



## **Patient Information Guide for the ReShape™ Procedure**

Before your procedure, please review this important information

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## **Why is it Important to Lose Weight?**

Being overweight can increase your risk of long-term health problems. It also makes it much harder to be active. People who are overweight or obese have an increased risk of high blood pressure, heart disease, stroke, type 2 diabetes, some types of cancer, infertility, osteoarthritis, back pain, gastric reflux, sleep apnea, and depression.

Studies have shown that most people who need to lose weight can become healthier when they lose even a small amount of what they weigh (about 5-10%). This means that if you weigh 200 pounds, your health will benefit from a weight loss of as little as 10 to 20 pounds. Greater weight losses may lead to even greater improvements.

Here are just a few of the ways losing weight may benefit you:

- It may increase your energy levels and enable you to be more active
- It may lower your cholesterol or other blood lipid levels
- It may improve or eliminate gastro-esophageal reflux (heartburn)
- It may reduce your blood pressure
- It may reduce aches and pains while increasing your ability to move around
- It may improve your breathing
- It may help you sleep better and wake feeling more rested
- It may help reduce your risk of developing type 2 diabetes, or reduce the severity of existing diabetes

## **Why Do Doctors Recommend the ReShape™ Procedure?**

Diet and exercise are a vital part of every weight-loss plan, but for many people diet and exercise alone may not be enough to achieve weight loss goals. Bariatric surgery is an option for those who qualify, but many fear associated surgical risks, while others want to avoid permanent changes to their stomach or intestines.

The ReShape Procedure is a nonsurgical alternative designed for those who have tried but failed in their efforts with diet and exercise and who wish to avoid, or don't qualify for, surgery. The ReShape™ Dual Balloon serves as built-in portion control to significantly aid in weight loss. This means that you can more easily stick to the diet and behavior changes that are required to reach your goals. The ReShape Procedure gives doctors another option to recommend for patients like you.

## What is the ReShape Procedure?

The ReShape Procedure is not a cure for obesity. It is an aid to achieving weight loss. While the ReShape Dual Balloon is in place, you will have the opportunity to develop new lifestyle skills. Working hard on these new habits will give you the best chance of losing weight with the ReShape Dual Balloon, and then remaining stable at your new, lower weight after the balloons are removed.

The ReShape Procedure has three phases:



### Phase One: READINESS

You and your health care team will first conduct a readiness assessment to determine if you are a good candidate for the procedure. You may be asked to attend an educational seminar where you will learn about the procedure, learn more about possible side effects, and review what to expect. Once you schedule your procedure, a history and physical examination will be performed, and you will be given instructions about what to eat before and after the procedure. You will also get instructions about medicines that will be prescribed to make you more comfortable following the placement of the balloon. All prescriptions given to you by your ReShape physician should be filled prior to the procedure

and taken as instructed. At this time you will also meet with a dietician, and possibly a fitness expert, who will provide nutrition and exercise guidelines.

#### Phase Two: JUMP START

During a short outpatient procedure, the ReShape stomach-filling dual balloon will be placed using a flexible endoscope. The ReShape Dual Balloon will reduce how much you can eat and the active weight loss phase will begin. You will also receive very important diet and exercise coaching to maximize weight loss, and tools to help you develop healthy weight management skills during the six months that the balloon is in place. After 6 months of weight loss powered by the ReShape Dual Balloon, dieting and regular exercise, the balloons will be removed during a short outpatient procedure.

#### Phase Three: HEALTHY LIVING

You will continue to receive medically supervised coaching for an additional six months to help reinforce the new eating and exercise habits that you have learned, while using the ReShape Dual Balloon. To help you succeed, you will have access to ReShape™ Healthy Living resources. While you may continue to lose weight during Phase 3, the goal of this phase is to teach you specific skills to help you maintain your new, lower weight.

