

# New Device Platform to Prevent Structural Heart Intervention Complications

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

- Grant/Research Support
- Scientific Advisory Board
- Executive Physician Council

## Company

- Edwards Lifesciences, Abbott
- Medtronic
- Boston Scientific Corp



# Types of Structural Heart Interventions (SHI)

- TAVR
- TMVR
- TEER: Mitral and Tricuspid
- TTVR
- LAA Occlusions



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# Complications of SHI

- Delivery: rigid catheter, large bore, steerability, imaging
- Accuracy/Ease of Use: too low/high, lateral/medial; embolization
- Durability
- Cerebral protection
- Specific complications: perivalvular leak, single leg detachment, LVOT obstruction (TMVR), coronary obstruction



# Clinical Factors

- Increase BMI
- Small height, tall (6'3")
- Rhythm (e.g. AF)
- Decreased EF
- Coronary disease
- Peripheral vascular disease

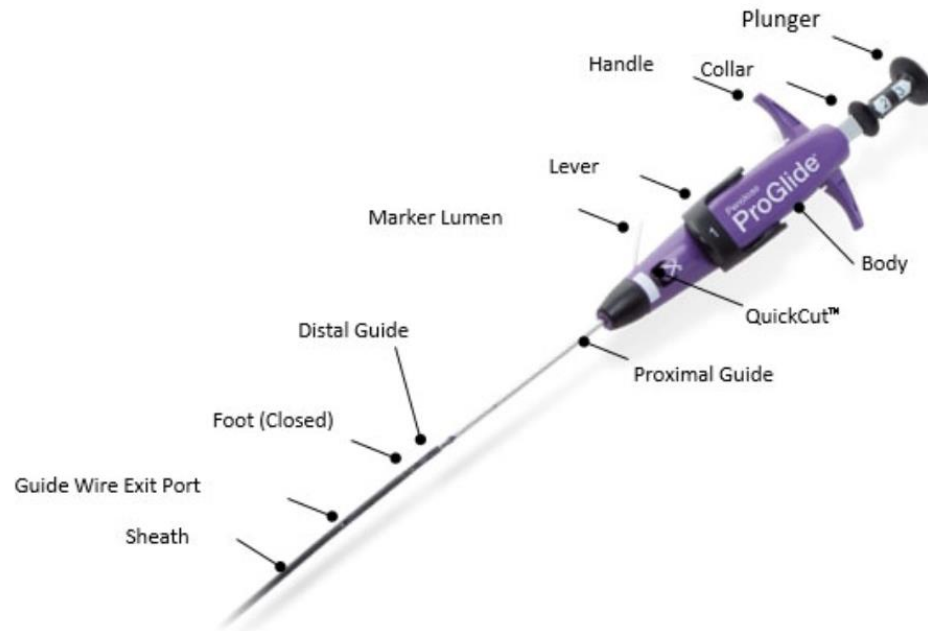


# Large Bore Closure

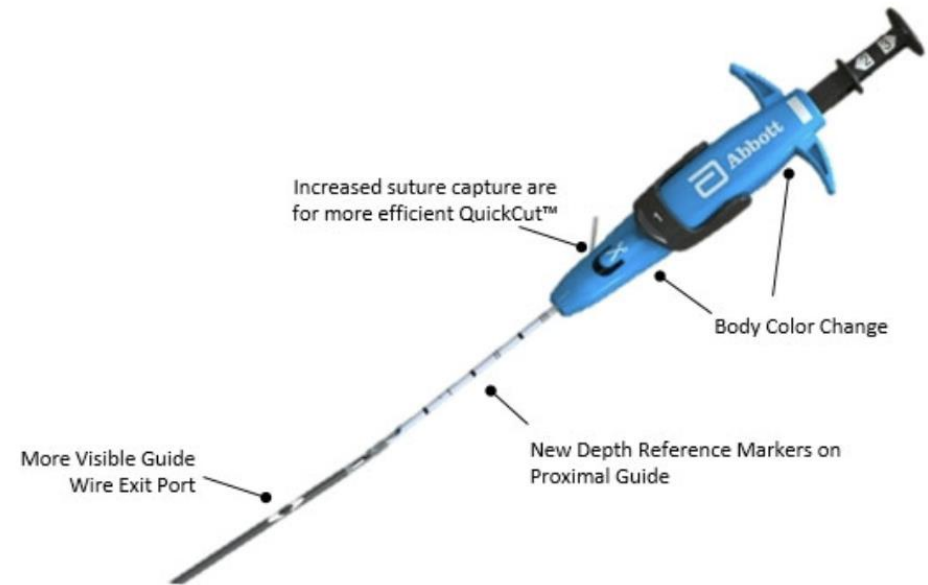


# Perclose Family

## Perclose™ ProGlide™ Device



## Perclose™ ProStyle™ Device





# Improvements Made to Perclose™ ProStyle™ SMCR System

## Perclose™ ProStyle™ Suture Trimmer



## Perclose™ ProStyle™ Device



Recalibrated Plunger mechanism for single-thumb deployment with no rebound

## Perclose™ Snared Knot Pusher



# MANTA

## Before Index Procedure

### 1 PRE-Locate

- INSERT LOCATOR UNTIL FLOW STARTS
- WITHDRAW UNTIL FLOW STOPS
- REINSERT 1 CM AND CONFIRM FLOW
- NOTE PUNCTURE DEPTH AT SKIN LEVEL

NOTE PUNCTURE DEPTH AT SKIN LEVEL

BLOOD FLOW

## After Index Procedure

### 2 Exchange MANTA Sheath

WITH DILATOR, INSERT SHEATH FULLY TO PUNCTURE DEPTH + 2 cm

### 3 Insert MANTA

INSERT TO SNAP

'SNAP'

### 4 Position & Release Toggle

ROTATE LEVER TO CLICK

'CLICK'

POSITION HANDLE TO PUNCTURE DEPTH

### 5 Deploy Collagen & Seal

WITHDRAW TO GREEN

HOLD AT GREEN CLICK

TAMP TO BLACK

30-45°

'CLICK'

Lock

# MANTA

**Arguably the best studied large bore closure device**

## ➤ *Prospective multicenter single-arm Studies*

- ✓ *SAFE ID*
- ✓ *CE Mark*
- ✓ *MARVEL (post-market)*

➤ *N = 891 patients*

## ➤ *Highlights*

- ✓ *Time to hemostasis 31 seconds*
- ✓ *Major vascular complications 4.4%*
- ✓ *Minor vascular complications 4.7%*
- ✓ *Bail-out surgery or covered stent in 3.6%*

## ➤ *Randomized Controlled Trials*

- ✓ *MANTA vs. 2 Proglides*
- ✓ *MASH TAVI (N = 210)*
- ✓ *CHOICE CLOSURE (N=516)*

➤ *N = 726 patients*

## ➤ *Highlights*

- ✓ *More additional closure devices with 2 proglides*
- ✓ *MANTA*
  - ✓ *Faster time to hemostasis*
  - ✓ *Trend for more major vascular complications*
  - ✓ *More any vascular complication*
  - ✓ *More endovascular bail-out*

