



Patient Information Guide for the *ReShape*[™] Procedure

Please review this information before your procedure.
Please talk to your doctor if you have any questions or do not
understand any of this information.

The *ReShape* Procedure is only available by prescription from a doctor.

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Glossary

- **Body Mass Index (BMI)** – a common measure, using a person’s height and weight, to tell whether a person is overweight or obese.
- **Device** – a product made for a particular purpose, such as helping you lose weight.
- **Endoscopy** – a procedure which allows a doctor to see the inside of your esophagus and stomach. This examination is performed using an endoscope (a tube that can bend and has a video camera on the end). The camera is connected to a video screen.
- **Esophagus** – the tube that allows passage of food, liquids, and saliva from your mouth to your stomach.
- **Gastric** – 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.) to limit the amount of food that can be eaten at one time. This small stomach pouch is connected to a part of the intestine that is lower than the place where the stomach connects to the intestinal tract. This increases feelings of fullness and also allows food to bypass the upper part of the intestine, which changes the way food is absorbed.
- **IV Fluids** – fluids that are delivered through a needle into a vein.
- **Patient Portal** – an Internet website available only to *ReShape* patients that allows you to track information like your weight, exercise, and foods that you eat.
- **Procedure** – a set of steps taken to accomplish a result, such as weight loss.
- **Serotonin Syndrome** – a possible life-threatening adverse drug reaction between two drugs.
- **Sleeve Gastrectomy** – a surgical weight loss procedure in which the stomach is reduced to about one quarter of its original size by taking out a large part of the stomach. The result is a sleeve or tube-like shape. The procedure permanently reduces the size of the stomach.
- **Target** – a thing you aim for, such as a certain amount of weight you are trying to lose.

What the *ReShape*™ Procedure is

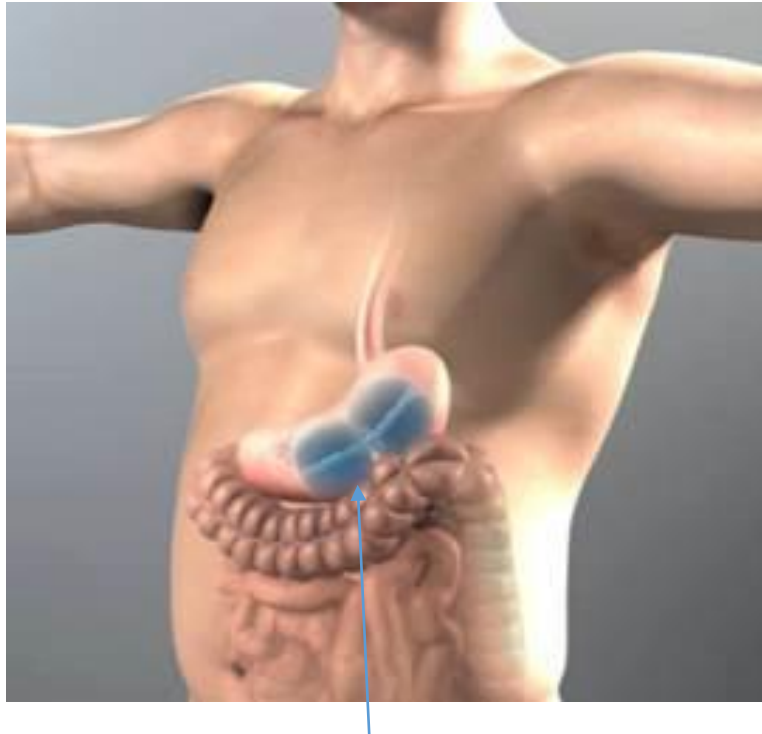
The *ReShape* Procedure is not a cure for obesity. It helps with weight loss. During the procedure you will have the chance to develop new lifestyle skills. Working hard on these new habits will give you the best chance of losing weight.

The *ReShape* Procedure has three parts:



What the *ReShape* device is

The device used in the *ReShape* Procedure is a dual balloon. The dual balloon is actually two separate silicone balloons with a silicone tube in the middle. The balloons are filled with about two cups of salt water (saline) and a blue dye that shows up in your urine if a balloon breaks. The filled balloons are sealed with mineral oil. They take up space in your stomach for 6 months to help you lose weight.



