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Medtronic Evolut Pro:
System Overview

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Disclosure Eberhard Grube, MD

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G – Grant and or Research Support E – Equity Interests S – Salary, AB – Advisory Board
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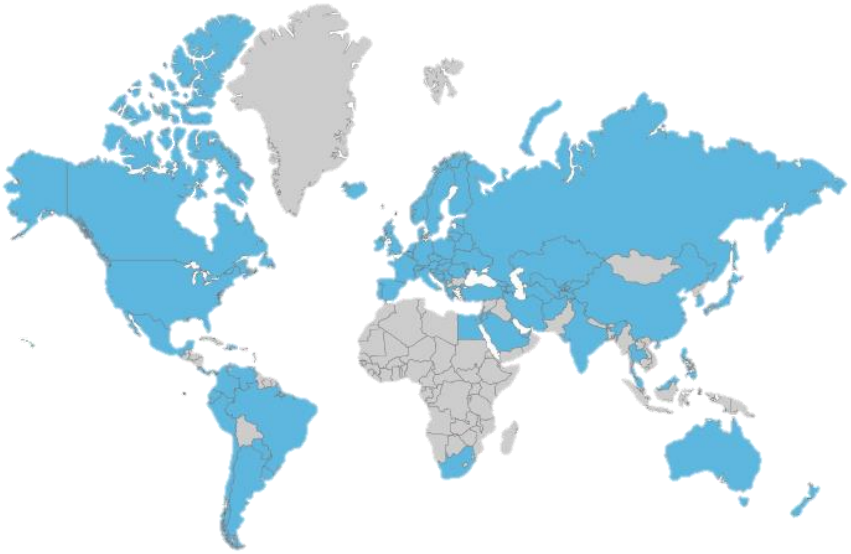
PROVEN PLATFORM PERFORMANCE
MEDTRONIC COREVALVE™ AND EVOLUT™ SYSTEMS

Medtronic CoreValve and Evolut R Systems have an extensive history of proven platform performance:

- **> 120,000 Implants**
- **> 1,000 Centers**
- **> 100 Countries**

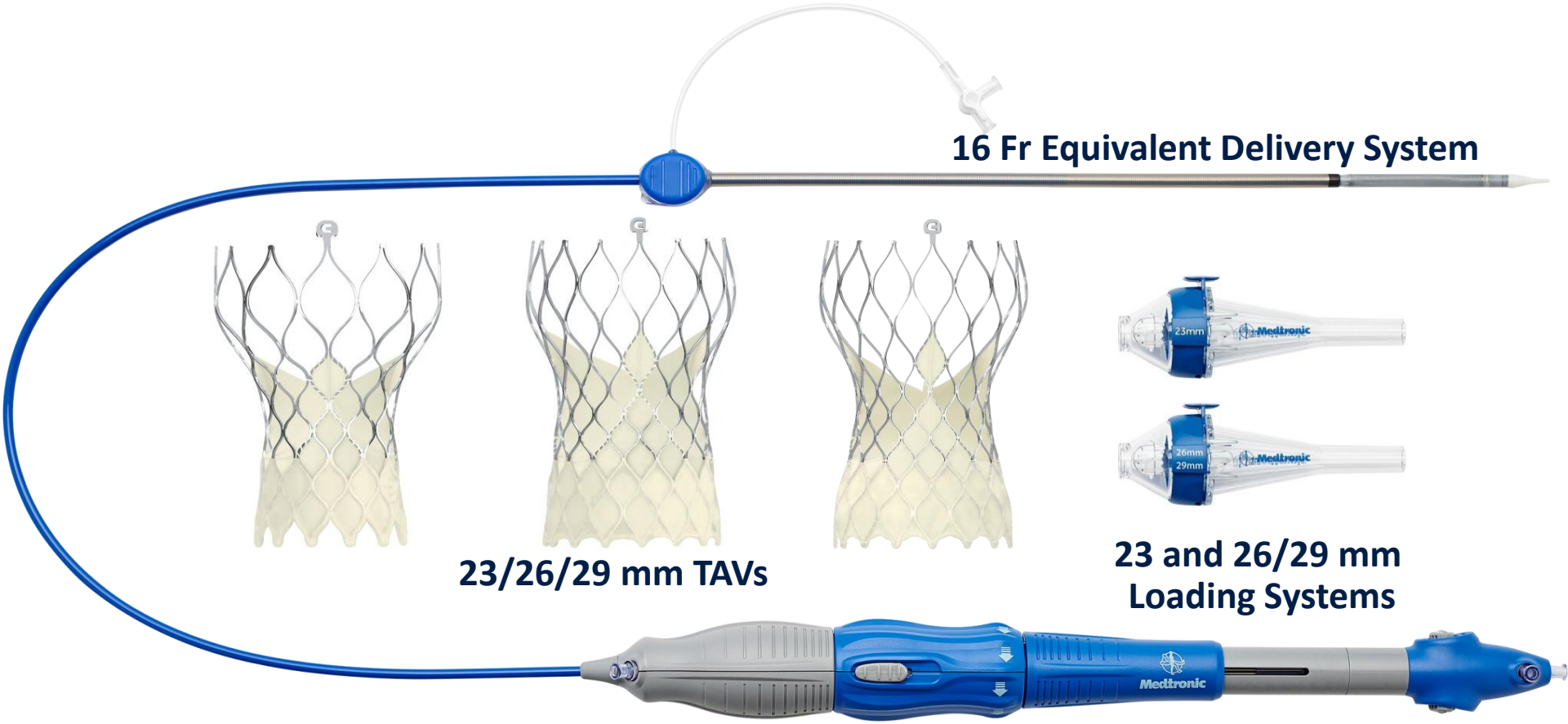


MEDTRONIC EVOLUT PRO SYSTEM
DESIGN GOALS

The Evolut PRO system is a next generation self-expanding transcatheter aortic valve (TAV) that is intended to achieve two primary performance goals:

1. **Provide Advanced Sealing**
   - Greater surface area contact
   - Low PVL Rates
2. **Maintain Proven Platform Performance**
   - Unsurpassed Hemodynamics
   - Control During Deployment
   - Low Delivery Profile

MEDTRONIC EVOLUT PRO SYSTEM
SYSTEM COMPONENTS



EVOLUT PLATFORM
INDICATED ANNULUS RANGE (MM)

Together, the Evolut PRO and Evolut R Systems treat the widest annulus range of any commercially available TAVR system*

