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Advancing science for life™

Structural Heart Update

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Senior Medical Director

Structural Heart Offerings

LAAC WATCHMAN™ Device



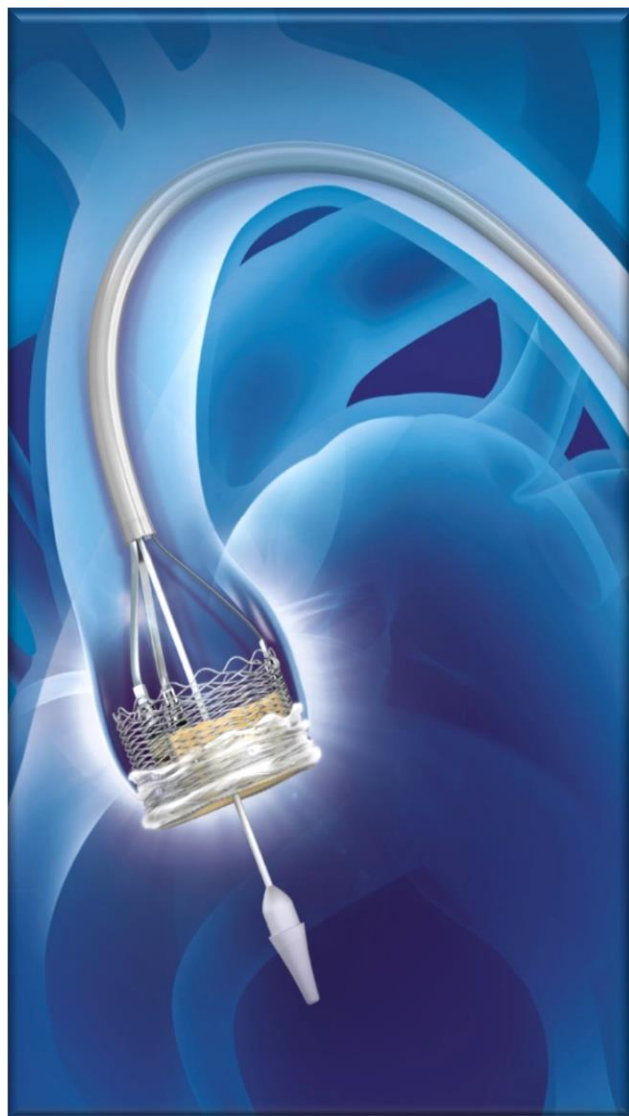
TAVR LOTUS Edge™ ACURATE neo™



CAUTION: Millipede IRIS is an investigational device and restricted under federal law to investigational use only. Not available for sale. Millipede is currently an investment, not an owned asset, of BSC. The LOTUS Edge and ACURATE neo Valves may only be used in countries where they are approved for use. The LOTUS Edge Valve is not available for sale in the European Economic Area. For education purposes only. The LOTUS Edge and ACURATE neo Valves are investigational devices in the United States and are not available for sale.

The LOTUS Edge™ Valve System

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Design Goals

- Maintain benefits of 1st generation Lotus
 - Adaptive seal to minimize PVL
 - Complete repositionability
 - Early valve function
- Improve delivery
 - Lower profile system
 - More flexible catheter
- Optimize deployment
 - Depth Guard™ limits depth of implant
 - One-view locking with additional RO Markers

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The ACURATE *neo*™ Valve

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Stabilization Arches

- Axial self-aligning

Upper Crown

- Minimal supra-annular anchoring
- Captures native leaflets and provides coronary clearance

Lower Crown

- Minimal protrusion into LVOT
- Low risk of conduction system interference



Supra-annular Valve

- Porcine pericardium leaflets
- BioFix™ anti-calcification process
- Low gradients

Pericardial Skirt

- Inner and outer anti-leak skirts

Self-expanding Nitinol Frame

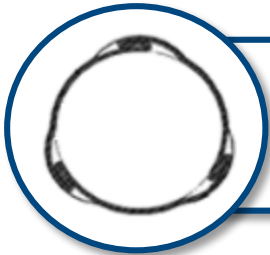
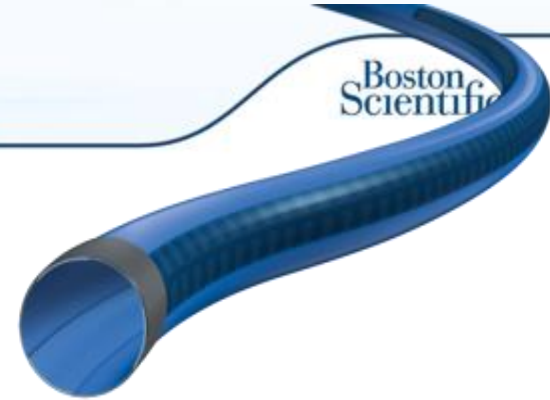
- Treats annulus from 21mm to 27mm

