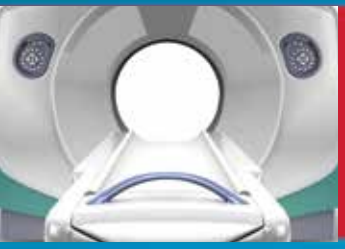
Medtronic

Evera MRI® XT & Evera MRI® S SureScan®

ICD SYSTEMS



Fit for LIVING. Fit for MRI.

FULL BODY FIRST MRI ICD

It’s contoured.

30% reduction in skin pressure, designed for greater patient comfort.[1]

It lasts longer.

Up to 25% greater longevity,[2] so patients spend less time getting device replacements and more time living.

It’s smart.*

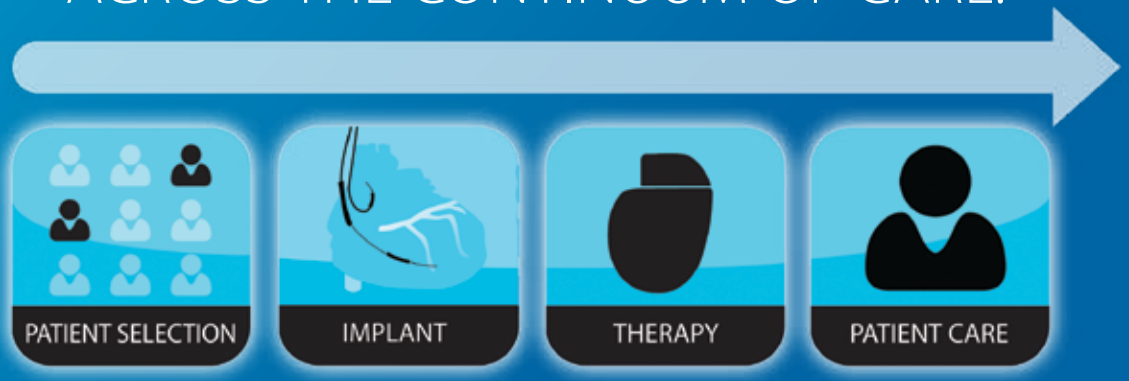
The most advanced shock reduction suite has been enhanced, so patients receive fewer inappropriate shocks.[3]

It’s MRI Access.

Featuring SureScan® MRI Technology, patients can get full MRI access with Evera MRI®.

Fit for Living. Fit for MRI.

