



vBloc
neurometabolic therapy

Enabling you to **Live Fully**

I knew it was time to take action and get the help I needed.

vBloc® patient

Obesity is a disease; it is not a choice.

vBloc Therapy is a new tool that helps control your appetite.

Experts agree that the **disease** of obesity is complex which may explain why losing weight and keeping it off is so difficult.

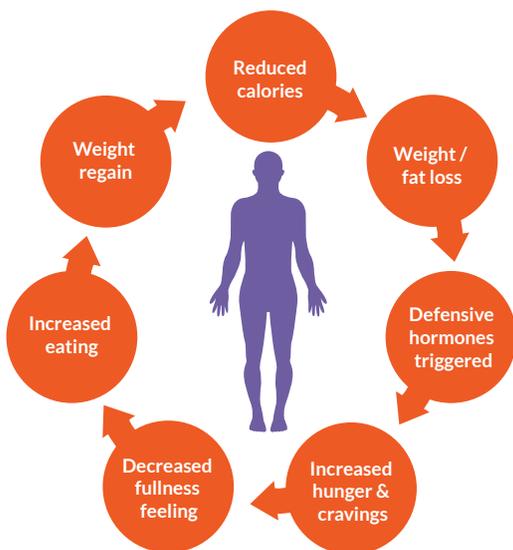
If you are living with **excess weight or obesity** that impairs your health or well-being, then you may be a candidate for **vBloc Neurometabolic Therapy**.



vBloc Therapy, delivered via the Maestro® System, is FDA approved for weight loss in adults with a Body Mass Index of 35-39.9 kg/m² with a related health condition, or a BMI of 40-45 kg/m². Individuals should have been unable to maintain weight loss by diet and exercise in a supervised program within the last 5 years before receiving the Maestro System.

The Weight Loss Regain Cycle

Understanding how your body regulates weight is important to understanding which weight loss option may be right for you.



THE IMPORTANT ROLE OF SIGNALS

Your body regulates weight through a complex process, each part “talking” to the others through brain and hormonal signals. Directing the overall process, the brain receives incoming messages and sends new instructions to your body in order to maintain what it feels is a healthy weight.

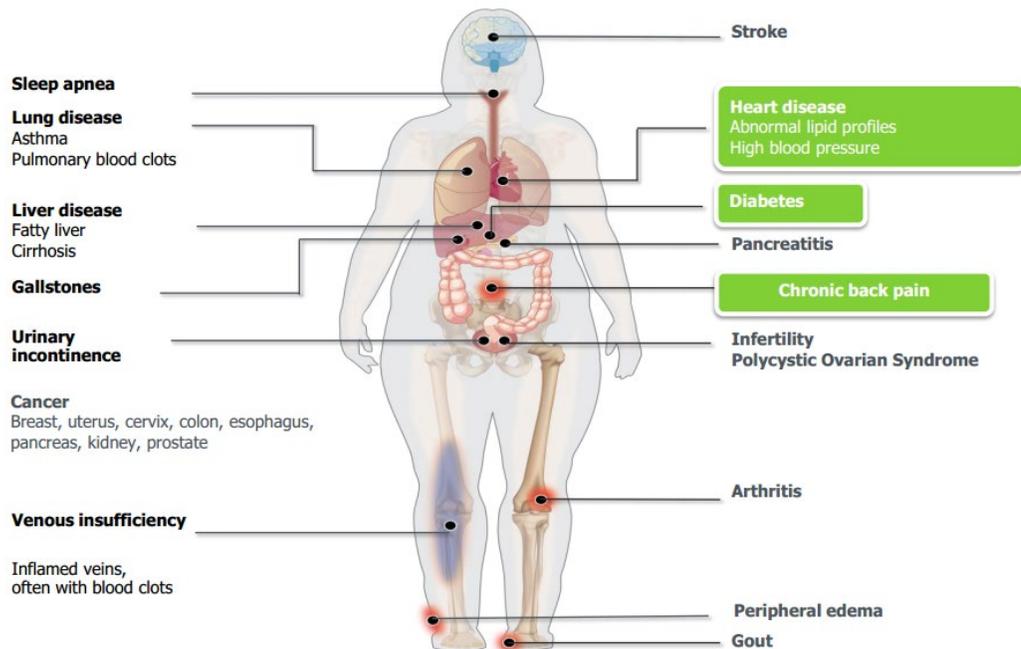
While not fully understood, the accumulation of fat levels causes a metabolic imbalance of hormonal and brain signals to occur, resulting in metabolic dysfunction of this regulation system.