ACURATE *neo2* CE Trial enrollment complete; IDE enrollment anticipated Q4 2018

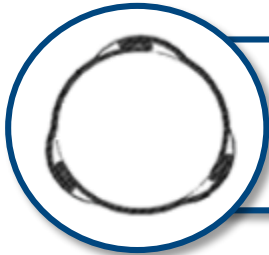
iSLEEVE™

Expandable Introducer Set

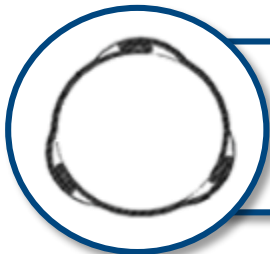
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ACURATE *neo*™ and iSLEEVE
Expanding Patient Access



ACURATE *neo* and 14F iSLEEVE expands access
into smaller and increasingly complex vasculature

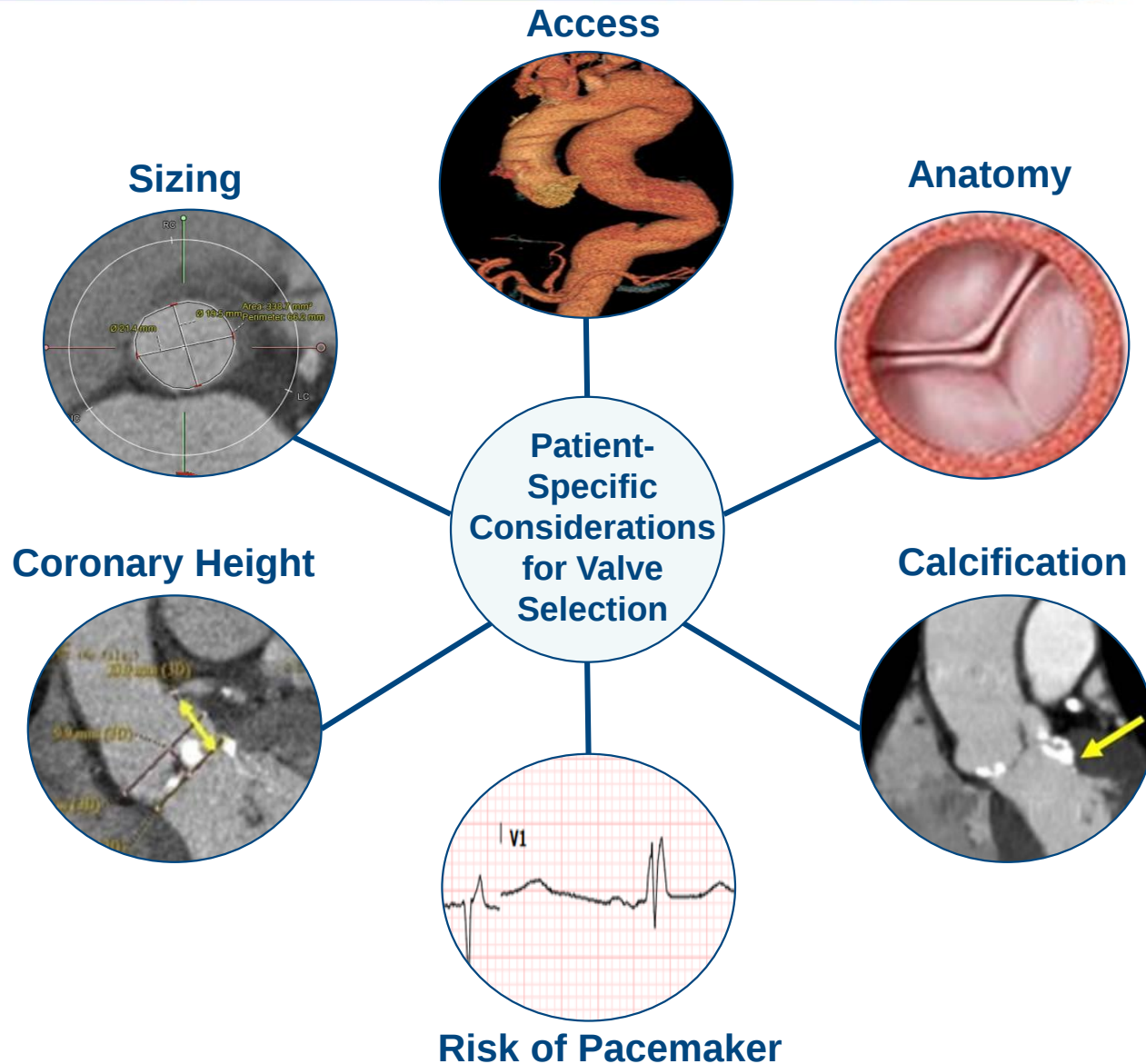


