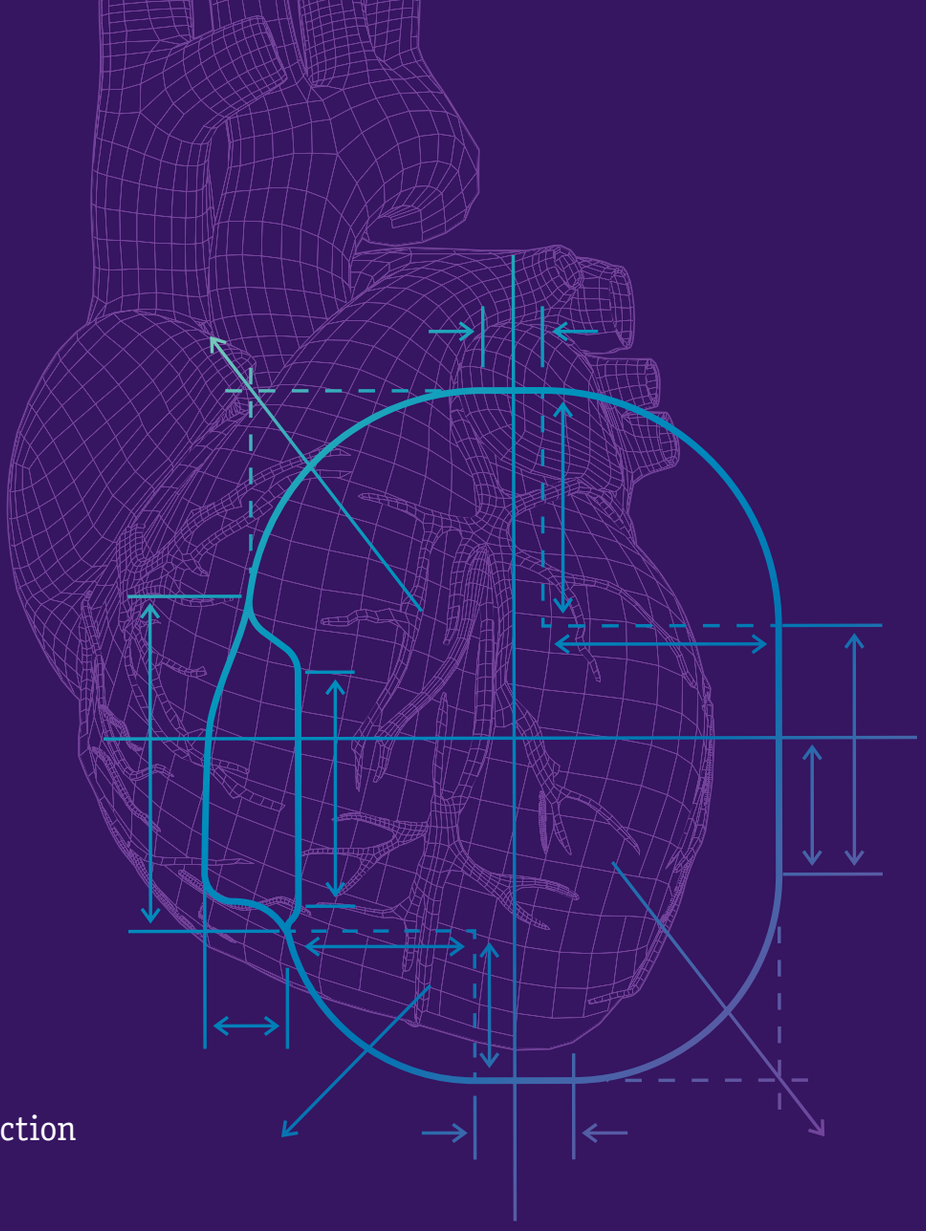
Boston Scientific
Advancing science for life™

S-ICD.
The **new standard** for sudden cardiac death prevention.

EMBLEM™ MRI
S-ICD SYSTEM



The new standard for protection that's anything but.

No matter the industry, the pattern of progress is predictable: people do things one way until a new standard is set, creating a compelling reason to make a change.