WEIGHT LOSS & REGAIN CYCLE

Always in self-preservation mode, the body treats dieting and subsequent fat loss as a threat. Various systems trigger a cascade of signals which act as the body’s defense mechanism to regain the excess weight.¹

This flood of signals increases feelings of hunger and cravings, and decreases the sense of fullness, causing you to eat more calories and put the weight back on.

Serious conditions may grow to become **life-threatening**



According to the National Institutes of Health:

Even modest weight loss of 5 to 10 percent of total body weight shows improvements in blood pressure, blood cholesterol, blood sugars.²

What it costs you

Obesity can damage confidence, health, and relationships, however, these are not the only impacts.

There are many monetary costs associated with obesity, such as diets, supplements, medications, and medical costs.

If you have a Body Mass Index of **>35**, you are likely paying **45%** more in health-care expenses.³

WHY DIET & EXERCISE MAY NOT BE ENOUGH

The body's natural fight to regain lost weight may explain why studies show that those who try losing weight through the traditional approach of diet & exercise, are not able to maintain significant weight loss.

Even more devastating to long term efforts to lose weight, the body will attempt to gain more weight with each loss – regain cycle, reaching a new high mark after a temporary period of weight loss.⁴



A Swedish study found that, on average, a 200-pound patient fighting obesity with diet and exercise alone would only be able to achieve a sustained weight loss of 4 pounds over 20 years.⁵

vBloc Therapy may be just the right fit for your lifestyle, providing the extra help you need to make the changes you desire.

A New Option

Enabling you



to



live fully

Unlike other treatments, vBloc Therapy does not prevent nutrient absorption or alter your anatomy. Because the therapy directly targets your source of hunger, losing weight does not require you to change the foods you eat.

Choosing vBloc means you do not have to avoid food groups or types.

Acting as a long-term support partner, vBloc is an active treatment that works throughout your day. Patients report that it helps them to eat less because they feel full longer.

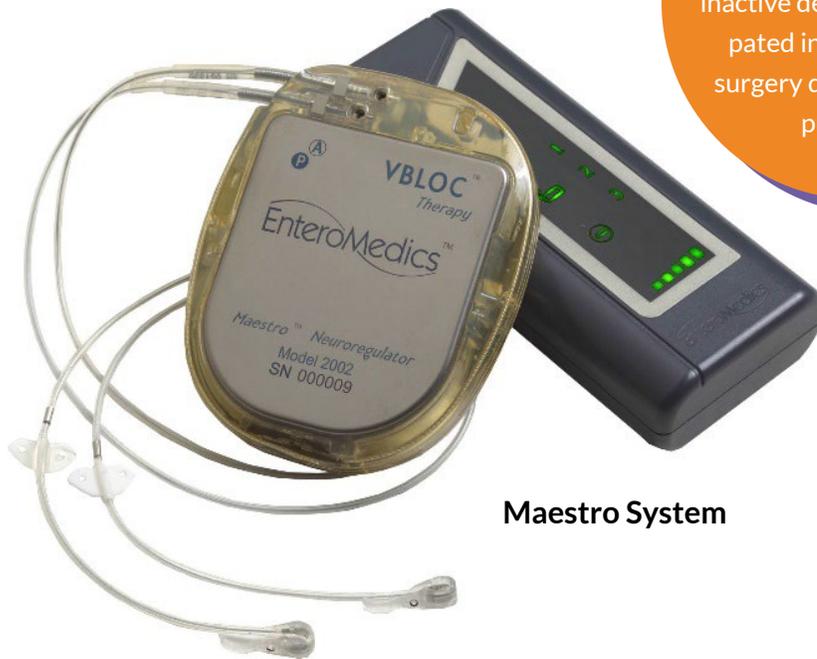
vBloc Therapy is completely reversible and can be deactivated or removed at any time.

