Lotus valve system: come è fatta? I materiali. Le caratteristiche principali, i punti critici.

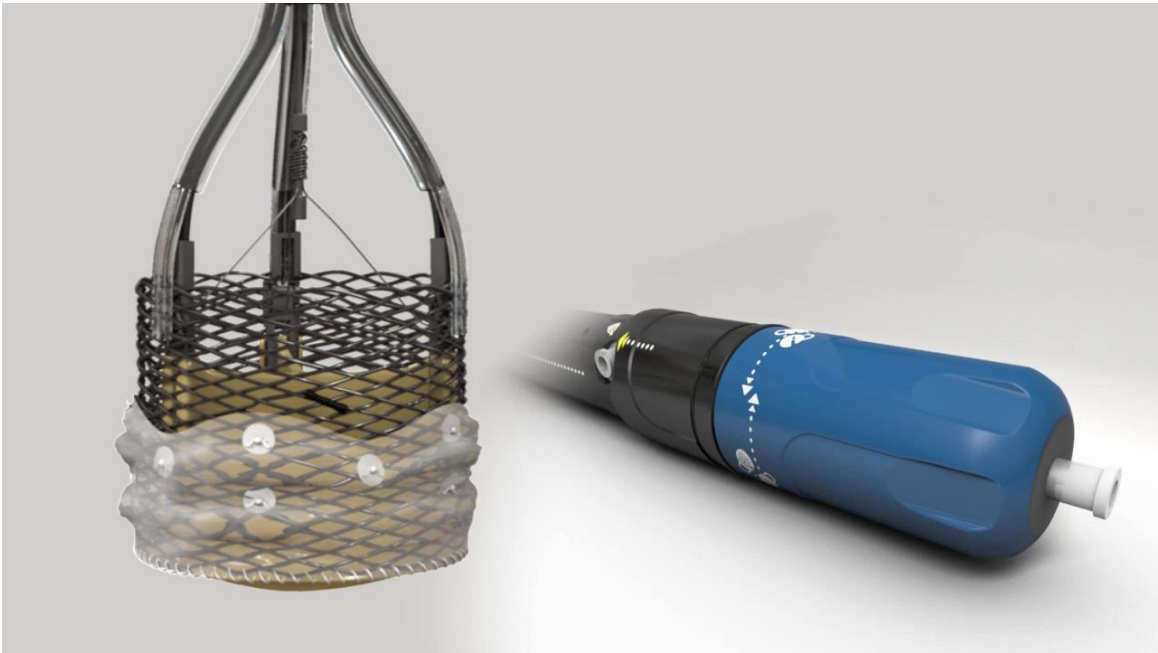
Dr.ssa Nedy Brambilla,
Istituto Clinico Sant'Ambrogio
Gruppo Ospedaliero San Donato,
Milano

Boston Scientific Structural Heart
Los Gatos, California

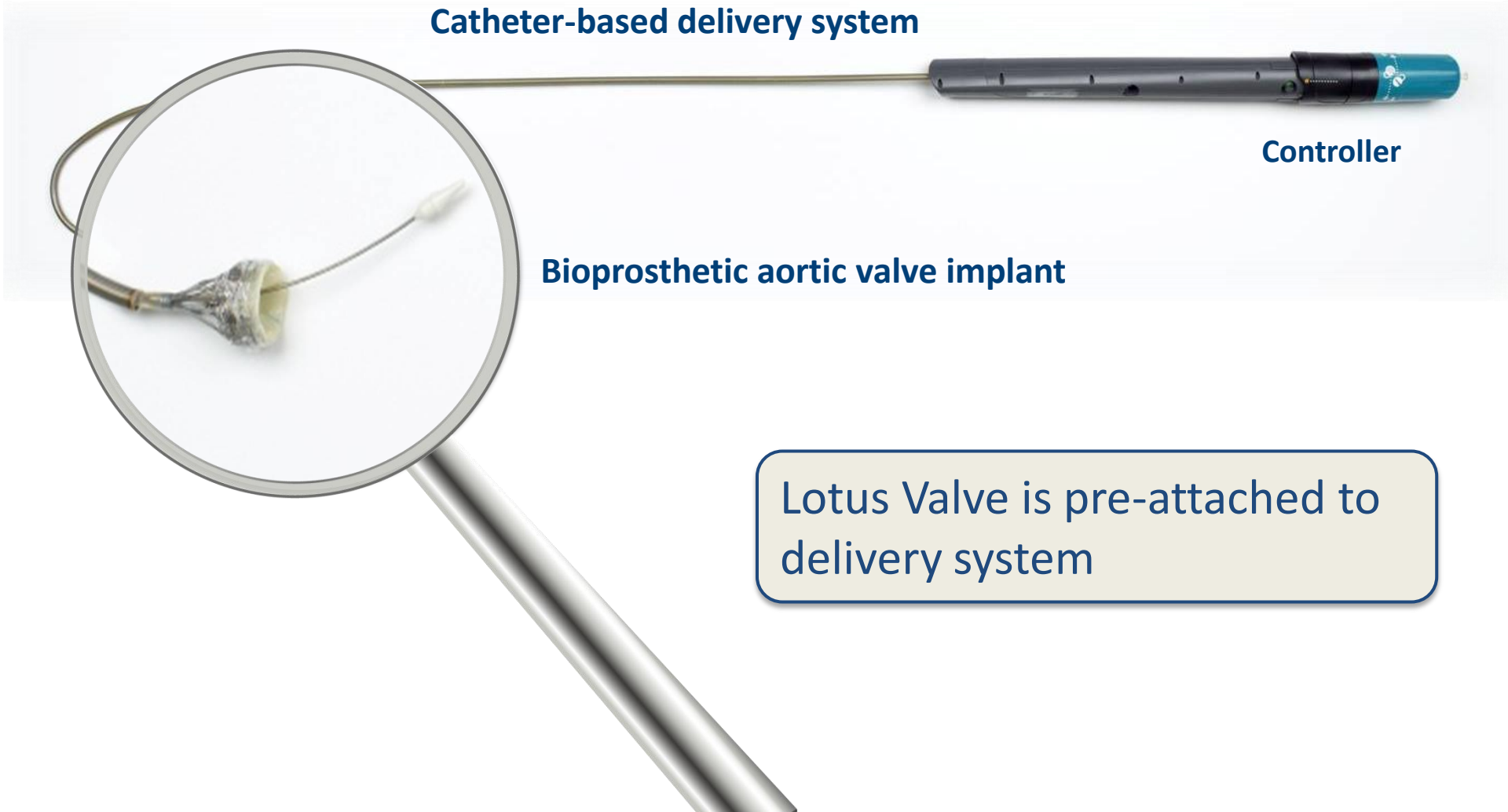
Lotus Valve Background

- Sadra Medical founded in 2004 in Los Gatos, CA
- First Human implant in 2007 (Germany)
- BSC acquisition completed in Jan 2011 ~$450m
- Approx. 300 Employees involved in R&D, Mfg and Clinical trials
- REPRISE Clinical Trials have implanted ~260 systems in EU & AUS
  - 12 month REPRISE II data
  - 30 days REPRISE 250 data
- CE Mk approval since Nov 2013
  - 25mm Launched in June 2014
  - Respond study and Reprise III study are currently enrolling

Device Description



Lotus Valve System Overview

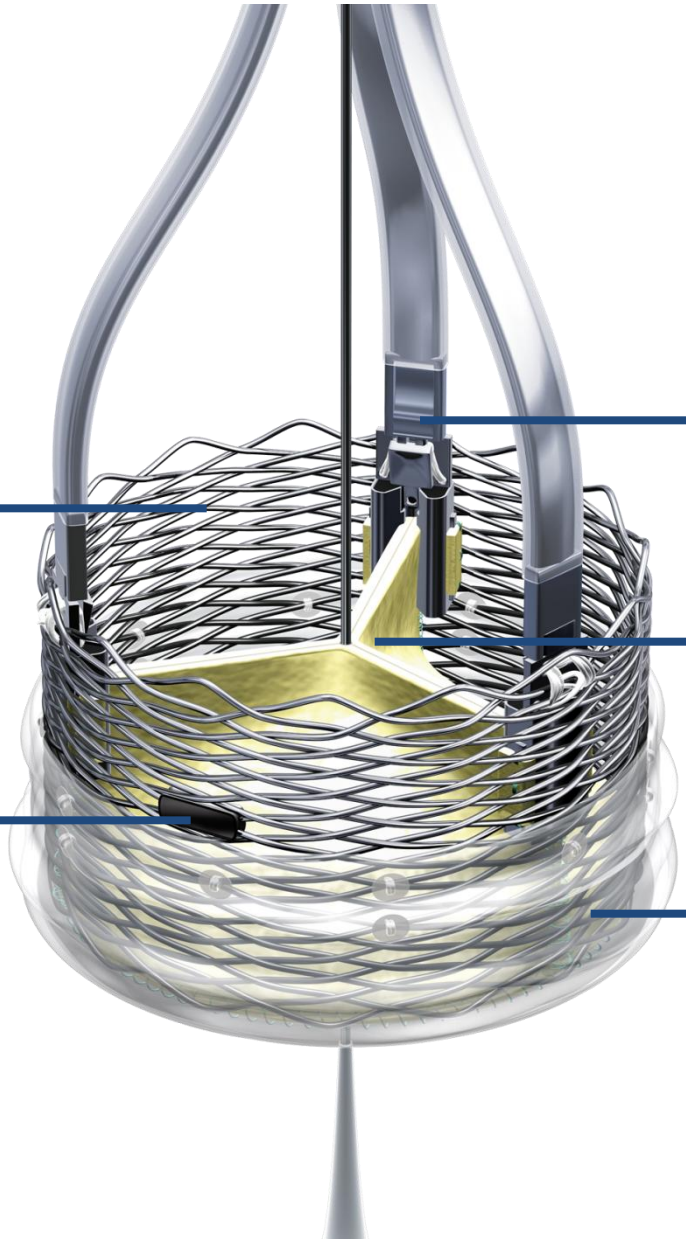


Lotus Valve is pre-attached to delivery system

Lotus Valve System Overview

Braided Nitinol Frame
Designed for strength, flexibility, and ability to retrieve, reposition, and redeploy

Central Radiopaque Positioning Marker
Aids precise positioning



Locking Mechanism
Enables operator control of implant

Bovine Pericardium
Proven long-term material

Adaptive Seal
(Polyurethane)
Minimizes paravalvular leak by conforming to irregular anatomical surfaces

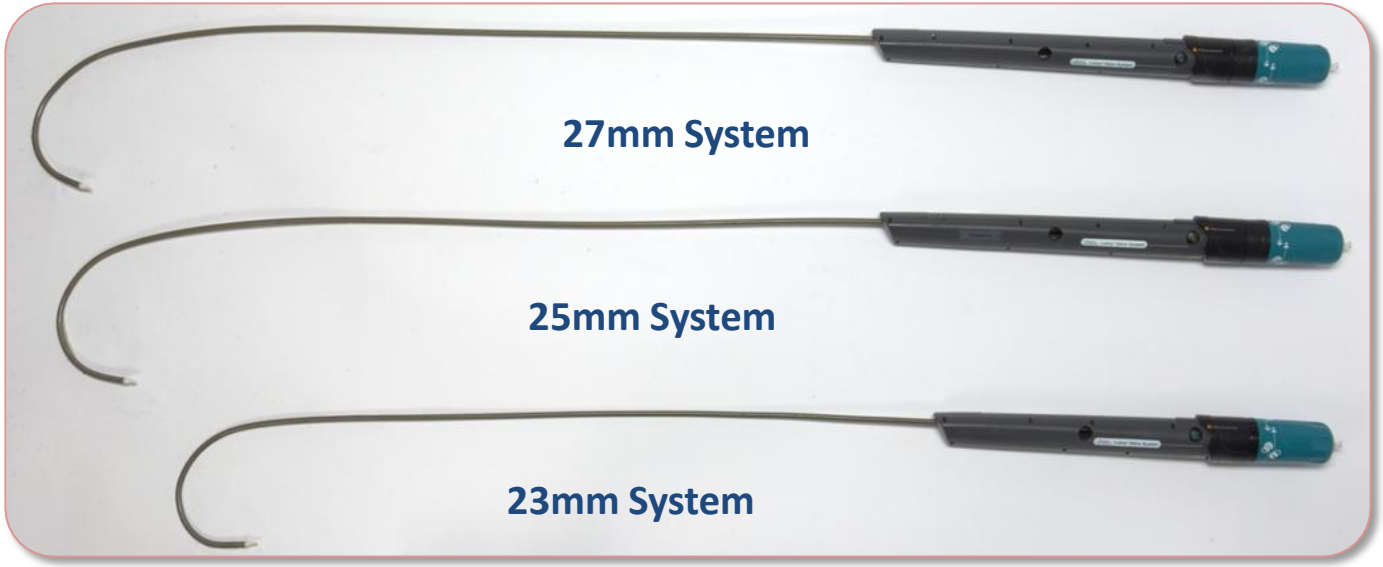
The Lotus Valve is available in three sizes

	23 mm Lotus Valve	25 mm Lotus Valve	27 mm Lotus Valve
Native Annulus Diameter*	≥20 mm and ≤23 mm	≥23 mm and ≤25 mm	≥25 mm and ≤27 mm
Deployed Lotus Valve OD	23 mm	25 mm	27 mm
Deployed Valve Height	19 mm	19 mm	19 mm

*As measured by baseline diagnostic imaging

The Lotus Valve System Dimensions

System	Minimum Catheter Length	Total Delivery System Length	Safari	GW Length	Lotus Sheath Size
23mm	103cm	148cm	0.035” (0.89mm)	260cm	LIS-S
25mm	113cm	166cm	0.035” (0.89mm)	300cm	LIS-L
27mm	113cm	166cm	0.035” (0.89mm)	300cm	LIS-L



Lotus™ Introducer Set

Lotus Introducer Sheath – Small for 23 mm

- ID 18F
- Access vessels **6.0 mm** or larger
- Sheath length 30.5 cm
- Review IFU prior to use

Lotus Introducer Sheath – Large for 25 and 27 mm

- ID 20F
- Access vessels **6.5 mm** or larger
- Sheath length 30.5 cm
- Review IFU prior to use

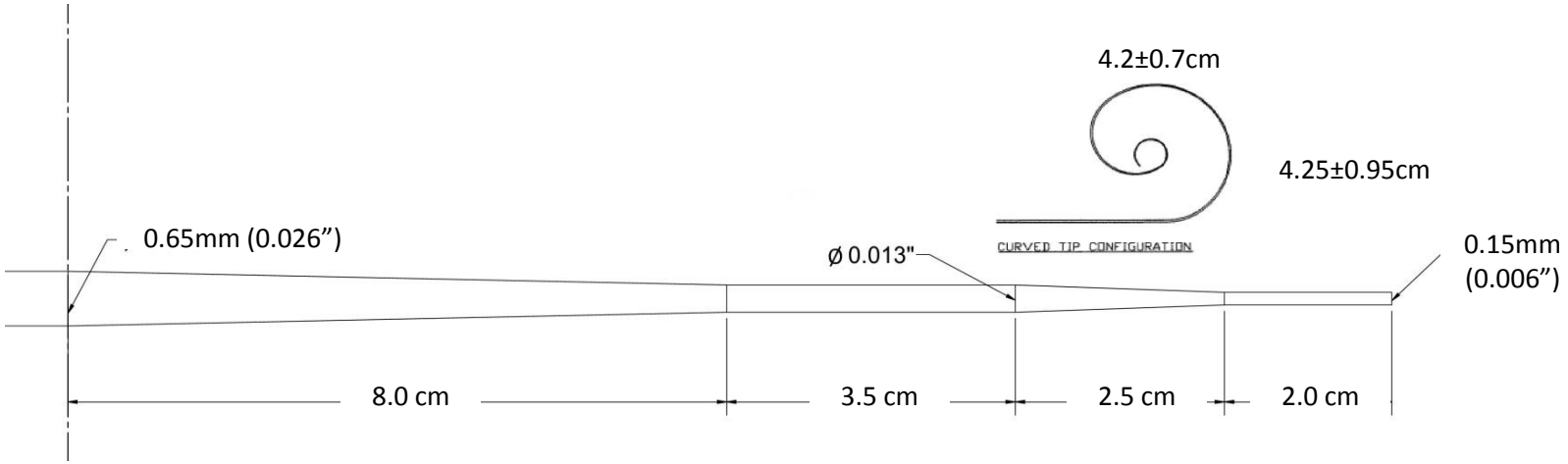
Safari™ Guidewire
Key Product Highlights

The Safari Guidewire is the first pre-shaped TAVI dedicated wire.

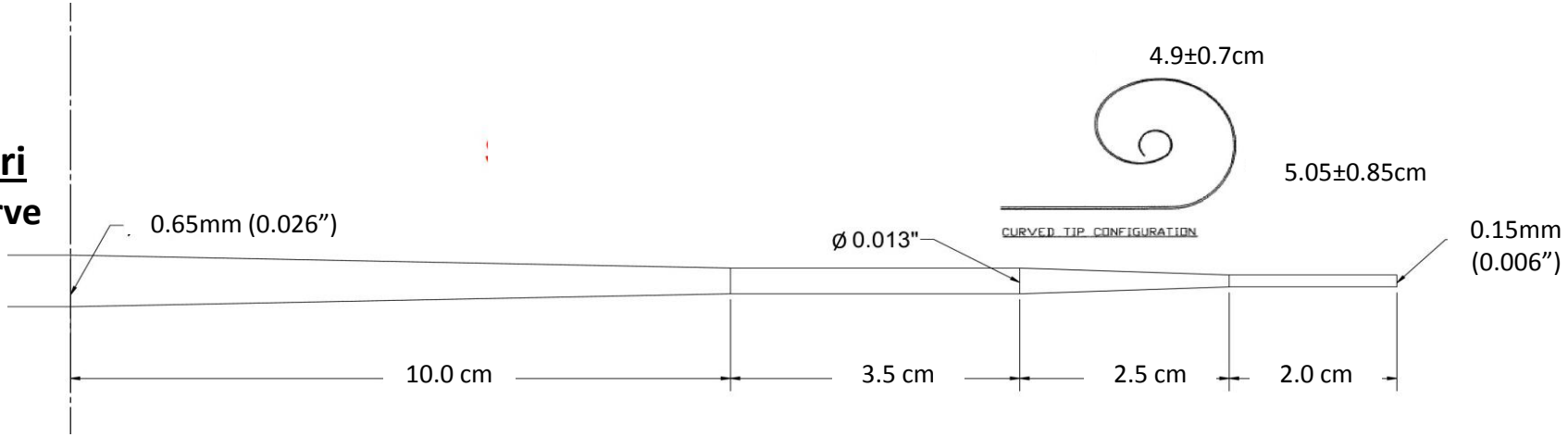
- Safari's pre-shaped architecture saves time and is designed to provide consistent, reliable performance
- Double curve is designed to facilitate stable, atraumatic placement during transcatheter aortic valve procedures
- Up to 50 % less force needed for device delivery due to the LUBRIGREEN™ PTFE coating*
- Two curve sizes accommodate varying anatomies and systolic contractions of the left ventricle
- Safari demonstrates shape retention through the procedure

*Force testing data with Amplatz 260cm Super Stiff & Safari 260cm guidewires, n=2 with 10 repetitions each. Data on file.

