Patient Information Booklet for the *TransPyloric Shuttle*® (TPS®)

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.

Federal law restricts this device to sale by or on order by a Physician.

*The **TransPyloric Shuttle/TransPyloric Shuttle Delivery Device** is the trade name for the FDA approved product.

Welcome to BAROnova®

If you are reading this booklet then you are looking for options to lose some weight. You are not alone. Losing weight is hard and finding the right solution for you is the key to supporting your journey. That's why BAROnova was founded. Our engineers, scientists, and physicians created the TransPyloric Shuttle (or TPS) to help you lose weight without surgery. So, no matter what you may have tried in the past, you have not tried anything like the TPS. We created it to help people lose as much weight as possible and to give people the opportunity to form lifestyle habits that keep weight off. In fact, we have clinically shown that people, on average, lose about 3.4 times more weight than with medically supervised diet and exercise alone over a 12-month treatment period.

This booklet should give you the necessary information you need about the TPS. If you have any additional questions, talk to your doctor. As you read through this booklet, we hope you decide that the TPS is the right option for you. Thank you for considering the TPS on your path to a healthier you.

Contents

What is the *TransPyloric Shuttle?*

The *TransPyloric Shuttle* (TPS) is a non-surgical device to help with weight loss. The TPS is made of soft, smooth silicone rubber and consists of a larger bulb, tether and smaller bulb (Figure 1). It is placed through your mouth, down your esophagus, and into your stomach during an endoscopic procedure that is performed under general anesthesia. The large bulb of the TPS is approximately the size of a small peach and it stays in your stomach for up to one year. The TPS works with the stomach's natural movement to slow food from passing through the stomach into the small intestine (slow gastric emptying) (Figure 2). The action of the TPS device is intended to help you feel fuller and have less desire to eat.

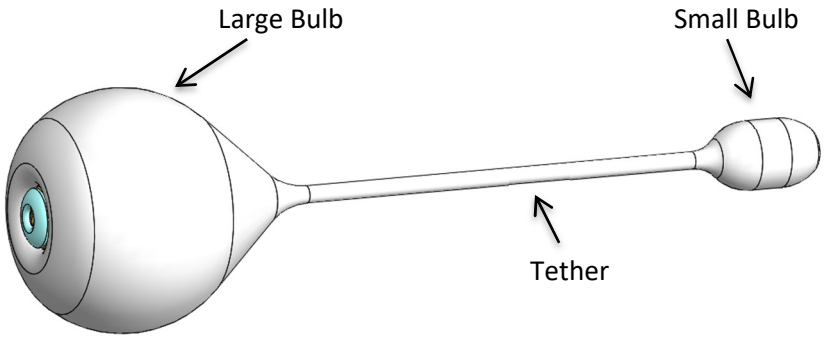

Figure 1. TPS device

Figure 2. TPS position in the stomach with slow emptying

The TPS device is placed into your stomach through your mouth (endoscopic procedure) and is intended to remain in your stomach for up to 12 months. During the treatment period you should receive lifestyle coaching to help develop new lifestyle skills. Working hard on these new habits will give you the best chance of losing weight.

At the end of the 12 months you will undergo a short non-surgical endoscopic procedure to remove the device.

How you lose weight with the *TransPyloric Shuttle*

The *TransPyloric Shuttle* (TPS) is a device that can help you lose weight. Unfortunately, however, it does not do all the work. In order to effectively lose weight with the TPS, there are a few things that need to be done.

- *Listen to your doctor* – it's important to follow the instructions of your doctor. He or she is very familiar with the TPS and with your medical history so you should always follow his or her instructions.
- *Carefully follow an appropriate diet* – while the TPS may make you feel full more quickly and for a longer period of time, you will still need to listen to your body and stop eating as soon as you feel full, eat smaller portions and be careful to eat lower calorie, healthy foods. Foods such as high calorie liquids are more easily absorbed and can bypass the TPS. Foods with high fat content or large portion sizes can make you feel uncomfortable or sick. You should learn to eat small portions of easily digestible healthy food. Learning a new lifestyle is key to your success in losing weight and keeping the weight off.
- *Exercise* – exercise takes work but it is important. Try to do simple things like walk around the block, take the stairs at work, park a little further away to work, and incorporate exercise into your daily routine. The truth is every bit helps and can increase the amount of weight you lose.