ReShape Dual Balloon in the Stomach

Why doctors use the *ReShape* Procedure

For many people diet and exercise alone may not be enough to hit weight loss targets. Bariatric surgery can be used for those who qualify, but many fear the surgical risks. Others want to avoid permanent changes to their body. The *ReShape* Procedure may be a nonsurgical choice for you if you are an adult with a body mass index (BMI) from 30-40 and have failed to lose weight with diet and exercise alone. You must also have one or more conditions related to your obesity (co-morbid conditions).

Who cannot have the *ReShape* Procedure (Contraindications)

- **CONTRAINDICATION:** You are not a candidate for the *ReShape* Procedure if you have ever developed a serotonin syndrome (with symptoms like confusion, headache, nausea and vomiting, rapid heart rate or severe sweating) that your doctor told you was due to the use of drugs that change the levels of serotonin in your body, and you are currently taking any of the following types of drugs:
 - Selective Serotonin Reuptake Inhibitors (SSRIs)
 - Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

- Monoamine Oxidase Inhibitors (MAOIs)
- **CONTRAINDICATION:** You are not a candidate for the *ReShape* Procedure if you have severe damage to the liver.
- **CONTRAINDICATION:** You are not a candidate for the *ReShape* Procedure if you take prescription aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants daily.
- **CONTRAINDICATION:** You are not a candidate for the *ReShape* Procedure if you are pregnant or breastfeeding.

Speak to your doctor for information on other conditions that may prevent you from having the *ReShape* Procedure. Additional reasons why you should not get the device (contraindications) may not be identified until the time of your medical history and physical with your doctor, or as a result of your endoscopic examination.

Things you must do to avoid serious harm (Warnings)

- **WARNING: DO NOT** have the *ReShape* Procedure if you:
 - Have ever had weight loss surgery. Failure to follow this warning may result in damage to your stomach or intestines that may require surgery to repair.
- **WARNING: RETURN** after 6 months to have the Dual Balloon taken out. If you do not, the device may deflate and move from your stomach into your intestine and cause a blockage that must be surgically taken out. This surgery could result in damage to your intestines or other organs.
- **WARNING: CHECK** to see if your urine is blue-green every time you urinate while the *ReShape* Dual Balloon is in your stomach. If you do not, you may miss that the balloon has deflated. The deflated device can move from your stomach into your intestine and cause a blockage that must be surgically taken out. This surgery could result in damage to your intestines or other organs.
- **WARNING: CALL** your doctor immediately if you see blue-green urine or have a sudden loss of your feeling of stomach fullness. If you do not, the device may deflate and move from your stomach into your intestine and cause a blockage that must be surgically taken out. This surgery could result in damage to your intestines or other organs.
- **WARNING: TAKE** daily acid-blocking medicine prescribed by your doctor (examples: Prilosec, Nexium) while the Dual Balloon is in your stomach. If you do not take this medicine daily, there is a higher risk of developing a stomach ulcer or small hole in your stomach (perforation).
- **WARNING: DO** immediately notify your doctor if you become pregnant while the device is in place. There is a risk that the blue dye (methylene blue) inside the balloon may cause birth defects if the balloon were to rupture and release the blue dye.
- **WARNING: KNOW** that if you are currently receiving serotonergic drugs including SSRIs, SNRIs, MAOIs and other prescription and over-the-counter drugs, there is a risk that you may develop a serotonin syndrome in the event that the balloon ruptures and the blue dye (methylene blue) is

released. You should immediately tell your doctor if you develop any symptoms of confusion, headache, nausea and vomiting, rapid heart rate or severe sweating, as these could be associated with serotonin syndrome.

- **WARNING: KNOW** that if a balloon ruptures, blue dye (methylene blue) would be released into your stomach. This blue dye is a drug that is used to diagnose and treat many types of medical conditions. In laboratory testing, this blue dye caused damage to some bacteria, animal cells, and human tissue. The effect of release of this blue dye into your stomach after a balloon ruptures is not known.

Risks of having the *ReShape* Procedure

The information in this section is based on a study of the device in 265 patients. In this study, some adverse events were not observed that were thought possible. The harm possible from them and their rates are unknown based on this clinical trial. It is also unknown what additional adverse events may develop and how many patients may develop them with more use of this device.