Safari Guidewire



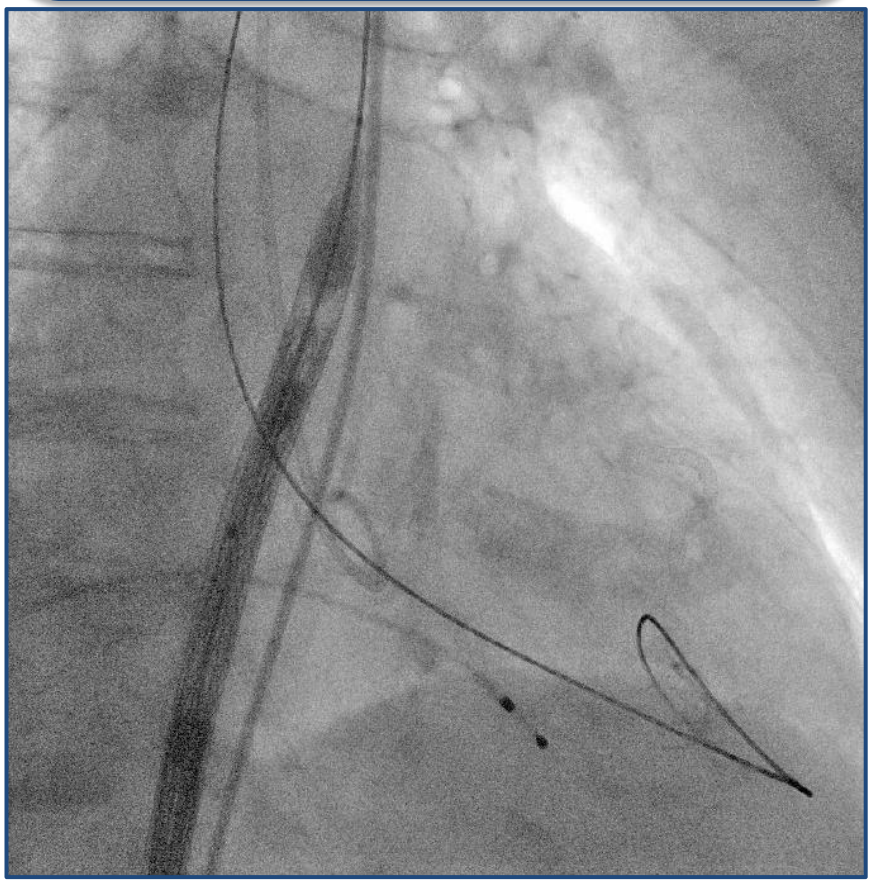
Safari
Small Curve



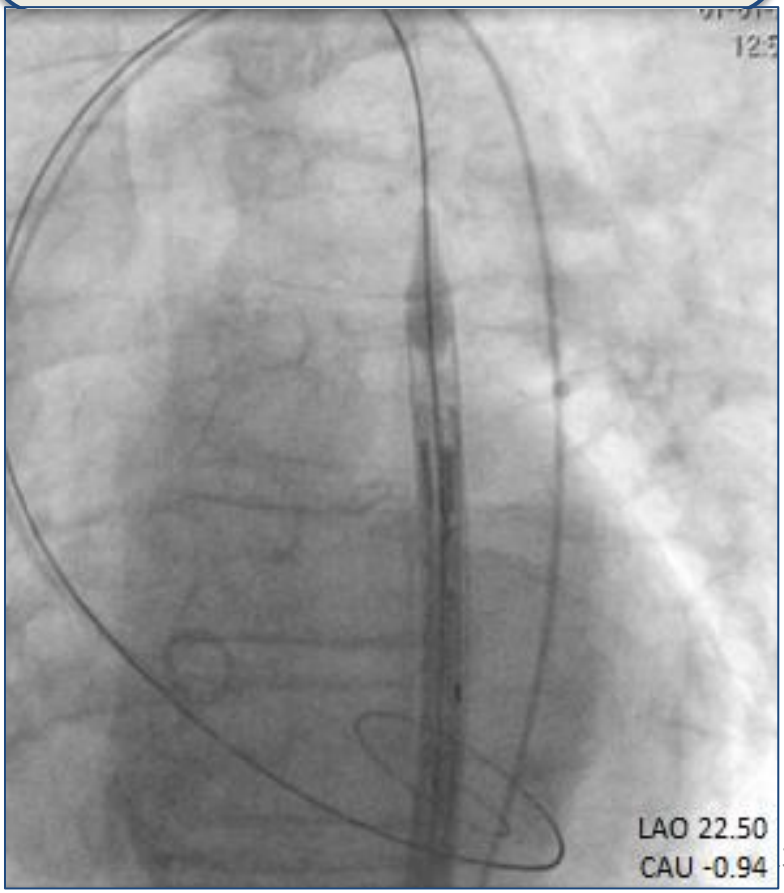
Safari
Large Curve

Device Tracking

- Understand the anatomical considerations to ensure **minimal** wire buckling during tracking in AP View.
- Ensure the **radiopaque marker** is to the right side while traversing the descending aorta



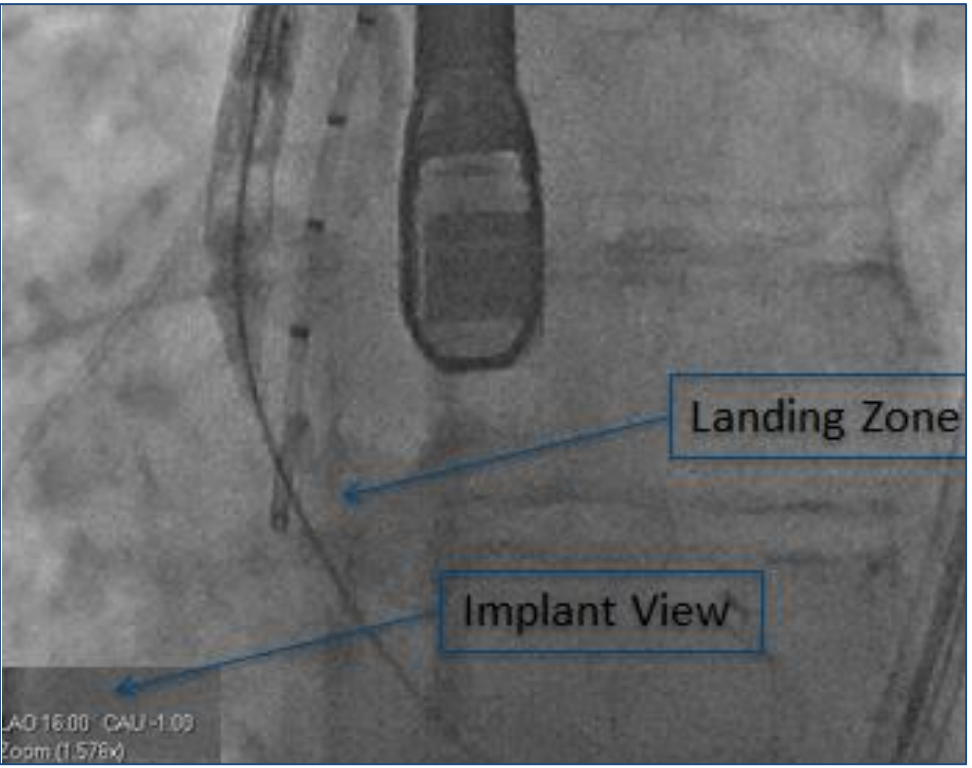
- View in LAO to see perpendicular to the arch, the radiopaque marker is orientated towards the outer curvature
- Do **NOT** apply torque to the catheter during crossing

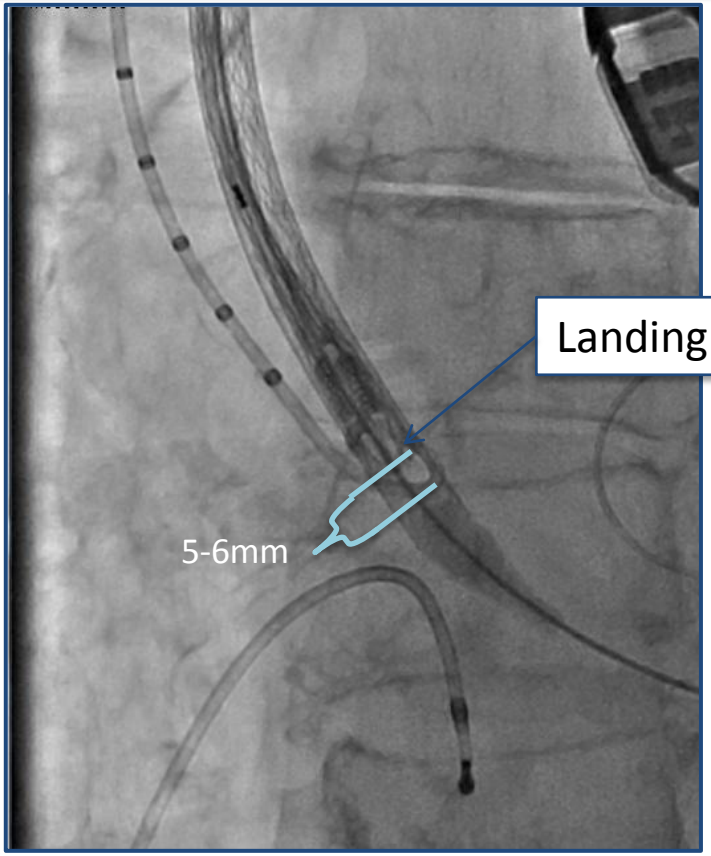


Begin Deployment

Pause to reconsider the anatomical landmarks *before* crossing the native valve. Identify the "landing zone".

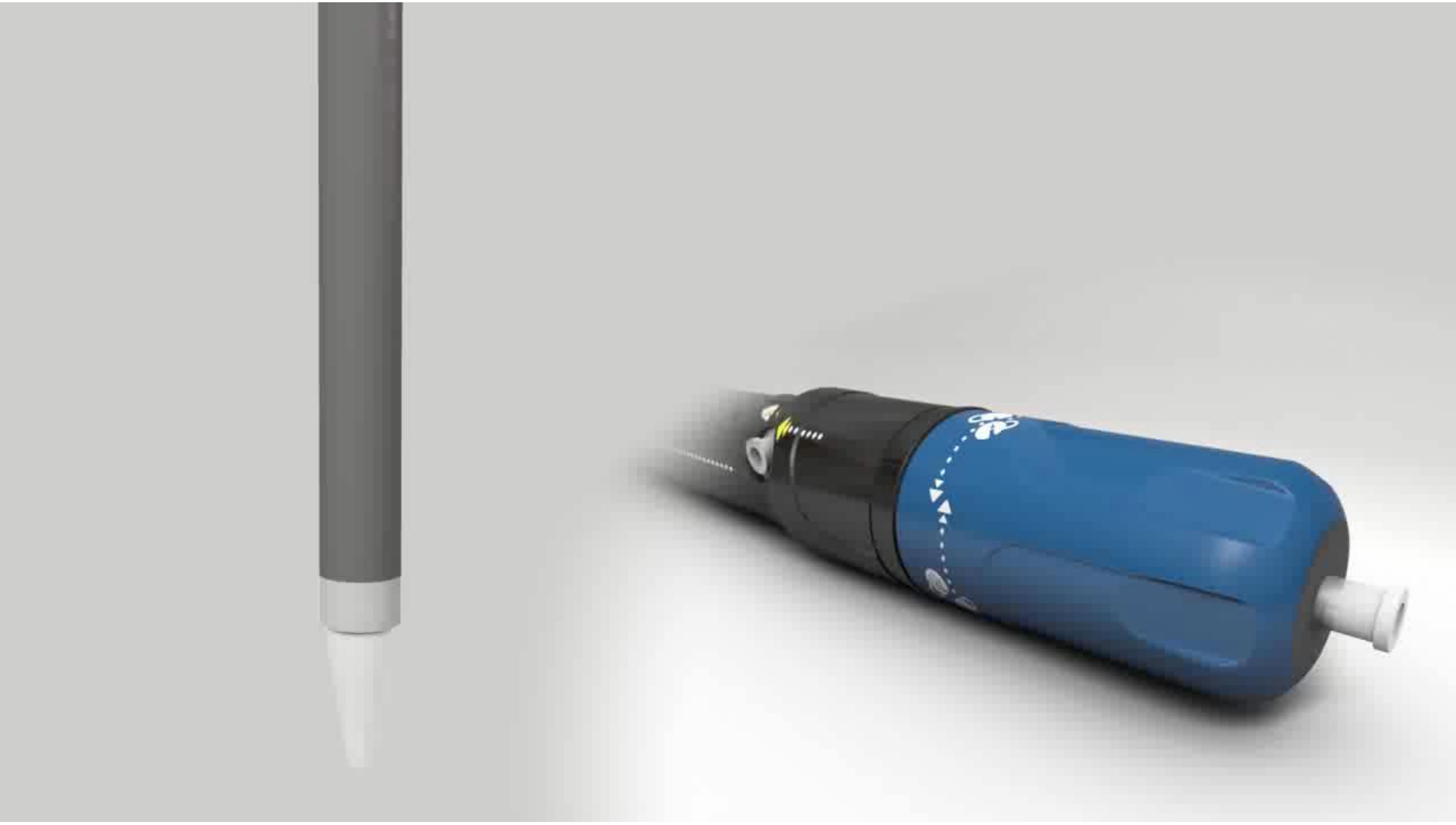
- While unsheathing, maintain the catheter tip below the level of the annulus by applying **forward pressure**
- Target the landing zone with the radiopaque marker about 5-6mm above the annulus (center of pigtail)





Lotus Valve Locking Mechanism

Unsheathing and resheathing the valve



Lotus Control Knob Function

Unsheathing/locking with counter-clockwise rotation

Unlocking/resheathing with clockwise rotation

Lotus Valve Configuration

1 **Elongated Configuration (for Delivery)**

Unsheathing/locking with counter-clockwise rotation

2 **Intermediate Configuration**

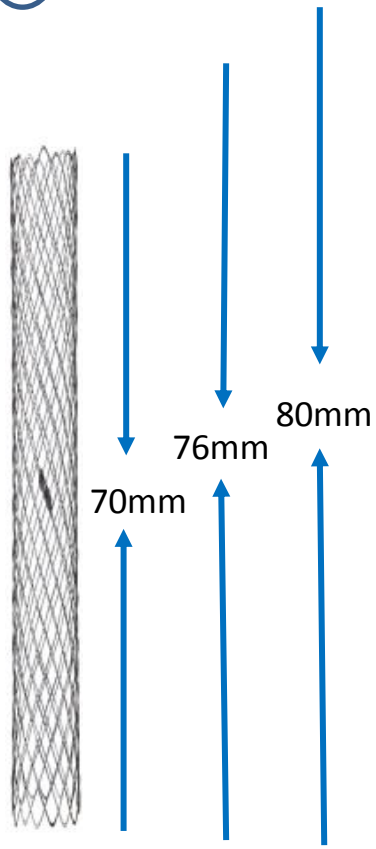
3 **Final Locked Configuration**

19mm

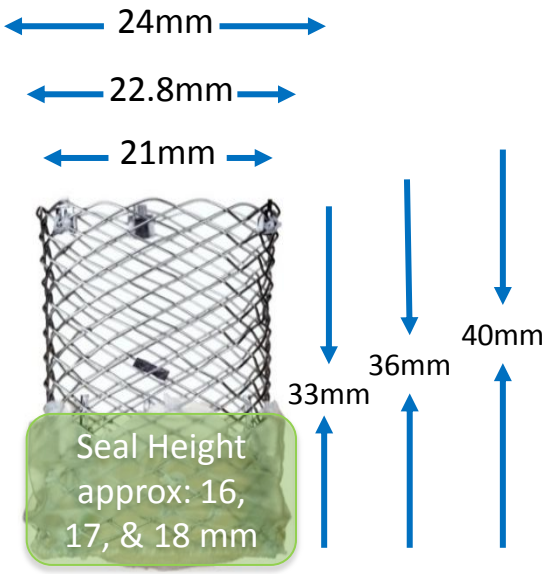
Unlocking/resheathing with clockwise rotation

The Lotus Valve Configuration-three sizes

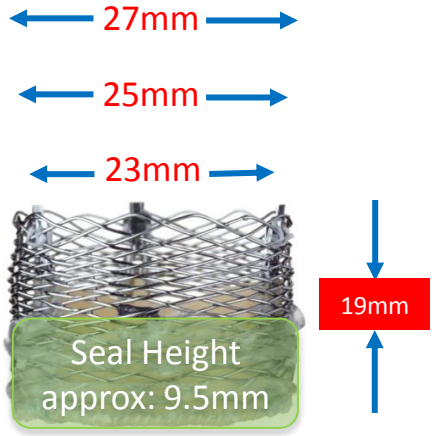
1 **Elongated Configuration (for Delivery)**