Is the *TransPyloric Shuttle* for you?

The *TransPyloric Shuttle* (TPS) is a device designed to help with weight loss. We created this non-surgical device to be different from other weight loss solutions available to you. Because it is different, it has different results. In clinical studies, the TPS has been shown to help people lose about 3.4 times more weight than with medically supervised diet and exercise alone over a 12-month treatment period.

Only you and your doctor can decide if TPS is right for you. TPS has a few unique benefits that you may consider.

- *TPS is non-surgical* – this means that when you choose TPS you don't have the risks that come with surgery, except for the anesthesia risks which you will also have with TPS procedures.
- *Longer duration of effect* –the TPS is in place for up to 12 months. The longer duration gives you more time to lose more weight and to help your new healthy habits to stick.
- *Effective* – The TPS can help people lose a significant amount of weight. Our clinical study showed that on average people lost about 3.4 times more weight than people who followed medically supervised diet and exercise alone over the 12-month treatment period. That's on average and some people lost much more than that but there were also people who did not lose a significant amount of weight. We can't guarantee results for everyone but the clinical results for TPS are significant.
- *Potential health benefits*– if you have weight-related conditions such as high-cholesterol, high blood pressure, diabetes, or are at risk of developing these conditions or simply want to look or feel better, physicians often recommend losing weight as one step to potentially improve those conditions. While there are many approaches to losing weight, the TPS may help you lose weight and achieve your health improvement goals.

If you have been unsuccessful at losing weight and do not want the risks that come with a bariatric surgery, then the non-surgical TPS may be right for you.

The TPS is only approved for adults with a BMI (Body Mass Index) of 30-40 kg/m^2. Patients with a BMI below 35 kg/m^2 should have at least one chronic condition such as diabetes, high blood pressure, or high cholesterol. The table below can help you tell if your BMI is within the approved BMI numbers for the *TransPyloric Shuttle.* 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 your height and weight come together is your BMI. If your BMI is blue, your BMI is within the BMI numbers approved for the *TransPyloric Shuttle*. Your doctor can also help you to find your BMI.

Height (in.) \ Weight (lbs.)	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320	330
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

Benefits of having the *TransPyloric Shuttle*

In the clinical study, the *TransPyloric Shuttle* was shown to help patients lose weight. Patients who received the TransPyloric Shuttle lost more weight than patients who just received medically supervised diet and exercise counseling alone. In study patients who received the assigned treatment and followed the protocol, patients who received the TransPyloric Shuttle lost an average of 9.5% of their weight during the 12-month treatment period while study patients who did not receive the device (the Control group) lost an average of 2.8% of their weight. This means that patients with the TPS lost about 3.4 times more weight than those patients with medically supervised diet and exercise alone.

Of course, individual results will vary and you must follow the physician's recommendations for diet and exercise to achieve results. In fact, while the average weight loss was 21 lbs., individual weight loss ranged from 81 lbs. to a weight gain of 8 lbs. About 67% of patients achieved 5% or more weight loss and 40% of patients achieved 10% or more weight loss by the time the device was removed.

Both groups of patients in the study answered questions about their quality of life before treatment and at 12 months. At the start of the study, the quality of life scores were similar for both the TransPyloric Shuttle and Control groups. By 12 months the scores for Total Score, Physical Function, Self-Esteem, Sexual Life and Work were improved in favor of the TransPyloric Shuttle group. Benefits of weight loss include reduced BMI and improvement in health risk factors such as blood pressure, insulin level and lipid profile.

Additional benefits include:

- A 15-minute outpatient procedure
- Does not require surgery
- No permanent change to your anatomy
- Generally able to return to work as soon as the next day
- Device 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 maintain weight loss long-term

Clinical study results with the *TransPyloric Shuttle*

The safety and effectiveness of the TPS was demonstrated in a clinical study performed at 9 sites in the United States. This study included 302 patients who had a BMI of 30-40 kg/m^2. Patients with a BMI of 30-35 kg/m^2 had at least one chronic condition such as diabetes, high blood pressure, or high cholesterol. The study was randomized in order to accurately measure the effectiveness and safety of the TPS. Patients either had the TransPyloric Shuttle placed up to 12 months and received diet and exercise coaching for 12 months (the TPS group) or just received the same medically supervised diet and exercise coaching for 12 months without the TPS (the Control group). The results of the two groups were then compared to see how much the TPS helped patients to lose weight.

