

Information from

Take the next step to a healthier life

What you need to know about LAP-BAND® System surgery: before, during, and after

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(words or terms that appear in **bold type** are defined in the glossary)

Taking the next step in your LAP-BAND® System journey

By seeing a surgeon to talk about the LAP-BAND® System, you have taken a very important first step toward a healthier, happier life. Knowledge is power, and the next step is for you to learn more about the LAP-BAND® System and understand what it can do for you.

The LAP-BAND® Adjustable Gastric Banding System can help you Tame your hunger™, achieve long-term weight loss, and produce positive, life-enhancing changes. Before you decide to schedule LAP-BAND® System surgery, it's important to understand that the LAP-BAND® System is a tool. You are the key to your own success, because the better use you make of this tool, the more likely you are to achieve your weight loss and health goals.

There is hope—there is help

The LAP-BAND® System is designed to help you lose excess body weight—and keep it off. Many of the known risks associated with gastric bypass surgery are lower with the LAP-BAND® Adjustable Gastric Banding System. LAP-BAND® System patients experience reduced surgical trauma, fewer complications, less pain and scarring, as well as a shorter hospital stay, and quicker recovery time.²⁻⁴ The LAP-BAND® System requires no stomach cutting, stapling of the stomach, or intestinal rerouting.

UNDERSTANDING OBESITY

Obesity is a life-threatening disease afflicting millions of Americans. About 31.4% of adults in the United States are obese.⁵

It is important to understand the difference between the terms **overweight** and obese. Overweight refers to an excess of body weight compared to set standards. The excess weight may come from muscle, bone, fat, and/or body water. Obesity refers specifically to having an abnormally high proportion of body fat. A person can be overweight without being obese, such as a bodybuilder or an athlete who has a lot of muscle. However, many people who are overweight are also obese.⁵

Obesity is associated with about 112,000 deaths each year in the United States relative to healthy-weight individuals.⁵ In fact, it is more damaging to your health than smoking and alcohol abuse.⁶ In addition, obesity is a major risk factor for serious medical conditions (**comorbidities**), such as⁷:

- **Type 2 diabetes**
- **Hypertension**
- **Heart disease**
- **Stroke**
- **Sleep apnea**
- **Respiratory problems**
- **Cancer**

- **Osteoarthritis**
- **Joint problems**

The good news is that by losing weight, you can improve, prevent, or lower your risk for these weight-related health conditions.

Causes of obesity

Obesity is not a sign that a person is out of control. It is a complex, chronic disease. Many things can contribute to this condition, such as:

- Energy balance—taking too much energy from food that is in excess of what the body needs can lead to weigh gain, depending on individual metabolism and activity level
- Heredity—if others in your family are obese, you have a higher risk for obesity
- Metabolic disorders—changes in metabolism, or how your body gets energy from good, may affect your energy balance and your weight
- Eating and social habits—eating an unbalanced diet, snacking between meals, and not getting enough exercise may all contribute to obesity
- Psychological factors—social or emotional eating is also one of the main causes of gaining excess weight

Any one or a combination of these factors can lead to obesity. Inherited conditions can't be changed, but you have the power to change your behavior patterns—and improve your own health and well-being—the LAP-BAND® Adjustable Gastric Banding System is a tool that can help you.

The costs of obesity

The national cost of this disease is very high. Based on 1998 estimates, annual medical costs to treat patients who are overweight and obese were approximately 79 billion, or 93 billion in 2002 dollars. The healthcare cost burden of being overweight and obese now rivals that of smoking.⁸

The personal cost of living with obesity can also be significant. Consider what you might spend on the following items:

- Out-of-pocket healthcare expenses
 - Over-the-counter medication costs
 - Co-pays for doctor office visits
 - Co-pays for lab work
 - Co-pays for specialists
 - Co-pays for physical therapist/allied health professionals
- Prescription co-pays
- Employment inactivity costs (days of missed work)
- Non-surgical weight loss programs
- Grocery and dining costs

These expenditures quickly add up. You may find that dramatic weight loss can greatly reduce your weight-related costs.

The threat of morbid obesity

Morbid obesity refers to that category of obese patients who carry a large and dangerous amount of excess body weight. In simple terms, it is defined as:

- BMI of 40 or greater
- Being at least 100 pounds overweight

Morbid obesity greatly increases the chance of developing health conditions that can result in significant physical, mental, and social disabilities. It can also lead to premature death. Morbidly obese as well as severely obese individuals with a BMI of 35 or more with obesity-related health problems may be considered candidates for weight loss surgery.

Measuring obesity

The most common measurement of obesity is the

Body Mass Index (BMI)

BMI is the body weight in pounds divided by the square of the height in inches (*see the formula for pounds and inches in the Glossary of Terms under Body Mass Index*). While BMI does not actually measure body fat, it tends to correlate well with the degree of obesity. It should not be used alone for diagnosis but can be useful as a general guideline.

The BMI calculation cannot distinguish between body fat and muscle. This could cause a very muscular person to be mistakenly classified as obese. For this reason, your physician should always consider your individual case. The obesity categories adopted in 1998 by the National Institutes of Health (NIH) are⁵:

- **BMI 19 to 24.9 – Healthy Weight**
- **BMI 25 to 29.9 – Overweight**
- **BMI 30 TO 34.9 – Obese**
- **BMI 35 to 39.9 – Severely Obese**
- **BMI 40 and up – Morbidly Obese**

BMI CHART (LBS/IN)
BMI = lbs./inches² x 703

		HEIGHT (FT)									
		4'9"	4'11"	5'1"	5'3"	5'5"	5'7"	5'9"	5'11"	6'1"	6'3"
WEIGHT (LBS)	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	

Body Mass Index Classification

Underweight	Ideal BMI	Overweight	Obesity	Severe Obesity	Morbid Obesity	Super Obesity
<19	19-24.9	25-29.9	30-34.9	35-39.9	40-49.9	50 or more

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.

OVERVIEW OF LAP-BAND ® SYSTEM SURGERY

The LAP-BAND ® Adjustable Gastric Banding System is a tool to help you achieve sustained weight loss by limiting how much you can eat, reducing your appetite, and slowing digestion.

To understand how the LAP-BAND ® System works, you first need to understand how food is digested and used by the body. The body gets energy from food while it passes through the **alimentary canal**, which consists of the mouth, esophagus, stomach, and small and large intestines. Digestion starts in the mouth with chewing and the addition of saliva. After food passes through the esophagus, the process continues in the stomach. The stomach then provides temporary storage for food. Gastric juices break down the food so that energy can be carried through the body by the blood.

The adjustable band of the LAP-BAND ® System is a silicone ring, which is implanted using a surgical procedure called **laparoscopy**, around the upper part of the stomach—like a belt—and filled with **saline** on the inner surface. This creates a new, small stomach pouch and leaves the larger part of the stomach below the band. The pouch above the band can then hold only a small amount of food.