# Imaging





# VeriSight Pro catheter features

**Outer diameter**

9 F

**Working length**

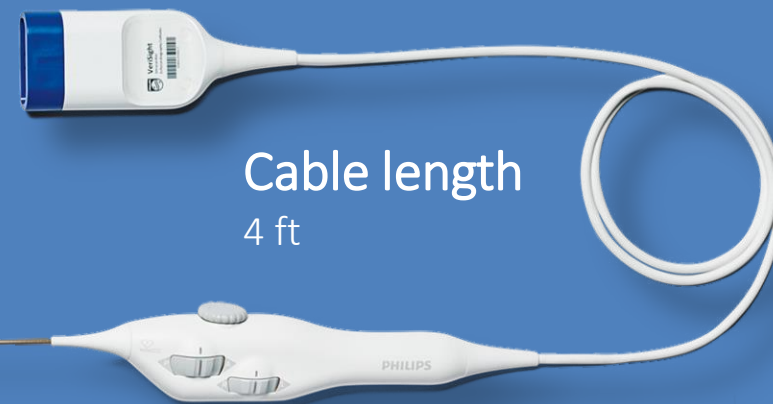
90 cm

**Cable length**

4 ft

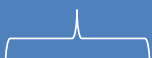
**Minimum sheath size**

10 F



**Catheter tip**

2 cm with softer<sup>1</sup> design



xMatrix 840 elements

90x90 Field of View

4-10 MHz

**Clutch**

Maintains deflections

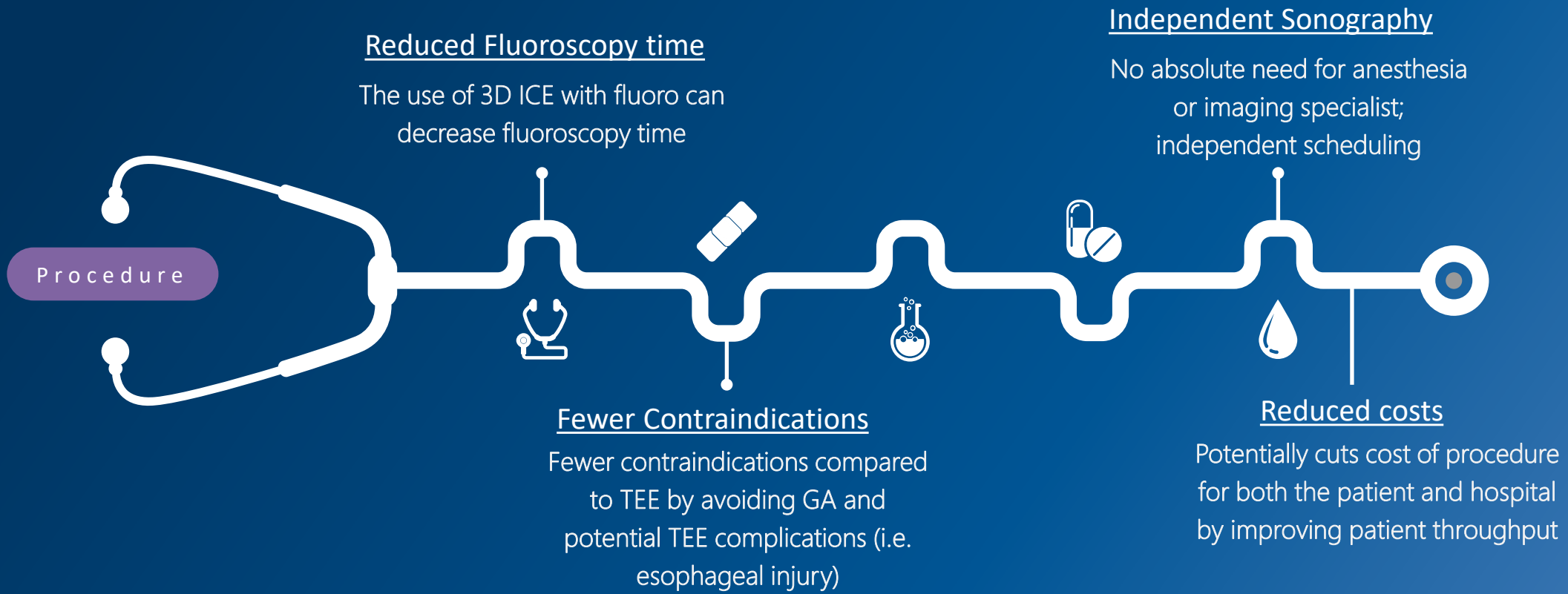


**Steering wheels**

4-way steering for A/P and L/R

<sup>1</sup>VeriSight handling claims validated by clinician feedback collected from a bench study, with a sample size of 16 physicians and 16 technicians, totaling 32 clinicians. Clinicians also provided feedback based on images taken by VeriSight Pro in a porcine model. Data on file (D000259724).

# Potential Procedural Benefits



# Advantages of 3D ICE



Clinical Need	TEE	2D ICE	3D ICE
2D imaging for diagnostics	✓	✓	✓
90x90 Field of view	✓		✓
Biplane views	✓		✓
Multiplanar reconstruction	✓		✓
Conscious sedation		✓	✓
Decreased hospital length of stay		✓	✓
Improved patient experience		✓	✓
Increased patient access to previously risky procedures		✓	✓
Independent sonography		✓	✓
No risk of esophageal perforation		✓	✓
Reduced contraindications		✓	✓
Reduced cost		✓	✓
Reduced fluoroscopy time		✓	✓
Enhanced cardiac structure views			✓
Increased patient throughput			✓

# Why 3D ICE?

- 3D structures of the heart and relation of various structures are easier to see and define
- Obtaining multiple planes simultaneously enables less catheter manipulation and faster image acquisition
- Provides live or retrospective access to any 2D imaging plane in a single acquisition using MPRs
- Real-time instantaneous acquisition and visualization using 3D Zoom, Live 3D, or 3D full volume.



