

# Patient Instructions

The following information should be provided to patients who are implanted with the BAROSTIM NEO System.

## POST OPERATIVE WOUND CARE

- Wound dressing should remain in place until instructed by your doctor
- Care should be taken when bathing to avoid pressing on the wound or the device
- DO NOT touch the surgical sites
- DO NOT lay on or push on the IPG (Implanted pulse generator - the device implanted in the chest)
- DO NOT manipulate the IPG or lead (device implanted in the neck) through the skin as it may damage the device, the tissue surrounding the device, or cause the lead to be disconnected from the IPG
- Strenuous activity should be restricted for 72 hours.
- Fever, redness, discharge or severe pain from the surgical sites after 3 days may be a sign of infection
  - If you have any of the symptoms above, DO NOT attempt to treat at home, contact your doctor as soon as possible
  - Infections caught early can generally be treated with antibiotics
  - More serious infections may require removal of the IPG and/or the lead

## GENERAL INFORMATION

- Continue medications, diet, exercise, and lifestyle modification as directed
- Carry Patient Identification card and present at security screenings
- IPG battery will deplete over time requiring replacement
- Follow-up doctor visits are required to assure proper system operation and response to therapy
- Contact your doctor immediately for:
  - Stimulation (tingling, twitching, difficulty speaking or swallowing)
  - Dizziness, chest pain, breathing problems, swelling of legs
  - Blood pressure or heart rate are unusually low

## WARNINGS / PRECAUTIONS

- Contact your doctor if you will be having a medical procedure:
  - Procedures such as electrocautery, therapeutic radiation, lithotripsy procedures, and external defibrillation may cause damage to the IPG
- To avoid temporarily stopping therapy, stay at least 15 cm (6 inches) away from devices with strong electrical or magnetic fields such as:
  - Strong magnets
  - Loudspeaker magnets
  - Electronic Article Surveillance (EAS) system (anti-theft detectors)
  - Arc welders
  - Induction furnaces
- Contact your doctor for guidance before entering environments which could adversely affect the operation of the IPG, including areas where warning notices are posted to prevent entry by patients with a pacemaker.
- DO NOT manipulate the IPG through the skin - this may damage or disconnect the lead from the pulse generator.
- DO NOT manipulate the lead through the skin - this may damage or disconnect the lead from the IPG and/or possibly cause damage to the carotid sinus.

Full Instructions for Use and a current copy of the information in this document is available at:  
[www.cvr.com/ifu](http://www.cvr.com/ifu)



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# The BAROSTIM NEO® System for the Treatment of Systolic Heart Failure

## Patient Information Guide

CVRx

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## 1. INTRODUCTION

You may have questions if you or a member of your family has been diagnosed with heart failure.

This guide is designed to help you learn more about heart failure in general and, more specifically, about systolic heart failure, including some of the risk factors that can cause this condition. This guide also explains some of the potential treatment options, including a treatment called BAROSTIM THERAPY®, delivered by an implantable device called the BAROSTIM NEO® System.

As with any medical condition, your doctor and healthcare team are the best sources of information. Your doctor will do a thorough examination to determine which treatment(s) are best suited to your needs and your specific medical condition(s). BAROSTIM THERAPY may be just one of these treatment options.

At the end of this guide, you will find a glossary of medical terms and space where you can make some notes. The terms that are defined in the glossary will be bolded throughout this guide. You may find it helpful to review these terms before reading this guide. It is also recommended to write down any questions you may have so that you can discuss them with your doctor and healthcare team.

The information in this guide does not replace any information provided to you by your doctor and is not intended to diagnose any medical condition.

## 2. ABOUT HEART FAILURE

### WHAT IS IT AND WHAT ARE THE MAIN TYPES OF HEART FAILURE?

The heart has four chambers, one of them, the **left ventricle**, fills with oxygenated blood coming from the lungs and pumps it out to the rest of the body. This occurs in two distinct phases. In the first phase, the left ventricle relaxes and fills with blood. This phase is called diastole (dye-ah-stolee). In the second phase, the left ventricle contracts and pumps blood out to the body. This phase is called systole (sis-toll-ee).

Heart failure, also known as **congestive heart failure (CHF)**, occurs when the left ventricle is not able to fill or pump appropriately to supply enough blood to meet the body's needs.