The LAP-BAND ® Adjustable Gastric Banding System also controls the **stoma** (stomach outlet) between the two parts of the stomach. The size of the stoma regulates the flow of the food from the upper to the lower part of the stomach. When the stoma is smaller, you feel full sooner and stay full longer. You have a feeling of **satiety**, which means you are not hungry between meals.

Why laparoscopic surgery?

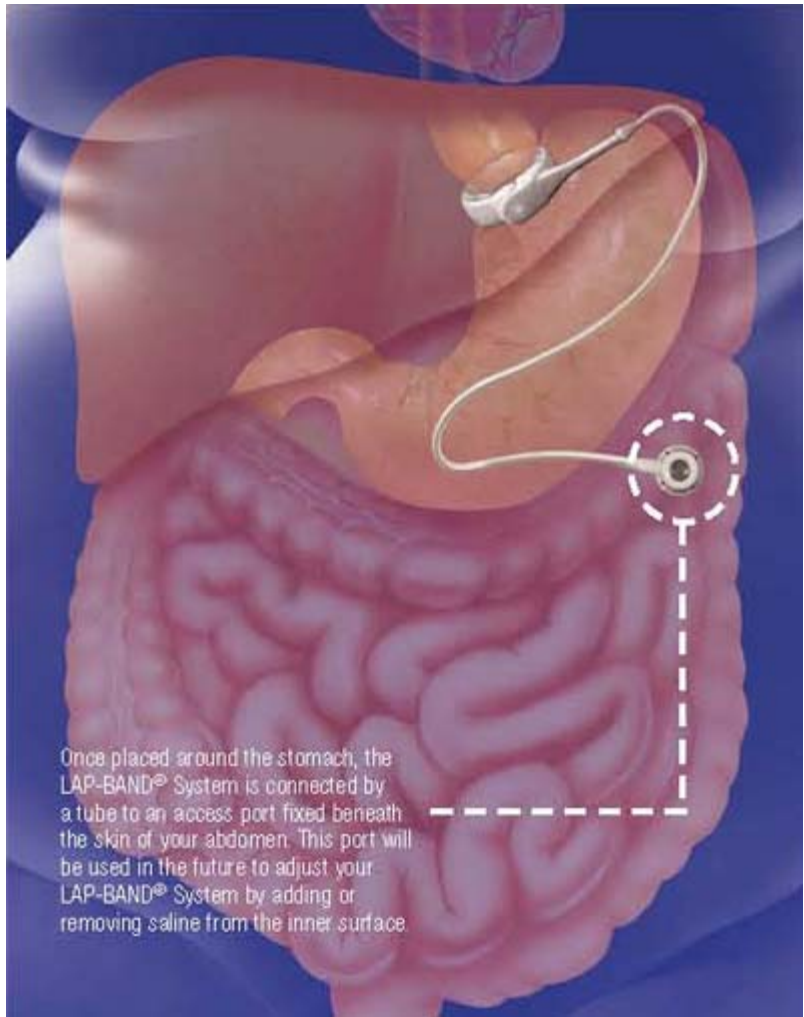
Laparoscopic surgery offers clear advantages over “open” surgery. Open surgery is more invasive than laparoscopic surgery. In open surgery, a large incision is made. In laparoscopy, the surgeon makes a few small incisions in the abdominal wall through which slender surgical instruments are passed. This technique eliminates the need for a large incision and creates less tissue damage. The small incisions result in less blood loss. After a laparoscopic surgery, most patients feel much less pain, there are fewer wound complications, and patients can have a shorter hospital stay. Laparoscopy patients also recover faster and are able to resume normal activities sooner. For example, patients who have LAP-BAND ® System surgery have a hospital stay that’s often approximately 24 hours, can return to normal activities in about a week, and achieve full surgical recovery in about 2 weeks.^{3,4}



Your surgeon implants the LAP-BAND® Adjustable Gastric Banding System around the upper part of your stomach.



Like a belt, the LAP-BAND® System is fastened around your upper stomach to create a new stomach pouch that limits and controls the amount of food you can eat.



Once placed around the stomach, the LAP-BAND® System is connected by a tube to an access port fixed beneath the skin of your abdomen. This port will be used in the future to adjust your LAP-BAND® System by adding or removing saline from the inner surface.



Your doctor can periodically adjust the LAP-BAND® Adjustable Gastric Banding System to best meet your personal needs.

The LAP-BAND® System can be adjusted

During surgery, the band portion of your LAP-BAND® System is connected by a tube to an access port placed beneath the skin of your abdomen. This enables your surgeon to adjust the LAP-BAND® System at a later point, if necessary, to meet your specific weight loss needs.

Being able to adjust the LAP-BAND® System gives you control. Your surgeon simply changes the size of your stoma by adding or removing saline inside the inner surface of the band through the access port. (See picture above.) If the band is too tight, your surgeon can “loosen” it by taking out some of the fluid. If the band is too loose, your surgeon can tighten it by adding more saline. Adjustability allows you and your surgeon to find the right level of restriction and the right rate of weight loss just for you!

When first placing the LAP-BAND® System, your surgeon usually leaves the band empty or only partially inflated. This gives you the chance to get acquainted with your LAP-BAND® System during the first few weeks after surgery. It is also meant to allow the new stomach pouch to heal completely and in the right position.

The LAP-BAND® System can be removed (reversed) if necessary

In addition to being adjustable, the LAP-BAND® System is also reversible. Under certain conditions, your surgeon may recommend LAP-BAND® Adjustable Gastric Banding System removal (to manage any adverse reactions you might have, if you can't lose enough weight, can't adjust to your new eating habits, or experience severe complications.) This decision will come after your surgeon consults with you. Generally, after LAP-BAND® System removal, your stomach will be restored to its original form and the digestive tract should function normally. Please keep in mind that when the LAP-BAND® System is removed, your weight will likely increase.

Does LAP-BAND® System surgery really work?

The LAP-BAND® System is a proven, effective long-term weight loss tool—more than 300,000 have been sold worldwide.⁹

Academic journals and publications, with up to 10 years of follow-up, confirm that LAP-BAND® Adjustable Gastric Banding System surgery has helped thousands of people lose weight and maintain their weight loss.¹⁰

Significant weight loss with fewer risks

Some people will lose more weight than others, but even if you don't reach your ultimate weight loss goal, chances are good that with significant weight loss, your health and self-image will improve.

Of course, the LAP-BAND® System, by itself, is not a cure for morbid obesity, nor will it ensure that you reach your goal—or even that you lose weight at all. The amount of weight you lose

depends both on the LAP-BAND® System and your motivation and commitment to a healthier lifestyle, including regular exercise and new eating habits.

The LAP-BAND® System was approved in the United States on the basis of a nonrandomized single-arm study (N=299). Significant improvement in percent of excess weight loss vs baseline was achieved at 12 months (34.5%), 24 months (37.8%), and 36 months (36.2%).