Image Courtesy: Dr.Natale/St.David's





# EchoNav



# Steerability



# TriClip G4 Transcatheter Valve Repair System

## Specifically Designed for TR



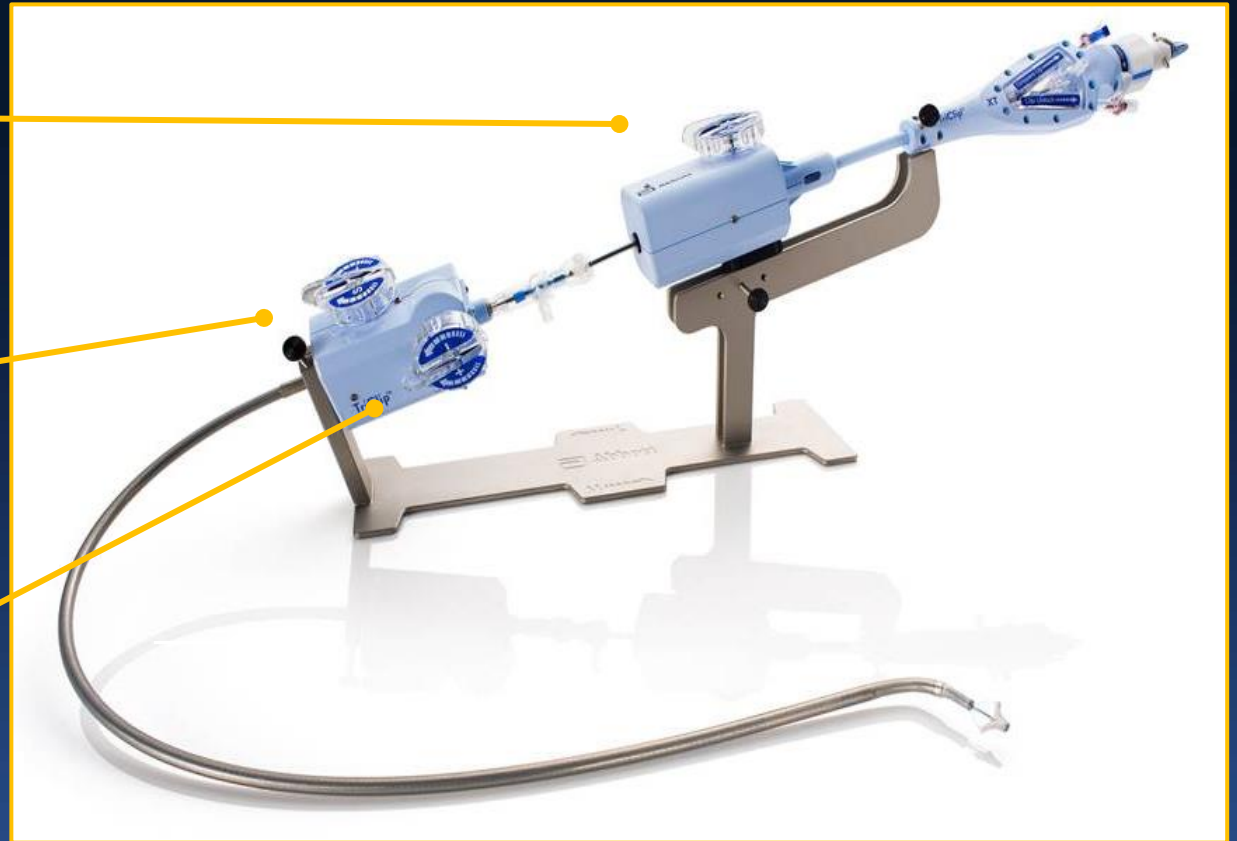
*Flex to TV,  
same as  
SGC*



*Placement on  
SGC increases  
S/L movement  
~4x*



*Height  
management*



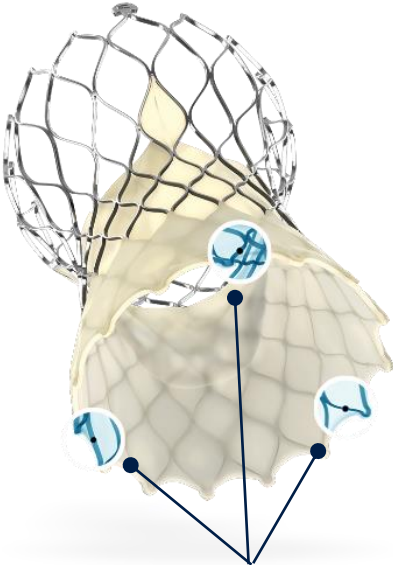
# Accuracy/Ease of Use



# WHAT'S NEXT: Evolut FX System

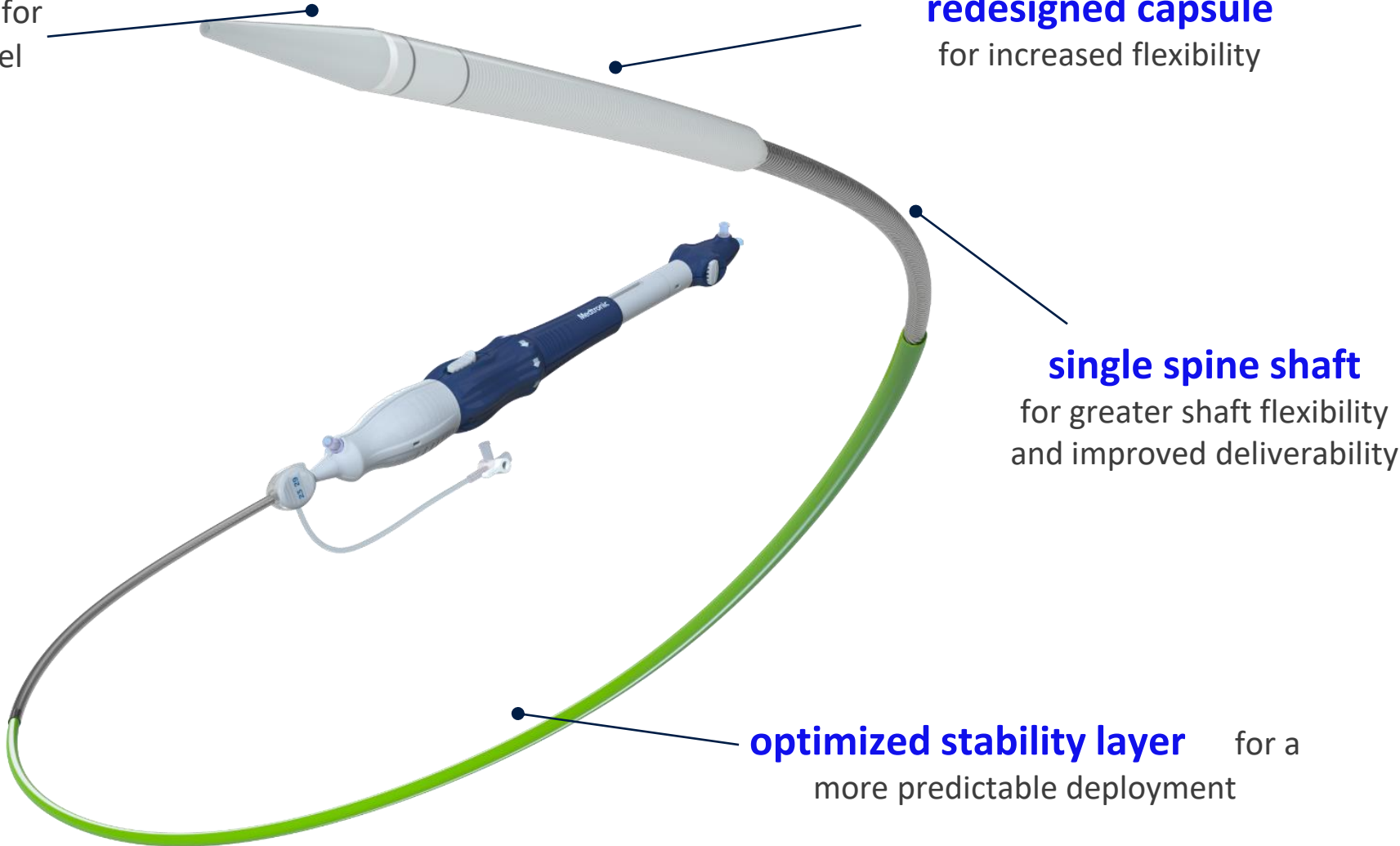
**redesigned tip** for more dilator like vessel access

**redesigned capsule** for increased flexibility



**enhanced visualization**

with radiopaque locators to identify commissures and assist ideal depth of implant