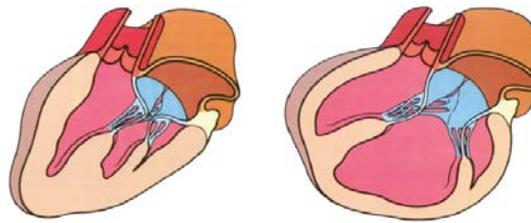
- When the left ventricle is too stiff to relax appropriately and fill with enough blood, the condition is called **diastolic heart failure or heart failure with preserved ejection fraction**.
- When the left ventricle is too weak to pump enough blood out to the body, the condition is called **systolic heart failure or heart failure with reduced ejection fraction**.

**Ejection fraction (EF)** is a measurement of the percentage of blood leaving your left ventricle each time it contracts. EFs of 50% or higher are considered normal. The most common method of assessing EF is an echocardiogram. Other methods include: cardiac catheterization, magnetic resonance imaging (MRI), computerized tomography (CT scan) and nuclear medicine scanning.

Note: The focus of this guide is on systolic heart failure, also known as heart failure with reduced ejection fraction. Therefore, going forward, whenever the terms “heart failure” or “CHF” are used, they refer only to this condition.

### WHAT CAUSES IT AND HOW CAN IT BE PREVENTED?

The most common cause of CHF is **coronary artery disease (CAD)**. This condition results in the buildup of fatty deposits (plaque) in your arteries, which may reduce blood flow to the heart and even cause a **heart attack** (a form of CAD that occurs suddenly). The inadequate blood supply to the heart, also known as **ischemia**, caused by coronary artery disease and heart attacks can damage the left ventricle causing it to become enlarged and weak.



**Normal Heart:**  
The heart squeezes, pumping blood out to the body.

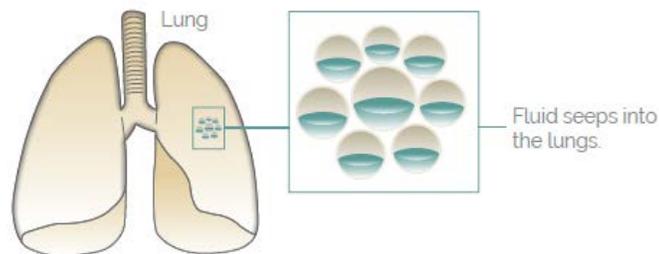
**Heart Failure:**  
The heart becomes enlarged and cannot squeeze strongly. This means it cannot pump enough blood around the body.

The best way to prevent heart failure is to prevent coronary artery disease. A few ways to reduce your risk of developing or exacerbating heart failure are:

- Eat a healthy, balanced diet
- Exercise regularly
- Don't smoke
- Keep your blood pressure under control
- Keep your diabetes under control

### COMMON SIGNS AND SYMPTOMS

The most severe manifestation of heart failure is called **pulmonary edema**. It occurs when the heart cannot pump out the oxygenated blood it receives from the lungs fast enough, which results in excess fluid building-up in the lungs and making it hard to breathe.



Pulmonary edema that occurs suddenly, acute pulmonary edema, is a medical emergency requiring immediate care. The signs and symptoms of acute pulmonary edema are:

- Extreme shortness of breath or difficulty breathing (dyspnea) that worsens with activity or when lying down
- A feeling of suffocating or drowning that worsens when lying down
- Wheezing or gasping for breath
- Cold, clammy skin
- Anxiety, restlessness or a sense of apprehension
- A cough that produces frothy sputum that may be tinged with blood
- Blue-tinged lips
- A rapid, irregular heartbeat (palpitations)

Long-term (chronic) pulmonary edema has the following signs and symptoms:

- Difficulty breathing with exertion
- Difficulty breathing when you're lying flat
- Wheezing
- Awakening at night with a cough or breathless feeling that may be relieved by sitting up
- Rapid weight gain
- Swelling in your lower extremities
- Fatigue



### 3. HOW IS HEART FAILURE TREATED?

Although heart failure can sometimes be reversed, as is the case when valve repair surgery is an option, it is most often an irreversible chronic disease requiring lifelong management. With proper treatment, signs and symptoms of heart failure can improve, and the heart sometimes becomes stronger. Treatment may help you live longer and reduce your chance of dying.<sup>1</sup>

#### MEDICATIONS

Doctors usually treat heart failure with a combination of medications. Some of the medications most often prescribed by doctors are:

