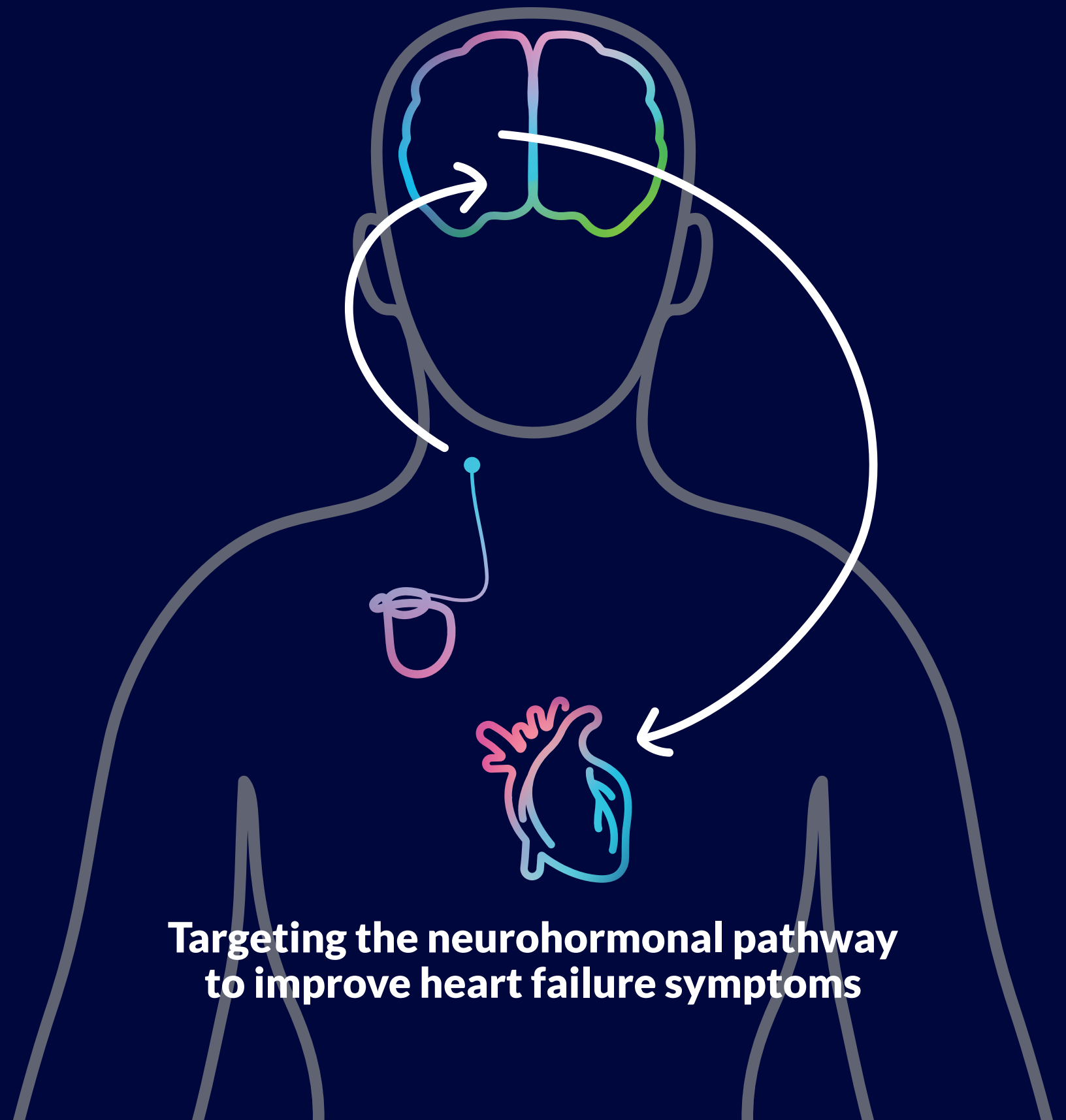
Barostim™

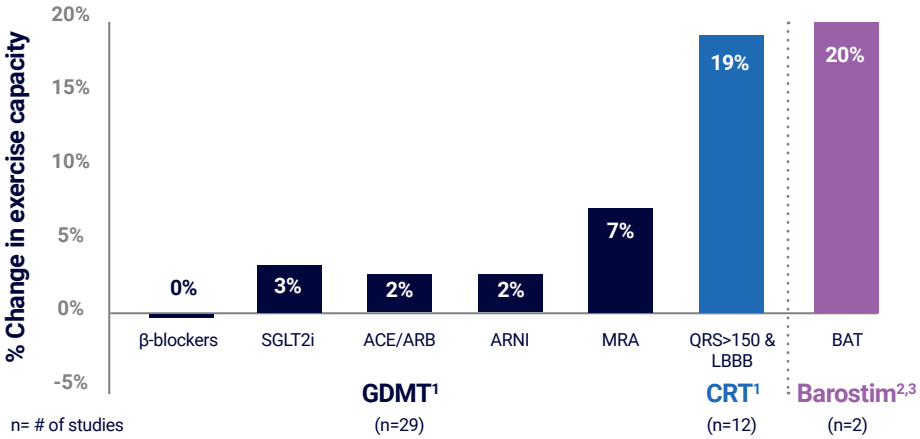
Outsmart the heart

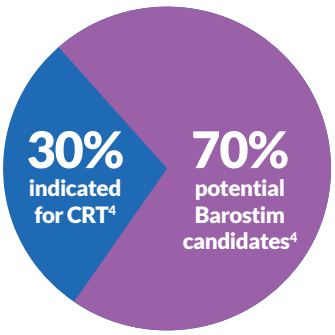


Targeting the neurohormonal pathway to improve heart failure symptoms