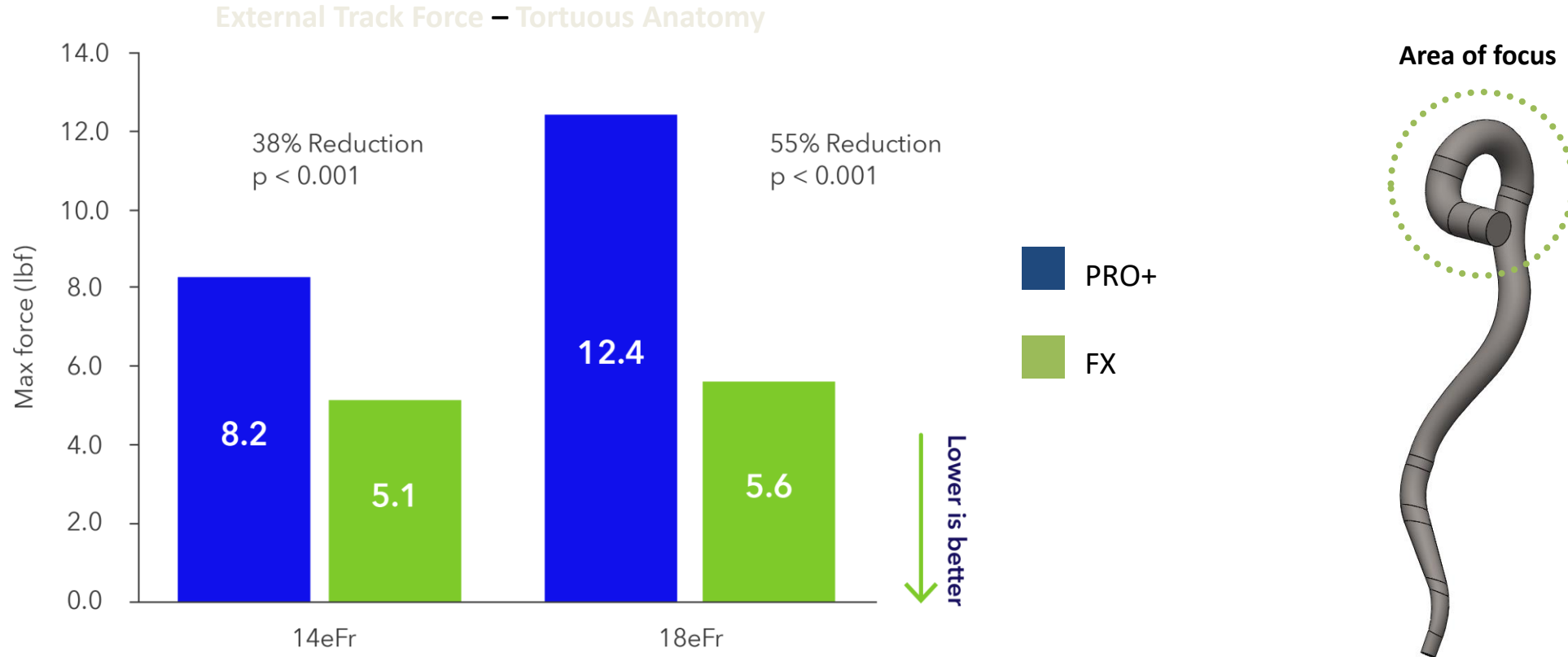


**single spine shaft** for greater shaft flexibility and improved deliverability

**optimized stability layer** for a more predictable deployment

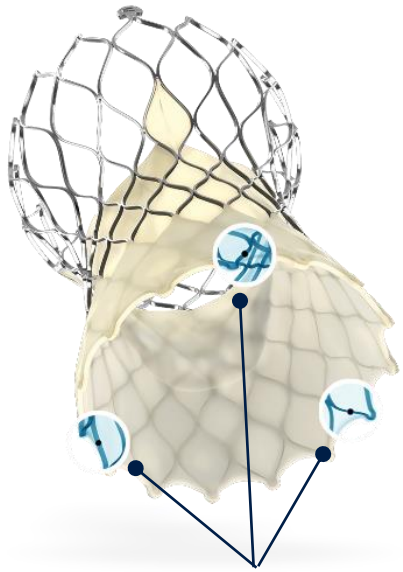
# Single-spine shaft for greater flexibility and improved deliverability<sup>1</sup>

Evolut™ FX has a lower tracking force in challenging anatomies compared to predicate.



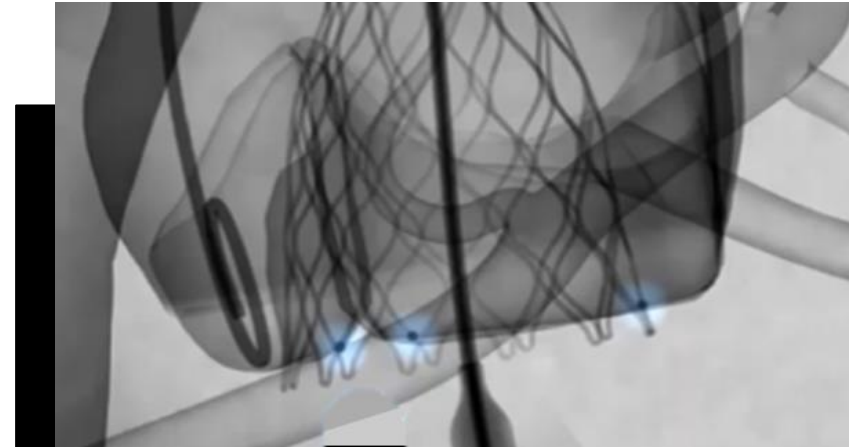
- <sup>1</sup> Performance as compared to Evolut™ PRO+ system in bench testing. Bench testing may not be indicative of clinical performance.
- FX 14eFR (n=15) vs PRO+ 14eFr (n=15) p<0.001. Delivery System Test Method for Tracking Force in 95th Percentile Tortuous Anatomy.
- Medtronic data on file. Evolut FX Marketing Claims Test Report D00512457 Rev B.

# Evolut FX System

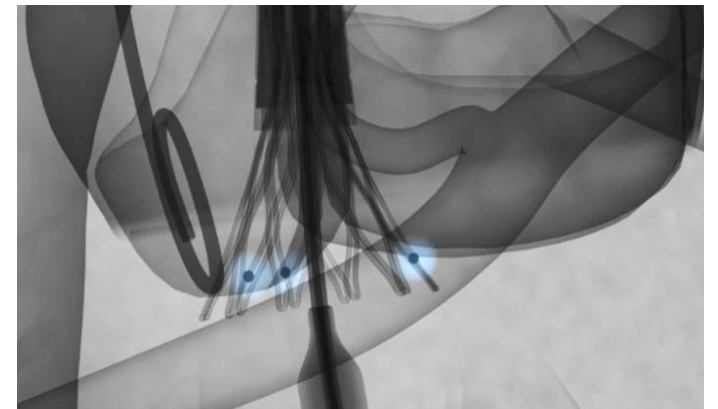


## enhanced visualization

with radiopaque locators to identify commissures and assist ideal depth of implant



**CLEAR DEPTH ASSESSMENT  
& COMMISSURE ALIGNMENT**



# SAPIEN X4: Provides Adjustable Valve Sizing

## SAPIEN 3 Ultra

4 valve sizes (3 mm increments)



20 mm



23 mm



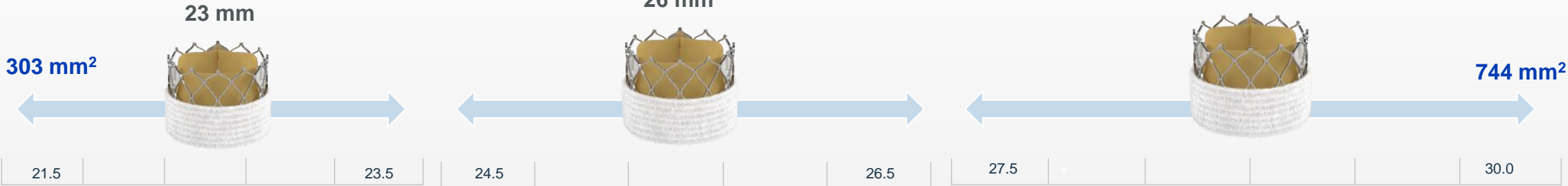
26 mm



29 mm

## SAPIEN X4

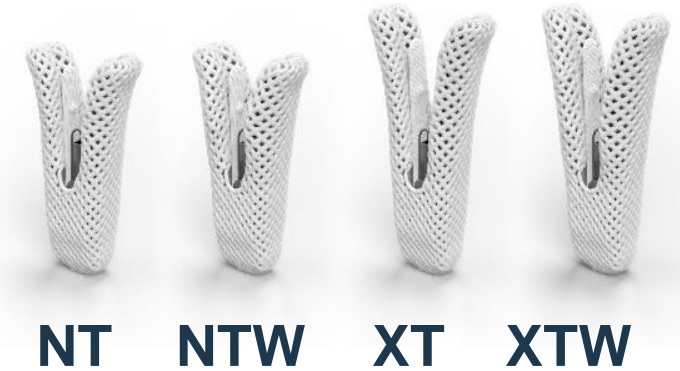
3 valve sizes, 16 unique deployment diameters (0.5 mm increments)





# Background and Objectives

- The **4<sup>th</sup> generation MitraClip™ G4 System** builds on the previous G3 system with two additional wider clip sizes: NTW and XTW, an independent grasping feature and improved clip deployment sequence
- The **EXPAND G4 study** was designed to confirm the safety and effectiveness of the 4<sup>th</sup> generation MitraClip G4 System in a contemporary, real-world setting
- This is the first complete analysis on core lab assessed 30-day outcomes from the entire study cohort of **1000+ subjects**