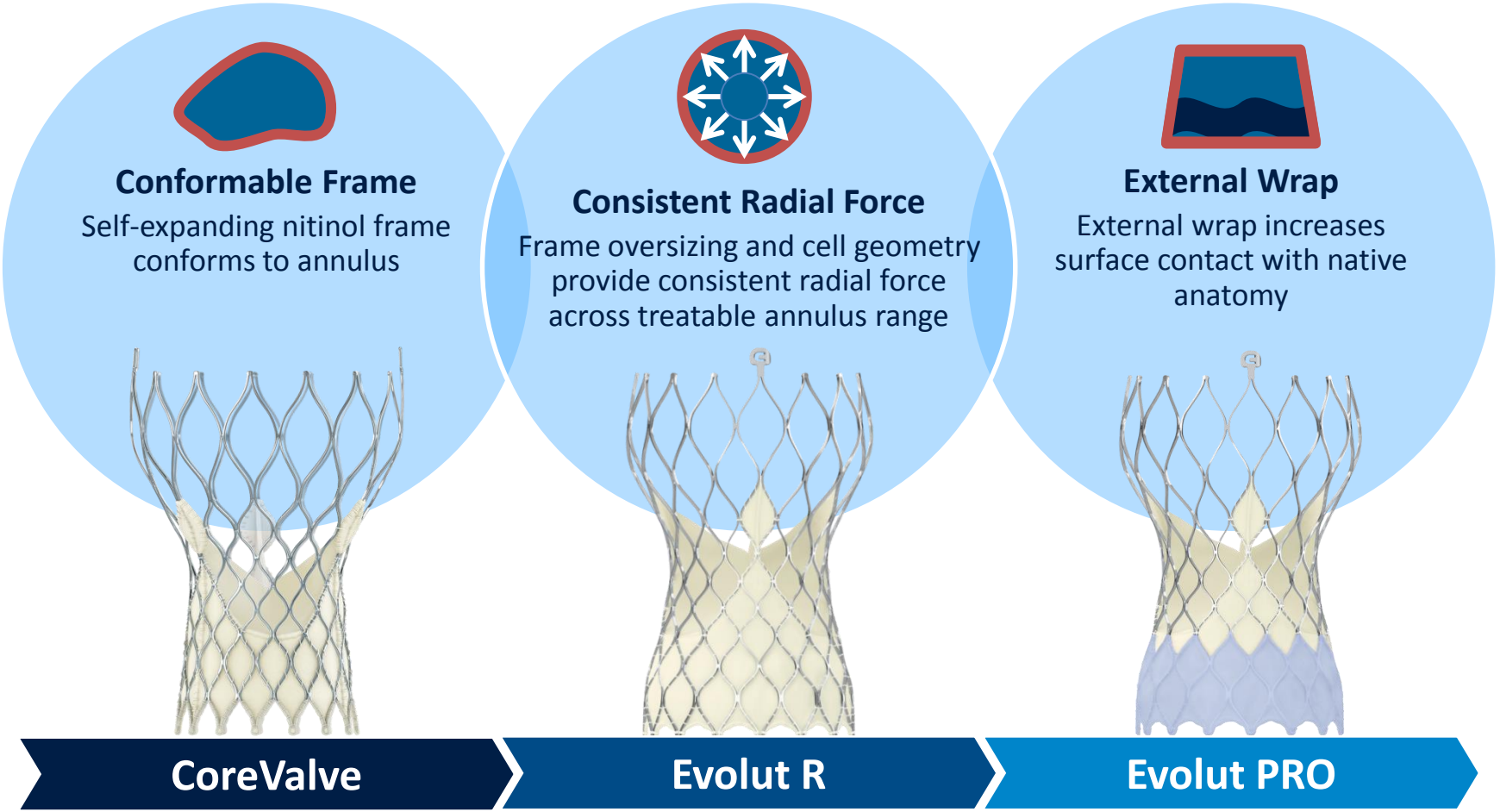
	Evolut PRO TAV									Evolut R TAV				
	23 mm			26 mm			29 mm			34 mm				
Diameter (mm)	17**	18	19	20	21	22	23	24	25	26	27	28	29	30
Perimeter (mm) †	53.4**	56.5		62.8			72.3			81.7				94.2

* Based on CT measurement
**Measurement for TAV in SAV only. | † Annulus Perimeter = Annulus Diameter x π

EVOLUT PRO DESIGN GOAL 1: ADVANCED SEALING

EVOLUT PRO TRANSCATHETER VALVE
ADVANCED SEALING

Building on Proven Design for Advanced Sealing



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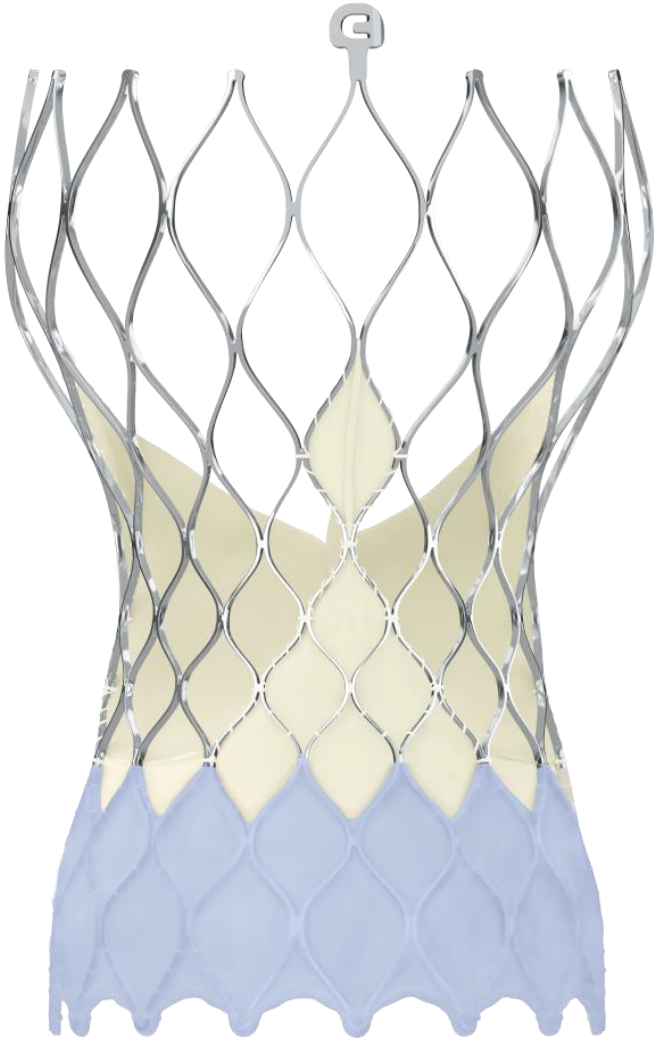
EVOLUT PRO
WRAP DESIGN AND CONSTRUCTION

- Evolut R TAV with added external porcine pericardial wrap
  - Identical frame and inner tissue as Evolut R
  - External wrap covers first 1½ inflow cells and extended skirt
- Sutures secure inner skirt and outer wrap together to the frame
  - Same number and location of sutures as Evolut R TAV

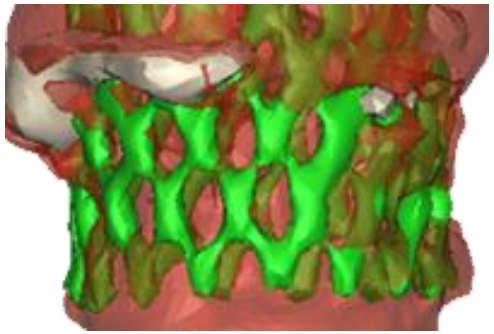


EVOLUT PRO EXTERNAL TISSUE WRAP
INCREASED SURFACE CONTACT WITH NATIVE ANATOMY

External Tissue Wrap Increases Surface Contact with Native Anatomy

- Surface contact between a transcatheter aortic valve and the native anatomy is critical for effective sealing
- Evolut PRO TAV's conforming frame and consistent radial force provide **contact at multiple levels**
- The external wrap provides added tissue volume between the TAV and native anatomy to help reduce gaps and **increase surface contact area**

Conforming Frame Seals at **Multiple Levels***



Bright Green = Contact with Native Anatomy

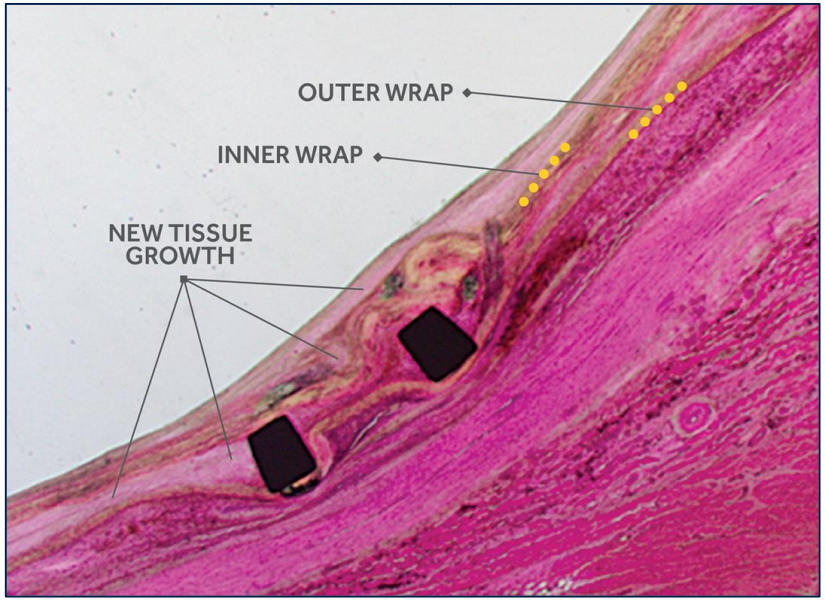
External Wrap Helps **Reduce Gaps** to **Increase Surface Contact**

*Bench top evaluation of the frame contacting the annulus based on a CT analysis of 1 patient; Image Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany
NOTE: Images are for illustrative purposes only and may not be indicative of clinical performance.

