MRI ACCESS

Evera MRI™ SureScan™
ICD Systems
CONTOURED.
Greater patient comfort with 30% reduction in skin pressure.¹

LONG-LASTING.
So patients can spend more time living, and less time receiving device replacements.

SMART.∗
The most advanced shock reduction suite, so patients receive fewer inappropriate shocks.²

The Evera MRI™ SureScan™ ICD system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. A complete SureScan ICD system, including the Evera MRI SureScan ICD and one or two SureScan ICD leads, is required for use in the MRI environment.

∗ SmartShock™

36% of ICD patients are likely to have an MRI ordered over 4 years³

Data from 2012 were used to project MRI utilization in the ICD patient cohort over 4 years; whereas the actual MRI utilization rate over 4 years was measured in the non-ICD cohort.

ICD Patients are not receiving MRIs

MRI 36%

Non-ICD Patient Cohort⁴
N = 9,385

MRI 1.4%

ICD Patient Cohort³
N = 9,385

¹ MRI ACCESS.
Introducing Evera MRI™, featuring SureScan™ MRI Technology.

³ MRI 36% of ICD patients are likely to have an MRI ordered over 4 years.

⁴ Non-ICD Patient Cohort
N = 9,385

² SMART.∗ The most advanced shock reduction suite, so patients receive fewer inappropriate shocks.

² SmartShock™

Evera MRI™ SureScan™ ICD system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. A complete SureScan ICD system, including the Evera MRI SureScan ICD and one or two SureScan ICD leads, is required for use in the MRI environment.

∗ SmartShock™
EXPANDING ACCESS

Together, we can now provide ICD patients optimal imaging, according to ACR.*5

WITH EVERA MRI PATIENTS HAVE ACCESS TO FULL BODY MRI SCANNING*6

<table>
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<tr>
<th>CT</th>
<th>MRI</th>
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<tr>
<td>Better for bony tissue</td>
<td>Superior for soft tissue</td>
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<tr>
<td>Uses ionizing radiation (multiple CT scans means added risk to patient as x-ray dose is cumulative)</td>
<td>Uses magnetic energy and RF (no cumulative dose risk)</td>
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<tr>
<td>Contrast, if used, is iodine based and may cause allergic reactions</td>
<td>Contrast (if used) has low risk</td>
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**Stroke patients with an ICD are not getting optimal diagnostic imaging**

44% of non-ICD patients undergo an MRI within 3 days of stroke or TIA diagnostic vs. 1% of patients with a traditional ICD.3

**Back Pain**

22% of non-ICD patients undergo an MRI within 30 days of back pain diagnosis vs. 0.7% of patients with a traditional ICD.3

**Joint Pain**

17% of non-ICD patients undergo an MRI within 30 days of joint pain diagnosis vs. 0.1% of patients with a traditional ICD.7

* American College of Radiology.
**PROVEN EVIDENCE AND EXPERIENCE**

SureScan Technology
backed by 5 prospective clinical trials and robust computer modeling

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<td>SureScan Pacing Lead and Industry Exclusive Modeling Capability</td>
<td>SureScan Lead with 400,000 Modeling Scenarios</td>
<td>464 SureScan Patients</td>
<td>263 SureScan Patients</td>
<td>Improve Modeling with Accuracy and Speed</td>
<td>5076 Lead, 6935M Lead, 6947M Lead with 2.3 million Modeling Scenarios10</td>
<td>5076 MRI Trial11</td>
<td>Sprint Quattro MRI™, 6947M and 6935M leads</td>
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**1997**

18+ YEARS
of MRI research experience

Industry-exclusive modeling testing safety of over 2.3 MILLION SCANNING SCENARIOS10

OVER 3,700 patients enrolled in SureScan Pacemaker and ICD PROSPECTIVE Clinical Studies7,8,10

6+ YEARS
of SureScan Pacemaker market experience

350,000+
SureScan Pacemaker and ICD Systems sold worldwide14

**2015**

Post-MRI Results12
- No MRI-related complications
- No difference in ventricular pacing capture thresholds or sensing amplitude between the MRI and control groups
- No impact on detection and therapy delivery

Evera MRI Clinical Study12
- Prospective, randomized study
- 275 patients at 42 centers globally
- No positioning restrictions
- Demonstrated that the system is safe and effective
BUILT FOR MRI

We specifically engineered the Evera MRI SureScan ICDs for the MRI environment, with enhancements that ensure patient safety during an MRI scan.\(^{10}\)

We made hardware component changes to ensure high energy fields do not damage circuits and firmware changes, for ease of use.\(^{10}\)

Leads: Now with MRI Access

Combine SureScan leads with a SureScan device in any combination.