OTHER WEIGHT LOSS OPTIONS

Non-surgical treatments: diet and exercise

The most common weight loss approach is to eat sensibly, eat less, and exercise more. A diet and exercise program, monitored by your doctor, should always be the first option when you try to lose weight. However, studies indicate that most people will not achieve long-term weight loss through dietary and behavior modification regimens alone.¹ Morbidly obese people have an even greater challenge sustaining weight loss and resolving their health conditions. Many people who lose weight through diet and exercise quickly regain it when the diet ends or they stop exercising regularly. The cycle of losing weight and gaining it back is called the “yo-yo effect.” While temporary weight loss can help, the “yo-yo effect” can also make it harder to lose weight in the future. Morbidly obese people may want to strongly consider weight loss surgery when other therapies fail.

Surgical treatments

If non-surgical methods have not helped you lose weight and keep it off, you still have another option. Studies demonstrate that weight loss surgery, compared to non-surgical treatments, yields the longest period of sustained weight loss in severely obese patients who have failed using other therapies.¹ But keep in mind that a positive attitude, self-discipline, and planning ahead are keys to the success of the surgery. Surgery can help you achieve your long-term goal only if you are ready for a lifetime commitment to losing weight and keeping it off.

There are several categories of weight loss (**bariatric**) surgery:

- Restrictive reduces the amount of food the stomach can hold, but doesn't interfere with normal digestion of food and nutrients.

The LAP-BAND® Adjustable Gastric Banding System is a restrictive procedure.

- Malabsorptive shortens the digestive tract to limit the number of calories and nutrients that can be absorbed.
- Combination restricts the amount of food the stomach can hold and reduces the number of calories absorbed by altering the digestive tract.

Other weight loss surgery procedures

Gastric bypass surgery (GBS)



GBS is the most common combined procedure in the United States. GBS can be done as an open or a laparoscopic procedure. First, the stomach is stapled to make a smaller pouch, thereby restricting food intake. Next, a section of the small intestine is attached (usually through stapling) to the pouch to allow food to bypass the lower stomach, the **duodenum** (the first segment of the small intestine), and the first portion of the **jejunum** (the second segment of the small intestine). As a result, a patient cannot eat as much and absorbs fewer nutrients and calories. In rare cases, a cholecystectomy (gall bladder removal) is performed to avoid the gallstones that may result from rapid weight loss.³

Advantages: With GBS, patients can lose weight quickly and continue to lose for 18 to 24 months after the procedure. A review of published studies showed that 5 years after surgery, GBS patients achieved an average weight loss of 58%. This kind of significant weight loss can help improve health problems associated with severe obesity, such as hypertension (high blood pressure), sleep apnea, type 2 diabetes, and osteoarthritis.^{3,12}

Disadvantages: Combined procedures like GBS can be more difficult to perform than restrictive procedures like LAP-BAND® System surgery. GBS is also more likely to result in long-term nutritional deficiencies. This is because the operation causes food to bypass the duodenum and

jejunum, where most iron and calcium are absorbed. Menstruating women may develop anemia because not enough vitamin B12 and iron are absorbed. Decreased absorption of calcium may also bring on osteoporosis and related bone diseases. Patients must take nutritional supplements that usually prevent these deficiencies.³

GBS may also cause “**dumping syndrome**,” an unpleasant reaction that can occur after a meal high in simple carbohydrates, which contain sugars that are rapidly absorbed by the body. Stomach contents move too quickly through the small intestine, causing symptoms such as nausea, bloating, abdominal pain, weakness, sweating, faintness, and sometimes diarrhea after eating.³

Risks: In addition to risks associated with restrictive procedures such as infection, combined procedures like GBS are more likely to lead to complications. The risk of death associated with GBS is less than 1%. Combined operations carry a greater risk than restrictive operations for abdominal hernias (up to 28%), which require a follow-up operation to correct. The risk of hernia, however, is lower (about 3%) with a laparoscopy.³

Other weight loss surgery procedures **Vertical banded gastroplasty (VBG)**



While VBG is a restrictive weight loss surgery, it is *not* the same as LAP-BAND® System surgery. VBG uses a fixed, non-adjustable band and staples to create a small stomach pouch, while LAP-BAND® System surgery does not involve any stomach stapling and is adjustable.³

While patients generally lose about half of their excess body weight in the first year after restrictive procedures, within 3 to 5 years VBG patients may regain some of the weight they lost. By 10 years, as few as 20% of VBG patients have kept the weight off. Although the risk of mortality is comparable to that of the LAP-BAND® System, the general rate of complications is higher. Moreover, between 15% and 20% of VBG patients may have to undergo a second operation for a problem related to the procedure. Once the most common restrictive operation, VBG is not often used today.³

Bilopancreatic diversion (BPD)



Like gastric bypass, BPD is a combined restrictive and malabsorptive surgical procedure. In BPD, which is even more complicated than gastric bypass surgery, the lower portion of the stomach is removed. The small pouch that remains is connected directly to the final segment of the small intestine, completely bypassing the duodenum and jejunum.³

Although most studies report that this procedure can lead to an average weight loss of 75% to 80% of excess weight, it is used less often than other types of operations because of the high risk for nutritional deficiencies. Menstruating women may develop anemia because not enough vitamin B12 and iron are absorbed. Decreased absorption of calcium may also bring on osteoporosis and related bone diseases. BPD patients must take nutritional supplements that usually prevent these deficiencies. They must also take fat-soluble (dissolved by fat) vitamins A,

D, E, and K supplements, and require life-long use of special foods and medications. BPD may also cause dumping syndrome.³

Combined surgical procedures, such as BPD, are more likely to lead to complications than restrictive procedures such as LAP-BAND® System surgery. Combined operations such as “open” BPD carry up to 28% greater risk than restrictive procedures for abdominal hernias, which require a follow-up operation to correct. The risk of hernia is about 3% when the laparoscopic technique is used. The risk of perioperative mortality with BPD with duodenal switch (2.5% to 5%) is higher than with GBS or LAP-BAND® System surgery.³

SURGICAL TREATMENTS COMPARISON CHART

	LAP-BAND® System	Gastric Bypass
DESCRIPTION	A restrictive procedure during which an adjustable gastric band is placed around the upper part of the stomach. This creates a smaller stomach pouch, which restricts the amount of food that can be consumed at one time and increases the time it takes for the stomach to empty. As a result, patients achieve sustained weight loss by limiting food intake, reducing appetite, and slowing digestion. ³	Gastric bypass (also known as the Roux-en-Y) is a combination procedure using both restrictive and malabsorptive elements. With this surgery, first the stomach is stapled to make a smaller pouch. Then most of the stomach and part of the intestines are bypassed by attaching (usually stapling) a part of the intestine to the small stomach pouch. The result is that you cannot eat as much, and you absorb fewer nutrients and calories. ³
ADVANTAGES	<ul style="list-style-type: none"> • Lower short-term mortality rate than gastric bypass¹⁰⁻¹² • Minimally invasive surgical approach • No stomach stapling or cutting, or intestinal rerouting • Adjustable • Reversible • Lower operative complication rate than with gastric bypass^{2,10} 	<ul style="list-style-type: none"> • Rapid initial weight loss³ • Minimally invasive approach is possible • Longer experience in the U.S. • Higher total average weight loss reported than with the LAP-BAND® System