PORCINE PERICARDIAL TISSUE INTERACTION

Animal Studies Suggest Favorable Response and Interaction with Native Tissue

- Low inflammatory response[1]
- **Stable and mature tissue growth** observed at 90 days post implant[1]
  - Thin and even layer of endothelial cells on inner lumen of device



Evolut PRO explanted from Porcine Model at 60 Days
Cross Section between Nodes 1 and 2, example picture from MDT research study on file illustrating tissue interaction.[2]

1. Medtronic data on file. 90 day porcine GLP Evolut R study, results may not be indicative of clinical performance
2. Medtronic, data on file. 60 day porcine research study model, results may not be indicative of clinical performance.

EVOLUT PRO DESIGN GOAL 2: PROVEN PLATFORM PERFORMANCE

EVOLUT PRO SYSTEM
PROVEN PLATFORM PERFORMANCE

Evolut R TAV

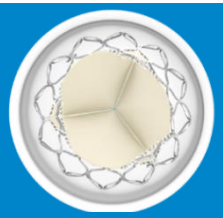
Proven Platform Performance

- Supra-annular valve function provides **unsurpassed hemodynamics**
- **Controlled, accurate deployment** with the ability to recapture and reposition
- **Lowest delivery profile** with integrated InLine Sheath

Evolut PRO TAV

PROVEN PLATFORM PERFORMANCE
EVOLUT FAMILY TAV DESIGN

SUPRA ANNULAR VALVE DESIGN
- Maximizes leaflet coaptation
- Promotes single digit gradients and large EOAs



PORCINE PERICARDIAL TISSUE
- Thin for low profile delivery
- Strength and pliability for durability

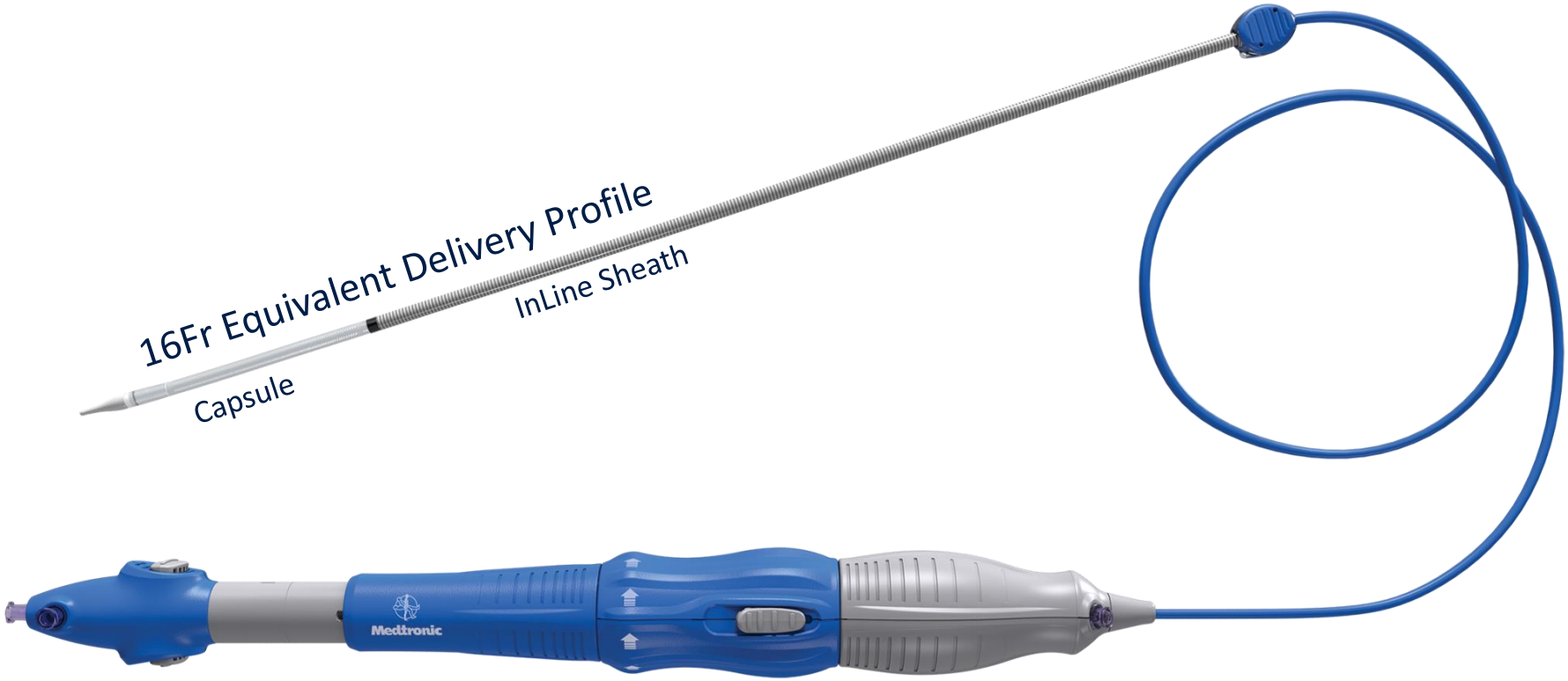
SELF-EXPANDING FRAME
- Conforms and seals to the annulus
- The foundation for recapturability

PROVEN PLATFORM PERFORMANCE
CONTROLLED, ACCURATE DELIVERY WITH ABILITY TO RECAPTURE

EnVeo™ R 16Fr Equivalent DCS enables controlled 1:1 Response with ability to Recapture

LOWEST DELIVERY PROFILE
5.5MM ACCESS VESSEL REQUIREMENT

EnVeo R InLine™ Sheath allows treatment of trans-arterial access vessel diameters ≥ 5.5 mm across all Evolut PRO valve sizes



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EVOLUT PRO DELIVERY CATHETER SYSTEM
DELIVERY PROFILE COMPARISON

Lowest delivery profile across **all valve sizes** with InLine Sheath

Evolut R 23/26/29 mm TAV		Evolut PRO /Evolut R 34 mm TAV
≥ 5.0 mm	Treatable Access Vessel Diameter	≥ 5.5 mm

18 Fr OD

14 Fr Equivalent

20 Fr OD

16 Fr Equivalent

The Evolut System retains its outer diameter as it enters the vessel and remains at this diameter as it is advanced to the annulus.

EVOLUT PRO
CLINICAL PERFORMANCE

EVOLUT PRO SYSTEM CLINICAL TRIAL
PATIENT CHARACTERISTICS

Characteristic, mean ± SD or %	N=60
Age, years	83.3 ± 7.2
Female	65.0
BSA, m^2	1.8 ± 0.2
STS – PROM, %	6.4 ± 3.9
NYHA Class III or IV	70.0
Peripheral vascular disease	43.3
Atrial fibrillation / atrial flutter	18.6
Diabetes mellitus	43.3
Severe aortic calcification	20.5
LV ejection fraction, %	58.9 ± 12.4
Pre-existing pacemaker	15.0

