



ImageReady MR Conditional Pacing & Defibrillation System Patient Guide for MRI scans

You MAY be eligible to have an MRI scan if you are implanted with a Boston Scientific ImageReady[™] MR-Conditional Pacing or Defibrillation System (device and lead wires designed to safely work in the MRI environment) and meet the conditions of use. Your heart doctor or healthcare provider will work with you to determine if you and your device can undergo an MRI scan.

Make sure you and your healthcare provider(s) are comfortable with the risks and benefits of having an MRI scan.

Common Questions

What is MRI?

Some pacemaker and defibrillator patients need to have MRI scans to diagnose their health conditions and determine proper treatment. MRI (Magnetic Resonance Imaging) is a diagnostic tool that uses different types of magnetics and electromagnetic fields to image soft tissue in the body.

Boston Scientific's ImageReady[™] MR-Conditional Systems are designed and tested for the ability to function correctly under specified conditions during an MRI scan.

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.
- Your implanted pacemaker or defibrillator and lead wire models are listed on your current medical device ID card. You should keep this card with you at all times, and take it with you when you meet with your heart doctor.
- Your heart doctor will check you and your ImageReadyTM MR-Conditional System to determine if you are eligible for an MRI scan.
- Even if your pacing or defibrillator 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.
- Always check with your heart doctor or a healthcare provider if you have questions before or after the MRI scan.





What can I expect during an MRI scan?

- Before the scan, your ImageReadyTM MR-Conditional System will be programmed to the MRI settings. These settings are necessary for you to receive an MRI scan.
- Your heart function will be monitored during the scan.
- Your ImageReady[™] MR-Conditional System may stay in the new 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 pacemaker or defibrillator. These signs apply to pacemaker or defibrillator 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.
 - You might feel slight movement or vibration of the pacemaker or defibrillator, or a warm sensation from the pacemaker or defibrillator.

What happens after the scan?

- After the scan, follow the directions provided by your heart doctor or healthcare provider.
- Your implanted ImageReadyTM MR-Conditional System may be checked to ensure it is working normally. The system may be programmed out of the MRI settings, or it may return to your normal settings automatically after a specific period of time set by your doctor.
- 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 pacing or defibrillator System must be checked for eligibility for a scan each time. If your implanted pacing or defibrillator System has changed, for example a new pacemaker or 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.

CAUTION: The law restricts these devices to sale by or on the order of a physician.

Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at <u>www.IFU-BSCI.com</u>. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. CRM-1887303-AB

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