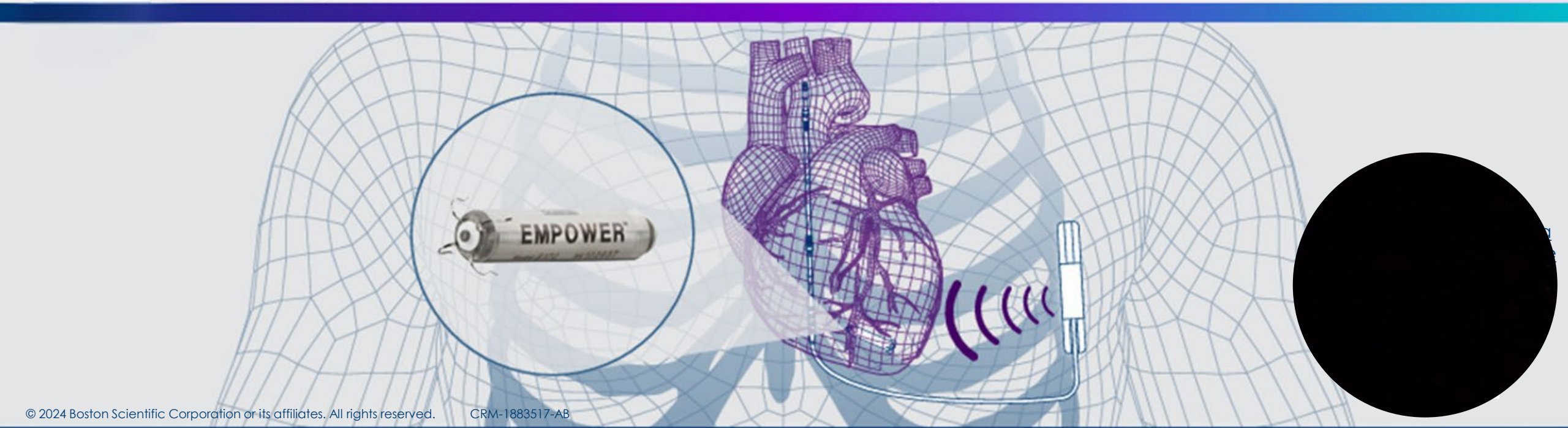
EMPOWER™
Leadless Pacemaker

Boston Scientific
Advancing science for life™

Pacing Performance of the First Leadless Pacemaker Communicating with an S-ICD from the full cohort of the MODULAR ATP study

2024 ESC Late Breaking Clinical Trials

Session: Smaller trials, trial updates, and other studies: devices, cardiac arrest and atrial fibrillation ablation



 CRM-1883517-AB

EMPOWER LP Pacing Performance

From the MODULAR ATP Trial

Boston Scientific

Once the EMPOWER LP and mCRM system receive FDA approval, EMPOWER will be the first and only LP designed to be a standalone VVIR pacemaker that is also only compatible with all EMBLEM S-ICD devices as part of the mCRM system designed to deliver painless ATP and/or brady pacing avoiding transvenous lead complications.[1]

Today we will review the results that support the EMPOWER LP as a standalone LP [16]:

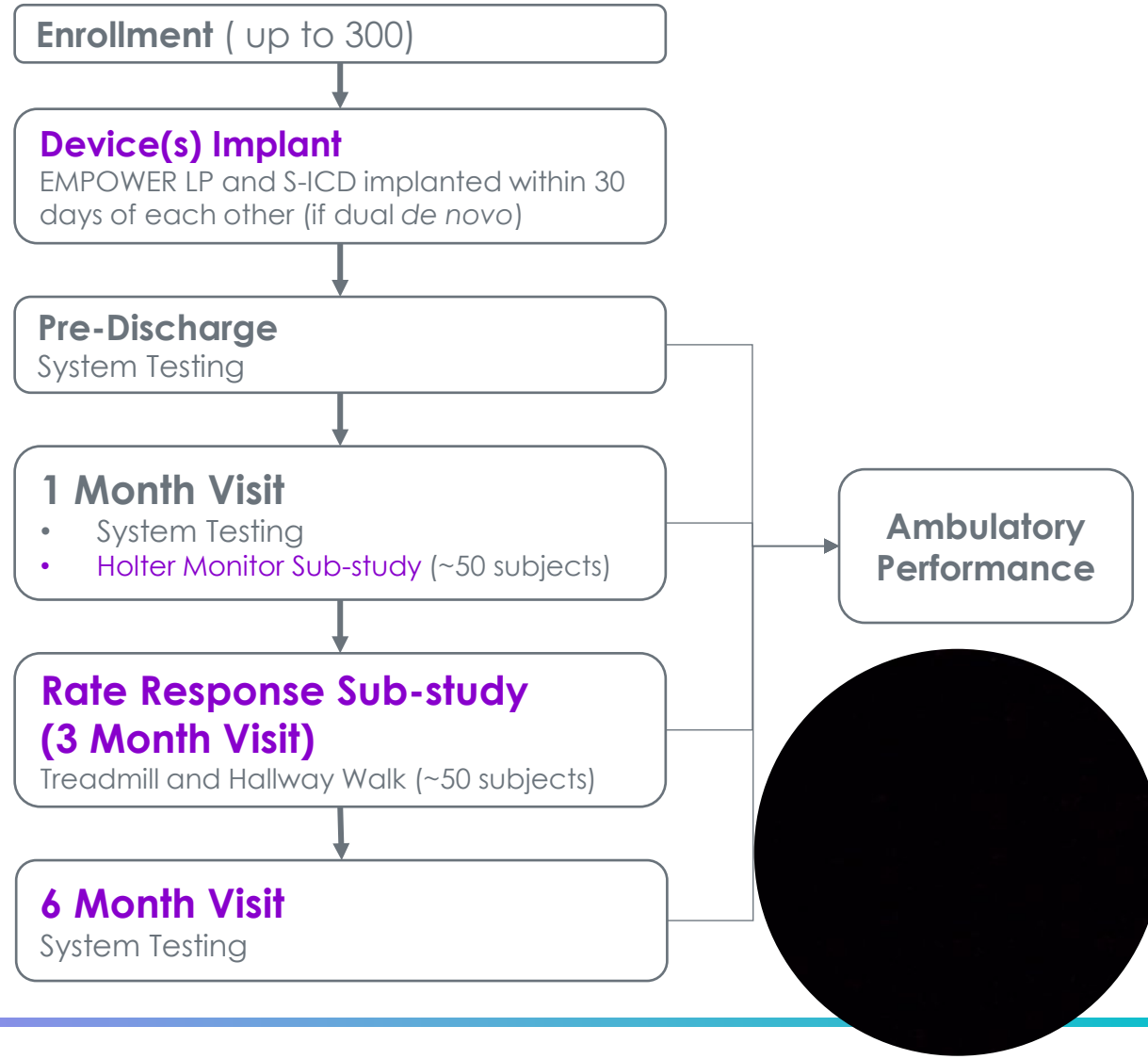
- 6 mo. outcomes from larger study cohort*:
  - Implant Success
  - Complications related to the leadless pacemaker (LP)
  - Pacing parameters
  - Ambulatory pacing burden
- Rate Response Sub-study (n=35)
- Holter Monitor Sub-study (n=31)