Forrest, et al., ACC, 2017

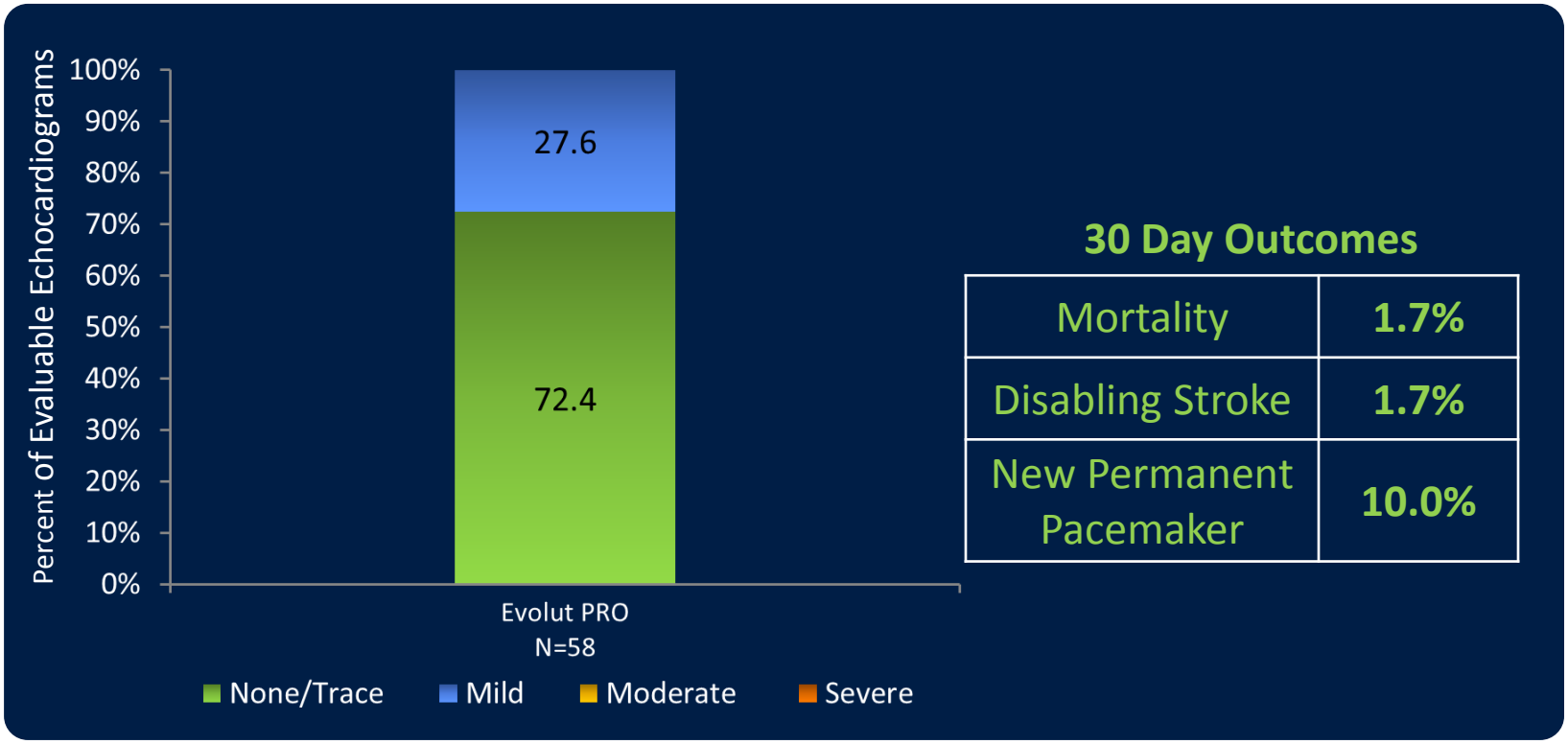
EVOLUT PRO SYSTEM CLINICAL TRIAL
PROCEDURAL OUTCOMES

Characteristic, % or mean ± SD	N = 60
General anesthesia	58.3
Iliofemoral access approach	98.3
Valve Size Implanted	
26 mm	40.0
29 mm	60.0
Pre-TAVR balloon dilation	51.7
Post-implant balloon dilation	26.7
Percentage of patients repositioned	35.0
Average implant depth, mm	4.3 ± 1.6

Forrest, et al., ACC, 2017

EVOLUT PRO SYSTEM CLINICAL TRIAL
ADVANCED SEALING

Low rates of PVL while maintaining
low rates of mortality, stroke, and need for pacemaker



30 Day Outcomes

Mortality	**1.7%**
Disabling Stroke	**1.7%**
New Permanent Pacemaker	**10.0%**

Forrest, et al., ACC, 2017

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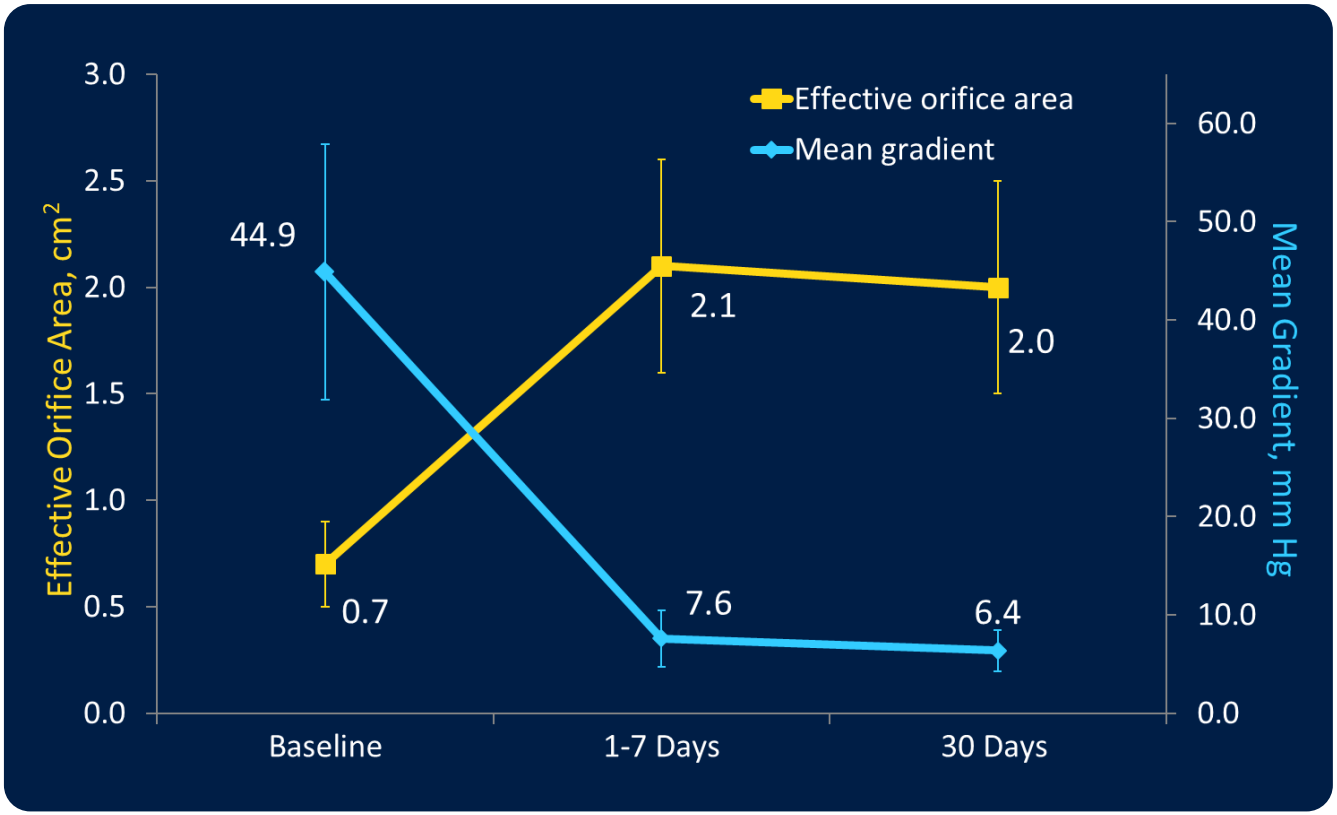
EVOLUT PRO SYSTEM CLINICAL TRIAL
UNSURPASSED HEMODYNAMIC PERFORMANCE