The weight loss curve for the TPS and Control groups is shown in Figure 3 below. Patients in the Control Group (Blue line) lost the majority of the weight in the first two months, did not lose much weight between 2 and 6 months, and regained weight between 6 and 12 months. In comparison, the TPS patients (Red line) resulted in continued weight loss throughout 12 months, with the maximum weight loss achieved at 12 months. The percent of total body weight loss was greater in the TPS Group compared to patients in the Control Group at all follow-up visits. Overall, on average, people with the

TPS lost about 3.4 times more weight than those without the TPS (Control group with medically supervised diet and exercise alone).

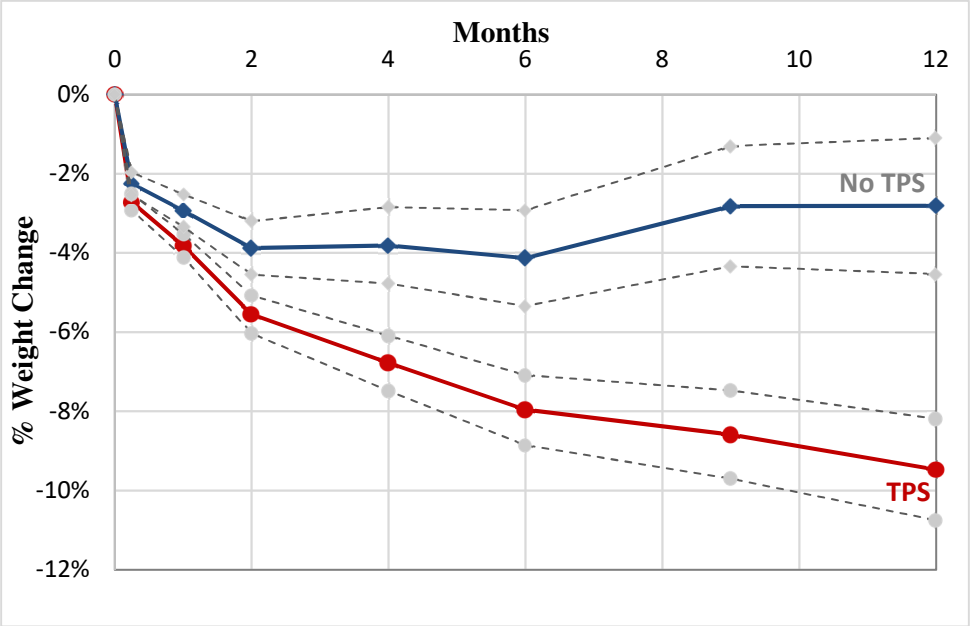

Figure 3. TPS and Control Group (no TPS) average weight change over Time in all patients who received the assigned treatment and followed the study protocol (Dotted lines represent the 95% confidence intervals around the means)

Who can receive the *TransPyloric Shuttle*

For many people, diet and exercise alone may not be enough to achieve weight loss targets. The *TransPyloric Shuttle* might be right for you if you are an adult with a body mass index (BMI) between 30 and 40 kg/m^2 and you have been unsuccessful in losing weight with diet and exercise alone. If your BMI is between 30 and 34.9 kg/m^2, you must also have one or more conditions related to your obesity (co-morbid conditions). Some examples of co-morbid conditions include high blood pressure, high cholesterol, and diabetes. To receive the TPS device, you must be willing to follow a 12-month program, which includes diet changes and exercise. Continuing this diet and exercise program after the TPS device is removed is encouraged for the best chance to maintain or continue the weight loss you achieved with the TPS.

If you are unsure if you have any obesity related conditions, your doctor can provide you with this information.

Who cannot have the *TransPyloric Shuttle* (Contraindications)

You are NOT a candidate for the TPS if:

- You have had prior surgeries or endoscopic procedures that have changed the anatomy of your gastrointestinal (GI) tract, such as a gastric sleeve or gastric band. Failure to follow this warning may result in damage to your stomach or intestines that may require surgery to repair.