ADVANTAGES (continued)	<ul style="list-style-type: none"> • Low malnutrition risk 	
	LAP-BAND ® System	Gastric Bypass
DISADVANTAGES	<ul style="list-style-type: none"> • Slower weight loss¹⁰ • Regular follow-up critical for optimal results • Requires an implanted medical device • In some cases, effectiveness may be reduced due to slippage of the LAP-BAND ® Adjustable Gastric Banding System³ • In some cases, the access port may leak and require minor revisional surgery³ 	<ul style="list-style-type: none"> • Cutting and stapling of stomach and bowel are required • More operative complications than with the LAP-BAND ® System^{2,13} • Portion of digestive track is bypassed, reducing absorption of essential nutrients³ • Medical complications due to nutritional deficiencies may occur³ • “Dumping syndrome” can occur³ • Non-adjustable • Extremely difficult to reverse • Higher perioperative mortality rate than LAP-BAND ® Adjustable Gastric Banding System^{10,12}
RISKS*	<p>Mortality rate: 0.05%¹² Total complications: 9%¹³ Major complications: 0.2%¹³ Most common include:</p> <ul style="list-style-type: none"> • Standard risks associated with major surgery • Nausea and vomiting¹⁴ • LAP-BAND ® System slippage • Stoma obstruction 	<p>Mortality rate: 0.5%¹² Total complications: 23%¹³ Major complications: 2%¹³ Most common include:</p> <ul style="list-style-type: none"> • Standard risks associated with major surgery • Nausea and vomiting³ • Separation of stapled areas¹⁴ (major revisional surgery) • Leaks from staple lines (major revisional surgery)¹³

*Published complication rates vary depending upon the institution and how the surgeon diagnoses and defines a particular complication.

DISADVANTAGES (continued)		<ul style="list-style-type: none"> Nutritional deficiencies³
	LAP-BAND ® System	Gastric Bypass
COST AND INSURANCE	<p>Generally speaking, both procedures will be covered by insurance, but check with your employer or your surgeon's office for specific information about your policy.</p> <p>Costs of LAP-BAND ® Adjustable Gastric Banding System surgery and gastric bypass surgery will vary depending on the site where the surgery occurs (in-patient or out-patient), the type of bypass procedure (laparoscopic or open), and how long you are required to stay in the hospital.</p>	
RECOVERY TIMELINE	<ul style="list-style-type: none"> Hospital stay is often approximately 24 hours⁴ Most patients return to normal activity in about 1 week⁴ Full surgical recovery usually occurs in about 2 weeks⁴ 	<p>With a laparoscopic approach:</p> <ul style="list-style-type: none"> Hospital stay is usually 48 to 72 hours⁴ Many patients return to normal activity within 2 to 3 weeks⁴ Full surgical recovery usually occurs within about 3 weeks⁴

DO I QUALIFY FOR LAP-BAND ® SYSTEM SURGERY?

You may be a candidate for the LAP-BAND ® System surgery if

1. You are at least 18 years old.
2. You are at least 100 pounds overweight, or your BMI is 40 or higher (or at least 35 if you have obesity-related comorbidities, such as type 2 diabetes). See the BMI chart on page 5.
3. You have been overweight for more than 5 years.
4. Your serious weight loss attempts have had only short-term success.
5. You are not suffering from any other diseases that may have caused your excess weight.
6. You are prepared to make substantial changes in your eating habits and lifestyle and are willing to continue working with the specialist treating you.
7. You do not drink alcohol in excess.

What if I don't qualify?

If your BMI is less than 40, the LAP-BAND ® Adjustable Gastric Banding System may not be right for you. However, your surgeon may consider it if you have health problems that are

related to obesity. Your surgeon may also consider other criteria. Ask him or her to discuss the criteria with you.

LAP-BAND® System contraindications

It is important for you to discuss your personal medical history in detail with your surgeon. This will help both of you to make sure that you don't have a health condition that rules out the LAP-BAND® Adjustable Gastric Banding System as a weight loss surgery option.

The LAP-BAND® System *is not* right for you if

1. You have an inflammatory disease or condition of the gastrointestinal tract, such as ulcers, severe esophagitis, or Crohn's disease.
2. You have severe heart or lung disease that makes you a poor candidate for surgery.
3. You have some other disease that makes you a poor candidate for surgery.
4. You have a problem that could cause bleeding in the esophagus or stomach. This might include esophageal or gastric varices (a dilated vein). It might also be something such as congenital or acquired intestinal telangiectasia (dilation of a small blood vessel).
5. You have **portal hypertension**.
6. Your esophagus, stomach, or intestine is not normal (congenital or acquired). For instance, you might have a narrowed opening.
7. You had experienced an intra-operative gastric injury, such as a gastric perforation at or near the location of the intended LAP-BAND® System placement.
8. You have **cirrhosis**.
9. You have **chronic pancreatitis**.
10. You are pregnant. (If you become pregnant after the LAP-BAND® Adjustable Gastric Banding System has been placed, the LAP-BAND® System may need to be deflated. The same is true if you need more nutrition for any other reason, such as becoming seriously ill. In rare cases, removal may be needed.)
11. You are addicted to alcohol or drugs.
12. You are under 18 years of age.
13. You have an infection anywhere in your body or one that could contaminate the surgical area.
14. You are on chronic, long-term steroid treatment.
15. You cannot or do not want to follow the dietary rules that come with this procedure.
16. You might be allergic to materials in the device.
17. You cannot tolerate pain from an implanted device.
18. You or someone in your family has an **autoimmune connective tissue disease**. This might be a disease such as **systemic lupus erythematosus** or **scleroderma**. The same is true if you have symptoms of one of these diseases.

Your surgeon will help you understand the problems your excess weight is causing. Also, your surgeon will make sure you know and agree that you must take on the responsibilities of adopting new eating patterns and a new lifestyle. If you are ready to take an active part in reducing your weight, your surgeon will consider the treatment. You should be well-informed

about the advantages, disadvantages, and risks involved. Be sure to investigate whether this treatment is right for you.

BEFORE AND DURING SURGERY

What happens before surgery?

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

- Dietitian
- Physiotherapist
- Psychologist
- Other specialists

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

What happened during surgery?

The LAP-BAND® Adjustable Gastric Banding System is usually placed laparoscopically under general **anesthesia**. This technique is considered minimally invasive.

- First, the surgeon makes a few small incisions in the abdominal wall for the insertion of narrow, hollow tubes in which surgical instruments are passed
- A narrow camera is also passed through a tube, so the surgeon can view the operative site on a nearby video monitor
- A small tunnel is made behind the top of the stomach to let the band part of the LAP-BAND® System through and allow it to be wrapped around the upper part of the stomach, almost like a belt
- The band part of the LAP-BAND® System is then locked securely around the stomach to form a ring, and part of the lower stomach is sutured over it
- The LAP-BAND® System is usually left empty or only partially filled for the first 4 to 6 weeks after surgery. The band is connected by a tube to an access port placed beneath the skin of your abdomen to allow for future adjustments
- To get a better understanding of your upcoming LAP-BAND® System surgery, ask your doctor about the Emmi™ interactive education program

WHAT TO EXPECT AFTER SURGERY

The first 24 hours after your surgery

Once the anesthesia has worn off, you may feel some pain, which can often be relieved with ordinary painkillers. Whether you've had the surgery in a hospital or in an out-patient setting, it

is important for you to get out of bed and start moving as soon as possible to help prevent blood clots and respiratory problems.