The S-ICD is the only ICD in the world to provide protection from both sudden cardiac death and the risks and complications associated with transvenous leads.

With 15+ years of clinical data and over 90,000 patients protected, the S-ICD's comparable efficacy to TV-ICDs is no longer a maybe—it's a certainty.[1]

Suitable for all ICD-indicated patients without a pacing indication—the majority of ICD patients—the S-ICD is the future of protection from sudden cardiac death. And the future is now.

Only one device offers **double protection.**

The EMBLEM™ MRI S-ICD is the only ICD in the world to protect against both sudden cardiac death and the risks and complications associated with transvenous leads. It's double protection you can feel confident about implanting, and with over 90,000 patients served, it's no longer novel or niche—it's the new standard.

Clinical Data

Several landmark trials now confirm: S-ICDs offer effective defibrillation while significantly reducing the risk of complications associated with transvenous leads.[2,3]

Technology Advancement

With advances in technology, 1-year inappropriate shock rates for contemporary EMBLEM MRI S-ICDs are now as low as 2.4%—in many cases lower than those observed with TV-ICDs.[3]

Implant Technique

Advances in implant technique have created a more predictable implant experience, improved cosmesis and more consistent outcomes.[17]

From new idea to new standard: **A history of S-ICD.**

90,000+ patients implanted with S-ICDs worldwide—and counting.

MODULAR ATP

PRAETORIAN DFT[9]

ATLAS Study[10] | 500pts

UNTOUCHED Study[3] | 1111pts

Post Approval Study[4] | 1637pts

PRAETORIAN Trial[2] | 849pts

PRAETORIAN XL

EFFORTLESS Registry[5] | 994pts

EFFORTLESS XL

IDE Study[6] | 330pts

CE Mark Study[7] | 55pts

2001–2008

Proof of Concept

Electrode configuration (2001–2004)

DFT (2004–2005)

First chronic implant (2006–2008)

2009

1st Generation

Introduction of the S-ICD System by Cameron Health

2010

2011

2012

Acquisition of Cameron Health

Dual Zone Programming

Use of conditional zone reduces inappropriate shocks and unnecessary therapy

2013

2014

SMR-8[8]

New double detection algorithm introduced with SMR-8

2015

2nd Generation

Smaller, thinner, longer-lasting device*

LATITUDE™ compatible

2016

3rd Generation

SMART Pass™

AF Monitor

MRI compatible

2017

AHA/ACC/HRS Guidelines[12]

Class I and IIa

Implant Optimizations

Automated screening

Electrode #3501

2-incision labeling

Intermuscular labeling

Electrode Delivery System (EDS)

2018

2019

2020

Model 3300 Programmer

AST 2.0

S-ICD app

2021 and beyond

Future Advancements

mCRM™ Modular Therapy Systems

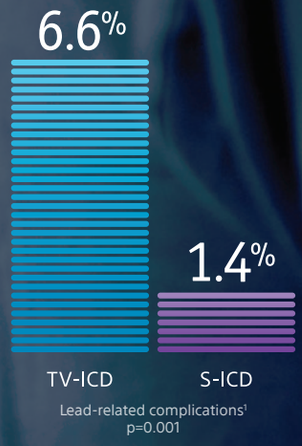
Enrollment Follow-Up Extension

*Than previous generations of S-ICD

Clinical Data

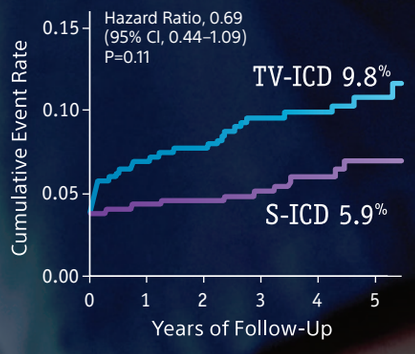
Comparable protection with fewer complications is more than possible—**it's proven.**

Results from the PRAETORIAN Trial—the landmark randomized head-to-head trial comparing S-ICD and TV-ICD—confirm S-ICD is non-inferior to TV-ICD in preventing sudden cardiac death.[2]