Novel Tri-Fold expansion is designed to
minimize vessel trauma

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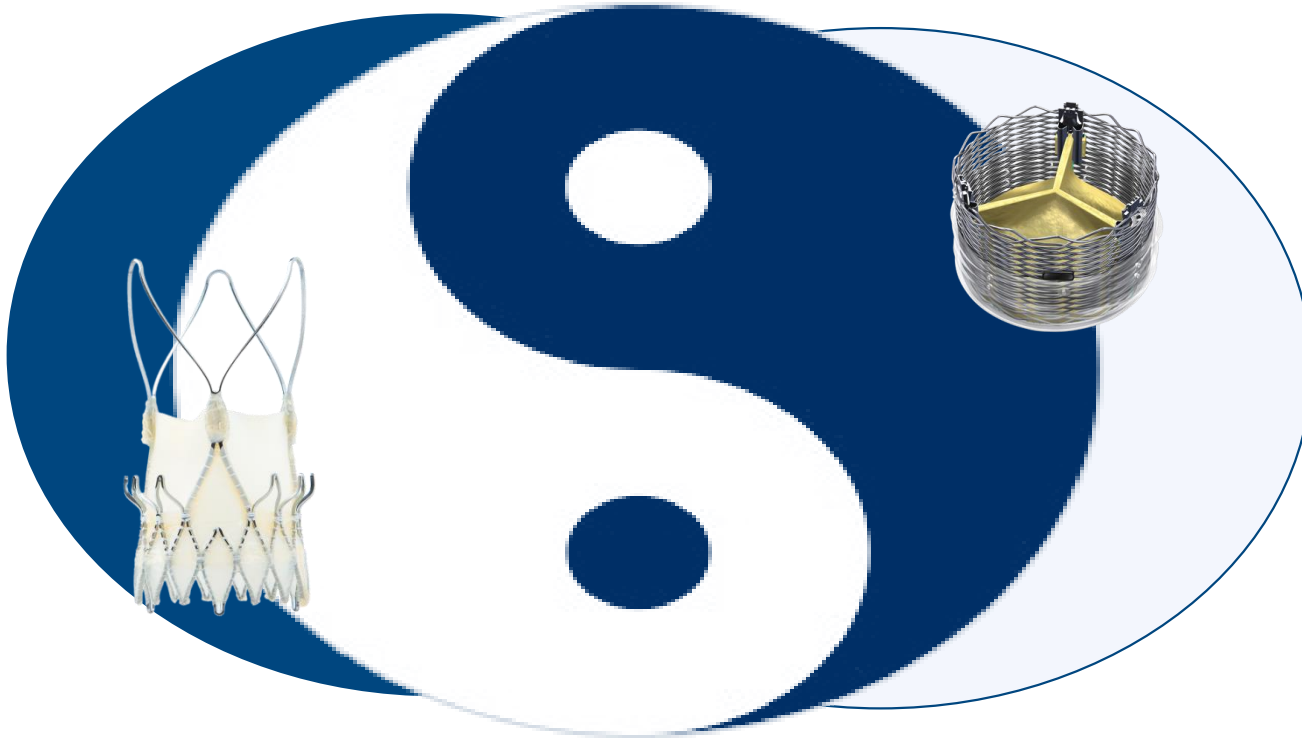
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BSC 2 Valve Strategy: The Right Valve for the Right Patient



ACURATE & Lotus: Complementary Valves

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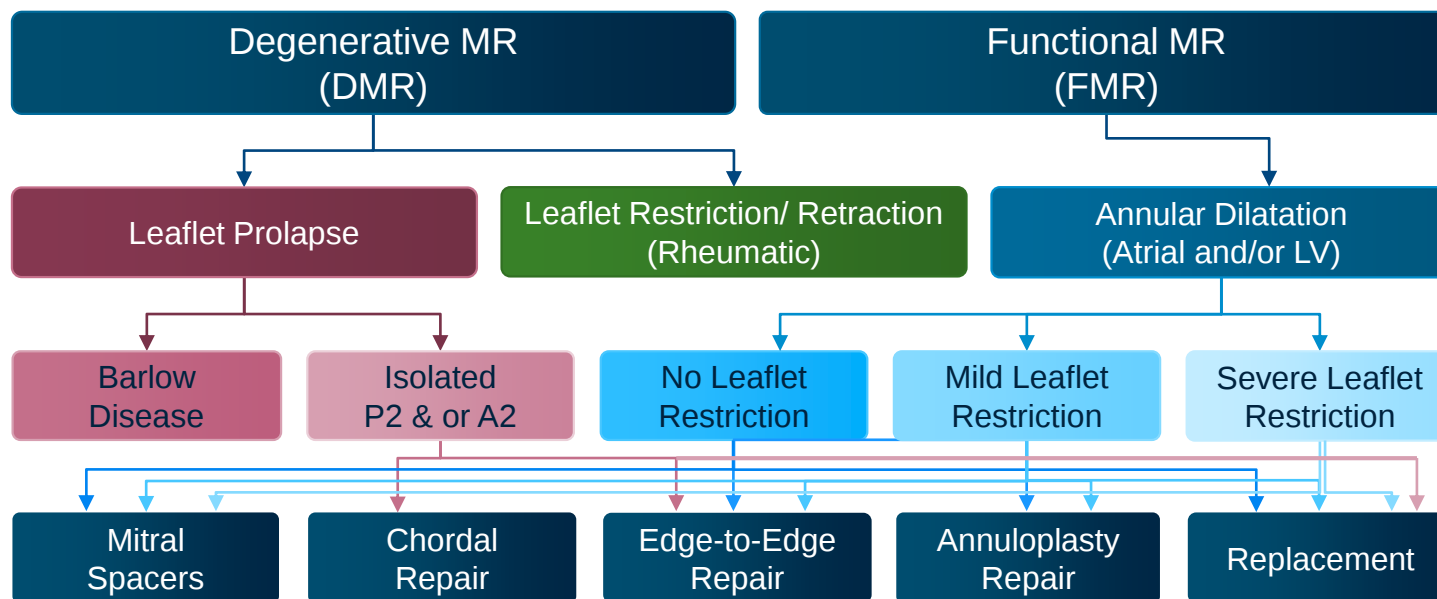