- **Diuretics.** Also known as water pills, they make you urinate more frequently and keep fluid from collecting in your body. Diuretics, such as furosemide, also decrease fluid in your lungs so you can breathe better.
- **Aldosterone antagonists.** These are potassium-sparing diuretics and include spironolactone and eplerenone.
- **Beta blockers.** These drugs slow your heart rate and reduce blood pressure, decreasing workload on the heart. Examples include carvedilol, metoprolol and bisoprolol.
- **Angiotensin-converting enzyme (ACE) inhibitors.** ACE inhibitors are vasodilators, they widen blood vessels to lower blood pressure, improve blood flow and decrease the workload on the heart. Some examples are enalapril, lisinopril and captopril.
- **Angiotensin II receptor blockers.** This category includes losartan and valsartan and has the similar benefits as ACE inhibitors. They are an alternative for people who can't tolerate ACE inhibitors.
- **Angiotensin Receptor-Neprylysin Inhibitor (ARNI) –** This new drug class has two main effects. The first is similar to the effect of ACEs and ARBs. The second, strengthens a hormonal system regulated by the heart muscle itself, which releases Brain Natriuretic Peptide (BNP). This hormone has multiple effects such as vasodilatation of blood vessels and increased fluid elimination by the kidneys. ARNIs are an option for those patients who continue having symptoms despite otherwise optimal treatment. Sacubitril Valsartan is the only drug currently in this category.

#### MEDICAL DEVICES

- **Implantable Cardioverter-Defibrillators (ICDs).** An ICD is an implantable device, similar to a pacemaker that monitors heart rhythm. If the heart starts beating at a dangerous rhythm, or if it stops beating, the ICD shocks it back into normal rhythm, potentially saving your life. It is indicated for people with high risk of sudden cardiac death. Most people indicated for ICDs have heart failure with ejection fractions of 35% or less.

- Cardiac Resynchronization Therapy (CRT), or biventricular pacing. A pacemaker that sends timed electrical impulses to both ventricles of the heart so that they pump in a more efficient and coordinated manner. Since an ejection fraction of 35% or less is required to be indicated for this device, it is often combined with an ICD. Patients with a wide QRS Complex are typically felt to benefit with these types of devices.<sup>2 3</sup>
- BAROSTIM NEO – A new implantable device approved for people with ejection fractions of 35% or less, for whom CRT is not an option. The BAROSTIM NEO System has been shown to reduce heart failure symptoms and improve quality of life in this patient population, who until now had limited treatment options.
- Ventricular Assist Devices (VADs). A VAD is a mechanical pump with both implantable and external components. It assists the left ventricle in pumping oxygenated blood out to the rest of the body. Initially, doctors only used VAD to help keep heart transplant candidates alive while they waited for a donor heart. The main reasons for this cautious approach to VAD implantation has been the high risk associated with VAD, the negative impact on quality of life and the high infection rates associated with an implanted device with external components, and its very high cost.<sup>4</sup> Recently though, due to the insufficient supply of donor hearts, VADs are sometimes also used as an alternative to transplantation.

#### **HEART TRANSPLANT**

Some people have such severe heart failure that medications and medical devices are not enough, they need to have their heart replaced with a healthy donor heart.

#### **4. WHO CAN GET THE BAROSTIM NEO SYSTEM AND WHY IS IT NEEDED?**

The BAROSTIM NEO System is for people with heart failure who meet the following criteria:

1. Are optimally medicated for their heart failure as determined by a medical doctor trained in the management of heart failure.
2. Despite being optimally medicated, their quality of life is significantly impacted by symptoms like breathlessness, chronic fatigue and/or swelling.
3. Have an ejection fraction of 35% or less.
4. Are not candidates for cardiac resynchronization therapy (CRT).

Despite advances in heart failure medications, millions of optimally medicated people with ejection fractions of 35% or less continue to experience debilitating symptoms. Many of them are not candidates for cardiac resynchronization therapy (CRT), which, until recently, was the only approved implantable medical device therapy to treat the symptoms of heart failure.

For this reason, CVRx Inc. developed the BAROSTIM NEO System, which has been shown to reduce the symptoms of heart failure in people who meet the above criteria.