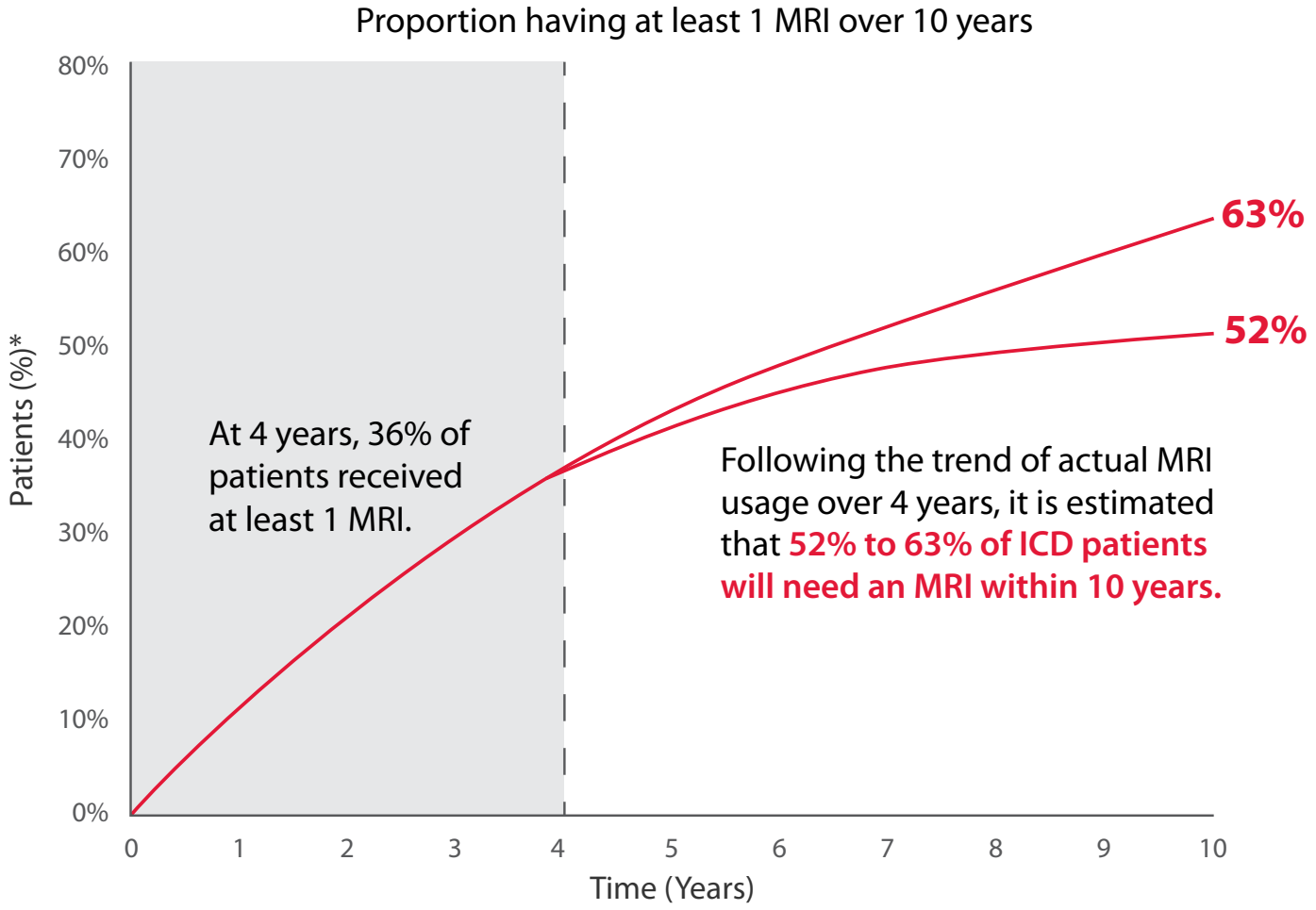
ACROSS THE CONTINUUM OF CARE.



* SmartShock®

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

52% to 63% of ICD patients will need an MRI within 10 years*

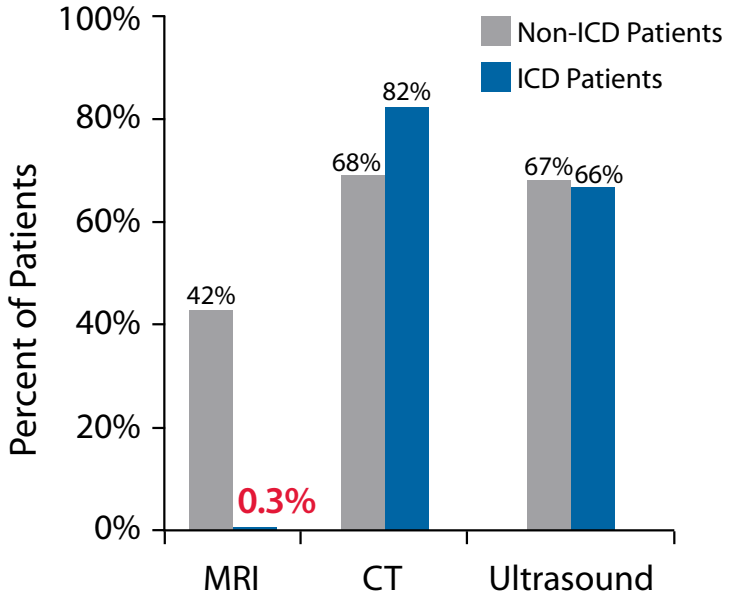


*Patient cohort represents ICD patients in terms of age, gender, and major comorbidities (N = 10,778).
Turakhia M, Reynolds M, Wolff S, et al. Medtronic Data on File 2013. Data from 2011 MarketScan® Commercial and Medicare database, Truven Analysis, Inc. were used for this research.