*Database snapshot from January 2024 had 293 patients enrolled and 183 patients completed their 6-month follow up. This is an ongoing study with up to 300 patients enrolled.

* Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

Trial Design Modular ATP trial

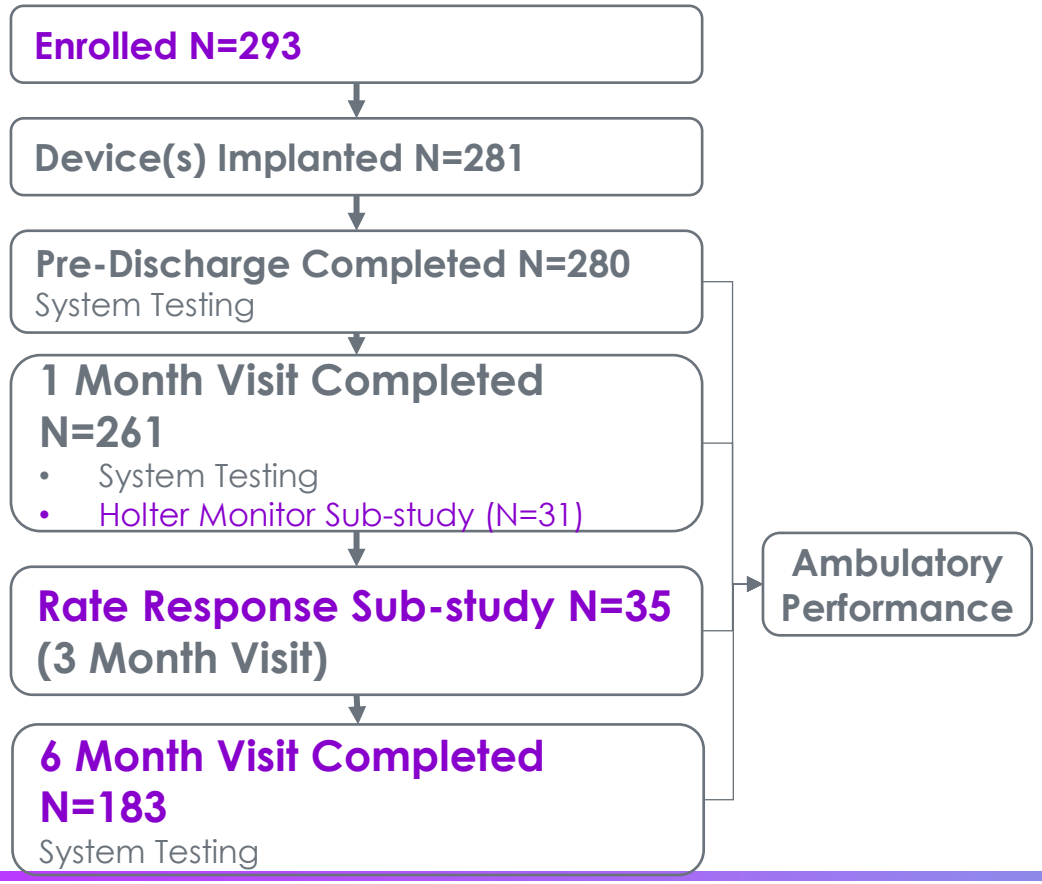
- **Inclusion:**
  - New ICD indication or previous S-ICD
    or TV-ICD to be extracted
  - High VT risk: History of
    - NSVT's + scar
    - VT's
    - ICMP EF <35%
    - NICMP EF <35% + scar
- **Exclusion:**
  Need for chronic pacing:
  Pacing not required for pacemaker-dependency, chronotropic incompetence, or ventricular dyssynchrony



Results

Modular ATP Study Cohort

- Ongoing Study
  - Database snapshot 24 Jan 2024
  - Median follow-up: 8.9 months



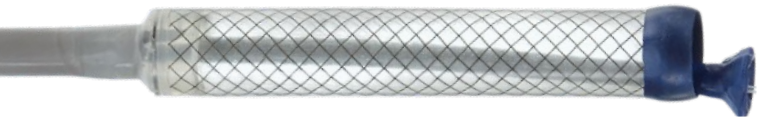
Patient Characteristics	N=293
Age, years	59±12
Female—# (%)	51 (17%)
Body-mass index, kg/m^2	30±6
Secondary prevention—# (%)	126 (43%)
LVEF, percentage	35±13
Ventricular Arrhythmias—# (%)	171 (58%)
Prior defibrillator—# (%)	
Transvenous defibrillator—# (%)	
Subcutaneous defibrillator—# (%)	

EMPOWER Delivery Catheter*

Design Features and Procedural Steps for Increased Patient Safety

Boston Scientific

Flexible Sleeve

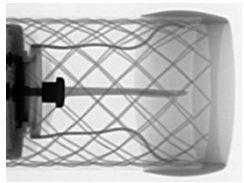


Soft, contoured tip designed to reduce pressure on cardiac tissue

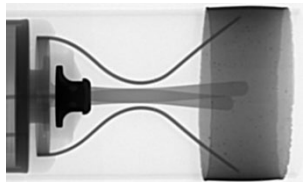
Extension Shaft

- Enables ideal RV septal implant location
- Limits pressure transmitted to cardiac tissue
- Allows fluoroscopic visualization of adequate contact with heart wall