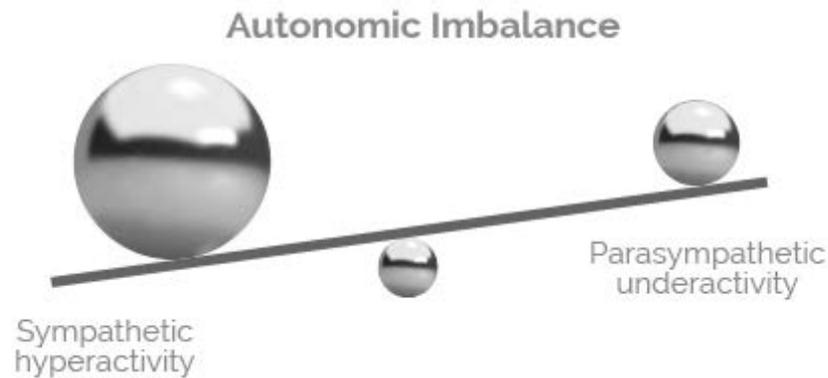
#### **5. HOW DOES THE BAROSTIM NEO SYSTEM WORK?**

##### **THE AUTONOMIC NERVOUS SYSTEM IS OUT OF BALANCE IN HEART FAILURE**

The brain controls the function of internal organs in your body, including those that make up the cardiovascular system, like the heart, blood vessels and kidneys through the **autonomic nervous system (ANS)**. The ANS works without you having to think about it and has two main divisions:

- **Sympathetic nervous system**– Responsible for the “fight-flight” reflex, it stimulates organs for increased physical activity.
- **Parasympathetic nervous system** – Relaxes organs and helps promote digestion.

In heart failure, there is an imbalance between these two divisions of the autonomic nervous system. The sympathetic system is overactive, and the parasympathetic system is suppressed. This imbalance is harmful to the heart.



### **BAROSTIM THERAPY IMPROVES AUTONOMIC NERVOUS SYSTEM BALANCE**

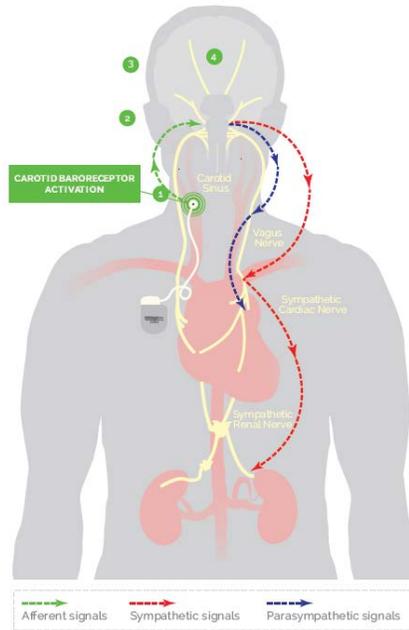
Special cells in the neck called **baroreceptors** (ba-roh-ree-sep-tors) sense how blood is flowing through the **carotid arteries** and relay this information to the brain through nerves in the form of electrical impulses. The brain interprets the information in these electrical impulses and in response balances the parasympathetic and sympathetic nervous systems to adjust the behavior of the heart, kidneys and arteries, regulating blood flow as needed.

The BAROSTIM NEO System is designed to balance the autonomic nervous system, the body's natural mechanism to adjust the behavior of the cardiovascular system, to improve blood flow and reduce symptoms in people with heart failure. It achieves this by delivering electrical impulses to the baroreceptors on one carotid artery. Studies have shown that the brain responds to these impulses by reducing sympathetic and increasing parasympathetic nervous activity, thus improving balance of the ANS.<sup>5,6</sup>

A balanced autonomic nervous system improves blood flow, reduces cardiac workload and is better for the heart. Studies have shown that people with heart failure implanted with the BAROSTIM NEO System experienced significantly better heart function and quality of life.<sup>6,7,8</sup>

**BAROSTIM NEO® IS DESIGNED TO USE A 4-STEP PROCESS TO MANAGE HEART FAILURE:**

- 1 BAROSTIM NEO sends signals via a wire (lead) to special cells in the carotid artery
- 2 These signals activate the body's baroreceptors
- 3 Baroreceptors send signals to the brain
- 4 The brain sends signals to the heart, kidneys and blood vessels that may improve heart function and reduce heart failure symptoms



## 6. HOW THE BAROSTIM NEO SYSTEM IS IMPLANTED AND WHAT TO EXPECT



The BAROSTIM NEO System requires the implantation of the following components:

- **Implantable Pulse Generator (IPG):** An IPG is implanted under the skin, below the collar bone, delivering electrical stimulation to the baroreceptors through the lead.
- **Carotid Sinus Lead:** A 2mm electrode is attached to the carotid artery in the neck (usually the right artery) and is then connected to the IPG.

Surgery takes about 1 hour and is performed in an outpatient setting under general anesthesia. Usually, you may go home the same day. Rest is recommended for a few of days to allow wounds to heal. Activities requiring extreme movements of the neck, such as golf or swimming, are not recommended for three weeks after surgery, otherwise you are encouraged to continue your normal daily activities.