On the day after the surgery, you will likely have an X-ray. This allows your medical team to see that the LAP-BAND® Adjustable Gastric Banding System is in the right place and that the new stomach outlet is open. You may be asked to swallow a liquid that can be seen on X-ray.

For patients who have their LAP-BAND® System surgery in a hospital setting, hospitalization is often approximately 24 hours. The hospital stay may be longer if there are complications, or if the surgeon has to convert to an “open” surgical procedure.

If there are no complications, you should be able to resume normal activities within a week or two after surgery.

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

Diet and nutrition in the first weeks after surgery

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

It is very important to follow your surgeon’s eating and drinking instructions right from the start after your surgery and in the weeks that follow. You must allow the new stomach structure to heal completely and in the right position. It may take a month or more for this to happen. It is important, especially in the early weeks, not to stretch the small stomach pouch above the LAP-BAND® System. Vomiting can do this, so it is important not to vomit. Vomiting can increase the chance of stomach tissue slipping up through the band. Talk to your doctor about how to prevent vomiting if you feel nauseous.

The first day after your surgery—clear fluids only

Right after the operation, you can take an occasional sip of water or suck on an ice cube. You shouldn’t drink more than this. The day after the operation, you can take a little more fluid, but only a small amount at a time. Besides water, you should also choose clear liquids that have an adequate number of calories. To prevent nausea and vomiting, do not drink too much.

1 to 2 weeks after your surgery—liquid diet

The goal during this early post-operative period is to protect the small stomach pouch. Only thin liquids can be tolerated at this time. It is also important to keep hydrated with lots of water.

Other liquids recommended during this phase include:

- Clear broth or soup (with no vegetables or meat and not creamy)
- Skim milk

- Fruit juice
- No sugar-added popsicles

3 to 4 weeks after your surgery—pureed foods

During this phase, you may start having slightly textured foods. Aim for the consistency of baby foods. This will help you transition to more solid foods later. Because protein is so important to help you maintain muscle while you are losing weight, eat protein-rich foods first, and then move on to fruits and vegetables. Foods in this stage may include

- Pureed skinless chicken or fish
- Mashed potatoes
- Peas
- Low-fat yogurt or pudding

In the first few weeks, you may be able to eat foods that might not be allowed in your diet later, since these foods may contain too many calories. In the first few weeks after your surgery, it is more important to let your stomach adjust to the LAP-BAND ® System than it is to lose weight. Also, your timing and progression into each dietary transition may vary. In general, you should follow the advice of your surgeon and/or dietitian about nutrition.

5 weeks after surgery—soft foods

Your meals can now include tender cooked foods such as fish and ground turkey. Make it a habit to chew foods well. If you have dentures, be sure to cut your food into small pieces and chew it thoroughly. If you don't follow these precautions, you may experience vomiting, stomach irritation, and swelling. You could also have stoma obstruction.

If solid foods cause nausea and vomiting, go back to the liquid diet you had earlier. Then you can slowly add soft foods and eventually transition to solid foods. Vomiting may increase the incidence of LAP-BAND ® System slippage, stomach slippage, or stretching of the small stomach pouch above the LAP-BAND ® System. Always ask your doctor or dietitian for advice that is specific to your situation.

Physical activity in the first weeks after surgery

Keeping active and following a daily exercise program will also help you achieve lasting weight loss with the LAP-BAND ® Adjustable Gastric Banding System. However, many patients who have LAP-BAND ® System surgery have been inactive for a long time due to decreased activity tolerance, psychological constraints, and in some cases, physical disabilities. That's why, in the first days and weeks after your surgery, it's important to start slowly—to give your new stomach structure time to heal, and also to allow your whole body to become accustomed to physical activity again. Over time, you can gradually build up to a more vigorous exercise program.

In the first 24 to 48 hours after surgery, it's important to get out of bed and move around, even if you're just taking a few steps at a time in the beginning.

In the first 1 to 2 weeks after your surgery, you'll find walking to be a simple, safe way to start getting exercise and building up your stamina. Try to cover a little more distance every day, first indoors, then outside. As days pass, you can also walk at a faster pace, but don't try running or jogging yet. In this time, you can also start doing other light forms of exercise—for example, moving your arms up and down, or, while seated, raising or stretching your legs.

Then, 3 to 4 weeks post-surgery, you can begin light aerobics. Important: Always check with your doctor about the amount and type of exercise that is best for you.

4 to 6 weeks after surgery—your first LAP-BAND® System adjustment

The first time the LAP-BAND® System is adjusted is usually 4 to 6 weeks after surgery, although the exact time will vary from patient to patient. You and your surgeon will decide when the right time is for your first LAP-BAND® Adjustable Gastric Banding System adjustment. To determine this, your surgeon will consider

- Your hunger
- Your weight loss
- The amount of food you can comfortably eat
- How frequently you exercise
- How much fluid is already in your LAP-BAND® System

Your long-term diet and nutrition plan for continued weigh loss and a healthier life

Your new diet and nutrition plan transitions again approximately 5 to 6 weeks after surgery and is the next step in your journey to achieving your weight loss goals and living a healthier, happier life with the LAP-BAND® System. The LAP-BAND® System is a tool; keeping to a health diet will help you use this tool to its best advantage.

The most important thing to remember is to eat only when you are hungry. When you can eat solid foods without problems, you will need to pay close attention to your diet. Liquids will pass through the reduced stomach pouch quickly and will not make you feel full. Therefore, you should avoid fluids that are high in calories—for example, high-calorie soft drinks.

The LAP-BAND® Adjustable Gastric Banding System was designed to restrict solids, not liquids. Drinking liquids during or immediately after meals tends to flush food through the pouch, and you will not get the prolonged feeling of satiety needed to help you eat less.

Staying hydrated throughout the day is important. Drink at least 6 to 8 cups of water every day and make sure you consume them between meals.

Many patients have a difficult time with solid foods during the morning hours. If this is true for you, you can “open up” your LAP-BAND ® System by starting with a couple of glasses of liquids before your first meal.

Too much food or big chunks of food can block the stomach pouch outlet. You can avoid this problem by chewing food well and eating small bits at a time. It is important to remember that your new stoma opening is approximately the size of a dime. Chew your food adequately, so that it can easily fit through the opening.

Eat only when you are hungry and not more than three small meals a day. Make sure that these meals contain adequate nutrients. Your stomach can only hold about ¼ cup of food or 2 oz. at a time. Stop eating when your hunger is gone or when you feel comfortable.

You may find that the small stomach pouch makes digestion of high-fiber, high-fat, and dry foods more difficult. Ask your surgeon and/or dietitian about your food choices.