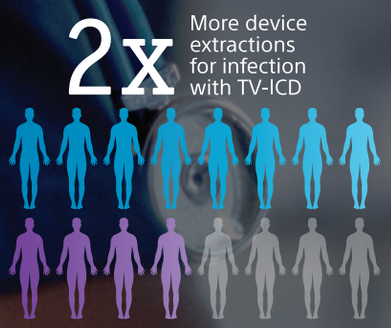


TV-ICD patients experienced 4X more lead-related complications than S-ICD patients did.[2]

TREND TOWARD FEWER DEVICE-RELATED COMPLICATIONS AT 4 YEARS[2]



With the initiated extended follow-up of PRAETORIAN XL, at 8 years trial authors hypothesize S-ICD will demonstrate superiority to TV-ICD for all device-related complications.



TV-ICD patients experienced 2X as many infections that required extraction compared to S-ICD patients.[2]

S-ICD has Class I and Class IIa recommendations for patients at high risk of infection, patients with inadequate venous access and patients without a pacing indication.[12]
In other words,
S-ICD is now recommended for the majority of ICD-indicated patients.

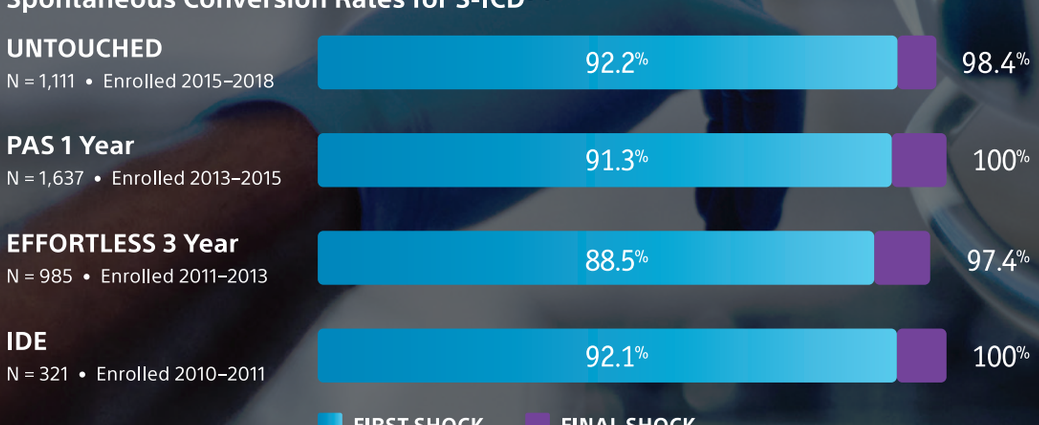
IAS rates for S-ICDs are reaching new lows, while spontaneous conversion rates remain high.

In the UNTOUCHED study, the 1-year inappropriate shock rate was 2.4% for those implanted with third-generation S-ICD technology—comparable to or lower than the rate observed with TV-ICDs in other studies, including the PRAETORIAN Trial.

2.4%
IAS with EMBLEM™ MRI S-ICD[2]

Spontaneous conversion rates for S-ICD are comparable to TV-ICD—and even better in certain studies.[2,3,13,14,15]

Spontaneous Conversion Rates for S-ICD[3-6]



LATITUDE™ data projects the average EMBLEM™ S-ICD longevity to be **8.7 years** in the real world.[16]

A **revolutionary** approach to interpreting heart rhythm.

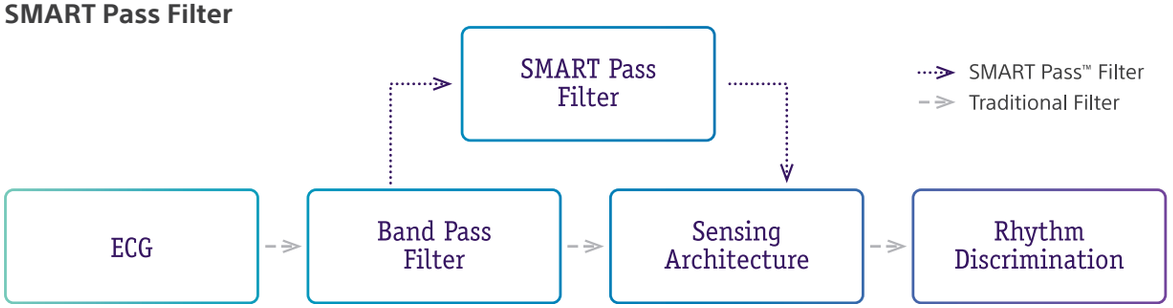
S-ICD uses highly sophisticated INSIGHT™ technology to identify and classify the whole heart rhythm, rather than individual beats—a method that allows it to more effectively sense, determine and convert VT/VF.[9]