Historically, ICD patients have not been getting optimal imaging,[4] based on ACR* recommendations

Stroke patients with an ICD are not getting optimal diagnostic imaging

42% of non-ICD patients undergo an MRI within 3 days of stroke or TIA diagnosis vs. **0.3%** of patients with a traditional ICD.[5]



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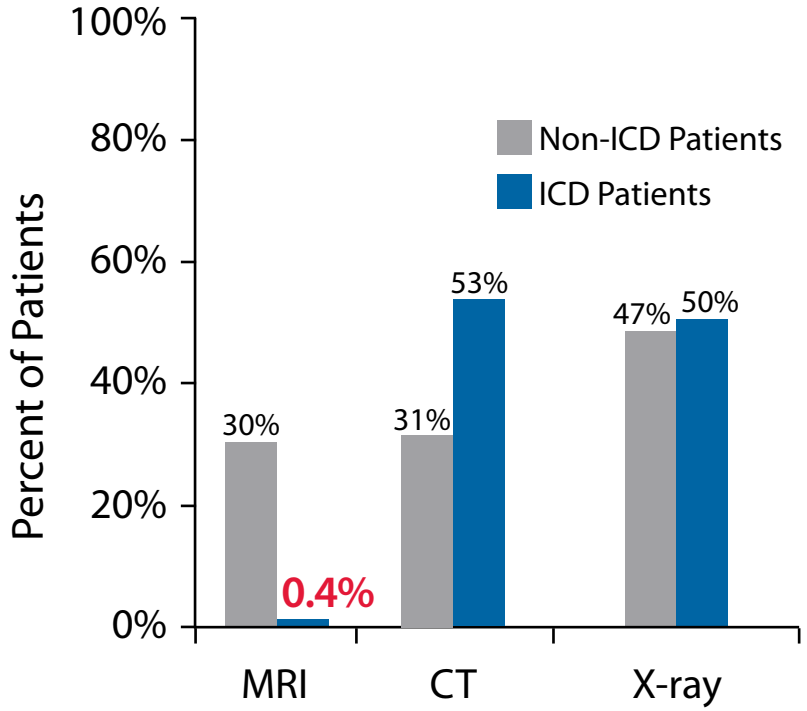
* American College of Radiology.

