Barostim™ Product Performance & Patient Experience Report

Overview

CVRx, Inc., is dedicated to partnering with clinicians to advance innovative device therapies that modulate the autonomic nervous system to meaningfully improve the lives of people with chronic disease.

Our pioneering technology, the Barostim System, is the first and only commercially available neuromodulation device indicated to improve symptoms for patients with systolic heart failure. Barostim works by electrically stimulating carotid baroreceptors which increases baroreflex signaling, rebalances the autonomic nervous system, and improves heart failure symptoms. Designed to address a significant unmet need, Barostim was one of the first therapies to receive approval through the Food and Drug Administration's (FDA) "Breakthrough Device" designation in 2019.

CVRx provides performance data for its pulse generators and carotid sinus leads in accordance with applicable FDA and European Union (EU) regulatory expectations. These results are routinely assessed through ongoing regulatory oversight and periodic audits conducted by the FDA and our EU Notified Body.

This Product Performance & Patient Experience Report contains Barostim therapy field performance data from U.S. commercial heart failure implants between 2020 and 2024 and will be updated periodically.

A message from our CEO

"At CVRx, we measure our success by the impact we have on patients. This report reflects our unwavering commitment to quality, transparency, and delivering therapies that help people with heart failure live fuller, more hopeful lives."

- Kevin Hykes, Chief Executive Officer

Commitment to Quality

As a pioneering company in autonomic neuromodulation, our company monitors product performance through rigorous testing, robust clinical evidence, and continuous post-market surveillance. Our commitment to improving patients' lives is built on a foundation of quality.

CVRx Quality Policy

- Deliver high quality and reliable products and services meeting or exceeding our customers' needs.
- Comply with quality and regulatory requirements and maintain an effective quality management system.
- Meet or exceed the high ethical standards expected by our patients, physicians, and the medical device industry.

This policy guides our daily decisions and long-term strategies, ensuring that quality remains at the core of our mission and operations.

Contact Information

For questions about Barostim, product performance data, or to speak with a CVRx representative, please contact us at: 1-763-416-2343 or visit www.barostim.com.

To report a product complaint or adverse event associated with Barostim, please submit details to vigilance@cvrx.com.

Product Performance

The Barostim System has three components: an implantable pulse generator (IPG) implanted in the prepectoral region (similar to a pacemaker), a unipolar carotid sinus lead (CSL) placed on the surface of the carotid artery, and an external programmer used to adjust device settings. CVRx monitors the safety and performance of Barostim through a post-market surveillance monitoring process and the FDA-regulated Medical Device Reporting (MDR) system. These mechanisms enable the collection and evaluation of both general and serious complications to ensure continued device reliability and patient safety.

Freedom from Device Malfunction

Figure 1 displays Barostim System freedom from device malfunction* over a 48-month period. This is estimated using the Kaplan-Meier statistical method and illustrates the probability that an IPG or CSL is free from malfunction for the specified period. The probability of 99.8% at 48 months indicates that through the stated follow up time, the Barostim System had a 0.2% risk of experiencing a malfunction.

***Note:** A device malfunction is defined as an event in which the IPG or CSL did not function as intended. Events due to external factors—such as extraneous stimulation resolved through reprogramming, inadvertent lead damage during procedures, or patient manipulation of the device—are not malfunctions under this definition.