Many vBloc patients are finding that their decision to take action results in the ability to revitalize their health and fully engage in all that life has to offer.

vBloc Neurometabolic Therapy is a totally new weight loss option. When diet and exercise haven't helped you meet your goals, this first-of-its-kind treatment could be an effective weight loss alternative.

vBloc Therapy is delivered through an implantable device called the **Maestro System**. This device intermittently blocks the signals between your stomach and your brain. Many individuals using vBloc Therapy report better control of hunger - this may provide an active tool to help you make healthier choices.

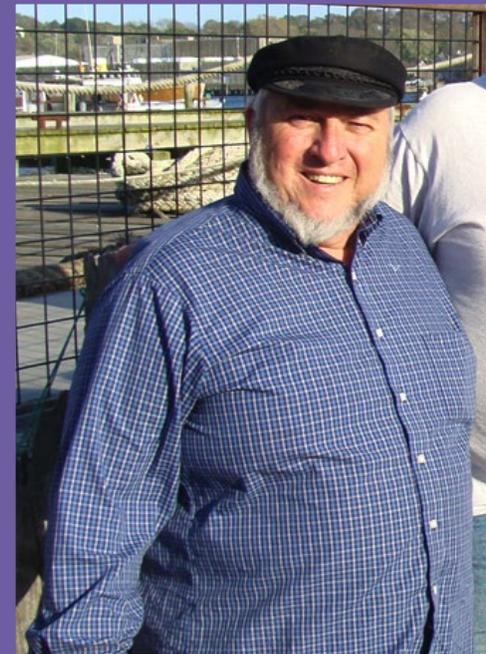
People who used vBloc Therapy lost more excess weight than those with an inactive device who participated in the same post surgery diet and exercise program.⁶



Maestro System

On average, people who received vBloc Therapy for 12 hours per day lost 28% of their excess weight, in one year.⁷

Meet Mike, before vBloc Therapy in 2011



Q: What was life like before you decided to take action?

A: Life was challenging. It was becoming harder to do the everyday things like taking a walk without becoming tired.

Q: What made you decide to commit to a new path?

A: There were signs that my health was starting to suffer because of my weight. I knew it was time to make some life changes so that I could get back to the things I loved like boating.

Health Condition	Before Therapy	3 Years After Implant
Weight	291 lbs	221 lbs
Cholesterol	217 mg/dl	178 mg/dl
Blood Pressure	150/95	121/74
CRP (Heart Disease Risk)	4.99	1.07

Patient-reported health data.

Mike, after vBloc Therapy in 2015

Q: What differences has that choice made in your life?

A: These days, I'm able to enjoy the activities I like with my family and friends. My passion is to be out on the water on a boat, and I don't have to worry about getting tired anymore and not being able to make it through the day. I just don't feel like I'm missing out on life anymore!

Q: What does it mean to you?