Axially Deploying Talons



EMPOWER



MDT Micra

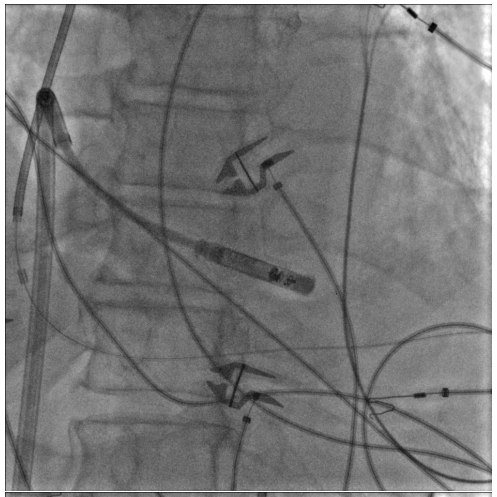
- Designed to penetrate ~2 mm axially into cardiac wall (same depth as transvenous active fixation leads)
- Significant forward pressure not required
- Implanter can control deployment speed

2-Step LCP Deployment

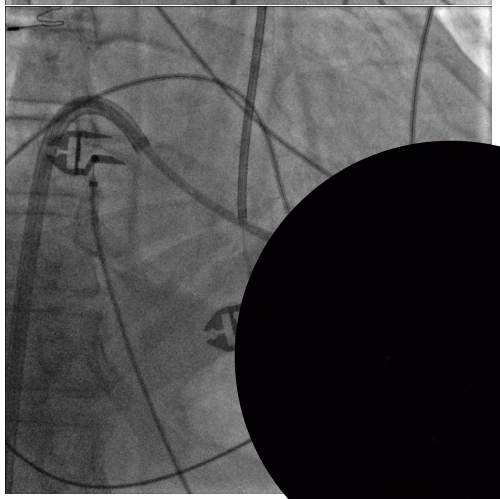
- 1: (safety button) deploy talons, limiting LP advancement and thus limiting pressure on cardiac wall
- 2: retracts sleeve from LP, releasing pressure from cardiac wall

Implantation in MODULAR ATP Patient

LAO



RAO



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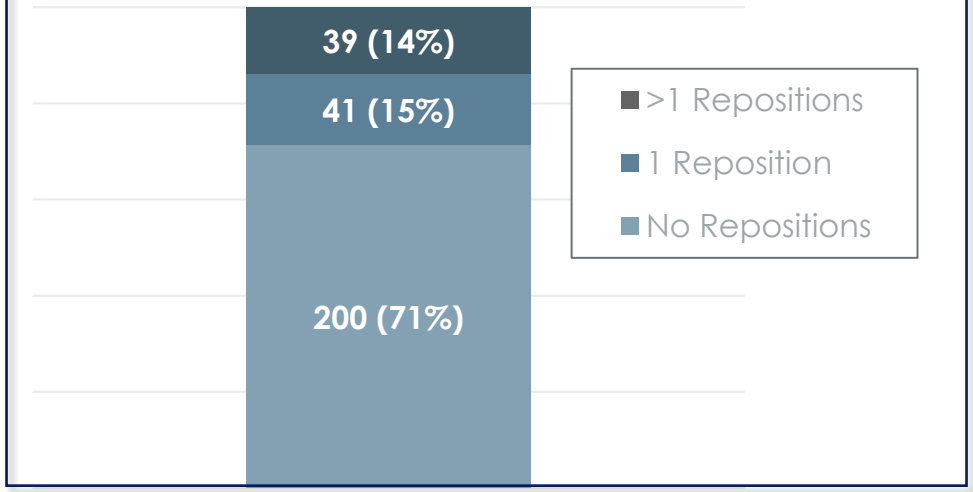
Results in larger patient cohort (n=280)

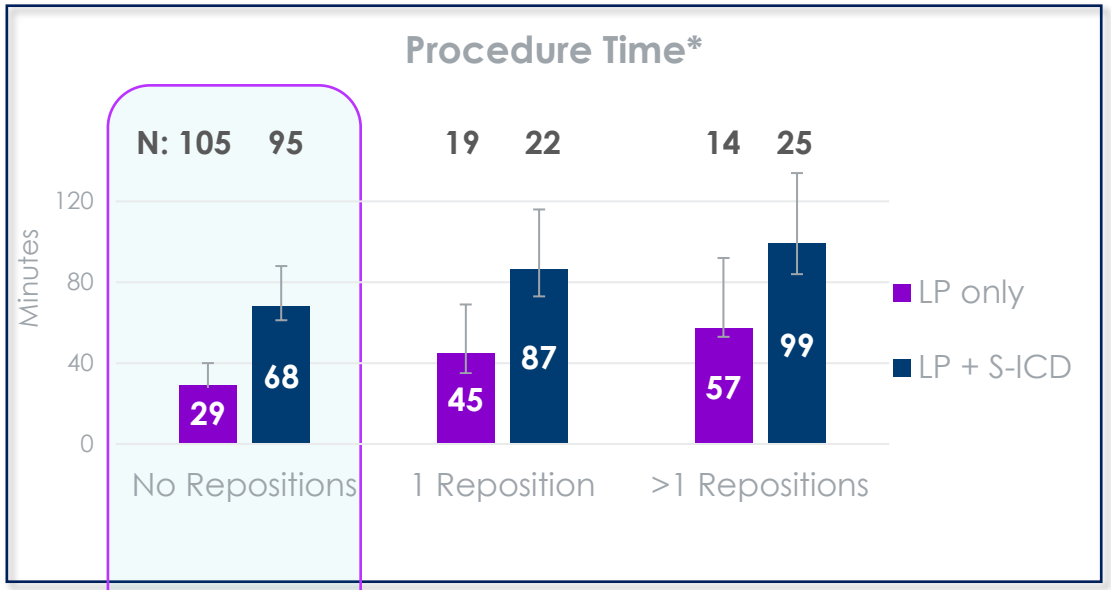
Leadless Pacemaker Implantations[16]