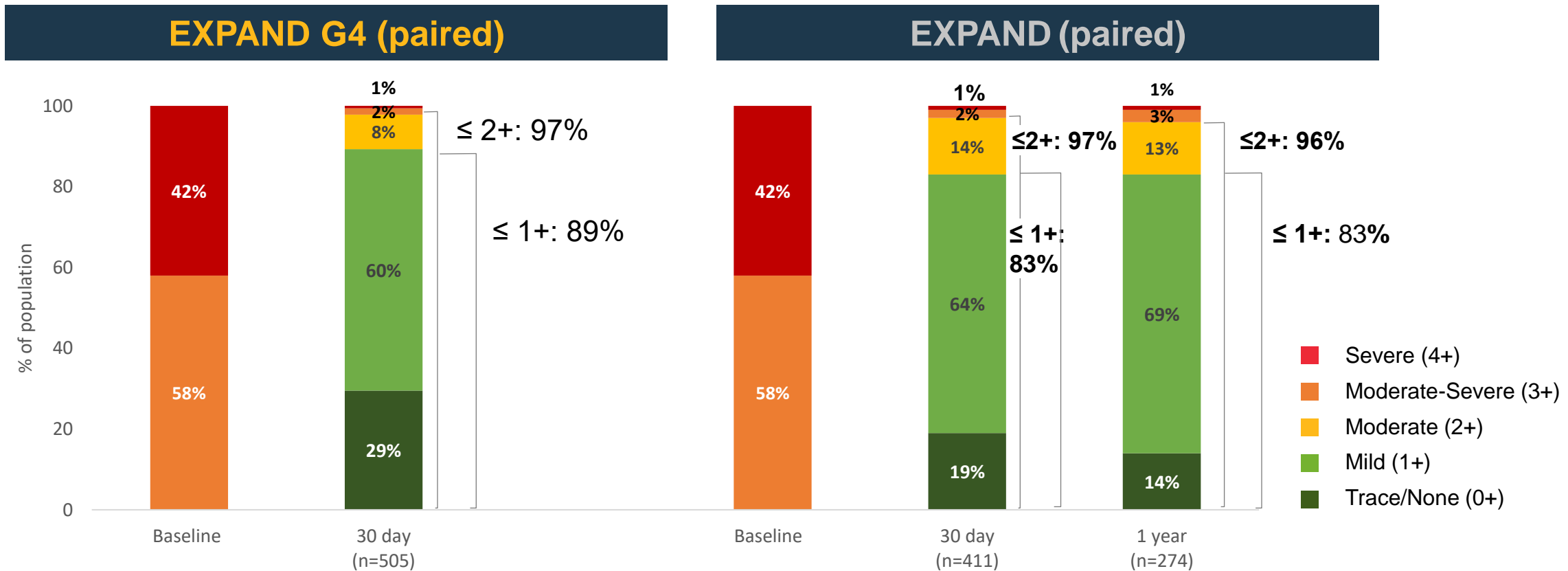


# Improved Procedural Outcomes

	EXPAND G4 (N=1164)	EXPAND <sup>1</sup> (N=1041)
<b>Implant Rate</b> % (n/N) [95% Confidence Interval]	<b>98.0% (1141/1164)</b> [97.1%, 98.7%]	98.9% (1030/1041) [98.1%, 99.5%]
<b>Acute Procedural Success (APS)*</b> % (n/N) [95% Confidence Interval]	<b>96.2% (1099/1143)</b> [94.9%, 97.2%]	95.8% (985/1028) [94.4%, 97.0%]
<b>Device Time<sup>†</sup> (min)</b> Median [Inter-Quartile Range]	<b>35.0 [21.0, 54.0]</b>	46.0 [30.0, 71.0]
<b>Procedure Time (min)</b> Median [Inter-Quartile Range]	<b>77.0 [56.0, 104.0]</b>	80.0 [54.0, 115.0]
<b>Clip Rate</b> Mean ± SD (N)	<b>1.4 ± 0.6 (1164)</b>	1.5 ± 0.1 (1041)

**EXPAND G4 demonstrates high procedural success rate with the shortest device and procedure times reported to date (24% reduction in device time compared to EXPAND)**

# Improved MR Reduction – compared to EXPAND

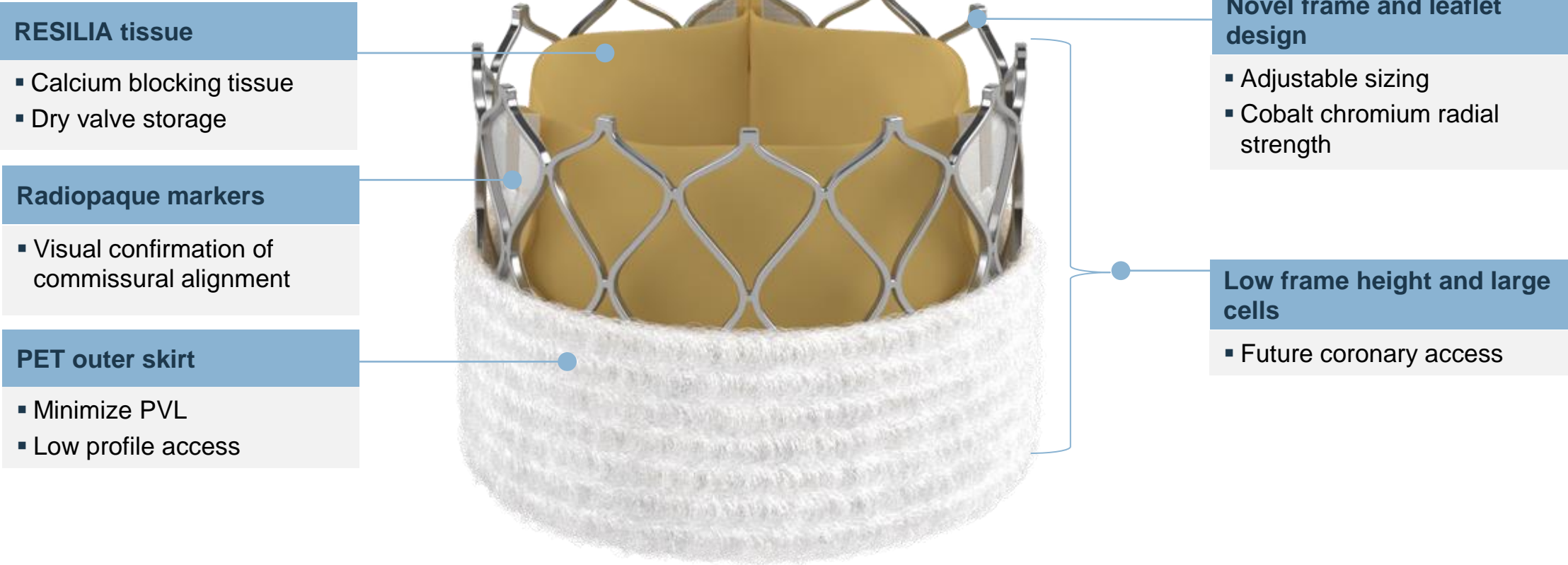


Compared to EXPAND (NTR/XTR), reduction to MR ≤ 1+ achieved in 89% vs. 83% (p=0.02)  
 None/Trace MR achieved in 29% vs 19% (<0.001)

# Durability



# SAPIEN X4 Transcatheter Heart Valve System

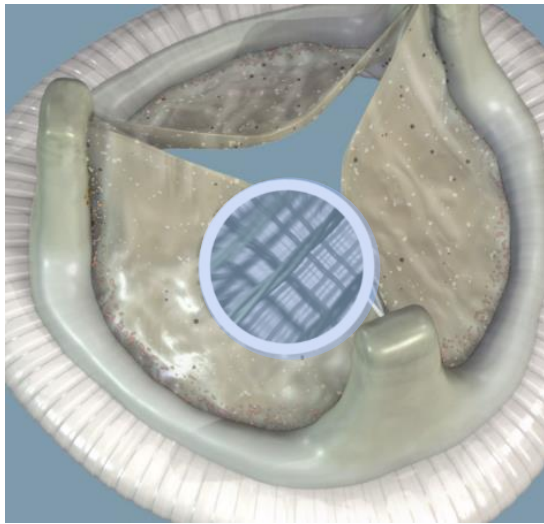


CAUTION: INVESTIGATIONAL DEVICES. Limited by Federal (US) law to investigational use only.