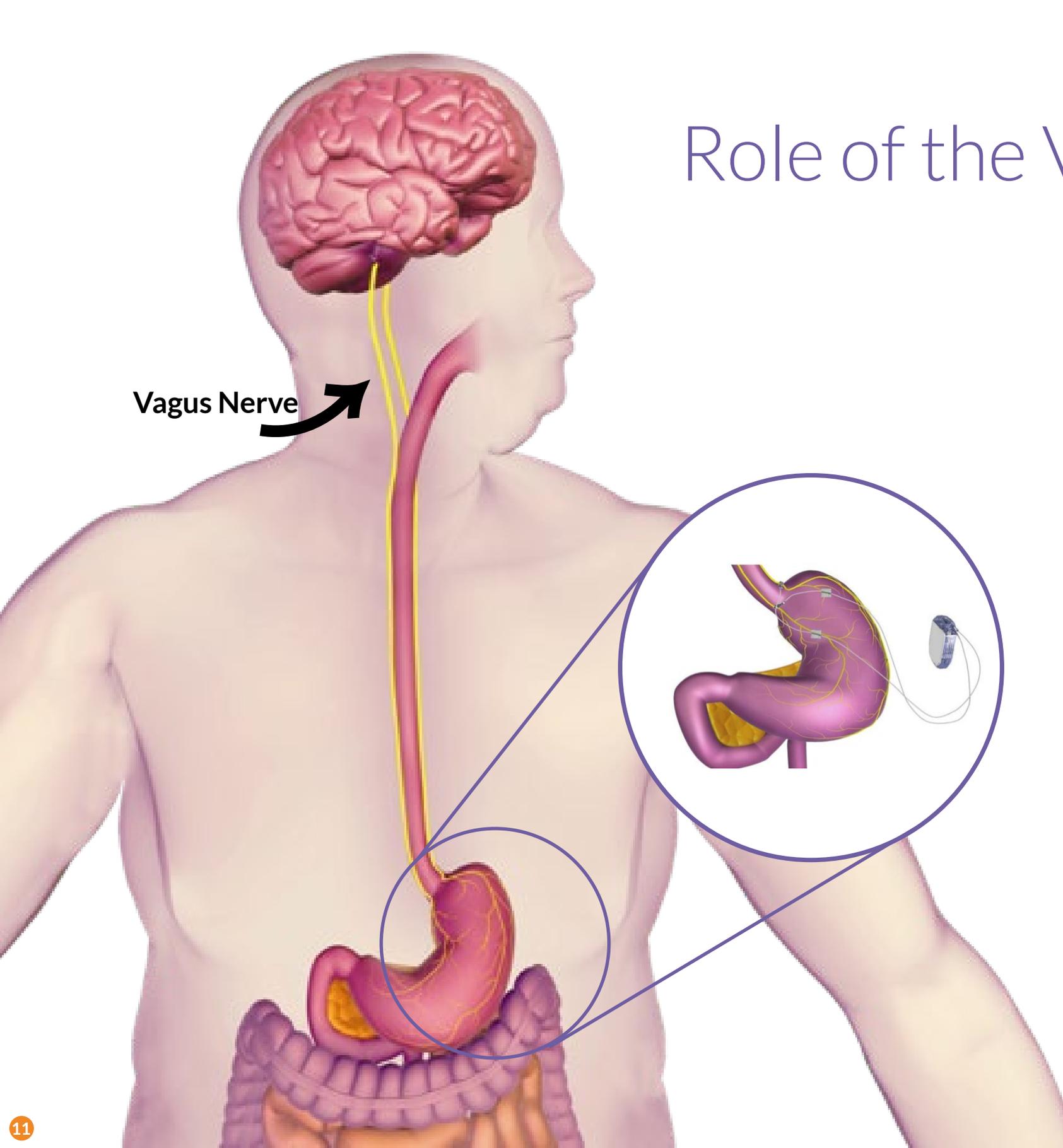
A: Today, I feel healthier than I have in years, and many of my old friends stop to ask me how I lost the weight. Sharing my experience with vBloc brings me a lot of happiness because I feel like I can help others with my story.

Individual results may vary. The most common adverse events were surgical pain, nausea and heartburn.



Role of the Vagus Nerve

Vagus Nerve



How Maestro Works

The Vagus Nerve sends signals between the brain and the stomach that control the sensation of hunger. vBloc Therapy intermittently blocks those signals. Many patients who have used vBloc Therapy report feeling full longer.

How Maestro is placed

The Maestro System is implanted by a metabolic & bariatric surgeon just under the skin, typically during an outpatient procedure that can be performed as a “same day” surgery.

The procedure is performed laparoscopically, using up to 5 small incisions in the abdomen to implant the leads. The neuroregulator is implanted under the skin.

During this procedure, the surgeon will also connect the two device wires around your Vagus Nerve in the area just above your stomach.

You will not be awake during your procedure, and your hospital or clinic stay will vary.