In a clinical study of 265 patients, the following procedure- and device-related serious side effects (serious adverse events) were reported with the *ReShape* Procedure:

Serious Side Effect (Serious Adverse Event)	Number of patients	Harm	Number of patients who had their balloon removed because of the serious side effect
Vomiting	12	Threw up food or drink	1
Abdominal pain	6	Pain in the general area between the ribs and the pelvis	2
Stomach ulcer	2	Damage to the surface of the stomach which can result in pain or bleeding	2
Stomach pain	2	Pain in the stomach	0
Nausea	1	Sensation of wanting to throw up	0
Esophagus puncture (perforation)	1	Damage to the esophagus resulting in hole through the wall of the esophagus	0
Esophagus injury	1	Damage to the lining of the esophagus that may cause pain or bleeding	0
Bleeding (upper gastrointestinal hemorrhage)	1	Bleeding in the stomach	1
Stomach discomfort	1	Discomfort in the upper abdominal area	1
Lung infection (pneumonia)	1	Serious bacterial or viral infection in the lungs	0

Muscle pain	1	Feeling of achiness all over	0
Vomiting with dehydration	1	Throwing up food or drink with potential severe fluid loss	0
Dehydration	1	Potential severe fluid loss	1

Serious side effects required hospitalization or treatment in an emergency room.

Other, possible serious side effects (adverse events) of the *ReShape* Procedure (including those related to endoscopy or sedation) which were not reported in the clinical study of 265 patients:

Possible Serious Side Effect	Harm (Possible Serious Adverse Event)
Patient did not have dual balloon taken out after 6 months	<p>Both of your balloons deflate and move from your stomach into your intestine and must be surgically taken out (device migration)</p> <p>Both of your balloons deflate and move from your stomach into your intestine, causing a blockage and requiring surgery (intestinal obstruction)</p> <p>Both of your balloons deflate and release blue dye (methylene blue) causing you to develop a serotonin syndrome</p> <p>Both of your balloons deflate and release blue dye (methylene blue) causing birth defects if you are pregnant</p>
Patient had both balloons deflate	<p>Both of your balloons deflate and move from your stomach into your intestine and must be surgically taken out (device migration)</p> <p>Both of your balloons deflate and move from your stomach into your intestine, causing a blockage and requiring surgery (intestinal obstruction)</p> <p>Both of your balloons deflate and release blue dye (methylene blue) causing you to develop a serotonin syndrome</p> <p>Both of your balloons deflate and release blue dye (methylene blue) causing birth defects if you are pregnant</p>
Patient saw blue-green urine but did not tell the doctor	<p>Both of your balloons deflate and move from your stomach into your intestine and must be surgically taken out (device migration)</p> <p>Both of your balloons deflate and move from your stomach into your intestine, causing a blockage and requiring surgery (intestinal obstruction)</p> <p>Both of your balloons deflate and release blue dye (methylene blue) causing you to develop a serotonin syndrome</p>

	Both of your balloons deflate and release blue dye (methylene blue) causing birth defects if you are pregnant
Heart attack (myocardial infarction)	Your heart muscle becomes temporarily or permanently damaged
Trouble breathing (respiratory distress)	You need to have a tube placed in your airway to help you breathe during the procedure to put the balloon in or take it out
Life threatening allergic reaction (anaphylaxis)	You need medications or need to have a tube placed in your airway to help you breathe during the procedure to put the balloon in or take it out
Blood circulation stops (cardiac arrest)	You need to have your heart restarted with medications or an electrical shock through your chest
Death	

Other procedure and device-related side effects (adverse events) of the *ReShape* Procedure reported during the clinical study:

Side Effect (Adverse Event)	Number of patients	Harm
Vomiting	87 out of 100 patients	Threw up food or drink
Nausea	61 out of 100 patients	Sensation of wanting to throw up
Abdominal Pain	55 out of 100 patients	Pain in the stomach or abdominal organs
Indigestion	18 out of 100 patients	Stomach feels full of gas, burping, pain or discomfort in the throat
Belching	17 out of 100 patients	Burping
Abdominal discomfort	13 out of 100 patients	Discomfort in the stomach or abdominal organs
Abdominal bloating	11 out of 100 patients	Stomach feels full of gas
Stomach inflammation	12 out of 100 patients	Pain in the stomach
Stomach ulcer	10 out of 100 patients	Pain in the stomach and on rare occasion can cause bleeding in the stomach
Sore throat	10 out of 100 patients	Pain in the throat or difficulty swallowing
Heartburn	7 out of 100 patients	Burning pain or discomfort in the chest or throat
One balloon deflated (no migration)	6 out of 100 patients	Possibility of increased appetite and exposure to methylene blue
Constipation	5 out of 100 patients	Having hard and/or infrequent bowel movements
Decreased appetite	4 out of 100 patients	Eating or drinking less frequently or smaller amounts
Abdominal tightness or tenderness	3 out of 100 patients	Pain or feeling of tightness in the stomach or abdominal organs
Diarrhea	3 out of 100 patients	Having frequent and/or watery stools
Not enough oxygen in the blood (hypoxia)	3 out of 100 patients	Shortness of breath due to inadequate supply of oxygen in the body
Chest or upper abdominal pain	2 out of 100 patients	Pain in the chest or upper abdomen
Dehydration	2 out of 100 patients	Potential severe fluid loss
Weakness	2 out of 100 patients	Fatigue or loss of muscle strength
Dizziness	2 out of 100 patients	Loss of balance or feeling faint
Esophageal injury	2 out of 100 patients	Damage to the lining of the esophagus that may cause pain or bleeding
Change of bowel habit	1 out of 100 patients	Change in the stool firmness or change in the number of bowel movements

Low level of potassium	1 out of 100 patients	Blood test shows that potassium level is low
Retching	1 out of 100 patients	Dry heaves
Headache	1 out of 100 patients	Head hurts
Back pain	1 out of 100 patients	Pain located in the back
Hiccups	1 out of 100 patients	Discomfort from hiccups
Stomach bleeding	1 out of 100 patients	Blood in the stomach
Muscle pain (myalgia)	1 out of 100 patients	Feeling of achiness all over
Cough	1 out of 100 patients	Irritation in the throat or pain in the chest
Flatulence	1 out of 265 patients	Passing gas
Gastric obstruction	1 out of 265 patients	A blockage in the stomach
Esophageal pain	1 out of 265 patients	Pain in the esophagus
Esophageal inflammation	1 out of 265 patients	Pain in the esophagus
Gastrointestinal injury	1 out of 265 patients	Damage to the lining of the stomach or intestines that may cause pain or bleeding
Difficulty swallowing (Dysphagia)	1 out of 265 patients	Difficulty in passing food through the esophagus and into the stomach
Tissue puncture of the esophagus (perforation)	1 out of 265 patients	Small hole that may need to be repaired
Tissue tear of the esophagus	1 out of 265 patients	Damage to the lining of the esophagus that may cause pain or bleeding
Bleeding stomach ulcer	1 out of 265 patients	Bleeding in the stomach as a result of damage to the lining of the stomach

*Side effects that happened during the study that were not related to the throat, stomach or intestines and which happened to less than 1 out of 100 patients are not reported in this table.

In the clinical study of 265 patients, the most common side effects (adverse events) of the *ReShape* Procedure were vomiting, nausea, and abdominal pain:

Side Effect (Adverse Event)	Number of patients who had side effect happen at any time during the study	Number of patients who had side effect begin within 3 days of the dual balloon being put in	Number of patients who had side effect begin within 3 days of the dual balloon being put in and last longer than 14 days	Number patients who had side effect begin within 3 days of the dual balloon being put in and last longer than 30 days
Vomiting	87 out of 100 patients	99 out of 100 patients	11 out of 100 patients	6 out of 100 patients
Nausea	61 out of 100 patients	90 out of 100 patients	24 out of 100 patients	17 out of 100 patients
Abdominal pain	55 out of 100 patients	81 out of 100 patients	33 out of 100 patients	20 out of 100 patients

If you have nausea and vomiting, it can be treated with anti-nausea medications. If your symptoms are more severe, fluids may be given to you through a needle in your vein. If you have abdominal pain, your doctor will prescribe pain medications as needed to control the pain. If you do not tolerate your symptoms, you always have the choice to have the balloon taken out before 6 months. In the clinical study, 15 out of 100 patients asked to have their dual balloon taken out before 6 months.

Benefits of having the *ReShape* Procedure

The *ReShape* dual balloon was shown to help patients lose weight. Patients who received the dual balloon lost more weight than patients who just received diet and exercise counseling alone. On average, the dual balloon patients lost twice as much weight as the patients who only received diet and exercise counseling. Study patients who received the dual balloon lost an average of 14.3 lbs. after the balloon was taken out at 6 months while study patients who did not receive the dual balloon lost an average of 7.1 lbs. (7.2 lbs. less than the dual balloon patients).

