BAROSTIM THERAPY™

The BAROSTIM NEO™ System

Physician Coding and Billing Guide

CVRx®

BAROSTIM NEO™ System Physician Billing Guide

The Physician Billing Guide provides information for physicians and healthcare facilities for BAROSTIM NEO System procedures.

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CVRx offers reimbursement hotline support and prior authorization services to all providers. Contact the CVRx Reimbursement Hotline at 763-416-2344 or Reimbursement@cvrx.com.

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BAROSTIM THERAPY Overview

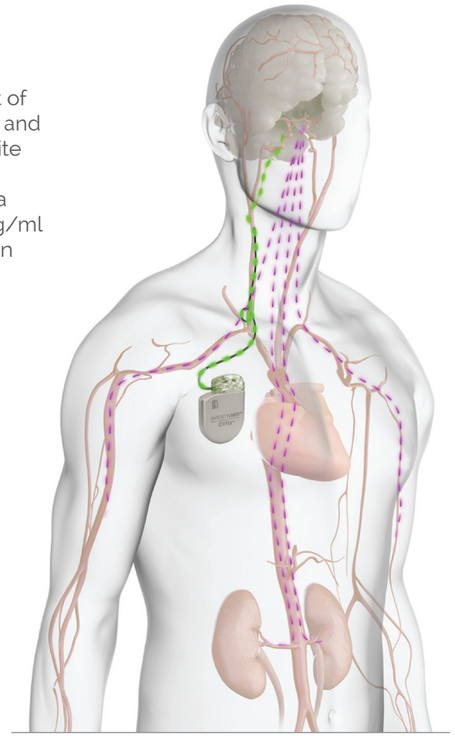
BAROSTIM NEO System

Heart failure is a condition where the heart cannot pump enough blood to meet the body's needs. Symptoms include shortness of breath, general fatigue or weakness and fluid retention. BAROSTIM NEO is an implantable neuromodulation therapy for the treatment of heart failure symptoms. The minimally invasive BAROSTIM NEO System uses CVRx's patented carotid baroreflex activation therapy (BAROSTIM THERAPY) technology to trigger the body's main cardiovascular reflex, thereby addressing the underlying causes of the progression of heart failure.

In clinical studies, BAROSTIM THERAPY has shown to significantly improve patient-centered symptomatic endpoints of quality of life score and exercise capacity. These results are supported by objective evidence of significant improvement of NT-proBNP.[1]

Indication[1]

The BAROSTIM NEO System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.



Contraindications[1]

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 bradyarrhythmia
- 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

Physician Coding and Billing Overview

The purpose of this document is to provide information on reporting of the BAROSTIM NEO baroreceptor activation neuromodulation procedure to physicians and their coding teams for purposes of coding and billing. It is the provider's responsibility to choose diagnosis codes that accurately describe the patient's condition and CPT codes reflecting the procedure performed. The medical record must contain the appropriate information to support medical necessity.

For questions regarding reimbursement and prior authorization, please call the CVRx Reimbursement Hotline at **763-416-2344** or email questions to **Reimbursement@cvrx.com.**

DIAGNOSIS CODES

BAROSTIM NEO is used to treat the symptoms of heart failure patients with reduced EF ≤35%, NYHA Class III or II (recent III) with a recent heart failure hospitalization, NT-proBNP < 1600 pg/ml and who are not indicated for cardiac resynchronization therapy as stated in the AHA/ACC/ESC guidelines.

When a patient with heart failure is implanted with BAROSTIM NEO, the following ICD-10-CM diagnosis may be reported. For those patients with a stated or implied causal relationship with hypertension, heart failure should be sequenced as a secondary diagnosis.

Initial System Implant or Battery (IPG) Replacement ICD-10-CM

ICD-10-CM[2]	Descriptor
I50.1	**Left ventricular failure, unspecified**
I50.2	**Systolic (congestive) heart failure**
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.3	**Diastolic (congestive) heart failure**
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.4	**Combined systolic (congestive) and diastolic (congestive) heart failure**
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.8	**Other heart failure**
I50.81	Right heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	**Heart failure, unspecified**

When a patient is seen for routine interrogation and programming, Z45.42 should be listed as the primary diagnosis with the underlying condition of the patient (ie, heart failure) listed as a secondary diagnosis.

Follow Up Interrogation Device Evaluation CD-10-CM

ICD-10-CM[2]	Descriptor
Z45.42	Encounter for adjustment and management of neurostimulator

CPT CODES

The CPT codes used by Physicians when reporting procedures involving the BAROSTIM NEO System are Category III CPT codes.