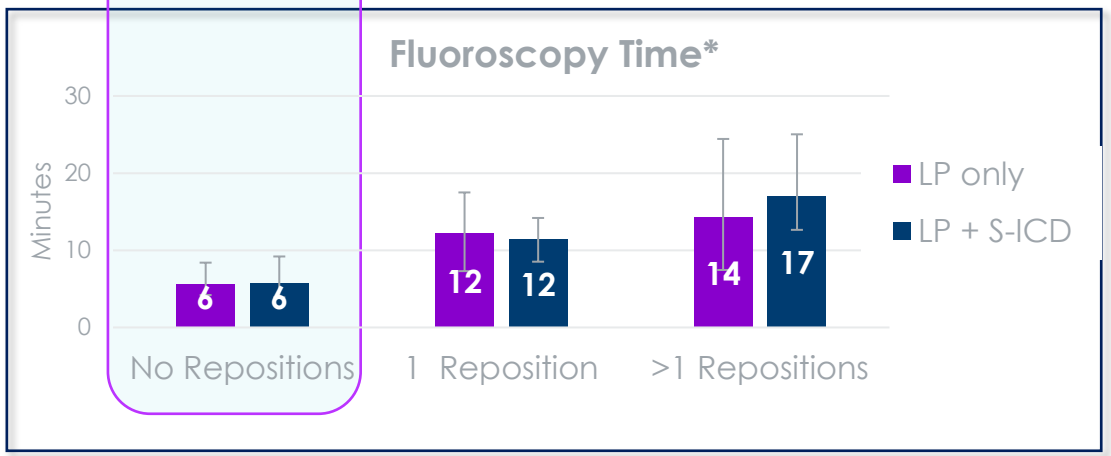
Demonstrated 100% successful LP implantation with no repositions in 71% of patients.



~50% Split Between Upgrade and Dual Denovo Implant Scenarios

- **Upgrade:** 138 LP only implantations
- **Dual Denovo:** 142 LP + S-ICD implantations



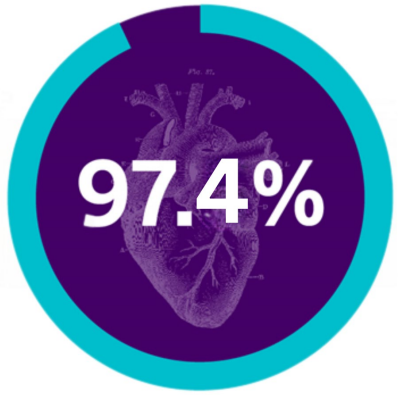


* Values are median and interquartile range

Results in larger patient cohort (n=281)

Complications[16]

The EMPOWER System demonstrated **97.4% freedom from major leadless pacemaker related complications** in the larger patient cohort (274/281) with no deaths associated which is consistent with the prior published results (n=162).[16]



EMPOWER's 6-month CFR are comparable to 6-month CFR of other LP systems[8]

	6-month complication free rate
Nanostim	93.3%[9]
Micra	96.0%[10]

7 (2.6%) of patients experienced 7 complications during LP implantation.

Complications (N=282)	Number of Events	Patients— no (%)
Related to LP and/or Procedure (during procedure)	**7**	**7 (2.6)**
Myocardial perforation with tamponade	3	3 (1.1)
Micro-dislodgement	1	1 (0.4)
LP inadvertently implanted in LV (patent foramen ovale)	1	1 (0.4)
Adverse reaction - Vasovagal/Syncope	1	1 (0.4)
Atrial Fibrillation (AF)	1	1 (0.4)
Related to LP device (post procedure)	**0**	**0 (0.0)**
Related to LP therapy (post procedure)	**0**	**0 (0.0)**

After device implantation, no patients experienced complications related to the LP device or its therapy.

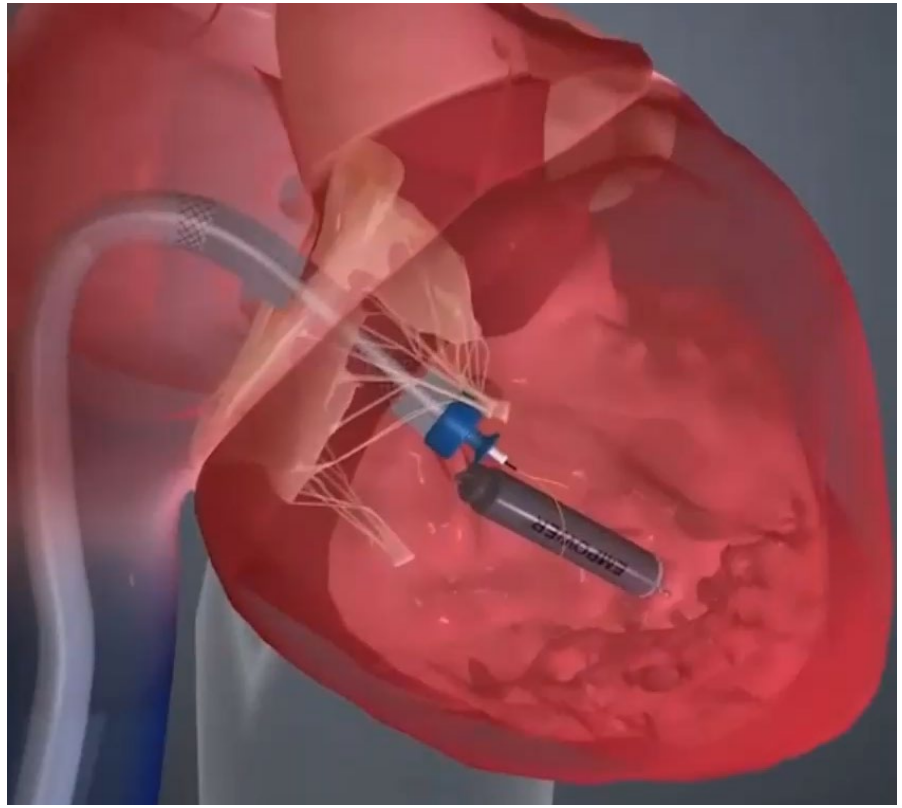
Results in larger patient cohort (n=280)

Chronic Retrievals[16]

In 1% of the patients (n=3), the EMPOWER LP required removal for clinical reasons and were successfully retrieved with no complications.