### **What Will Happen On the Day the ReShape Balloon is Inserted?**

The ReShape Dual Balloon is made up of two independent silicone balloons that are connected by a silicone tube. It is meant to stay in the body temporarily, and must be removed at the end of six months. The ReShape Dual Balloon is placed in your stomach during a short outpatient procedure in the doctor's office. Before this happens, you will be made comfortable with an intravenous medication that causes conscious sedation (light anesthesia). Your doctor will use a flexible tube, with a camera on the end, to inspect your stomach and esophagus, and will then insert the uninflated ReShape Dual Balloon down your throat and into the stomach. The two balloons are then inflated with approximately two cups of saline (salt water). The placement procedure typically takes less than 20 minutes.

Remember that the ReShape Dual Balloon causes no permanent change to the stomach; it simply occupies space. The inflated balloons will increase your feeling of fullness and decrease the amount of food your stomach can hold. The ReShape Dual Balloon will remain in your stomach for six months. At the end of this time, the balloons will be removed during a short outpatient procedure.



### **What Should I Expect After the Procedure is Over?**

Because you received sedation, you will need someone to drive you home to ensure your safety. The first few days may be uncomfortable, as your stomach gets used to the presence of the balloons. You

may experience nausea, vomiting, bloating, diarrhea, and cramping until your body adjusts. These symptoms are normal and should be expected. They may occasionally be severe, and your physician will provide contact information for advice and help, if needed, to ensure you successfully adapt.

The length of time it takes to adapt to the balloon varies from person to person, but symptoms generally resolve in a few days. You will be given medications to take in case you experience nausea and vomiting, gastric acid, spasms, anxiety, and/or pain. Make sure that you take your medications as prescribed to help manage these symptoms.

## **What Risks and Side Effects Are Possible?**

The most common side effects of the ReShape Procedure are vomiting, nausea, and abdominal pain. In a clinical study of 265 patients who received the ReShape Dual Balloon, 87% of patients had some vomiting, 61% reported nausea, and 55% had abdominal pain.

In 99% of cases, these side effects were mild to moderate. In most patients, the symptoms got better within one week of having the balloon placed.

If you experience nausea and vomiting it can be treated with anti-nausea medications. If the symptoms are more severe, fluids may be given through an IV. Patients with abdominal pain may receive pain medications as needed to control discomfort.

In some cases, patients do experience more severe episodes of nausea and vomiting, which can last longer than one week. Of every 100 patients who receives the ReShape Dual Balloon, between 5 and 10 patients request removal of the balloons before six months because of intolerance. In 90-95% of treated patients, the procedure is tolerated well.

You should be aware that the ReShape Balloon has the risk of deflating while in your stomach. In 6% of cases studied, one of the two balloons deflated. The balloons are filled with a mixture of saline and blue dye, which acts as a visual indicator if there is a deflation. Most of the time, the patient became aware of the deflation when he/she saw blue-green urine. In these cases, the balloons were removed at the time of deflation. In a smaller number of cases, no blue-green urine was noticed, but a balloon was found to be deflated at the time of removal at six months. It is important to inspect the color of your urine regularly during the time the ReShape Dual Balloon is in your stomach in order to detect such an event, and if you observe such a change in color to blue or green, to call your physician within 24 hours.

Here is a list of other, less common, side effects of the ReShape Dual Balloon:

- Upset stomach or indigestion: 18%
- Belching: 17%
- Abdominal discomfort: 13%
- Abdominal distension or rigidity: 13%
- Stomach inflammation: 11%
- Stomach ulcer: 10%
- Sore throat: 10%
- Gastroesophageal reflux disease (heartburn): 7%

- Constipation: 5%
- Diarrhea: 3%
- Dehydration: 2%
- Weakness: 2%
- Dizziness: 2%

Other possible, serious risks related to the ReShape Dual Balloon may include, but are not limited to:

- Esophageal or stomach perforations (tissue puncture)
- Infection
- Device migration (both balloons deflate and move from the stomach into the intestines) that may require surgical removal to prevent an intestinal obstruction.
- Intestinal obstruction

There are some risks that may rarely be associated with having endoscopy and sedation. These include:

- Hypoxia (inadequate oxygen in the blood)
- Myocardial infarction (heart attack)
- Perforation (tissue puncture)
- Infection
- Pneumonia (lung infection)
- Respiratory distress (trouble breathing)
- Adverse reactions to sedation (headache, muscle pain, nausea)
- Anaphylaxis (life threatening allergic reaction)
- Cardiac arrest (blood circulation stops)
- Death