2 **Intermediate Configuration**

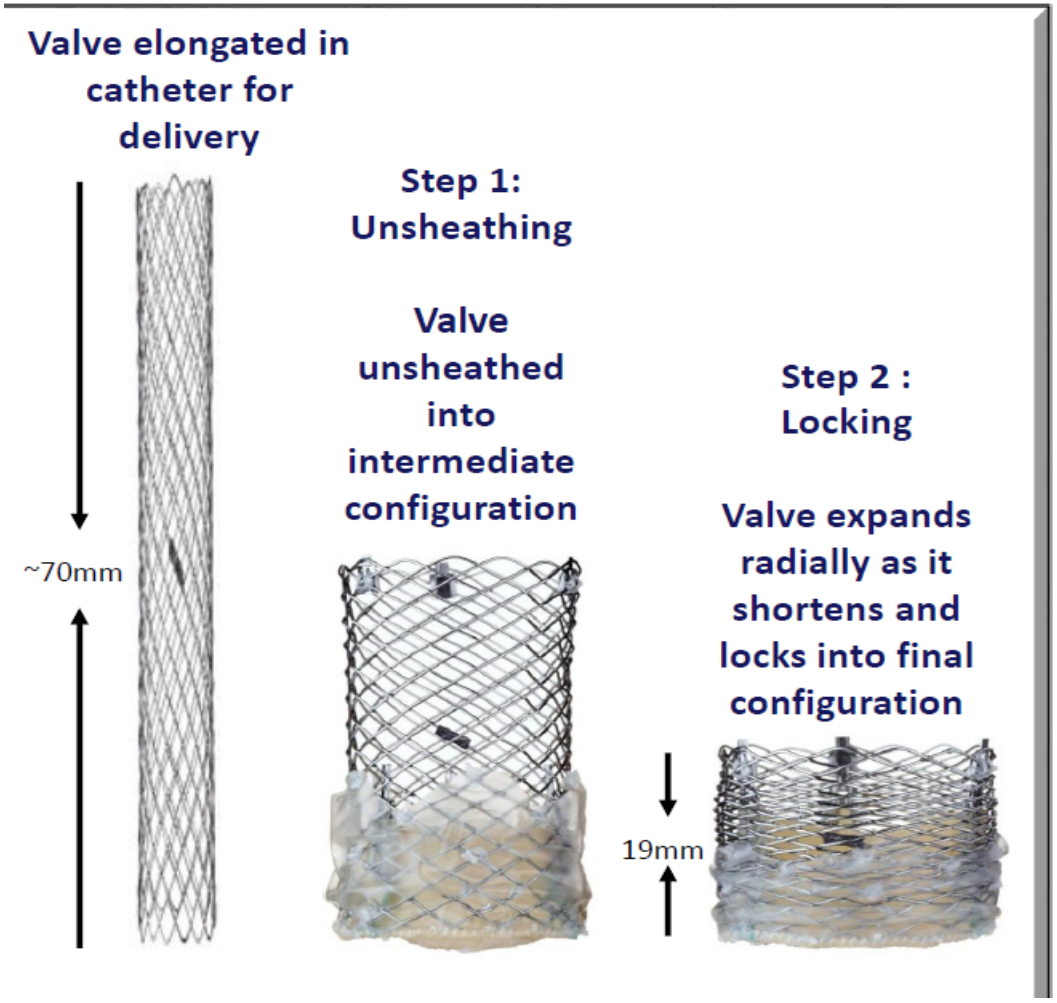


3 **Final Locked Configuration**



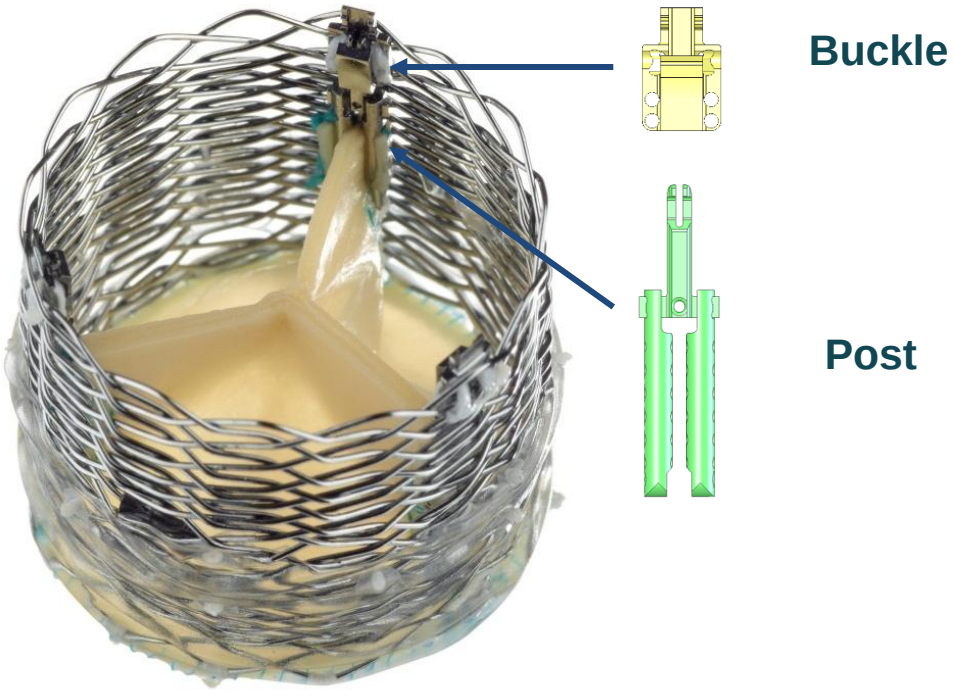
Lotus Valve System Design Goals

Controlled Mechanical Expansion



- Valve deployed via controlled mechanical expansion.
  - ➢ It is neither balloon expandable nor self expanding.
- No rapid pacing during deployment
- Valve functions early enabling controlled deployment
- No valve movement on release

Lotus™ Valve Locking Mechanism



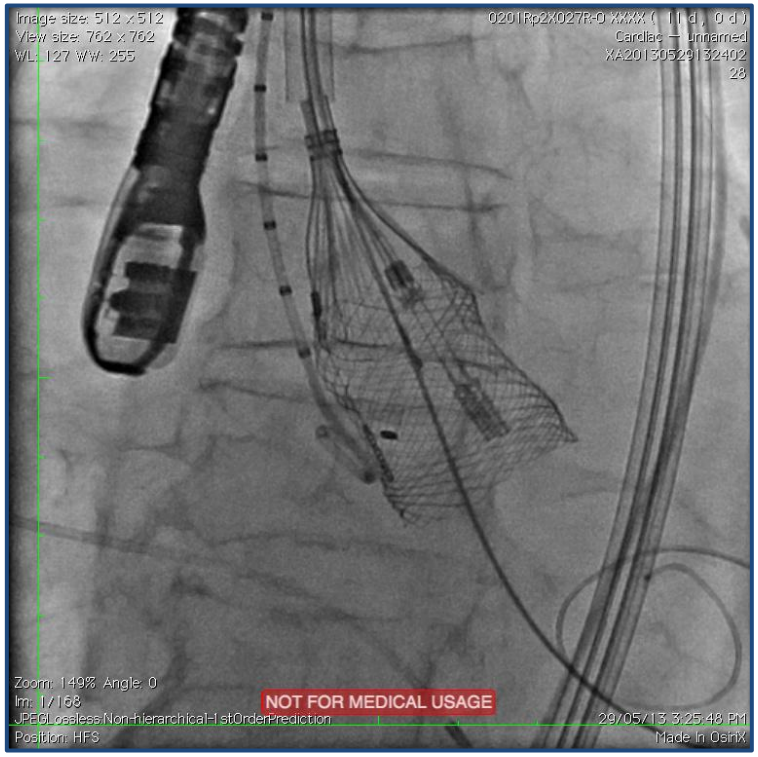
Locking and Unlocking

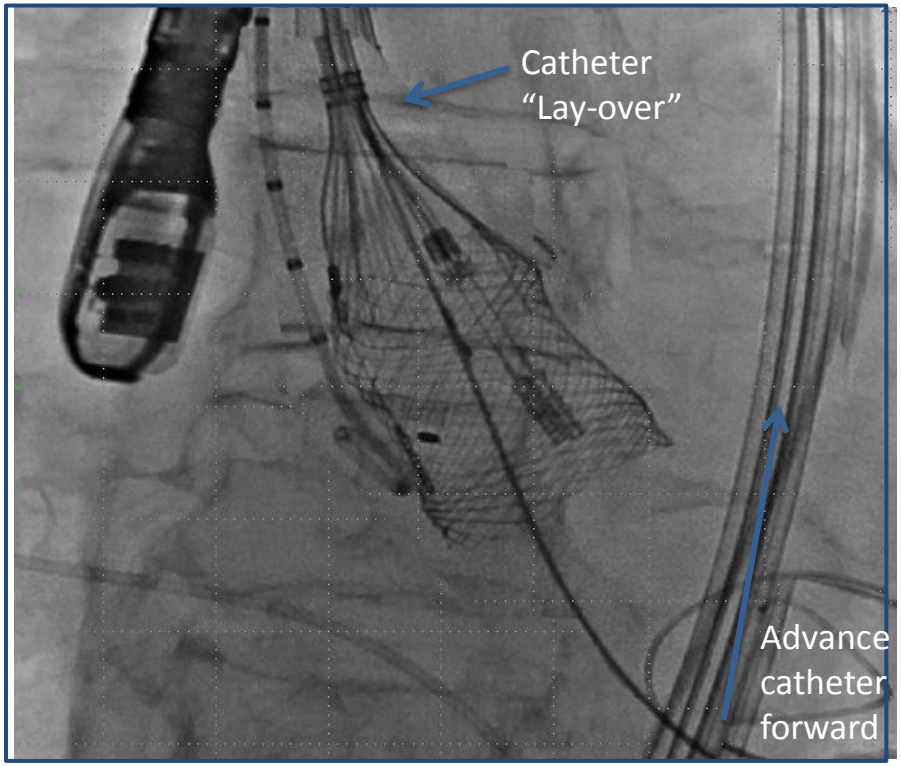
Buckle

Post

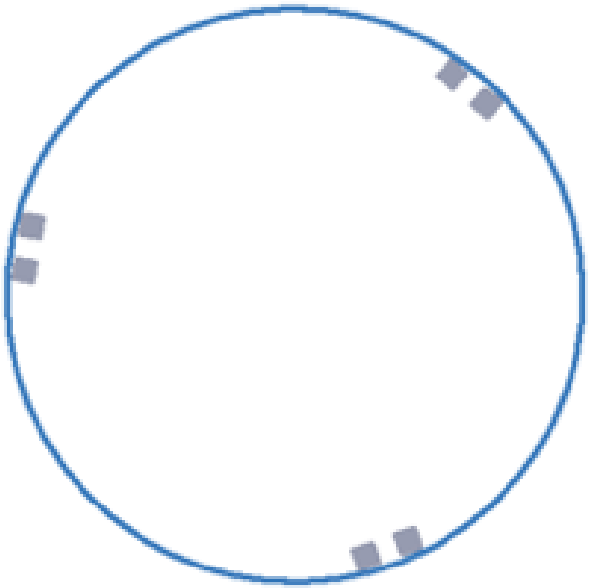
Lay-over

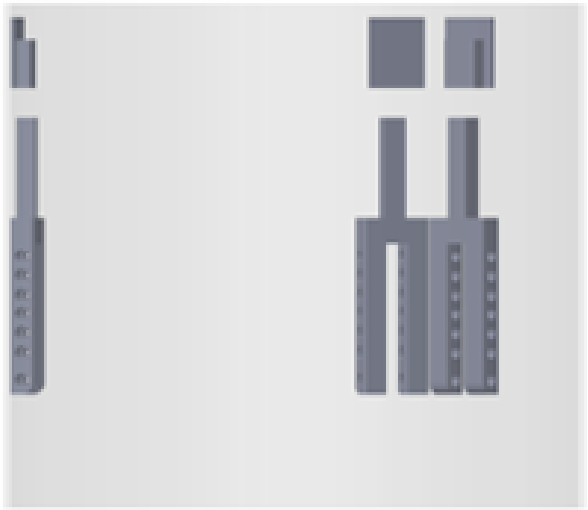
As the waist forms and marker position is stable, **“lay-over”** the catheter by applying forward pressure to coaxially align valve with the flow plane. Maintain to lay-over during to lead in and to aid with locking.





Ideal View for Lead-in Alignment Assessment



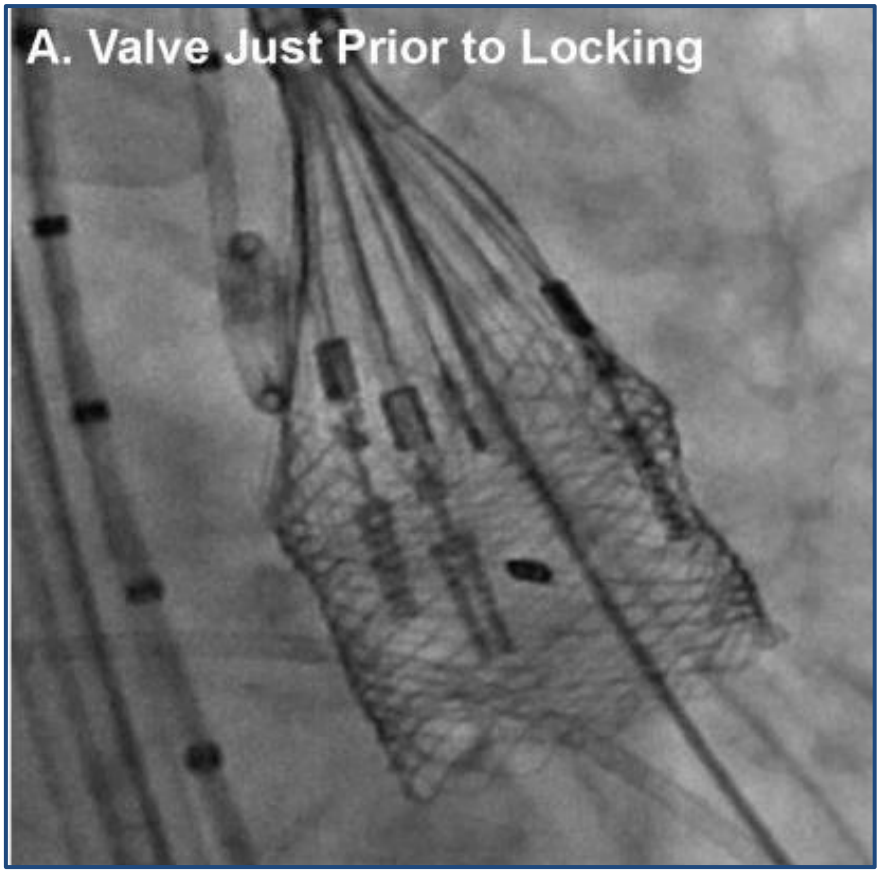


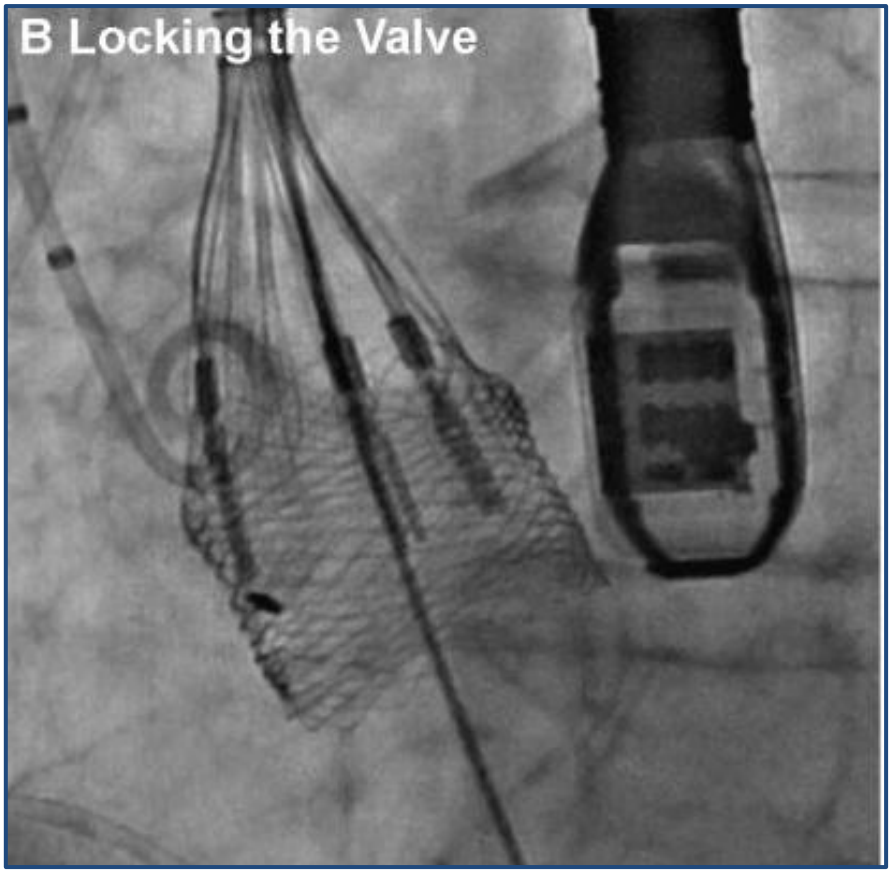
- During lead-in, a single view may be used to check for twisting of the posts
- The ideal view is one in which:
  - Two of the buckles/posts appear close to each other in the center of the valve
  - The third on the edge of the valve
- Always see two face-on “tuning forks” and one post side-on
- **Ensure** Posts and Buckles are Aligned

View is applicable for lead-in assessments <u>ONLY</u>

Locking

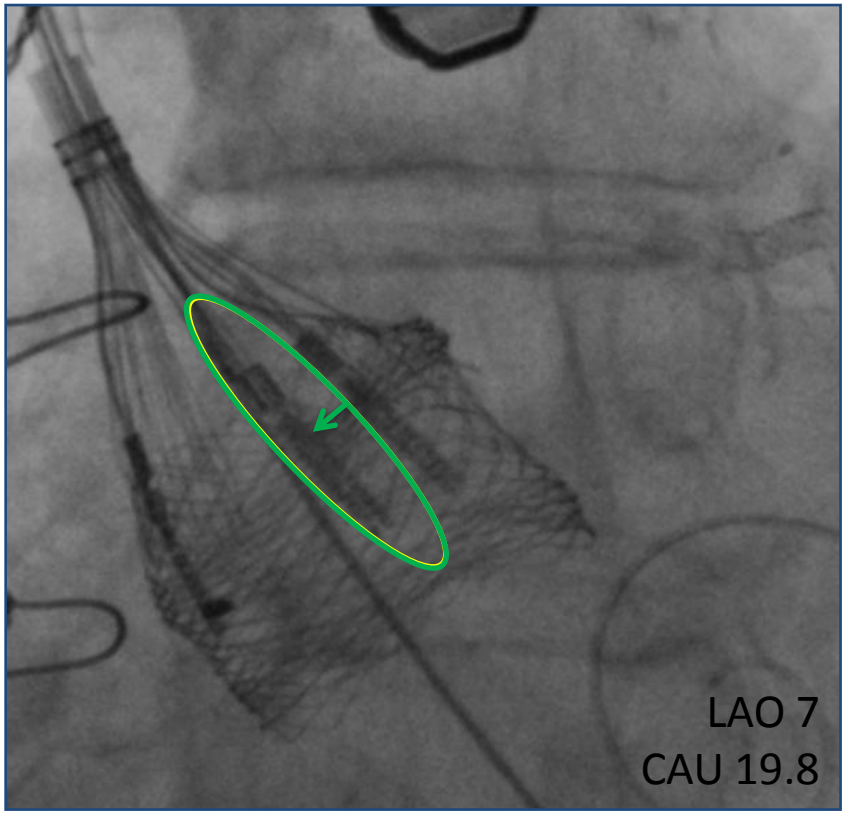
Continue to shorten and lock the valve, wait and watch for locking while slowly turning the controller until resistance has built up (prior to Click). Check for gaps to be closed between posts and buckles





Visualization of Locked Buckles/Posts

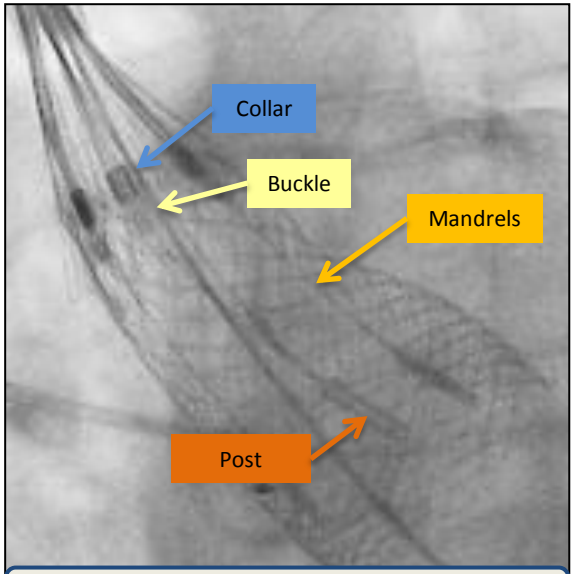
Confirm locked valve in 3 view rotation. View each buckle/post on face (LAO-Cranial to RAO-Caudal)



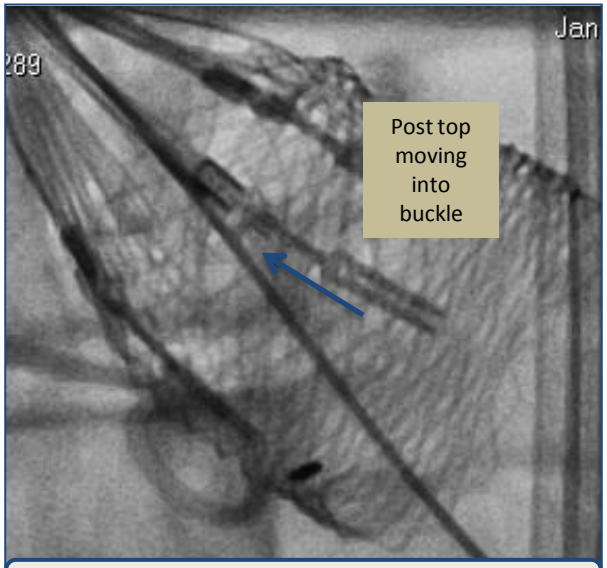
Good visualization of two post-buckles

Assess the Gap between the buckle and post top to confirm locking.

