

# Boston Scientific

Advancing science for life™

## Rhythm Management

Cardiac Rhythm Management and Electrophysiology

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# Safe Harbor for Forward-Looking Statements



This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like “anticipate,” “expect,” “project,” “believe,” “plan,” “estimate,” “intend” and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could differ materially from the expectations and projections expressed or implied by our forward-looking statements.

Factors that may cause such differences can be found in our most recent Form 10-K and Forms 10-Q filed or to be filed with the Securities and Exchange Commission under the headings “Risk Factors” and “Safe Harbor for Forward-Looking Statements.” Accordingly, you are cautioned not to place undue reliance on any of our forward-looking statements. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which they may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Market Estimates: Unless noted otherwise, all references to market sizes, market share positions, and market growth rates are BSX internal estimates.

# Broad Portfolio of Innovative Products and Solutions to Address Large Markets

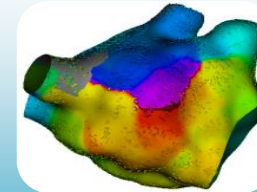
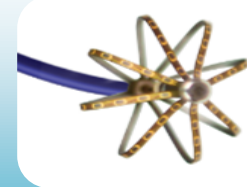
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## Left Atrial Appendage Closure



**WATCHMAN™**

## Mapping & Ablation



**RHYTHMIA™**

## Patient Management



**LATITUDE™**



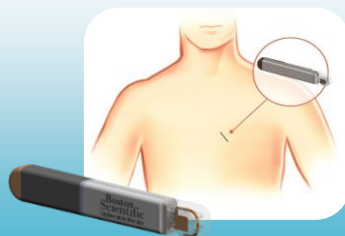
**Clinical  
Evidence**

## Modular CRM Systems\*



**mCRM™**  
Modular CRM Systems

## Diagnostics & Monitoring\*



**HEARTLOGIC™**  
Heart Failure Index

## Cardiac Rhythm Management

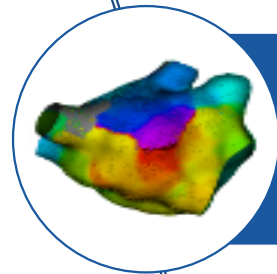


**ENDURALIFE™**  
Battery Technology

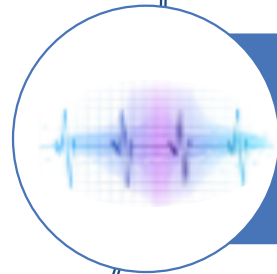




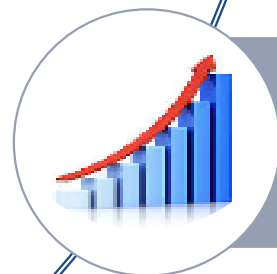
Expand CRM Leadership Position



Scale EP and Expand EP Portfolio Offering



Enter New Segments/Markets



Achieve Profitability Targets

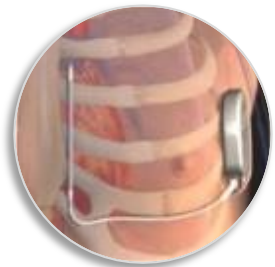
# Rhythm Management: Category Leadership & Key Growth Drivers

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## ICD/CRT-D



**RESONATE™ HV**  
Family of Devices  
Next gen platform  
compatible with  
HeartLogic™ + MRI



**EMBLEM™ MRI S-ICD**  
MRI compatibility,  
remote-monitoring  
enabled



**ENDURALIFE™**  
Battery Technology  
Industry-leading  
longevity

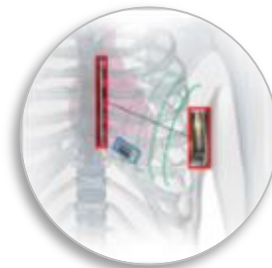
## Pacemaker



**Accolade™ MRI**  
Ingevity™ pacing lead;  
full-body MRI (1.5T and  
3T) & wireless patient  
monitoring



**Valitude™**  
**X4 Quad CRT-P**  
More pacing vectors;  
industry- leading  
longevity. MRI labeling  
expected 2H/2018



**mCRM™: S-ICD +  
Leadless Pacemaker\***  
Developing modular  
system: single-  
chamber pacemaker  
with S-ICD  
compatibility for ATP