**Defibrillation Leads**
- Designed for Reliability
- Proven by Active Monitoring

With over 10 years of experience, the Sprint Quattro\(^*\) family of leads has proven performance you can depend on for your ICD patients. The 6947M and the 6935M are now approved for use in the MR environment.

**Pacing Leads**
The 5076 and 5086 pacing leads have been tested and approved for use in the MR environment.

**PHYSIOCURVE\(^{TM}\)**

30% reduction in skin pressure\(^1\)

- Tapered at the header and bottom of device to reduce skin pressure and promote patient comfort
- Smaller footprint for a smaller incision
- Designed with lead wrap in mind: Landing area to minimize additional stress on the lead\(^{15}\)

SureScan Systems proven to mitigate the following hazards\(^{10}\):

- ✓ force, torque and heating
- ✓ unintended cardiac stimulation
- ✓ device interactions in the MRI
UNMATCHED ASSURANCE
Our performance assurance program demonstrates the confidence we have in SmartShock.
We will reimburse up to $500 to any patient with an eligible device* — one with SmartShock or SmartShock 2.0 Technology — who receives an inappropriate shock, to help cover certain unreimbursed medical expenses incurred while seeking medical care.**

* Eligible devices: Viva™ XT, Viva S, Protecta™ XT, Protecta ICD CRT-Ds; Evera MRI™ XT, Evera MRI S, Evera™ XT, Evera S, Protecta XT, Protecta ICDs.
** SmartShock Technology algorithms must be programmed “ON” (with parameter settings below) at the time of the inappropriate shock. Medtronic will cover uninsured medical expenses, not to exceed $500, per patient shocked event. This offer is valid for the lifetime of the device.

98.5% of dual chamber and triple chamber patients and 97.5% of single chamber patients were free from inappropriate shocks at one year.2

Inappropriate shock rates for Single, Dual and Triple Chamber ICD patients

- Single Chamber
- Dual and Triple Chamber

No. at Risk: 713

8 YEARS Warranty for Evera MRI XT DR*

10 YEARS Warranty for Evera MRI XT VR*

98.5%
97.5%
Dual and Triple Chamber
Single Chamber

9.7 YEARS Projected Longevity
Single Chamber
Evera MRI XT and Evera MRI S

11 YEARS Projected Longevity
Dual Chamber
Evera MRI XT

* Limited lifetime warranty, some restrictions may apply. The limited lifetime warranty applies to the performance of the device and includes some reimbursement to patients of unreimbursed medical expenses. The warranty is limited to the provisions in the written Limited Warranty document that accompanies each product. Consult the written limited warranty document for details, a copy of which will be provided upon request.
Brief Statement for Evera MRI™

The Evera MRI SureScan™ defibrillation system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MR machine when used according to the specific MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Indications for Use

The Evera MRI SureScan system is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use according to the specified MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Contraindications

The Evera MRI SureScan system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia or sepsis. The device is contraindicated for patients who have a unipolar pacemaker implanted. The device is contraindicated for patients with incessant VT or VF. For dual chamber devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia.

Warnings and Precautions

Changes in patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors or abandoned leads; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; a SureScan defibrillation system implanted in the left or right atrium or right ventricle; pacing capture thresholds ≤ 2.0 V at a pulse width of 0.4 ms; no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is programmed to On. Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T MRI system with operating frequency of 64 MHz, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. Scanner must be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg).

Continuous patient monitoring is required while MRI SureScan is programmed to On. While MRI SureScan is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased.

Potential Complications

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate tachyarrhythmia episodes, acceleration of ventricular tachycardia and surgical complications such as hematoma, infection, inflammation and thrombosis. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation or exit block.

The Evera MRI SureScan system has been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MR-induced stimulation on leads resulting in continuous capture, VT/VF and/or hemodynamic collapse.

See the MRI SureScan Technical Manual before performing an MRI Scan and Device Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1(800) 328-2518 and/or consult Medtronic’s website at www.medic.com or www.mrisurescan.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

References

4. Medtronic data on file 2015: Data from MarketScan® 2012 Commercial and Medicare Database, Truven Health Analytics.