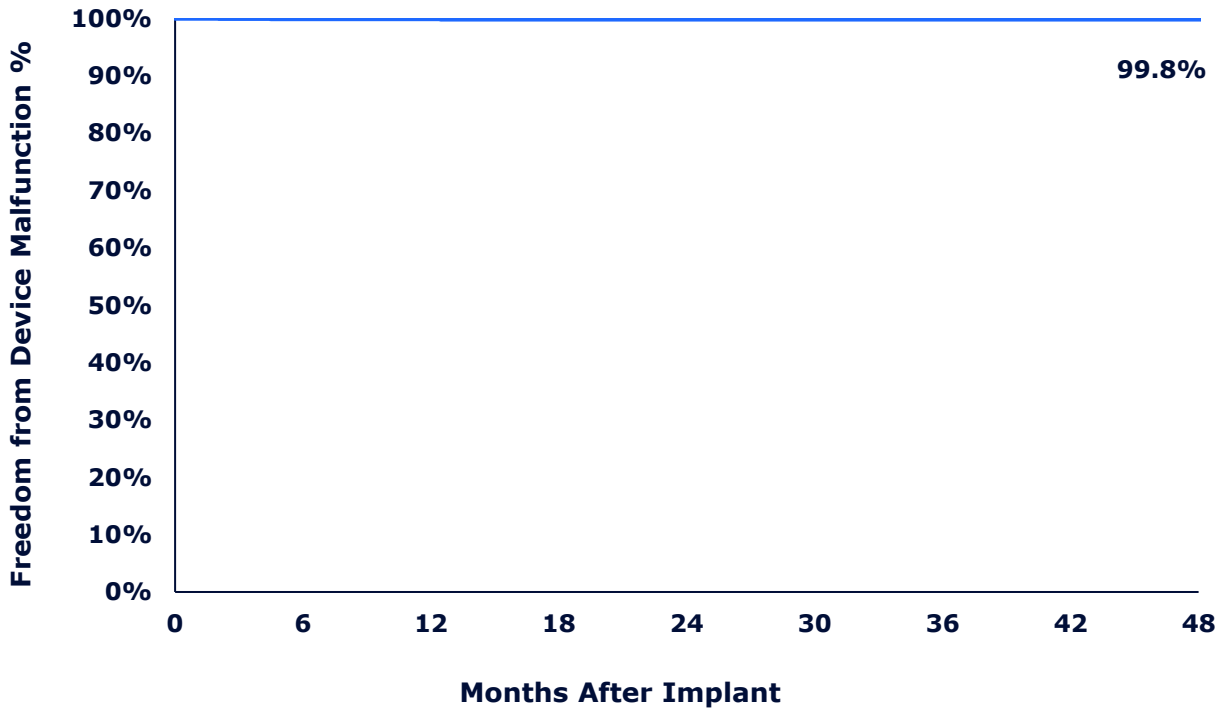

Figure 1: Freedom from Device Malfunction

Freedom from Secondary Surgery

Figure 2 displays Barostim System freedom from secondary surgery* over a 48-month period. This is estimated using the Kaplan-Meier statistical method and is intended to illustrate the probability that an IPG or CSL is free from any secondary surgical intervention for the specified period. The probability of 95.5% at 48 months indicates that the Barostim System has a 4.5% risk of requiring secondary surgery through 48 months.

***Note:** Secondary surgery is defined as any surgical intervention involving the Barostim System, including device explantation, surgical revision or any other surgical intervention.

