CVRx™
Medicine *Re*Envisioned™

MRI USE INSTRUCTIONS

1. SCOPE

This document is a supplement. For full system description and instructions for use, please refer to the System Reference Guide. If you have any questions or require any clarifications please contact your CVRx representative or call CVRx at 1-877-691-7483.

2. MR UNSAFE DEVICES

The following IPGs and leads are contra-indicated for MR exposure:

- IPG Models 2000 (Rheos™), 2100 (Barostim *neo*™ *legacy*), 2101 (XR-1)
- Lead Models 1010, 1014
- Leads repaired with Lead Repair Kit Model 5010

3. MR CONDITIONAL USE INSTRUCTIONS

A. MR Conditional System Configuration

- IPG Model 2102 (Barostim *neo*™)
- Lead Models 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037

The Barostim *neo* device is manufactured with a titanium case and contains various other metals within the case. The leads are manufactured of stainless steel and various other metals. Non-clinical testing has demonstrated that the Barostim *neo* system is MR Conditional.

Patients implanted with this system can be subject to an MR scan under the following conditions:

B. For Head and Brain Imaging using a Transmit/Receive Head Coil

- Static magnetic field of 1.5 Tesla (1.5T).
- Maximum spatial gradient field less than or equal to 21 T/m.
- Use only transmit/receive head coil (without neck accessory coil).
- Imaging of the head with the patient in the head first supine position.
- Maximum head averaged specific absorption rate (SAR) of 3.2 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - ***Note:*** *The head coil should be the controlling condition.*
- Implanted systems with a single lead or with dual lead (unilateral or bilateral) configuration with or without the Barostim *neo* IPG (stimulator) may be scanned.
- The Barostim *neo* IPG must be programmed OFF (non-therapeutic mode) prior to scanning and in such a state will function as an effectively passive device.
- Following MR exposure, when the device is turned on, proper functionality of the device must be confirmed.

RF Heating

Under the scan conditions defined above, the Barostim *neo* system is expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.

MRI Artifacts

In non-clinical testing, under the scan conditions defined above, the image artifact caused by the device extends approximately 48mm from the Barostim *neo* IPG (stimulator) when imaged with a gradient echo pulse sequence and a 1.5T MRI system. The artifact extends approximately 6mm from an individual lead when imaged with a gradient- or spin-echo pulse sequence and a 1.5T MRI system.

Displacement

Magnetically induced displacement force and torque testing indicated that the implants posed no known elevated risks with regard to displacement force and torque in the MR environment.

C. For Lower Extremity Imaging

- Static magnetic field of 1.5 Tesla (1.5T).
- Maximum spatial gradient field less than or equal to 21 T/m.
- Maximum MR system reported Average Specific Absorption Rate (SAR) of 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode
- Conventional horizontal cylindrical bore MRI scanner
- Patient in a feet first (supine, prone or lateral decubitis position)
- Transmission with the body coil or with a transmit/receive coil that does not extend outside of the bore
- Location of the entirety of the implanted Barostim *neo* system is outside of the MR scanner cylindrical bore.

  Additionally, if using an MRI scanner with bore length less than 48":

  - and the patient has an implanted barostimulator device with attached leads, maintain at least a 24" separation between the center of the bore and any part of the Barostim *neo* system.
  - and the patient has the lead(s) alone, maintain at least a 25.5" separation between the center of the bore and any part of the Barostim *neo* lead(s).
- Implanted systems with a single lead or with dual lead (unilateral or bilateral) configuration with or without the Barostim *neo* IPG (stimulator) may be scanned.
- The Barostim *neo* IPG must be programmed OFF (non-therapeutic mode) prior to scanning and in such a state will function as an effectively passive device.
- Following MR exposure, when the device is turned on, proper functionality of the device must be confirmed.

RF Heating

Under the scan conditions defined above, the Barostim *neo* system is expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.

MRI Artifacts

No image artifact is associated with scanning under these conditions, as the device will be outside of the field of view associated with the scan.

Displacement

Magnetically induced displacement force and torque testing indicated that the implants posed no known elevated risks with regard to displacement force and torque in the MR environment.

D. MR Warnings

- When scanning with a body coil transmission, all parts of the Barostim *neo*™ system must be out of the cylindrical bore of the MR scanner or unsafe heating may result.
- RF Head coil scanning may not be performed with the body coil in transmit mode. Use of body coil transmission can result in unsafe heating with this device. It is noted that some head coils compatible with 1.5T scanning are receive-only and rely on the body coil to transmit RF. Receive-only head coils may not be used.
- Do not subject the system to MR if the lead is suspected to be damaged, cut, or has been repaired using a Model 5010 Lead Repair Kit. If there is uncertainty as to whether the lead has been repaired it is suggested that an X-ray be performed to verify. Acceptable lead condition should be verified using lead impedance measurement using the CVRx programmer. If an implanted lead impedance measurement indicates "Low" or "High", MR is contraindicated.

- Do not bring any component of the Model 9010 Programmer System or the External Inhibit Magnet into the MR environment.

E. MR Precautions

- Prior to scanning, the patient should be instructed to notify the MR system operator of pain, discomfort, heating or other unusual sensations in the area of the device or leads which may require termination of the MR procedure.
- Monitor the patient status while therapy is turned off.

⚠ CANADA ONLY: EXCLUSIVELY FOR CLINICAL INVESTIGATIONS.

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