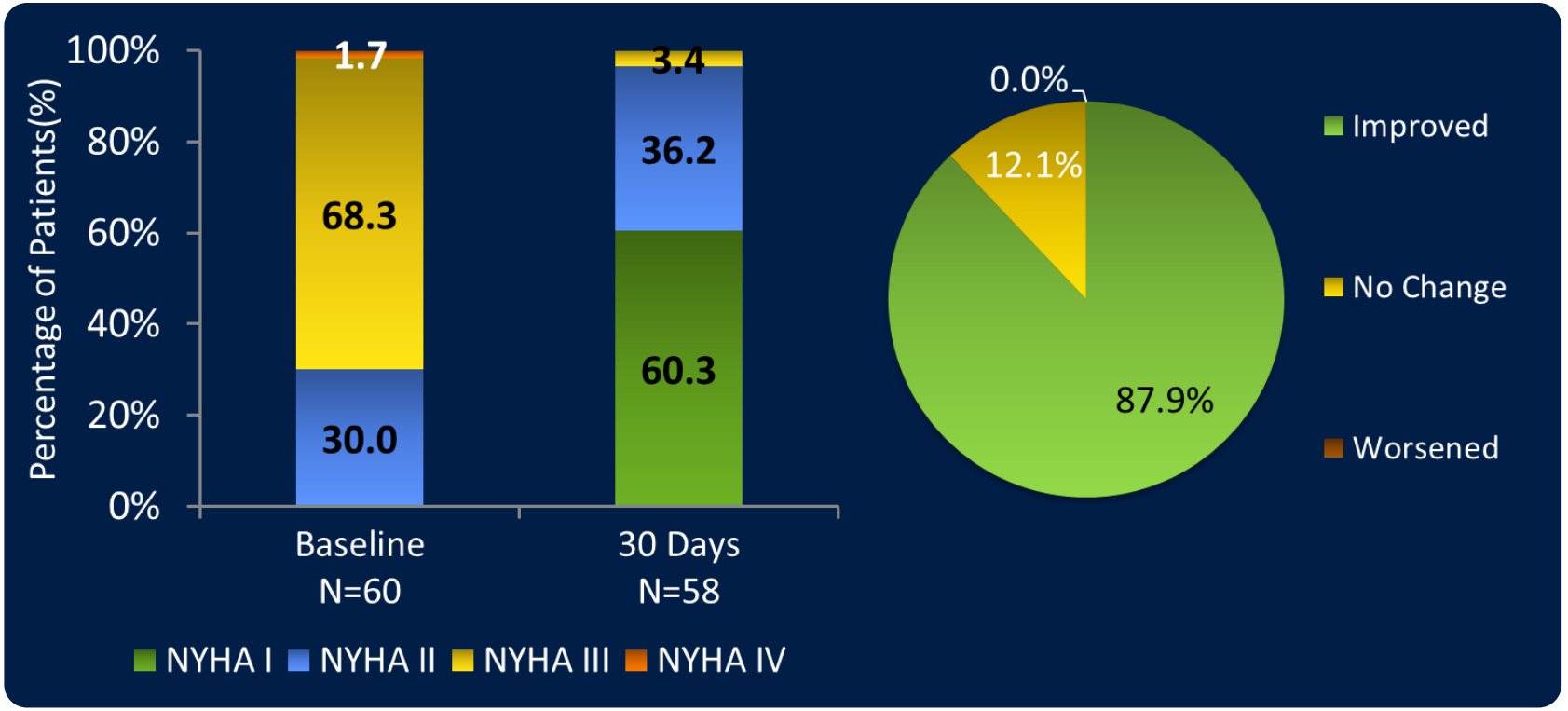
Supra-annular valve function provides single-digit gradients and large effective orifice areas



Forrest, et al., ACC, 2017

EVOLUT PRO CLINICAL TRIAL
SYMPTOMATIC IMPROVEMENT

87.9% of survivors improved NYHA class at 30 days



Forrest, et al., ACC, 2017

EVOLUT PRO
TRANSFEMORAL PROCEDURE & CASE EXAMPLE

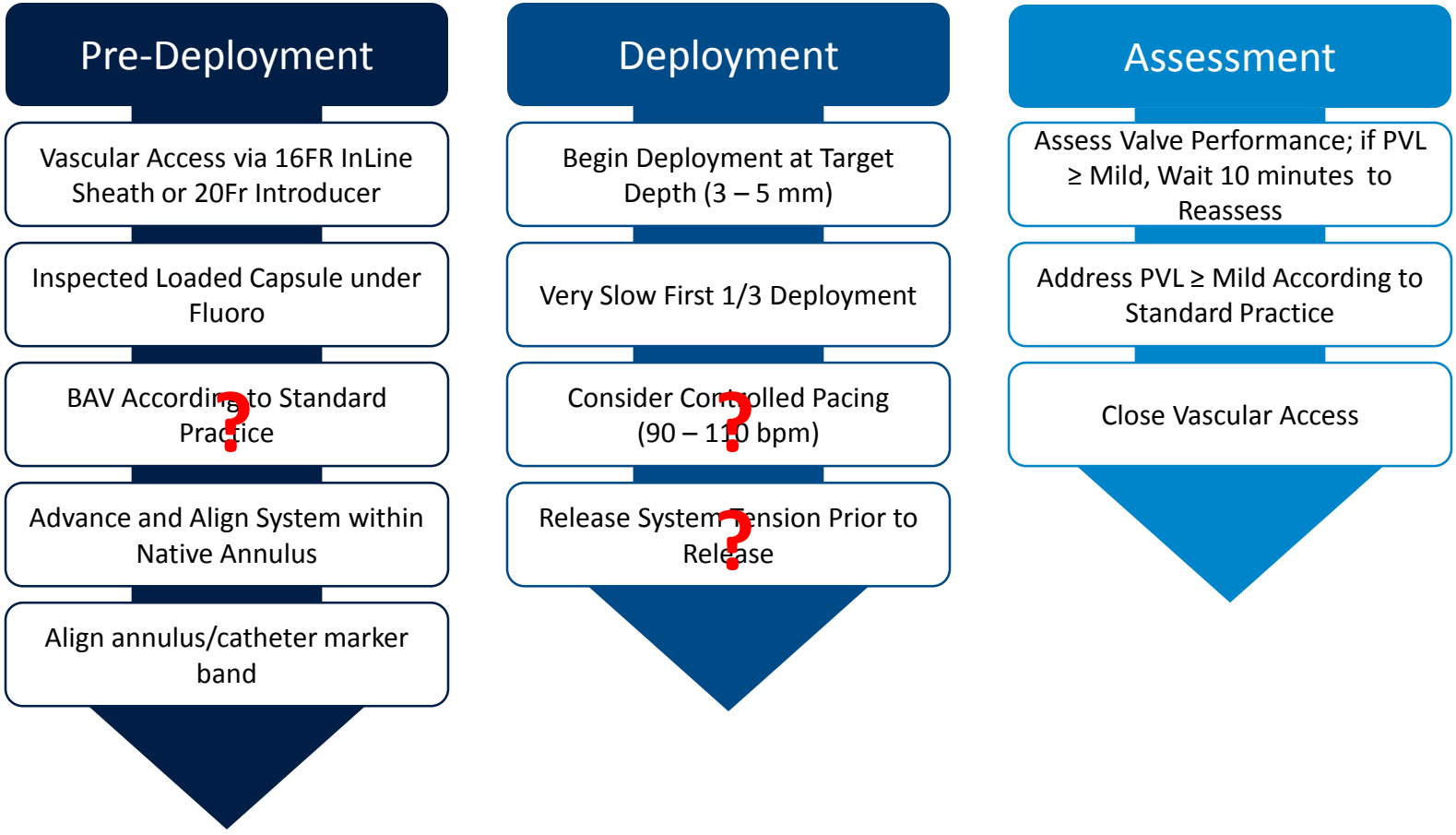
EVOLUT PRO/ EVOLUT R PATIENT SELECTION
AORTIC ROOT CRITERIA

Valve Size Selection	Evolut PRO TAV			Evolut R TAV
				
Size	23 mm	26 mm	29 mm	34 mm
Annulus Diameter	17*/18 – 20 mm	20 – 23 mm	23 – 26 mm	26 - 30 mm
Annulus Perimeter (π x Diameter)	53.4*/ 56.5 – 62.8 mm	62.8 – 72.3 mm	72.3 – 81.7 mm	81.7 – 94.2 mm
Sinus of Valsalva Diameter (Mean)	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	≥ 15 mm			≥ 16 mm

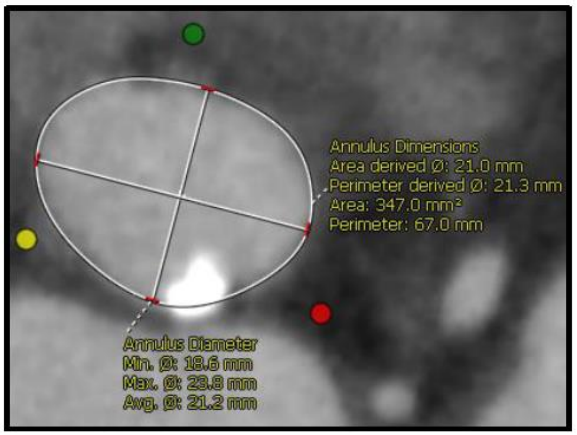
* Measure for TAV in SAV only

EVOLUT PRO PROCEDURE
PROCEDURE OVERVIEW

Controlled, Accurate Deployment via Familiar Evolut Procedure and Best Practices



EVOLUT PRO CASE EXAMPLE
AORTIC ROOT MEASUREMENTS



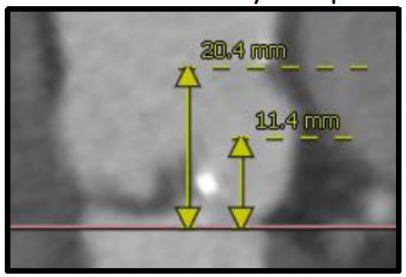
35% cardiac phase

Ao Annulus mean diameter 21.2 mm

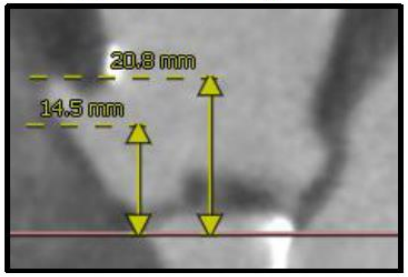
23.8 x 18.6	**Major x Minor aortic annulus diameter**
67.0	**Aortic Annulus perimeter (21.3** x 3.14**)**
34.8	**Max Ascending Aorta diameter**
28.4 – 29.0	**Sinus of Valsalva diameter** (Mean 28.6)
20.2 – 20.8	**Sinus of Valsalva height** (Mean 20.5)
25.9 – 26.9	**Sinotubular Junction Diameter (STJ)**