## Diagnostics



**HeartLogic™**  
HF Dx solution:  
a composite alert  
to provide advanced  
notice of heart failure  
hospitalizations



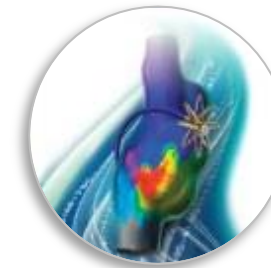
**Implantable  
Cardiac Monitor\***  
Developing  
arrhythmia  
monitoring device

## LAAC



**WATCHMAN**  
Left atrial  
appendage  
closure device

## Electrophysiology



**RHYTHMIA™ HDx**  
Mapping &  
navigation platform



**Atrial Fibrillation  
Solutions**  
Navigation-enabled,  
open-irrigated, &  
MiFi catheters



**Other EP Solutions**  
Recording systems,  
diagnostic catheters,  
and accessories

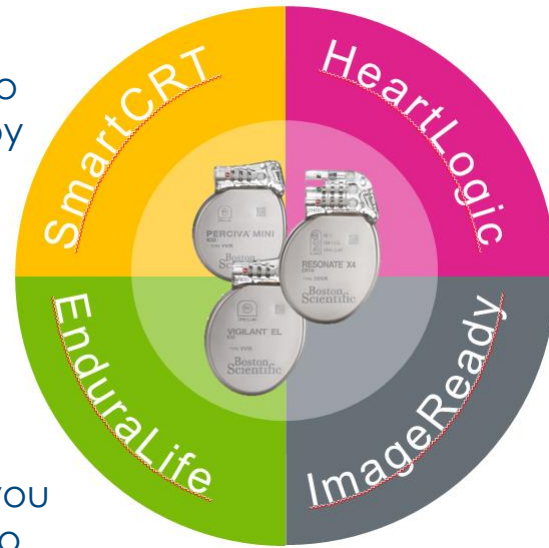
# High Voltage Portfolio – Resonate Family

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## SmartCRT™

Technology

SmartCRT™ is Boston Scientific's approach to personalize CRT therapy



## EnduraLife™

Battery Technology

EnduraLife™ Battery Technology provides you with clinical freedom to make programming decisions without worrying about the battery.

## HeartLogic™

Heart Failure Diagnostic

HeartLogic™ shifts heart failure patient management from reactive treatment to proactive care,

## ImageReady™

MR-Conditional Systems

When connected to specific Boston Scientific leads, Resonate Family devices are considered MR-conditional to support patient needs for MRI scanning.

## HeartLogic™ Clinical Investments

MANAGE\_HF

MANAGE\_HF II

PREEMPT\_HF

Economic Value Pilots

Robust clinical pipeline driving towards clinical and economic outcomes

## Economic Value

## HeartLogic™ Risk Share Program:

Undetected ADHF Hospitalizations

HeartLogic offers early opportunity to participate in risk sharing agreements and Value Based Care

**HeartLogic™**  
Heart Failure Diagnostic

Differentiated platform fuels sustainable growth in High Voltage segment

# Driving Global Leadless Expansion with Modular CRM (mCRM™) EMBLEM™ MRI S-ICD and EMPOWER™ MPS



## S-ICD System Enhancements

### EMBLEM MRI S-ICD<sup>1</sup>

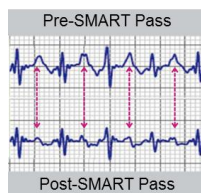


- 40,000 WW Implants<sup>1</sup>
- 8.75 Years mean projected longevity<sup>2</sup>
- 1.5T MRI system
- AF Monitor & Alert



Automated Screening Tool

**SMART Pass Algorithm**  
Advanced Filtering  
~4% Projected IAS<sup>3</sup>



New S-ICD Electrode with Integrated Sleeve



New S-ICD Electrode Delivery System

Additional Investments in S-ICD Implant Improvements

## Modular CRM Systems\*



Preloaded delivery catheter with extendable inner catheter



31.9 mm x 6 mm  
0.8 cc

Active fixation talons  
Tether / Snare port



## Clinical Leadership

**UNTOUCHED:** Primary prevention penetration; results 2020

**PRAETORIAN (ISR):** TV-ICD/S-ICD Head-to-head; results 2020

**PRAETORIAN DFT (ISR):** Eliminate Conversion Testing; FPI 2018

**EMPOWER / MODULAR ATP Trials:** IDEs enrollments start 1H19

## Future S-ICD Systems

- Streamline patient pre-implant screening
- Support for modular, multi-chamber leadless systems
- Patient access to data
- Options for smaller S-ICD form factor

