

ImageReady™ MR Conditional Defibrillation System Patient Guide for MRI Scans

Overview

Magnetic Resonance Imaging (MRI) is a diagnostic test that uses a powerful magnet and radio waves to produce images of the human body. Most defibrillation systems are not compatible with an MRI scan procedure or with being near MRI scanners. However, some defibrillator patients need to have MRI scans to diagnose their health conditions and determine proper treatment. Boston Scientific has a defibrillation system that can be scanned when certain conditions are met. This includes programming the defibrillator to special settings for MRI.

You **MAY** be eligible to have an MRI scan if you are implanted with the Boston Scientific ImageReady MR Conditional Defibrillation System which has been tested for use with MRI scans. Your heart doctor or healthcare provider will work with you to determine if you and your defibrillation system can undergo an MRI scan.

Talk to your heart doctor about the risks and benefits of having an MRI scan.

Your defibrillator system contains an Armature or Piezo Beeper. The Piezo Beeper is designed to withstand the strong magnetic fields associated with MRI scanners without being damaged. The Armature Beeper contains a magnetic component, therefore coming into contact with the strong magnetic field of an MRI scanner may cause a permanent loss of Armature Beeper volume on the defibrillator. Talk to your heart doctor to determine the beeper type in your defibrillator system. For Armature Beeper, talk to your heart doctor to weigh the benefit of the MRI procedure against the risk of losing the Beeper.

Common Questions

To be eligible for an MRI scan, you must have an ImageReady MR Conditional Defibrillation System implanted. The clinic performing the scan must use an MRI machine that meets the conditions of use of the ImageReady Defibrillation System.

Common questions include:

1. Am I able to have an MRI scan?
 - If a healthcare provider recommends an MRI scan, talk to your heart doctor before scheduling your MRI scan.
 - Coming into contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Armature Beeper volume on the defibrillator. Talk to your heart doctor to weigh the benefit of the MRI procedure against the risk of losing the Armature Beeper.
 - Your heart doctor will check you and your ImageReady Defibrillation System to determine if you are eligible for an MRI scan.
 - Even if your defibrillation system is eligible, you may have other implanted devices or metal in your body that may prevent you from having an MRI scan.

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- You must be physically capable of having an MRI scan. This means that you can lay flat during the scan, and tolerate how the defibrillator functions during the scan.
- Always check with your heart doctor or a healthcare provider if you have questions before or after the MRI scan.

2. What can I expect during an MRI scan?

- Your implanted defibrillation system is listed on your current medical device ID card. You should keep this card with you at all times, and take it with you to the MRI facility.
- Before the scan, your defibrillator will be programmed to the MRI settings. These settings are necessary for you to receive an MRI scan. While programmed to these settings, the device cannot deliver shocks and may not provide pacing therapy. Your heart rate may feel different from what you are accustomed to. Therefore, talk to your heart doctor to understand the monitoring you will receive for the entire time your defibrillation system is in the MRI settings.
- Your defibrillator may stay in the MRI settings for a limited time. If so, you or your caregiver may be notified of the duration of time your device will remain in the MRI settings. The MRI scan needs to be completed before that time expires.
- You may see signs at the MRI facility that warn you not to enter if you have a defibrillator. These signs apply to defibrillation systems that are not eligible, programmed, and cleared to have an MRI scan. Always check with a healthcare provider if you have questions.
- During the MRI scan, you may experience the following:
 - Loud noises are part of a normal MRI scan; the noises are not coming from your defibrillator.
 - Slight movement, vibration, or a warm sensation from the defibrillator.

3. What happens after the scan?

- After the scan, follow the directions provided by your heart doctor or healthcare provider.
- Your implanted ImageReady Defibrillation System may be checked after the MRI to ensure it is working normally. The defibrillation system may be manually programmed out of the MRI settings, or it may return to your normal settings automatically after a specific period of time set by your heart doctor.
- Due to the potential permanent loss of Armature Beeper volume on the defibrillator caused by an MRI scan, your heart doctor may recommend using a patient monitoring system or more frequent in-clinic follow-ups after an MRI scan.
- If you experience any new symptoms after the scan, contact your heart doctor or healthcare provider.
- If you need additional MRI scans, you and your ImageReady Defibrillation System must be checked for eligibility for a scan each time. If your implanted defibrillation system has changed, for example by implant of a new defibrillator or lead wires, or if aspects of your health have changed, it is possible that you are no longer eligible for an MRI scan.

For additional reference information, go to
www.bostonscientific.com/patientlabeling.



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