other information provided by your specialist.

Even if you meet all of these criteria, your specialist may still recommend a different treatment option.

What makes you a poor candidate for the LAP-BAND® System

Many factors can make you a poor candidate for the LAP-BAND® System and your specialist will know how to determine them. Your specialist may decide the LAP-BAND® System is not right for you if:

Warning *You have a disease or condition, such as severe heart or lung disease, that your specialist determines makes you a poor candidate for surgery.*

Any surgery involves some amount of risk. Risks can be from the surgery itself or from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions. Your risks will vary depending on your weight, age, and medical history. Your specialist will assess if you are healthy enough for surgery.

Warning *Your throat (esophagus), stomach, or intestine is not normal. For instance, you might have a narrowed opening.*

Because the LAP-BAND® System works by controlling the amount of food that can move from the throat into the stomach, an abnormal or narrowed opening could cause a blockage of your throat. This could cause stretching (dilatation) of the esophagus. Very rarely, this can cause damage to the throat that would require the LAP-BAND® System to be removed. Your specialist can assess your specific risks and determine if the

LAP-BAND® System is right for you.

Warning *You are pregnant.*

For now, you should focus on being healthy during your pregnancy. Healthy eating, not weight loss, should be your main concern. Any abdominal surgery involves some amount of risk and LAP-BAND® surgery is not recommended while you are pregnant.

Once you have a LAP-BAND® System, it will not interfere with you if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because your period may become more regular. If you need to eat more while you are pregnant, the band can be loosened. After the pregnancy, it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

Warning *You are addicted to alcohol or drugs.*

If you are addicted to alcohol or drugs, it may be hard for you to make major, lifelong changes to your eating habits. The LAP-BAND® System will not work without these changes and you should not have this procedure. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

Also, any surgery involves some amount of risk. Risks can be from the surgery itself and from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions, including drug or alcohol addiction. Your risks will vary depending on your weight, age, and medical history. Your specialist will



assess if you are healthy enough for surgery.

Warning *You are under 18 years of age.*

The LAP-BAND® System is currently not approved for use in people under the age of 18 years old by the US Food and Drug Administration (FDA).

Warning *You don't understand how the LAP-BAND® System works.*

If you don't understand how the LAP-BAND® System works, it may be hard for you to make major, lifelong changes to your eating habits. The LAP-BAND® System will not work without these changes and you should not have this procedure until you understand how the LAP-BAND® System works. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

Warning *You are not prepared to set a lifetime weight goal and make major, lifelong changes to your eating habits required to meet that goal.*

You must be willing and able to make major, lifelong changes to your eating habits. The LAP-BAND® System will not work without these changes, and you should not have this procedure if you are not prepared to make these changes. Not following the strict food rules can cause side effects and risks that can be serious, even deadly.

Caution *You have an inflammatory disease or a problem with the digestive tract, such as stomach ulcers or Crohn's disease.*

If you have any of these problems or take certain medicines to treat these problems, you may bleed during surgery or have trouble healing. Tell your doctor about your health problems and any medicines you are taking. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

Caution *You have a medical problem that could cause bleeding in the throat (esophagus) or stomach. These could be problems developed over time that cause veins and/or blood vessels to get bigger, such as esophageal or gastric varices (a dilated vein). This could also include conditions you may have been born with, such as congenital or acquired intestinal telangiectasia (dilation of a small blood vessel).*

These problems are rare but can cause bleeding during surgery. You may not know if you have a problem before you have surgery. Your specialist will decide if he or she can

continue with surgery if he or she finds you have any of these problems.

Caution *You have portal hypertension (high blood pressure in your veins).*

Any surgery involves some amount of risk. Risks can be from the surgery itself or from the medicines used during the procedure. Surgery risks are greater when the patient is obese or has other serious health conditions. Your risks will vary depending on your weight, age, and medical history. Your specialist will assess if you are healthy enough for surgery.

Caution *You have experienced an injury, such as a tear, at or near the location of the intended band placement.*

Any injury where the LAP-BAND® System will be placed should be fully healed before surgery. Do not get a LAP-BAND® System if you have any damage because it could slow healing and increase bleeding. It could also cause the LAP-BAND® System to erode the stomach and you would need an additional surgery to remove the LAP-BAND® System. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

Caution *You have cirrhosis, other types of liver disease, or chronic pancreatitis (a swollen or inflamed pancreas that lasts for a long time).*

These problems may indicate that you are not healthy enough for surgery, or that surgery could cause internal bleeding. These problems are rare. You may not know if you have a problem before you have surgery. Your specialist will decide if he or she

can continue with surgery if he or she finds you have any of these problems.

Caution *You have an infection somewhere in your body or one that could affect the surgical area.*

An infection could increase the risk of surgery and potentially lead to problems with the LAP-BAND® System.

Caution *You are on constant, long-term steroid treatment.*

If you have used steroid medicines for a long time, it may be harder to heal after the LAP-BAND® surgery. This could cause an increased risk of problems. Tell your doctor about any medicines you are taking. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

Caution *You are allergic to materials in the device.*

Allergies to the materials in the LAP-BAND® device are rare. Tell your specialist if you have an allergy to

silicone, nickel, or titanium. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

Caution *You think you will not be able to stand the postoperative pain or have a history of not being able to stand pain in general.*

Pain from LAP-BAND® surgery is usually felt in the areas around the cuts (incisions) made during surgery. Most people find the pain to be mild to medium. Pain is often treated with over-the-counter medicines such as nonsteroidal anti-inflammatory drugs (like ibuprofen) or acetaminophen. Tell your specialist if you have concerns about pain. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

Caution *You have an autoimmune connective tissue disease, which might be a disease such as systemic lupus erythematosus or scleroderma. The same is true if you have symptoms of one of these diseases.*





What are the risks?

Before you decide on getting a LAP-BAND® System, you should know what the risks of the procedure are. Talk with your specialist in detail about all the possible risks and complications. This information will help you make an informed decision.

Warning Any type of surgery involves some degree of risk, including abdominal surgery and weight-loss surgery. Surgical risks are even greater when the patient is obese or has other health problems. Specific risks will vary depending on a person’s weight, age, and medical history.

The LAP-BAND® System placement includes the same risks as all major surgeries. Risks of general surgery may include:

- Damage to the spleen or liver that can sometimes cause the removal of the spleen
- Damage to major blood vessels
- Lung problems
- Blood clots (thrombosis)
- Tearing or infection of the wound
- Tearing of the stomach or esophagus during surgery

Death is one of the risks of surgery. It can occur any time during the operation or as a result of complications from the operation, despite all the precautions that are taken by your specialist. In over 15 years of use of the LAP-BAND® System, deaths have occurred in 0.006% of patients (about 1 in 17,000).

If you have these problems, or take certain medicines to treat these problems, you may bleed during surgery or have trouble healing. Tell your doctor about your health problems and any medicines you are taking. Your specialist can assess your specific risks and determine if the LAP-BAND® System is right for you.

You must talk to your specialist about all of your health issues, especially if there are some you do not understand fully or you have symptoms you do not understand.

In addition to the risks of general surgery, the following risks and complications are possible following the LAP-BAND® System procedure:

| What adverse events could happen if I get a LAP-BAND® System? | How likely is it that this adverse event would happen to me? In the first year after placement of the LAP-BAND® System... | What could happen if I experience this adverse event? | What should I do if I experience this adverse event? |
|--|--|---|--|
| You may throw up (vomit) or cough up food that you just ate (regurgitation) | 51% of patients with a BMI of 40 or greater experienced vomiting and/or nausea in the clinical trial. 29% of patients with a BMI between 30 and 40 experienced vomiting or regurgitation in the clinical trial. | Throwing up is unpleasant and may cause dehydration. | After your surgery, 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 very important to follow your eating and drinking instructions after the operation. To help prevent adverse events, you must choose the right foods, eat small meals, eat slowly, and chew food thoroughly. If you cannot eat or drink for more than 12 hours, you should call your doctor. |
| You may have difficulty swallowing (dysphagia) | 9% of patients with a BMI 40 or greater had difficulty swallowing in the clinical trial. 22% of patients with a BMI between 30 and 40 had difficulty swallowing in the clinical trial. | If you have difficulty swallowing, it may be hard for you to take in enough food and fluids to get enough nutrients. | |
| You could experience gastroesophageal reflux disease (GERD) | 34% of patients with a BMI of 40 or greater reported GERD in the clinical trial. 15% of patients with a BMI between 30 and 40 reported GERD in the clinical trial. | GERD can damage the throat (esophagus) from stomach acid backing up (refluxing). This can make swallowing difficult. | |
| You may feel nausea | 51% of patients with a BMI of 40 or greater experienced nausea and/or vomiting in the clinical trial. 5% of patients with a BMI between 30 and 40 experienced nausea in the clinical trial. | Nausea is unpleasant and can make it difficult to eat or drink. If this happens over a long time, you could become dehydrated. | |
| You may experience indigestion or upset stomach (dyspepsia) | 0.7% of patients with a BMI of 40 or greater experienced indigestion or upset stomach in the clinical trial. 5% of patients with a BMI between 30 and 40 experienced indigestion or upset stomach in the clinical trial. | Indigestion and upset stomach can be unpleasant. This can make it difficult to eat or drink. If this happens over a long time, you could become dehydrated. | |
| You feel pain in your abdomen | 27% of patients with a BMI of 40 or greater reported pain in their abdomen in the clinical trial. 5% of patients with a BMI between 30 and 40 reported pain in their abdomen in the clinical trial. | Pain from LAP-BAND® surgery is usually felt in the area around the cut (incision). Most people find the pain to be mild to medium. | Pain is often treated with over-the-counter medicines such as nonsteroidal anti-inflammatory drugs or acetaminophen. Tell your specialist if you have concerns about pain. |
| You experience pain following the surgical procedure to implant the LAP-BAND® System | 5% of patients with a BMI of 40 or greater reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial. 19% of patients with a BMI between 30 and 40 reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial. | | |
| You have pain at the site where the LAP-BAND® System was implanted | 5% of patients with a BMI of 40 or greater reported pain at the incision site following the surgical procedure to place the LAP-BAND® System in the clinical trial. 5% of patients with a BMI between 30 and 40 reported pain following the surgical procedure to place the LAP-BAND® System in the clinical trial. | | |