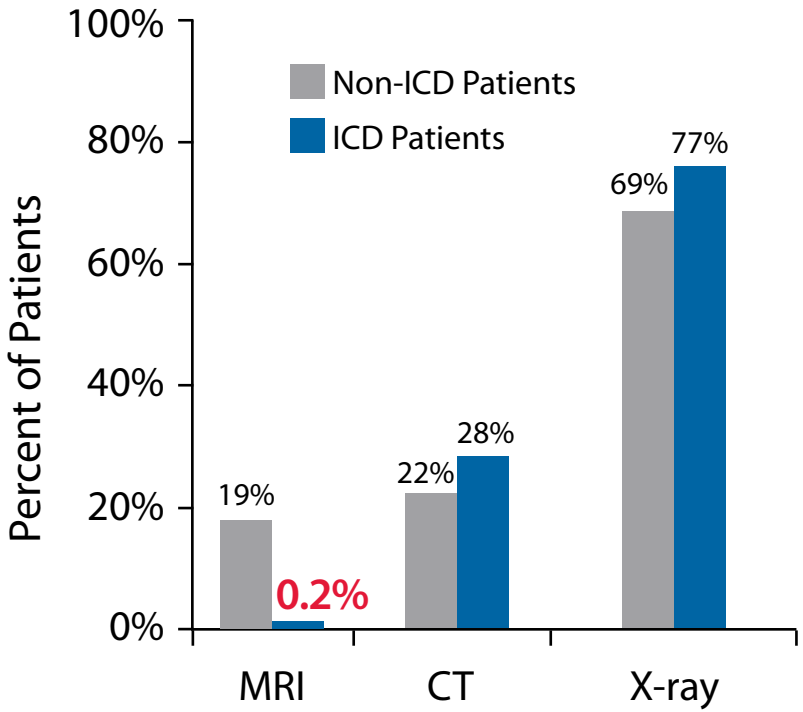
Back Pain

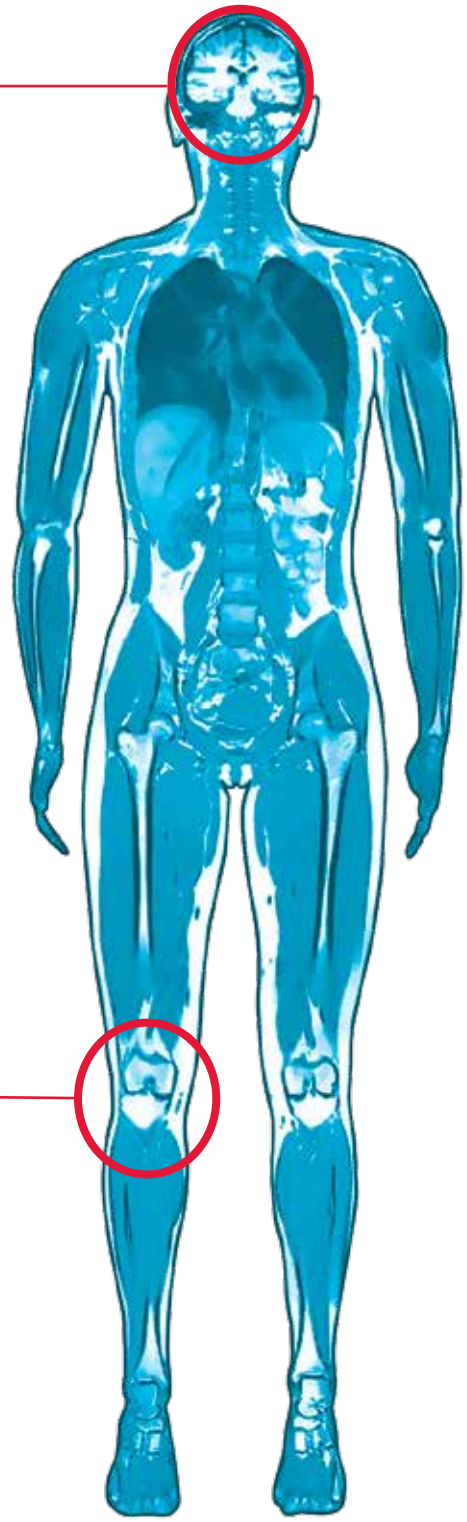
30% of Non-ICD patients undergo an MRI within 30 days of back pain diagnosis vs. **0.4%** of patients with a traditional ICD.[5]



Joint Pain (Knees, ankles, elbows, shoulders, & wrists)

19% of Non-ICD patients undergo an MRI with 30 days of joint pain diagnosis vs. **0.2%** of patients within a traditional ICD.[5]





Patients have access to full body MRI scanning

with Evera MRI

No MRI exclusion zone

No MRI scan duration restriction

No patient height restrictions

MRI possible
for the entire life of the system

No patient condition restrictions
such as fever[6]

Until a patient needs a scan, it's difficult to predict which part of the body will need to be scanned.

EVIDENCE AND EXPERIENCE

The SureScan Journey: 17+ years to provide a full featured ICD with full body MRI scanning

DEVELOP:
5086 MRI Pacing Lead and Industry Exclusive Modeling Capability

1997

TEST:
5086 Lead with **400,000** Modeling Scenarios

VALIDATE:
EnRhythm MRI® and Advisa MRI Clinical Studies
727 patients

2008
First SureScan Pacemaker System

Specifically **Engineered for MRI**

SureScan® devices are built to withstand the MRI environment. Device enhancements are made to allow MRI scanning.

Mitigates the following hazards:

- ☑ force, torque, and heating
- ☑ unintended cardiac stimulation
- ☑ device interactions in the MRI

REFINE:
Improve Modeling with **Accuracy** and **Speed**

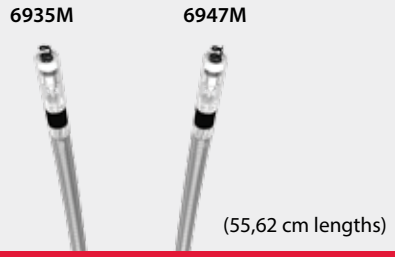
TEST:
5076 Lead, 6935M Lead, 6947M Lead with **2.3 million Modeling Scenarios**