Your New Life

What to expect after your procedure

Typically, patients are able to go back to work within a few days. Your metabolic & bariatric surgical team will support you with:

- Follow-up office visits, especially in the first year of therapy;
- Education on how to use and maintain your Maestro System.

The professional healthcare team that works with you includes clinical nurses, coordinators, nutritionists, and behavioral specialists who are experienced in working closely to support people as they lose weight.

They will help guide you on your journey and be your first point of contact for any questions or concerns.

Usually, your device will be programmed to deliver at least 12 hours of therapy each day, while you are awake. Some programming adjustments may be needed to optimize your therapy. For optimal performance, it is important to routinely recharge the Maestro device. You will learn to charge and manage the battery life of your neuroregulator.

You may feel full:

- Longer
- After eating smaller portions.

As a tool, the Maestro System will be the most effective when used in combination with healthy eating habits and physical activity.

Your surgeon will provide specific recovery instructions and let you know when to return to the office to program your vBloc Therapy delivery.



Transmit coil



Mobile charger



Neuroregulator



Surgical Considerations

Who is not a candidate?

vBloc should not be used for patients with:

Cirrhosis of the liver (disease of the liver) .

Portal Hypertension (high blood pressure in the veins of liver).

Esophageal Varices (enlarged veins at bottom of esophagus).

Significant Hiatal Hernia.

Have another permanently implanted, electrically powered device (e.g., heart pacemaker, implanted defibrillator or neurostimulator).

Planned MRI or diathermy.

Patients at high risk for surgical complications.



Additional Considerations

Pregnancy: Safety and effectiveness of the Maestro System has not been established for use during pregnancy. If you become pregnant, your surgeon or nurse may choose to turn off your neuroregulator.

Improved health conditions

Feeling healthy is important to helping you focus on the things you love. The weight loss vBloc Therapy provides may lead to improvements in cholesterol levels, blood pressure, and glucose levels.

In one study, patients on vBloc Therapy lost weight and saw improvements in their type 2 diabetes and hypertension measures.⁹

Lower complication rate than other surgical devices

vBloc Therapy has been demonstrated to have a lower complication rate than those reported for traditional weight loss device procedures.⁸

If you're concerned about the complications that come with traditional weight loss surgery, vBloc may be the right alternative for you, giving you peace of mind while helping you achieve your health-related goals.

vBloc Therapy can provide you with safe, meaningful weight loss.

“What you do today can improve all your tomorrows.”

- Ralph Marston -

The Patient Journey

Am I a candidate?

You may be a candidate for vBloc Therapy if you meet these criteria:

1. BMI of 35 to 39.9 with a health-related condition such as:
 - Type 2 Diabetes
 - Sleep Apnea
 - High Blood Pressure
 - High Cholesterol
2. BMI of 40 to 45
3. Been unable to maintain weight loss through diet and exercise in a supervised program within the last 5 years
4. Be at least 18 years of age

Interested in financing options?



Financial barriers should not stand in the way of achieving your health goals. Lenders can provide financing that you can use to pay for the procedure.

When you speak with a lender, be sure to ask them to explain a range of solutions, such as flexible monthly payments and reasonable interest rates, secured and unsecured loans, higher approval rates, and quick application and approval processes.

You should also know that weight loss procedures are considered medical expenses by the IRS and may be tax deductible. Consult with your tax advisor to learn more.

**Explore your options
with our partner at:**

www.americanhealthcarelending.com

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Information

Important Safety Information: Talk with your doctor about the full risks and benefits of vBloc Therapy and the Maestro Rechargeable System.

What is the Maestro System Used For: The Maestro System is for use in helping with weight loss in people aged 18 years through age 65 who are obese, with a Body Mass Index (BMI) of 40 to 45 kg/m², or a BMI of 35 to 39.9 kg/m² with a related health condition such as high blood pressure or high cholesterol levels. Individuals should have first tried to lose weight by diet and exercise in a supervised program within the last 5 years before receiving the Maestro System.