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Transcatheter Mitral – Our Key Criteria

- ☐ Safe procedure
- ☐ Percutaneous (TF / TS) access
- ☐ Physiologically sound mechanism of action
- ☐ Familiar & straightforward steering / controls
- ☐ Procedural imaging utilizes currently available tools
- ☐ Minimize device footprint
- ☐ Customizable / retrievable
- ☐ Preserve options for future intervention

Transcatheter Mitral Valve Treatment Options by Disease State



- Estimate of 2.0M patients with FMR (44%) and 2.6M with DMR (56%) in the US¹
- Market estimate \$3B by 2025
- Repair is preferred over replacement whenever possible
- Annuloplasty is the cornerstone of repair
 - For FMR, the standard of care is a stand-alone **complete** ring annuloplasty
 - Potential for future combination therapies in DMR patients

Millipede IRIS™ Transcatheter Mitral Repair System

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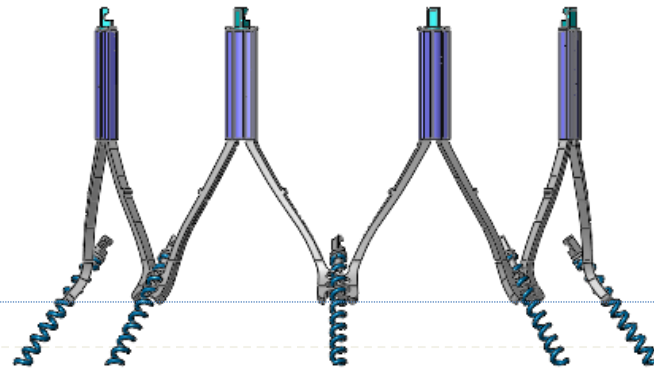
Millipede IRIS Design Goals

- Complete, semi-rigid annular ring with a Nitinol frame
- 24F Transfemoral-transseptal venous access
- Adjustable, repositionable and retrievable
- Customizable to patient's anatomy & disease state
- Preserves native anatomy for future options
- Compelling early safety and efficacy data

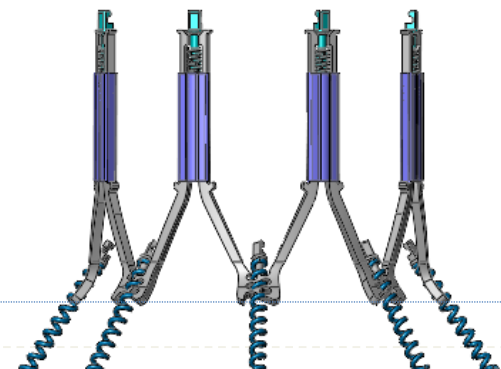
Three Installation Steps:



Placement

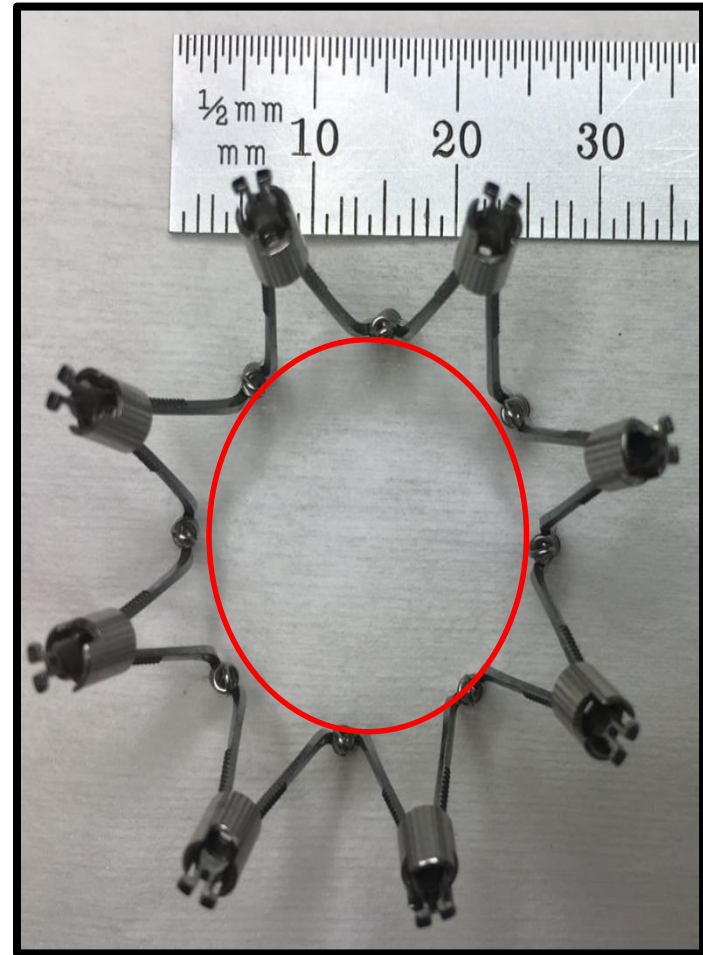
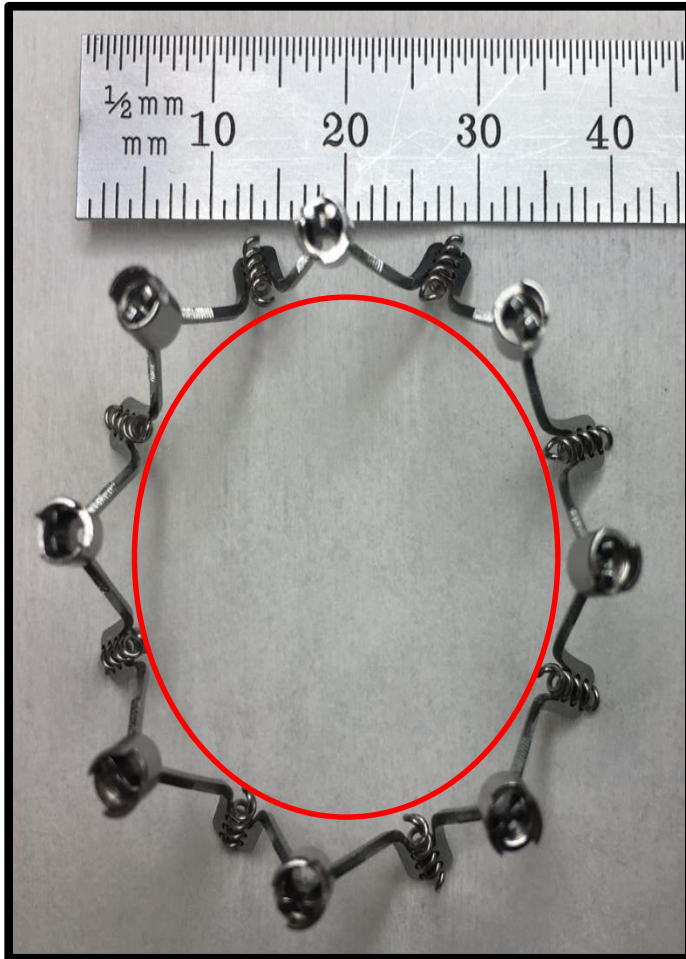


Anchoring



Actuation

Adjustable Ring Implant



Millipede IRIS™ Transcatheter Delivery System

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**Steering to land device
is MitraClip-like**

**Adjustment knobs
control anchoring and
actuation**

Standard SH Imaging:
1. Fluoro to get into LA
2. TEE to land device
3. ICE to locate anchors