**EMBLEM S-ICD continues to be the 1<sup>st</sup> & only S-ICD globally – ongoing share advantage**

# Clinical Evidence and Society Guidelines Support Broad S-ICD Coverage by U.S. Payers



## Medicare and Commercial Payers

- Medicare National Coverage Determination provides coverage consistent with S-ICD labeling for all Medicare and Medicare Advantage beneficiaries;
- All major U.S. Commercial Plans offer positive S-ICD coverage affecting over 92% (>187M) Commercial covered lives<sup>5</sup>;
- Cigna and United Healthcare recently expanded S-ICD coverage to be consistent with labeling, broadening coverage for a combined 41M lives.

## 2017 AHA/ACC/HRS Guidelines Provide Class I and Class IIa Recommendations<sup>4</sup>

### 11.1. Subcutaneous Implantable Cardioverter-Defibrillator

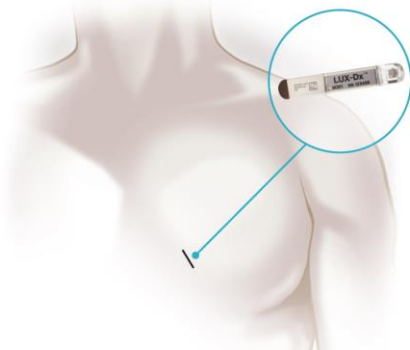
Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator		
References that support the recommendations are summarized in Online Data Supplement 55.		
COR	LOE	Recommendations
I	B-NR	1. In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (1-4, 6-8).

The new guidelines, coupled with the most recent long-term clinical and real-world outcome data, provide further confirmation that the S-ICD System can and should be considered as a first-line therapy for those ICD-indicated patients without a pacing indication

# LUX-Dx™ Insertable Cardiac Monitor Entering a New ~\$750M Adjacency in 2019

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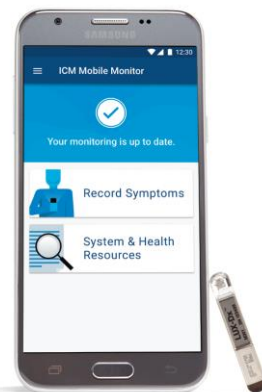
**Diagnostic-only device platform  
designed for cardiac monitoring  
and extensible to other diseases\***



**Insertable Monitor**



**Implant Tools**



**Mobile Data Transmission enabled by an  
Interactive, Smartphone-App Interface**

## **Arrhythmia Management (Syncope and AF)**

- Competitive device characteristics and implant experience
- Algorithms to detect atrial arrhythmias, pause, bradycardia and tachycardia
- System differentiation: interactive mobile patient experience and remote data management system
- Commercial synergies with BSX businesses
- FDA and CE Mark expected 2019

# WATCHMAN™ LAAC Device Global Leadership

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**WATCHMAN FLX™**

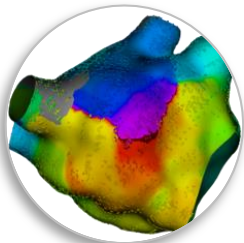
## WATCHMAN™

- 50,000 worldwide implants
- China poised to become #2 global market
- Japan on track for 2019 launch
- Target 500 WATCHMAN U.S. centers YE 2018
- NESTed registry presented at ACC 2018<sup>6</sup>
  - Acute data on 1,000 patients
  - ~1.5% Major Adverse Event Rate
- Next generation WATCHMAN FLX™\*
  - PINNACLE FLX IDE
  - First patient implanted May 7, 2018

# Electrophysiology: Platform Emerging to Generate Growth > Market

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## Electrophysiology Portfolio