Procedure time, post implantation	Retrieval Reason
4 months	Inadvertent implant in LV through PFO
12 months	Development of complete Heart block
22 months	Elective decision from heart transplant team upon advancement of disease state

- All successfully retrieved
- No complications

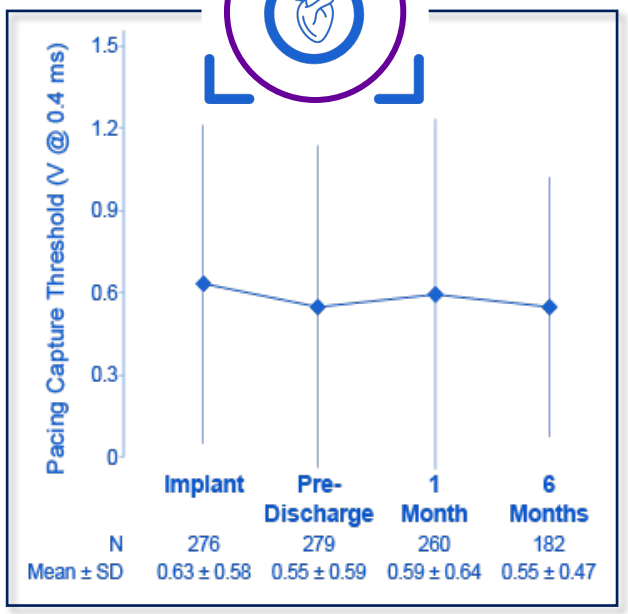


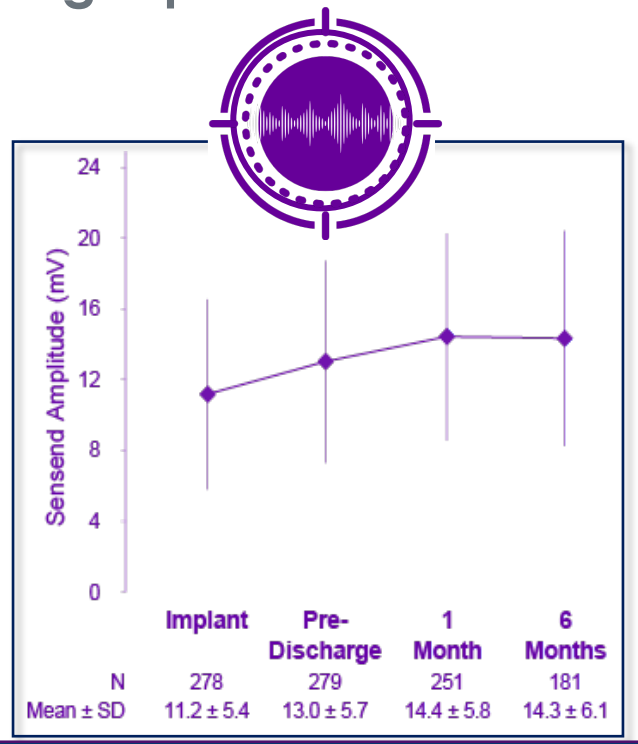
No devices have been retrieved/abandoned due to device failures.

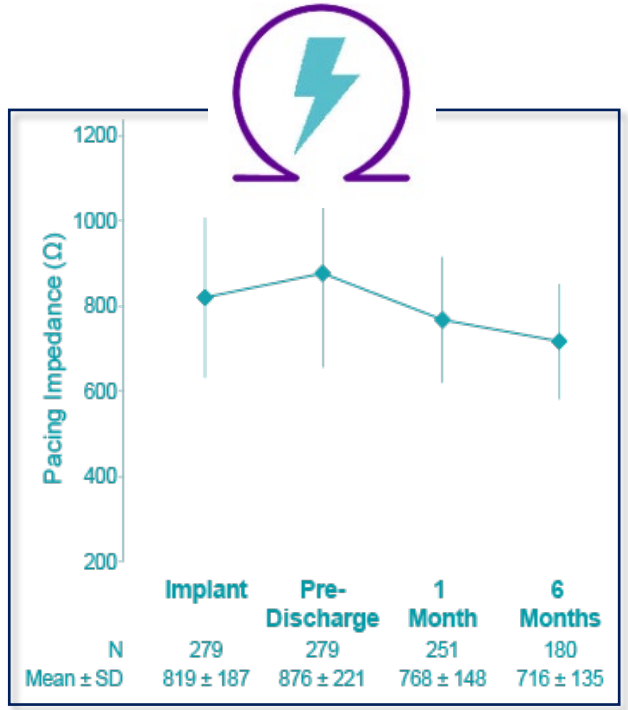
Results in larger patient cohort

Pacing Performance[16]

The EMPOWER LP showed Stable pacing parameters at 6 months analyzed off the larger patient cohort.[16]







EMPOWER LP has consistent electrical performance over time including pacing capture threshold 0.55 ± 0.47 V measured at 0.4 ms, sensed amplitude 14.3 ± 6.1 mV, and consistent pacing impedance of 716 ± 135 Ω.