The general guide below can help you create healthy meals that contain adequate nutrients but little sugar and fat.

Good food choices

1. Fruits and vegetables

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

2. Breads and Cereals

- 1 small portion of low-sugar cold or hot cereal
- ½ to 1 slice of toasted whole wheat or rye bread each day. **Note:** Some patients have difficulty eating bread.

3. Meat, fish, poultry, eggs

1 oz. to 2 oz. of meat, fish, or poultry or 1 egg each day. (Remove all visible fat from the meat. Remove the skin from the poultry. Prepare the meat in ways that need very little fat. Grilling, steaming, microwaving, or boiling are all good ways to do this.) **Note:** Some patients have difficulty eating meat.

4. Dairy products

Milk and yogurt are calories in liquid form. However, these types of foods have calcium, which makes them an important part of a healthy daily diet, so choose a maximum of 2 cups of skimmed milk or low-fat yogurt and 1 oz. of cheese a day.

5. **Fats**

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

6. **Drinks**

Drink as many calorie-free liquids per day as you wish (though not with meals).

Suitable drinks are:

- Tea or coffee (black) with low-calorie sweetener
- Water
- Non-carbonated beverages containing few or no calories

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

Foods to avoid

Some foods have a concentrated supply of calories with little nutritional value and should be avoided as much as possible. They include foods such as

- Syrups
- Cakes
- Biscuits
- Jam
- Honey
- Pies
- Chips
- Pastries

Alcoholic drinks should also be consumed in moderation, for example, no more than a glass of wine per day.

Common problem foods

Some foods have difficulty passing through the opening of the stoma and may cause blockage.

These include foods such as

- Dry meat
- Shrimp
- Untoasted or doughy bread
- Pasta
- Rice
- Peanut butter
- Dried fruit
- Fibrous vegetables like corn, asparagus, and celery
- Nuts

- Coconut
- Popcorn
- Greasy or fried food
- Seeds and skins of fruits and vegetables
- Membrane of citrus fruits

Introduce these foods slowly and individually to see if they are tolerated. Always be careful, chew well, and follow your surgeon's or dietitian's advice.

WHAT ABOUT THE REST OF MY LIFE?

Ten Important Guidelines You Need to Know

These guidelines for eating, drinking, and exercising can help patients achieve success with the LAP-BAND® Adjustable Gastric Banding System. Check with your surgeon to make sure they are consistent with your personal needs.

1. Eat only when you are hungry and no more than three small meals a day
2. Eat slowly and chew thoroughly
3. Stop eating as soon as you feel full
4. Do not drink while eating
5. Do not eat between meals
6. Eat only good-quality food
7. Avoid fibrous food
8. Drink enough fluids during the day
9. Drink only low-calorie liquids
10. Exercise at least 30 minutes a day

Adjusting to your new life

Remember, the LAP-BAND® Adjustable Gastric Banding System can be adjusted to meet your specific weight loss needs. This feature allows you and your surgeon to find the right level of restriction just for you! Adjustments can be key to your success with the LAP-BAND® System.

Being able to adjust the LAP-BAND® System gives you control. If you are not losing weight steadily (1 to 2 pounds per week), you are hungry often, your meals are bigger and small meals do not satisfy, then your LAP-BAND® System is too loose. Your surgeon can tighten it by adding saline. On the other hand, if you are having difficulty eating, swallowing or experience reflux, your LAP-BAND® Adjustable Gastric Banding System may be too tight. Remember, a tighter LAP-BAND® System is not necessarily better. Too much restriction can tempt you to seek foods that “slip past” the LAP-BAND® System with liquid calories or high-calorie soft foods such as ice cream. If your LAP-BAND® System is too tight, your surgeon can “loosen” it by taking out some of the fluid.



Only a trained clinician and no one else can adjust your LAP-BAND® Adjustable Gastric Banding System. Never try to do your own adjustments—you could cause adverse reactions or damage your LAP-BAND® System.

To get the best results, you may need more than one adjustment. During each adjustment, only a very small amount of saline will be added to or removed from the LAP-BAND® System. The LAP-BAND® System journey is different for each person and the exact amount of fluid required

to make the stoma the right size is unique. An ideal “fill” level should be just tight enough to let you gradually lose weight. That means you should still be able to eat enough to get the nutrients that you need while still reducing the overall amount you can eat.

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

Make regular exercise a part of your new life

Exercise can help improve your general health and incorporating regular physical activity into your lifestyle will be as important as your new nutrition plan. You may find it hard to exercise as much as you should. But get started, even if it is a little at first. The more weight you lose, the easier it should get. Start with simple exercises such as walking and swimming. Gradually expand your program to include more vigorous forms of exercise such as cycling, jogging, and aerobics.

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

Remember that you should always check with your doctor about the amount and type of exercise that is best for you.

Motivation is key

Surgery is a major step on the road to successful and sustained weight loss. The next step is to learn how to live with the LAP-BAND® System—and to learn about a new, healthy lifestyle that can help you keep the weight off successfully. This multi-faceted living program will include

- Routine check-ups with your surgeon
- Ongoing LAP-BAND® System adjustments, as needed
- Regular attendance at support group meetings

Your long-term success will depend on you and the partnership between you, your surgeon, and your weight management team. Working closely with them, following their advice, and communicating openly with them is very important. They will help you learn to use the LAP-BAND® Adjustable Gastric Banding System as a tool to help you lose and keep off your excess weight and live a healthier, happier life.

FREQUENTLY ASKED QUESTIONS

Q: Will I be sick frequently after the operation?

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

Q: How long will it take to recover after surgery?

A: If LAP-BAND® Adjustable Gastric Banding System surgery is performed laparoscopically, patients typically spend less than 24 hours in the hospital. Most patients return to work in about a week, and to exercise in about a month to 6 weeks. In the case of open surgery, or if there are complications, recovery may take longer.

Q: How much weight will I lose?

A: Weight loss results vary from patient to patient, and the amount of weight you lose depends on several things. The LAP-BAND® System needs to be in the right position, and you need to be committed to your new lifestyle and eating habits. Weight loss surgery is not a miracle cure, and the pounds won't come off by themselves. It is very important to set achievable weight loss goals from the start. A weight loss of 2 to 3 pounds a week in the first year after the operation is possible, but 1 pound a week is more likely. Twelve to 18 months after the operation, weekly weight loss is usually less.

Gradual yet steady weight loss with the LAP-BAND® System can be healthy for you. Losing weight too quickly creates a health risk and can lead to a number of problems. The main goal is to have weight loss that prevents, improves, or resolves health problems connected with severe obesity.

Q: Does the LAP-BAND® System require frequent visits to my doctor after surgery?

A: Check-ups with your doctor are a normal and very important part of the LAP-BAND® System follow-up. Many surgeons see their patients weekly or biweekly during the first month and every 4 to 12 weeks for the first year. Adjustments may be performed during some of these visits. It is typical for follow-up visits to be scheduled every 3 to 6 months during the second and third year, depending on the individual case.