Mapping and Navigation



Therapeutic Catheters



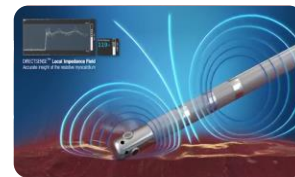
Diagnostic Catheters



EP Recording Systems



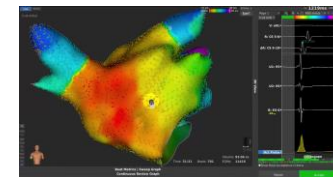
**DIRECTSENSE\***



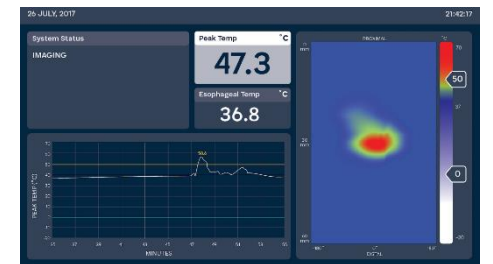
Therapeutic Catheters

- IntellaNav ST
- IntellaNav MiFi OI
- IntellaNav StablePoint\*\*

**LUMIPOINT\*\***



**APAMA RF Balloon System\*\***



**Securus Thermal Monitoring System**

\* Not yet available for commercial sale in the U.S.

\*\* Under development and not yet available for commercial sale

## Next Generation Navigation Enabled Therapeutic Catheters

- INTELLANAV™ MiFi OI catheter
  - Navigation-enabled, mini-electrode technology with Total Tip Cooling™
  - FDA & CE mark approved

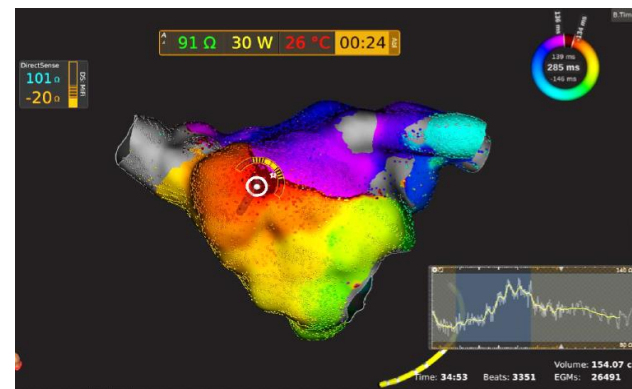


- INTELLANAV™ ST catheter
  - Trusted BLAZER™ Platform meets HD mapping with the precision of small ablation tip
  - FDA approved



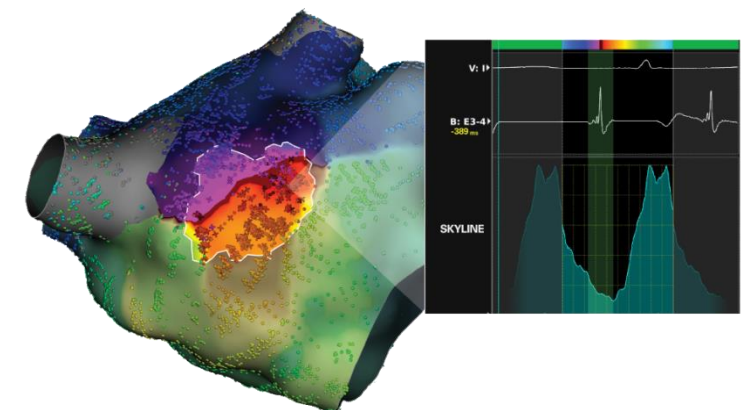
## DIRECTSENSE™ Technology

- Enhanced confidence in the location, stability, and proximity of a catheter relative to tissue
- Software upgrade to RHYTHMIA HDx™ when used with the IntellaNav™ MiFi OI catheter
- Q2 2018 Full EU launch. US launch pending FDA feedback



## LUMIPOINT™ Software Module

- First ever suite of tools for automated map analysis, enabling rapid and high confidence map interpretation.
- Software license available on RHYTHMIA HDx™ systems
- US & EU launch expected Q4 2018



## INTELLANAV STABLEPOINT™

- Navigation-enabled force-sensing catheter on a Total Tip Cooling™ Platform
- CE Mark: expected 2H 2019