For the first few months after surgery, your medical team will gradually adjust your BAROSTIM NEO System parameters on a weekly or bi-weekly basis using a wireless programmer. In three months, you may experience improvements in quality of life and ability to exercise.<sup>7,8</sup>

## 7. WHAT ARE THE BENEFITS ASSOCIATED WITH THE BAROSTIM NEO SYSTEM?<sup>6,7</sup>

- Reduces symptoms and improves quality of life,
- Improves physical function and capacity to exercise.

## 8. WHAT ARE THE RISKS ASSOCIATED WITH THE BAROSTIM NEO SYSTEM?

The type and frequency of complications reported in studies from implanting the BAROSTIM NEO System were similar to those from implanting a typical pacemaker.<sup>7,8</sup> However, people implanted with the BAROSTIM NEO System are anticipated to be exposed to operative and post-operative risks similar to related surgical procedures involving the neck as well as the chest. The potential hazards may include, but are not limited to:

- Wound Complication – including hematoma (i.e. bruising and/or swelling)
- Infection – the need for antibiotics or possible removal of the BAROSTIM NEO System
- Need for reoperation – operation to explant/replace IPG or CSLs due to tissue damage, infection, tissue erosion, IPG migration, and/or device failure
- Hypotension – a decrease in systolic and diastolic blood pressure below normal levels that may result in dizziness, fainting, and/or falls
- Nerve Damage/
- Surgical or anesthetic complications
- Allergic Reaction
- Cardiac Arrhythmias
- Injury to baroreceptors – an injury that results in baroreflex failure
- Arterial damage – including carotid artery rupture or hemorrhage (sudden and significant blood loss at a site of blood vessel rupture that may require reoperation or transfusion)
- Exacerbation of Heart Failure
- Stroke or Transient Ischemic Attack (TIA) – neurological deficits
- Worsening of chronic kidney disease
- Death

For a list of all potential benefits and risks go to [www.cvr.com/benefit-risk-analysis/](http://www.cvr.com/benefit-risk-analysis/)

## 9. GLOSSARY

- **Autonomic nervous system (ANS)** - the part of the nervous system responsible for control of the bodily functions not consciously directed, such as breathing, the heartbeat, and digestive processes.
- **Baroreceptors** - Special cells that sense blood flow in arteries and send this information via nerves to the brain in the form of electrical impulses.
- **Carotid arteries** – The carotid arteries are major blood vessels in the neck that supply blood to the brain, neck, and face. There are two carotid arteries, one on the right and one on the left.
- **Congestive heart failure (CHF)** - a weakness of the heart that leads to a buildup of fluid in the lungs and surrounding body tissues.
- **Coronary artery disease (CAD)** – A condition results in the buildup of fatty deposits (plaque) in your arteries, which may reduce blood flow to the heart and even cause a heart attack.
- **Diastolic heart failure** – Type of heart failure in which the left ventricle is too stiff to relax appropriately and fill with enough blood, also known as heart failure with preserved ejection fraction.
- **Ejection fraction** - A measurement of the percentage of blood leaving your left ventricle each time it contracts.

- **Heart attack** – A form of CAD that occurs suddenly.
- **Ischemia** - an inadequate blood supply to an organ or part of the body.
- **Left bundle branch block** - A cardiac conduction abnormality seen on the electrocardiogram (ECG). In this condition, activation of the left ventricle of the heart is delayed, which causes the left ventricle to contract later than the right ventricle.
- **Left ventricle** – Chamber of the heart responsible for pumping oxygenated blood coming from the lungs to the rest of the body.
- **Parasympathetic nervous system** - Division of the ANS that relaxes the organs and helps promote digestion.
- **Pulmonary edema** - A severe manifestation of heart failure is pulmonary edema. This occurs when the heart cannot pump out the blood it receives from the lungs fast enough causing a backlog which results in excess fluid building-up in the lungs and making it hard to breath.
- **QRS Complex** - The QRS complex is a name for the combination of three of the graphical deflections seen on a typical electrocardiogram (EKG or ECG).
- **Sympathetic nervous system** – Division of the ANS responsible for the “fight-flight” reflex, prepares the body for increased physical activity
- **Systolic heart failure** – Type of heart failure in which the left ventricle is too weak to pump enough blood out to the body, also known as heart failure with reduced ejection fraction.

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## 11. NOTES

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