- You have abnormal anatomy at your throat or esophagus that could affect the passage of an endoscope or devices during TPS delivery or removal.
- You have a condition that would put you at risk of upper GI bleeding, such as erosive esophagitis, esophageal or gastric varices (veins in your esophagus or stomach that bleed), telangiectasias (spider veins) or other abnormalities.
- You have a patulous (wide open or distended) gastroesophageal junction.
- You have a history of structural or functional disorders of the stomach including, gastroparesis (stomach emptying disorder), gastric ulcer, gastric mass or cancer, chronic gastritis (stomach irritation), gastric varices, large hiatal hernia (> 4 cm), pyloric stricture or any other disorder of the stomach.
- You have inflammatory or other condition of the GI tract, such as Crohn's disease.
- You have an untreated Helicobacter pylori infection. Having this infection increases the possibility of gastric irritation and ulcers.
- You have stomach or duodenal ulcers.
- You take prescription aspirin, anti-inflammatory agents, or other gastric irritants daily. Taking these drugs on a daily basis increases the possibility of gastric irritation and ulcers when you have the TPS device in your stomach.
- You have a bleeding condition or take blood thinner medications.
- You are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant. Not taking these medications increases the possibility of gastric irritation and ulcers.
- You have cirrhosis, portal hypertension, and/or esophageal varices.
- You have been diagnosed with an eating disorder including but not limited to binge eating disorder, compulsive overeating disorder, or you have other psychiatric illness. You have an allergy to any of the materials used in the TransPyloric Shuttle (e.g. silicone, barium sulfate and parylene).
- You have any other condition that may put you at risk for endoscopic procedure or anesthesia, such as poor general health or history and/or symptoms of severe renal, liver, cardiac, and/or lung disease.
- You are pregnant or plan to become pregnant in next 12 months.

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

Risks Related to Endoscopy

Placing and removing the TPS involves a 15-minute endoscopy procedure performed in an outpatient setting. While this type of procedure has been done millions of times in the U.S., there are still risks that come with the procedure. The most common risks of endoscopy include bleeding, infection, and tearing of the esophagus or stomach. These problems occur in about 3–5 of every 10,000 endoscopies. Risks related to general anesthesia during endoscopic procedures are rare. You might feel groggy and a little confused when you first wake up from the anesthesia. The most common side effects of general anesthesia include, but are not limited to, allergic reaction, adverse reaction to sedation (headache, muscle pain, nausea), respiratory arrest (breathing stops) or distress (difficulty breathing), heart attack, cardiac arrest (blood circulation stops), death, low oxygen level, infection, or pneumonia. You should talk to your doctor about the risks related to general anesthesia. Your doctor may give you medications

after the procedure to reduce pain and nausea. Patients with heart, lung, kidney, liver, or other chronic diseases are at higher risk for side effects from medications. In order to reduce the chance of having a side effect during the TransPyloric Shuttle procedures, you should follow your doctor's instructions on how to prepare for endoscopy, such as not eating and stopping certain medications.

Risks of having the *TransPyloric Shuttle*

In the clinical study, 1 out of 213 patients had procedure-related serious side effects (serious adverse events), and 5 out of 203 patients developed serious device-related side effects when the *TransPyloric Shuttle* was in the body. The specific side effects are summarized in the table below.

Serious Side Effect (Serious Adverse Event)	Number of patients	Harm	Number of patients who had their device removed because of the serious side effect
Upper abdominal pain	1 out of 203	Pain in upper abdomen	1
Gastric ulcer	1 out of 203*	Damage to the surface of the stomach	1
Vomiting	1 out of 203*	Threw up food or drink	1
Device impaction	4 out of 203*	Unable to accept device in body without adverse effects or a blockage in the stomach	4
Esophageal rupture	1 out of 213**	Damage or hole in the esophagus	1
Pneumothorax	1 out of 213**	Air leak in the chest cavity	1

**Device impaction included the patient with vomiting and the patient with gastric ulcer.*
*** Esophageal rupture and pneumothorax occurred in the same patient.*

These serious side effects required hospitalization or treatment in an emergency room.

TPS delivery may not be successful in all patients. In the clinical study, device placement was unsuccessful in 9 out of the first 107 patients (8.4%). Following a minor device modification, device placement was unsuccessful in 1 out of the final 106 patients (0.9%).