(Continues on next page)

(Continued from previous page)

| What adverse events could happen if I get a LAP-BAND® System? | How likely is it that this adverse event would happen to me? In the first year after placement of the LAP-BAND® System... | What could happen if I experience this adverse event? | What should I do if I experience this adverse event? |
|--|--|---|--|
| You have a leak in the LAP-BAND® device | In over 15 years of use of the LAP-BAND® System, leaks have occurred in 0.850% of patients. | A leak in the LAP-BAND® System will not allow the device to work properly and will need to be corrected surgically. | A leak in your LAP-BAND® System will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device. |
| Your new stomach pouch stretches (pouch dilatation) after surgery | 24% of patients with a BMI of 40 or greater experienced a pouch dilatation and/or band slip in the clinical trial. 1% of patients with a BMI between 30 and 40 experienced a pouch dilatation in the clinical trial. In over 15 years of use of the LAP-BAND® pouch dilatations have occurred in 0.03% of patients. | A slip in the placement of the LAP-BAND® System will not allow the device to work properly and will need to be corrected. | A slip in your LAP-BAND® System will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device. |
| Your LAP-BAND® System slips (moves from its original position) after surgery | 24% of patients with a BMI of 40 or greater experienced a LAP-BAND® System slip and/or pouch dilatation in the clinical trial. 1% of patients with a BMI between 30 and 40 experienced a LAP-BAND® System slip in the clinical trial. In over 15 years of use of the LAP-BAND® System, slips have occurred in 0.13% of patients. | A slip in the placement of the LAP-BAND® System will not allow the device to work properly and will need to be corrected. | A slip in your LAP-BAND® System will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device. |
| Your LAP-BAND® System erodes into the lining of the stomach | 1% of patients with a BMI of 40 or greater experienced a LAP-BAND® erosion in the clinical trial. 0.7% of patients with a BMI between 30 and 40 experienced a LAP-BAND® erosion in the clinical trial. In over 15 years of use of the LAP-BAND® erosion has occurred in 0.046% of patients. | Erosion of the LAP-BAND® System may cause pain and will not allow the device to work properly. This will need to be corrected surgically. | If your LAP-BAND® System erodes into the stomach, it will need to be fixed with a surgical procedure. Your doctor may also choose to remove the LAP-BAND® device. |
| You experience stretching of the esophagus (esophageal dilatation) | 2% of patients with a BMI of 40 or greater experienced esophageal dilatation in the clinical trial. 1% of patients with a BMI between 30 and 40 experienced esophageal dilatation in the clinical trial. In over 15 years of use of the LAP-BAND® System stretching of the esophagus has occurred in 0.021% of patients. | Stretching of the esophagus may cause pain and will not allow the LAP-BAND® System to work properly. This will need to be corrected. | If your LAP-BAND® System causes stretching of the esophagus, the band will need to be deflated. An additional surgical procedure may be necessary to reposition or remove the band. To help prevent esophageal dilatation eat small meals, eat slowly, and chew food thoroughly. |

Other adverse events that were considered to be related to the LAP-BAND® System, and which occurred in less than 1% of the patients

with a BMI of 40 or greater during the first 3 years, included: esophagitis (inflammation of the esophagus), gastritis (inflammation of the stomach),

hiatal hernia (stomach protruding into the chest), pancreatitis (inflammation of the pancreas), abdominal pain, hernia, incisional infection, infection, redundant skin, dehydration, gastrointestinal perforation (tear of the stomach), diarrhea, abnormal stools, constipation, flatulence (gas), dyspepsia (upset stomach), eructation (belching), cardiospasm (disorder of the muscles used in swallowing), hematemesis (vomiting blood), asthenia (fatigue), fever, chest pain, incision pain, contact dermatitis (inflammation of the skin due to contact with a substance), abnormal healing, edema (accumulation of fluid in the skin), paresthesia (numbness or tingling), dysmenorrhea (abnormal periods), hypochromic anemia, band leak, cholecystitis (inflammation of the gallbladder), esophageal dysmotility (disorder of the muscles used to transport food to the stomach), esophageal ulcer (sore), port displacement, port-site pain, spleen injury, and wound infection.

Other adverse events that were considered to be related to the LAP-BAND® System, and which occurred in less than 5% of the patients with a BMI between 30 and 40 during the first year, included:

medical device complication (band too tight, tubing migrated into a hernia), device malfunction (flipped port), dehydration, diarrhea, gastritis (inflammation of the stomach), syncope (fainting), seroma (pocket of clear fluid), abdominal discomfort, flatulence (gas), gastrointestinal motility disorder (disorder of the muscles used to transport food to the stomach), esophageal obstruction, esophageal spasm, bronchitis, implant-site infection, nail infection, postoperative infection, urinary tract infection, chills, implant-site hemorrhage (bleeding), implant-site irritation, pyrexia (fever), alopecia (hair loss), hypotrichosis (abnormal hair growth), night sweats, skin irritation, arthralgia (joint pain), back pain, muscle spasms, headache, anemia, blood folate decrease, depression, and hypertension (high blood pressure).

The importance of your body mass index (BMI)

Knowing your body mass index (BMI) may help you understand if the LAP-BAND® System is right for you.

Your body mass index is the number you get if you divide your weight in kilograms by your height (in meters) squared.



| Obesity Categories | |
|---|---|
|  | HEALTHY WEIGHT BMI 18.5 to 24.9 |
|  | OVERWEIGHT BMI 25 to 29.9 |
|  | OBESE BMI 30 to 34.9 |
|  | SEVERELY OBESE BMI 35 to 39.9 |
|  | EXTREMELY OBESE BMI 40 and Up |

It is essentially a way to combine your height and weight into a single measure. It helps determine how much excess weight you carry.

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.

To find out your BMI, see the BMI table on the next page.

If your BMI is 30 or more, you are said to be obese. Although it depends on height, usually people who are obese (BMI over 30) are at least 30 pounds overweight. That means you are at risk for health problems. If your BMI is 40 or more, you are said to be extremely obese, with a high risk of health problems. Surgery is a good approach for people with a BMI of 30 or more whose weight is impacting their health.

Benefits

The benefit of the LAP-BAND® System is weight loss, which in turn can lead to improvements in other health conditions. The device will not work or will not work well if you are not willing to make a major, lifelong change to your eating habits. If you do not make the major, lifelong changes required, you will have endured the risks of surgery and of having an implanted LAP-BAND® System for the rest of your life without getting the benefits of the device.

Your first step is committing to a goal.

Removing the LAP-BAND® System

The LAP-BAND® System is an implanted device intended for long-term use, but it may need to be removed, repositioned, or replaced to manage complications or adverse events or if you aren't losing as much weight as your specialist feels you should be losing.


If the LAP-BAND® System has been placed laparoscopically, it may be possible to remove it the same way. However, an open procedure may be necessary to remove it. In the US clinical study of extremely obese adults (BMI of 40 or greater), the majority of the LAP-BAND® Systems that were removed were done laparoscopically.

LAP-BAND® Eligibility




HEALTHY WEIGHT TO OVERWEIGHT

NO





OBESE TO EXTREMELY OBESE

YES

What is your BMI?

On the left, find the row that's closest to your weight. Then, find the column that's closest to your height. In the rectangle where your row and column cross, you'll see your BMI.

See what color that rectangle is. Then, look below the table to see what the color means.

| | HEIGHT (FEET) | | | | | | | | | |
|-----|---------------|-------|------|------|------|------|------|-------|------|------|
| | 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 |

Obesity Categories

Healthy weight
19 to 24.9

Overweight
25 to 29.9

Obese
30 to 34.9

Severely Obese
35 to 39.9

Extremely Obese
40 and up

12

LEARN MORE, VISIT LAPBAND.COM

lapband
SYSTEM

13

In the US clinical study of obese adults, all were removed laparoscopically. After the LAP-BAND® System is removed, the stomach normally returns to the size it was before surgery. It is common for people to regain weight after having their LAP-BAND® System removed.

The LAP-BAND® System is intended to stay in place for the rest of your life.

If your LAP-BAND® System is removed, readjusted, or replaced, the surgery will have the same risks as with any other surgery. The risk of some problems increases with any added procedure.

Your specialist will be able to explain this to you fully. You may also find out more about surgery and its risks at one of the sites of the National Institutes of Health: <http://www.nlm.nih.gov/medlineplus/surgery.html>.

An important decision

Should you have surgery for weight loss? That’s a decision you’ll have to make after a careful discussion with your doctor and a specialist who is certified to perform the LAP-BAND® System surgery.

In the end, your specialist is the best person to decide if you are eligible for the LAP-BAND® System, and if the system is appropriate for you. It may also be worthwhile for you to read the rest of this booklet and learn more about what’s involved.

Forms you might have to review, fill out, or even sign

Your specialist plays an important part in helping you to decide if the LAP-BAND® System is right for you. If your specialist gave you this brochure, he or she may ask you to review, fill out, or sign the following forms located in the back of the brochure.

● **My Specialist Gave Me This Brochure**

This form shows that you received this brochure from your specialist.

● **I Read and Understood What’s in This Brochure**

This form shows that you have read the brochure, understood its contents, and received counseling from your specialist.

● **Pledge Card**

This card shows you are willing to set a goal of making major, lifelong changes to your eating habits.

● **8 Rules For Success**

These 8 rules will help you get the best results from the LAP-BAND® System.