## **What Additional Information Do I Need to Know?**

After your procedure, you must be aware of some important information. Please read carefully:

- You must have the Dual Balloon removed after 6 months. If the balloons stay in your stomach for more than 6 months there is a much greater risk that one or both could deflate and cause a blockage in your intestines.
- You must take daily acid-blocking medicine (examples: Prilosec, Nexium) while the Dual Balloon is in your stomach. There is a higher risk of developing a stomach ulcer or perforation (small hole in the stomach) if you do not take this medication daily.
- You must contact your doctor immediately if you see blue-green urine or have a sudden loss of your normal feeling of stomach fullness. The balloons contain a blue-green dye that will appear in your urine if one of the balloons deflates. It is very important that you contact your doctor immediately if you see blue-green urine, as the deflated balloon must be removed right away. The risk of a blockage in the intestines is higher if the balloon is not removed promptly.

## What Are the Benefits of the ReShape Procedure?

There are many benefits to be gained from treatment with the ReShape Dual Balloon. These may include:

- Significantly more weight loss compared to diet and exercise alone (on average, more than twice the weight loss)
- A short, outpatient procedure
- Does not involve surgery
- Removable at any time if not tolerated, without any permanent changes to your body
- Improved quality of life (e.g., physical functioning)
- Improvements in co-morbid (obesity-related) conditions such as high blood pressure, diabetes and cholesterol
- Help with reducing the amount of food that you eat by increasing the sensation of fullness, allowing you to follow your diet and lose weight more easily
- Continue to eat the foods you like, just smaller portions
- No change in the way food is absorbed
- Significant professional support to help you change your eating habits and maintain weight loss long-term

## What Additional Support Will I Receive?

A unique and very important feature of the ReShape Procedure is the support and medically supervised coaching it offers. Learning how to eat and exercise for maximum results will be a central part of your ReShape experience. You will receive diet and exercise coaching during the six months the ReShape Balloon is in place and for six months following removal. Your program will be conducted by licensed dietitians, doctors, and nurses at your weight loss facility. This support and education is vital and is intended to help you change your relationship with food, focus on eating smaller, healthier portions, and achieve long-term success.





## Am I Eligible for the ReShape Procedure?

In order to qualify for the ReShape Procedure, you must have a body mass index (BMI) of 30-40, and you must have failed to lose significant weight with diet and exercise alone. You must also have one or more “co-morbid” (obesity-related) conditions.

The chart below can help you determine if you fall into the approved BMI range for the ReShape Procedure. To use the table, find your height in the left-hand column. Then move across the top and find your weight. The number in the box where the two columns intersect is your BMI. If your BMI falls within the shaded area, you are within the range approved for the ReShape Procedure. Your doctor can also help you to determine your BMI.

		Weight (lbs.)																	
		160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330
Height (in.)	5'0"	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63	65
	5'1"	30	32	34	36	37	39	42	44	45	47	49	51	53	55	57	59	61	63
	5'2"	29	31	33	34	36	38	40	42	44	46	48	50	51	53	55	57	59	61
	5'3"	28	30	32	33	35	37	39	41	43	44	46	48	50	52	53	55	57	59
	5'4"	27	29	31	32	34	36	38	40	41	43	45	46	48	50	52	53	55	57
	5'5"	26	28	30	31	33	35	37	38	40	42	43	45	47	48	50	52	53	55
	5'6"	25	27	29	30	32	34	36	37	39	40	42	44	45	47	49	50	52	53
	5'7"	25	26	28	29	31	33	35	36	38	39	41	42	44	46	47	49	50	52
	5'8"	24	25	27	28	30	32	34	35	37	38	40	41	43	44	46	47	49	50
	5'9"	23	25	26	28	29	31	33	34	36	37	39	40	41	43	44	46	47	49
	5'10"	23	24	25	27	28	30	32	33	35	36	37	39	40	42	43	45	46	47
	5'11"	22	23	25	26	28	29	31	32	34	35	36	38	39	41	42	43	45	46
	6'0"	21	23	24	25	27	28	30	31	33	34	35	37	38	39	41	42	44	45
	6'1"	21	22	23	25	26	27	29	30	32	33	34	36	37	38	39	41	42	44
	6'2"	20	21	23	24	25	27	28	30	31	32	33	35	36	37	39	40	41	42
	6'3"	19	21	22	23	24	26	28	29	30	31	33	34	35	36	38	39	40	41
6'4"	19	20	21	23	24	26	27	28	29	31	32	33	34	35	37	38	39	40	