Barostim is an option to improve exercise capacity in the 70% of patients not indicated for CRT

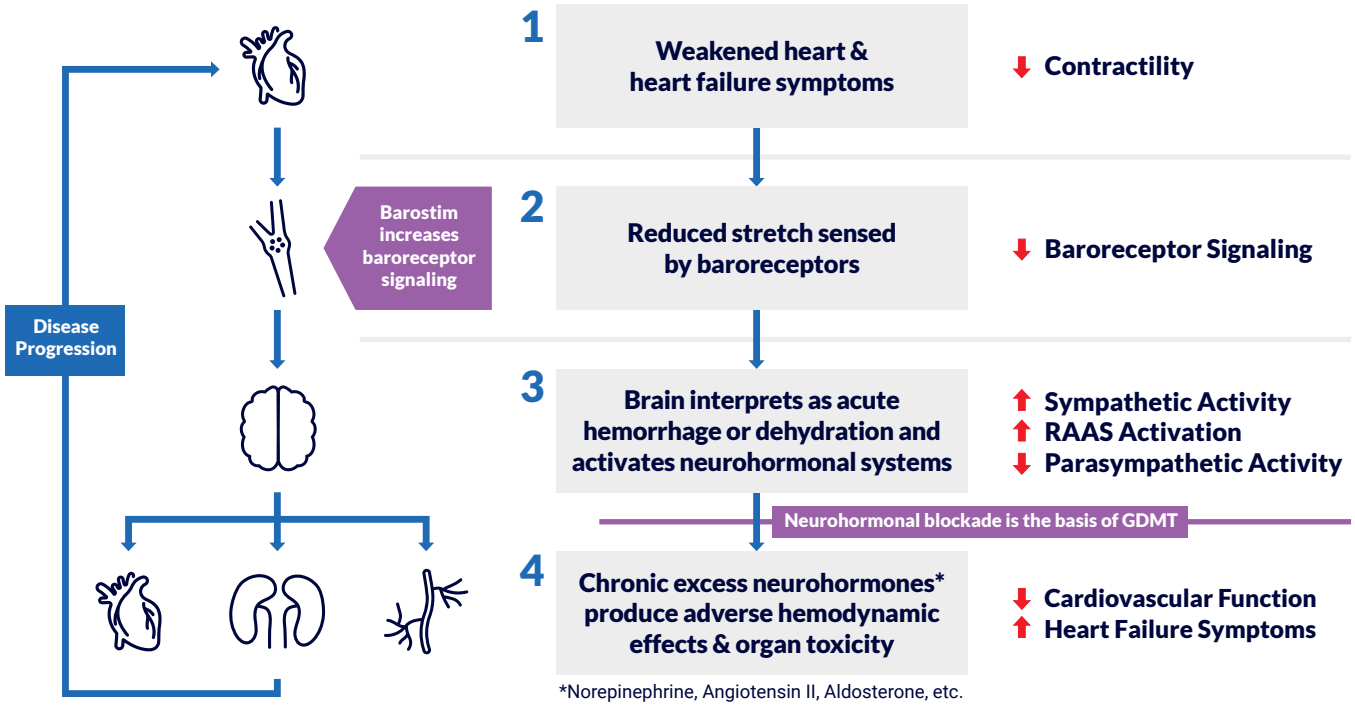
GDMT improves heart failure mortality and morbidity in HFrEF patients, but only shows modest improvement in exercise capacity.[1]