● **Questions To Ask LAP-BAND® Specialists**

This checklist was designed to help you remember the things you want to discuss with the specialists you may consider.

2. Understanding Obesity

What is obesity?

The LAP-BAND® System is designed to treat obesity. But what exactly is obesity, anyway?

Obesity is a medical condition in which a person has much more body fat than is healthy. In fact, there may be enough extra fat to hurt a person’s health, and even reduce the number of years he or she is expected to live.

Obesity is measured by the body mass index (BMI). The body mass index is a number that compares your weight to your height. This number tells how much excess weight you have. A healthy BMI is no more than 25. A person who is considered obese may have a BMI of 30, or even higher. To find out what your BMI is, look at page 13.

You may hear doctors talk about different degrees of obesity. Obesity starts when a person has a BMI of 30. A BMI of 40 or more is considered morbid obesity. “Morbid” might sound like an odd word to describe someone’s weight. It means that the excess weight can cause diseases—which doctors sometimes call “morbidity.”

What causes obesity?

If you are a person with obesity you may wonder, “What caused me to be obese? Is it my fault?” First, read about the 5 main causes of obesity below—and then we’ll ask these questions again.

Cause 1 • Energy imbalance

To work properly, your body needs the

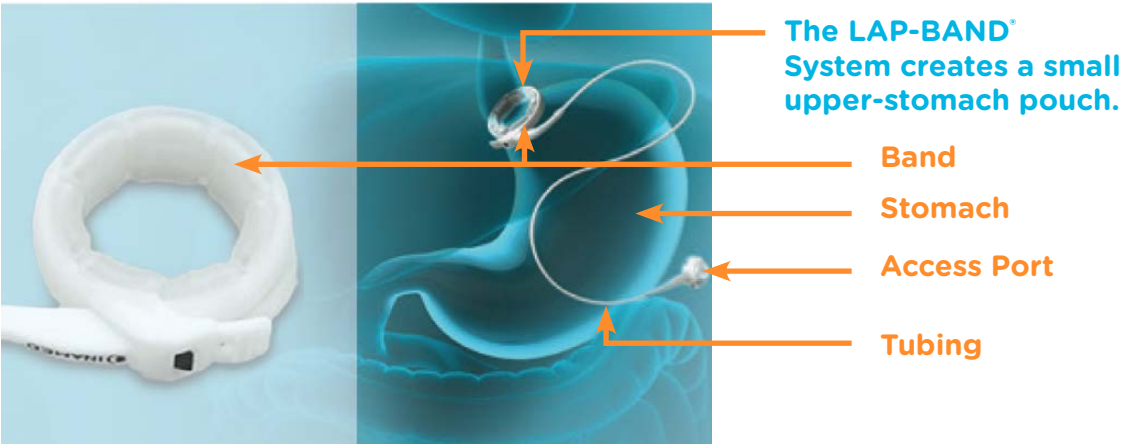
What is the LAP-BAND® System?

The LAP-BAND® System is an implanted soft adjustable band made of silicone that your specialist places around the upper part of your stomach. The band creates a small stomach pouch above where it sits, with the rest of your stomach below. With the band, you need less food to feel full and you feel full for a longer time. This, combined with a major,

lifelong change to your eating habits, helps you lose weight.

The band is hollow, almost like an inner tube, and is filled with a saline solution. The band is connected by a thin tube to a “port” that sits under your skin, to one side of your belly button.

To make the band tighter or looser, a trained health professional uses a fine needle to inject or remove saline solution through the port. This can be done during a routine office visit.



energy that comes from food. When your food gives you the same amount of energy your body needs, your weight stays the same. If your food gives you more energy than you need, some energy is left over. Your body stores that leftover energy as fat. If your body does not burn that extra fat, you gain weight.

The amount of energy you need from food depends on how fast your body uses energy. Some people use energy faster than others. We say they have a high metabolism. Other people use energy slower than others. We say they have a low metabolism.

A low metabolism makes it harder to keep weight at a healthy level and can contribute to obesity.

Cause 2 • Metabolic disorders

Some people have metabolic disorders—medical conditions that keep certain body organs from functioning normally and which affect metabolism. One common example of a metabolic disorder is diabetes. Trouble with the thyroid gland can also affect metabolism.

People with metabolic disorders often have extra difficulty controlling their weight and may struggle with obesity.

Cause 3 • Heredity

Your heredity is the traits you inherit from your parents. If your parents are tall, blue-eyed, or dark-haired, chances are greater that you will be, too. Obesity works the same way. If members of your

family are obese—like your parents or brothers and sisters, for example—then chances are greater that you will be.

A study done in Canada showed that this is true. The study looked at 12 pairs of identical twins—people with identical heredity. In the study, all of the twins ate more calories than their bodies needed, and gained different amounts of weight. But within each pair, both twins gained the same amount of weight. That suggests their heredity has a lot to do with weight gain. Everyone inherits a certain chance of having obesity, and everyone’s chance is different.

In addition, research shows that some weight-related body processes don’t work as well in people with obesity as in others. These processes include how the body burns fat, how much energy it needs (metabolism), and how hunger and fullness are felt.

What does all this mean? It means that if someone inherits a tendency to gain weight, or inherits weight-related body processes that don’t work well, this heredity may help cause him or her to become obese.

Cause 4 • Eating and activity habits

We all have habits. For example, you might be in the habit of watching TV after work. Often, we form our habits without thinking much about them. Once they are formed, habits can become strong.

Some habits have to do with eating, and some eating habits can lead to obesity if they become too frequent. Here are some examples:

- Eating fast food
- Eating high-calorie snacks

- Eating large portions
- Eating food that’s full of fat or sugar
- Drinking high-calorie soft drinks or coffee drinks

How much physical activity you get can become a habit, too. If you get in the habit of always taking a car instead of walking, or always using an elevator instead of stairs, your body burns fewer calories and turns more of your food into fat. That can contribute to obesity. In short, if you take in more calories than you burn, you will gain weight.

Cause 5 • Psychological factors

Sometimes we eat because we are hungry. But sometimes we eat because of thoughts and feelings—psychological factors.

For example, we may eat to ease stress, such as before a presentation or a big family event. We may eat for comfort when we are sad. Sometimes we eat to be social, like at a party where snacks are served. For some people, the smell or color of food triggers them to eat. For others, certain situations trigger them to eat, like being out with friends or watching TV.

These psychological factors can be very powerful. By leading us to eat when our bodies don’t really need the extra food, they can contribute to obesity.

So, now let’s ask our questions again. What causes someone to be obese? Is it his or her fault?

As you’ve seen, many powerful causes of obesity are out of our control. People cannot control their heredity, their metabolism, or the medical conditions that may affect how their bodies use food energy. But they

Weighing more than you should is bad for your health.

work on their habits, thoughts, and feelings. It is not easy, and it won’t happen overnight, but choosing to do something about obesity is a decision every person can make.

Why is obesity a problem worth solving?

Why is obesity considered to be such a problem? Why is it so important to do something about it? What are the benefits of losing the weight?

There is a long list of illnesses associated with obesity. Here are some serious ones:

- High blood pressure
- Heart disease
- High cholesterol
- Coronary artery disease
- Gallbladder problems
- Type 2 diabetes (a disease in which the body doesn’t produce enough insulin)
- Breathing problems such as asthma
- Certain types of cancer
- Sleep apnea (a sleeping disorder that causes pauses in breathing during sleep)
- Osteoarthritis
- Gastroesophageal reflux disease (acid reflux)
- Joint problems

People cannot control their heredity, but choosing to do something about their obesity is a decision every person can make.

Risks to your health

If you are a person with obesity, you probably already know that weighing more than you should is bad for your health. There’s no way to sugarcoat it: people who are obese are much more likely to get serious illnesses. Once you have an illness, obesity can make it much worse.

The more weight you gain, the more risks you face. As a result of all this, your life expectancy is shorter.

As if all that wasn’t enough, if you are a woman, obesity can also affect your ability to get pregnant and raise your risk of health problems during pregnancy and childbirth. It even makes it harder for you to get the exercise that could help your health improve.

You are at a crossroads. If you are obese now, the odds are high that, without effective action, you’ll be obese for the rest of your life—facing all of the health risks we’ve discussed. But if you take action, you can change the course of your health for the better.

Weight loss can help improve asthma, sleep apnea, diabetes and other weight-related conditions. And it can reduce the chance that many serious illnesses will strike you later in life. Losing your excess weight makes it easier for you to maintain a healthy, active lifestyle.

Risks to your mental and social well-being

All of us deserve to have fun and friends. But for some adults, obesity

affects the way they feel about themselves and hurts their social life.

There can be many reasons for this. Some obese people are excluded from social groups. Some find it harder to make friends or to date. Some feel uncomfortable participating in sports or wearing swimsuits. If these kinds of experiences go on long enough, some people may find themselves isolated from other people and feeling depressed.

Not everybody with obesity faces all of these difficulties. Even so, if you are obese you might know what it’s like to feel that you’re treated differently than people of average weight, or that people don’t see you for who you really are.

Inconveniences of everyday life

If you are a person with obesity, it can be harder to do many of the normal, day-to-day things that many people take for granted.

For example, if you have to walk a few blocks or climb stairs, you may get tired quickly or have breathing problems. You may have to spend extra time shopping to find clothes that you feel comfortable in and look good in. Bus or plane seats, restaurant booths, and cars may be too small and uncomfortable to sit in. It may be hard to tie your shoes or scratch an itch.

All in all, obesity can be a hassle.

What are your options for dealing with obesity?

There are several options to treat obesity. Some treatments do not involve surgery and some do.

Nonsurgical treatments for obesity

The most common approach for losing

weight is to exercise more, eat less, and eat healthier food. When you do these things, you burn more calories than you eat, which is the key to losing weight. But if you are a person with obesity, this approach may not be enough. Sticking to a diet and maintaining an appropriate activity level is hard to do.