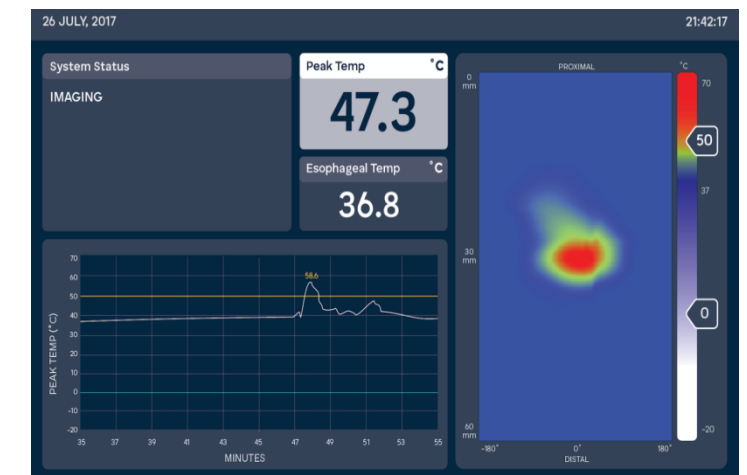
## Apama Single-Shot RF Balloon

- Irrigated, single-shot RF balloon system designed to provide customizable energy delivery
- CE Mark: expected 1H 2019
- U.S. Clinical IDE start 1H 2019



## Securus Esophageal Temperature Monitoring

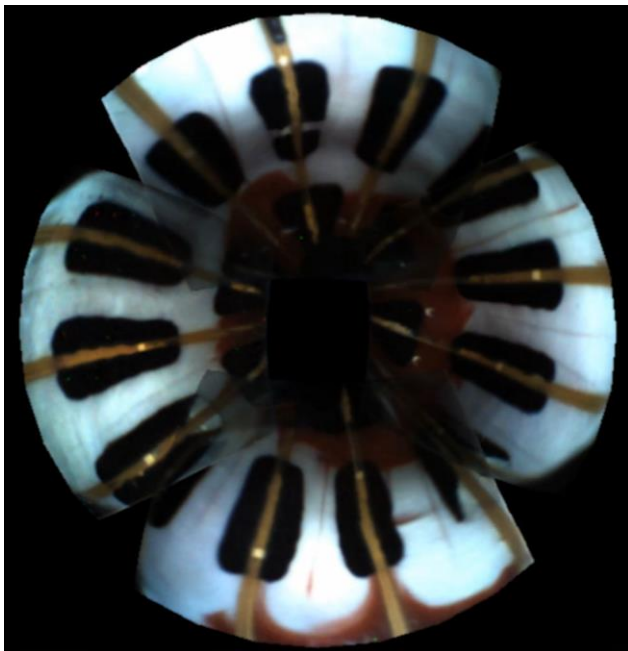
- Temperature probe collects energy radiating off the esophageal wall
- Differentiated display and real time temperature monitoring
- US & EU launch 2019



# Apama RF Balloon Catheter Technology: Expanding our Therapeutic Portfolio

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**Apama RF Balloon Catheter System strengthens EP Portfolio by expanding treatment options for patients with Atrial Fibrillation into “Single-Shot” PVI Balloon Market**



