

# IMPACT OF SMART PASS AND OTHER ADVANCEMENTS ON REDUCTION OF INAPPROPRIATE SHOCKS FOR S-ICD

## Evolution of S-ICD Technology and Clinical Practice to Reduce Inappropriate Shocks

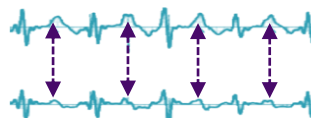
### Dual Zone Programming

Conditional zone reduces IAS and unnecessary therapy

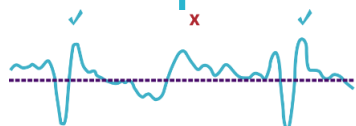


### SMART Pass

SMART Pass reduces the amplitude of lower frequency signals, such as T-waves, by applying an additional high pass filter.

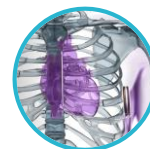


2012 2013 2014 2015 2016 2017 2018 2019 2020



SMR-8

A new double detection algorithm was introduced with SMR-8



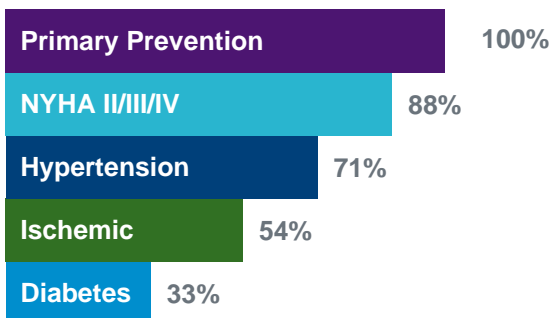
UNTOUCHED

UNTOUCHED combined prescriptive programming (conditional zone of 200 bpm and a shock zone of 250 bpm) with EMBLEM S-ICD technology and a patient cohort representative of those most commonly receiving ICDs (primary prevention, LVEF  $\leq$  35%).

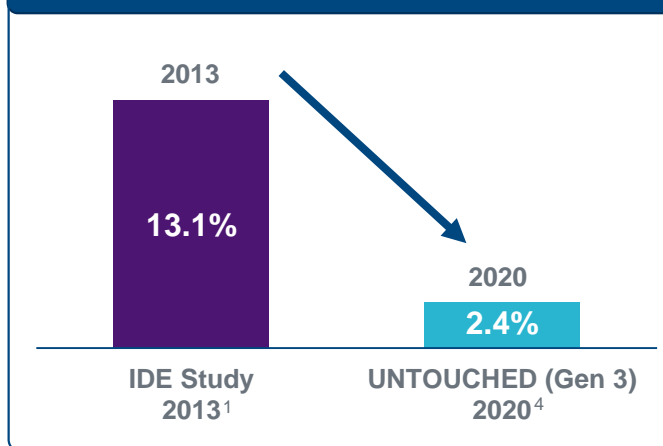
## The IAS Rate of 2.4% at 1 Year for EMBLEM™ MRI S-ICDs in UNTOUCHED is Lowest Reported, Despite a Cohort with More Left Ventricular Dysfunction and Heart Failure<sup>4</sup>

### UNTOUCHED Patient Demographics:

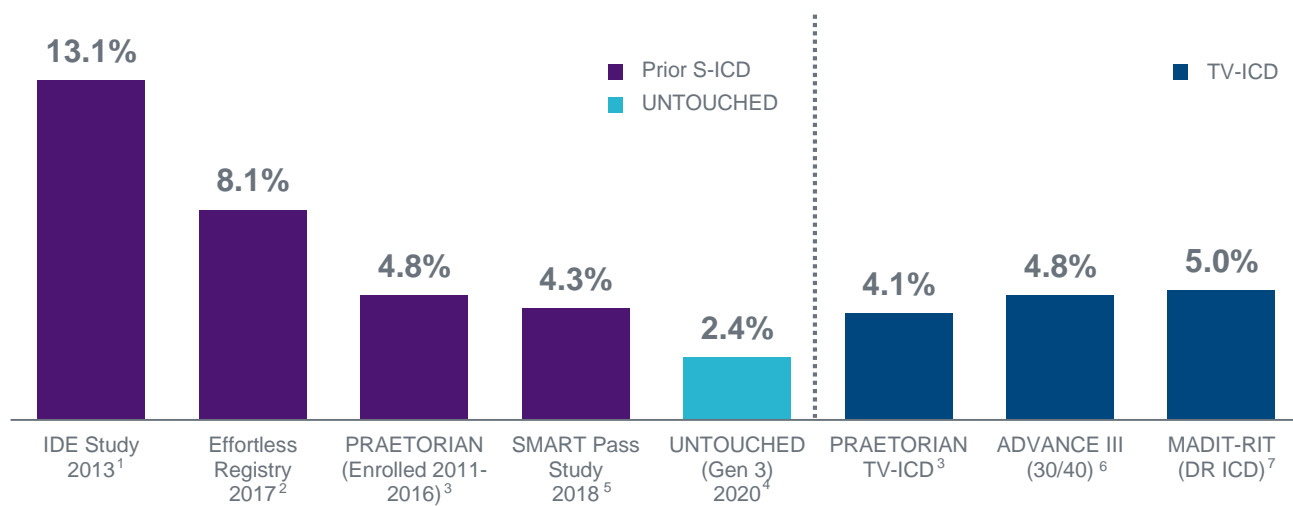
- N = 1,111
- Mean Age: 56  $\pm$  12
- LVEF %: 26  $\pm$  6



### Annual Rate of Inappropriate Shocks



# The IAS Rate of 2.4% at 1 Year for EMBLEM™ MRI S-ICDs in UNTOUCHED is Lower than IAS Rate in TV-ICD Studies<sup>4</sup>



1. Weiss, et al. The Safety and Efficacy of a Totally Subcutaneous Implantable-Defibrillator. CIRCULATION. Vol. 128, no. 9. (August 2013.): 944-953.
2. Boersma, L, Barr, C, Knops, R, et al., Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study. JACC, 2017.
3. Knops R. et al., The PRAETORIAN Trial. HRS LBCT-01 2020.
4. Gold, MR, et al. The UNTOUCHED Study. Circulation. 2020.
5. Theuns, et al. Prospective Blinded Evaluation of a Novel Sensing Methodology Designed to Reduce Inappropriate Shocks by S-ICD. Heart Rhythm. 2018.
6. Gasparini, et al., Long Detection Programming in Single-Chamber Defibrillators Reduces Unnecessary Therapies and Mortality. JACC: Clinical Electrophysiology, 2017.
7. Kutiyifa, et al., Novel ICD Programming and Inappropriate ICD Therapy in CRT-D Versus ICD Patients: A MADIT-RIT Sub-Study. Circ Arrhythm Electrophysiol, 2016.

**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 reached may lead to premature battery 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 reached may lead to premature battery 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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