Some people work with a doctor or a dietician to help them change their lifestyle. A program focused on better eating habits and greater activity levels can help you lose weight. Some people use prescription or over-the-counter drugs to try to lose weight. People who use drugs to lose weight often regain the weight over time and sometimes end up weighing even more.

Some people replace meals with special drinks/shakes. Many people who lose weight this way quickly gain it back when the diet ends. This yo-yo effect can lead to additional weight gain and make it harder to lose weight in the future.

Some people use other options such as going under hypnosis or seeking behavior therapy or counseling.

However, studies show that diets, drugs, weight loss aids, and other temporary measures usually don’t help people with obesity to maintain permanent weight loss and a healthy lifestyle over the long run.

Surgical treatments for obesity

If you have tried diet and exercise and other methods, but they have not helped you to lose weight and keep it off, surgery may be another option to consider. Weight loss surgeries are meant for people who are suffering from obesity.

If you have tried diet and exercise and other methods, but they have not helped you to lose weight and keep it off, surgery may be another option to consider.

If you are considering surgery to treat obesity, it is important to understand your options. No matter which kind of surgery you may choose, remember that to succeed, you must change your habits for the rest of your life. While the surgery will help, you must commit to eating less food and eating healthier food, changes which can be very challenging.

Comparing surgical treatment options

Surgery to treat obesity works in one or more ways. Restrictive surgery reduces how much food the stomach can hold. Malabsorptive surgery shortens the digestive tract. In both cases, your body doesn’t get as many food calories as before.

Following is a short overview of the two most common types of surgery for obesity. Gastric bypass and the LAP-BAND® System are two surgical ways to treat obesity. In the gastric bypass, the stomach is made smaller, usually with staples, and attached to the lower part of the intestines, shortening the digestive tract. In the LAP-BAND® System procedure, the stomach is wrapped with an adjustable silicone band that creates a small upper pouch. The band can be tightened or loosened without surgery. Both surgeries carry risks.

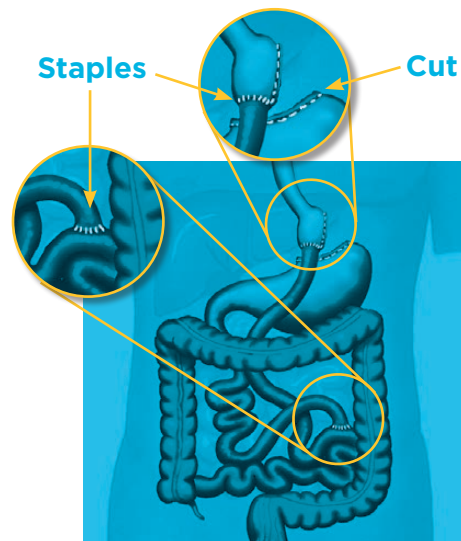
To find a LAP-BAND® System certified surgeon in your area, use the specialist locator at lapband.com.

Losing your excess weight makes it easier for you to maintain a healthy, active lifestyle.

TWO COMMON TYPES OF SURGERY FOR OBESITY

1. Gastric Bypass

In this procedure, the surgeon makes the stomach smaller, usually by stapling off a part of it from the rest, and then attaches a part of the intestines to it. Because the stomach is smaller, patients cannot eat as much food as before. Since the bypassed section of their intestines no longer digests food, patients absorb fewer nutrients and calories from food. Gastric bypass surgery is a restrictive and malabsorptive type of surgery. This surgery can be reversed, if necessary.

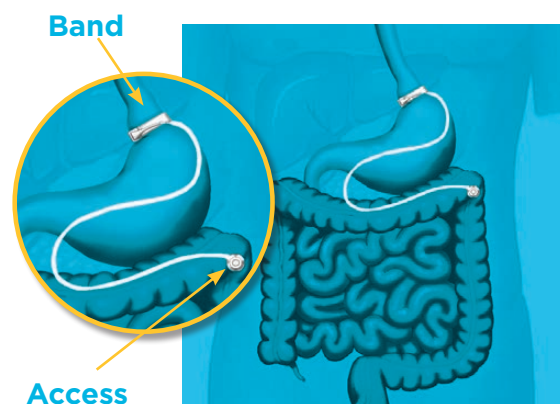


GASTRIC BYPASS

2. The LAP-BAND® System

During LAP-BAND® System surgery, the specialist makes the stomach smaller by placing an adjustable silicone band around the upper part of the stomach. This reduces how much food the stomach can hold and makes patients feel fuller sooner so they eat less. LAP-BAND® surgery is a restrictive type of surgery.

The LAP-BAND® System requires no cutting or stapling of your stomach. The LAP-BAND® System can be tightened or loosened to fit the needs of your changing body in the months and years following surgery. The LAP-BAND® System can also be removed, if necessary.



THE LAP-BAND® SYSTEM

lower pouch. The band is about the size of a small napkin ring. It opens up to go around your stomach, then fastens shut.

The band is adjustable. The inside part of the band is hollow, almost like an inner tube, and it holds a saline solution (salty water). This inside part is connected by a thin, flexible tube to an access port that sits under your skin on one side of your belly button. To make the band tighter or looser, your specialist can use a fine needle to inject or remove saline solution through the access port.

The system is not visible from the outside. The gastric band itself is not visible anywhere on your body. You may be able to feel the access port under your skin, but usually no one will be able to see it.

How is the band placed?

Your specialist places the band around the upper part of your stomach through a surgical procedure. The procedure is done under general anesthesia, meaning that you are put to sleep. It's usually done as a laparoscopic procedure, meaning that it is done through several small incisions (cuts.) This is different from an open procedure, which is done through one large cut.

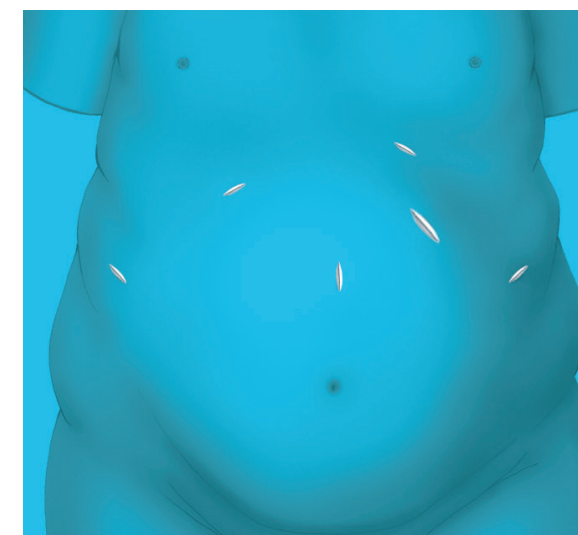
Benefits of laparoscopic procedures

Because surgery can usually be completed through a laparoscopic procedure, most people who receive the LAP-BAND® System can enjoy the benefits of this less-invasive method. These benefits include:

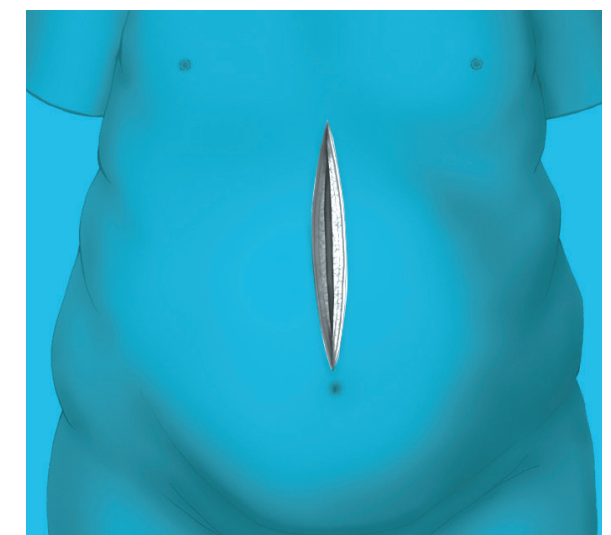
- Fewer complications: Studies show laparoscopic surgery is less risky than open surgery.
- Less pain: After a laparoscopic surgery, most people feel much less pain compared to open surgery.
- Faster recovery: Patients heal more quickly and can return to their normal routine in less time.
- No large scars: If the procedure is completed laparoscopically, there are usually only several small scars, each about half an inch to an inch long. The scar on the access port may be 1 to 3 inches long.

If you need an open procedure

Sometimes laparoscopic surgery can't be done, or the specialist may need to change to an open surgery during the operation. There could be a number of



LAPAROSCOPIC PROCEDURE



OPEN PROCEDURE

For more information, visit a website of the National Institutes of Health: <http://www.nlm.nih.gov/medlineplus/weightlossurgery.html>, or visit the Obesity Action Coalition website: <http://www.obesityaction.org>.

Only your specialist will be able to tell you which surgery, if any, makes sense for you.

3. Understanding the LAP-BAND® System

What is the LAP-BAND® System?

The LAP-BAND® System includes a special device (the band) that restricts the capacity of your stomach.

The device is a silicone band that's placed around your stomach and divides it into 2 sections—a small upper pouch and a larger

reasons for this. For instance, bleeding or problems placing the LAP-BAND® System could make an open procedure necessary.

If the specialist needs to switch to an open procedure during surgery, you will not be aware of it because you are already under anesthesia. In an open procedure, the specialist will make a larger incision (cut) in the abdomen to perform the operation.

In the US clinical study of adults with a BMI of 40 or greater, about 5% of the patients were switched to an open procedure after laparoscopic surgery started. In the second US clinical study of obese adults with BMI between 30 and 40, none of the patients were switched to an open procedure after laparoscopic surgery started.

How does the LAP-BAND® System work?

Once the LAP-BAND® System is in place, how does it work to help you lose weight?