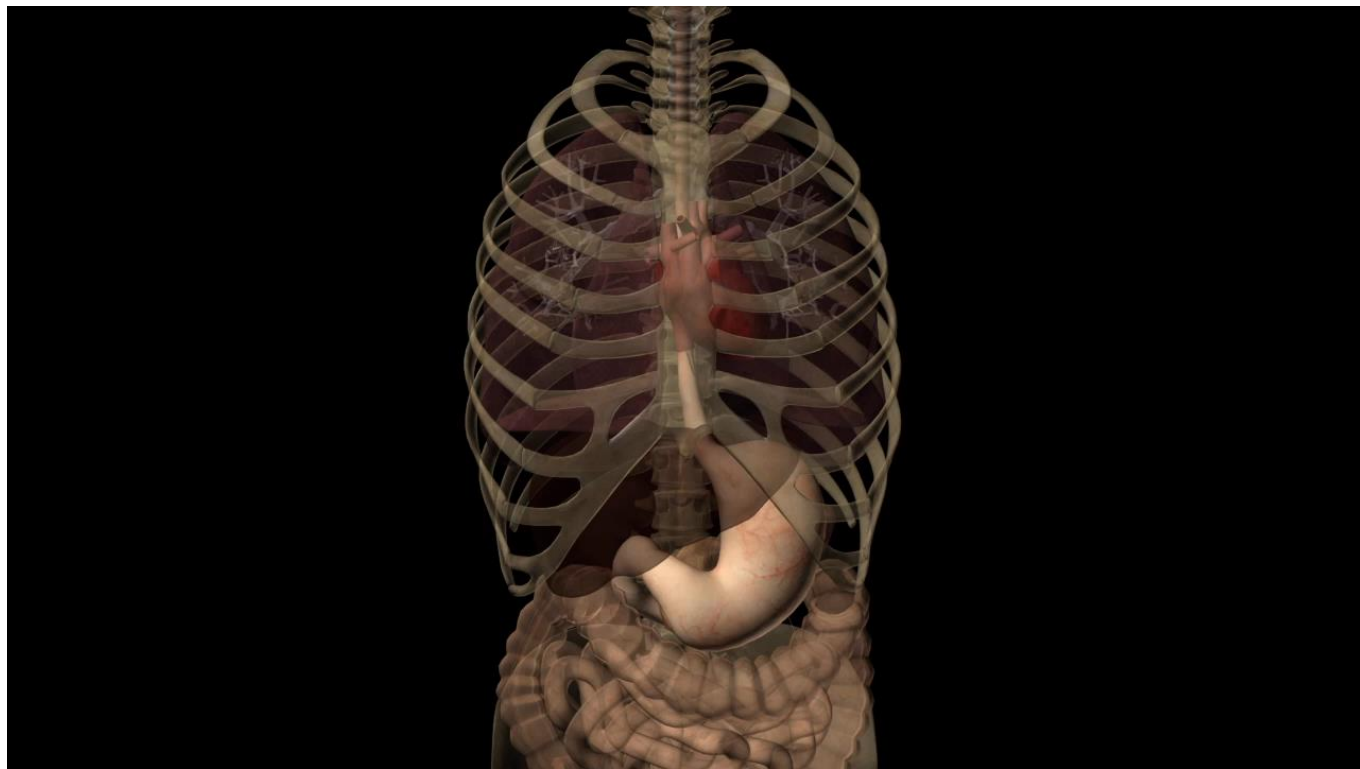
## Design Goals:

- Irrigated, single-shot RF balloon system designed to provide customizable energy delivery
- Validation of electrode contact from built-in cameras designed for real-time visualization of tissue apposition
- Integrated pacing and sensing capabilities intended to streamline procedure
- CE Mark & U.S. IDE start targeted H1: 2019

# Securus Medical Acquisition: New Technology for Esophageal Temp Monitoring

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**Utilizes infrared technology to provide physicians with a more accurate tool for rapid, continuous measurement of esophageal temperatures**



- Temperature probe collects energy radiating off the esophageal wall and converts it to an intuitive image of the surface temperatures
- Rotating probe monitors a 6cm segment of the esophagus and takes 7,680 readings per second, creating a comprehensive 6cm x 360° view of the esophageal wall
- US/EU Commercialization targeted H1: 2019

# HRS and ESC-HF: New Data Highlights



## HRS Late Breaking Science

Title	Presenter	Presentation Details
<b>CABANA:</b> Catheter Ablation vs. Antiarrhythmic Drug Therapy for Atrial Fibrillation: The Results of the CABANA Multicenter International Randomized Clinical Trial ( <i>ISR</i> )	Packer	LBCT I 9:12 a.m. Thursday
Device-related Thrombus After Left Atrial Appendage Closure with <b>Watchman:</b> Incidence, Predictors and Outcomes	Reddy	LBCT II 9:12 a.m. Friday
A Prospective, Blinded Evaluation of a Novel Filter <b>SMARTPASS</b> Designed to Reduce Inappropriate Shocks by the Subcutaneous Implantable Defibrillator	Brouwer	LBCT III 5:45 p.m. Friday

## Other HRS Highlights

Topic	Data Presented
<b>New Technologies in EP</b>	Procedural data from AF-FICIENT study with <b>APAMA RF</b> balloon demonstrates procedure time reduction compared to cryo or RF point by point $74 \pm 29.5$ vs $124.4 \pm 39$ ( $p < 0.0001$ ) and $140.9 \pm 54.9$ ( $p < 0.0001$ ), respectively. Data from both HEAT-AF and AF Safe Temp demonstrated performance of the novel <b>Securus</b> technology for esophageal heat monitoring
<b>mCRM</b>	The EMBLEM™ MRI S-ICD and <b>Empower™</b> Modular Pacing System continue to perform as expected in pre-clinical studies, setting the stage for human pivotal trials in 1H 2019.
<b>ICM</b>	First reports of BSC <b>ICM</b> algorithm – True sensitivity 99.5%, with a false positive rate of 0.016 episodes/pt-mo. (Significant improvement over existing ICM AF algorithms)
<b>S-ICD: Advancing Implant Approach</b>	3 abstracts on <b>DFT</b> including impedance versus success and positioning versus success with <b>The Praetorian Score</b> , which provides more specific parameters for S-ICD placement with a positive predictive value of 98% for conversion success.
<b>Low EF Alerts Proven Effective @ UPMC</b>	Patients with a provider randomized to receiving alerts of low EF were more likely to be referred to EP (HR=1.23), receive an ICD (HR 1.35) and less likely to die (HR 0.85, $p=0.091$ )