Millipede IRIS System Animation

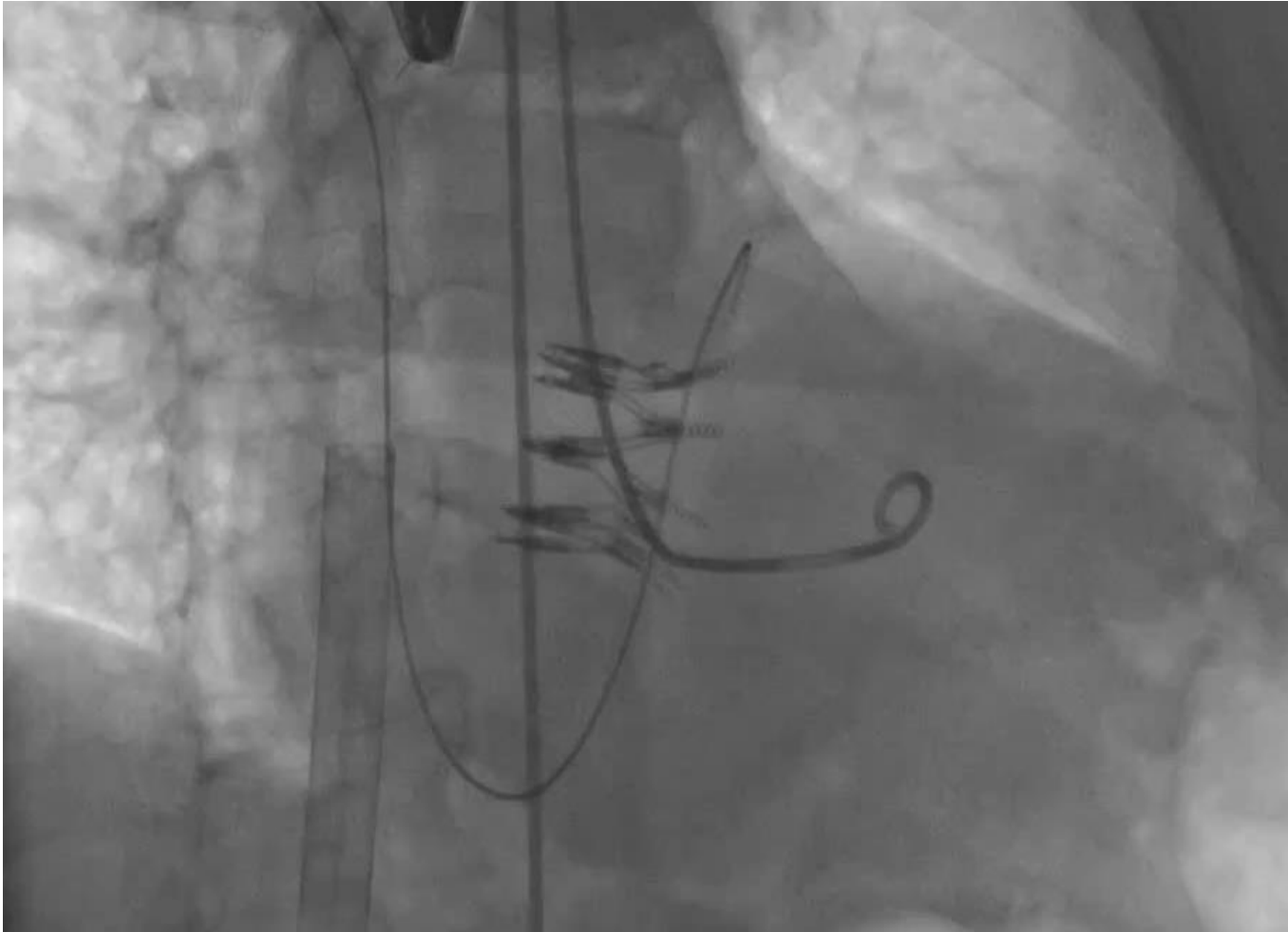
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Millipede IRIS In Vivo

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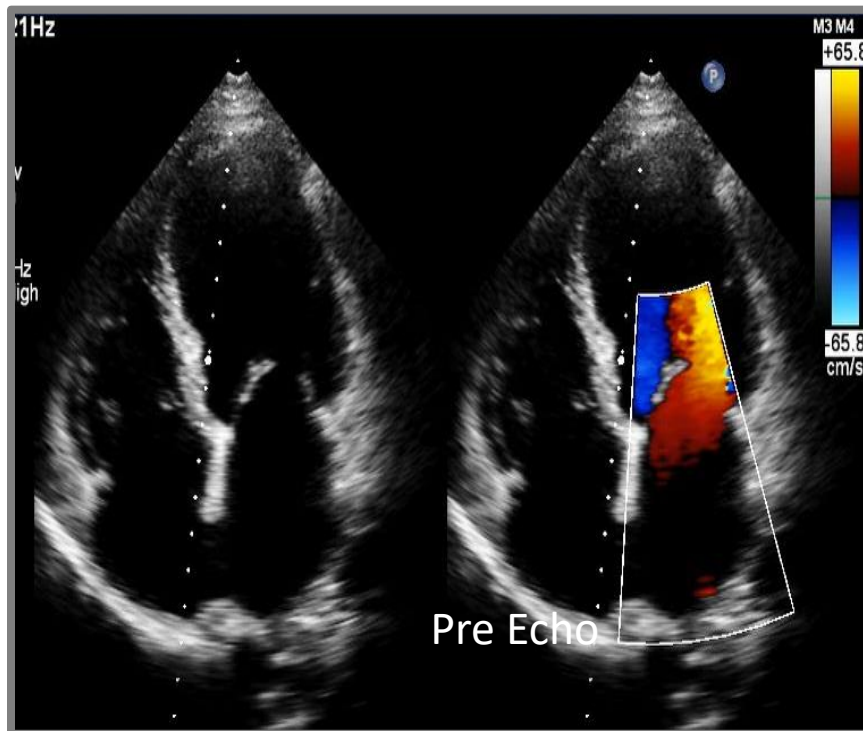