With the band in place, the small pouch above the band can hold only a small amount of food. In order to be digested, the food has to pass through the opening between the upper pouch and lower pouch. The band controls the size of the opening, called the stoma, which controls how quickly food can pass from the upper to the lower pouch. The smaller the stoma, the longer it takes for food to pass from the upper to lower pouch.

With the band in place, you are less hungry, it takes less food for you to feel full, and you feel full for a longer time. You eat less food, which means

What happens in the surgery?

The specialist makes a few small cuts between one-half inch and one inch long on your belly and inserts narrow tubes to guide the surgical tools. A special camera in one tube shows the specialist what is happening.

Using long, thin tools, the specialist places the band around the top part of your stomach, creating a small upper-stomach pouch.

The specialist then sews part of the lower stomach over the band to hold it in place. The rest of the lower stomach stays in its normal position.

The specialist places the access port under your skin and connects it to the band's tubing. The port is sewn to part of your abdominal muscle.

your body draws on its fat reserves to get the energy it needs, and you lose weight.

How does the LAP-BAND® System help you lose weight?

The LAP-BAND® System helps you lose weight in 3 ways:

- Control of hunger
- How much your stomach can hold
- The amount of time that you feel full

As a result, your body absorbs fewer calories from food and burns fat to replace the missing calories. You lose weight.

Your role

Being successful with the LAP-BAND® System depends on you making a major, lifelong change to your eating habits, a change which is very hard to make. You have to set a goal and stick to it. If you don't, you may lose no weight or very little. In addition, you will have undergone the risks of surgery and of living with an implanted LAP-BAND® System without taking full advantage of the benefits. The LAP-BAND® System has the potential to change your life, but the change has to start with you.

Adjustable based on your progress

One of the benefits of the LAP-BAND® System is that it can be adjusted to give you and your specialist control of your progress. If the band is too loose and you are not losing weight (or not losing enough), your specialist can add more saline to your band to make the opening smaller. If the band is too tight, the specialist can remove some saline.

Follow-up visits for adjustments are a critical step for a successful LAP-BAND® patient.

Why is it called LAP-BAND®?

The name "LAP-BAND®" combines the surgical technique (laparoscopic) with the product name (gastric band).

The band can be adjusted as your needs change

With the LAP-BAND® System, your band can be adjusted by adding or removing saline solution. Your specialist can tighten it to help you keep losing weight or loosen it for a better fit. It can also be loosened in case of illness.

Day of surgery

The band is at its widest opening, with very little saline inside.

Four to 6 weeks after surgery

Saline may be added to tighten the band and help you lose weight.

Adjustments as needed

Saline is added to or removed from the band to fit your needs. See your specialist monthly.



LAP-BAND® SYSTEM
DEFLATED



LAP-BAND® SYSTEM
INFLATED

The LAP-BAND® System has the potential to change your life, but the change has to start with you.

Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight. Adjustments are a part of the follow-up for the procedure and are usually done during a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be performed in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few minutes. Most patients say it is nearly painless.

If for any reason you need to loosen the band’s restriction—for example, if you become pregnant or ill—your specialist can deflate the band partially or completely.

Except in an emergency, only a surgeon or clinician trained and authorized by Apollo Endosurgery, Inc. (the company that makes the LAP-BAND® System) should adjust your band.

In an emergency, someone familiar with the handling of ports and Huber needles can deflate the band then call a LAP-BAND® specialist. Never try to adjust your own band. You could injure

If for any reason you need to loosen the band’s restriction—your specialist can deflate the band partially or completely.

yourself and damage the LAP-BAND® System. If you move or are traveling, you should work with your specialist to understand the best places to receive ongoing or emergency care.

To get the best results, you will likely need several adjustments over time. During each adjustment, only a very small amount of saline will be added to or removed from the band. The exact amount of fluid required to make the stoma the right size is different for each person. An ideal “fill” should be just tight enough to let you lose weight steadily over time. That means you should still be able to eat enough to get the nutrients you need while still reducing the overall amount you can eat.

Weight loss with the LAP-BAND® System is typically slow and steady, compared to other surgical methods of weight loss. The band should not be tightened too quickly or too tightly to try to speed up weight loss. This could cause the stomach pouch and/or esophagus (the tube that connects your mouth to your stomach) to become enlarged. You should be able to eat most foods, just smaller portions.

The LAP-BAND® System and pregnancy

The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because 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 it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

Designed for long-term use

The LAP-BAND® System is designed to stay in your body long-term. It does not need to be removed, but if a problem occurs or you do not lose weight, your specialist may reposition, remove, or replace it.

If the LAP-BAND® System was placed laparoscopically, it may be possible to reposition, remove, or replace it in the same way. This is an advantage of the LAP-BAND® System. Rarely, an open procedure is needed to remove it.

If you are considering having your LAP-BAND® System removed, you should discuss your concerns with your specialist. Removing the band will allow your stomach to return to the size it was before your surgery and your digestive tract to the way it normally functions, which means your weight will likely increase.

Benefits of the LAP-BAND® System

There is no way to predict how much weight you will lose with the LAP-BAND® System. Some people lose more weight with the LAP-BAND® System than others. Getting the LAP-BAND® System doesn’t guarantee that you will reach your goal weight or even lose weight.

The LAP-BAND® System will not solve your weight problem by itself—you have

You must be willing to make major, lifelong changes to your eating habits for the LAP-BAND® System to work. These changes are very challenging.

to set a goal to make major, lifelong changes to your eating habits. That means eating less food and eating healthier food, changes which are very challenging. How much weight you lose depends on how committed you are to doing your part. It is possible to lose 2 to 3 pounds a week in the first year after the operation, but 1 pound a week is more likely. It is also possible to lose less or none at all. Individual results vary. Twelve to 18 months after the operation, weekly weight loss usually slows or stops.

How much weight have other people lost?

In a clinical study of extremely obese adult patients (BMI 40 or greater) from 1995 to 2001, the average patient lost approximately 36% of his or her excess weight 3 years after surgery. In a different clinical study of obese adult patients (BMI between 30 and 40) from 2007 to 2009, the average patient lost approximately 65% of his or her excess weight 1 year after surgery.

Excess weight means the extra pounds you carry above your ideal weight. For example, if your ideal weight is 155 pounds and you weigh 255 pounds, then you are 100 pounds overweight. This is your excess weight. If you lose 33% of your excess weight, then you lose 33 pounds.

The following tables show how much excess weight different adult patients lost in the 2 studies.

In the clinical studies, patients who weren't considered good candidates for surgery were excluded as were

patients who weren't healthy, had the presence of infection, had an underlying condition, had undergone a previous surgery in their stomach area, or for whom surgery was to be their first attempt at weight loss.

Results with the LAP-BAND® System

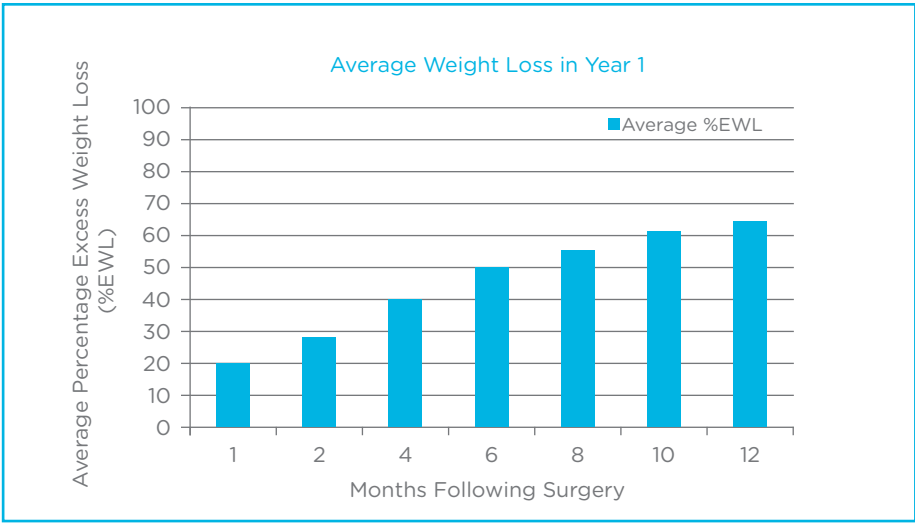
Results of the first study (from 1995 to 2001) of extremely obese adults using the LAP-BAND® System for 3 years

| In these patient groups: | Here's how many got these results: | | | | | |
|--------------------------------------|--------------------------------------|--------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| | Gained more than 5% of excess weight | Had no change in excess weight | Lost more than 25% of excess weight | Lost more than 33% of excess weight | Lost more than 50% of excess weight | Lost more than 75% of excess weight |
| All 178 patients | 2% 4 patients | 5% 9 patients | 62% 110 patients | 52% 93 patients | 22% 39 patients | 10% 18 patients |
| The 24 diabetic patients | 4% 1 patient | 0% 0 patients | 50% 12 patients | 46% 11 patients | 13% 3 patients | 8% 2 patients |
| The 55 superobese patients (BMI 50+) | 0% 0 patients | 9% 5 patients | 58% 32 patients | 53% 29 patients | 15% 8 patients | 4% 2 patients |

Results of the second study (from 2007 to 2009) that looked at obese adults with BMI between 30 and 40 using the LAP-BAND® System for 1 year

| In these patient groups: | Here's how many got these results: | | | | | |
|--------------------------|--------------------------------------|--------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| | Gained more than 5% of excess weight | Had no change in excess weight | Lost more than 25% of excess weight | Lost more than 33% of excess weight | Lost more than 50% of excess weight | Lost more than 75% of excess weight |
| All 143 patients | 0% 0 patients | 1% 2 patients | 89% 127 patients | 83% 119 patients | 69% 98 patients | 38% 55 patients |

The average weight loss over the first year of the study is shown in the following chart.