A condition or disorder that commonly accompanies obesity is called a “co-morbidity.” In order to qualify for the ReShape Procedure, you must have at least one of these conditions. Co-morbidities include: high blood pressure, high cholesterol, diabetes, and other illnesses or conditions that have become associated with being significantly overweight. If you are not sure whether you have any obesity related conditions, your doctor can provide this information.

You will not be eligible for the ReShape Procedure if you have ever had weight loss surgery, if you are not willing or cannot participate in the ReShape diet and coaching program, or if you are pregnant or breastfeeding.

## What Facts Should I Consider Before Deciding on the ReShape Procedure?

- Remember that no two patients are alike. While people treated with the ReShape Dual Balloon lost, on average, more than twice the amount of patients treated with diet and exercise alone, you may lose more or less weight during treatment.
- During treatment and after removal of the ReShape Dual Balloon, you must continue to follow your physician-recommended diet and exercise routines to obtain the best weight loss results. Without permanent changes to your eating habits and lifestyle, weight regain is likely. Make sure you are committed to making these changes prior to deciding on the ReShape Procedure.
- Be sure to explore all options. The ReShape Procedure is not the only treatment available. Alternatives include diet and exercise programs or prescription medications, and—for patients who qualify—surgical options (gastric band, gastric bypass, sleeve gastrectomy). Each alternative has its own advantages and disadvantages. You should fully discuss these alternatives with your doctor to select the method that best fits your needs.

## Dietary Guidelines

NOTE: This is only a guideline. You should follow the dietary instructions provided by your health care provider.

### Preparing for the ReShape Procedure: Balloon Insertion

- 48 hours before your procedure: eat ONLY soft foods – meat in any form is prohibited
- 24 hours prior to your procedure: consume only **clear liquids**
- **12 hours before your procedure: stop all food and drink**

It is critical that you come to the procedure with an EMPTY stomach. If there are food remnants, you will not be able to have the balloon inserted.

### What Can I Eat After My Procedure?

After your procedure, it will take time for your stomach to adjust to the presence of the balloon. You will gradually be able to move from drinking liquids to eating food. You will do this in four stages. Once your body has accepted any stage (you are eating or drinking without discomfort), you can move on to the next one.

#### Stage 1: Clear liquids only (usually from Days 1-3 after the procedure)

Clear liquids (examples):

- Broth
- Jell-O
- Ice chips
- Small sips of water
- Apple juice

Warm fluids may be better tolerated than cold drinks.

Avoid carbonated drinks that may cause gas and bloating.

### Stage 2: Smooth, Pureed Texture Food (typically, Days 4-7 Post Procedure).

You can create pureed foods by putting them in a blender that is powerful enough to puree. Good pureed foods (examples):

- Protein shakes
- Cottage cheese
- Yogurt (without chunks of fruit)
- Pureed fruit
- Cooked and pureed vegetables
- Soups (strained or blended)
- Baby food

### Stage 3: Soft and Crunchy Texture Foods (typically, Days 8-10 Post Procedure)

Soft and crunchy texture foods (examples):

- Tofu
- Soft poached fish
- Soft seafood
- Scrambled eggs
- Cottage cheese
- Saltine crackers
- Well-cooked vegetables and soft fruit with skin removed

### Stage 4: Normal Texture Food (typically, Day 11 Post Procedure and Beyond)

General recommendations:

- Pay close attention to your body's sensations before, during, and after meals. Stop eating at the earliest sign of fullness or discomfort under your breastbone. Stop eating when you no longer feel hunger.
- Chew slowly and thoroughly. Each meal should take at least 15-20 minutes.
- Introduce new foods one at a time to rule out intolerance. If a food is not tolerated, it may cause pressure or pain near your breastbone. If this occurs, you may find it helpful to return to liquids or purees for a couple of days until your stomach feels calm again. If the pressure or pain persists, discuss your symptoms with your dietitian.