The most common side effects (adverse events) related to the *TransPyloric Shuttle* were nausea, upper abdominal pain, vomiting and indigestion (dyspepsia). The procedure and device-related side effects (adverse events) of the *TransPyloric Shuttle* most commonly reported during the clinical study are listed in the table below:

	Number of TPS patients who had side effects related to the Device (out of 203 patients)	**Number of TPS patients who had side effects related to the Procedure (out of 213 patients**	**Description**
Patients with Any Events	201 (99.0%)	136 (63.85%)	Patients with any side effects in any part of the body
Patients with GI Events	200 (98.5%)	87 (40.9%)	Patients with any side effects in esophagus, stomach or intestine
Nausea	128 (63.1%)	41 (19.3%)	Sensation of wanting to throw up
Abdominal pain upper	127 (62.6%)	30 (14.1%)	Pain in the abdomen
Vomiting	118 (58.1%)	22 (10.3%)	Threw up food or drink
Dyspepsia	111 (54.7%)	22 (10.3%)	Stomach feels full of gas, burping, pain or discomfort in the throat
Diarrhea	77 (37.9%)	4 (1.9%)	Having frequent and/or watery stools
Abdominal distension	75 (36.9%)	18 (8.5%)	Stomach feels full of gas, bloating
Gastroesophageal reflux	70 (34.5%)	8 (3.8%)	Stomach acid flows back up the esophagus causing pain or discomfort in the chest or throat (heartburn)
Belching (Eructation)	67 (33.0%)	12 (5.6%)	Burping
Gastritis erosive	27 (13.3%)	2 (0.94%)	Inflammation or damage to stomach surface
Gastric mucosa erythema	23 (11.3%)	1 (0.5%)	Redness of the stomach surface
Gastric ulcer	21 (10.3%)	0 (0.0%)	Damage to the surface of the stomach which can result in pain or bleeding
Sore throat (Oropharyngeal pain)	25 (12.3%)	76 (35.7%)	Pain in the throat or difficulty swallowing

If you have nausea and vomiting, it can be treated with anti-nausea medications. If your symptoms are more severe, fluids can be administered intravenously. If you have stomach pain or cramps, your doctor will prescribe pain medications as needed to control the pain. You have the choice to have the device removed before 12 months if you cannot tolerate your symptoms or have achieved your weight loss goals. In the clinical study, 46 of 203 patients (22.7%) had the TPS device removed prior to 12 months, among them 30 were due to adverse events such as device intolerance or symptoms and 16 were due to other reasons such as moving away, unwilling to comply with study visits, pregnant, etc.

Other possible serious side effects related to the TPS, anesthesia, or endoscopy could include allergic reaction, respiratory arrest (breathing stops), cardiac arrest (blood circulation stops) or death. These side effects were **NOT** seen in the clinical study so it is unknown whether other adverse events may occur. The TPS device side effects after 12 months are unknown. The TPS should be removed at 12 months.

What are the first steps

You should start by doing your research. If you want to find out more about TPS ask your doctor. 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 procedure to put the *TransPyloric Shuttle* in and take it out of your stomach

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

Your doctor will place the *TransPyloric Shuttle* in your stomach during a short procedure that usually takes about 15 minutes. First you will receive general anesthesia using medication so that you will not feel anything during the procedure. The anesthesiologist will deliver liquid medication through an IV tube in your arm or using gas mediation delivered through a mask. Once you're asleep, the anesthesiologist will insert a tube into your mouth and down your windpipe to ensure you get enough oxygen and protect your lungs from fluids. 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 a flattened version of the TransPyloric Shuttle down your throat and into the stomach, where it is formed into its intended shape (see Figure 4).