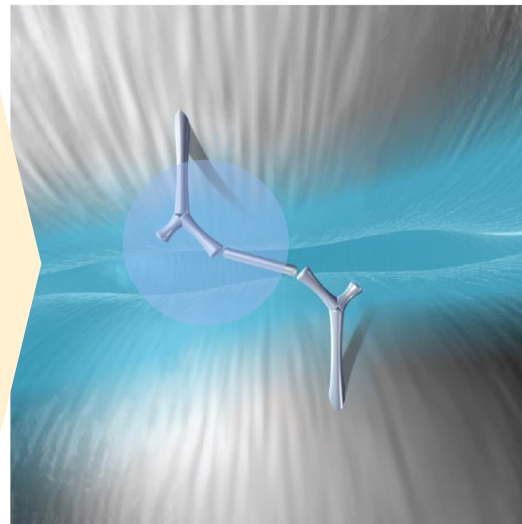
# Multiple factors influence tissue calcification, some of which are inherent to the current technology (e.g. free aldehydes)

Glutaraldehyde Fixation

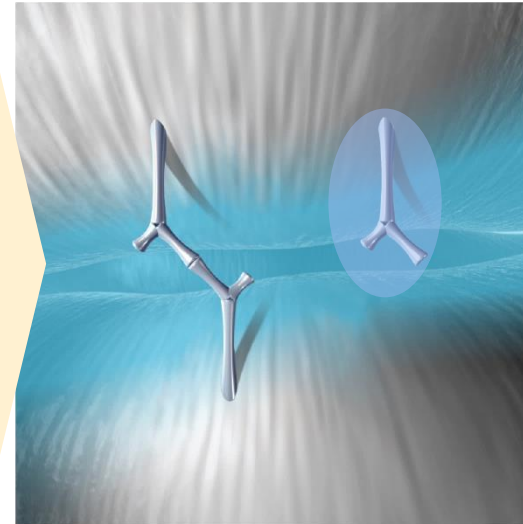
Glutaraldehyde Storage



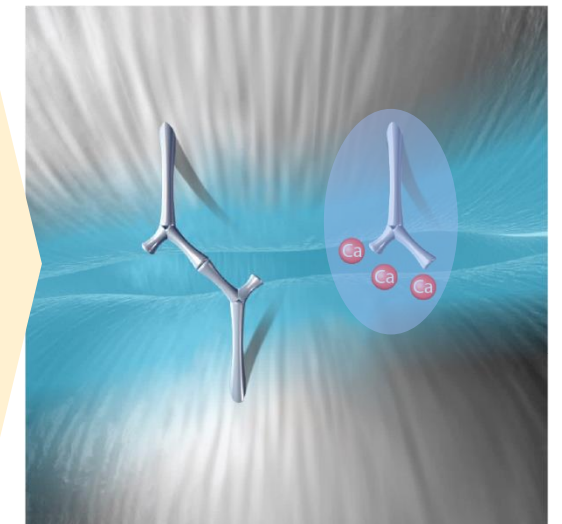
Collagen fibers consist of free amino acid sidechains



Glutaraldehyde fixation strengthens the tissue by creating crosslinks, within the collagen matrix



However, a side effect of glutaraldehyde fixation and storage is the introduction of free aldehydes



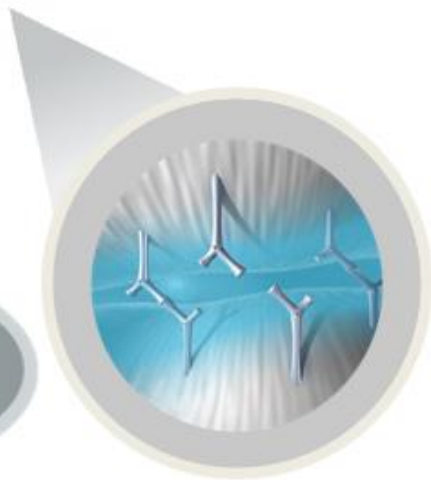
Calcium binds to free aldehydes in vivo

Tissue exposure to free aldehydes during glutaraldehyde fixation and storage is a major cause of calcification.

# RESILIA tissue is bovine pericardial tissue transformed by the addition of a novel integrity preservation technology

## Integrity Preservation Technology

Effectively eliminates free aldehydes while preserving and protecting the tissue



Free Aldehydes



Stable-Capping  
Permanently blocks free aldehydes



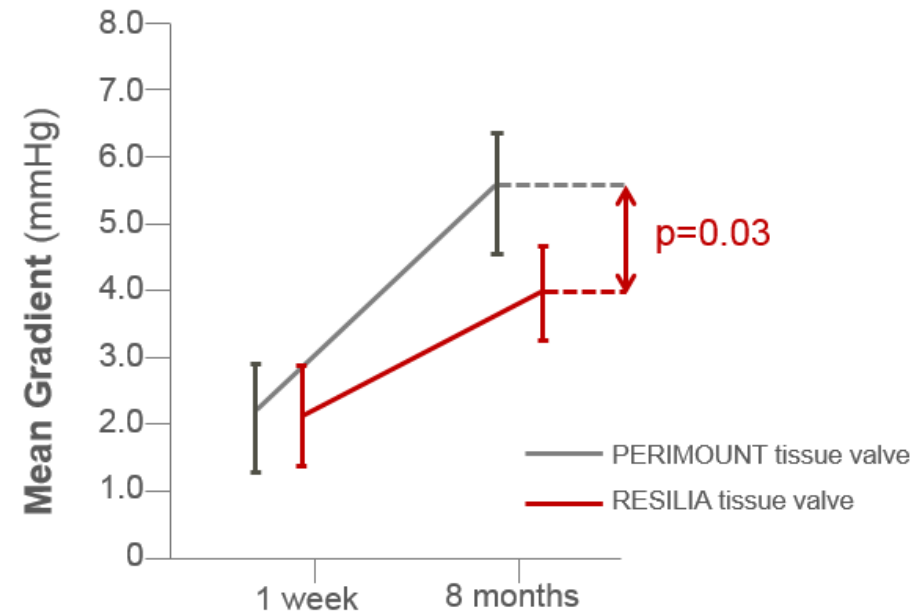
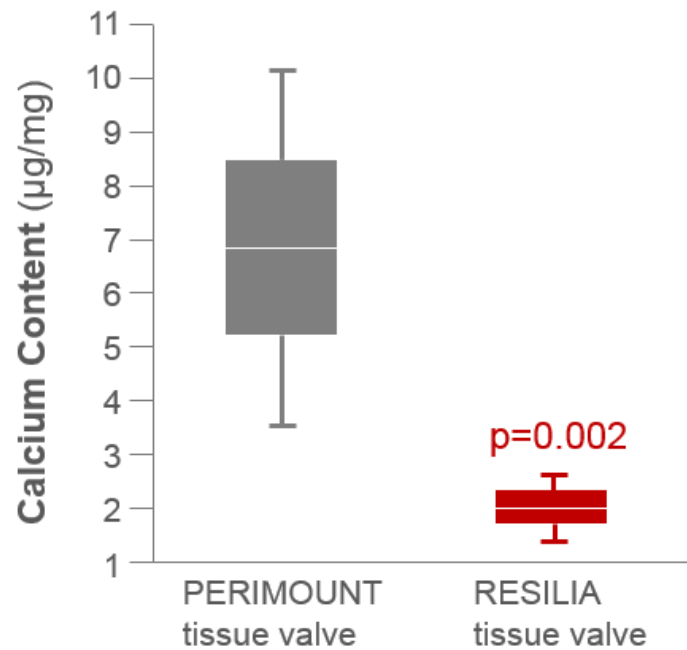
Glycerolization  
Glycerol displaces water in the tissue and preserves tissue integrity, which enables dry storage