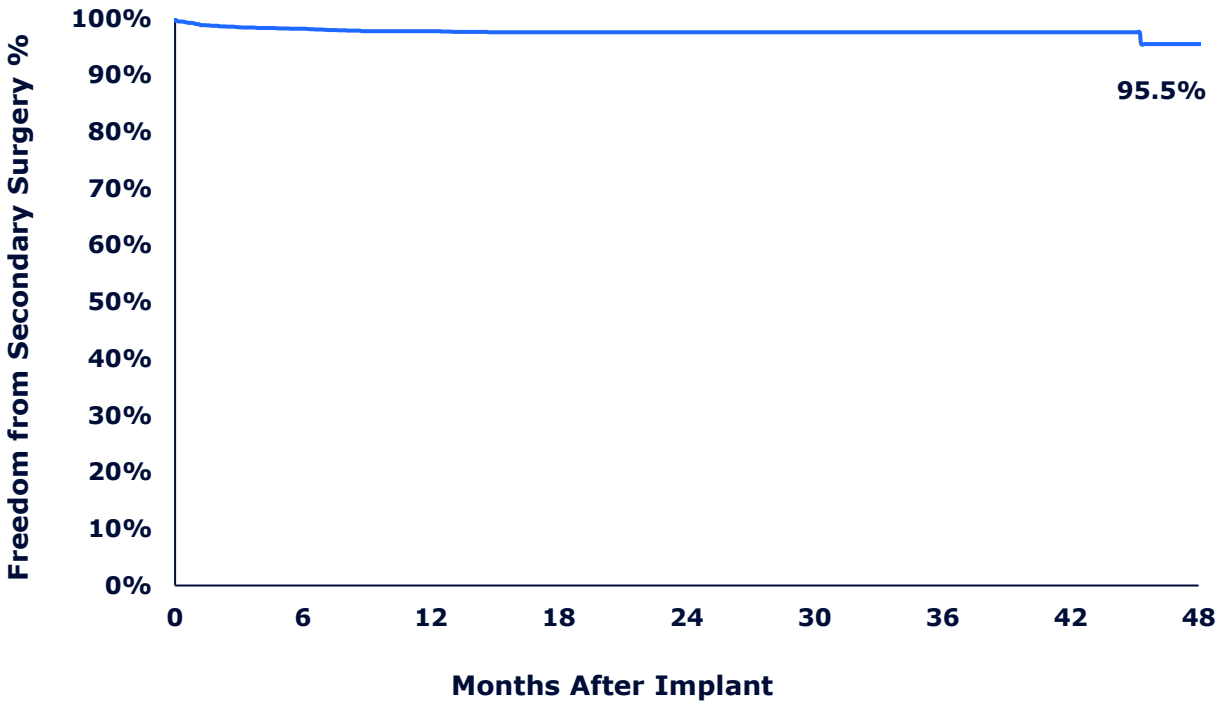

Figure 2: Freedom from Secondary Surgery

Patient Experience

Patient Complications

CVRx collects post-market surveillance data on complications intraoperatively, during the postoperative follow-up period, and throughout the lifespan of the device. **Table 1** displays the most common complications; all other types occurred in fewer than 1% of patients. The values represent patient occurrence rates for each complication (i.e., the percentage of patients who experienced each specific type of complication at least once).

Complication Types	Patient Rate
Extraneous Stimulation	6.8%
Pain	2.2%
Lead Related	1.4%
Infection	1.3%
Each Other Complication Type	**<1.0%**

Table 1: Patient Complications

Patient Extraneous Stimulation Resolution Rate

Extraneous stimulation refers to unintended activation of tissues near the electrode or in the area of the IPG pocket. Among the 6.8% of patients who experienced extraneous stimulation (as shown in **Table 2**), Figure 3 shows that 90% of cases were resolved.

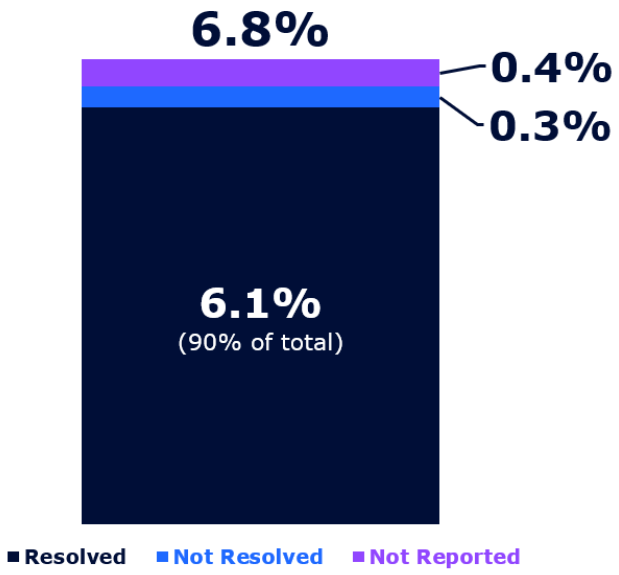

Figure 3: Patient Extraneous Stimulation Resolution Rate

Patient Lead Complication Subtypes

Among the 1.4% of patients who experienced lead related complications (as shown in **Table 2**), Figure 4 displays the complication subtypes, which include the following:

1. **Lead Failure – 0.58%**: Includes lead mechanical failures such as lead fracture / damage or high / low impedance
2. **Procedural Related – 0.65%***: Includes complications originating from procedural events such as accidental cuts, tight leads, or lead detachments / disconnections / movement
3. **Patient Behavior Related – 0.14%**: Includes complications originating from patient behaviors, such as lead manipulation resulting in damage

***Note:** Lead detachment refers to the lead detaching from the carotid artery. A lead disconnection refers to the lead disconnecting from the IPG. No impedance indicates the system was unable to measure any impedance value.