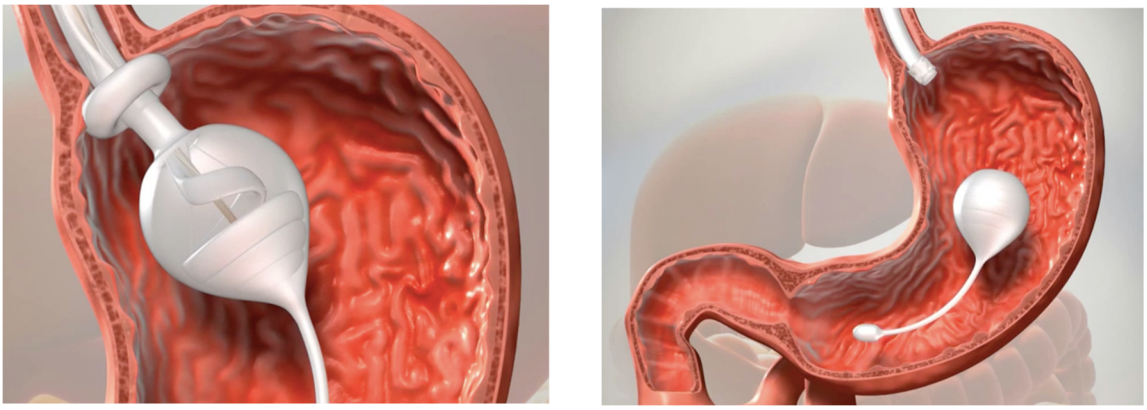

Figure 4. TPS being formed into intended shape

After the procedure, you may have nausea, vomiting, and stomach pain and may also have indigestion, 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.

When you are done losing weight or after 12 months, your doctor will take the *TransPyloric Shuttle* out of your stomach during a short outpatient procedure. First you will receive general anesthesia as described above. Then your doctor will use a tube that can bend and has a camera on the end to view the device. Your doctor will remove the *TransPyloric Shuttle* from your stomach through a tube. Taking the device out typically takes less than 20 minutes.

What happens after the *TransPyloric Shuttle* is put into your stomach

An important part of the *TransPyloric Shuttle* procedure is the support and supervised coaching. Learning how to eat and exercise will be a part of your *TransPyloric Shuttle* experience. You will receive diet and exercise coaching during the twelve months the *TransPyloric Shuttle* is in place.

During the 12 months when you have the device, you will either meet personally with the staff at your weight loss center, by phone call or by computer. For example, clinical study patients had weight measurements taken and reviewed their diet and exercise with the staff over the course of treatment. The staff gave clinical study patients suggestions for changes or improvements as needed. You will receive the similar treatment or more. You will record your weight, monitor what you eat, and receive educational support and customized coaching based on your progress. You will learn and practice healthy habits that will help you to lose weight and keep the weight off.

To achieve the best weight loss results, it is important that you follow the diet and exercise coaching for the full 12 months to reach the best weight loss. The *TransPyloric Shuttle* is designed to help you feel full. If you do not decrease your portion size and total calories, you may feel sick or receive little to no benefit from the *TransPyloric Shuttle*.

Precautions

You must follow the diet, exercise, and other directions from your doctor and your coaching program while the *TransPyloric Shuttle* is in place. If you do not follow directions, you may not lose weight or you may not maintain the weight you have lost already.

Tell your doctor right away if you feel nonstop nausea, or if you cannot stop vomiting. Tell your doctor right away if you develop severe abdominal pain. If you do not tell your doctor about your nausea or vomiting, your body could become dehydrated which may harm your kidneys and heart. You may need to go to the hospital if symptoms persist. Your doctor may need to treat you with medicine, give you IV fluids or have your *TransPyloric Shuttle* removed. The *TransPyloric Shuttle* may obstruct the stomach outlet. You should seek immediate medical attention if you experience persistent upper abdominal pain, nausea or vomiting for greater than 12 hours.

The TransPyloric Shuttle is contraindicated in pregnant females and the safety and effectiveness of the device has not been established with breastfeeding. As soon as you know you are pregnant, tell your doctor so the *TransPyloric Shuttle* can be removed. If you are a breastfeeding mother or planning to become pregnant within the next year, you should not receive the *TransPyloric Shuttle*.

You must **RETURN** by 12 months to have the *TransPyloric Shuttle* taken out. The safety and effectiveness of the device beyond 12 months is not known.

Always tell your health care provider that you have the *TransPyloric Shuttle*. Show them your Patient ID Card.

Warnings

• **DO NOT** have the *TransPyloric Shuttle* procedure if you have ever had weight loss surgery. Prior surgery or endoscopic intervention that has altered the anatomy of esophagus, stomach or intestine is contraindicated for the *TransPyloric Shuttle* procedure. Failure to follow this warning may result in damage to your stomach or intestines that may require surgery to repair.
• **TAKE** daily acid-blocking medicine prescribed by your doctor (examples: Prilosec, Nexium) while the *TransPyloric Shuttle* 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).

