Cardiology and Radiology Checklists

IMAGEREADY™

MR-Conditional Defibrillation Systems

PATIENT NAME **D.O.B.**

PG MODEL # **ATRIAL LEAD** **RV LEAD** **LV LEAD**

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

RESOURCES

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

- Boston Scientific MRI Technical Guide www.bostonscientific.com/manuals/
- Boston Scientific ImageReady www.BostonScientific.com/imageready
- Boston Scientific Technical Services Hotline 1800 245 559 (Australia), 0800 742 678 (New Zealand)

OFF-LABEL MRI SCAN

☐ My patient **DOES NOT HAVE** a complete ImageReady™ MR-Conditional Pacing 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. Boston Scientific 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.

CARDIOLOGY CONDITIONS OF USE

- ☐ Patient is implanted with an ImageReady™ Transvenous Defibrillation System with all ports occupied by a lead or port plug.
- ☐ Pulse generator in MRI Protection Mode during scan.
- ☐ Bipolar pacing operation or pacing off.
- ☐ No other active or abandoned implanted devices, components, or accessories present, such as lead adapters, extenders, leads, or pulse generators.
- ☐ 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 does not have elevated body temperature or compromised thermoregulation at time of scan.
- ☐ 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 electrode revision or surgical modification of the ImageReady™ MR-Conditional System.
- ☐ No evidence of a fractured electrode or compromised pulse generator-electrode system integrity.
- ☐ Pacing threshold ≤ 2.0 V in pace-dependent patients.

RADIOLOGY CONDITIONS OF USE

- ☐ MRI magnet strength of 1.5T (64 MHz) or 3T (128 MHz)
- ☐ Maximum spatial gradient 50 T/m (5,000 G/cm).
- ☐ Horizontal, ^{1}H proton, closed bore scanners only.
- ☐ RF exposure limits:

  1.5T
  - Normal Operating Mode1 must be observed for the entire active scan session (Whole body averaged, ≤ 2.0 W/Kg; Head, ≤ 3.2 W/Kg)

  3T *(Patient landmark/scan isocenter at or superior to the C7 certebra)*
  - Normal Operating Mode or First Level Controlled Operating Mode must be observed for the entire active scan session

  3T *(Patient landmark/scan isocenter inferior to the C7 vertebra)*
  - B1+rms must be ≤ 2.8 microtesla (μT)
- ☐ Gradient Field limits – Maximum specified gradient slew rate ≤ 200 T/m/s per axis.
- ☐ There are no restrictions for positioning the 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 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).

1 As defined in IEC 60601-2-33, 201.3.244, 3rd Edition.
2 Refer to the MRI Technical Guide: ImageReady™ MRI Defibrillation System as the system is designated as MR-Conditional in accordance with specific conditions.

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