Category III CPT codes are temporary codes that represent new and emerging technologies, procedures and services. They do not have a Medicare national fee schedule payment amount, nor are assigned RVUs. As such, payers typically will determine payment amounts for Category III CPT codes on a claim-by-claim basis, based on the description of the procedure, the provider's billed charges, the provider's contract with the payer, and any additional information associated with the claim that documents the time and complexity of the work associated with the service.

Implant Procedure

The BAROSTIM NEO system implant or replacement procedure is reported with the following code:

CPT® Code[3]	Descriptor	2020 Medicare National Average Payment
Implant procedure		
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing

Initial System Implant CPT Modifier (if Assistant Surgeon Involved)

The BAROSTIM NEO system implantation may involve an assisting physician. In this case, the assistant surgeon should append the -80 modifier to the CPT code 0266T on the physician professional services claim.

CPT/HCPCS Modifier

Modifier[3]	Descriptor
-80	Assistant surgeon During certain operations, one physician assists another physician in performing a procedure. The physician who assists the operating surgeon would report the same surgical procedure as the operating surgeon. The assistant surgeon generally is present during the entire operation or a substantial portion of the operation to provide assistance to the operating physician.

Interrogation and Device Programming

In a separate encounter, the BAROSTIM NEO device will require interrogation device evaluation with or without programming. These procedures are reported with the following codes. Whenever programming is performed, it is essential that physicians individually document the specific parameters changed for coding purposes.

CPT® Code[3]	Descriptor	2020 Medicare National Average Payment
Interrogation device evaluation		
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day)	Carrier Pricing
Interrogation device evaluation with programming		
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report; with programming	Carrier Pricing

Revision, Removal, Replacement Procedures

At some time during its lifecycle, the BAROSTIM NEO device may require revision, removal, or replacement. These procedures are reported with the following codes:

CPT® Code[3]	Descriptor	2020 Medicare National Average Payment
Lead replacement		
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing
Battery replacement		
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing
System explant (remove device and lead)		
0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing
Lead removal / lead repair		
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing
Device explant / device revision		
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	Carrier Pricing

CPT CATEGORY III CODES AND NECESSARY CROSSWALK

The following is not legal or coding advice. See important disclaimer on page 2.

When submitting information with claims to support medical necessity for a Category III CPT code, such as the BAROSTIM NEO system implant 0266T code, providers may choose to reference or Crosswalk a Category I CPT procedure code with similar or equivalent resources (i.e. RVUs) to the BAROSTIM NEO implant in a separate letter to the payer. This can help facilitate a fee schedule determination when established payments or RVUs do not exist, i.e. CPT category III codes.

This comparable procedure should have similar physician work, medical decision making and practice expense to the procedure performed utilizing the BAROSTIM NEO System. It will be important for the provider to document the resources and time associated with providing the service in order to allow for appropriate consideration of the payment for the procedure. Information should include a statement of the similarities and differences in work, expertise and practice expense between the procedures.

A category I crosswalk CPT code should not be entered directly into the physician claim form CMS-1500. The Crosswalk Category I CPT code should be referenced in a Crosswalk letter and sent to the payer along with other supporting documentation.

Contact CVRx Reimbursement at 763-416-2344 or Reimbursement@cvrx.com. to receive Crosswalk template letter.

Category I CPT codes that may be appropriate for Crosswalk to the BAROSTIM NEO System implant

CPT® Code[3]	Crosswalk CPT	Descriptor	Total Non-Facility RVU
System Implant			
0266T	64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	18.06
	33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber	26.62
Battery Replacement			
0268T	61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	14.93
Interrogation, Interrogation with programming			
0272T	95970	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/ transmitter, without programming	0.54
0273T	95976	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1.16
	95977	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	1.51

If physicians are employed by the hospital and their compensation is based on productivity from an RVU tracking methodology, it is important to work closely with the hospital administrators in benchmarking BAROSTIM NEO implantation procedures to a procedure with established RVU's utilizing similar resources, time, competency and risk. These discussions should happen in advance of a BAROSTIM NEO implant being performed.

GLOBAL PERIODS AND POST-OPERATIVE FOLLOW-UP VISITS

Category III CPT codes are not assigned global periods, so any subsequent visits or services may be billed independently from the initial procedure. The following E/M CPT codes may be used to report follow-up visits. If device interrogation/programming is also performed, the -25 modifier may be added to the E/M code to indicate that it is a separate service.

CPT® Code[3]	Descriptor
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.

BILLING REQUIREMENTS

Medicare has specific instructions for submitting physician claims. Prior authorization is a good time to check for the payer's billing requirements specific to implantable devices.

