

IMAGEREADY™

MR-Conditional Systems

Commonly Asked Questions

You may be eligible to have an MRI scan if you are implanted with the Boston Scientific ImageReady MR-Conditional Pacing System (pacemaker and lead wires designed to 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 pacing system can undergo an MRI scan.

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

What is MRI?

- Some pacemaker 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 Pacing Systems are designed, optimized, 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 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 ImageReady Pacing System to determine if you are eligible for an MRI scan.
- Even if your pacing 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 ImageReady MR-Conditional Pacing System will be programmed to the MRI settings. These settings are necessary for you to receive an MRI scan. While your pacing system is programmed to these settings, your heart rate may be different from what you are accustomed to.
- Your heart function will be monitored during the scan.
- Your ImageReady MR-Conditional Pacing 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. These signs apply to pacing 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 a warm sensation from the pacemaker.

What happens after the scan?

- After the scan, follow the directions provided by your heart doctor or healthcare provider.
- Your implanted ImageReady MR-Conditional Pacing System may be checked to ensure it is working normally. The pacing system may be programmed out of the MRI settings, or it may return to your normal pacing 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 system must be checked for eligibility for a scan each time. If your implanted pacing system has changed, for example a new pacemaker or lead wires, or if aspects of your health have changed, it is possible that you are no longer eligible for an MRI scan.

Pacemakers

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. With all medical procedures there are risks associated. In regard to an implanted pacemaker, the risks include but are not limited to inappropriate heart rate response to exercise, lead moves out of place, loss of stimulation capability, allergic reaction, fluid underneath the skin, and infection. In rare cases device failure or death can occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to www.bostonscientific.com, or you can request a copy by calling 1-866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave. N., St. Paul, MN 55112. (Rev. K)