Sinus Height

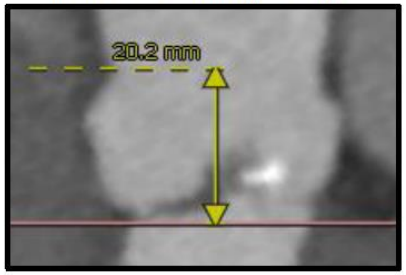
Left Coronary Cusp



Right Coronary Cusp

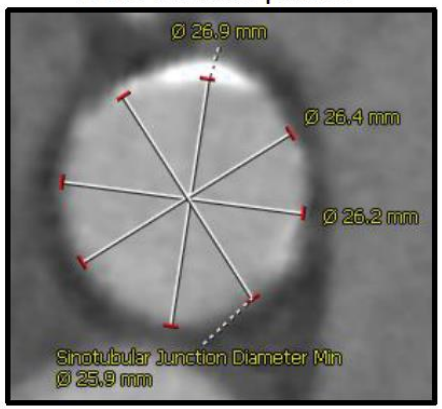


Non Coronary Cusp

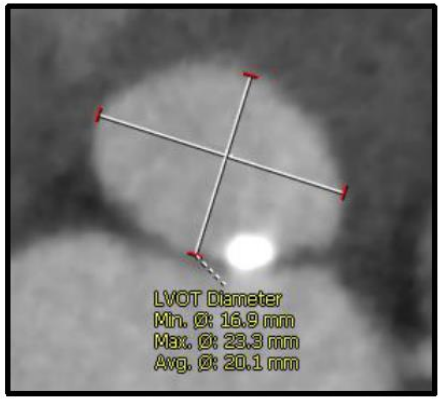


SOV diameter

60% cardiac phase



LVOT



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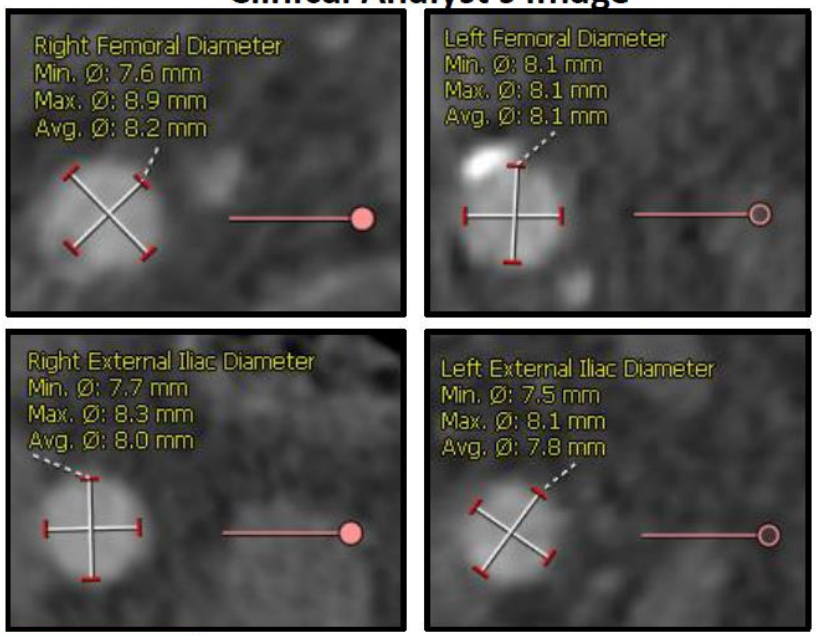
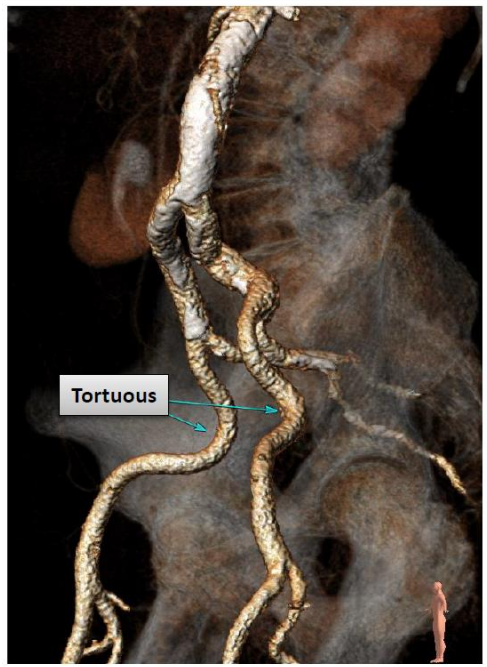
EVOLUT PRO CASE EXAMPLE
ACCESS MEASUREMENT AND ASSESSMENT

Clinical Analyst's Image





7.6 x 8.9	**RFA min. diameter**
7.7 x 8.3	**RIA min. diameter**
8.1 x 8.1	**LFA min. diameter**
7.5 x 8.1	**LIA min. diameter**