Success factors

Many factors contribute to the success or the failure of a LAP-BAND® patient, and individual results vary. Patients who have had the LAP-BAND® System placed well are more likely to experience success than those who don't. In the clinical study, 1 out of 10 patients needed to have their LAP-BAND® System fixed or readjusted. Patients who are committed to making major, lifelong changes to their eating habits are likely to do better with the LAP-BAND® System than those who don't.

Patients who attend at least 6 follow-up sessions with their specialist have significantly better results than those who attend fewer.

What are the advantages of the LAP-BAND® System?

The LAP-BAND® System is adjustable, and it is easier to remove the LAP-BAND® System than it is to reverse other weight-loss surgeries. Also, the

surgery for a LAP-BAND® System is less invasive. The following are its 5 biggest advantages:

1 • The LAP-BAND® System process is less invasive

Compared to other surgeries used to treat obesity, LAP-BAND® System placement causes the least amount of trauma to the body. There is no need for cutting or stapling the stomach. Also, the LAP-BAND® System can usually be placed laparoscopically. A completed laparoscopic procedure results in fewer complications, less pain, faster recovery, and smaller scars.

2 • The LAP-BAND® System is adjustable

Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight.

With the LAP-BAND® System, there is no need for cutting or stapling the stomach.



Ask your LAP-BAND® Specialist about the risks and complications involved with having this procedure.

size it was before the LAP-BAND® System was implanted. It's easier to remove the LAP-BAND® System than it is to reverse other weight loss procedures. Reversing other procedures typically leaves your stomach with staples and more traumatized tissue.

4 • The LAP-BAND® System may require less hospital time

After the LAP-BAND® System is placed laparoscopically, patients normally leave the hospital or surgical center within a day. If a large incision is required or if there are complications, more time in the hospital or surgical center may be needed.

5 • Recovery with the LAP-BAND® System may be quicker

After the procedure, patients usually get back to their normal activities in a week or two. It may take longer if there are complications.

Who is eligible for the LAP-BAND® System?

As mentioned at the beginning of this brochure, the decision to have surgery for weight loss is a decision you'll want to make together with your doctor and your certified LAP-BAND® System specialist. In the end, your specialist is the best person to decide if the LAP-BAND® System is right for you.

4. Understanding the Process

The more you know about getting a LAP-BAND® System, the better prepared you'll be. This section will take you through a general overview of what happens and what you can expect. Your experience might be different and your specialist is the only person who will be able to fully describe the process you'll follow.

The more you know about the LAP-BAND® System, the more prepared you will be.

If you have questions about the process as you are reading, jot them down. Use the checklist "Questions to Ask LAP-BAND® Specialists" located at the back of this brochure. Bring your checklist when you meet with your specialist and ask him or her all of your questions.

GETTING A LAP-BAND® System: A STEP-BY-STEP OVERVIEW

1. Find a specialist

Find a LAP-BAND® System certified surgeon you're comfortable with. Your specialist is your guide throughout the process.

2. Meet with the experts

Meet with your specialist and other experts to help you understand the procedure and how to plan for it.

3. Get ready for surgery

You'll have some medical tests done to make sure you are ready. Your specialist may have you exercise and start a special diet.

4. Have the surgery

The surgery usually takes less than an hour and many patients are able to return home the same day. Some patients stay in the hospital or surgical center for a day or more afterward.

5. Recover from surgery

You'll need to take it easy for a while after surgery. Most patients get back to normal activities within a week or two.

6. Get used to the LAP-BAND® System

For 6 weeks, you'll follow a special diet, moving gradually from liquids to soft foods.

7. Get adjusted

Your LAP-BAND® System is loose when you first get it. The specialist will tighten it, usually within 4 to 6 weeks. More adjustments will likely be needed.

8. Work on your new habits

To succeed with the LAP-BAND® System, you must stick to your goal of making major, lifelong changes to your eating habits.

Adjustments are a part of the follow-up for the procedure and are usually done in a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be carried out in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few minutes. Most patients say it is nearly painless.

3 • The LAP-BAND® System can be removed

If the LAP-BAND® System is removed, the stomach generally returns to the

Any surgery poses risks. It is important for you to consider these as you make your decision.

Finding a LAP-BAND® Specialist

Your first step is to find a specialist: certified LAP-BAND® System surgeon. It's a good idea to speak with more than one specialist and find the one you feel comfortable with. You can find a specialist who has been trained to implant the LAP-BAND® System at lapband.com. Chances are, there is one close to you no matter where you live in the United States.

Before your surgery

Initial meetings with specialist and other experts

Before your surgery, you should talk about the procedure in detail with your specialist. Your specialist 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 dietician (someone who specializes in diet and nutrition)
- A physical therapist (someone who specializes in helping the body move and function well)
- A psychologist (someone who specializes in evaluating and improving emotional well-being)
- Other specialists

Presurgical meeting with specialist and anesthetist

You will discuss your entire medical history with your specialist and anesthetist. This includes current and past medical conditions, illnesses or injuries, as well as allergies to medications. You will also have the chance to get answers to all of your specific questions regarding the LAP-BAND® System and your surgery. It is

important for you to disclose all of your health conditions and to answer all the specialist's questions thoroughly and to the best of your ability. Your specialist can make the best decisions for you when he or she knows your complete health profile.

Getting ready for your surgery

Medical tests

You will need to have many tests done before your surgery. These are to make sure you are healthy enough for the surgery. These tests may include a chest X-ray, a blood pressure test, blood tests, and other tests.

Get the things you'll need

As your surgery date gets near, you'll want to collect some of the things you'll need after the surgery. Your specialist will provide you with a complete list. Some things you'll want with you include:

- Comfortable, loose-fitting clothes such as a sweat suit, slip-on shoes, pajamas/nightgown, robe, slippers, and toiletries if staying overnight in the hospital or surgical center
- A small, soft pillow to cushion your lap from the car seatbelt on the ride home
- A complete list of your current medications and 2 days' supply of each one
- Some magazines and books
- Your insurance and other key information together in an envelope

Things you'll want at home include:

- Supply of ice chips for sipping
- Consommé (beef, chicken, or vegetable broth with no added

vegetables or meat)

- Skim milk
- Sugar-free popsicles and fruit juice

Having your surgery

The day before your surgery

Your specialist will provide a complete list of instructions to help you get ready. For example, he or she might tell you that you shouldn't eat or drink anything starting at midnight before the morning of your surgery.

Arriving at the hospital or surgical center

You'll go to the hospital or surgical center either the day before your surgery or the morning of your surgery. Most specialists ask you to arrive well in advance of the time of your procedure. The specialist or someone from the specialist's team will meet with you and nurses will help you to get ready.

You should also bring an adult who will stay with you until the surgery is completed.

Having your surgery

When it is time for the surgery, you will receive general anesthesia. This will relax your muscles and make you become unconscious so that you will not feel any pain during your surgery. You may be in the operating room for 2 or 3 hours, but the actual procedure typically takes about half an hour to an hour.

Most surgeries are completed using the laparoscopic procedure explained on pages 20-21. Sometimes, however, the specialist may need to change to an open procedure during the surgery. In an open procedure, the specialist will

make a larger incision in the abdomen to perform the operation.

If you have an open procedure, you will need to stay in the hospital or surgical center longer because there could be more problems. It will also take more time for you to get back to your normal routine.

In the U.S. clinical study of extremely obese adults in 1998 to 2001, about 5% of the patients were switched to an open procedure after laparoscopic surgery started. No patients in the U.S. clinical study of obese adults in 2007 to 2009 were switched to an open procedure.

After your surgery

When you wake up

Once the anesthesia has worn off and you are awake, you may feel some pain around where the specialist made cuts. Many patients report a dull ache around the larger cut on their torso where the access port is. This pain can usually be relieved with normal painkillers such as acetaminophen and usually goes away in a day or two.

The staff will also help you get out of bed and start moving as soon as possible. This will help prevent blood clots, breathing problems, and bedsores.

The next day (or before leaving the same day)

On the day after the surgery, your health team may check to make sure your LAP-BAND® System is in the right place and that the new stomach outlet is open. They may use a fluoroscope (type of X-ray) to see inside you. You may be asked to swallow a liquid that can be seen on the X-ray.

How long you'll stay

After a laparoscopic surgery, you will normally leave the hospital or surgical center within one day. The hospital or surgical stay may be longer after an open procedure or if there are problems. If there are no problems, you should be able to get back to normal activities within a week or two after the surgery.

Recovering from the surgery

Follow your specialist's guidelines

After your surgery, your specialist and his or her team of experts will give you specific instructions designed just for you. Be sure you know and understand these instructions. Discuss your diet with your specialist and dietician, and follow their advice. They can help you learn and get used to the changes in lifestyle and eating habits you need to make.

The following information is based on the instructions patients generally follow. The time periods are true for most patients. And the time you spend in each phase may be different.

While you're recovering, it's important to eat and drink the right way

It will take a month or more for your new stomach structure to heal completely. It is very important to follow your eating and drinking instructions after the operation.

Your specialist or dietician will create an eating and drinking plan that is specific to your needs.

Your specialist or dietician will provide you with a detailed eating plan that includes portion sizes and explains what foods to choose and how to chew them, but, in general, eating or drinking too much or too fast, not chewing foods properly, or eating the wrong foods can cause you to vomit. It is important to avoid vomiting because vomiting can stretch the small stomach pouch above the band. Vomiting can also increase the chance of stomach tissue slipping up through the band or lead to other problems.

Having your LAP-BAND® System adjusted

The LAP-BAND® System can be adjusted to meet your specific needs. That is one of the benefits of the system. This feature allows you and your specialist to find the level of tightness that's right for you.

Getting used to the band

When your specialist first places the band, it is usually empty or partially filled. This lets you get used to it during the first few weeks after surgery. It also allows for healing to occur around the new band site.

Having your first adjustment

Usually, the first adjustment is 4 to 6 weeks after surgery, but the timing and amount of adjustments may be different for each person. The first adjustment typically makes the band a little tighter to help you lose weight.