## ESC-HF Meeting: HeartLogic

Study	Abstract Presentations
<b>Multi-SENSE</b>	6 Abstracts accepted, continuing to highlight insights into HF with new sensors and HeartLogic Index

# Demonstrated History of Financial Results



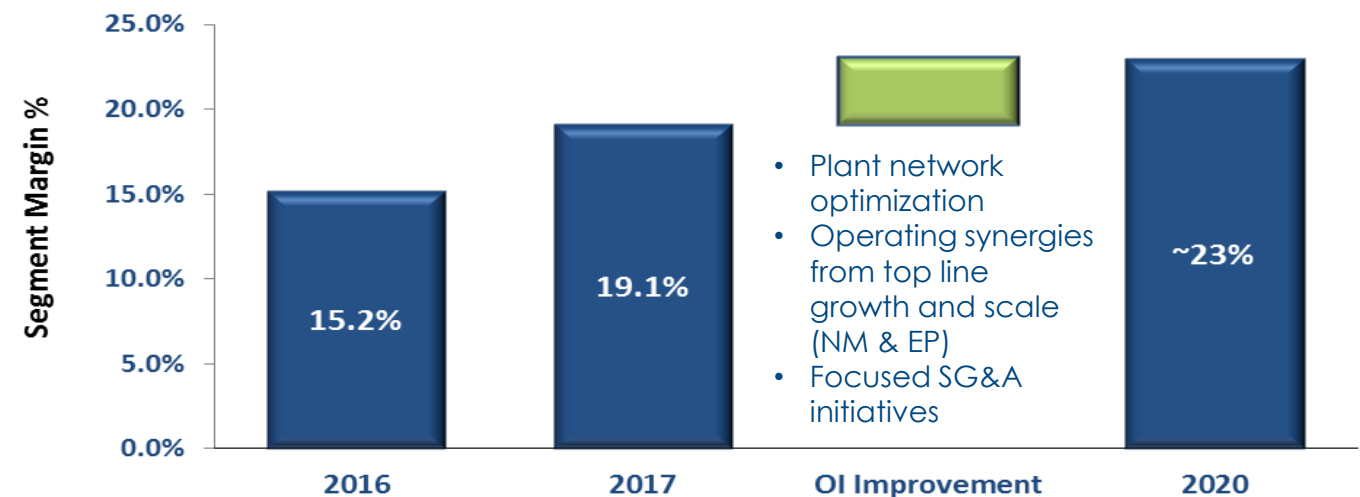
## Historical RM Performance

- CRM revenue growth outpacing Core CRM market dynamics
- EP revenue growth is accelerating as Rhythmia and ablation portfolio expands
- Strong cadence of product approvals and launches
- Historical adjusted RM segment margin doubled from 2013 through 2017

## New Rhythm & Neuro Segment Goals\*

- Top line potential in Neuromodulation (SCS & DBS) & Electrophysiology expected to accelerate growth.
- CRM continues to expand into adjacencies & maximizes high voltage investments & replacement curve.
- Continue to expect ~400 bps of improvement in segment margin by 2020

## New Rhythm & Neuro Segment As Reported Segment Results & Guidance



# References

- 1.) Boston Scientific S-ICDs sold to date from Q1 2018 Product Performance Report (PPR)
- 2.) Internal analysis of Emblem device longevity on Latitude.
- 3.) Theuns, D, et al. Evaluation of a Novel Algorithm Designed to Reduce Oversensing in the S-ICD. *HRS 2016*; AB05-01.
- 4.) Al-Khatib, SM, Stevenson, WG, Ackerman, MJ, et al., 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. *Heart Rhythm*, 2017.
- 5.) Commercial covered lives based on data available from Policy Reporter.
- 6.) Varosy P et al. *JACC* 2018; 71(11S): A320.

# Q&A