
Field Safety Notice

Barostim *neo*® System,
FSCA-001, 2016-01-06
Device modification, labelling change

Date: 2016-01-06

Attention: Treating Physician

Details on affected devices:

Affected Device(s)	Model Number	Market Dates
Implantable Pulse Generator (IPG)	2102	30-Jan-2012 to Present
CVRx Programmer System	9010	30-Jan-2012 to Present

Description of the problem:

CVRx is informing you of a medical device documentation correction related to the potential that permanent communication loss may occur as a result of maintaining an active communication link with the programmer while the Implantable Pulse Generator is exposed to Magnetic Resonance Imaging (MRI). This hazard is avoidable with simple precautions as outlined below.

Advise on action to be taken by the user:

NOTE: This is a hazard only for patients who are being exposed to MRI, and can be avoided.

CVRx has updated the labelling for MR Conditional use, and would like to call your attention to the following steps, which should be performed before exposing the patient to the MR environment:

1. Terminate therapy
2. End the programming session
3. Turn the Programmer System off
4. Ensure the Programmer System remains off until the patient exits the MR environment
5. Turn therapy on after the patient exits the MR environment and confirm proper device functionality

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Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation.

Distributors: Please transfer this notice to other organisations on which this action has an impact.

Contact reference person:

Your local CVRx Field Clinical Specialists, Sales Representative, or Distributor can assist you with these steps for patients who need an MRI. If you have any questions and cannot reach your local support person, please contact:

+1 877 691 7483 (answered 24 hours/day, 7 days/week) or

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We regret any difficulties or inconvenience this may cause you and your patients.

The undersigned confirms that this notice will be sent to the appropriate Regulatory Agencies.

Best regards,

Dean Bruhn-Ding
Vice President Regulatory Affairs & Quality Assurance
CVRx, Inc.
www.cvrx.com