Barostim FAQs

# How does Barostim work?

In heart failure, the heart struggles to pump blood effectively. This causes baroreceptors – sensors on the carotid artery – to send fewer signals to the brain. This causes the brain to trigger a stress response to force the heart to work harder, and over time, worsens the symptoms of heart failure.

Barostim is an implantable device that delivers gentle electrical pulses to the baroreceptors. This increases the signals to the brain, which reduces the stress response and improves heart failure symptoms.

# What is unique about Barostim?

Unlike other heart failure device therapies, Barostim contains no hardware in the heart or vasculature. It is a neuromodulation device that uses the power of the brain to rebalance the autonomic nervous system and improve the symptoms of systolic heart failure.

Heart failure is a chronic, progressive condition that often requires lifelong management. Doctors treat heart failure with a combination of medications which have been shown to help improve life expectancy and relieve symptoms of the disease. There are also medical device therapies available depending on the type and class of heart failure a patient has. Despite advancements in heart failure medications, some patients continue to experience symptoms that impact their daily life. Barostim is designed to help patients that despite receiving optimized heart failure medications, their symptoms significantly impact their daily life and reduce the activities they can do.

# What is the baroreflex?

Baroreflex (“BARE-oh-REE-flex”) or baroreceptor reflex are terms used to describe the body's

rapid response system for dealing with changes in the blood flow regulation system.

The human body has its own physiologic mechanisms for sensing changes in blood pressure and other blood flow changes. This natural system is largely located in the brain, as well as the walls of the carotid arteries, which are the vessels in the neck that supply blood to the brain.

Pressure sensors, called baroreceptors, are found on the carotid artery and in the carotid sinus. These sensors measure and report blood flow to the brain, which compares it to the body’s needs. For example, higher blood pressure is good for exercising, while lower blood pressure is appropriate during sleep or other periods of reduced activity.

# Who is a candidate for Barostim?

Patients are eligible for Barostim if they meet the following indications:

* + Diagnosed with NYHA Class III or II (with a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices)\*
	+ Have an ejection fraction (a measure of how much blood your heart pumps) of 35% or less
	+ Have an NT-proBNP < 1,600 pg/mL

\*Guideline directed medical therapy according to AHA/ACC/ESC guidelines

# What are the benefits of Barostim?

Barostim has been shown to safely improve symptoms of heart failure and quality of life for patients. The BeAT-HF pivotal trial results showed Barostim plus heart failure medications provide significant symptom improvements for heart failure patients beyond medications alone, including2:

* + **Exercise capacity:** Barostim patients were able to walk about 60 yards farther in 6 minutes than patients on medications alone2
	+ **Quality of life:** Barostim patients reported almost 3 times greater improvement in quality of life scores than patients on medications alone2
	+ **Functional status:** Two out of three patients with Barostim improved at least one NYHA class in 6 months2
	+ **High response rate:** 94% of Barostim patients had significant improvement in at least one of three measures of symptom improvement3\*

\*quality of life, exercise capacity, or heart failure symptoms

# What does the surgical procedure entail?

Barostim is implanted in a safe surgical procedure where the Carotid Sinus Lead is sutured to the carotid artery and the Barostim NEO implantable pulse generator (IPG) is inserted in a small pocket under the skin, similar to a pacemaker. The procedure typically takes about an hour, and most patients go home the same day. The system contains no hardware in the heart or vasculature.

# References:

1. Lewis G et al. Circ Heart Fail. 2022 May; 15(5):510-524
2. Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13
3. Abraham WT, et al. Symptomatic endpoint responder rates to Barostim Therapy, ESC Abstract 2019