Q: Does the LAP-BAND® System limit any physical activity?

A: The LAP-BAND® Adjustable Gastric Banding System should not hamper physical activity, including aerobics, stretching, and strenuous exercise.

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

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

Q: Do I have to be careful with the access port just underneath my skin?

A: The access port is placed under the skin in the abdominal wall, and once the incisions have healed, it should not cause discomfort or limit any physical exercise. The only sensation you may experience from the port occurs when you go in for adjustments. If you feel persistent discomfort in the port area, talk to your doctor.

Q: Can other people see that I have a port?

A: The port is placed under your skin and is generally not noticeable even if that area of your abdomen is exposed.

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

A: Although the LAP-BAND® Adjustable Gastric Banding System is not meant to be removed, it can be, in some cases laparoscopically. Surgeons report that the stomach generally returns to its original shape once the LAP-BAND® System is removed. After the removal, though, you may gain more weight.

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

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

Q: Is it true that the LAP-BAND® System seems “tighter” in the morning?

A: This is a fairly common feeling, especially for people with a LAP-BAND® Adjustable Gastric Banding System that is too tight or just after an adjustment. During the day, the water content in the body changes and this may cause the LAP-BAND® System to feel “tighter” some of the time. Some women have also noticed that the LAP-BAND® System feels tighter during menstruation.

Q: Will I feel hungry or deprived with the LAP-BAND® System?

A: The LAP-BAND® System helps you eat less and feel full in two ways—first by reducing the capacity of your stomach, and second, by increasing the time it takes food to get through the digestive system. After a small meal, the amount of which varies from person to person, you should feel full. If you follow the nutrition guidelines when you choose your food and chew it well, you should not feel hungry or deprived. Remember that the LAP-BAND® Adjustable Gastric Banding System is a tool to help you change your eating habits.

Q: What will happen if I become ill?

A: One of the major advantages of the LAP-BAND ® System is that it can be adjusted. If your illness requires you to eat more, the LAP-BAND ® System can be loosened by removing saline from it. When you have recovered from your illness and want to lose weight again, the LAP-BAND ® System can be tightened by increasing the amount of saline.

If the LAP-BAND ® Adjustable Gastric Banding System cannot be loosened enough, it may have to be removed.

Q: What about pregnancy?

A: Becoming pregnant can be easier as you lose weight. Your menstrual cycle may become more regular. If you need to eat more while you are pregnant, the LAP-BAND ® System can be loosened. After pregnancy, the LAP-BAND ® System may be made tighter again and you can resume losing weight.

Q: Will I need to take vitamin supplements?

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

Q: What about other medications?

A: You should be able to take prescribed medication, though you may need to use capsules. Break big tablets in half or dissolve them in water, so they do not get stuck in the stoma and make you sick. Always ask the doctor who prescribes the drugs about this. Your surgeon may tell you to avoid taking aspirin and other non-steroidal anti-inflammatory pain relievers because they may irritate the stomach. The problems these drugs may cause could result in LAP-BAND ® System removal.

Q: What if I go out to eat?

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

Q: What about alcohol?

A: Alcohol has a high number of calories and breaks down vitamins. An occasional glass of wine or other alcoholic beverage, though, is not considered harmful to weight loss.¹⁵

Q: Can I eat anything in moderation?

A: After your stomach has healed, you may eat most foods that don't cause you discomfort. However, because you can only eat a little, it is important to include foods full of important vitamins and nutrients, such as those recommended in the nutrition section of this booklet and as advised by your surgeon and/or dietitian. If you eat foods that contain lots of sugar and fat or

drink liquids full of “empty” calories, such as milkshakes, the effect of the LAP-BAND® Adjustable Gastric Banding System may be greatly reduced or even cancelled.

Q: Will I suffer from constipation?

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

One final point: It is important to ask your surgeon all the questions you have about weight loss surgery and the LAP-BAND® System. It is also essential that you follow his or her advice.

GLOSSARY OF TERMS

Alimentary Canal

The passage along which food passes for digestion, also known as the gastrointestinal tract. It includes the mouth, esophagus, stomach, small intestine, and large intestine (colon and rectum – also called the gut).

Anesthesia

The loss of sensation and feeling. Also refers to the process or drugs used to produce this effect. Anesthesia is commonly employed prior to surgery, so that a patient will not feel any pain or discomfort.

Autoimmune Connective Tissue Disease

A disease involving the immune system that attacks the framework of the cells of the body.

Bariatric

Related to the branch of medicine that deals with the prevention and treatment of obesity.

Bariatric Surgeon

A surgeon who specializes in the surgical treatment of obesity.

Biliopancreatic Diversion (BPD)

A surgical procedure used to treat obesity that removes approximately two-thirds of the stomach and rearranges the intestines, so that digestive enzymes have less contact with the foodstream. This procedure serves to impair nutrient absorption and thus dramatically reduce caloric intake, even when average-sized portions are consumed. While this procedure produces rapid weight loss that is more significant than with other obesity surgeries, it also carries a substantially higher risk of post-operative nutritional problems (including malnutrition). Also called the Scopinaro procedure.

Body Mass Index (BMI)

The most widely used measurement for obesity. The BMI approximates body mass, using a mathematical ratio of weight and height (kg/m^2) or weight in pounds divided by height in inches squared and this amount multiplied by 703. A BMI of 30 or more is regarded by most health agencies as the threshold for obesity. A BMI of 40 or more generally qualifies as morbid obesity. However, note that BMI measurements in bodybuilders and athletes may not be accurate determinants of obesity because the BMI does not distinguish between muscle and fat.

Cancer

An umbrella term for more than 100 life-threatening disease characterized by the uncontrolled, abnormal growth of malignant cells. These harmful cells may spread locally or through either the bloodstream or lymphatic system. One of the comorbidities associated with morbid obesity.

Chronic Pancreatitis

A progressive inflammatory disease of the pancreas, which may be accompanied by abdominal pain and problems in digestion.

Cirrhosis

A chronic condition in which the liver becomes scarred, fibrous, and filled with fat, thus reducing its ability to function.

Comorbidity

A medical condition that exists in addition to and is caused or worsened by obesity or any other primary disease being studied or treated. With sufficient weight loss, obesity-related comorbidities such as type 2 diabetes, hypertension, and sleep apnea generally improve or completely resolve.

Contraindication

A factor that makes a particular treatment or procedure inadvisable.

Dumping Syndrome

A physiological reaction frequently seen following gastric bypass surgery. This operation is designed to alter the function of the stomach and intestines and interrupt normal digestion. Therefore, whenever patients eat certain foods, such as sugar and sweets, they may experience “dumping,” characterized by symptoms of nausea, flushing and sweating, light-headedness, and water diarrhea. This complication has been reported by some gastric bypass patients, while LAP-BAND® System patients do not suffer from it.

Duodenum

The first segment of the body’s small intestine; connected to the stomach.