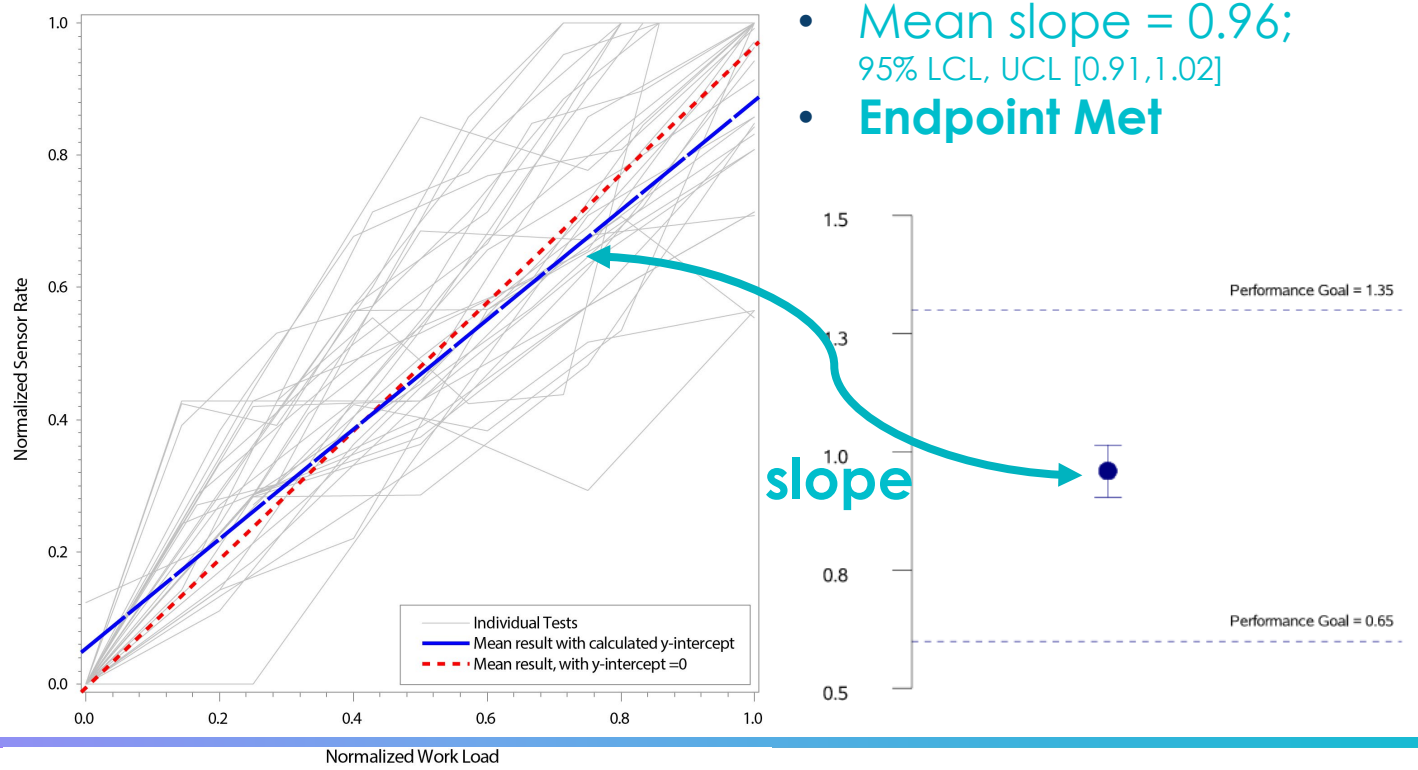
Pacing Performance Results

Rate Response Sub-study[16]

Performance Endpoint 2: The LP accelerometer-based rate response was validated on a treadmill test (n=35) and met endpoint with a mean Metabolic-Chronotropic Relation (MCR) slope of 0.96 from the Kay-Wilkoff model (95% confidence limits 0.91-1.02).

Patient Characteristics	N=35
Age–yr	54±11
Female	4 (11.4)
Body-mass index†	31.0±5.5

The EMPOWER LP rate response was proportional to the workload, confirming its effectiveness in adapting to patient's physical activity levels.[16]



- Mean slope = 0.96;
  95% LCL, UCL [0.91,1.02]
- **Endpoint Met**

Pacing Performance Results

Holter Sub-study[16]

The MODULAR ATP trial included ICD patients who were not pacer dependent. Therefore, the **Holter monitor sub-study** included an initial **in-office period of 25-35 minutes** during which a patient's pacemaker was programmed with a lower rate limit (LRL) higher than their intrinsic rate to promote pacing. Afterwards, the LRL was reprogrammed to the intended permanent setting for the remainder of the **ambulatory16-24-hour Holter monitor recording period.**

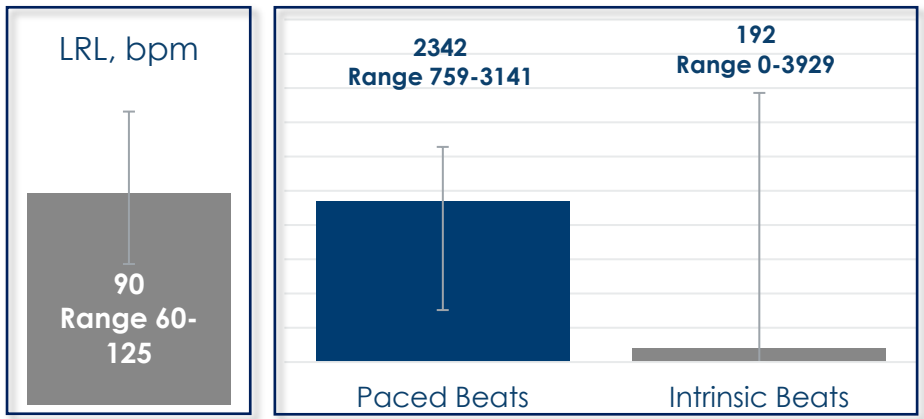
The Holter monitor sub-study was used to evaluate the pacemaker's ability to operate as a standard VVI pacemaker (sense intrinsic cardiac activity and pace appropriately in the absence of intrinsic cardiac activity, as programmed).

The Holter Monitor Sub-study provided Confirmation of Leadless Pacemaker Functionality.

The leadless pacemaker (LP) operates as intended, providing pacing support when necessary and refraining from pacing when it is not required.

