



ImageReady™ MR Conditional S-ICD 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. Some S-ICD patients need to have MRI scans to diagnose their health conditions and determine proper treatment. Boston Scientific has an S-ICD system that can be scanned when certain conditions are met. This includes programming the S-ICD 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 S-ICD 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 S-ICD system can undergo an MRI scan.

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

Common Questions

To be eligible for an MRI scan, you must have an ImageReady MR Conditional S-ICD System implanted. The clinic performing the scan must use an MRI machine that meets the conditions of use of the ImageReady S-ICD 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 can cause a permanent loss of the Beeper volume on the S-ICD. Talk to your heart doctor to weigh the benefit of the MRI procedure against the risk of losing the Beeper.
 - Your heart doctor will check you and your ImageReady S-ICD System to determine if you are eligible for an MRI scan.
 - Even if your S-ICD system is eligible, you may have other implanted devices or metal in your body that may prevent you from having an MRI scan.
 - You must be physically capable of having an MRI scan. This means that you can lay flat during the scan, and tolerate how the S-ICD functions during the scan.
 - Always check with your heart doctor or a healthcare provider if you have questions before or after the MRI scan.

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2. What can I expect during an MRI scan?

- Your implanted S-ICD 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 S-ICD 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 shock therapy. Therefore, talk to your heart doctor to understand the monitoring you will receive for the entire time your S-ICD system is in the MRI settings.
- Your S-ICD will stay in the MRI settings for a limited time. 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 S-ICD 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 S-ICD.
 - Slight movement, vibration, or a warm sensation from the S-ICD.

3. What happens after the scan?

- After the scan, follow the directions provided by your heart doctor or healthcare provider.
- Your implanted ImageReady S-ICD System may be checked after the MRI to ensure it is working normally. The S-ICD 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 permanent loss of Beeper volume on the S-ICD 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 S-ICD System must be checked for eligibility for a scan each time. If your implanted S-ICD system has changed, for example by implant of a new S-ICD or electrode, or if aspects of your health have changed, it is possible that you are no longer eligible for an MRI scan.

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