### **Preparing for the ReShape Procedure: Balloon Removal**

- 48 hours before your procedure: eat ONLY soft foods – meat in any form is prohibited
- 24 hours before your procedure: consume only **clear liquids**
- **12 hours before your procedure: stop all food and drink**

It is critical that you come to the procedure with an EMPTY stomach. If there are food remnants, you may need a special tube inserted down your throat to keep your windpipe clear of food during the balloon removal procedure.

## Patient ID Card

You will receive a ReShape Implant Card following your procedure. Carry your ReShape Implant Card with you as notification to care providers that you have a ReShape Dual Balloon. If you lose this card, please contact your doctor's office to receive a replacement card.

## Follow Up Visits

It is extremely important that you follow the schedule your doctor provides regarding follow up visits. You will be seen at regular intervals while the balloon is in place. It is absolutely necessary you return for your six-month visit to have the balloon removed. Leaving the balloon in place for longer than six months is associated with significant medical risk. After the balloon is removed, you will continue to be seen at regular intervals for diet and exercise coaching appointments over an additional six-month period.

## When to Call your Doctor

After the procedure, your doctor will provide you with instructions about when to call. In general, you should call your doctor if:

- You cannot keep food or liquids down
- You have sudden onset of abdominal pain
- You see blue-green urine
- You have a sudden loss of satiety (the usual sense of fullness you feel with the balloon)
- You experience increased hunger and/or weight gain

## Glossary of Related Terms

- **Body Mass Index (BMI)** – a common measure, using an individual's height and weight, to estimate whether an individual is overweight or obese.
- **Deep Conscious Sedation** – a procedure where you are given a sedative (medication) through an intravenous line to relax you and reduce your sensation during the balloon placement and removal procedures.
- **Endoscopy** – a procedure which allows a doctor to see the inside of your esophagus and stomach. This examination is performed using an endoscope (a flexible tube with a video camera on the end). The camera is connected to a video screen that displays the image.
- **Esophagus** – the tube that allows passage of food, liquids, and saliva from your mouth to your stomach.
- **Gastric** – pertaining to the stomach.
- **Gastric Banding** – a surgical weight loss procedure in which a silicone band is placed around the outside of the stomach to limit the amount of food that can be eaten at one time.
- **Gastric Bypass** – a surgical weight loss procedure in which the stomach is divided to make a small pouch (about 1 oz. in volume) to limit the amount of food that can be eaten at one time. This small stomach pouch is connected to a section of the intestine that is lower than the place where the stomach normally connects to the intestinal tract. This increases feelings of fullness

and also allows food to bypass the upper section of the intestine, which changes the way food is absorbed.

- **Gastric Sleeve (Sleeve Gastrectomy)** – a surgical weight loss procedure in which the stomach is reduced to about 25% of its original size by surgical removal of a large portion of the stomach. The result is a sleeve or tube-like structure. The procedure permanently reduces the size of the stomach.
- **Gastroesophageal Reflux Disease (GERD)** – a condition in which the stomach contents (food or stomach acid) leak backwards from the stomach into the esophagus. This action can irritate the esophagus, causing heartburn and other symptoms.
- **Intubation** – placement of a tube into the windpipe to help keep the windpipe clear of any fluids or food.
- **IV Fluids** – fluids that are delivered through a needle into a vein.
- **Proton Pump Inhibitors (PPIs)** – a type of drug which reduces stomach acidity.
- **Satiety** – a feeling of fullness after eating.
- **Sleeve Gastrectomy** – a surgical weight loss procedure in which the stomach is reduced to about 25% of its original size by surgical removal of a large portion of the stomach. The result is a sleeve or tube-like structure. The procedure permanently reduces the size of the stomach.



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