Glycerolized Tissue



## Significant improvement in anti-calcification and sustained hemodynamic properties compared with the PERIMOUNT valve



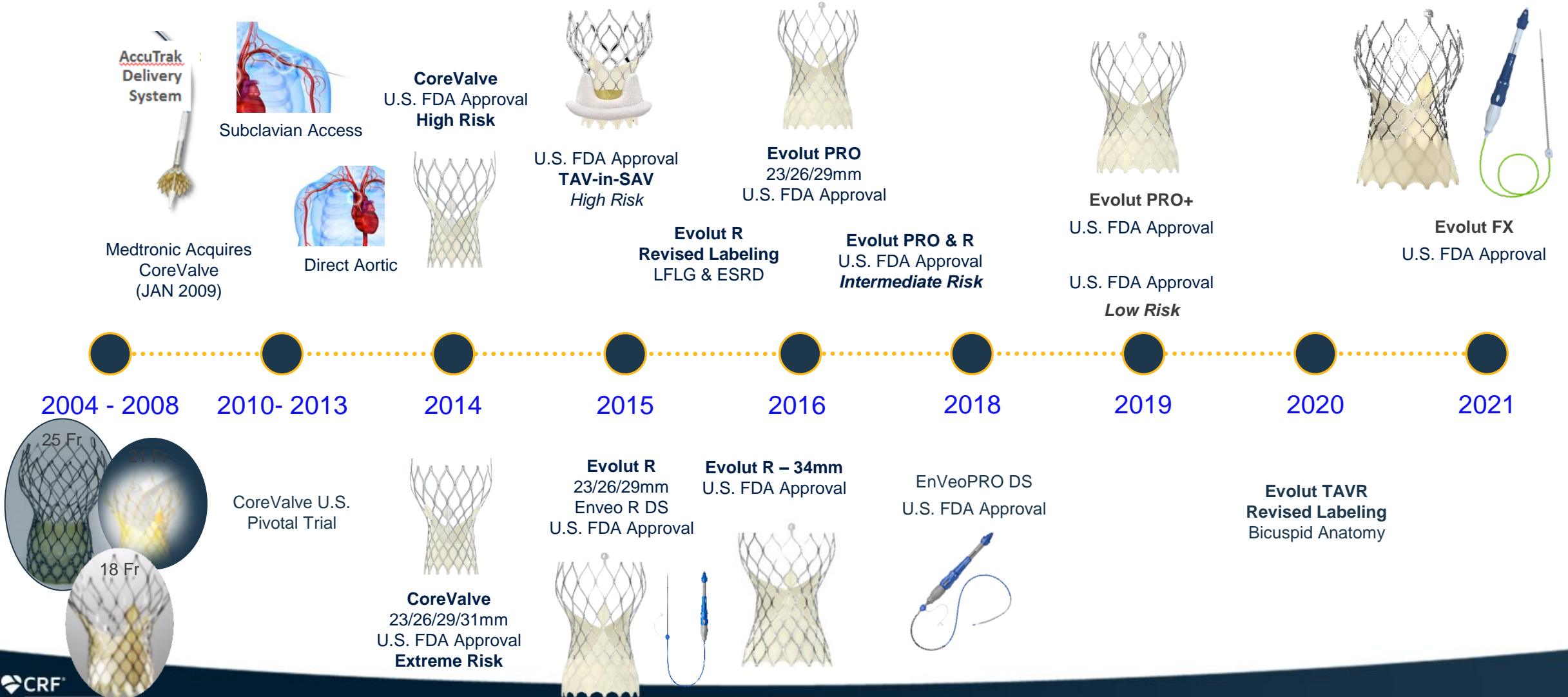
Calcium content was 72% lower, and mean gradient was significantly lower than in the control group\*



# Special: Perivalvular Leak



# SUPRA-ANNULAR SELF-EXPANDING TAVR



# SAPIEN Design Evolution



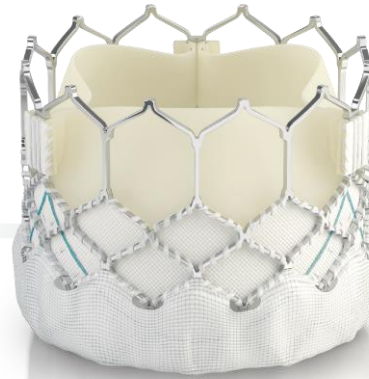
**SAPIEN valve**

- Stainless Steel
- Bovine pericardium
- 23-26mm valves
- 22/24F access



**SAPIEN XT valve**

- Cobalt chromium
- Bovine pericardium
- 20-29mm valves
- 16-20F access



**SAPIEN 3 valve**

- Low profile valve design
- PET outer skirt
- 20-29mm valves
- 14-16F access



**SAPIEN 3 Ultra valve**

- Enhanced PVL solution
- 20-26mm valves
- 14F access

2007

2020

# Special: Coronary Obstruction/Access

- X4
- EvolutR Pro+



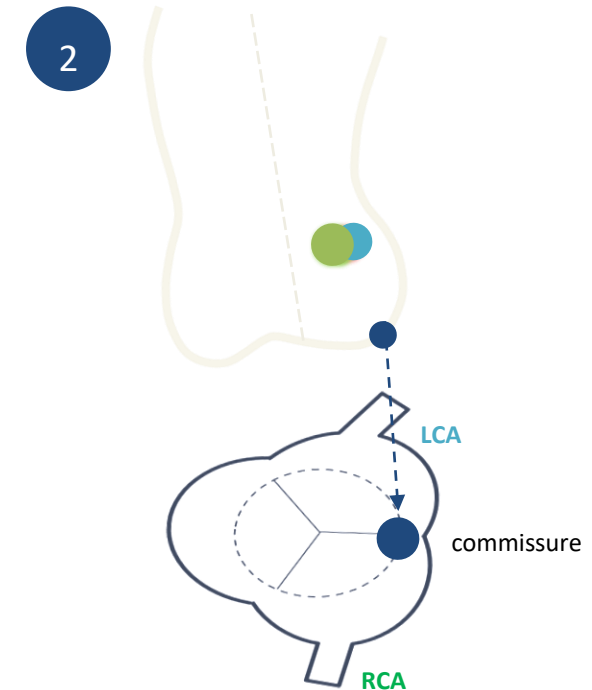
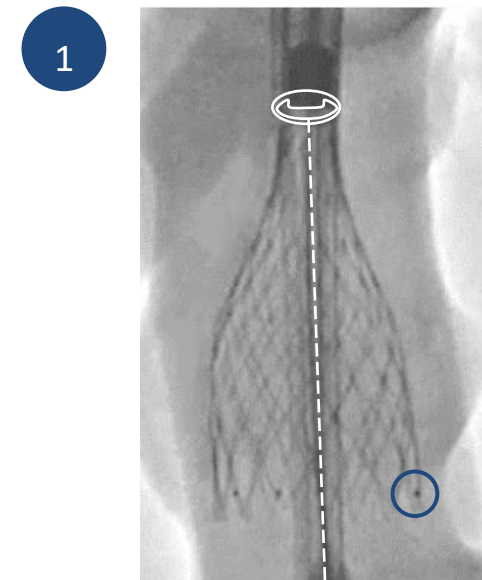
# Commissure alignment

## Procedural vision expanded

Using the valve features of the Evolut™ FX system, and with improved procedural technique, early experience shows a 95% success rate in achieving commissure alignment.<sup>1</sup>

