Cardiology / Radiology Checklists

IMAGEREADY ™

MR-Conditional Transvenous Defibrillation Systems

PATIENT NAME D.O.B.

MODEL #s	ICD/CRT-D	ATRIAL LEAD	RV LEAD	LV LEAD

Use the following checklists to ensure that patients who have a Boston Scientific Transvenous Defibrillation System labeled MR-Conditional can receive an MR-Conditional scan. Only specific combinations of Boston Scientific MR-Conditional pulse generators and MR-Conditional leads constitute a valid ImageReady™ MR-Conditional Transvenous Defibrillation System for use in a 1.5 Tesla environment.

RESOURCES

Confirm that the patient has a valid ImageReady™ MR-Conditional Transvenous Defibrillation System by referring to the below resources:

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

CARDIOLOGY CONDITIONS OF USE[1]

- ☐ Patient is implanted with an ImageReady™ MR-Conditional Transvenous Defibrillation System.
- ☐ 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.
- ☐ Pulse generator implant location restricted to left or right pectoral region.
- ☐ At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR-Conditional Transvenous Defibrillation System.
- ☐ No evidence of a fractured lead or compromised pulse generator-lead system integrity.

RADIOLOGY CONDITIONS OF USE[1]

- ☐ MRI magnet strength of 1.5 T only.
- ☐ Radio Frequency (RF) field of approximately 64 MHz.
- ☐ Maximum spatial gradient 20 T/m (2,000 G/cm).
- ☐ Horizontal, ^{1}H proton, closed bore scanners only.
- ☐ Specific Absorption Rate (SAR) limits for the entire active scan – Normal Operating Mode[a]
  - Whole body averaged, ≤ 2.0 watts/kilogram (W/Kg)
  - Head, ≤ 3.2 W/Kg
- ☐ Gradient Field limits – Maximum specified gradient slew rate: ≤ 200 T/m/s per axis.
- ☐ There are no restrictions for positioning the Transvenous Defibrillation System within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted. Local transmit coils may be used but should not be placed directly over the Transvenous Defibrillation System.
- ☐ Patient in supine or prone position only.
- ☐ Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG) for the entire duration in which the pulse generator is in MRI Protection Mode. Ensure backup therapy is available (external rescue).

[a] As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.

[1] Refer to the MRI Technical Guide: ImageReady™ MRI Defibrillation System as the system is designated as MR-Conditional in accordance with specific conditions.