To determine if you are ready for an adjustment, your specialist will consider:

- Your hunger
- Your weight loss
- The amount of food you can

EATING DURING RECOVERY

To allow your stomach to heal correctly, you'll ease your way back to solid foods. Following is a general overview on how it will be done. Your specialist or dietician will provide you with a detailed eating plan designed just for you that may differ from this plan.

First 2 days after surgery

Drink water or clear liquids and suck on ice chips.

Day 3 through day 7

Keep a liquid diet of chicken, beef, or vegetable broth (none with cream), skim milk, no-sugar-added fruit juice, sugar-free frozen fruit juice on a stick, and water.

Day 8 through day 21

Eat smooth pureed protein such as fish or chicken, pureed vegetables, fruit smoothies, hummus, egg salad, cottage cheese, pureed soup, gelatin, baby food, mashed potatoes, apple sauce, and low-fat yogurt or pudding. Drink liquids, but not with meals.

Day 22 through day 42

Add soft foods like fish or ground turkey. Your specialist or dietician

will provide a complete list of the foods that will be appropriate. Drink liquids, but not with meals.

Once you begin to add foods that require chewing, your specialist or dietician will explain to you how to cut your food into small pieces and chew foods well enough for your new stomach opening to accommodate.

If you don't follow this advice, you may experience stomach irritation and vomiting. These can cause the stomach pouch to expand, increase the chance of stomach tissue slipping up through the band, or increase the chance of the band slipping out of place. You could also get blockage of the stomach.

If solid foods cause nausea and vomiting, your specialist may advise you to go back to the liquid diet you had earlier and stay with it for a longer time.

comfortably eat

- Your exercise routine
- How much fluid is already in your band

Don't rush it

Don't be in a hurry to have this adjustment before you are ready. Your specialist's goal is for you to experience steady, safe weight loss, not weight loss

in a hurry. Your specialist will know the best time for an adjustment.

Second adjustment

After the first adjustment and living with the band for a while, most people need another adjustment. If you have no weight loss for more than 3 weeks, have an increased appetite or feel hungry again less than 4 hours after a meal, it

Your goal to make major, lifelong changes to your eating habits is critical to your success.

could be a sign that your band is too loose. If you regurgitate food, experience discomfort while eating, or have a night cough, it could be a sign that your band is too tight. Let your specialist know so that he or she can decide.

Maintenance

After the second adjustment, your specialist will monitor your weight loss progress and adjust the band when needed. Everyone requires a different restriction level and adjustment schedule for optimal results. In the first year, you may need anywhere from 1 to 10 adjustments. After the first year, it could be months or years until your next adjustment. If you are several years post-op, you may still require an adjustment.

Long-term follow-up is the key to success.

Will I need plastic surgery for removal of the extra skin from weight loss?

Your specialist will talk to you about what makes sense for you. In general, you should not consider plastic surgery for at least a year or 2 after the LAP-BAND® System operation. Sometimes the skin will mold itself around your new, smaller body shape. You should give your skin time to adjust before you consider having more surgery.

Troubleshooting

If any of the following conditions occur, please contact your specialist immediately. It could be the sign of band slippage, a serious condition:

- Nausea or vomiting that continues
- Night cough or night reflux (bringing up stomach juices)
- Asthma or worsening of asthma
- Being able to eat less
- Being suddenly able to eat more, then vomiting a few hours later
- Severe pain
- Difficulty swallowing or inability to swallow

In an emergency, contact your specialist. Your specialist may temporarily deflate your band to fix the slippage. If necessary, your specialist will reposition or replace the band through surgery. If you can't reach your specialist, you should proceed to the nearest hospital emergency room. Any clinician trained in the handling of ports and Huber needles will be able to deflate your band if necessary. Your specialist should be notified as soon as possible.

Other reasons to talk to your specialist

- Becoming pregnant
- Being diagnosed with a serious illness
- Feelings of hunger return less than 4 hours after a meal
- Discomfort

Your new habits

Once you and your body have gotten used to the LAP-BAND® System, you will embark on a new life. You have set

a goal to make a major lifelong change to your eating habits, and this change is a critical part of you succeeding in your weight loss.

A healthy, balanced diet

An important part of these new habits is your diet. From now on, you'll eat less food than you were used to before surgery and eat a healthier, more balanced diet. Because the band limits how much you can eat, it helps you to follow this plan. But in the end, your commitment to your new eating habits will determine how much weight you lose.

Your specialist or dietician will work with you to create an eating and activity plan that meets your needs. Here are some guidelines for the diets you follow beginning in week 4 after surgery, as you add soft foods and then foods that require chewing.

Eight important rules and how to make them work

1. Eat only when you are hungry—about three small meals a day.

The LAP-BAND® System creates a small stomach pouch that can hold only about **one-quarter cup** (approximately 2 ounces) of food. If you try to eat more than this at one time, you may become nauseous or 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 not exceed this amount.

2. Eat slowly and chew very well.

Food can pass through the new stoma (stomach opening) only if it has been chewed into very small pieces. Always remember to take more time for your meals and chew your food very well.

3. Stop eating as soon as you feel full.

Remember to eat your protein first. By doing so, you are ensuring that you're getting in the proper fuel. Once your new stomach pouch is full, your body receives a signal that you have eaten enough. It takes time, though, for you to become aware of this signal, so space out your bites. If you rush through your meal, you may eat more than you need. This can lead to nausea and vomiting. Take time to eat and enjoy your meal.

Making good choices

To succeed with the LAP-BAND® System, you'll need to make good food choices every day. Here's an example of what one day's worth of good choices might look like. Your specialist or dietician will work with you to design a meal plan that's right for you.

Breakfast

Plain tea or coffee • Small bowl of hot cereal • Cup of low-fat yogurt

Lunch

Iced tea • Wheat toast with cheese • Fresh pear

Dinner

Fruit smoothie • Grilled chicken • Salad, low-fat dressing

Follow the exercise plan your specialist or dietician provides you.

You want to feel satiated, not stuffed and uncomfortable. Try to recognize the feeling of fullness—then put your utensils down.

4. Be active.

This rule is important. Physical activity burns calories and is important to successful weight loss. And don't be intimidated by strenuous exercise regimens. Lots of calorie-burning activities can be rewarding and fun.

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. Patients with proper "fill" levels do not feel hungry in between meals. If you do, this may be a sign that the LAP-BAND® System is too loose and you should tell your doctor.

6. Eat only high-quality food.

Your meals should be high in protein and vitamins. Don't fill your small stomach pouch with "junk" food that lacks vitamins and other important nutrients. Avoid foods high in fat and sugar. Instead, choose fresh vegetables, fruit (but not fruit juice), meat, and whole grain cereals. Ask your doctor or dietitian before you take any vitamin supplements.

7. Drink only low-calorie liquids.

Drinks, including those containing calories, simply run through the narrow outlet created by the band. If you drink high calorie liquids, even healthy ones like fruit juices, you may not lose weight, even if you otherwise follow your diet.

8. Stay on top of your aftercare.

Aftercare is essential to your success. Always keep in contact with your specialist and remain engaged in your weight-loss program.

Summary of 8 important rules for success

Here are 8 rules that will help you get the best results from the LAP-BAND® System. Your motivation to follow a healthier new lifestyle is key to success.

- 1. Eat only when you are hungry—about three small meals a day.**
- 2. Eat slowly and chew very well.**
- 3. Stop eating as soon as you feel full.**
- 4. Be active.**
- 5. Do not eat between meals.**
- 6. Eat only high-quality food.**
- 7. Drink only low-calorie liquids.**
- 8. Stay on top of your aftercare.**

5. Making Your Decision

A life change

Congratulations. Deciding to tackle your obesity is a big decision and one that can have positive impact on your future. We hope reading this brochure has helped you understand how the LAP-BAND® System works as well as the journey you'll take if you get the LAP-BAND® System. Your specialist is the only person who can fully answer all the questions you may have.

As you've learned, the LAP-BAND® System is not a miracle cure. Not everyone will lose weight or keep it off. Individual results vary. To achieve long-lasting weight loss, you will need to commit to making a major, lifelong change to your eating habits.

Finding a specialist

Your first step towards successful surgical weight loss involves finding a specialist: a surgeon qualified to perform LAP-BAND® System surgery. An experienced LAP-BAND® System specialist will not just determine if this procedure is right for you and perform your surgery, but will also help you with your payment options and presurgical and postsurgical information.

You can find a list of qualified LAP-BAND® System specialists near you at www.lapband.com.

A careful decision

A decision to get the LAP-BAND® System should be made carefully after

talking to your specialist. We hope this brochure has helped you determine the questions and issues you want to discuss with him or her. It's very important that you and your specialist have an in-depth discussion about the potential risks and rewards of choosing the LAP-BAND® System before you make your decision.

Good luck to you!

6. Frequently Asked Questions

Q: How much weight will I lose?

A: There is no way to predict how much weight you will lose with the LAP-BAND® System. Some people lose more weight with the LAP-BAND® System than others. Getting the LAP-BAND® System doesn't guarantee that you will reach your goal weight or even lose weight.

The LAP-BAND® System will not solve your weight problem by itself. You have to set a goal to make major, lifelong changes to your eating habits. That means eating less food and eating healthier food, changes which are very challenging. How much weight you lose depends on how committed you are to doing your part. It's possible to lose 2 to 3 pounds a week in the first year after the operation, but 1 pound a week is more likely. It's also possible to lose less or none at all. Individual results vary. Twelve to 18 months after the operation, weekly weight loss usually slows or stops.

Q: How much weight have other people lost?

A: In a clinical study of extremely obese adult patients (BMI 40 or greater) from 1995 to 2001, the average patient lost approximately 36% of his or her excess weight 3 years after surgery. In a different clinical study of obese adult patients (BMI between 30 and 40) from 2007 to 2009, the average patient lost approximately 65% of his or her excess weight 1 year after surgery.