2014

Evera MRI: First SureScan ICD System

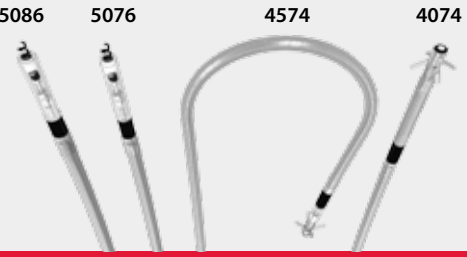
Leads: **NOW** with **MRI ACCESS**

MR-Conditional Leads to complete the SureScan System



Defibrillation Leads

Designed for Reliability. Demonstrated by Active Monitoring. With over 10 years of experience, the Sprint Quattro family of leads has demonstrated 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

Since the launch of the 5086 MRI Pacing lead, the 5076, 4574, and 4074 pacing leads have been tested and approved for use in the MR environment.

17+ years
of MRI research experience

Industry-Exclusive modeling testing
2.3 million scanning scenarios

Over 2,700
patients enrolled in SureScan Pacemaker Post-market Clinical Studies

5+ years
of SureScan Pacemaker Market Experience

200,000 +
SureScan Pacemaker Systems implanted worldwide

Advanced ICD Technology with **Full Body** MRI Access

Full Body MRI

PhysioCurve®

Designed for patient comfort. 30% less skin pressure versus conventional ICD shapes.[1]

SmartShock® Technology

Six Medtronic exclusive algorithms. The PainFREE SST study showed 98% of patients are free of inappropriate shocks at one year.[3]

Greater Longevity

Up to 25% greater longevity[2]

MVP®*

Reducing unneccesary ventricular pacing has been shown to reduce the risk of AF.[7-10] MVP has been shown to reduce unnecessary ventricular pacing.[11]

OptiVol® **

Fluid Status Monitoring

CareLink® Network

Remote monitoring capability for all cardiac devices

Complete Capture Management™

Extends longevity of the device by up to one year[12]

AF Diagnostics*

AT/AF Detection Accuracy[13,14]

Atrial ATP*

In combination with MVP, reduce permanent AF by 61% compared to standard dual chamber pacing[15]

* Dual chamber only
** Evera MRI XT devices only

PhysioCurve

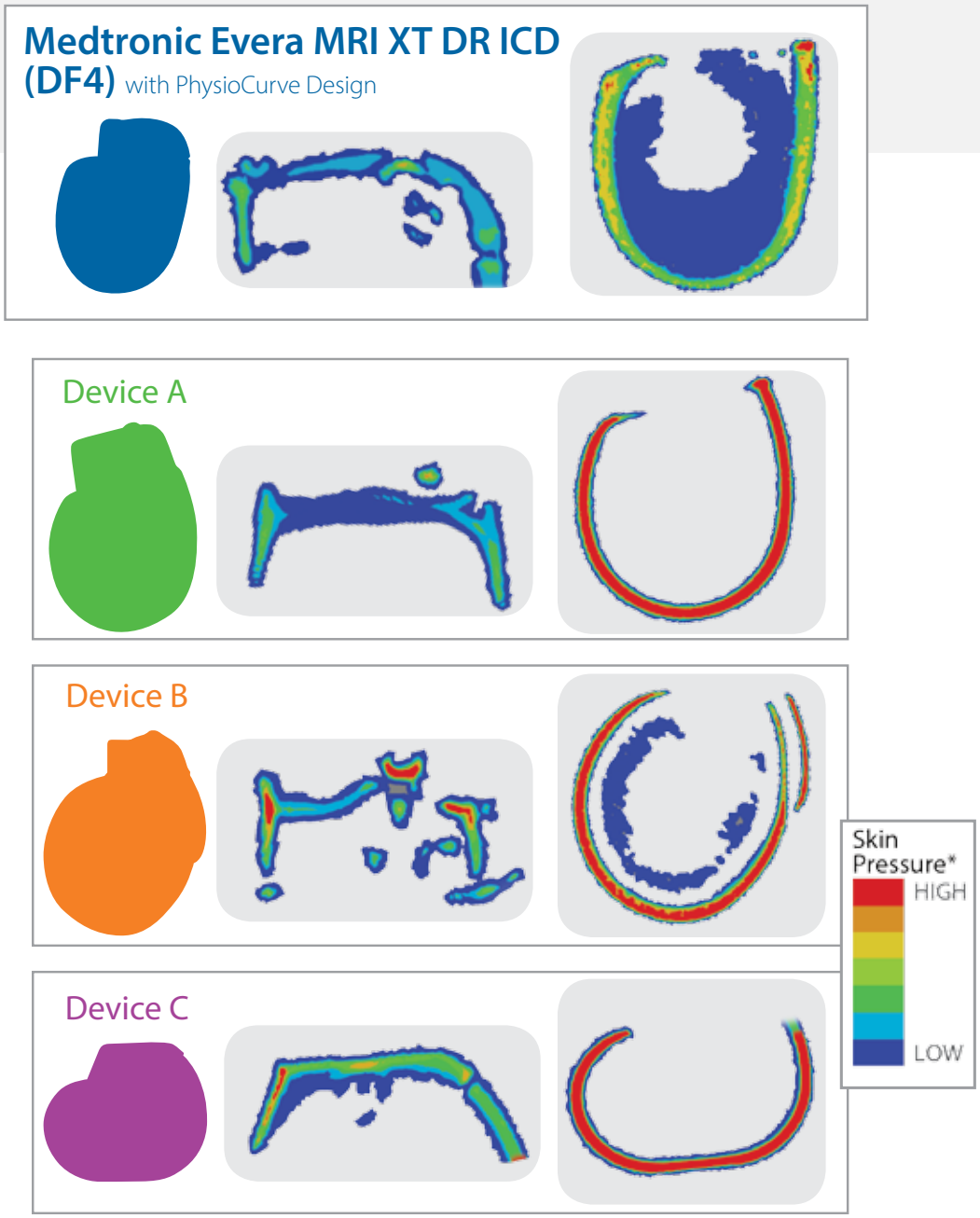
30% reduction in skin pressure[1]