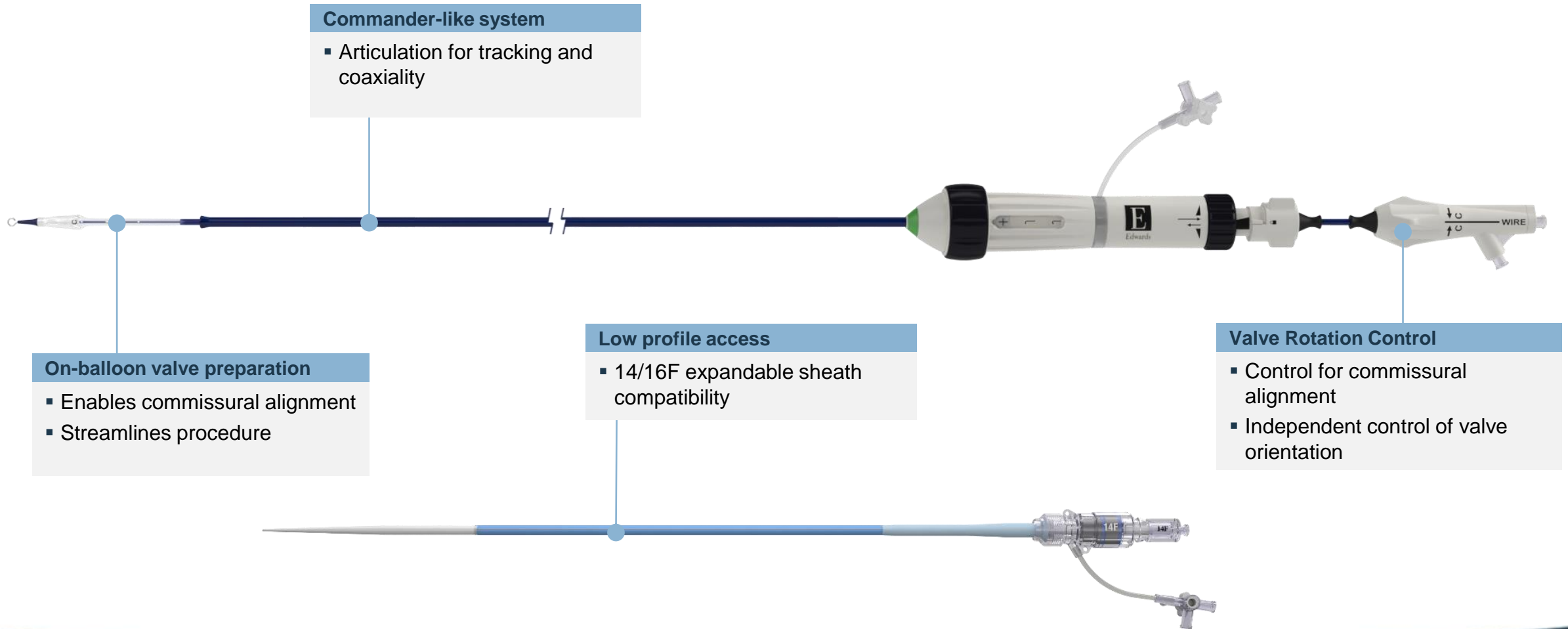
## TAV marker alignment in cusp overlap view

- 1 Radiopaque markers are a visual reference for TAV commissure location and alignment during deployment.
- 2 Existing implant views (cusp overlap) provide standard anatomical reference point to identify native commissure.



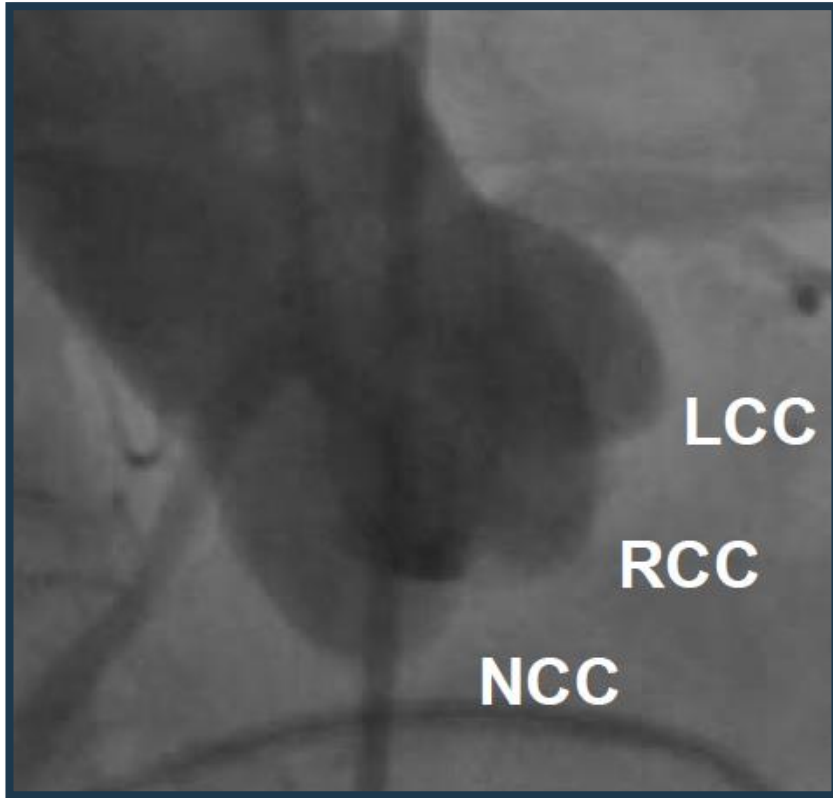
<sup>1</sup>Tang GHL. First-in-Human Multicentre Experience of TAVI with the Supra-annular Self-Expanding Evolut FX System. Presented at PCR London Valves 2022; November 28, 2022; London, England.

# SAPIEN X4 Delivery System

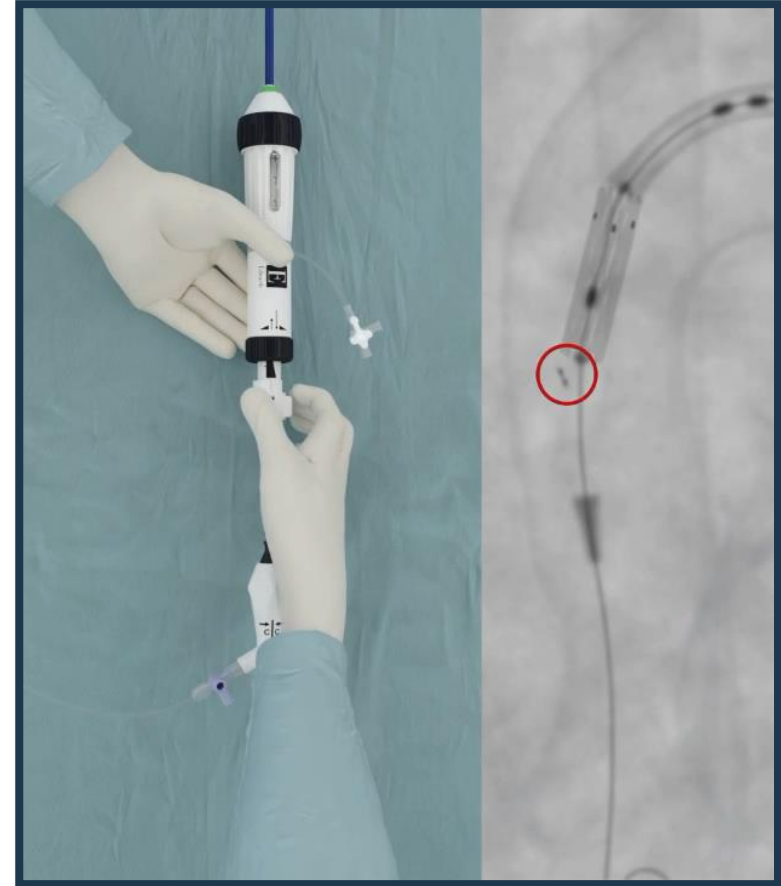


# Commissural Alignment with SAPIEN X4

**1. Standard 3 cusp view**



**2. Align radiopaque marker prior to deployment**



# Unaddressed “Complications”:

- Lifelong management of AS (TAVR Forever?)
- TMVR without LVOT obstruction concerns
- TTVR without pacemaker and RV dysfunction concerns

