

## Evera MRI™ SureScan® ICD

The Medtronic Evera MRI™ SureScan® implantable cardioverter defibrillator (ICD) is the first FDA-approved ICD for use with magnetic resonance imaging (MRI) scans positioned on any part of the body.

Until now, patients with ICD systems have been contraindicated by the FDA from receiving MRI scans because of potential interactions between the MRI and device function, which might result in risk to patients. These MRI restrictions have resulted in a critical unmet need as data have shown that, within four years, more than one-third of patients with ICDs – 36 percent – are likely to need an MRI.<sup>1</sup>

The Evera MRI ICD system – composed of the Evera MRI ICD and Sprint Quattro® Secure MRI SureScan® DF4 leads – includes hardware and software design enhancements from previous generation devices that allow it to safely undergo full-body MRIs, while maintaining the same longevity, proven shock reduction and physiological size and shape of the original Evera® ICD.



### Specific Device Features

- **PhysioCurve® Design:** A contoured shape with thin, smooth edges that better fits inside the body, increasing patient comfort by reducing skin pressure by 30 percent<sup>2</sup>
- **Greater Battery Longevity and MR-Conditionality:** Industry-leading projected battery longevity and proprietary battery technology, offering up to a 25 percent increase in battery longevity (up to 11 years) compared to previous devices<sup>3-10</sup>
- **Paired with Sprint Quattro Secure® MRI SureScan DF4 Leads:** The Sprint Quattro® Secure MRI SureScan DF4 leads are part of the Sprint Quattro Secure family of ICD leads, which has 10 years of proven performance with active monitoring,<sup>11</sup> and is safe for use in an MRI environment<sup>12</sup>
- **SmartShock™ 2.0:** Exclusive, industry-leading shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms<sup>13</sup>
- **OptiVol® 2.0 Fluid Status Monitoring and Complete Diagnostics:** Designed to identify patients at risk of worsening heart failure and atrial fibrillation

### Evera MRI Clinical Trial

The Evera MRI Clinical Trial was the first randomized study of an ICD system that allows for full-body 1.5 Tesla (the field strength of the magnet) MRI scans. Results showed that full-body MRI scans do not affect the Evera MRI ICD's ability to detect potentially lethal heart rhythms and deliver life-saving therapy.<sup>14</sup>

- **Safe: 100 percent** freedom from MRI-related complications ( $p < 0.0001$ )
- **Effective:** The MRI scan did not have any impact on the Evera MRI device's sensing, detection or therapy delivery in patients who experienced ventricular tachycardia/ventricular fibrillation (an abnormally fast or quivering heart rhythm) post-MRI. (34 cases of VT/VF in 24 patients, of which 20 were induced and 14 were spontaneous)<sup>14</sup>
  - No patients who underwent an MRI experienced a significant increase in the pacing capture threshold (PCT), the amount of energy needed to stimulate the heart.

<sup>1</sup> Nazarian S, Reynolds M, Ryan M, et al. Estimating the Likelihood of MRI in Patients After ICD Implantation: A 10-Year Prediction Model. *J Am Coll Cardiol.* 2015;65(10S)

<sup>2</sup> Flo, Daniel. Device Shape Analysis. January 2013. Medtronic data on file.

<sup>3</sup> Knops P, Theuns DA, Res JC, et al. Analysis of implantable defibrillator longevity under clinical circumstances: implications for device selection. *Pacing Clin Electrophysiol.* October 2009;32(10):1276-1285.

<sup>4</sup> Schaer BA, Koller MT, Sticherling C, et al. Longevity of implantable cardioverter defibrillators, influencing factors, and comparison to industry-projected longevity. *Heart Rhythm.* December 2009;6(12):1737-1743.

<sup>5</sup> Biffi M, Ziacchi M, Bertini M, et al. Longevity of implantable cardioverter-defibrillators: implications for clinical practice and health care systems. *Europace.* November 2008;10(12):1288-1295.

<sup>6</sup> Kallinen L, et al. 2009. <http://spo.escardio.org/eslides/view.aspx?eevtid=33&id=1913>.

<sup>7</sup> Thijssen J, Borleffs CJ, van Rees JB, et al. Implantable cardioverter-defibrillator longevity under clinical circumstances: an analysis according to device type, generation, and manufacturer. *Heart Rhythm.* April 2012;9(4):513-519.

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- <sup>8</sup> Shafat T, Baumfeld Y, Novack V, et al. Significant differences in the expected versus observed longevity of implantable cardioverter defibrillators (ICDs). *Clin Res Cardiol*. Published online July 14, 2012.
- <sup>9</sup> Horlbeck FW, Mellert F, Kreuz J, et al. Real-world data on the lifespan of implantable cardioverter-defibrillators depending on manufacturers and the amount of ventricular pacing. *J Cardiovasc Electrophysiol*. December 2012;23(12):1336-1342.
- <sup>10</sup> Evera XT DR/VR Manual.
- <sup>11</sup> Medtronic Product Performance Report, 2012 Second Edition, Issue 66.
- <sup>12</sup> Models 6935M (55cm, 62cm) and 6947M (55cm, 62cm)
- <sup>13</sup> Auricchio, Angelo et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. *Heart Rhythm*. Published online: January 27, 2015
- <sup>14</sup> Gold MR, Torsten S, Schwitter J, et al. Full-Body MRI Scanning in Patients with an ICD: Primary results of the randomized Evera MRI Study. *J Am Coll Cardiol*. Published online May 14, 2015.