Designed with lead wrap in mind: Landing area to minimise additional stress on the lead[16]

Tapered at the header and bottom of device to promote patient comfort

Smaller footprint for a smaller incision

* Pressure contour plots are scaled relative to each other: header to header, device body to device body. The device body pressure uses an enhanced scaling to demonstrate the pressure differences across the device body; therefore actual pressure is not relative to the header pressure. Note: Analysis for Evera and Device A dual chamber ICDs with DF4 connectors were used. Analysis for Devices B and C used dual chamber ICDs with DF-1 connectors.



SmartShock 2.0

Evera MRI XT

Now with 30/40 NID* nominal

Out of the box settings
clinically shown to reduce shocks

Medtronic **made a promise** about SmartShock Technology:
98% of patients would be free of inappropriate shock at 1 year.[17]

Medtronic **fulfilled this promise.**
PainFREE SST Study showed in real-life patients:

98.2% **97.6%**

98.2% of DR and CRT-D patients and 97.6% of VR patients were free of inappropriate shocks at 1 year.[3]

* Number of intervals to detect.

Greater Longevity*

Evera MRI XT builds upon Medtronic's historical device longevity and proprietary battery technology, offering up to 25% greater longevity than Medtronic's Protecta devices[18] so patients spend less time getting device replacements and more time living.

Backed by industry leading warranties

Evera MRI DR — **8 Year Warranty** (5 years full, 3 years prorated)

Evera MRI VR — **10 Year Warranty** (6 years full, 4 years prorated)

25%
Greater Longevity

*The service life projections are based on the following assumptions.
- Semi-annual maximum energy charging frequency
- Pre-arrhythmia EGM storage programmed to On for a 6-month period (two 3-month follow-up intervals), over the entire life of the device
- A quarterly schedule of Medtronic CareLink® Monitor remote transmissions
- Typical shelf storage time before implant. Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

OptiVol 2.0 Fluid Status Monitoring (in Evera MRI XT only)

Maximise accuracy in predicting worsening heart failure[19]

PARTNERS HF showed that OptiVol and the Cardiac Compass® Report identified patients with 5.5 times greater risk of heart failure hospitalisation within the next 30 days.[20]

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More information:

- *www.mrisurescan.com*
- *wwwp.medtronic.com/mrc*

To view device manuals, please visit one of the websites listed above

Brief Statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

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