Physician Billing on the CMS-1500[4]

1500 Form Locator		Notes
Item Number	Title	
Item 21 (1-4)	Diagnosis or Nature of Illness or Injury	Enter the ICD-10 CM diagnosis codes to identify the patient's diagnosis and/or condition
Item 23	Prior Authorization Number	Enter payer's prior authorization number (if obtained prior to the procedure)
Item 24D	Procedures, Services or Supplies	Enter CPT codes for each procedure or service rendered, with one CPT code in each line. Include modifiers if needed, eg. -80, if assistant surgeon
Item 24E	Diagnosis Pointer	Point the services in 24 D to the diagnosis codes listed in 21 1-4

Claim Submission

Traditional Medicare Insurance

Traditional Medicare plans are administered by Medicare Administrative Contractors (MACs). MACs usually do not require prior authorizations. When submitting a claim to the MACs, the following information may be needed:

1. BAROSTIM NEO FDA approval letter
2. BAROSTIM NEO pivotal trial publication
3. CVRx BAROSTIM CFS (one page summary of all BAROSTIM NEO clinical trials)
4. Crosswalk letter (should be filled out by the provider office)
5. Paper claim CMS 1500 (should be filled out by the provider office)
6. If assistant surgeon filing with modifier 80, the office has to submit a separate letter that explains the medical necessity for the need of the assistant surgeon
7. Detailed medical notes (operative report) which capture both the procedural information that documents the time and complexity of the work associated with the service and the patient's medical condition

Commercial Insurance (Medicare Advantage and Commercial Plans)

Commercial payers often require prior authorization for an elective procedure such as BAROSTIM NEO implantation. When submitting a claim to the commercial insurance, the following information may be needed:

1. BAROSTIM NEO FDA approval letter
2. BAROSTIM NEO pivotal trial publication
3. Crosswalk letter (should be filled out by the provider office)
4. Paper claim CMS 1500 (should be filled out by the provider office). **Please ensure the Prior Authorization number is included in every claim submitted to commercial insurance providers.**
5. If assistant surgeon filing with modifier 80, the office has to submit a separate letter that explains the medical necessity for the need of the assistant surgeon
6. Detailed medical notes (operative report) which capture both the procedural information that documents the time and complexity of the work associated with the service and the patient's medical condition

CVRx will provide BAROSTIM NEO clinical and FDA evidence materials. For questions regarding claim submission materials, please call the CVRx Reimbursement Hotline at **763-416-2344** or email questions to **Reimbursement@cvrx.com**.

Medicare Appeal Process

To receive assistance with filing appeals or reconsideration request, contact the CVRx Reimbursement Hotline at 763-416-2344 or email reimbursement@cvrx.com.

Medicare Claims are typically processed within 30 days of submission. If denied – The physician must file a request for redetermination within 120 days from the date of receipt of the Remittance Advice.

- Medicare requires a signature on each appeal--please sign the appeal letter and the redetermination form and send to the address provided with:
  - Copy of the Explanation of Benefit (EOB)
  - Patient pre-op notes and surgical consult
  - Prior authorization number (if obtained)
  - Copy of completed patient selection checklist
  - Operative report notes
  - Clinical articles and coding information on BAROSTIM Therapy

Medicare Administrative Contractors (MACs) generally issue a decision within 60 days of receipt of the request for redetermination. If denied – The physician must file a request for reconsideration within 180 days of receipt of the decision.

- Medicare requires a signature on each appeal – please sign the appeal letter and reconsideration form and send to the address provided with:
  - Copy of the EOB
  - Patient pre-op notes
  - Copy of completed patient selection checklist
  - Op-notes
  - Clinical articles and coding information included in the packet
- Generally, a qualified independent contractor sends a decision to all parties within 60 days of receipt of the request for reconsideration

BAROSTIM NEO™ Brief Summary for Physicians

The BAROSTIM NEO™ System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

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. Do not use Magnetic Resonance Imaging (MRI) on patients implanted with the system. 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.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. See System Reference Guide 950120-001 for a complete instruction for use and a description of indications, contraindications, warnings, precautions and adverse events.

References:

1 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050
2 ICD-10-CM 2020. American Medical Association, Chicago, IL 2019.
3 Current Procedural Terminology 2020, American Medical Association. Chicago, IL 201. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
4 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180050
National Uniform Claim Committee, 1500 Health Insurance Claim Form Reference Instruction Manual. Version 9.1 5/14.

CVRx. Inc.
9201 West Broadway Ave., Suite 650
Minneapolis, MN 55445
Phone: (763) 416-2840
Fax: (763) 416-2841
www.cvrx.com

CAUTION: Federal law restricts this device to sale by or on the order of a physician. For a list of all potential benefits and risks go to www.cvrx.com/benefit-risk-analysis/

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