Excess weight means the extra pounds you carry above your ideal weight. For example, if your ideal weight is 155 pounds and you weigh 255 pounds, then you are 100 pounds overweight. This is your excess weight. If you lose 33% of your excess weight, then you lose 33 pounds. Please see study results table and chart on pages 26 and 27.

Q: What factors contribute to success?

A: Many factors contribute to the success or the failure of a patient who has had the LAP-BAND® System implanted, and individual results vary. Patients who have had the LAP-BAND® System placed well are more likely to experience success than those who don't. In the clinical study of extremely obese adults, 1 out of 10 patients needed to have their LAP-BAND® System fixed or readjusted. Patients who are committed to making major, lifelong changes to their eating habits are likely to do better with the LAP-BAND® System than those who don't. Follow-up visits for adjustments are a critical step for a successful LAP-BAND® System patient. Patients who attend at least

6 follow-up sessions with their specialist have significantly better results than those who attend fewer.

Q: When will I need an adjustment?

A: Usually, the first adjustment is 4 to 6 weeks after surgery, but the timing and amount of adjustments will be different for each person. The first adjustment typically makes the band a little tighter to help you lose weight.

To determine if you are ready for an adjustment, your specialist will consider:

- Your hunger
- Your weight loss
- The amount of food you can comfortably eat
- Your exercise routine
- How much fluid is already in your band

Don't be in a hurry to have this adjustment before you are ready. Your specialist's goal is for you to experience steady, safe weight loss, not weight loss in a hurry. Your specialist will know the best time for an adjustment.

Q: How is the LAP-BAND® System adjusted?

A: Follow-up visits for adjustments are a critical step for a successful LAP-BAND® System patient. Adjusting the size of the opening controls the amount of food it takes for you to feel full, which is an important feature as you begin to lose weight. Adjustments are a part of the follow-up for the procedure and are usually done during a routine office visit. You will not have to stay overnight or have another surgery. Adjustments may be carried

QUESTIONS TO ASK LAP-BAND® SPECIALISTS

You can use the following checklist to help you remember the things you want to discuss with the specialists you consider. A copy of this list is available at the end of this brochure for you to tear out and take with you to your appointment.

The specialist's experience

- ☐ What procedures do you offer?
- ☐ How many weight-loss surgeries have you done?
- ☐ How many LAP-BAND® System procedures have you done?

Other questions

- ☐ May I see a sample of the LAP-BAND® System?
- ☐ What is the average excess weight loss experienced by your LAP-BAND® System patients? How about for other options?
- ☐ What are the most common complications you see with the LAP-BAND® System procedure? How does that compare to other options?
- ☐ Will I experience improvement with my weight-related health conditions? What have your patients experienced?
- ☐ How will I know if I'm a good candidate for surgery?

Cost, support and follow-up care

- ☐ What is the cost of this procedure? Do you accept my insurance?
- ☐ Can your office help me with insurance approval or financing?
- ☐ How do adjustments work, and how often will I need adjustments during the first year? Ongoing?
- ☐ How will you work with my primary care/family physician or other doctors I'm currently seeing for treatment?
- ☐ Do you have a team to address weight-related health conditions, dietary instruction, exercise training, nursing care, and psychological counseling if I need it?
- ☐ Do you offer support groups for postsurgery patients?
- ☐ What help can you give me to help inform my family and friends so that they can help me with this process?

out in the X-ray department so that the access port can be clearly seen. Local anesthesia may be needed to numb the skin around the access port. A fine needle is passed through the skin into the access port to add or remove saline. This process usually takes only a few

minutes. Most patients say it is nearly painless. If for any reason you need to loosen the band's restriction—for example, if you become pregnant or ill—your specialist can deflate the band partially or completely.

Q: What will happen if I become pregnant?

A: The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant. In fact, becoming pregnant may be easier as you lose weight because 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 it may be tightened again, and then you can go back to losing weight. The band will not harm you or the baby.

Q: Will I need plastic surgery for removal of the extra skin from weight loss?

A: Your specialist will talk to you about what makes sense for you. In general, you should not consider plastic surgery for at least a year or two after the LAP-BAND® System operation. Sometimes the skin will mold itself around your new smaller body shape. You should give your skin time to adjust before you consider having more surgery.

Resources/to find out more

- National Institutes of Health Medline Site:
<http://www.nlm.nih.gov/medlineplus/weightlosssurgery.html>
- Obesity Action Coalition:
www.obesityaction.org
- LAP-BAND® System website:
www.lapband.com

Special notice

The manufacturer of the LAP-BAND® 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 part or all of it may break or fail at any time after implantation. Some causes of partial or complete failure of the System may include expected or unexpected bodily reactions to the presence and position of the implanted device, rare or uncommon medical complications, failure of one of the parts of the LAP-BAND® System, and normal wear and tear. In addition, the LAP-BAND® System may be easily damaged by improper handling or use of the device. Please refer to the risk section at

the beginning of the brochure for a presentation of the general and specific risks and possible complications associated with the use of the LAP-BAND® System.



The LAP-BAND® System will not interfere with you becoming pregnant or with your pregnancy if you become pregnant.

Q: Can the LAP-BAND® System be removed?

A: The LAP-BAND® System is designed to stay in your body long-term. It does not need to be removed, but if a problem occurs or you do not lose weight, your specialist may reposition, remove, or replace it.

If the LAP-BAND® System was placed laparoscopically, it may be possible to reposition, remove, or replace it in the same way. This is an advantage of the LAP-BAND® System. Rarely, an open procedure is needed to remove it.

If you're considering having your LAP-BAND® System removed, you should discuss your concerns with your specialist. Removing the band will allow your stomach to return to the size it was before your surgery and your digestive tract to the way it normally functions, which means your weight will likely increase.

For more information about obesity and the LAP-BAND® System, please visit

www.lapband.com

or call

1-800-LAP-BAND
(1-800-527-2263)

Please be certain to consult your specialist before starting any weight-loss program.

CAUTION:
THIS DEVICE IS RESTRICTED TO
SALE BY OR ON THE ORDER
OF A DOCTOR.

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MY SPECIALIST GAVE ME THIS BROCHURE

(TO BE SIGNED BY PATIENT UPON RECEIPT OF THIS BROCHURE AND STORED IN THE PATIENT FILE)

My specialist has given me the brochure “The LAP-BAND® System, Surgical Aid in the Treatment of Obesity, A decision guide for adults” for my use before my surgery.

Patient Signature Date

Patient Name Printed

Specialist Signature Date

Specialist Name Printed

I READ AND UNDERSTOOD WHAT’S IN THIS BROCHURE

(TO BE SIGNED BY PATIENT AFTER HE OR SHE HAS READ THIS BROCHURE AND STORED IN THE PATIENT FILE)

I have read the brochure “The LAP-BAND® System, Surgical Aid in the Treatment of Obesity, A decision guide for adults” and understand the risks that it describes. I understand the potential problems described and the symptoms and conditions that may not make the LAP-BAND® System right for me. I have discussed the risks with my specialist, and I know and understand that not all risks connected with this product can be predicted. I acknowledge that there can be serious risks even with the best medical manufacturing, technology, and surgical care. I fully accept the risks and possible problems associated with the LAP-BAND® System procedure and believe that the benefits of the device and procedure outweigh the risks. I take full responsibility for my choice and choose to proceed with the LAP-BAND® System surgery.

Patient Signature Date

Patient Name Printed

Specialist Signature Date

Specialist Name Printed

QUESTIONS TO ASK LAP-BAND® SPECIALISTS

The specialist’s experience

- ❑ What procedures do you offer?
- ❑ How many weight-loss surgeries have you done?
- ❑ How many LAP-BAND® System procedures have you done?

Other questions

- ❑ May I see a sample of the LAP-BAND® System?
- ❑ What is the average excess weight loss experienced by your LAP-BAND® System patients? How about for other options?
- ❑ What are the most common complications you see with the LAP-BAND® System procedure? How does that compare to other options?
- ❑ Will I experience improvement with my weight-related health conditions? What have your patients experienced?
- ❑ How will I know if I’m a good candidate for surgery?

Cost, support and follow-up care

- ❑ What is the cost of this procedure? Do you accept my insurance?
- ❑ Can your office help me with insurance approval or financing?
- ❑ How do adjustments work, and how often will I need adjustments during the first year? Ongoing?
- ❑ How will you work with my primary care/family physician or other doctors I’m currently seeing for treatment?
- ❑ Do you have a team to address weight-related health conditions, dietary instruction, exercise training, nursing care, and psychological counseling if I need it?
- ❑ Do you offer support groups for postsurgery patients?
- ❑ What help can you give me to help inform my family and friends so that they can help me with this process?

PLEDGE CARD

I am willing to set a goal of making major, lifelong changes to my eating habits. These changes will be very challenging and not all patients succeed.

My long-term weight loss goal is

Signed

Date

SUMMARY OF 8 IMPORTANT RULES FOR SUCCESS

Here are 8 rules that will help you get the best results from the LAP-BAND® System. Your motivation to follow a healthier new lifestyle is key to success.

1. Eat only when you are hungry—about three small meals a day.

2. Eat slowly and chew very well.

3. Stop eating as soon as you feel full.

4. Be active.
5. Do not eat between meals.

6. Eat only high-quality food.

7. Drink only low-calorie liquids.

8. Stay on top of your aftercare.



Here's To Health!

Just by reading this program guide, you have already made a positive step on your weight loss journey. Remember that losing weight won't happen overnight. And that's OK. We are here to help and are dedicated to supporting you at every stage of your journey, be it from decision-making to aftercare.

We're right there with you.

Have questions? Talk to a LAP-BAND® System specialist, or call us any time at 1-800-LAPBAND.

lap·band™
S Y S T E M