Barostim complements neurohormonal blockade by working earlier in the same pathway[5]

Barostim works by electrically stimulating carotid baroreceptors which increases baroreceptor signaling, rebalances the autonomic nervous system and improves heart failure symptoms.

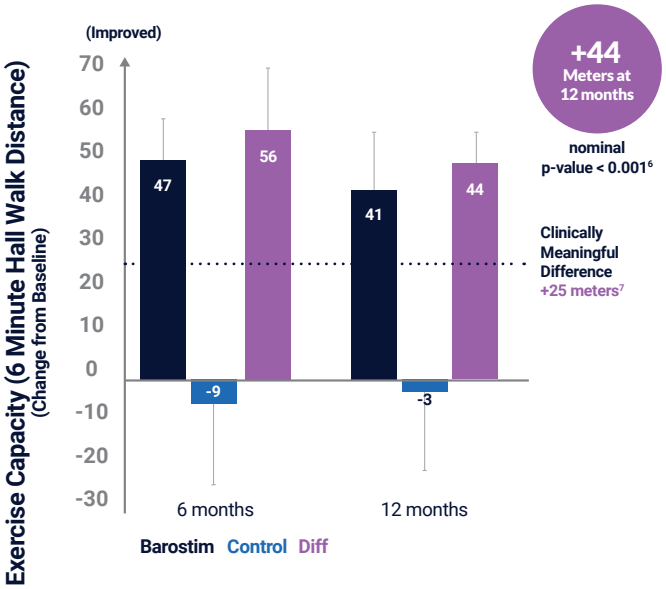


*Norepinephrine, Angiotensin II, Aldosterone, etc.

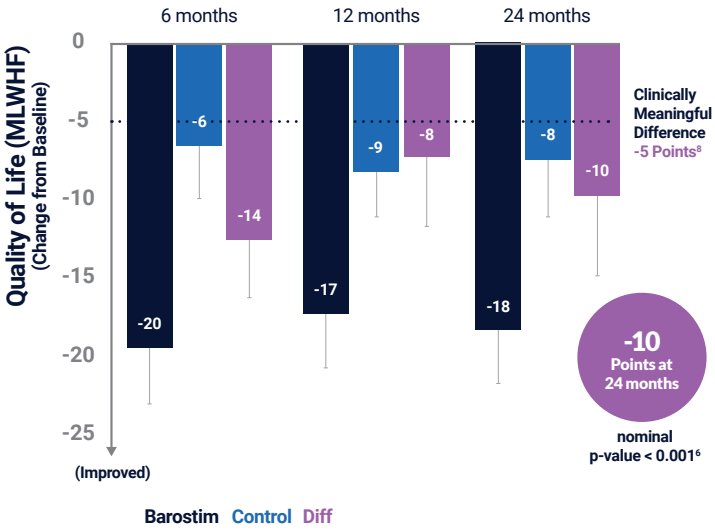
Sustained symptomatic improvements

Barostim plus GDMT provides significant and meaningful improvements for heart failure patients beyond GDMT alone