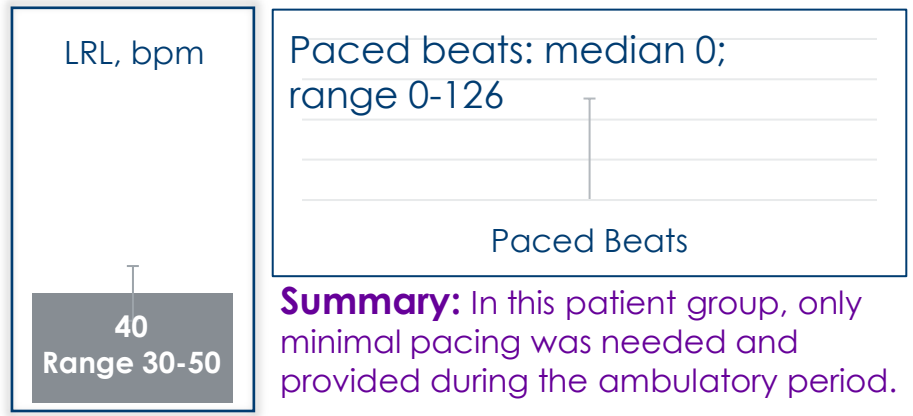
In a group of patients (n=31) that generally do not need pacing, data showed that the device properly performed overdrive VVI pacing over 99.96% of the time.[16]

In-office Period



Results: No over sensed beats, no loss of capture, and max 1 under-sensed event/patient.[16]

Ambulatory Period



Summary: In this patient group, only minimal pacing was needed and provided during the ambulatory period.

Results: VVI performance (mean 23.7±2.0 hours) found no over-sensed, no loss of capture, and max 1 under-sensed beats/patient.[17]

MODULAR ATP LP Summary

6-months Follow-Up[16]

Implantation and Safety

- 100% successful LP implantation
- >70% at the first location, with no reposition.
- Major lead-related complications in 7 patients (2.6%)

Pacing Performance

- Stable pacing parameters
- Rate response study results support LP accelerometer for VVIR pacing
- Holter sub-study supports pacing support

The 6-month results of the MODULAR ATP trial demonstrate that the EMPOWER LP is effective in providing VVIR pacing in the first ATP-capable leadless pacemaker.

mRCM™ System – designed for the future of personalized patient care

- Upon the EMPOWER™ Leadless Pacemaker* and mCRM system* receiving FDA approval, EMPOWER will be the first and only LP designed to be a standalone VVIR pacemaker** that is compatible with all existing EMBLEM™ S-ICD devices as part of the mCRM system.[1]
- Will provide an upgrade pathway to patients with an EMBLEM S-ICD who develop a need for ATP or VVIR pacing.[1]
- Designed to deliver painless intracardiac ATP and/or brady pacing.[1,7,8,16]
- Designed to provide upgrade pathways regardless if the EMBLEM S-ICD or EMPOWER LP is implanted first.[1]

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** Rate-response results will be reported in a future publication.

Practical Implications of the MODULAR AT EMPOWER LP Pacing Performance Data

"Successful performance of the EMPOWER™ Leadless Pacemaker in the MODULAR ATP study provides crucial evidence that it will function as a standalone pacemaker to treat bradycardia, in addition to its anti-tachycardia pacing capabilities when used in connection with the EMBLEM™ S-ICD," said Kenneth Stein, M.D., senior vice president and global chief medical officer, Boston Scientific. "We believe this device will provide additional options for physicians to treat cardiac arrhythmias, without subjecting patients to the risks of more invasive, lead-based approaches – a capability that will make it a strong addition to the Boston Scientific portfolio."

- Ken Stein MD, Global Chief Medical Officer BSC

"We saw excellent, overall clinical performance of the EMPOWER Leadless Pacemaker in the MODULAR ATP trial, including a high rate of successful implants, few complications, and stable pacing parameters," said Prof. Lluis Mont, Atrial Fibrillation Unit Head, Hospital Clinic, University of Barcelona, Spain. "These findings indicate that the device can function as a standalone pacemaker to provide rate-responsive bradycardia pacing to patients, and complement data previously published from this study, which showed a high percentage of pain-free termination of spontaneous tachyarrhythmia episodes when used in connection with the EMBLEM S-ICD."

- Professor Lluis Mont, MODULAR ATP Investigator and Presenter of EMPOWER LP Pacing Parameters Data at ESC LBCT 2024

References

1. Lloyd MS, Brisben AJ, Reddy VY, et al. Design and rationale of the MODULAR ATP global clinical trial: A novel intercommunicative leadless pacing system and the subcutaneous implantable cardioverter-defibrillator. Heart Rhythm O2. 2023;4(7):448-456. Published 2023 Jun 2. doi:10.1016/j.hroo.2023.05.004.

2. Knops RE, Pepplinkhuizen S, Delnoy P, et al. Device-related complications in the subcutaneous and transvenous ICD: a secondary analysis of the PRAETORIAN trial. Eur Heart J. Aug 28 2022;43(47):4872-4883. doi:10.1093/eurheartj/ehac496

3. Healey JS, Krahn AD, Bashir J, et al. Perioperative Safety and Early Patient and Device Outcomes Among Subcutaneous Versus Transvenous Implantable Cardioverter Defibrillator Implantations : A Randomized, Multicenter Trial. Ann Intern Med. Nov 8 2022;175(12):1658-1665. doi:10.7326/M22-1566

4. Leong D, Dokainish H, Mondesert BA, et al. LB-456090-2 Effects of Implantable Cardioverter-Defibrillator Leads on the Tricuspid Valve and Right Ventricle: A Randomized Comparison of Transvenous versus Subcutaneous Leads. Heart Rhythm. May 16 2023.

5. Payne JE, Gold MR. A Substernal Defibrillator Lead With Pacing Capability: Another Tool in the Toolbox? JACC Clin Electrophysiol. Feb 2019;5(2):197-198. doi:10.1016/j.jacep.2018.12.006.

6. Romers H, van Dijk V, Boersma L. Evolution of extravascular implantable cardioverter-defibrillator therapy for ventricular arrhythmias. Heart Rhythm O2. Jan 2023;4(1):59-64.

7. Knops R. et al. Tachycardia Therapy and Trial Endpoint Results of the First Modular, Intra-body, Communicating Subcutaneous Defibrillator-Leadless Pacemaker System: MODULAR ATP Interim Cohort. Heart Rhythm Society Late Breaking Clinical Trials and Science LB-469805-03. 2024.

8. Knops RE, Lloyd MS, Roberts PR, et al. A Modular Communicative Leadless Pacing-Defibrillator System. N Engl J Med. 2024. DOI: 10.1056/NEJMoa2401807.

9. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker. N Engl J Med 2015;373(12):1125-35. DOI: 10.1056/NEJMoa1507192.

10. Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med 2016;374(6):533-41. DOI: 10.1056/NEJMoa1511643.