• **DO NOT** take any stomach irritating medicines like non-steroidal anti-inflammatory drugs (NSAIDs) or Aspirin while the *TransPyloric Shuttle* is in your stomach. Some examples of NSAIDs are Motrin or Advil. Please read the warnings on any medicines that you might take to see if they can hurt your stomach. You might get ulcers or bleeding if you take these kinds of medications while the *TransPyloric Shuttle* is in your stomach.

• **CALL** your doctor immediately if you develop persistent nausea and vomiting, and/or stomach pain. The *TransPyloric Shuttle* may cause persistent blockage of the pylorus and may need to be removed.

When to call your doctor

After the TransPyloric Shuttle 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 *TransPyloric Shuttle* is right for you. You can also find out more at www.BAROnova.com.

Patient ID Card

You will receive a *TransPyloric Shuttle* ID Card following your procedure. Carry your *TransPyloric Shuttle* ID Card with you to show other doctors and care providers that you have a *TransPyloric Shuttle* device. The back of the Patient ID Card has information regarding MRI (Magnetic Resonance Imaging) safety conditions. If you lose this card, please call your doctor's office to receive a replacement.

Glossary

• **Adverse Event:** Any painful, uncomfortable, or troublesome medical episode in a patient.

• **Anesthesia:** Medications that reduce pain from part of your body or make you sleep or feel sleepy so that you don't feel pain during a medical procedure

• **Anesthesiologist:** A doctor specializing in the use and administration of anesthesia for medical procedures. An anesthesiologist gives you the medications and checks your health while the medication is in your body.

• **Body Mass Index (BMI):** A common measure, using a person's height and weight, to tell whether a person is overweight or obese.

- 18-25 – healthy
- 25-30 – overweight
- 30 or above – obese

• **Cholesterol:** A type of fat in your blood. If you have too much cholesterol, it starts to build up in your blood vessels and can cause restricted blood flow, clots, or serious heart problems.

• **Clinical Study:** A scientific trial to test new medicines or medical devices in a controlled way to find out how well they work.

• **Diabetes:** A disease that affects the way your body handles glucose, a type of sugar, in your blood.

• **Device:** A product made for a particular purpose, such as helping you lose weight.

• **Diet and Exercise Program:** A program given to you to exercise (brisk walk) regularly and follow a healthy, low calorie diet

• **Duodenum:** The first part of the small intestine immediately beyond the stomach.

• **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:** Referring 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.) 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.

• **Gastro-intestinal (GI) Tract:** This includes the path from your mouth to your anus that includes the esophagus, which allows food and liquids to pass, the stomach and the intestines.

• **Gastroesophageal Reflux:** When stomach acid or stomach content flows back into the food pipe (esophagus). Reflux can irritate the esophagus, causing heartburn and other symptoms.

• **Gastric Outlet Obstruction:** A situation in which normal emptying of the stomach is mechanically affected. This may result in nausea and/or vomiting.

• **Hypertension:** High blood pressure.

• **Intravenous:** Fluids delivered through the vein, typically used for rehydration.

• **Magnetic Resonance Imaging (MRI):** A painless medical imaging method that uses a large magnet, radio waves and a computer to form pictures of the inside of your body

• **Nutritionist:** A trained person who helps others plan what foods to eat that are good for their health.

• **Obesity:** A medical condition in which extra body fat builds up to the point that it may be unhealthy. People with a BMI of 30 and above are obese.

• **Procedure:** A set of steps taken to accomplish a result, such as weight loss.

• **Proton Pump Inhibitor (PPI):** A group of drugs that helps to reduce stomach acid production.

• **Pylorus:** The opening from the stomach into the duodenum (small intestine).

• **Side Effect:** Something bad or harmful that can happen as a result of a medical treatment that may or may not be expected.

• **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 goal you aim for, such as a certain amount of weight you are trying to lose.

• **TransPyloric Shuttle (TPS):** A device used to help with weight loss. It works by taking up space in the stomach and intermittently slowing gastric emptying.

• **Ulcer:** A sore that can be found in the stomach lining or small intestines. They can occur when there is irritation from acid or mechanical devices.