IMAGEREADY™
MR-Conditional Systems

Boston Scientific
Advancing science for life™

Commonly Asked Questions

You may be eligible to have an MRI scan if you are implanted with the Boston Scientific ImageReady MR-Conditional System (device 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 MR-Conditional 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 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, 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 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 ImageReady 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 ImageReady MR-Conditional Systems will be programmed to the MRI settings. These settings are necessary for you to receive an MRI scan. While your 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 Systems 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 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 ImageReady 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.

Pacemakers

Important Safety Information
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. Some of the risks encountered during the implant procedure include, but are not limited to, the following: Bleeding, formation of a blood clot, damage to adjacent structures (tendons, muscles, nerves), puncture of a lung or vein, damage to the heart (perforation or tissue damage), dangerous arrhythmias, heart attack, stroke, death. Some of the risks encountered after the system is implanted may include, but are not limited to, the following: Infection, erosion of the skin near your device, lead(s) may move out of place in the heart, device may move from the original implant site, difficulty coping with having an implanted device. The device might be prevented from pacing due to electromagnetic interference. Electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on
the surrounding tissues, including heart tissue and nerves. You may receive pacing therapy when it is not needed (unnecessary therapy). The device might not be able to detect or appropriately treat your heart rhythms. The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. You may experience some discomfort from the incision as you recover from the surgery. You may experience some discomfort from the incision as you recover from the surgery. With all medical procedures there are risks associated. 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. Rx only

Implantable Cardioverter Defibrillators

Important Safety Information
An implantable cardioverter defibrillator is designed to monitor and treat 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. Some of the risks encountered during the implant procedure include, but are not limited to, the following: Bleeding, formation of a blood clot, damage to adjacent structures (tendons, muscles, nerves), puncture of a lung or vein, damage to the heart (perforation or tissue damage), dangerous arrhythmias, heart attack, stroke, death. Some of the risks encountered after the ICD system is implanted may include, but are not limited to, the following: Infection, erosion of the skin near your device, lead(s) may move out of place in the heart, device may move from the original implant site, difficulty coping with having an implanted device. The device might be prevented from shocking or pacing due to electromagnetic interference. Electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves. You may receive a shock or pacing therapy when it is not needed (unnecessary therapy). The device might not be able to detect or appropriately treat your heart rhythms. The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. You may experience some discomfort from the incision as you recover from the surgery. With all medical procedures there are risks associated. 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. Rx only

Implantable Devices
Cardiac Resynchronization Therapy Devices

Important Safety Information
Cardiac resynchronization therapy pacemakers (CRT-P) and defibrillators (CRT-D) are designed to treat heart failure patients who may or may not have symptoms or who may have symptoms despite the best available drug therapy. They are also designed to help your heart pump more effectively and meet your body's need for blood flow. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. Some of the risks encountered during the implant procedure include, but are not limited to, the following: Bleeding, formation of a blood clot, damage to adjacent structures (tendons, muscles, nerves), puncture of a lung or vein, damage to the heart (perforation or tissue damage), dangerous arrhythmias, kidney failure, heart attack, stroke, death. Some of the risks encountered after the ICD system is implanted may include, but are not limited to, the following: Infection, erosion of the skin near your device, lead(s) may move out of place in the heart, device may move from the original implant site, difficulty coping with having an implanted device. The device might be prevented from shocking or pacing due to electromagnetic interference. Electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves. You may receive a shock or pacing therapy when it is not needed (unnecessary therapy). The device might not be able to detect or appropriately treat your heart rhythms. The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. You may experience some discomfort from the incision as you recover from the surgery. With all medical procedures there are risks associated. 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. Rx only

Device Quality and Reliability
It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device. 92481216 (Rev. B.4)

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CRM-362703-AB