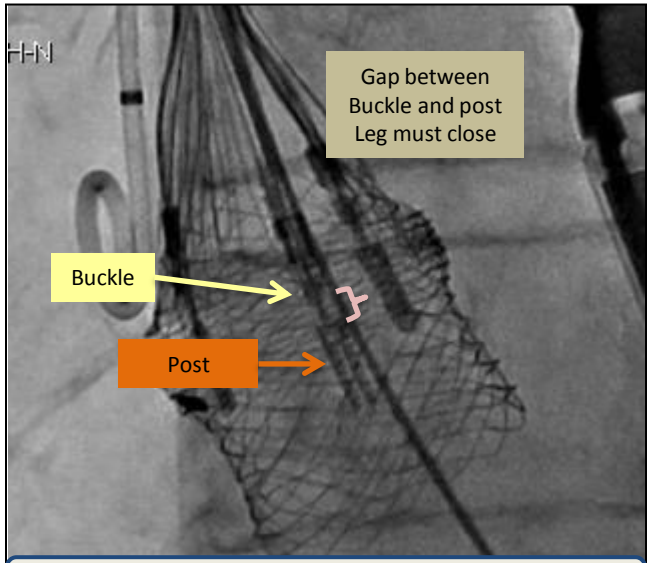
Visualization of Locking Procedure



Unsheathed

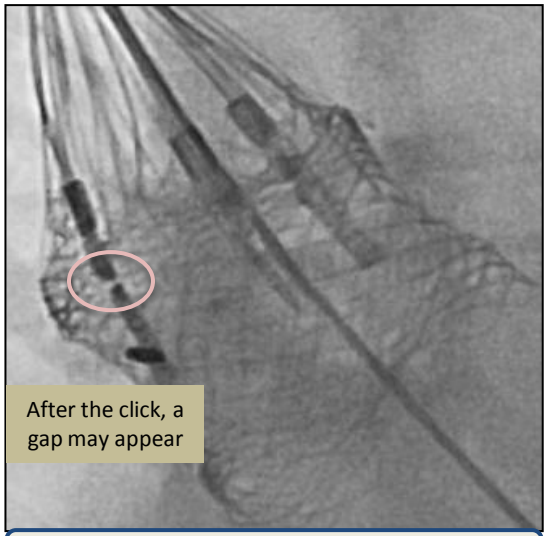


Lead-in



Locking – Closing Gaps

Locked

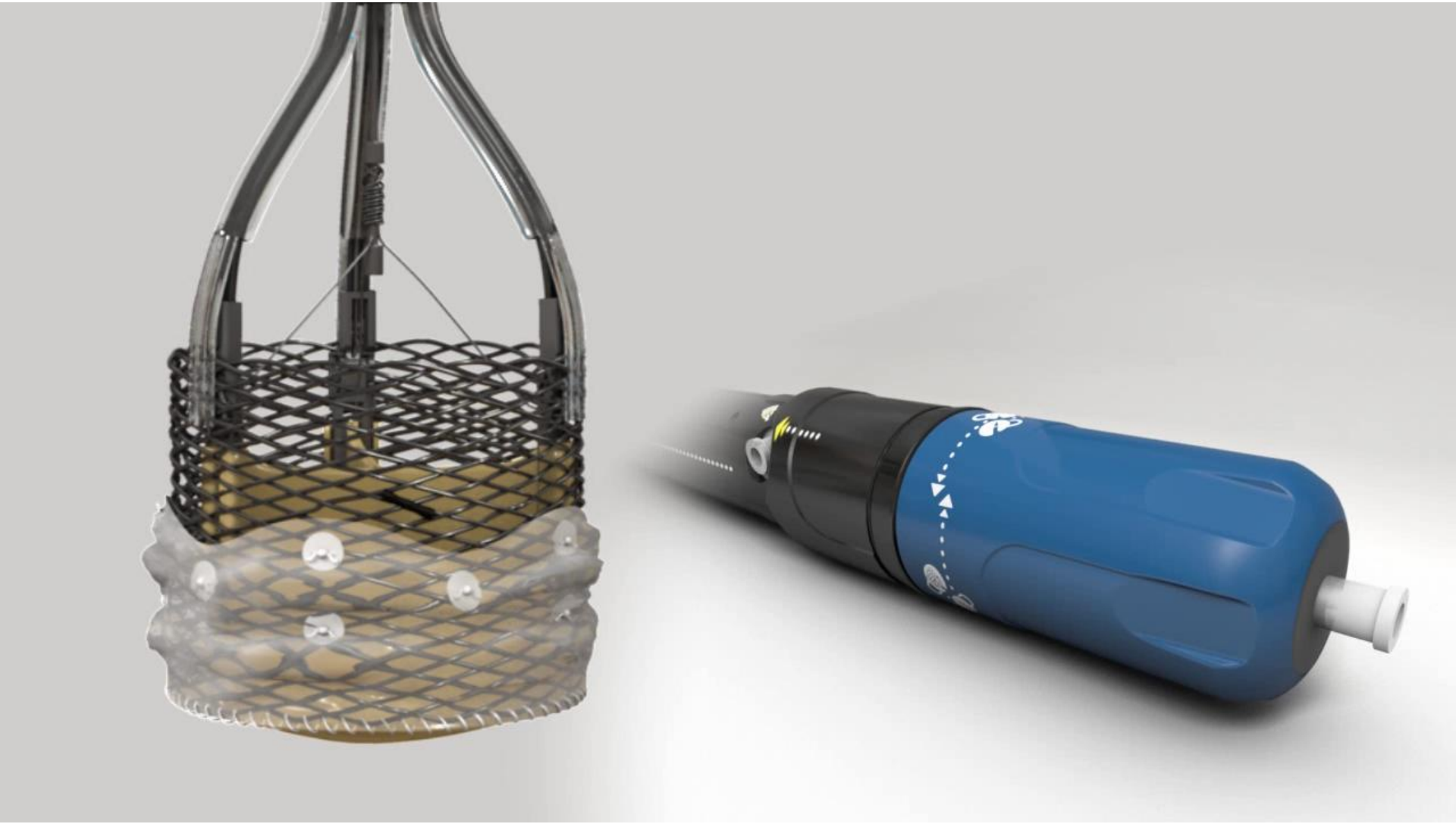


Locked – Click – Gaps open

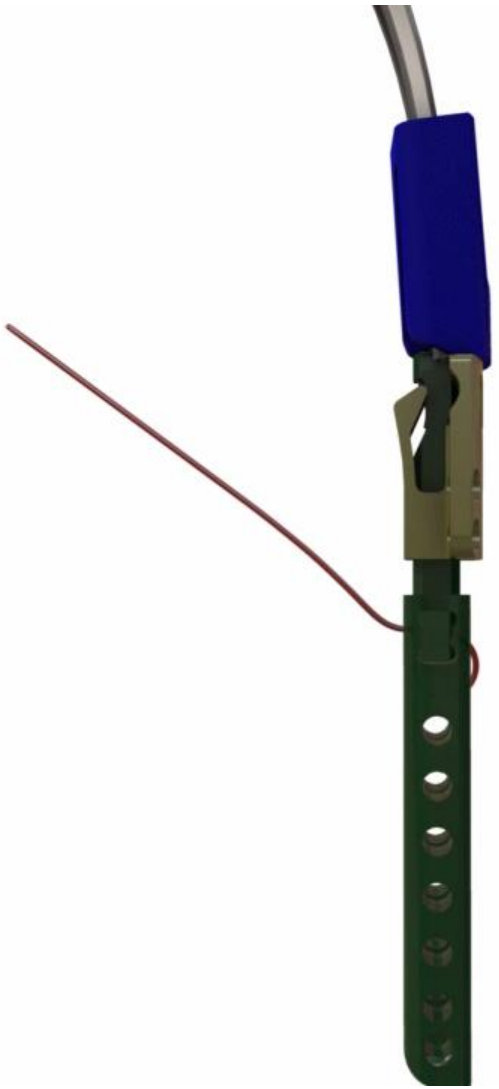
Releasing the Lotus™ Valve

SH-281406-AA November 2014

Two-Step Release Mechanism

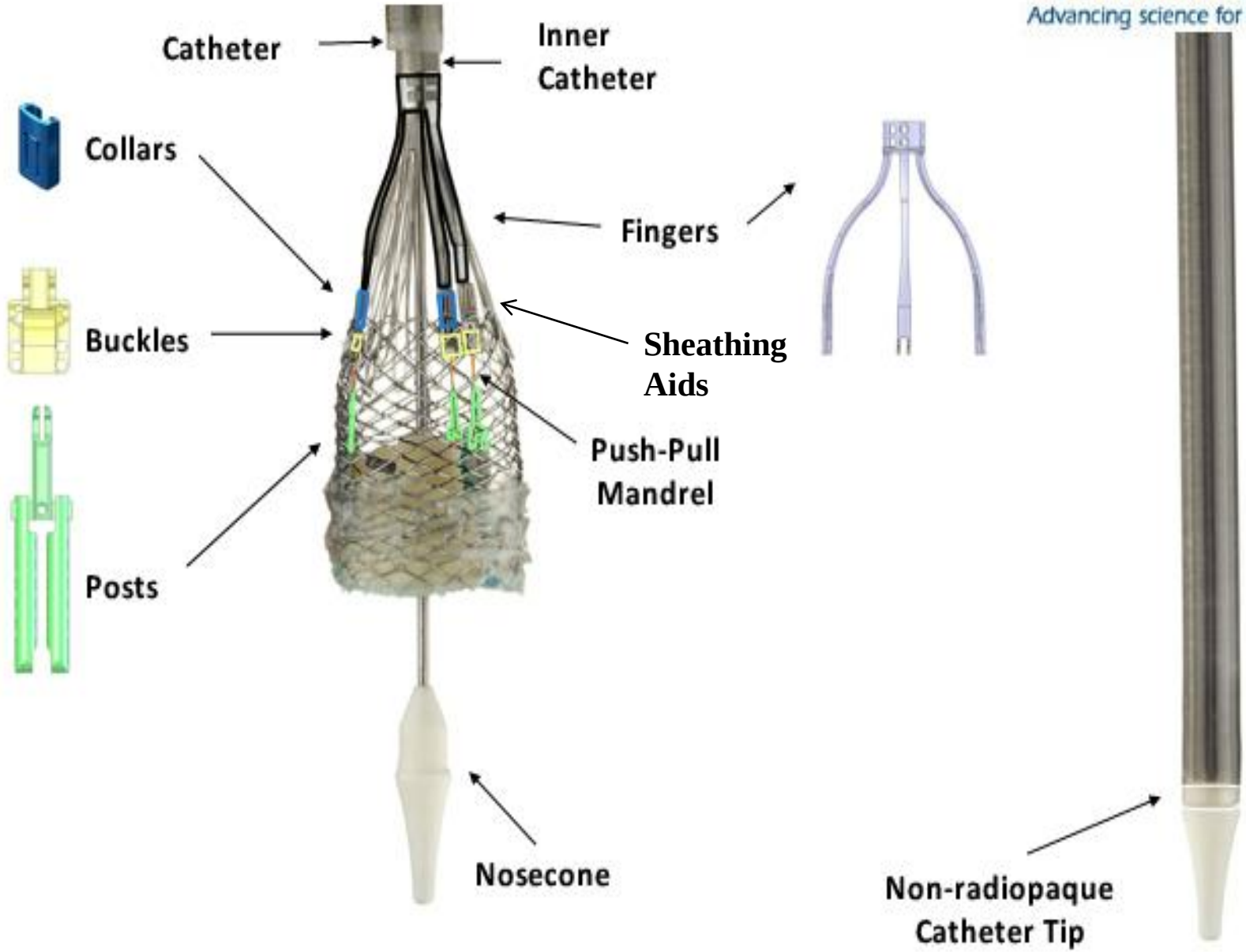


Two-Step Release Mechanism



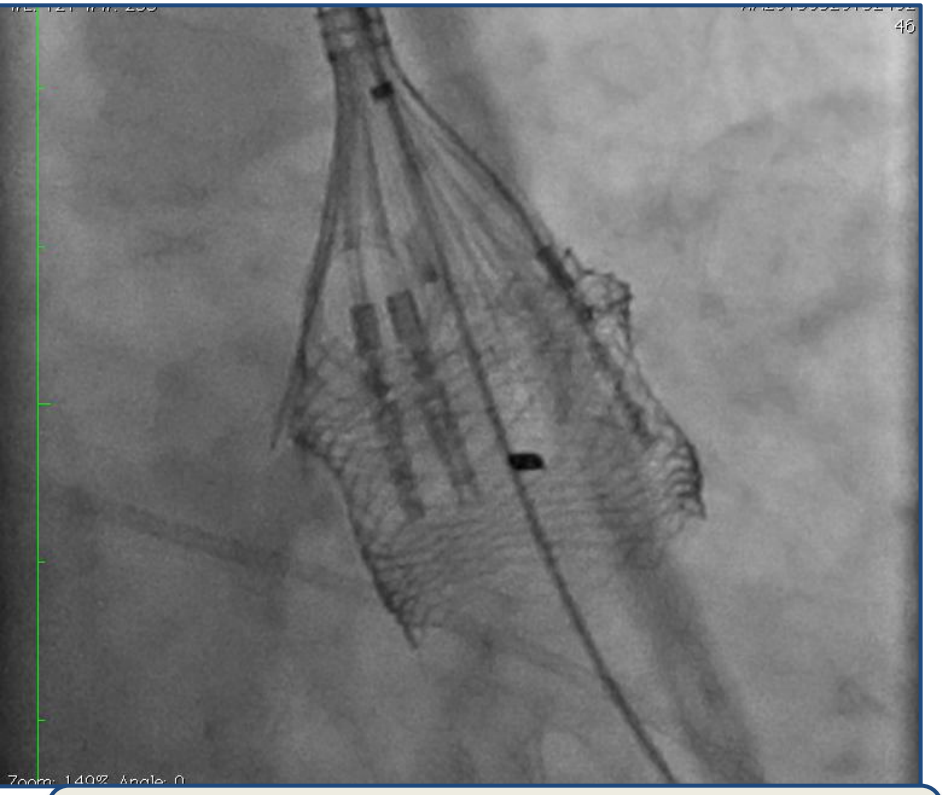
Delivery Catheter

Boston Scientific
Advancing science for life™



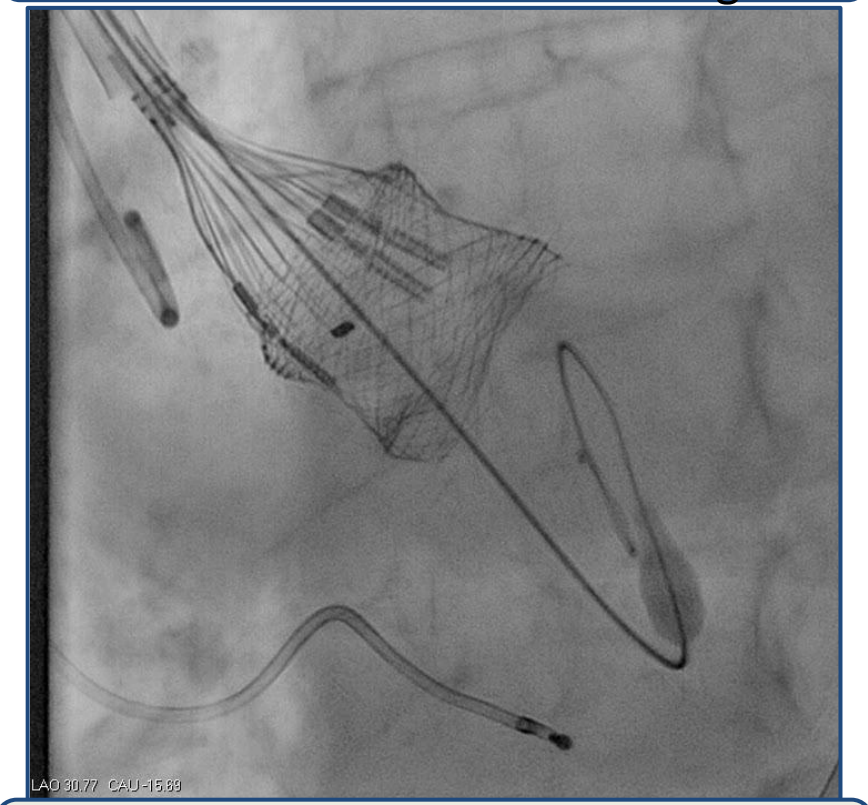
Release Valve

Release Phase I: Rotate Release Collar to the Pause sign and wait.



- Watch for the release coil to move into the outer catheter
- This is the last point in which you may fully retract the device

Release Phase II: Observe retraction of collars and detachment of fingers



- Find a neutral catheter position, watch for the retraction of the collars
- Maintain the Outer Catheter position during complete retraction the device

Main features

Key Product Highlights

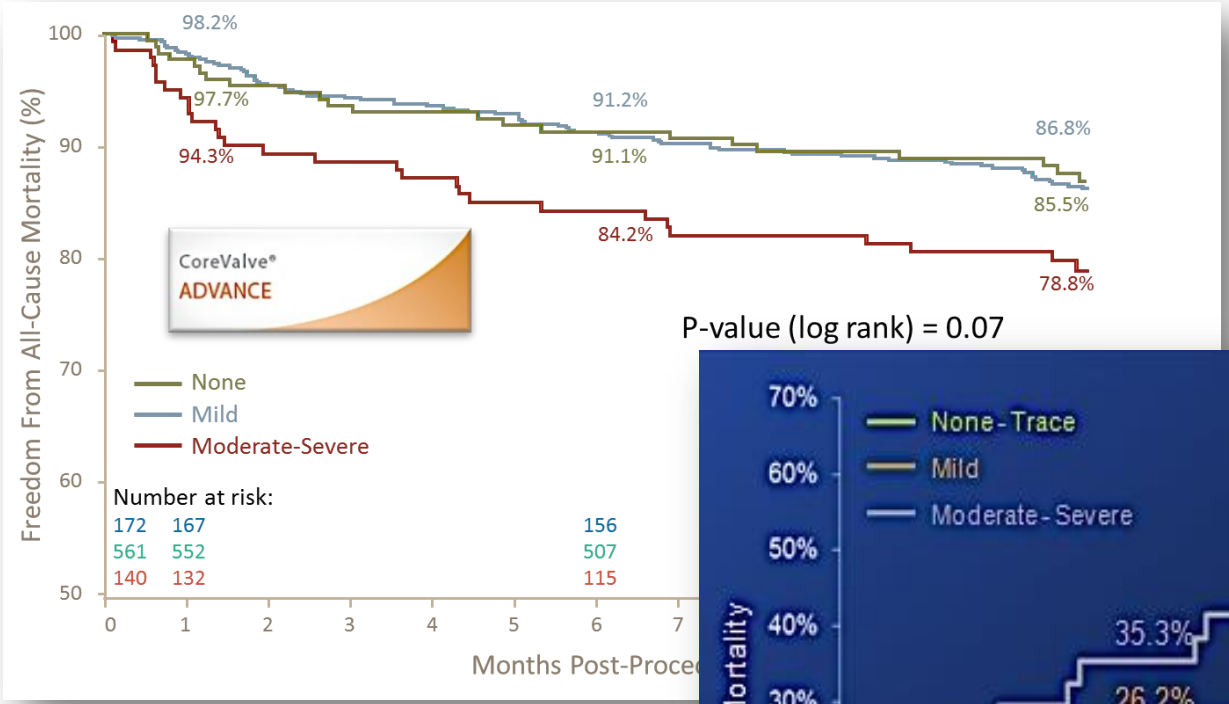
The Lotus™ Valve System gives physicians the **Power of Control** during TAVR procedures.