The new standard for smarter sensing.

Far-field sensing allows S-ICD to capture a high-definition, morphologically rich signal with up to 41 points on every QRS complex (compared to typically just 8 points for the intracardiac signal of TV-ICDs).

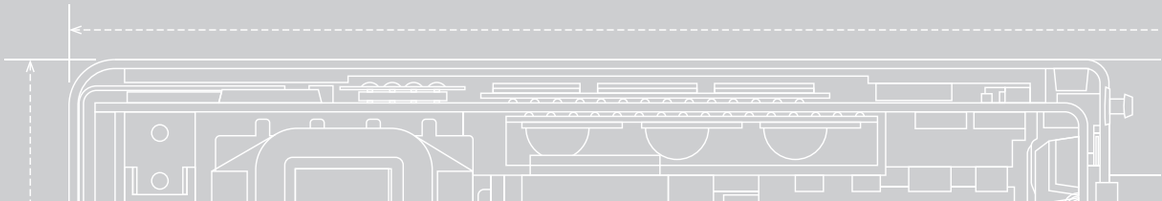
Advancements such as optimized patient screening, dual zone programming, double detection algorithms and the SMART Pass™ filter have reduced the S-ICD's inappropriate shock rate to half the rate of TV-ICDs.[4]

SMART Pass Filter

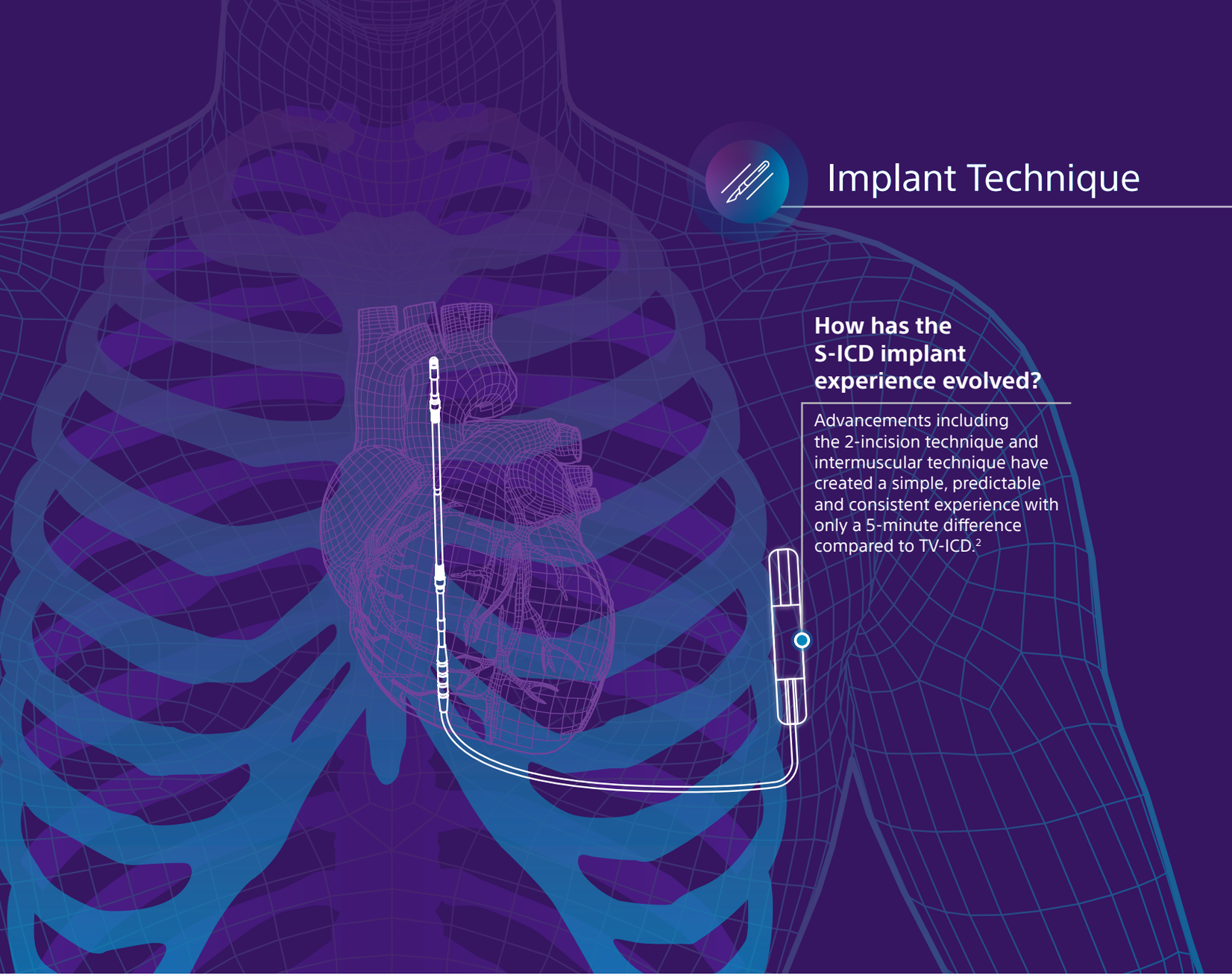


From screening to follow-up, our innovative technology is designed to improve your experience today while expanding the possibilities for tomorrow.

- Easily screen all ICD-indicated patients without a pacing indication with the new and enhanced features of the **EMBLEM MRI S-ICD Automated Screening Tool (AST) 2.0.**
- Screen, implant and follow-up S-ICD patients on the **LATITUDE Programming System, Model 3300.**
- Remotely monitor patients between visits with the **LATITUDE NXT Patient Management System.**



Implant Technique



How has the S-ICD implant experience evolved?

Advancements including the 2-incision technique and intermuscular technique have created a simple, predictable and consistent experience with only a 5-minute difference compared to TV-ICD.[2]

One less incision creates two important benefits.

By eliminating the superior parasternal incision used in the three-incision technique, the two-incision technique reduces the average procedure time by 17.3 minutes (P<0.0001) and improves cosmetic outcomes.[18]

Our technology. Your expertise.

By positioning the device between the anterior surface of the serratus anterior and the posterior surface of the latissmus dorsi, the intermuscular technique helps drive a predictable and consistent implant experience in several ways:[16]

- Device is in the optimal position for DFT and impedance measurements
- Reduced risk of pocket complications (erosion and infection)
- Reduced device migration
- Improved patient comfort and cosmesis
- Can benefit patients with both low and high BMI

As the only ICD with double protection, now is the time to **choose S-ICD first.**