Contraindications: You should not have an implanted Maestro Rechargeable System if you have cirrhosis (a disease of the liver), portal hypertension (high blood pressure in the veins of the liver), esophageal varices (enlarged veins at the lower end of the tube between the mouth and the stomach) or an uncorrectable, clinically significant hiatal hernia (a condition where part of the stomach pushes up or through the diaphragm where the tube between the mouth and the stomach passes through to connect to the stomach); patients for whom magnetic resonance imaging (a type of medical imaging that uses strong magnets and pulses of radio waves) is planned; patients at high risk for surgical complications; patients who have a permanently implanted, electrical-powered medical device; or patients for whom diathermy (a type of medical procedure that heats and destroys tissue) is planned.

Warnings/Precautions/Adverse Events: Seek guidance from your doctor before you undergo a medical or surgical procedure, as interaction of the Maestro System with certain medical therapies, procedures or other implanted or body worn medical devices may harm you, cause damage to the implanted device or may turn therapy off. These may include, but are not limited to, lithotripsy (use of high energy shock waves to break up stones), radiation, mono polar electrosurgical instruments (a type of surgical instrument), positron emission tomography scans (a type of medical imaging), radiofrequency ablation (a method of destroying tissue used during surgery), heart pacemakers, defibrillators, neurostimulators, and insulin pumps. Turning, twisting, or manipulating the implanted components may damage the nerves or implanted device. System components must be kept charged to prevent damage, which may require additional surgery to replace the implanted device. The neuroregulator should be fully charged prior to turning it off. The Maestro System is MR Unsafe, including for patients in which the Maestro System was explanted and not all components were removed. Portable outlets or extension cords should not be connected to the AC recharger. Do not immerse external system components in fluid. Keep strong magnets at least 6 inches away from the implanted device. The Maestro Rechargeable System may activate metal detectors or other security systems. Strong magnetic fields systems that emit radio frequency signals may interfere with the function of the Maestro System. The neuroregulator and mobile charger should be turned off near metal detectors, other security systems, strong magnetic fields and radio frequency emitting systems. The mobile charger should be turned off while aboard aircraft. Infection at the implant site may occur and could require use of antibiotic medications, surgery, or device explant. Do not modify any components of the system. Safety and effectiveness of the Maestro Rechargeable System has not been established for use within a hyperbaric chamber (chamber designed to supply oxygen at a higher than normal air pressure), with external defibrillation, during pregnancy, or for use in patients under 18 years of age. The capacity of the rechargeable neuroregulator battery will diminish over time, requiring longer or more frequent charging. Do not operate the system in flammable environments, or if components appear damaged. Do not cover the mobile charger when in use to prevent overheating and damage. You may not be able to operate the Maestro System if you have impaired vision. Make sure all of your health care providers are aware that you have an implanted Maestro System. The most common related adverse events that were experienced during clinical study of the Maestro Rechargeable System included pain, heartburn, nausea, difficulty swallowing, belching, wound redness or irritation, and constipation.

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- 5 Caille E, Rodriguez C, Walker-Thurmond K. Overweight, obesity, mortality from cancer in a prospectively studied cohort of adults. *NEJM* 2003; 348(17):1625-38.
- 6 Patients in the control (Sham) arm of the ReCharge study participated in the same diet and exercise program as the patients receiving the active Maestro system, but lost significantly less weight.
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- 9 Shikora S, et al. Vagal Blocking Improves Glycemic Control and Elevated Blood Pressure in Obese Subjects with Type 2 Diabetes Mellitus. *Journal of Obesity*, 2013. <http://dx.doi.org/10.1155/2013/245683>

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Conversations at “**EnteroMedics**” on **Twitter** and **Facebook** for regular updates and information about future events.



Regulatory Status

The Maestro System, delivering vBloc Therapy, is FDA approved for weight loss in adults with a Body Mass Index of 40-45 kg/m² or 35-39.9 kg/m² (with a related health condition). Individuals should have been unable to maintain weight loss by diet and exercise in a supervised program within the last 5 years before receiving the Maestro System.

Questions?

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