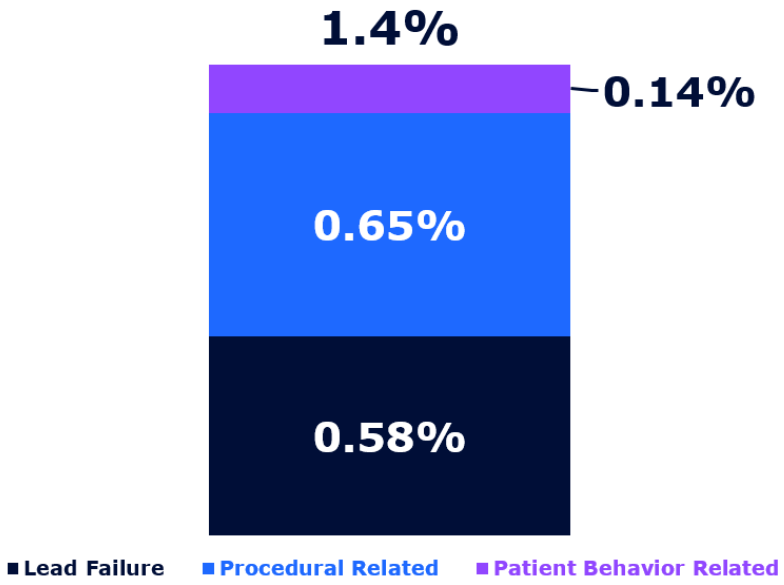

Figure 4: Patient Lead Complication Subtypes

Patient Infections

Among the 1.3% of patients who experienced device-related infections (as shown in **Table 2**), Figure 5 represents the percentage of patients requiring explant as a result of the infection.

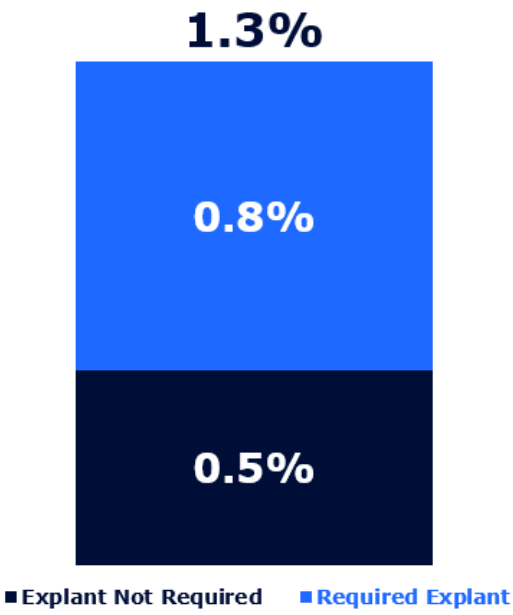

Figure 5: Patient Infections

Barostim™

Outsmart the heart

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™ Brief Summary for Physicians

The Barostim System 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 for improvement of patients' heart failure functional status, six-minute hall walk, and quality of life.

Patients are contraindicated if they have bilateral carotid bifurcations located above the level of the mandible, baroreflex failure or autonomic neuropathy, uncontrolled symptomatic cardiac bradyarrhythmias, carotid artery stenosis greater than 50% caused by atherosclerosis, as determined by ultrasound or angiographic evaluation, 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, blood pressure and heart rate should be monitored during Carotid Sinus Lead placement and when adjusting stimulation parameters intra-operatively, system programming post-implantation, should 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, or any other potentially hazardous patient responses are observed. For patients who currently have an implanted electrical medical device, physicians must verify compatibility with the implanted device during implantation of the system as well as whenever settings are changed in either implant. 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 and NEO2 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 System should not be implanted. 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 system may affect the operation of other implanted devices such as cardiac defibrillators, pacemakers, or neurological stimulation systems.

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 Barostim may include, but are not limited to: stroke, transient ischemic attack (TIA), systemic embolization, surgical or anesthetic complications, infection, wound complications, arterial damage, pain, transient, temporary or permanent 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.

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