- Know your procedural result **before valve release**
- Help reduce complications with **precise placement and complete repositionability**
- Minimize paravalvular leak with the innovative **Adaptive Seal™ Technology**

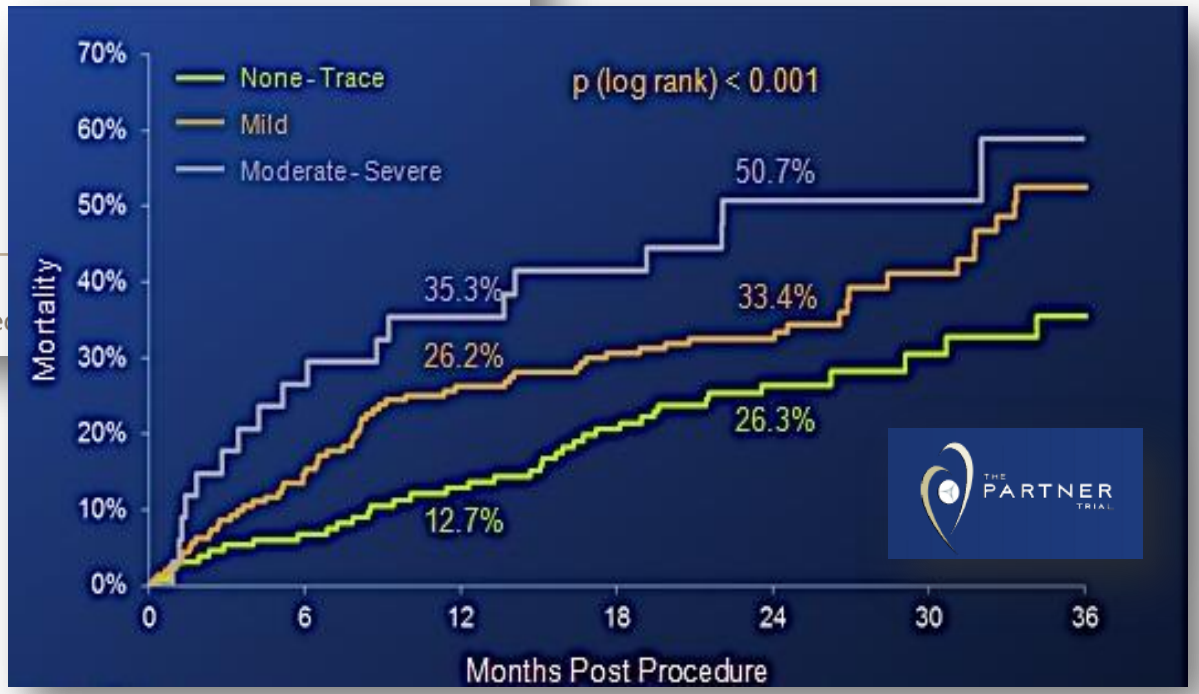
Valve implantation

Final result

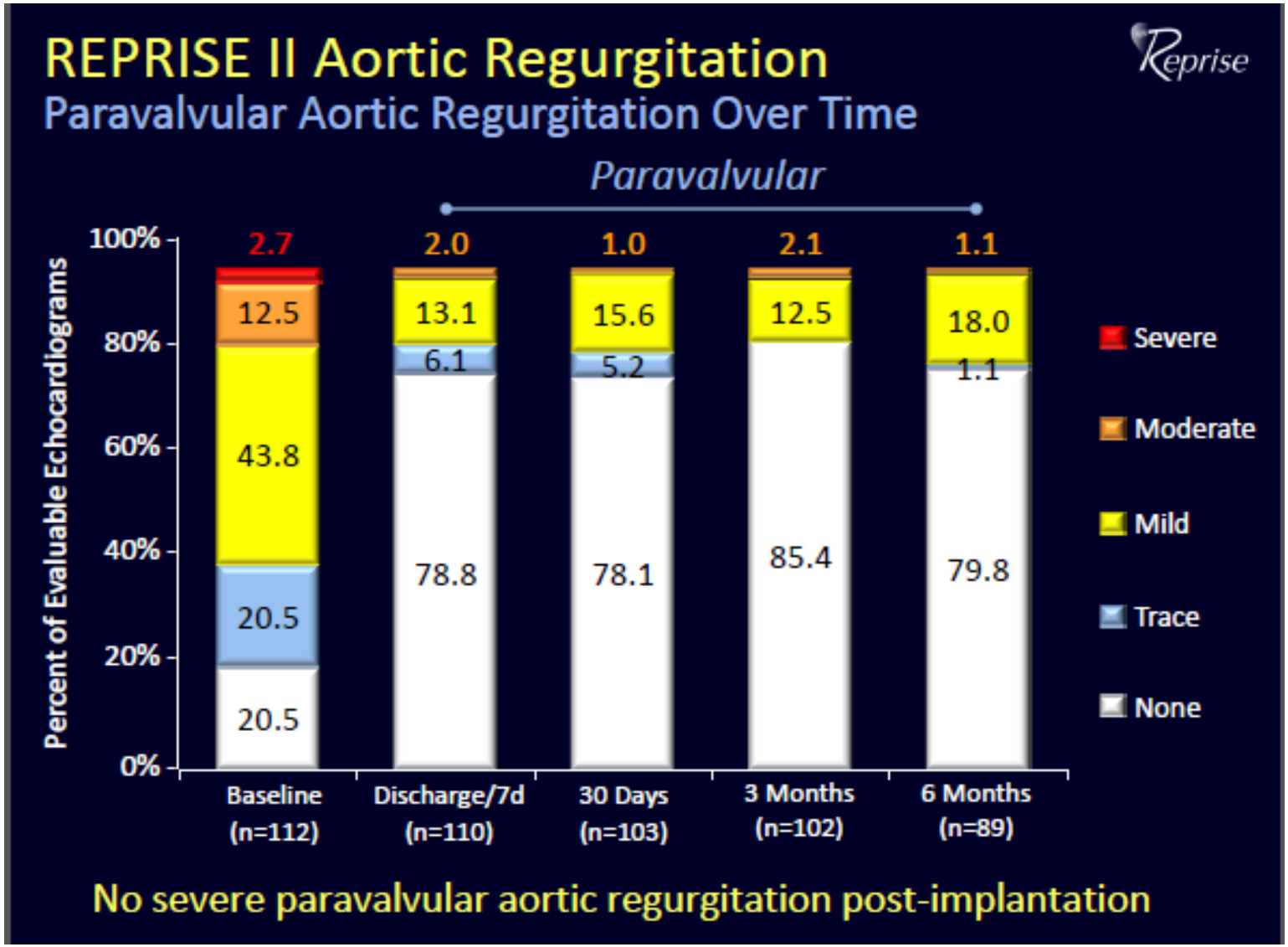
Survival by Aortic Regurgitation



P-value (log rank) = 0.07



Paravalvular Aortic Regurgitation



Circularization of the Annulus

Balloon-expandable prosthesis

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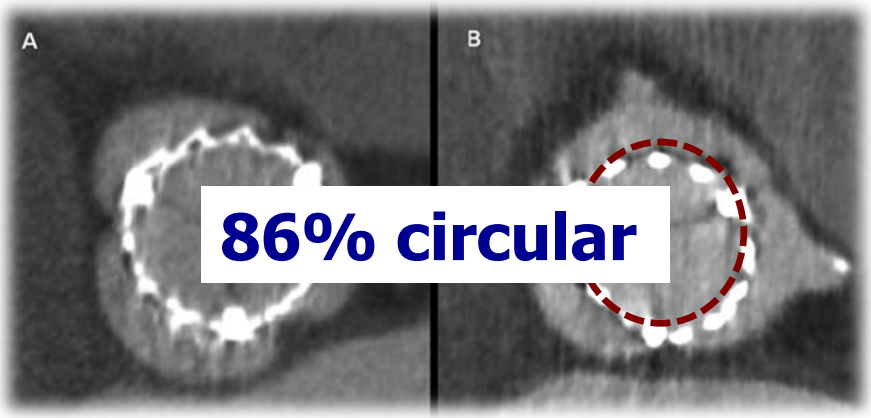
Prosthesis "remodels" the annulus



Delgado et al. Euro Heart J 2010;31:1114-1123

Self-expanding prosthesis

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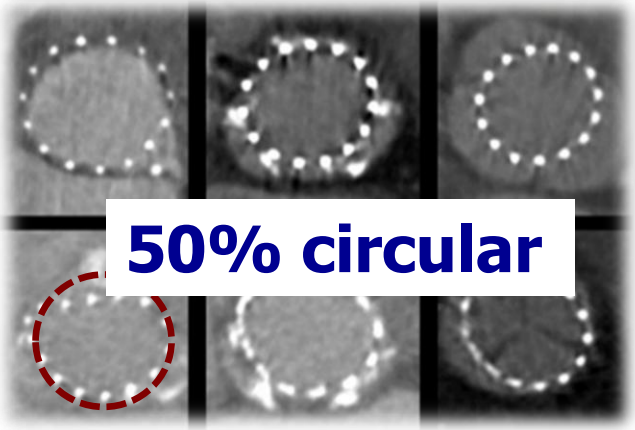
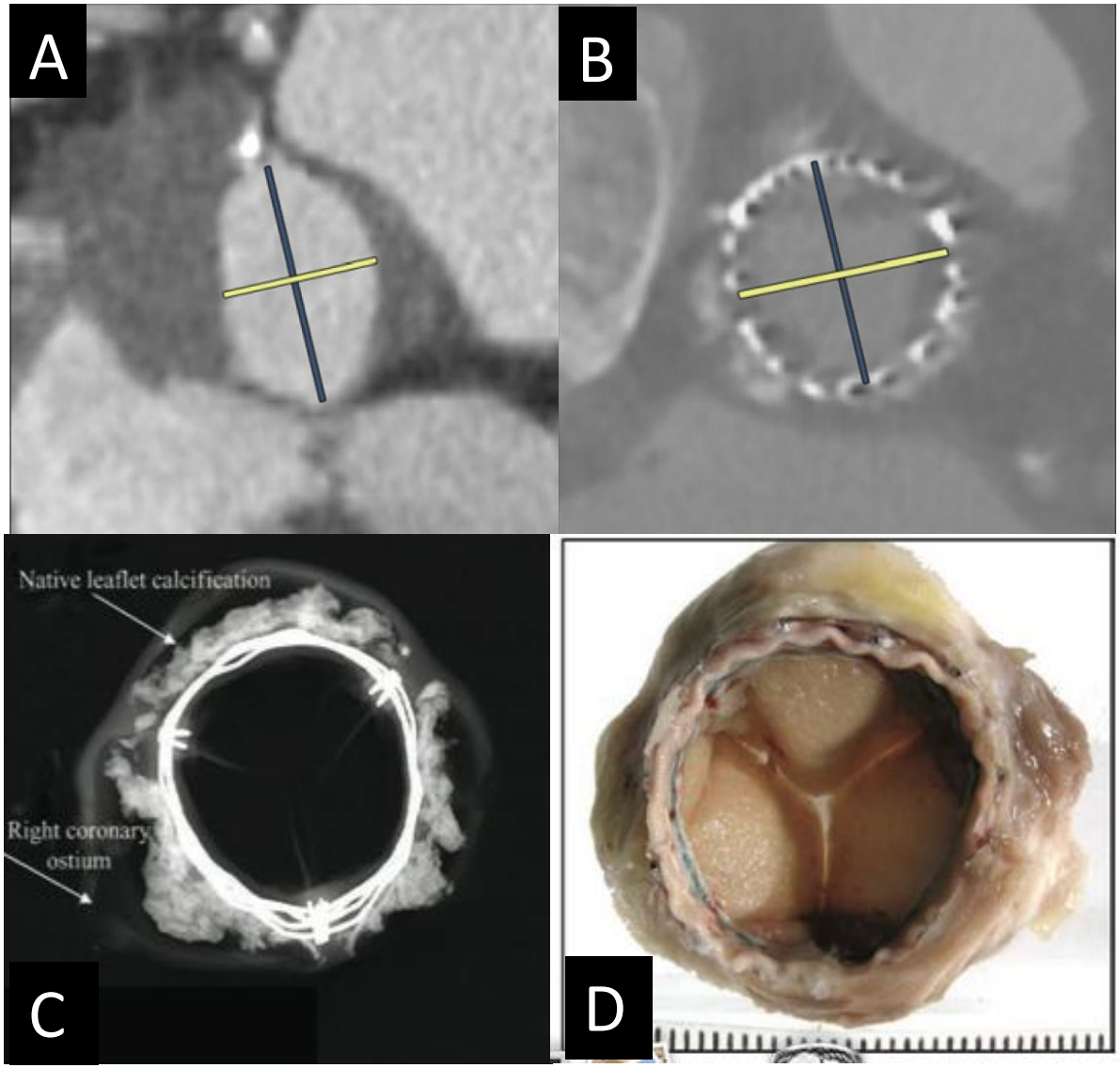
The "annulus" remodels the prosthesis



Schultz C et al. JACC 2009; 54:911-8

Courtesy of Nic Piazza

Eccentricity of the Annulus Post Lotus



Controlled Mechanical Expansion Prosthesis

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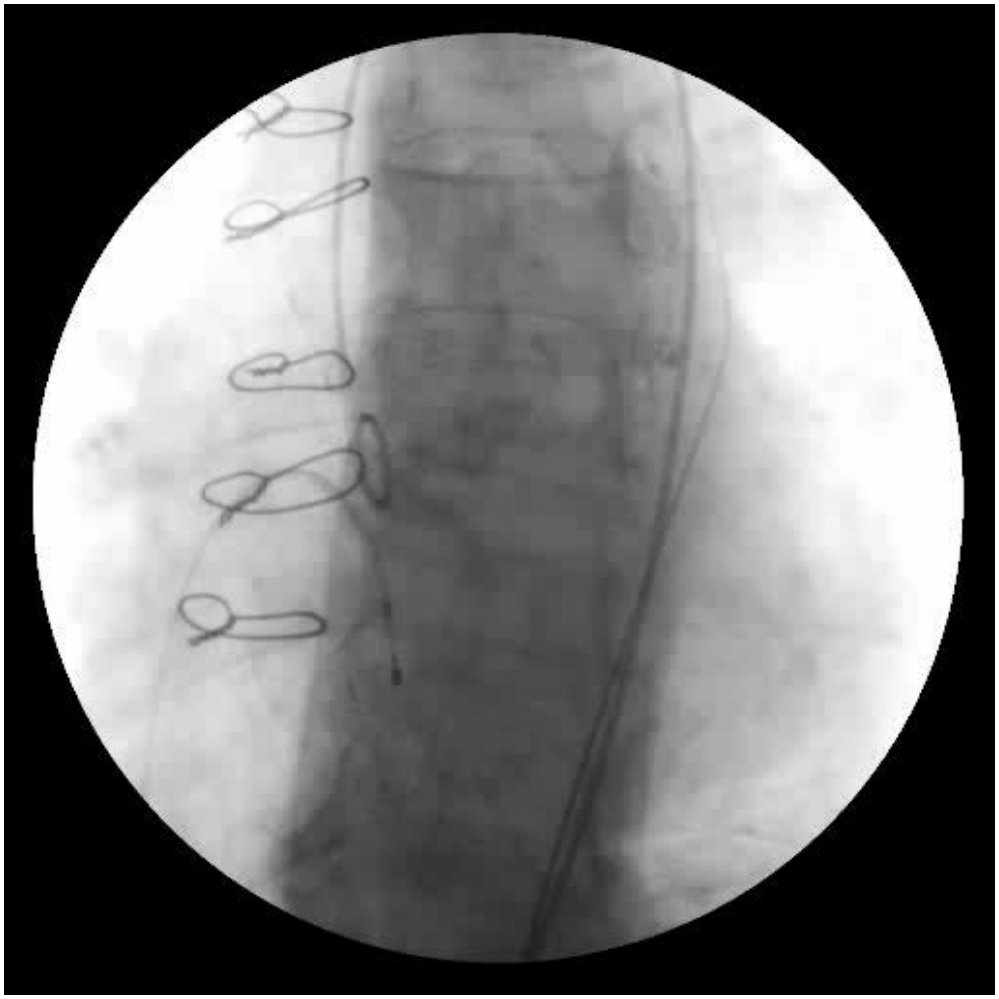
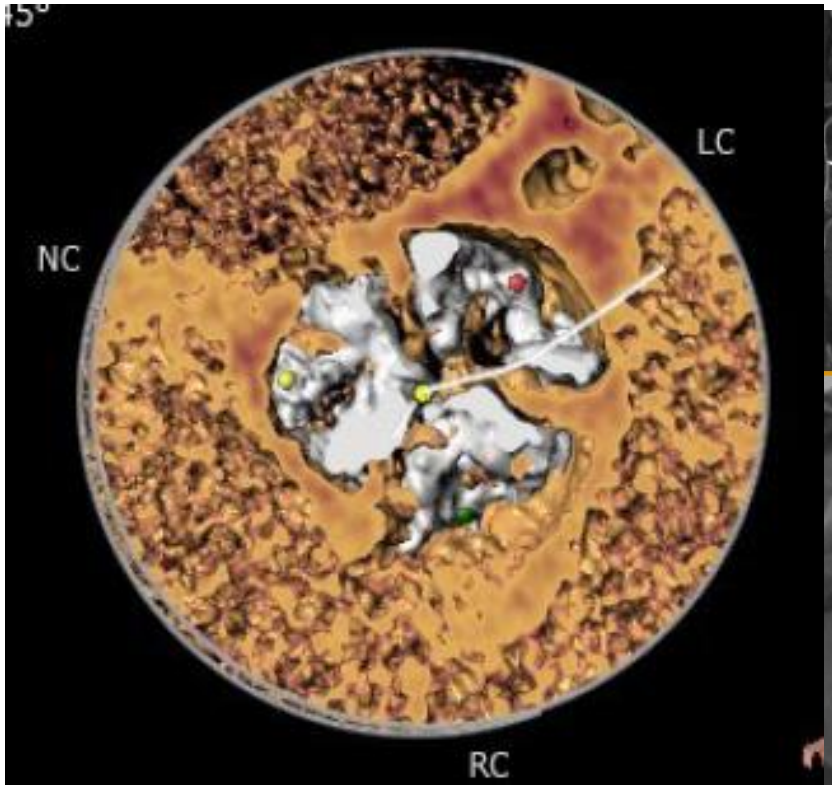
Prosthesis "remodels" the annulus