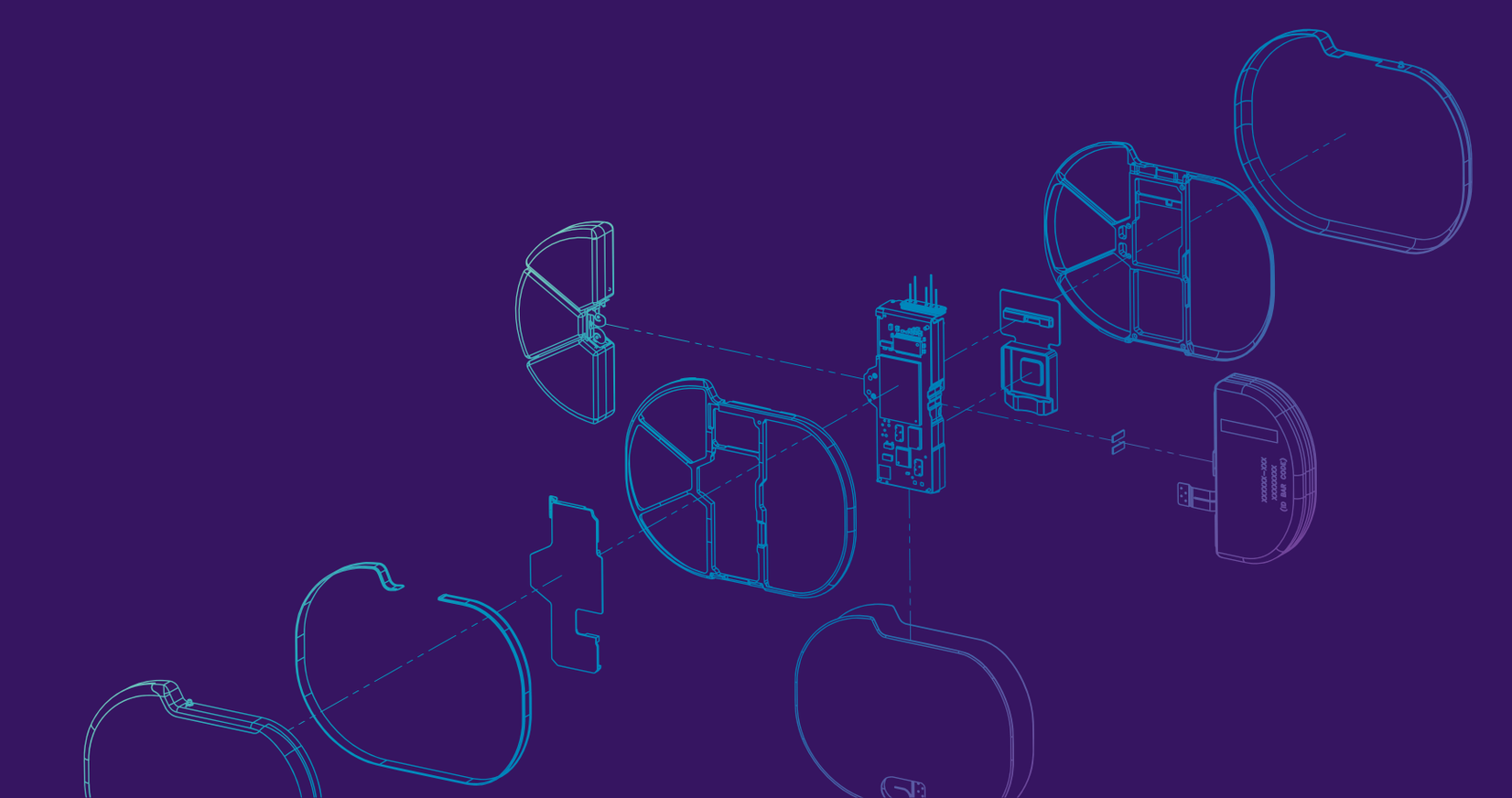
S-ICD has come a long way. It's no longer the niche solution it once was. In fact, it's now suitable for the majority of ICD-indicated patients, and has provided protection without the risks of transvenous leads for over 90,000 patients and counting.

With fewer lead- and device-related complications and lower inappropriate shock rates than TV-ICDs, plus continued innovation in technology and implant technique, there are more reasons than ever before to choose S-ICD.

The future of modern cardiac rhythm management has arrived, and with it a new standard for sudden cardiac death prevention.

That new standard is S-ICD.

Learn more about EMBLEM™ MRI S-ICDs at **bostonscientific.com/sicd**



EMBLEM™ MRI S-ICD SYSTEM

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

EMBLEM™ MRI S-ICD System

INDICATIONS FOR USE

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

CONTRAINDICATIONS

Unipolar stimulation and impedance-based features are contraindicated for use with the S-ICD System.

WARNINGS

Concomitant use of the S-ICD System and implanted electromechanical devices (for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death. Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions changes which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan.

Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

POTENTIAL ADVERSE EVENTS

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, injury to or pain in upper extremity, including clavicle, shoulder and arm, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

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EDUCARE More information, training resources and CME credits available on SICDTraining.com