

Cardiology Order Form

IMAGEREADY™

EMBLEM™ MRI S-ICD System

PATIENT NAME _____

D.O.B. _____

MODEL #s _____

S-ICD _____

ELECTRODE _____

According to Boston Scientific's device labeling, the following Conditions of Use **MUST BE MET** for a patient with an ImageReady™ EMBLEM™ MRI S-ICD System to undergo an MR-Conditional scan. Adherence to the Conditions of Use **MUST BE VERIFIED** prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR-Conditional scan.

RESOURCES

Confirm that patient has a complete ImageReady™ MR-Conditional S-ICD System by referring to the below resources:

- ▶ Boston Scientific MRI Technical Guide, ImageReady™ MR-Conditional S-ICD System
- ▶ www.BostonScientific.com/imageready
- ▶ Boston Scientific MRI Hotline 1.844.4.BSC.MRI (1.844.427.2674)

OFF-LABEL MRI SCAN

My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional S-ICD System and/or **DOES NOT MEET** the Conditions of Use listed below. Because not all Conditions of Use have been met, the scan is off-label. BSC labeling warns of potential risks for off-label MRI scans and does not promote nor encourage this use. Use the Cardiology Order Form *Off-Label MRI Scan* to specify programming parameters during off-label MRI scans.

CONDITIONS OF USE

- Patient is implanted with an ImageReady™ MR-Conditional S-ICD System.
- No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, 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.

MRI PROTECTION MODE PARAMETERS

Defibrillation therapy will be disabled while in MRI Protection Mode. Program MRI Protection Mode during scan with these parameters.

MRI Protection Timeout 6 H (nominal) 9 H 12 H 24 H

NOTE

Do not leave the pulse generator in MRI Protection Mode any longer than necessary following the scan. Beeper may no longer be usable following MRI scan.

DATE _____

PHYSICIAN SIGNATURE _____

PHYSICIAN NAME _____