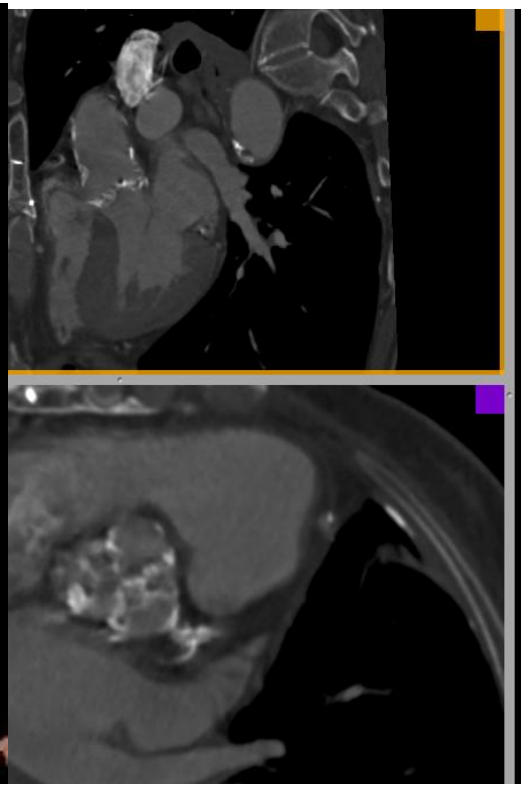
Leipsic J et al. JACC Cardiovasc Imaging

Severe calcifications



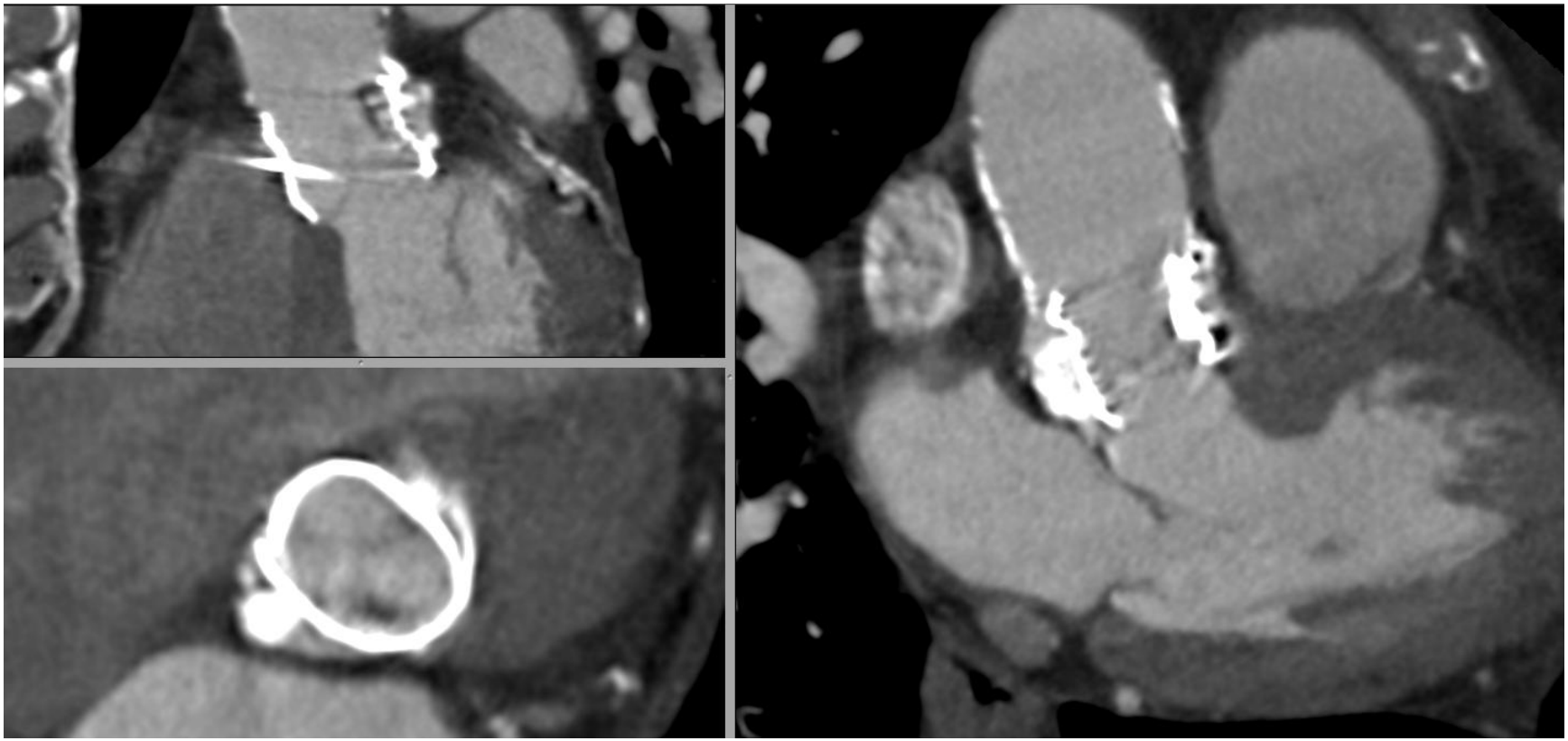
MSCT
Calcium distribution





Final result

MSCT post-TAVI



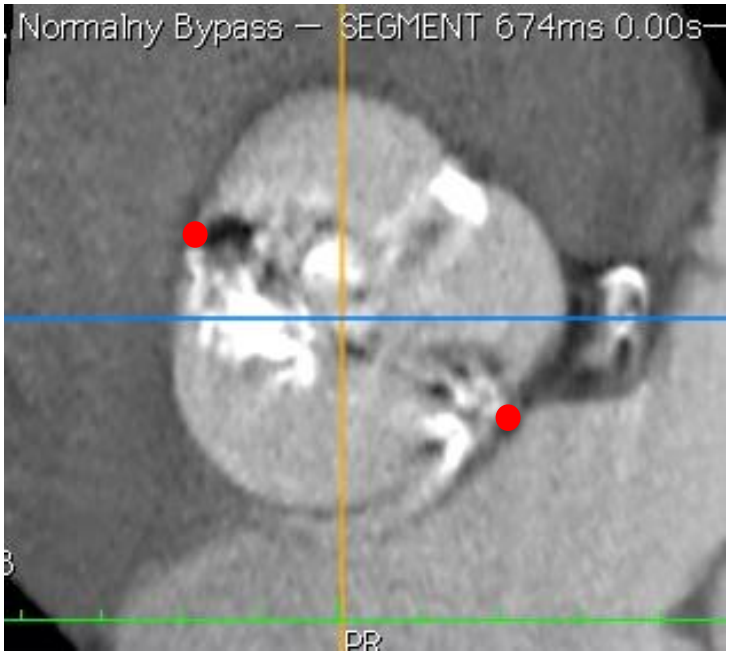
Bicuspid Valve

Clinical Reality

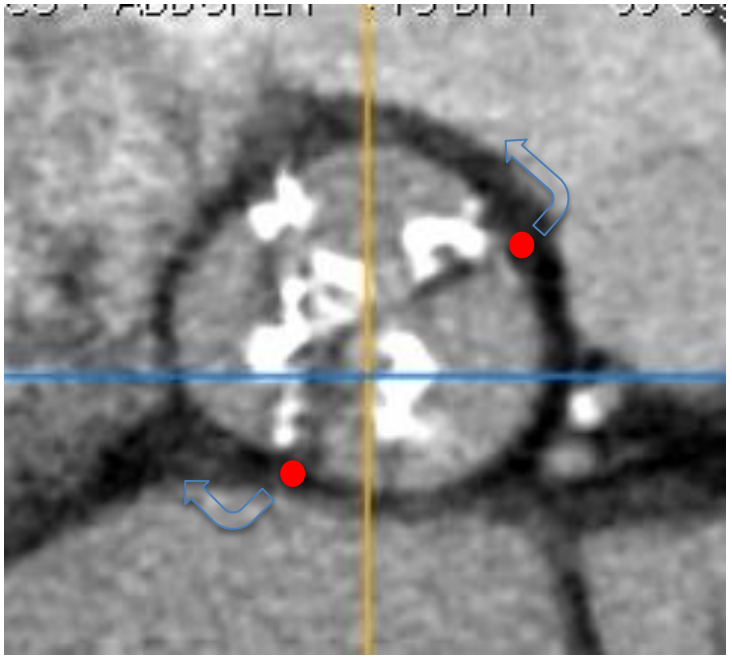
leaflets with fused commissure

vs

bi-leaflets with Raphe



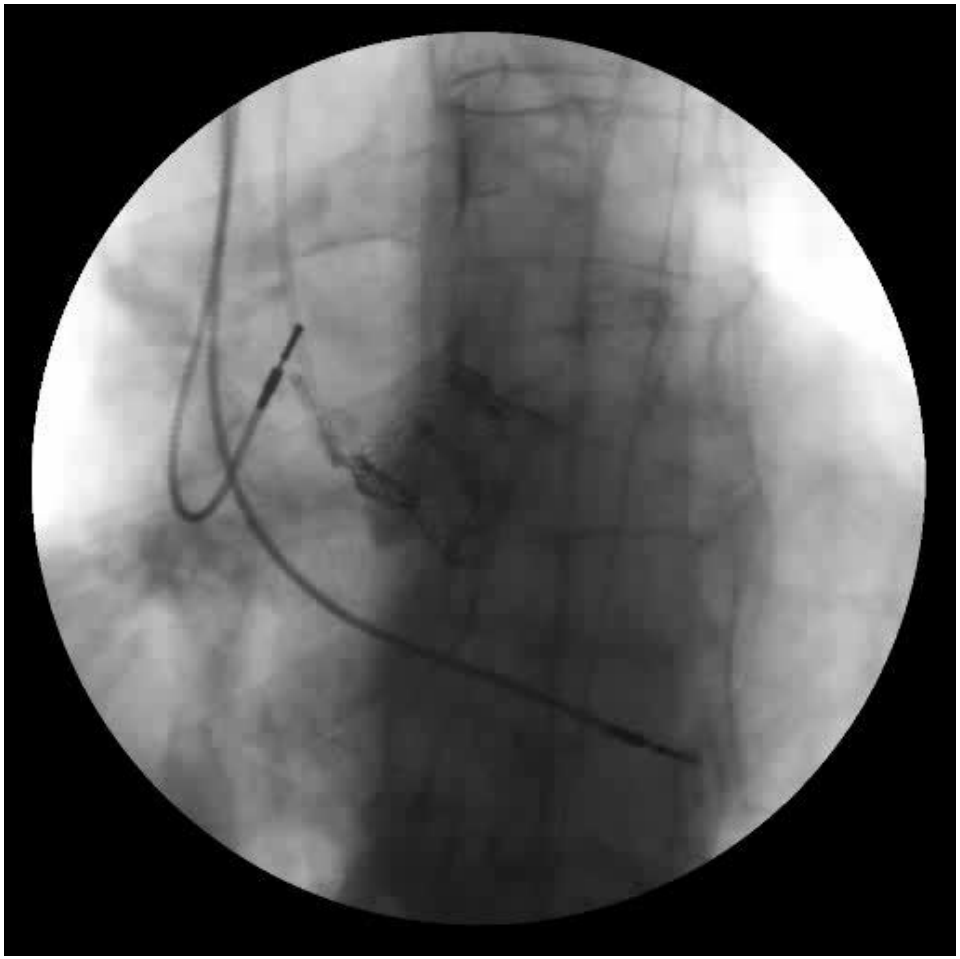
180°



120°

Bicuspid Valve

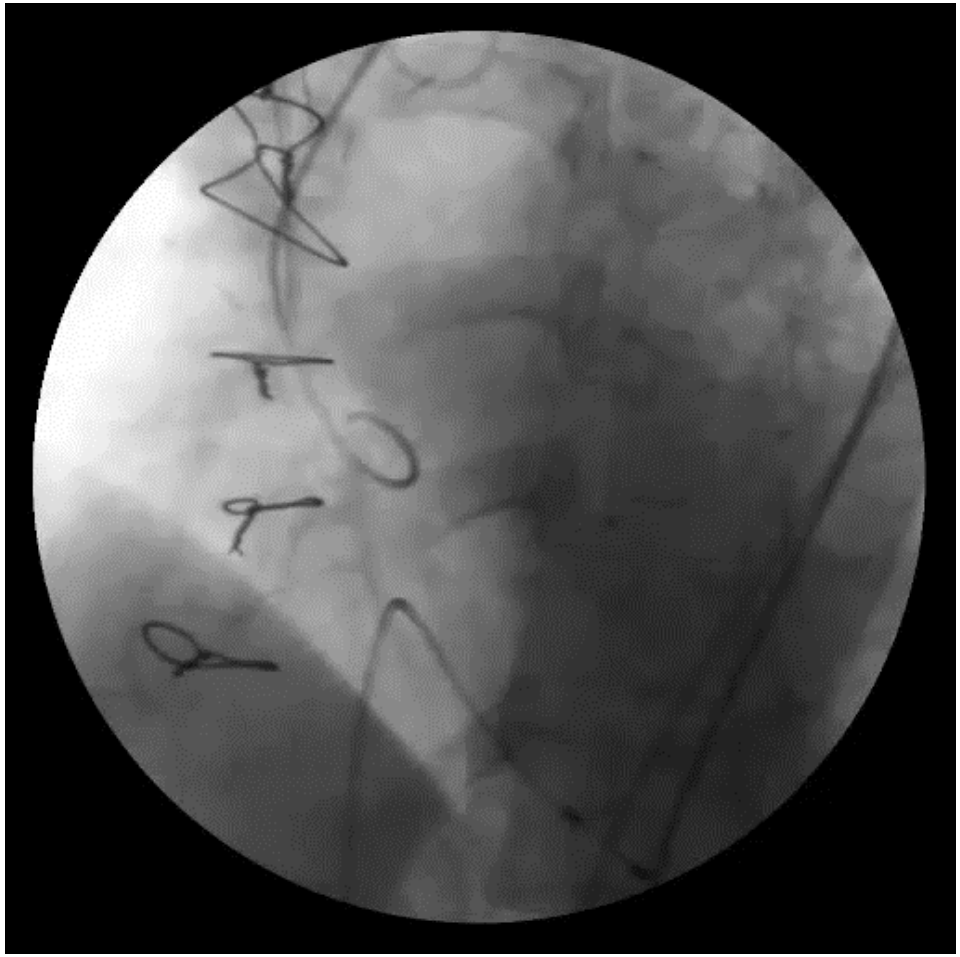
Bicuspid Valve – final result

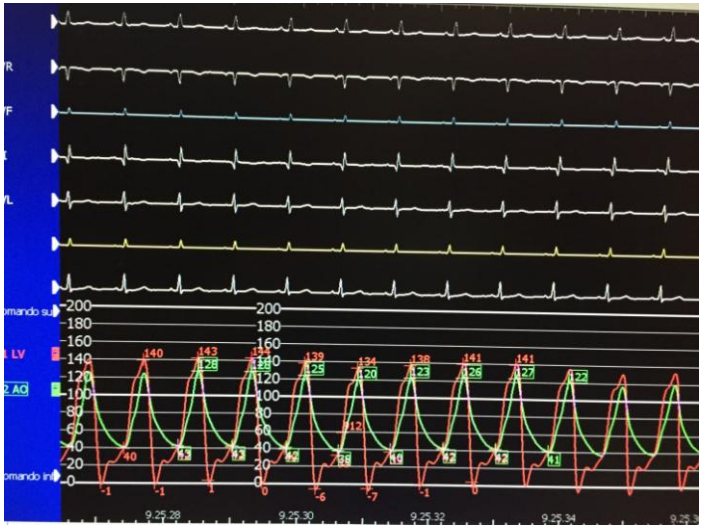


Horizontal aorta

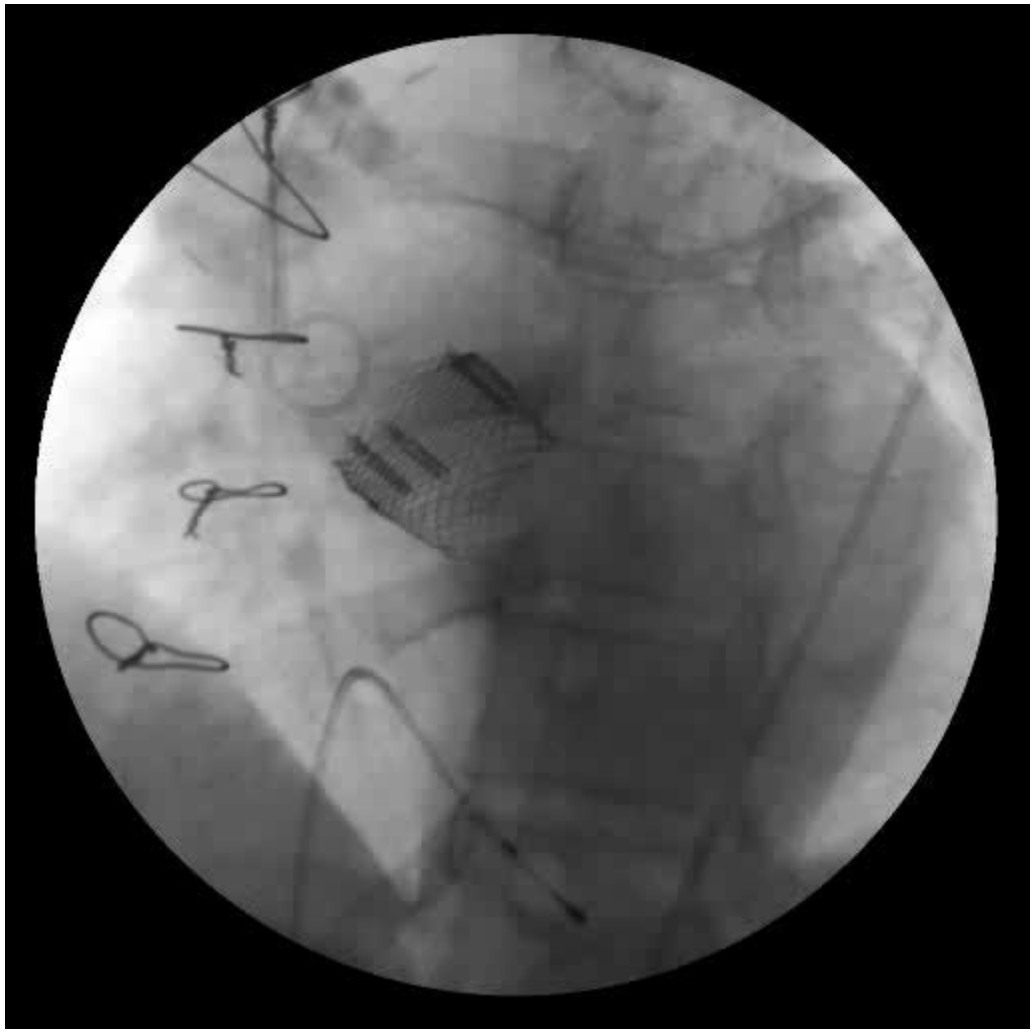
Lay-over - Final result

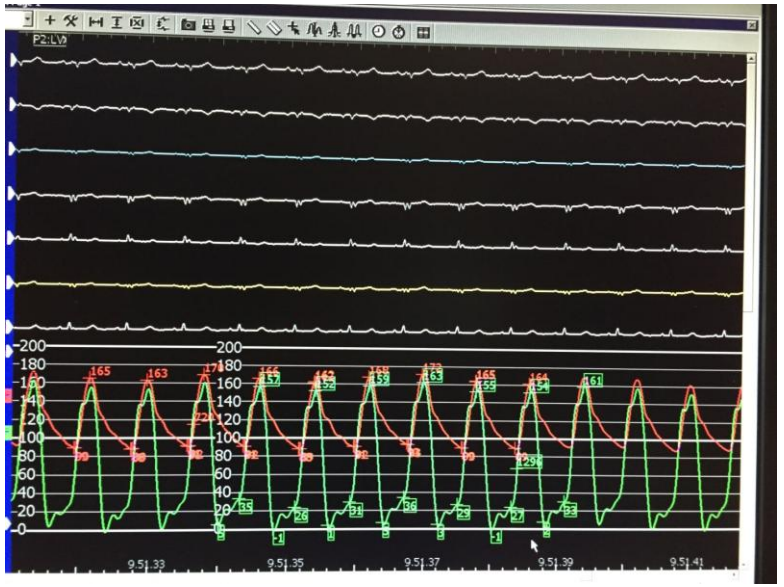
Off label indications
Aortic regurgitation



