Standard Letter
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Reveal Plus (Model # 9526) Insertable Loop Recorder (ILR)

Magnetic and Radio Frequency (RF) fields produced by MRI may adversely affect the data being stored by the Reveal Plus Insertable Loop Recorder (ILR).

Since the ILR contains ferromagnetic components, the strong magnetic field of the MRI system may apply a mechanical force on the ILR. The patient may be able to feel this magnetic force on the ILR. While this does not represent a safety hazard, the patient should be made aware of this possibility to avoid undue patient concern.

Reveal DX (Model # 9528) and Reveal XT (Model # 9529) Insertable Cardiac Monitor

Non-clinical testing demonstrates that Reveal DX and Reveal XT devices are safe for use in the MRI environment when used according to these instructions.

The Reveal DX and Reveal XT can be safely scanned in patients under the following conditions:

MRI Equipment Requirements

- The MRI equipment must be a closed bore, cylindrical magnet with a static magnetic field of 1.5 Tesla (T) or 3.0 T.
- MRI equipment must be used in normal operating mode (based on standards defined in IEC 60601-2-33). Refer to Reveal DX or Reveal XT Clinician Manual for additional information.
- If local or surface coils are needed, please refer to the Reveal DX or Reveal XT Clinician Manual for additional information.

MRI Procedural Requirements

- Verify that the Reveal DX or the Reveal XT is at least 6 weeks post-implant. This waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of device “tugging” caused by the magnetic fields.
- Verify that the Reveal DX or Reveal XT implant location is in the subcutaneous tissue of the chest region.
- Uninterrupted duration of active scanning (when RF and gradients are on) over the chest during MRI must not exceed 30 minutes. A waiting period of at least 10 minutes is required if additional chest scans are necessary.

MRI potential adverse events

- An implanted Reveal DX or Reveal XT may be subject to interactions in the MRI environment. The device design minimizes the potential adverse effects that may result from these interactions. Patients may experience minor discomfort due to tissue heating or "tugging."
- The MRI environment may interfere with the device's capability to detect irregular heart rhythms and therefore, diagnostic information collected during the MRI procedure may result in falsely detected episodes.

Preparing a Reveal DX or the Reveal XT for an MRI procedure

- Check that additional implantable devices are not present, including abandoned pacing leads. Medtronic has not tested interactions with all other implanted devices or abandoned pacing leads.
- The MRI procedure may overwrite the recorded data in the Reveal DX or the Reveal XT. Print or save the data stored in the Reveal DX or Reveal XT to diskette before the MRI.
- The Patient Assistant and the Medtronic CareLink Model 2090 Programmer are not MRI safe and should not be brought into MRI controlled room (magnet room).

Post-MRI operation

- Check the programmed parameters of the Reveal DX or the Reveal XT after the MRI procedure.
- Print or save the data collected during the MRI procedure to diskette because the MRI procedure may temporarily affect the Reveal DX or the Reveal XT's event detection and recording. The date and time of the MRI procedure should be recorded under the Patient icon in the notes section for future reference. Note: The Cardiac Compass trend data cannot be cleared and might show irregularities at the time of the MRI operation.