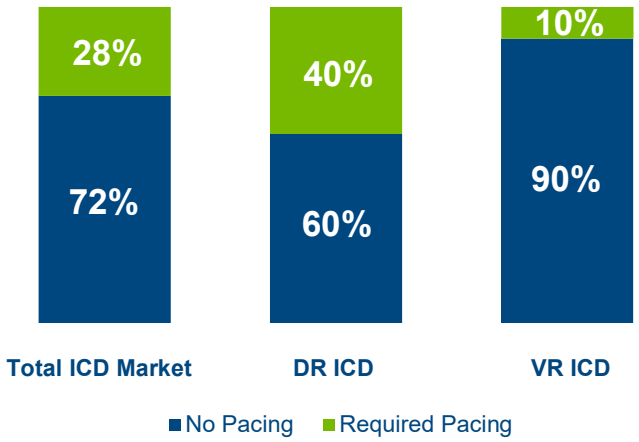
BRADYCARDIA PACING NEED IN ICD PATIENTS

PACING INDICATION AT IMPLANT

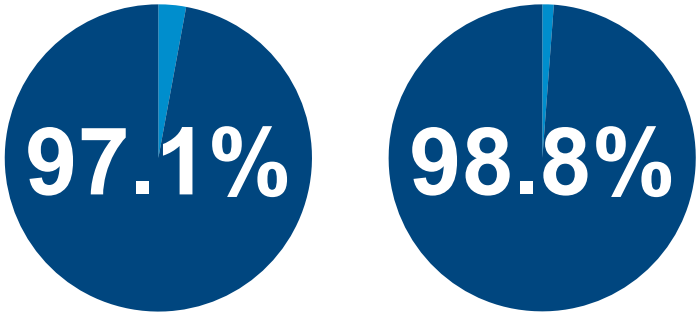
Many ICD Patients Had No Pacing Indication at Implant[1,2]



A published study indicates 72% of ICD patients had no pacing need at implant. LATITUDE data indicates this figure is 90% for VR ICD patients under age 75.

REAL WORLD PROGRAMMING

Few VR ICD Patients Receive Pacing[3]



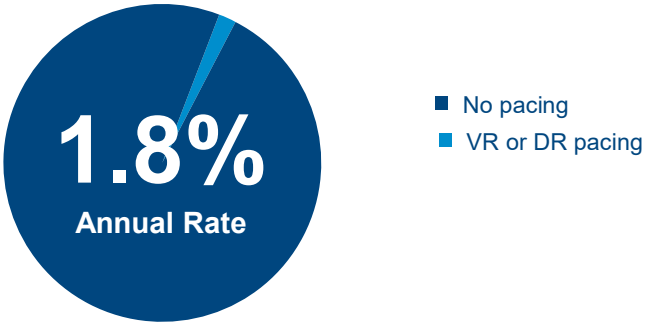
of VR ICD Patients 50 to 70 are programmed ≤ VVI-50

of VR ICD Patients 50 to 70 had < 5% Pacing

According to real-world programming in LATITUDE, 97.1% of patients 50 -70 years of age are programmed to ≤ VVI50 and 98.8% rarely receive pacing.

PREDICTING FUTURE PACING NEED

History of AF and Advanced Age (> 80)[4,6]

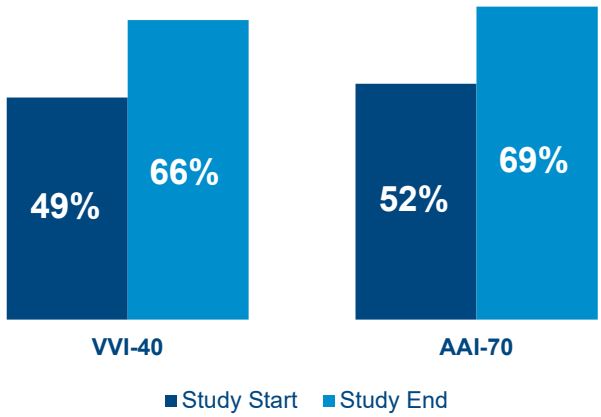


Effect	Odds Ratio (95% CI)	P value
Ongoing AF at implant	11.717 (7.21-19.05)	<..0001
Age > 80	3.29 (1.36-7.91)	0.008

SCD-HeFT demonstrated that only 1.8% of ICD patients per year may develop a need for pacing.[7] The predictors of RV pacing in ICD patients without baseline pacing needs were determined to be history of AF and patient age greater than 80.[4]

BETA BLOCKERS

DAVID II Shows Tolerance in Patients with VVI Pacing[5]



VVI patients averaged 2% pacing at 24 months follow-up with 66% of VVI patients at targeted daily beta blocker doses. DAVID II further suggested that active pacing is not necessarily required to attain adequate dosing levels of beta-blockers.

1. Data on DR devices from Gasparini et al. JACC EP 2017
2. Data on VR devices from LATITUDE Boston Scientific data on file 2018.
3. LATITUDE Data from 2017, all VR ICDs models from TELIGEN™ or newer, patients 90 years of age or less, At least 110 days of counter data since last reset and 200 days since initial implant. Data on file.
4. Abstract 19187: Predictors of Right Ventricular Pacing in ICD Recipients Without Baseline Pacing Needs. Shadi Kalantarian, Haikun Bao, Paul W Jones, Kenneth M Stein, Daniel J Friedman, Frederick A Masoudi, Jeptha P Curtis and Joseph G Akar. Circulation. 2017;136:A19187, originally published November 11, 2017
5. Wilkoff BL, et al. The DAVID (Dual Chamber and VVI Implantable Defibrillator) II trial. J Am Coll Cardiol. 2009 Mar 10;53(10):872-80. doi: 10.1016/j.jacc.2008.10.057.
6. Gillespie, S, Incidence of pacemaker implantation in SCD-HeFT: Are single-chamber ICDs enough in heart failure? Heart Rhythm, 2014. Vol. 11(No. 5 May Supplement): p. PO 01-32

The 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.
Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev. E) 046774 AI

Boston Scientific
Advancing science for life™

Rhythm Management
Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112
Tel: 651.582.4000 Fax: 651.582.4166
Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3288
www.bostonscientific.com

CRM-697503-AA