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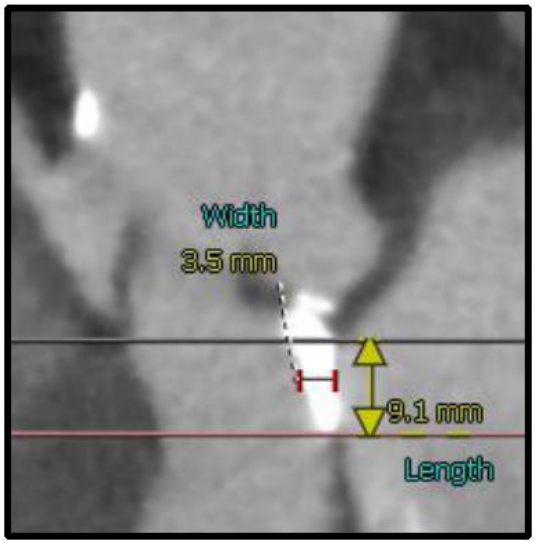
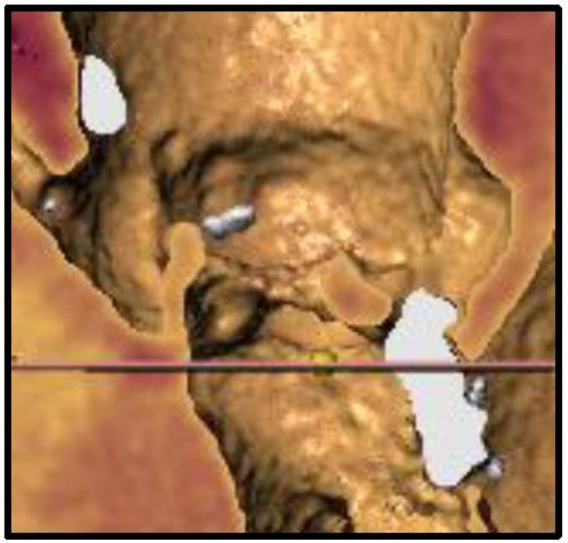
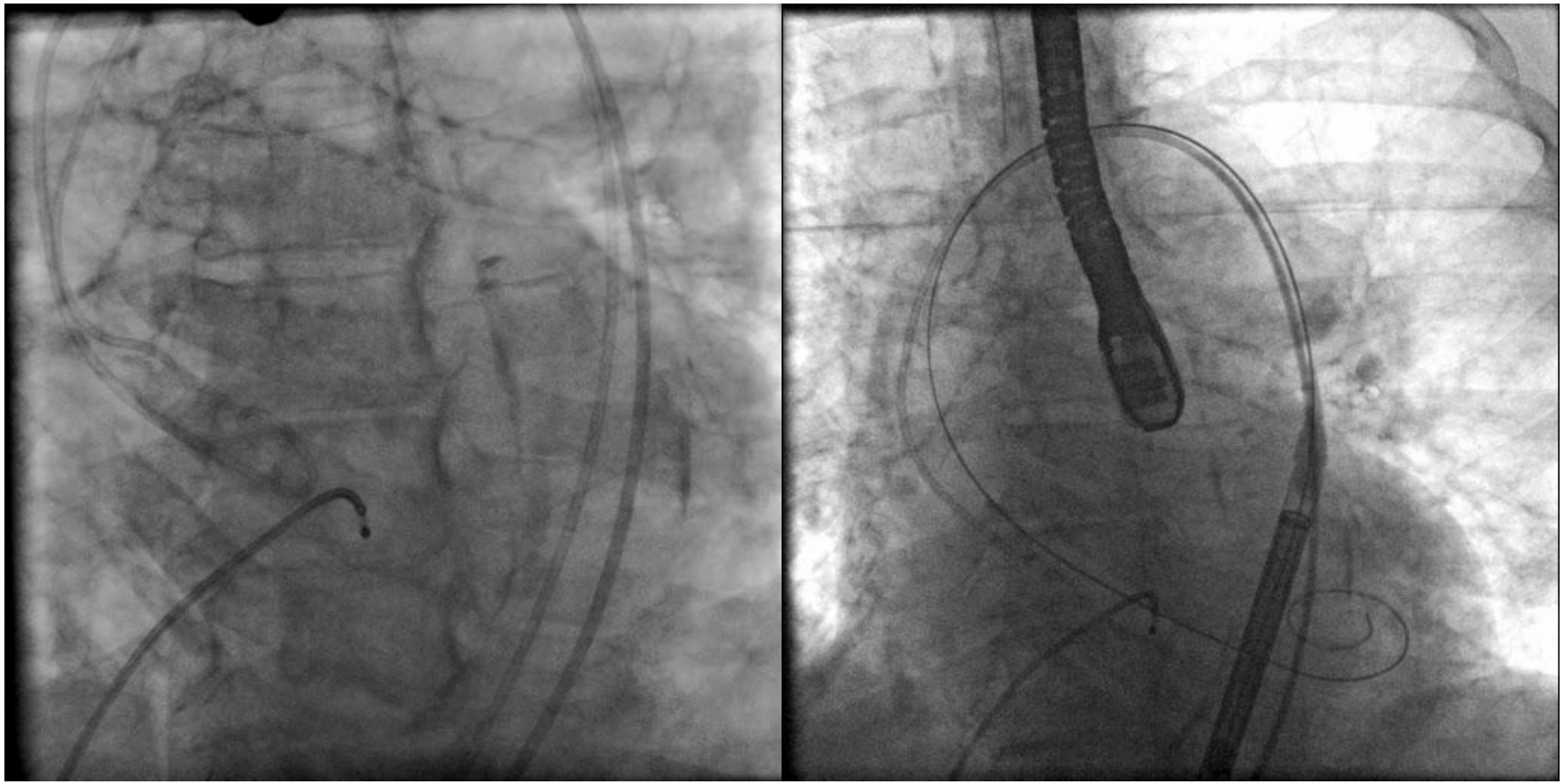
EVOLUT PRO CASE EXAMPLE
ANNULAR AND LVOT CALCIFICATION ASSESSMENT