On average, 6 months after the study patients had their dual balloon removed, patients kept off 9.9 of the 14.3 lbs they lost with the balloon in place.

Good things about the *ReShape* Procedure

- A 20 minute outpatient procedure
- Does not use surgery
- Balloons can be taken out at any time if not tolerated
- Continue to eat the foods you like, just smaller amounts
- Support to help you change your eating habits and keep weight loss long-term

How to decide about the *ReShape* Procedure

The *ReShape* Procedure might be right for you if you are an adult with a body mass index (BMI) from 30-40 and you have failed to lose weight with diet and exercise alone. You must also have one or more conditions related to your obesity (co-morbid conditions). Some examples of these conditions of obesity include high blood pressure, high cholesterol, and diabetes. If you are not sure whether you have any obesity related conditions, your doctor can provide this information.

During treatment with the *ReShape* Dual Balloon and after it is taken out, you must continue to follow your doctor-recommended diet and exercise to have the most weight loss. Without changes to your eating habits and lifestyle, weight regain is likely. Make sure you are ready to reduce your total number of calories, eat smaller amounts of food and exercise regularly before choosing the *ReShape* Procedure.

Be sure to ask questions about other weight loss treatments. The *ReShape* Procedure is not the only treatment choice. Other choices include diet and exercise programs or prescription medications, and—for patients who qualify—surgery (gastric band, gastric bypass, sleeve gastrectomy). You should talk with your doctor to pick the one that best fits your needs.

The table below can help you tell if your BMI is within the approved BMI numbers 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 (with clothes on but without shoes). The number in the box where your height and weight come together is your BMI. If your BMI is blue, your BMI is within the BMI numbers approved for the *ReShape* Procedure. Your doctor can also help you to find out 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

What are the first steps In the *ReShape* Procedure

Your doctor will ask about your medical history and perform an exam to help determine if this procedure may be a good choice for you. You will also be told about prescription medicines that you will need to take. It is recommended that you fill all prescriptions before the procedure. At this time you will also meet with a dietician to receive information on nutrition and exercise requirements.

What happens during the procedures to put the *ReShape* Dual Balloon in and take it out of your stomach

Talk with your doctor before the procedure to learn about any dietary rules.

On the day the *ReShape* Balloon is put in

Your doctor will place the *ReShape* Dual Balloon in your stomach during a short outpatient procedure. First you will be made comfortable with an intravenous medication that causes conscious sedation (light anesthesia). Then your doctor will use a tube that can bend and has a camera on the end to check your stomach and esophagus. Your doctor will then place the uninflated *ReShape* Dual Balloon down your

throat and into the stomach (Fig. 1). The balloons are then inflated with about two cups of saline (salt water) and a blue dye (methylene blue) that shows up in your urine if a balloon breaks (Fig. 2). The filled balloons are sealed with mineral oil. Putting the dual balloon in typically takes less than 20 minutes.

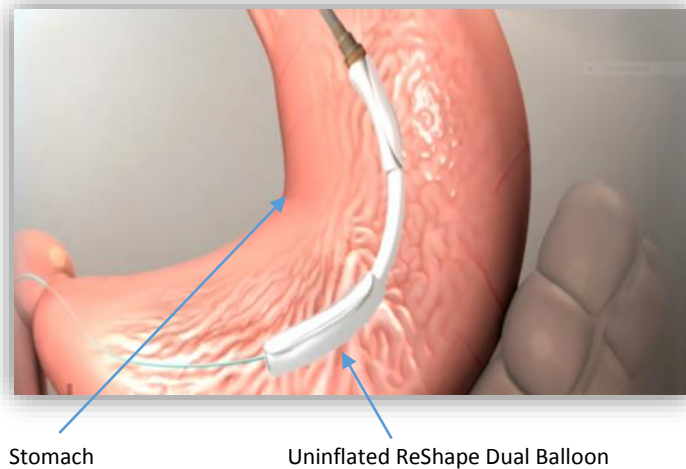


Fig. 1

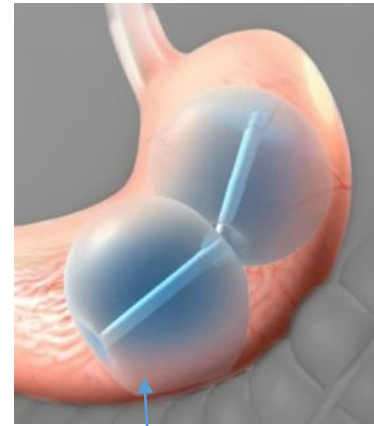


Fig. 2

You will likely have nausea, vomiting, and abdominal pain and may also have bloating, diarrhea, and cramping. All of these are common and should be expected. Sometimes they may be severe and your doctor can provide medicine and advice to help. Make sure that you take your medications as prescribed.