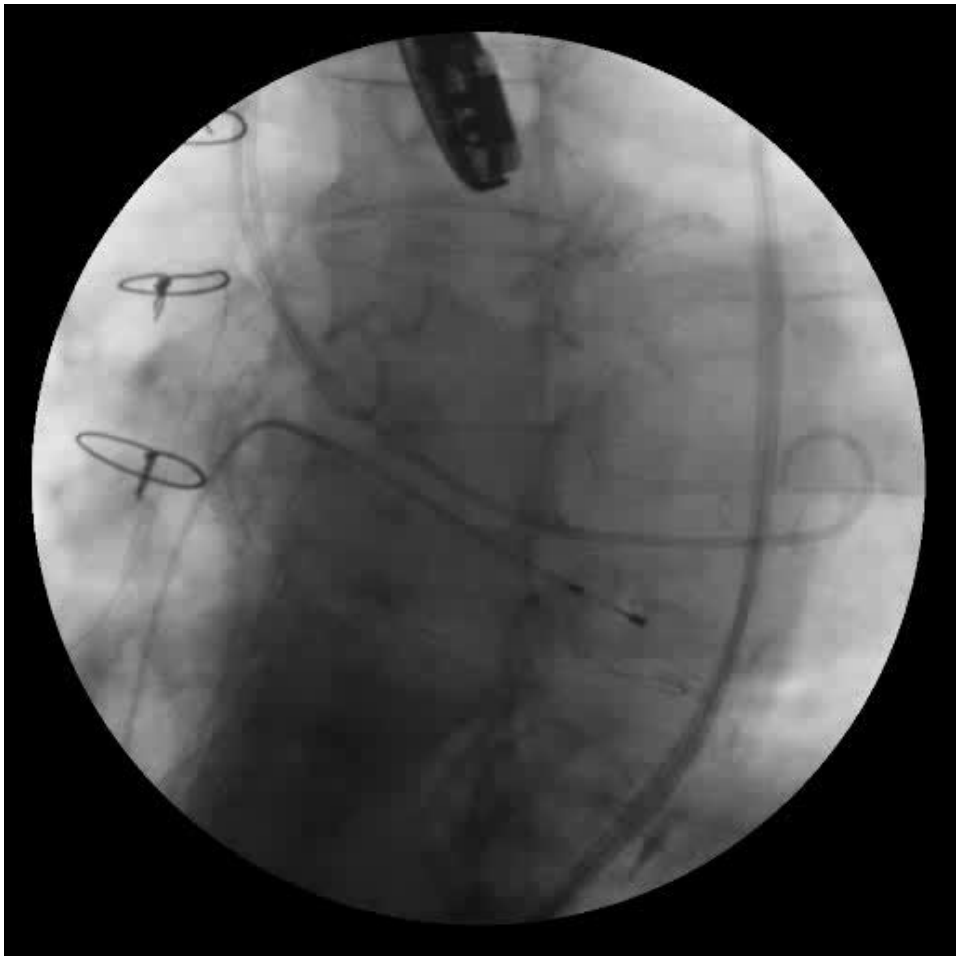


Oversizing-Final result

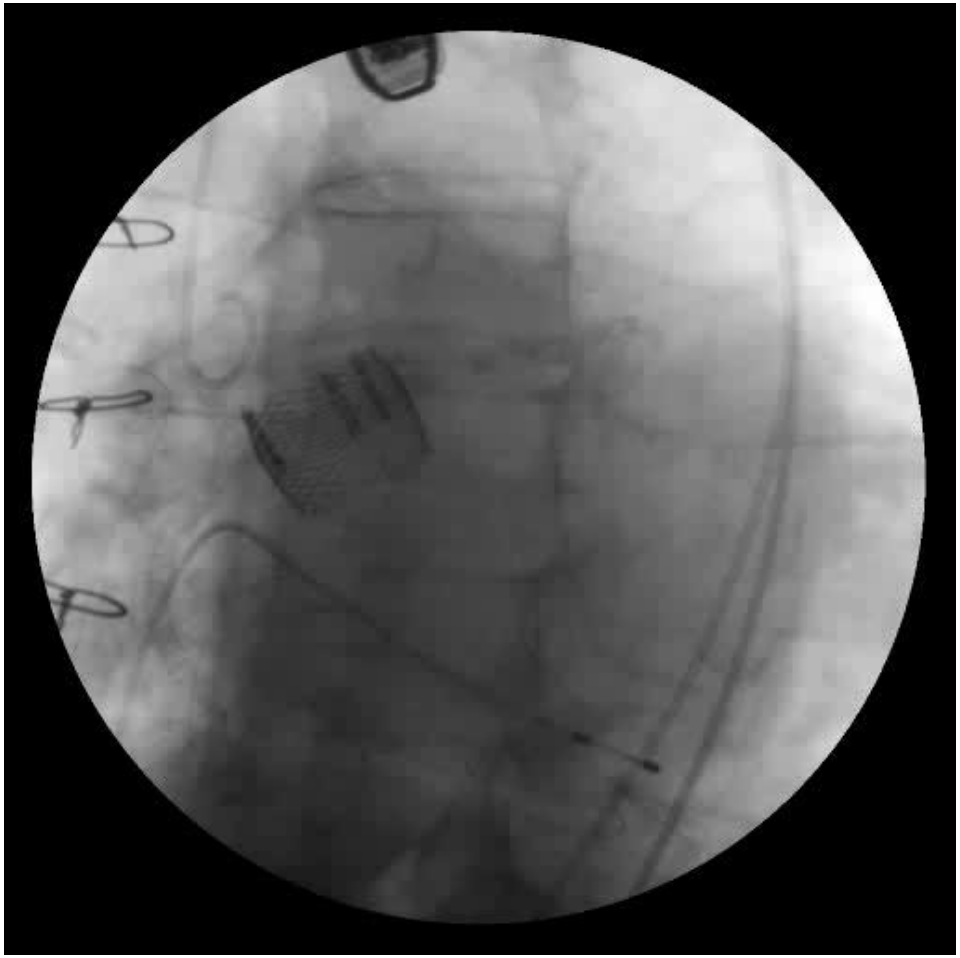




Off label indications
valve in valve (Gewear 28 + stentless)

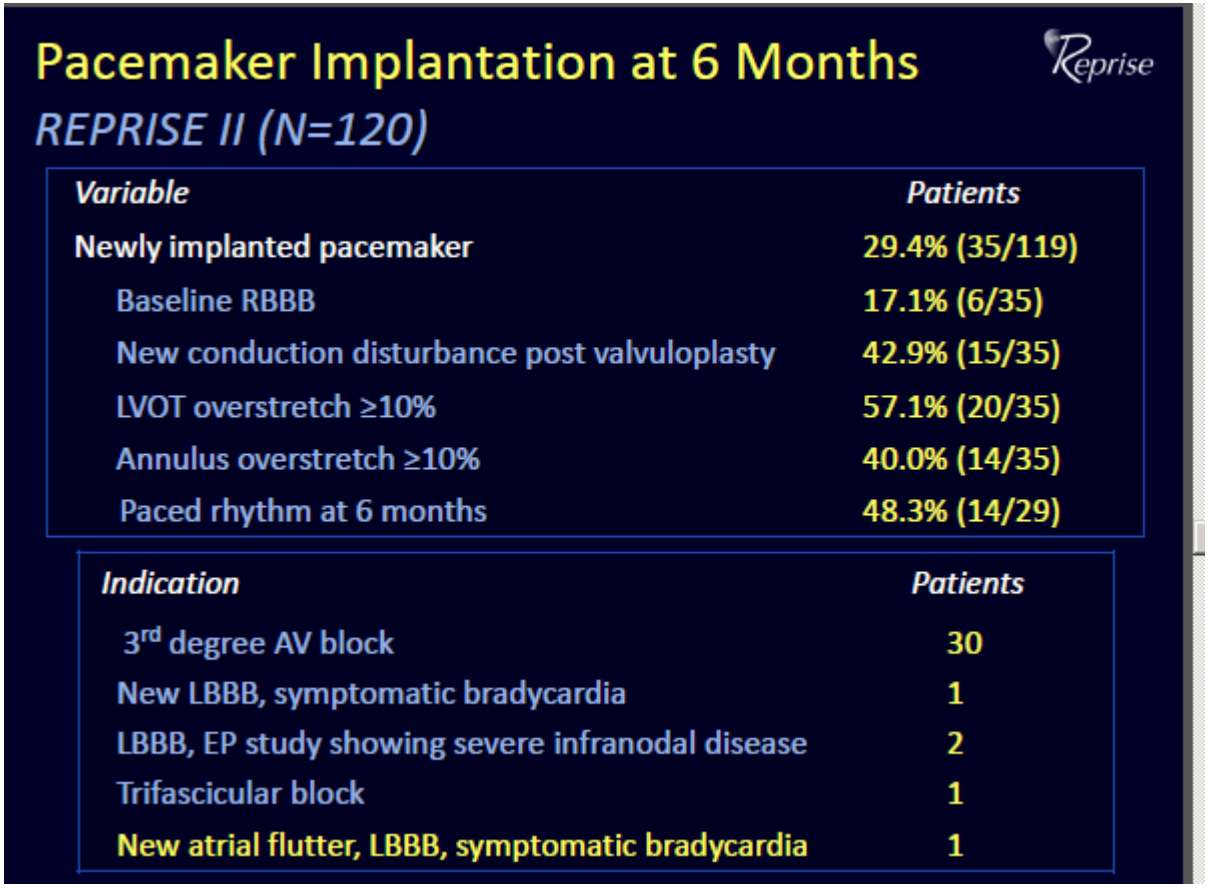


Final result



Critical points

Pacemaker



Pacemaker Implantation at 6 Months

Reprise

REPRISE II (N=120)

Variable	*Patients*
Newly implanted pacemaker	29.4% (35/119)
Baseline RBBB	17.1% (6/35)
New conduction disturbance post valvuloplasty	42.9% (15/35)
LVOT overstretch ≥10%	57.1% (20/35)
Annulus overstretch ≥10%	40.0% (14/35)
Paced rhythm at 6 months	48.3% (14/29)

Indication	*Patients*
3rd degree AV block	30
New LBBB, symptomatic bradycardia	1
LBBB, EP study showing severe infranodal disease	2
Trifascicular block	1
New atrial flutter, LBBB, symptomatic bradycardia	1

We have 5 out of 27 pts (18%) they were all among the first few cases, i.e. during the learning curve

Valve Sizing – Basic Rules

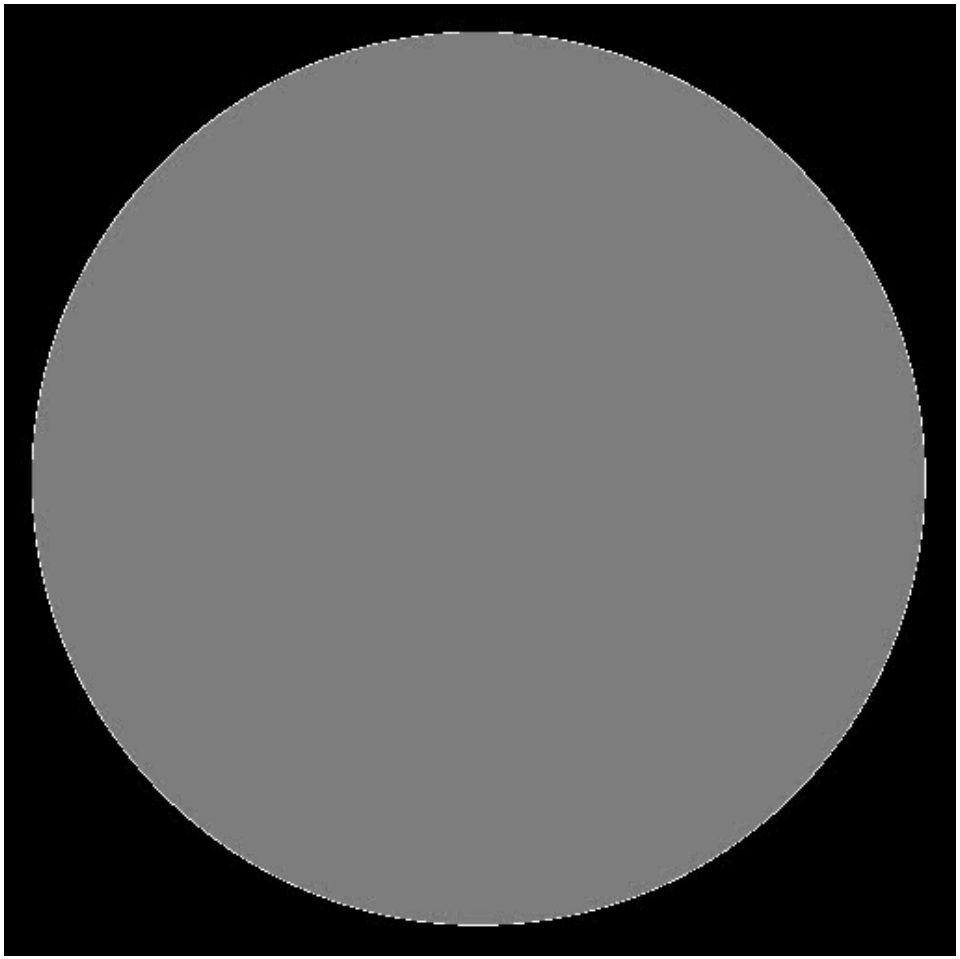
Very Important!

- Choose the right size not an oversize
  - Under sizing cannot be corrected by balloon expansion and may risk PVL, valve migration or embolization
  - Oversizing may prevent the valve from locking and may induce AV block resulting in PPM implant after the procedure
- Use the Sizing Chart

Sizing Chart

CT Measurements for Patient Screening		23 mm	25 mm	27 mm
Actual Lotus Valve	Diameter (mm)	23	25	27
	Perimeter (mm)	72.3	78.5	84.8
	Area (mm^2)	415.5	490.9	572.6
Annulus	Diameter (mm)	20 ≤ ideal ≤ 23	23 ≤ ideal ≤ 25	25 ≤ ideal ≤ 27
	Perimeter (mm)	62.8 ≤ ideal ≤ 72.3	72.3 ≤ ideal ≤ 78.5	78.5 ≤ ideal ≤ 84.8
	Area (mm^2)	314 ≤ ideal ≤ 415.5	415.5 ≤ ideal ≤ 490.9	490.9 ≤ ideal ≤ 572.6
LVOT	Diameter (mm)	20 ≤ ideal ≤ 23	23 ≤ ideal ≤ 25	25 ≤ ideal ≤ 27
	Perimeter (mm)	62.8 ≤ ideal ≤ 72.3	72.3 ≤ ideal ≤ 78.5	78.5 ≤ ideal ≤ 84.8
	Area (mm^2)	314 ≤ ideal ≤ 415.5	415.5 ≤ ideal ≤ 490.9	490.9 ≤ ideal ≤ 572.6
	Unsuitable area (mm^2)	**< 280**	**< 330**	**< 390**
SOV	Area too small (mm^2)	< 540	< 595	< 650
	Ideal area (mm^2)	> 600	> 700	> 800
	Area too large (mm^2)	> 1100	> 1200	> 1300
Annulus to Coronary Height	Height (mm)	Caution if < 10 mm; need to also consider sinus area		
Choosing between the margin of the valve sizes	Annulus			
	LVOT			
	SOV			
	Burden of Calcium			

Vascular complications

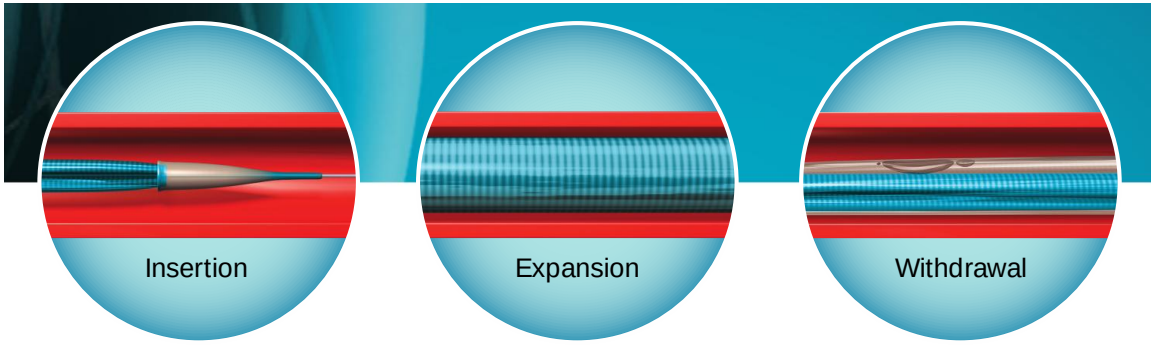


Different option: only for Lotus 23

- **Folded distal end premounted over a central balloon catheter**
- **Balloon inflation expands the sheath to appropriate size**

