

Patient Instructions

The following information should be provided to patients who are implanted with the Barostim System.

POST OPERATIVE WOUND CARE

- Wound dressing should remain in place until instructed by your doctor
- Care should be taken when bathing to avoid pressing on the wound or the device
- DO NOT touch the surgical sites
- DO NOT lay on or push on the IPG (device implanted in the chest)
- DO NOT manipulate the IPG or lead (device implanted in the neck) through the skin as it may damage the device, the tissue surrounding the device, or cause the lead to be disconnected from the IPG
- Fever, redness, discharge or severe pain from the surgical sites after 3 days may be a sign of infection
 - o If you have any of the symptoms above, DO NOT attempt to treat at home, contact your doctor as soon as possible
 - o Infections caught early can generally be treated with antibiotics
 - More serious infections may require removal of the IPG and/or the lead

GENERAL INFORMATION

- Continue medications, diet, exercise, and lifestyle modification as directed
- Carry Patient Identification card and present at security screens
- IPG battery will deplete over time requiring replacement
- Follow-up doctor visits required to assure proper system operation and response to therapy
- Contact your doctor immediately for:
 - o Stimulation (tingling, twitching, difficulty speaking or swallowing)
 - o Dizziness, chest pain, breathing problems, swelling of legs
 - o BP or heart rate are unusually low

WARNINGS / PRECAUTIONS

- Contact your doctor if you will be having a medical procedure:
 - Procedures such as MRI, electrocautery, therapeutic radiation, lithotripsy procedures, and external defibrillation may cause damage to the IPG
- To avoid temporarily stopping therapy, stay at least 15 cm (6 inches) away from devices with strong electrical or magnetic fields such as:
 - o Strong magnets
 - o Loudspeaker magnets
 - o Electronic Article Surveillance (EAS) system (anti-theft detectors)
 - o Arc welders
 - o Induction furnaces

- Contact your doctor for guidance before entering environments which could adversely affect the operation of the IPG, including areas where warning notices are posted to prevent entry by patients with a pacemaker.
- DO NOT manipulate the IPG through the skin this may damage or disconnect the lead from the pulse generator.
- DO NOT manipulate the Carotid Sinus Lead through the skin - this may damage or disconnect the lead from the IPG and/or possibly cause damage to the carotid sinus.

Full Instructions for Use and a current copy of the information in this document is available at: www.cvrx.com/ifu

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