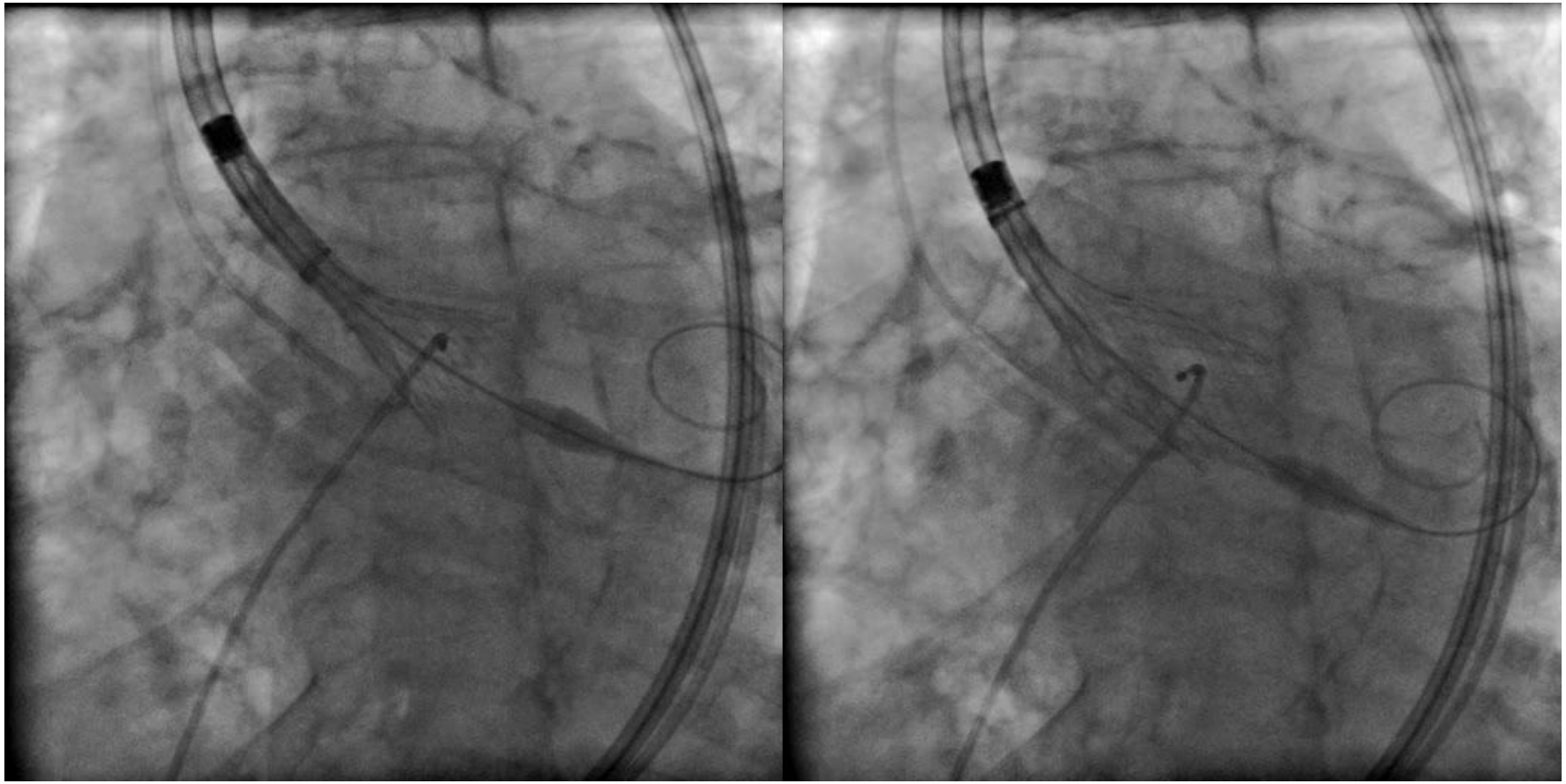


EVOLUT PRO CASE EXAMPLE
SYSTEM TRACKING



EVOLUT PRO CASE EXAMPLE
VALVE DEPLOYMENT TO POINT OF NO RECAPTURE

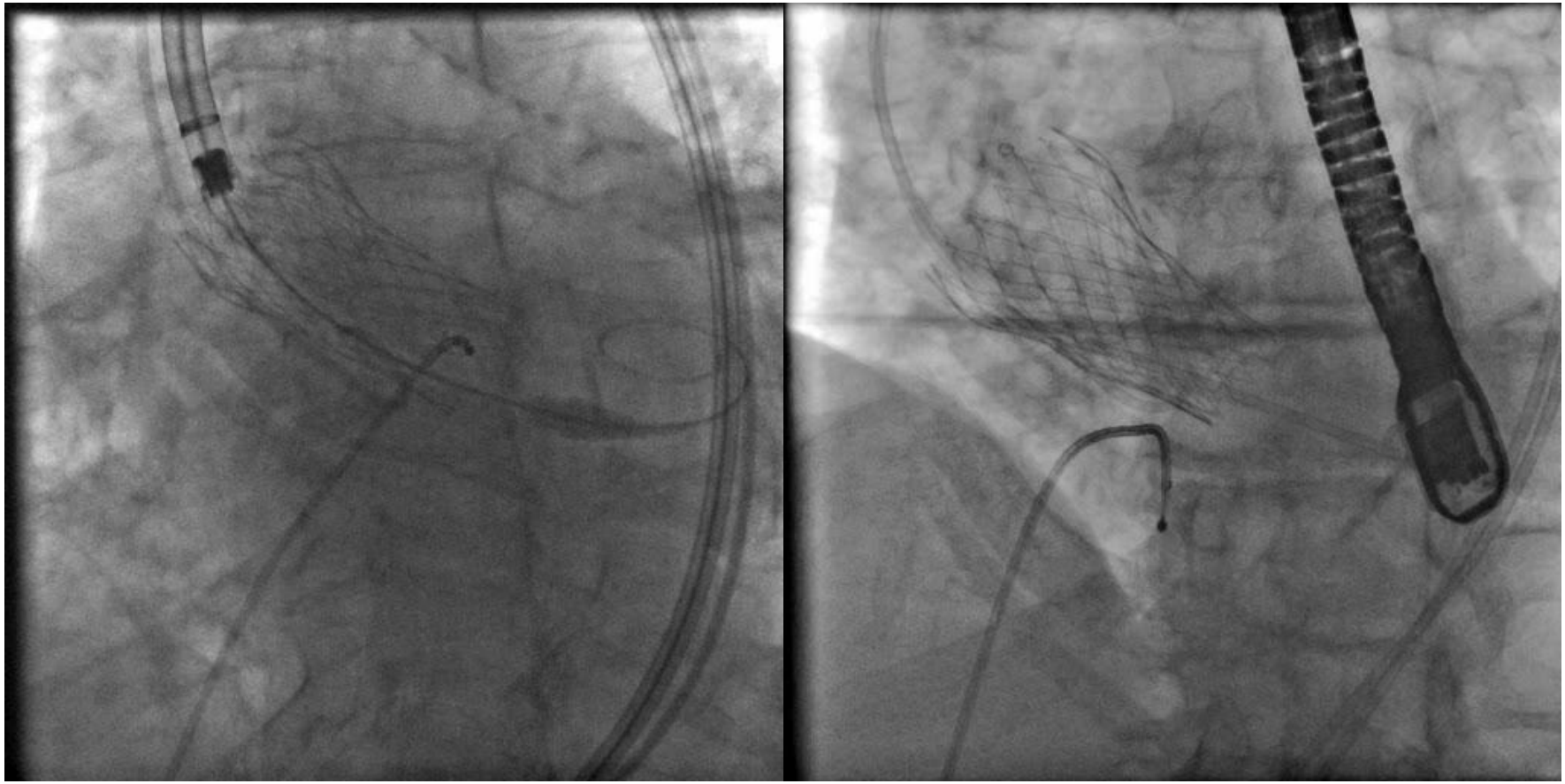
Controlled, 1:1 Response with Ability to Recapture*



*Able to recapture up to three times before reaching the point of no recapture; upon third recapture the system must be removed from the patient and replaced with a new delivery system and TAV.

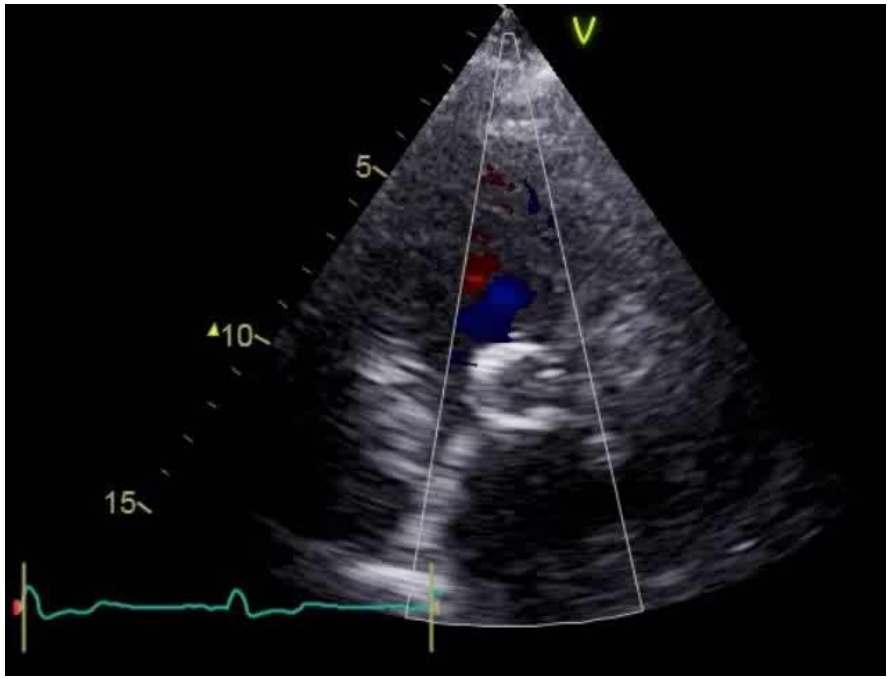
EVOLUT PRO CASE EXAMPLE
VALVE RELEASE AND ASSESSMENT

Conformable frame, Consistent Radial Force, and External Wrap for Advanced Sealing



EVOLUT PRO CASE: LVOT CALCIFICATION
AR AT DISCHARGE AND 30 DAYS

Unsurpassed Hemodynamics



Site Reported AR*:

- **Discharge = None**
- **30 Days = None**

- *Represents one case only and may not be indicative of clinical performance in other patients.

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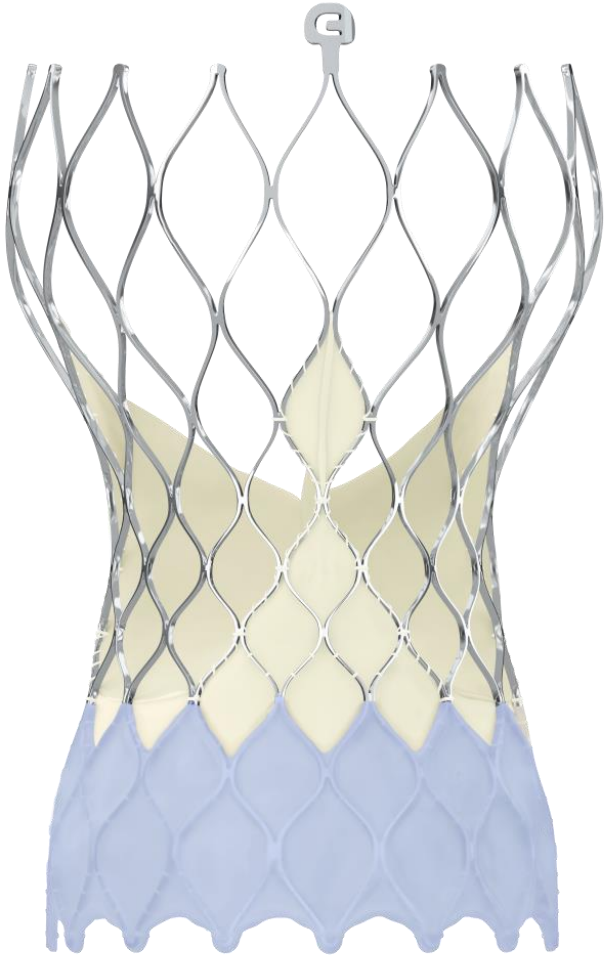
MEDTRONIC EVOLUT PRO SYSTEM
SUMMARY

Intended for Advanced Sealing

- Conforming frame and consistent radial force provide contact at multiple levels in various annulus shapes
- External tissue wrap increases surface contact area

Proven Platform Performance

- Controlled, accurate deployment with the ability to recapture
- Supra-annular valve function provides unsurpassed hemodynamics
- Lowest delivery profile with integrated InLine Sheath



Thank you for your kind attention!