11. Knops RE, van der Stuijt W, Delnoy P, et al. Efficacy and Safety of Appropriate Shocks and Antitachycardia Pacing in Transvenous and Subcutaneous Implantable Defibrillators: Analysis of All Appropriate Therapy in the PRAETORIAN Trial. Circulation 2022;145(5):321-329.

12. Wathen MS, DeGroot PJ, Sweeney MO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular tachycardia in patients with implantable cardioverter-defibrillators: Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (PainFREE Rx II) trial results. Circulation 2004;110(17):2591-6. DOI: 10.1161/01.CIR.0000145610.64014.E4.

13. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med. 2022;387(14):1292-1302.

14. Crozier I, Haqqani H, Kotschet E, et al. Three-year chronic follow-up from the pilot study of a substernal extravascular implantable cardioverter-defibrillator. Europace 2023;25(10). DOI:10.1093/europace/euad301.

15. May 18, 2024. Boston Scientific Press Release: Results of the MODULAR ATP Trial.

16. Mont L. et al. Pacing Performance of the First Leadless Pacemaker Communicating with an S-ICD from the full cohort of the MODULAR ATP study. European Society of Cardiology Late Breaking Clinical Trials and Science, September 2, 2024.

17. BSC Data on File

EMBLEM™ MRI S-ICD System

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 "Instructions for Use" and MRI Technical Guide for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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 electro-mechanical 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. • All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific or Cameron Health S-ICD System only. Connection of any S-ICD System components to a non-compatible component has not been tested and could result in failure to deliver life-saving defibrillation therapy. • Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death. • Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Refer to "S-ICD System and Pacemaker Interaction" on page 73 for more information. • Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing. • Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient. • Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response. • In patients with a deep implant placement (greater distance between the magnet and the pulse generator), magnet application may fail to elicit the magnet response. In this case the magnet cannot be used to inhibit therapy. • Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. • High shocking electrode impedance may reduce VT/VF conversion success. • When positioning the electrode and pulse generator, avoid excessive tension on the electrode, particularly if the electrode body extends over the pulse generator. This could cause structural damage, abrasion, and/or conductor discontinuity. • Although pliable, the electrode is not designed to tolerate excessive flexing, tight radius bending, kinking, or twisting. This could cause structural damage, conductor discontinuity, electrode migration, and/or dislodgement. • Electrode fracture, abrasion, under-insertion of the electrode connector into the pulse generator connector port, or a loose setscrew connection may result in compromised sensing, loss of therapy, or inappropriate therapy. • Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing. • Determine if the device and programmed parameters are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy. • During a device software update, tachycardia therapy is suspended. Always monitor the patient and have external defibrillation equipment available during interrogation. • 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 (and higher) as defined by the American College of Radiology Guidance Document on MR Safe Practices. • 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. • Immersion in saltwater and similar conductive fluid environments (i.e. ocean, saltwater pools) may divert some defibrillation shock energy away from the patient's heart into the surrounding conductive fluid (as evidenced by a lower-than-normal shock impedance). This may reduce VT/VF conversion success, especially in patients with low BMI.

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. • The S-ICD System has not been evaluated for pediatric use. • The S-ICD System does not provide long-term bradycardia pacing, cardiac resynchronization therapy (CRT), or antitachycardia pacing (ATP). • When implanting the S-ICD system in a patient with sternal wires, ensure that there is no contact between the sternal wires and the distal and proximal sense electrodes (for example, by using fluoroscopy). Compromised sensing can occur if metal-to-metal contact occurs between a sense electrode and a sternal wire. If necessary, re-tunnel the electrode to ensure sufficient separation between the sense electrodes and the sternal wires. • Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.

Electromagnetic Interference (EMI) Precautions • Avoid electromagnetic interference (EMI). Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. • Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation. • Examples of potential EMI sources are: o Electrical power sources o Arc welding or resistance welding equipment (should remain at least 24 inches from the implant) o Robotic jacks o High voltage power distribution lines o Electrical smelting furnaces o Large RF transmitters such as radar o Radio transmitters, including those used to control toys o Electronic surveillance (antitheft) devices o An alternator on a car that is running o Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies o Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine) • Home appliances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site. • Electronic Article Surveillance (EAS) and security systems. Advise patients how to avoid impact to cardiac device function due to antitheft and security gates, tag deactivators, or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, at checkout counters, in public libraries, and in point-of-entry access control systems. Patients should avoid lingering near or leaning against antitheft and security gates and tag readers. In addition, patients should avoid leaning against checkout counter-mounted and handheld tag deactivation systems. Antitheft gates, security gates, and entry control systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic antitheft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor. • Cellular phones. Patients should not carry a cellular phone within 15 cm (6 inches) of the implanted device in order to avoid interaction which may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Advise patients to hold cellular phones to the ear opposite the side of the implanted device, and to avoid storing a cellular phone within 15 cm (6 inches) of the implanted device. Examples of storage locations to be avoided include a breast or other shirt pocket, on a belt, or in a handbag held near the implant location. • Static magnetic fields. Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may suspend arrhythmia detection. Examples of permanent magnet—containing sources to be aware of include: o Industrial motors if held within 60 cm (24 inches) of the pulse generator o MRI scanners o Large stereo speakers if held within 60 cm (24 inches) of the pulse generator o Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator o Magnetic wands such as those used for airport security and in the Bingo game o Cellular phones, ear buds, or headphones, if held within 15 cm (6 inches) of the pulse generator o Magnetically attached charging port or cable, such as used in laptops or cellular phones, if held within 15 cm (6 inches) of the pulse generator o Be aware of other body-worn items which may contain magnets, such as wrist bands, jewelry, clothing, nametags, CPAP masks, etc.

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 • Organ injury or perforation • Pneumothorax • Post-shock/post-pace discomfort • Premature battery depletion • Random component failures • Stroke • Subcutaneous emphysema • Surgical revision or replacement of the system • Syncope • Tissue damage • Tissue redness, irritation, numbness or necrosis • Vessel injury or perforation.

Transient procedural adverse events are expected in some patients. These include, but are not limited to, discomfort, pain and other systemic symptoms that might be related to medications or other interventions performed during implant.

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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