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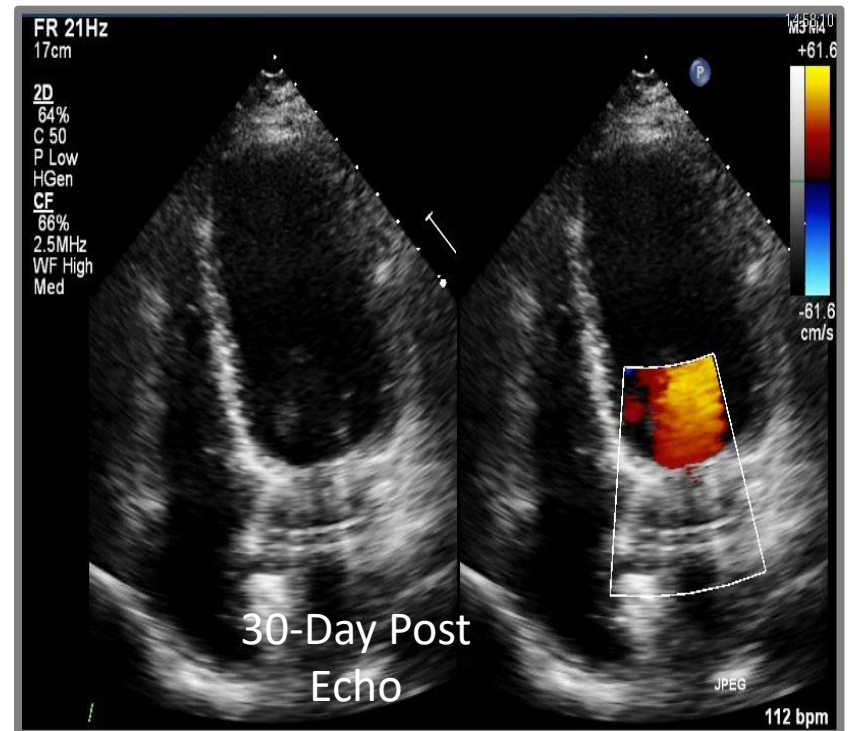
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Pre and 30-Day Follow Up