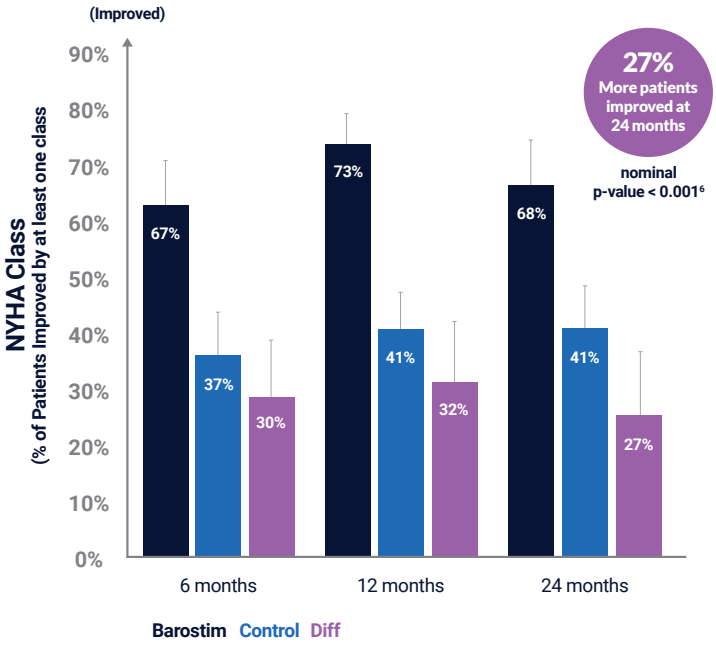
Exercise capacity (6MHW)[6]



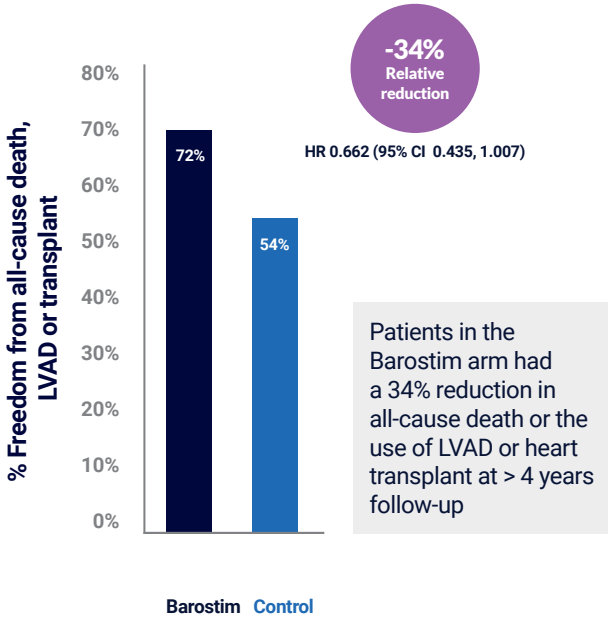
Quality of life (MLWHF)[6]



Functional status (NYHA Class)[6]



Freedom from all-cause death, LVAD or transplant[6]



Patients in the Barostim arm had a 34% reduction in all-cause death or the use of LVAD or heart transplant at > 4 years follow-up

Safe implant procedure

The Barostim System is implanted in a safe surgical procedure where the Carotid Sinus Lead is sutured to the carotid sinus and the Barostim NEO™ IPG is inserted in a standard device pocket.

Procedures are typically performed on an outpatient basis.

The system contains no hardware in the heart or vasculature.

97%

Freedom from major adverse neurological or cardiovascular system or procedure-related event rate in the Barostim arm[6]

Indications

- NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices)*
- LVEF ≤ 35%
- NT-proBNP < 1,600 pg/mL

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

1. Lewis G et al. Circ Heart Fail. 2022 May; 15(5):510-524; 2. Abraham WT, Zile MR et al. JACC: Heart Failure 2015 June; 3(6):487-496; 3. Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13; 4. Heidenreich PA, et al. 2022 Circulation. 2022;145:e895–e1032; Class I and Class IIa recommendations; 5. Adapted from Packer M, The neurohormonal hypothesis: A theory to explain the mechanism of disease progression in heart failure. JACC 1992; Hartupee and Mann, Neurohormonal activation in heart failure with reduced ejection fraction, Nature Reviews in Cardiology 2017; Mann and Felker, Mechanisms and Models in Heart Failure, Circulation 2021; 6. Zile MR, et al. Eur J Heart Fail. 2024 Apr 12; 7. Gremeaux V, et al. Arch Phys Med Rehabil. 2011;92(4):611-619.; 8. Rector TS, et al. J Card Fail. 1995;1(3):201-216.

