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Cardiology Checklist for the IMAGEREADY™ MR-Conditional Systems

EMBLEM™ MRI S-ICD System

This form contains confidential patient information, and should be treated with proper care and precaution and not shared except as needed. Refer to the Boston Scientific ImageReady MR-Conditional S-ICD System MRI Technical Guide[1] or www.bostonscientific.com/imageready for a full list of warnings, precautions and complete instructions for using the ImageReady MR-Conditional S-ICD System.

Patient Name: _____

S-ICD Model: _____ Electrode Model: _____

Conditions of Use - Cardiology

According to the ImageReady MR-Conditional S-ICD System MRI Technical Guide, the following Conditions of Use must be met in order for a patient with an ImageReady MR-Conditional S-ICD System to undergo an MRI scan.

- ☐ Patient is implanted with an ImageReady MR-Conditional S-ICD System (see reverse).
- ☐ No other active or abandoned implanted devices, components or accessories present such as lead adaptors, extenders, leads or pulse generators.
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ As soon as MRI Protection Mode is programmed, the patient must be continuously monitored by pulse oximetry and electrocardiography (ECG). Ensure backup therapy is available (external rescue).
- ☐ Patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.
- ☐ Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- ☐ At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady MR-Conditional S-ICD System.
- ☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.

Scanning Procedure

The following Scanning Procedure information is included in the Radiology Checklist and is being provided for your information.

Pre-Scan

1. Ensure patient meets all Cardiology Conditions of Use for MRI scanning (see left column).
2. Exposure to MRI scanning can cause a permanent loss of the Beeper volume. The physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.
3. As close to the start of the scan as possible, program the pulse generator into MRI Protection Mode and begin continuous monitoring of the patient.
4. Print the MRI Protection Settings Report, place it in the patient's file, and provide to radiology personnel.
   - The report documents MRI Protection Mode settings and details. If the Time-out feature is used, the report includes the exact time and date when MRI Protection Mode will expire via the Time-out feature.

During Scan

5. Ensure the patient is continuously monitored by pulse oximetry and electrocardiography (ECG), with backup therapy available (external rescue), while the device is in MRI Protection Mode.

After Scan

6. Ensure the pulse generator is returned to pre-MRI operation, either automatically if the Time-out feature was set, or manually using the programmer. Perform follow-up testing of the defibrillation system after exiting MRI Protection Mode, and continue patient monitoring until the pulse generator is returned to pre-MRI operation. Follow-up testing of the S-ICD system may be performed after exiting MRI Protection Mode.
7. The Beeper may remain disabled upon exiting MRI Protection Mode.

Warnings:

- Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.
- If the MRI Protection Time-out value is programmed to Off, the patient will not receive Tachycardia therapy until the pulse generator is programmed out of MRI Protection Mode and back to normal operation.
- The Programmer (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the Programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

IMAGEREADY™ MR-Conditional Systems

EMBLEM™ MRI S-ICD Components for 1.5T

Only specific combinations of pulse generators and electrodes constitute an ImageReady MR-Conditional S-ICD System that is valid for use with **1.5 T scanners**.

ImageReady™ MR Conditional S-ICD System Components for 1.5 T

Component	Model Number(s)	MR Status	1.5 T
Pulse Generators			
EMBLEM™ S-ICD	A209	MR Conditional	✔
EMBLEM™ MRI S-ICD	A219	MR Conditional	✔
Electrodes and Accessories			
EMBLEM™ S-ICD Electrode	All models	MR Conditional	✔
Q-TRAK S-ICD Electrode	All models	MR Conditional	✔
Suture Sleeves for S-ICD Electrodes	All models	MR Conditional	✔
Programmer			
EMBLEM™ S-ICD Programmer	All models	MR Unsafe*	NA

***Warning:**

- The Programmer/Recorder/Monitor (PRM) is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

EMBLEM™ MRI S-ICD System from Boston Scientific CRM

Indications for Use The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.

Warnings Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise its functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Do not implant in MRI site Zone III. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher). During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information.
Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.
For a list of all potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. Rx only.
(Rev A)

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