Pre-Procedure



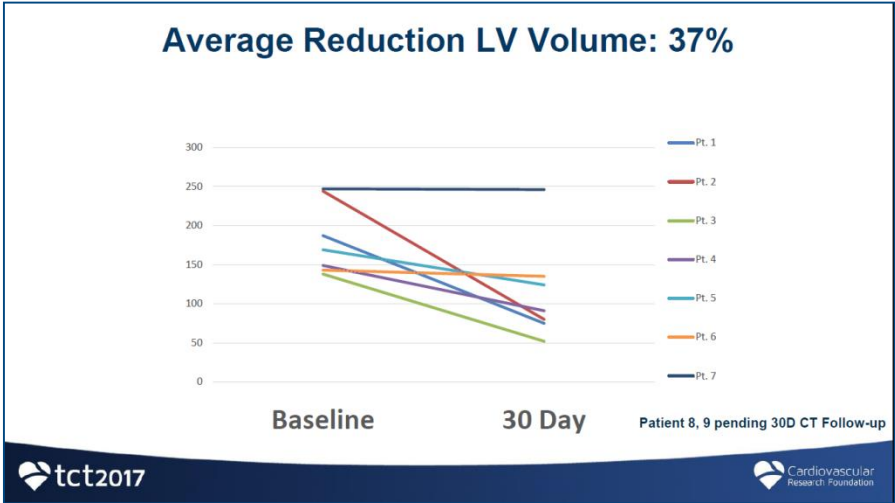
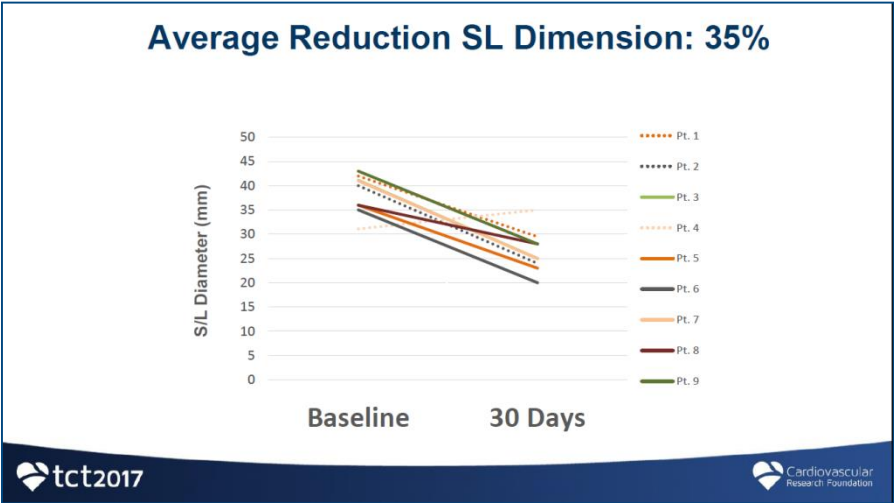
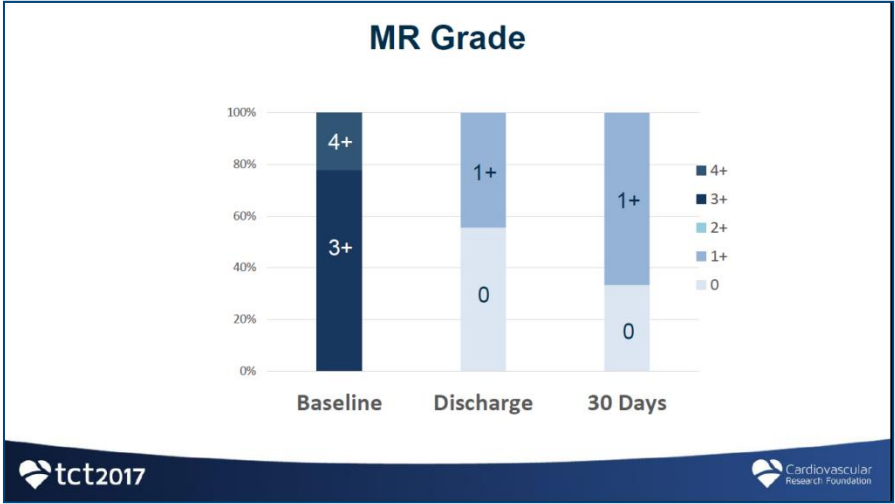
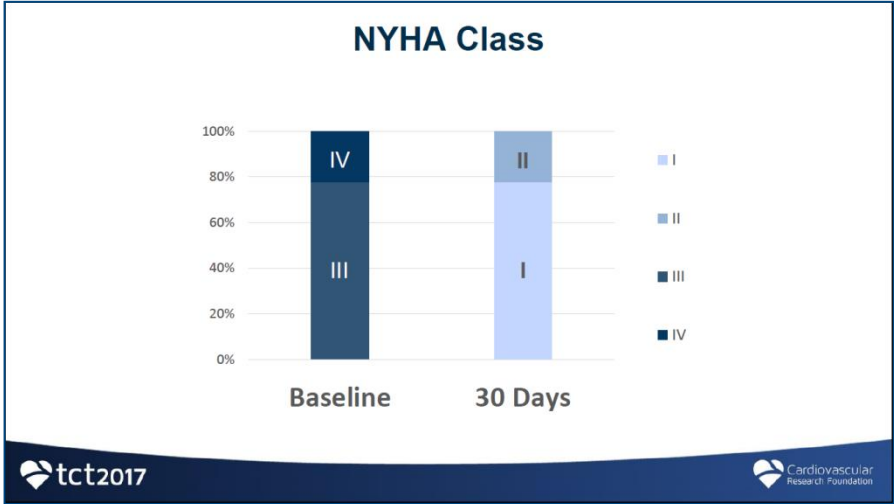
30-Day Follow Up



Initial Experience with the Millipede IRIS Device Implant Protocol

- Key Inclusion Criteria:
 - 3 or 4+ ischemic or nonischemic FMR with mitral annular dilatation
 - NYHA class II, III, or IVa
 - LVEDD $\leq$ 65mm
 - Must be candidate for surgical mitral valve correction
- Major Exclusions:
 - LVEF $<20\%$
 - Untreated CAD or revasc within 30 days
 - Aortic valve disease
 - PASP $>70\text{mmHg}$
 - Right-sided CHF with RV dysfunction
 - Any prior mitral or tricuspid valve surgery
 - Active infection or life expectancy <12 months
- Phase 1 patients received Millipede IRIS surgically, Phase 2 patients received Millipede IRIS via catheter

Millipede IRIS Early Clinical Data



N=9; Data presented by Jason Rogers, MD at TCT 2017

Summary



Boston Scientific is:

Potential Future

- Committed to a robust **clinical structural heart program** to reach a wide variety of patients
- Dedicated to **innovation** in SH technology
- Anticipating much more to come...**stay tuned**

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