Gastric Bypass

A surgical procedure for the treatment of obesity where a thumb-sized stomach pouch is created using stapling techniques to divide the stomach and then connect the outlet of the pouch directly to the intestine (also known as the bowel), essentially “bypassing” the lower stomach. The flow of digestive juices is preserved, however. This procedure achieves its effect by restricting the volume of food consumed and also the type of food consumed. Gastric bypass surgery can be performed via open surgery (one large incision) or less invasively with laparoscopic techniques (several tiny incisions). Produces rapid and significant weight loss but is associated with higher perioperative mortality and complication rates than the LAP-BAND® System. Also known as Roux-en-Y or RYGB.

Heart Disease

Any of a number of diseases related to the heart and blood vessels. Also known as coronary artery disease. When grouped together, these diseases are the leading cause of death in the United States.

Hypertension

The medical term for high blood pressure. Usually, this means that a patient has a blood pressure of 140/90 or higher. In older adults, this number is adjusted upwards slightly. The top number is systolic pressure (pressure in blood vessels when the heart is pumping out blood), while the bottom number represents diastolic pressure (when the heart is at rest). This condition is also associated with obesity due to the excess weight that the heart has to sustain.

Jejunum

The second or middle section of the small intestine; located between the duodenum and ileum.

Joint Problems

Health issues related to the point of connection between two bones or elements of the skeleton (especially if it allows motion).

Laparoscopy (Laparoscopic Surgery)

A minimally invasive surgical approach where the surgeon makes several small incisions to access the interior of the body. A long, slender camera attached to a light source and specially designed instruments are used to perform the operation. Compared to the large incision of conventional open surgery, there is typically less pain and scarring following this operation. Usually, hospital stay and overall recovery time are also reduced.

Morbid Obesity (Morbidly Obese)

A disease in which excess weight begins to interfere with basic physiological functions such as breathing and walking. Generally, it can be defined as being 100 pounds overweight. A more precise indicator, however, is a Body Mass Index (BMI) of 40 or greater.

Obesity

A condition where there is excess body weight due to an abnormal accumulation of fat. Defined objectively as a Body Mass Index (BMI) of 30 or more, obesity is associated with markedly increased health risks.

Osteoarthritis

A degenerative joint disease that occurs when joint cartilage wears down and opposing bone surfaces rub against each other. Osteoarthritis does not result from inflammation, like rheumatoid arthritis. It is usually accompanied by pain and stiffness. Although the condition tends to occur in the elderly, it is also associated with obesity, which places undue stress on weight-bearing joints.

Overweight

A condition of increased body weight compared to established standards. The weight may result from bone, fat, muscle and/or water. Defined objectively as a Body Mass Index (BMI) of 25 to 29.9.

Portal Hypertension

An increase in the blood pressure within a system of veins in the stomach, intestine, spleen and pancreas, which can interfere with your normal blood flow.

Respiratory Problems

Health issues related to the lungs or the act of breathing.

Saline

A salt solution (sodium chloride) similar to tears, the body's natural liquid. Used to fill the inner surface of the LAP-BAND ® System to adjust the degree of restriction and the rate of weight loss.

Satiety

A state of being satisfied or gratified to the fullest extent. Satiety is equated with complete fullness, in which the person is unable to eat any more food.

Scleroderma

A disease of the skin and connective tissue that causes the skin to become hard and can result in hair loss.

Sleep Apnea

The temporary cessation of breathing during sleep. Typically, the sufferer will awake gasping for breath. Sleep apnea may occur repeatedly, resulting in a poor night's sleep and daytime drowsiness. One of the comorbidities associated with morbid obesity.

Stoma

The outlet to the stomach created by stapling or placing the LAP-BAND® Adjustable Gastric Banding System around its upper part, which divides the stomach into two parts—the small upper stomach pouch and the lower stomach—resulting in restriction of the amount of food the stomach can hold and increasing the time it takes to empty. The LAP-BAND® System allows the stoma to be adjusted by inflating or deflating the inner surface of the LAP-BAND® System in order to modify the degree of restriction.

Stroke

A sudden loss of brain function due to a blockage or rupture in a blood vessel that supplies oxygen to the brain. Depending on the affected area of the brain, a stroke may lead to muscular coordination problems, slurred speech, blindness, paresis [weakness], unconsciousness, paralysis, coma, or death. One of the comorbidities associated with morbid obesity.

Systemic Lupus Erythematosus

A chronic inflammatory connective tissue disease marked by skin rashes, joint pain and swelling, inflammation of the kidneys, inflammation of the fibrous tissue surrounding the heart (i.e., the pericardium), as well as other procedures.

Type 2 Diabetes

A chronic endocrine disorder characterized by the inability to properly utilize sugar, specifically glucose, a simple carbohydrate. This results in excessively high glucose levels in the blood. Diabetes involves either a relative or absolute shortage of insulin, a hormone that regulates the body's breakdown of carbohydrates. A higher percentage of obese individuals have type 2 diabetes than does the general population.

Vertical Banded Gastroplasty (VBG)

A surgical procedure for the treatment of morbid obesity that staples the stomach and reduces its size to a thumb-sized pouch. The outlet to the pouch is reinforced with a synthetic mesh band. The result is a marked restriction in the volume of food that can be consumed, inducing the feeling of satiety after only a few bites. Staple line disruption results in weight regain. Also know as “Stomach Stapling” or “Gastric Stapling.”

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A BRIEF DESCRIPTION OF RELEVANT INDICATIONS FOR USE, CONTRAINDICATIONS, WARNINGS AND ADVERSE EVENTS OF THE LAP-BAND ® SYSTEM

Indications: The LAP-BAND ® System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 pounds or more over their estimated ideal weight.

Contraindications: The LAP-BAND ® System is not recommended for non-adult patients, patients with conditions that may make them poor surgical candidates or increase the risk of poor results, who are unwilling or unable to comply with the required dietary restrictions, or who currently are or may be pregnant.

Warnings: The LAP-BAND ® System is a long-term implant. Explant and replacement surgery may be required at some time. Patients who become pregnant or severely ill, or who require more extensive nutrition may require deflation of their LAP-BAND ® Systems. Patients should not expect to lose weight as fast as gastric bypass patients, and LAP-BAND ® System inflation should proceed in small increments. Anti-inflammatory agents, such as aspirin, should be used with caution and may contribute to an increased risk of LAP-BAND ® System erosion.

Adverse Events: Placement of the LAP-BAND ® System is major surgery and, as with any surgery, death can occur. Possible complications include the risks associated with the

medications and methods used during surgery, the risks associated with any surgical procedure, and the patient's ability to tolerate a foreign object implanted in the body.

Band slippage, erosion and deflation, obstruction of the stomach, dilation of the esophagus, infection, or nausea and vomiting may occur. Reoperation may be required.

Rapid weight loss may result in complications that may require additional surgery. Deflation of the band may alleviate excessively rapid weight loss or esophageal dilation.

Not all contraindications, warnings or adverse events are included in this brief description. More detailed risk information is available at 1-800-LAP-BAND.

Important: This is a brief introduction. Please contact your physician or surgeon regarding the possible risks and benefits of obesity surgery.

CAUTION: This device is restricted to sale by or on the order of a physician.