On the day the *ReShape* Balloon is taken out

Talk with your doctor before the procedure to learn about any dietary rules.

Your doctor will take the *ReShape* Dual Balloon out of your stomach during a short outpatient procedure. First you will be made comfortable with an intravenous medication that causes conscious sedation (light anesthesia). Then your doctor will use a tube that can bend and has a camera on the end to view the dual balloon while draining it (Fig. 3). Once your doctor drains the fluid from the dual balloon, it is taken out of your stomach (Fig. 4). Taking the dual balloon out typically takes less than 20 minutes.



Tube drains fluid from ReShape Dual Balloon

Fig. 3



Stomach Drained ReShape Dual Balloon

Fig. 4

What happens after the *Dual Balloon is put into your stomach*

An important part of the *ReShape* Procedure is the support and supervised coaching. Learning how to eat and exercise will be a 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 after it is taken out.

Once every month for 12 months you will meet with the staff at your weight loss center. This timing is the same as what the clinical study patients received. Clinical study patients had weight measurements and reviewed their diet and exercise with the staff at each monthly visit. The staff gave clinical study patients suggestions for changes or improvements as needed. At each monthly meeting, you will receive that treatment and more, including:

- Customized coaching based on your progress
- Diet support
- Exercise support
- Educational support
- Review of your *ReShape* Patient Portal
- Body composition and weight measurements
- Review of your targets and online support
- Behavioral and emotional support in one-on-one or group sessions as needed

It is important that you follow the diet and exercise coaching for the full 12 months to reach the best weight loss. You will also need to use the Healthy Living tools, like the *ReShape* Patient Portal, to help track what you are eating and how much you are exercising. If you do not reduce your total calories, eat smaller amounts of food and exercise regularly, you may receive little or no help from the *ReShape* Procedure.

When to call your doctor

After the dual balloon is put in, your doctor will tell you when to call. Please review the “Things you must do to avoid serious harm (Warnings)” in this Patient Information Guide for other times when you must call your doctor.

Where you can find out more

Please talk with your doctor to find out more about your condition and whether the *ReShape* Procedure is right for you.

Patient ID Card

You will receive a *ReShape* ID Card following your procedure. Carry your *ReShape* ID Card with you to show other doctors and care providers that you have a *ReShape* dual balloon. If you lose this card, please call your doctor’s office to receive a new card.

How clinical studies were done

A clinical study, called the REDUCE Pivotal Trial, was performed at 8 hospitals in the United States. This study included 326 patients who had a BMI of 30-40. These patients also had some other medical condition related to their obesity (obesity-related comorbidity). Patients either had the dual balloon placed for 6 months and received diet and exercise coaching for 12 months or just received diet and exercise coaching for 6 months. The patients who received the dual balloon and the diet and exercise coaching were chosen by chance (like flipping a coin). By chance, 187 patients received the dual balloon plus diet and exercise coaching and 139 patients received only diet and exercise coaching. Patients who just received diet and exercise coaching for 6 months were given the choice to have the dual balloon put in after they completed the first 6 months of diet and exercise coaching. Seventy-seven of these patients chose to have the dual balloon put in and had another 6 months of diet and exercise coaching. Therefore, a total of 264 study patients had a dual balloon put in.

The clinical study patients were all at least 22 years old with a BMI 30-40 and at least one obesity related health condition. They were not allowed to be in the clinical study if they ever had weight loss surgery, would not or could not follow the *ReShape* diet and exercise program, or if they were pregnant or breastfeeding. The balloon was put in and taken out just like your balloon is put in and taken out. All clinical study patients had monthly follow up visits for 12 months where the doctor's staff collected information on weight loss and side effects and the patients received diet and exercise counseling on reducing total calories, eating smaller amounts of food and exercising regularly.



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03-0312 Rev. C