Important Safety Information

CAUTION: Federal law restricts this device to sale by or on the order of a physician. See Instructions for Use 900133-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events.

Barostim is indicated for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of ≤ 35%, and a NT-proBNP <1600 pg/ml. Barostim delivers Baroreflex Activation Therapy to improve patients' heart failure functional status, six-minute hall walk, and quality of life.

Patients are contraindicated if they have been assessed to have bilateral carotid bifurcations located above the level of the mandible, baroreflex failure or autonomic neuropathy, uncontrolled symptomatic cardiac bradyarrhythmias, carotid atherosclerosis that is determined by ultrasound or angiographic evaluation greater than 50%, ulcerative plaques in the carotid artery as determined by ultrasound or angiographic evaluation, known allergy to silicone or titanium.

Warnings include: only trained physicians may use this system, prescribing physicians should be experienced in the diagnosis and treatment of heart failure and should be familiar with the use of this system, monitor blood pressure and heart rate during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively, post-implantation, program the system to avoid the following: heart rate falls below 50 beats per minute (BPM), or systolic pressure falls below 90 mmHg, or diastolic blood pressure falls below 50 mmHg, or problematic adjacent tissue stimulation is noted, or undesirable interaction indicated by monitoring of any other implanted electrical device (see "Device Interaction Testing" in Section 10), or any other potentially hazardous patient responses are observed. Improper system implantation could result in serious injury or death. Do not use diathermy therapy including shortwave, microwave, or therapeutic ultrasound diathermy on patients implanted with the system. Patients should be counseled to 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 tag deactivators, arc welders, induction furnaces, and other similar electrical or electromechanical devices. This would include not placing items such as earphones in close proximity to the implanted pulse generator. The IPG may affect the operation of other implanted devices such as cardiac defibrillators, pacemakers, or neurological stimulation systems. For patients who currently have an implanted electrical medical device, physicians must verify compatibility with the implanted device during implantation of the system. Contralateral implant of the Barostim NEO IPG may help to reduce potential interactions. Interactions are more likely in devices that contain a sensing function, such as an implantable cardiac defibrillator or pacemaker. If an interaction is observed, the Barostim NEO IPG should be programmed to reduced therapy output settings in order to eliminate the interaction. If necessary, change settings in the other implant only if the changes are not expected to negatively impact its ability to perform its prescribed therapy. During the implant procedure, if device interactions cannot be eliminated the Barostim NEO System should not be implanted.

Precautions include: the system should be implanted and programmed carefully to avoid stimulation of tissues near the electrode or in the area of the IPG pocket. Such extraneous stimulation could involve the following: the regional nerves, causing laryngeal irritation, difficulty swallowing, or dyspnea, the cervical musculature, causing intermittent contraction, skeletal muscles, causing intermittent contraction around the IPG pocket. Proper sterile technique during implantation should be practiced and aggressive pre-operative antibiotics are recommended. Infections related to any implanted device are difficult to treat and may necessitate device explantation. It is anticipated that subjects will be exposed to operative and post-operative risks similar to related surgical procedures involving the neck and/or a pacemaker implant. These risks and potential risks of chronic device based baroreflex activation may include, but are not limited to: stroke, transient ischemic attack (TIA), systemic embolization, surgical or anesthetic complications, infection, wound complications, arterial damage, pain, nerve damage/stimulation, hypotension, hypertensive crisis, respiratory, exacerbation of heart failure, cardiac arrhythmias, tissue erosion/IPG migration, injury to baroreceptors, fibrosis, allergic reaction, general injury to user or patient, need for reoperation, secondary operative procedure, and death. Patients implanted with the system may receive Magnetic Resonance Imaging (MRI) only when all MR Conditional safety parameters are met as listed in the instructions for use.

For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/
For a list of all applicable patents, see www.cvrx.com/patent-marking.

CVRx
Outsmart the heart

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