STFI2135 da 15F a 21F

Different option: for Lotus 23, 25 & 27

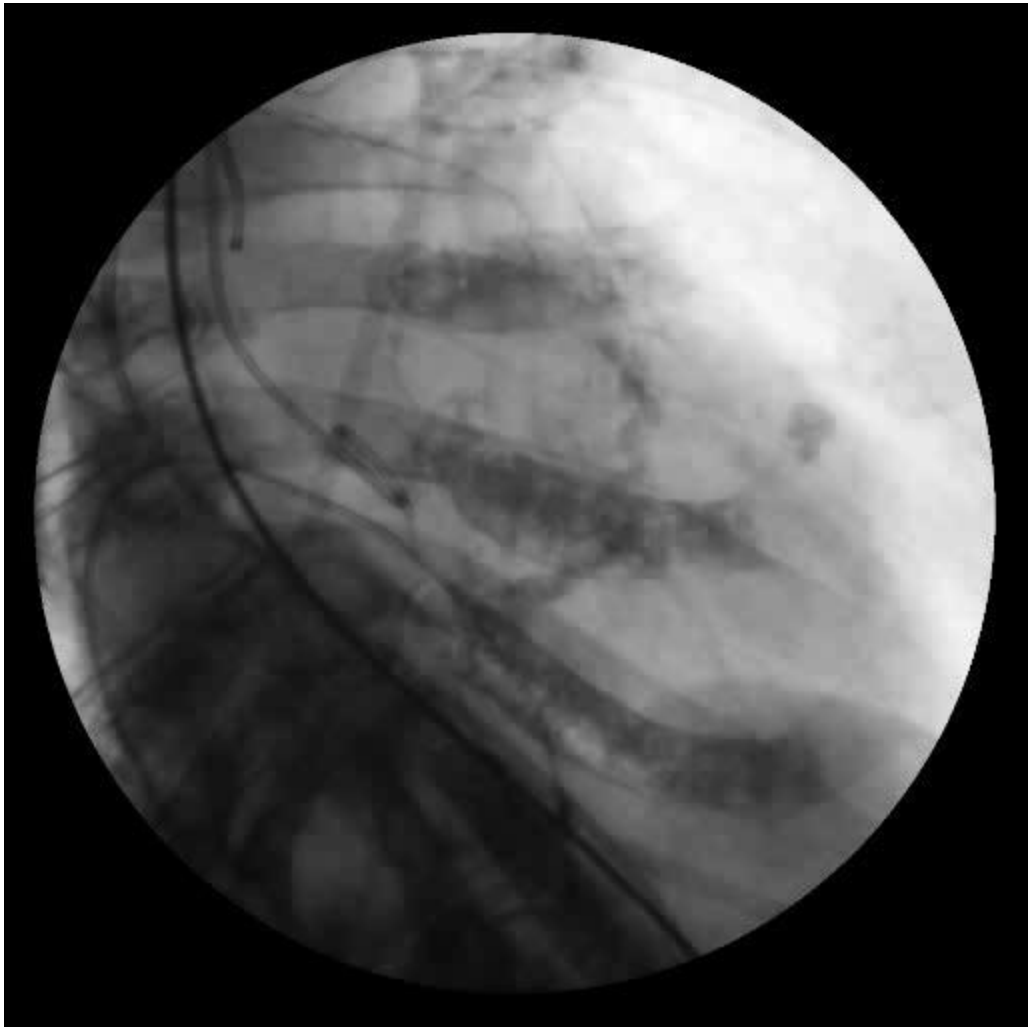


- Insert at a low profile
- Expand to a predictable operating profile
- Collapse and remove at a low profile

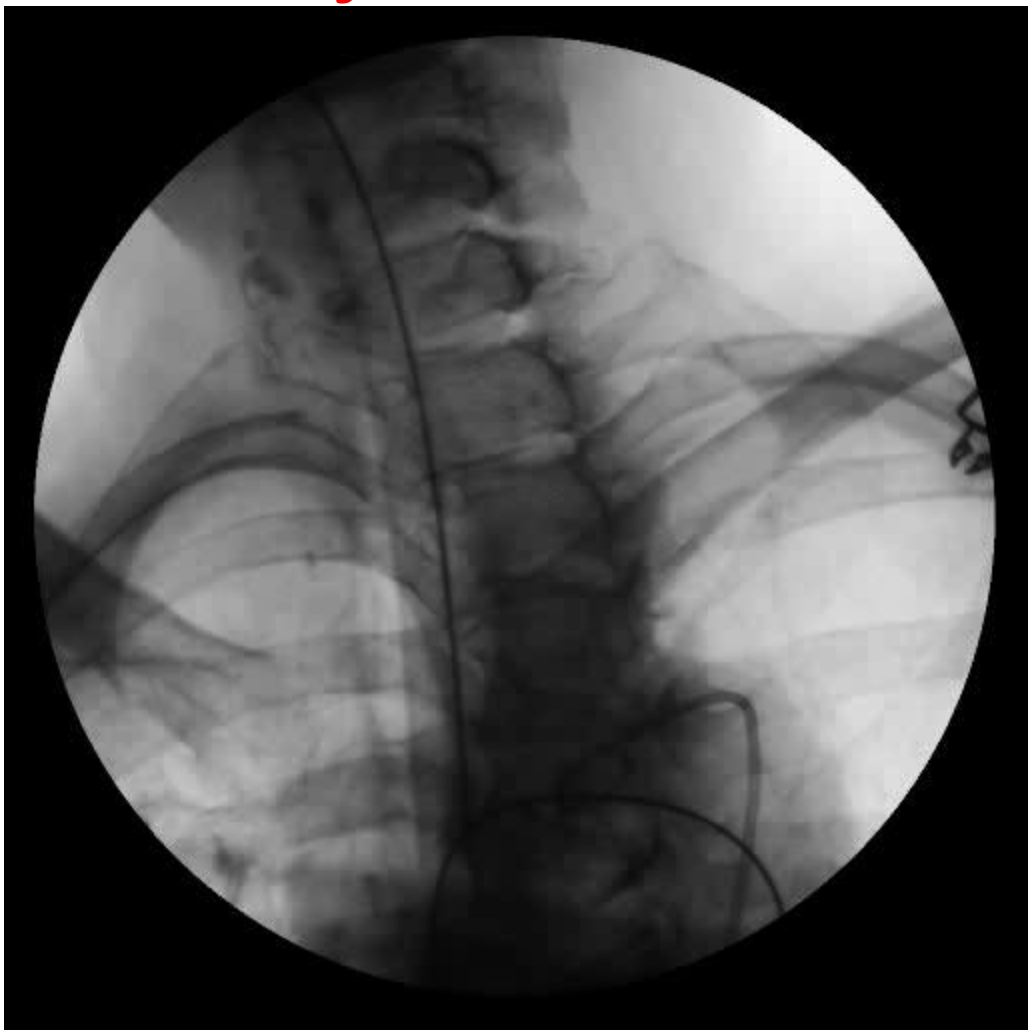
SOLOPATH® Re-collapsible Balloon Access System

SR2235 (da 13.5F a 22F)

Severe tortuosity of aorta

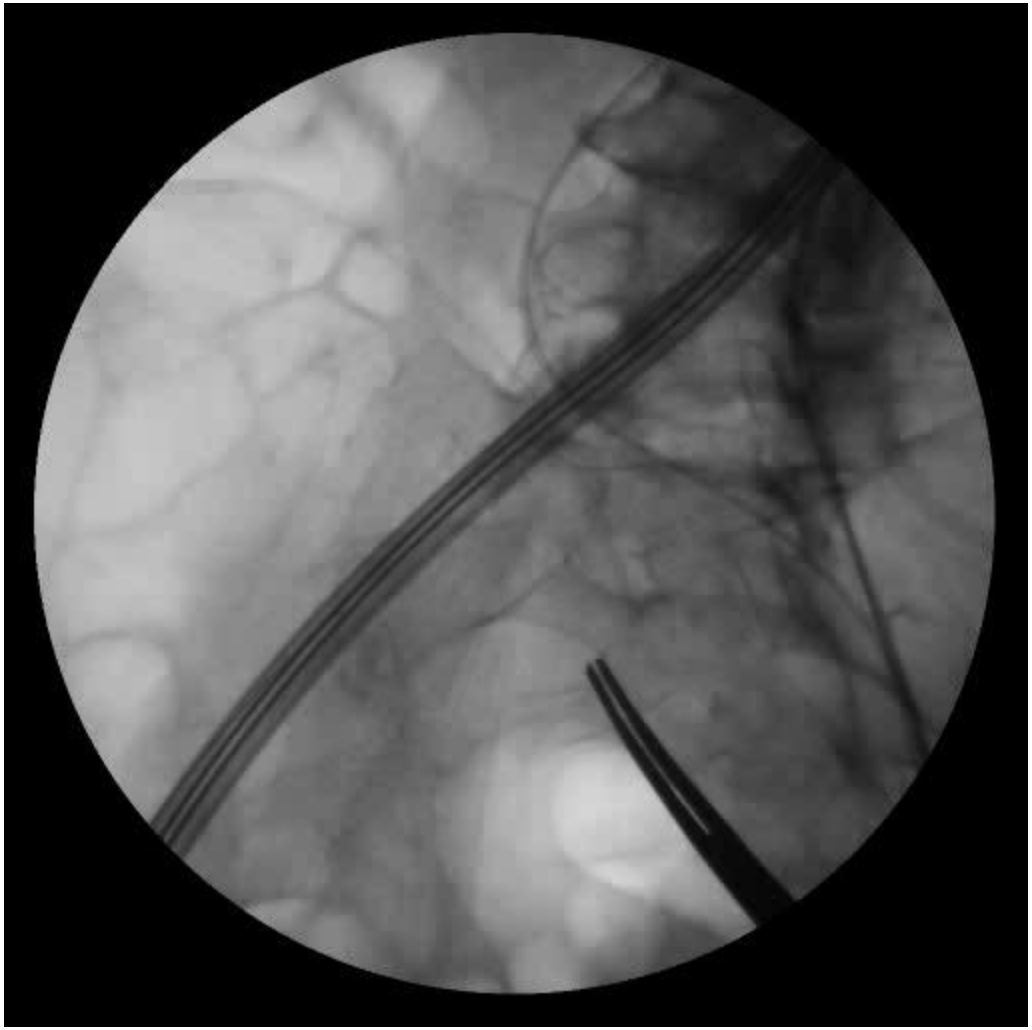


Angulated aortic arch-descending aorta junction



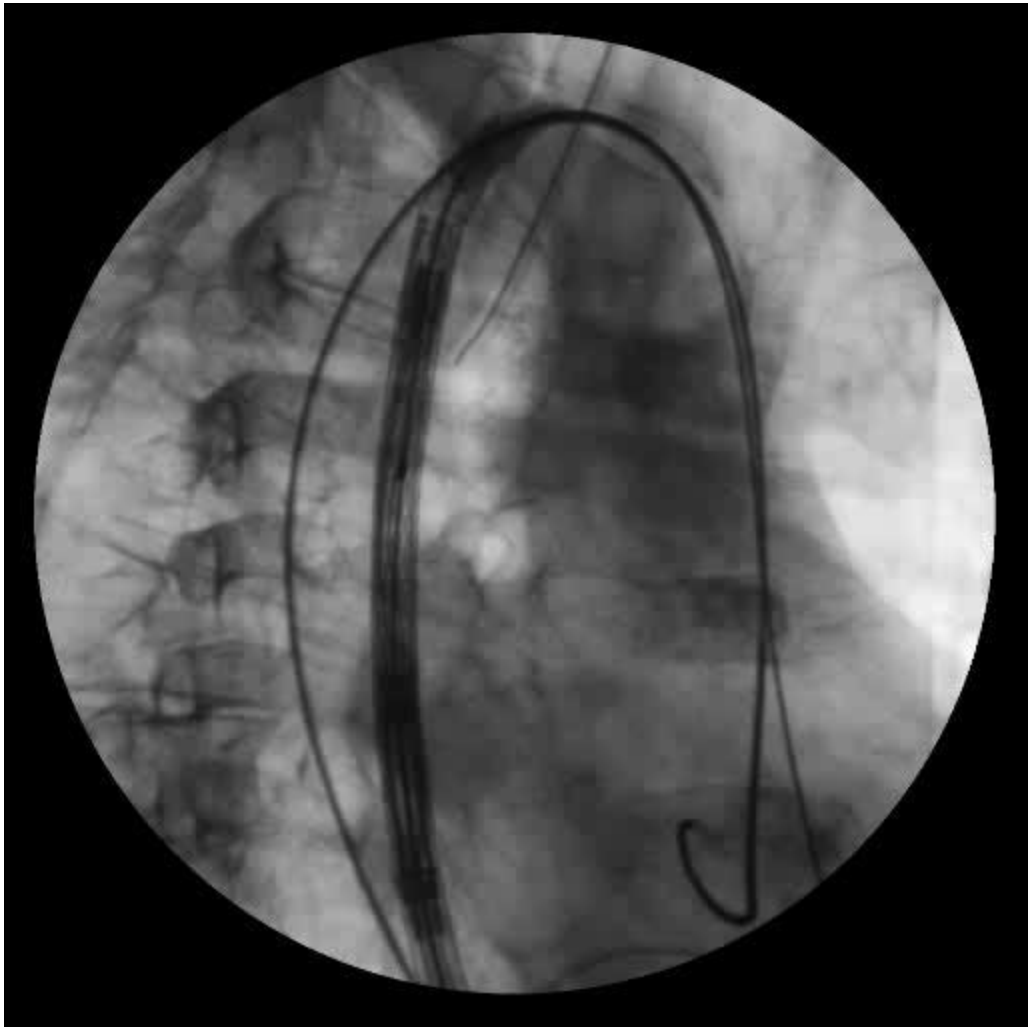
MSCT

Tortuosity of ilio-femoral axis



Failure of advancing delivery system

Failure of advancing delivery system



Lotus™ Valve System
Product Pipeline & Design Goals*

Boston Scientific
Advancing science for life™

2013

23 & 27 mm Lotus

23mm 27mm

Safari Wire

2014

25 mm Lotus

25mm

Expandable Sheath Compatibility*

Direct Aortic Feasibility *

2015 & beyond

Small Curve Safari *

NG Lower Profile Delivery System *

- Assured Locking
- Flexibility & Trackability
- Reduced GW Interaction

New Lotus Dedicated Sheath Technology *

21 & 29 mm Lotus *

21mm

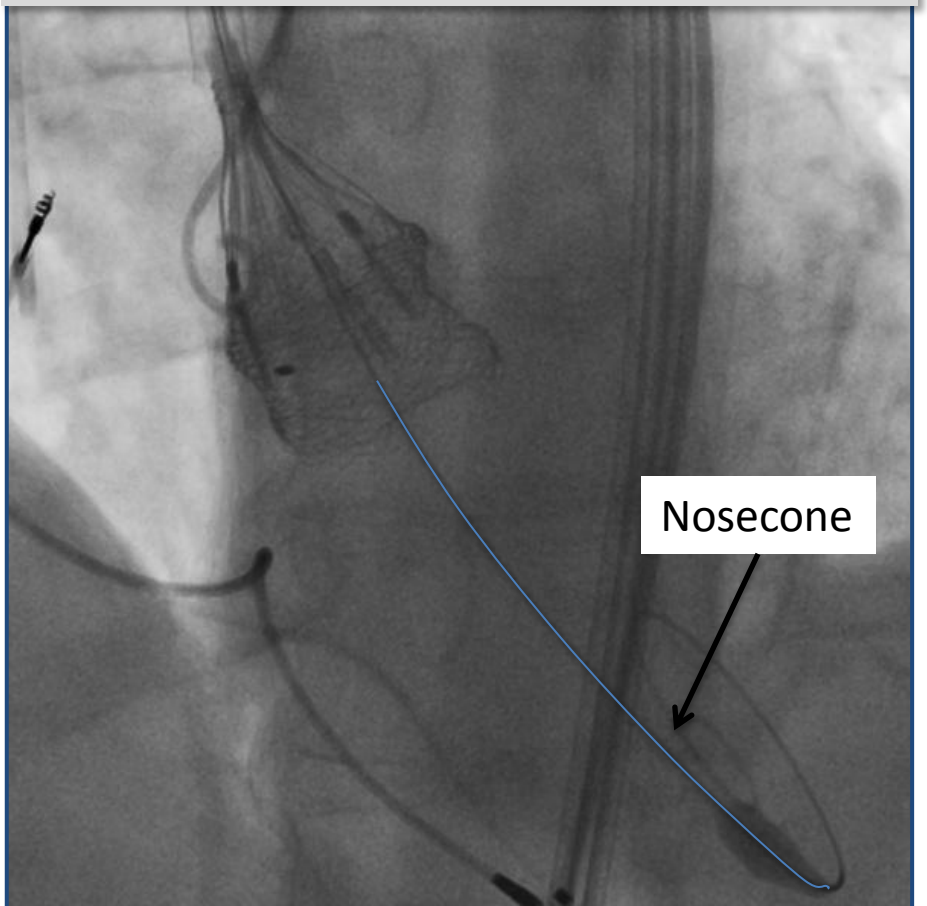
29mm

* Future Lotus product portfolio and are only displayed for informational purposes, not available for sale

Thank You
for your attention

Guidewire Management is Important Throughout Procedure

Nosecone Length (Annulus to Nosecone)	
23 mm	64 mm
25 mm	67 mm
27 mm	69 mm



Nosecone extends significant distance into ventricle during final phases of deployment

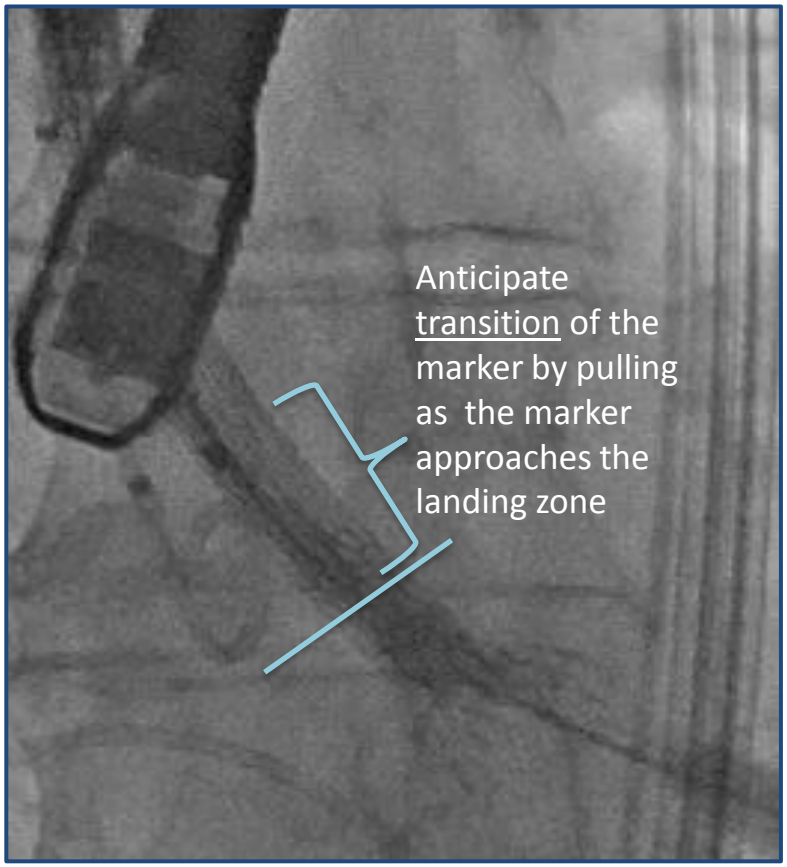
Ensure nosecone tracks smoothly away from apex

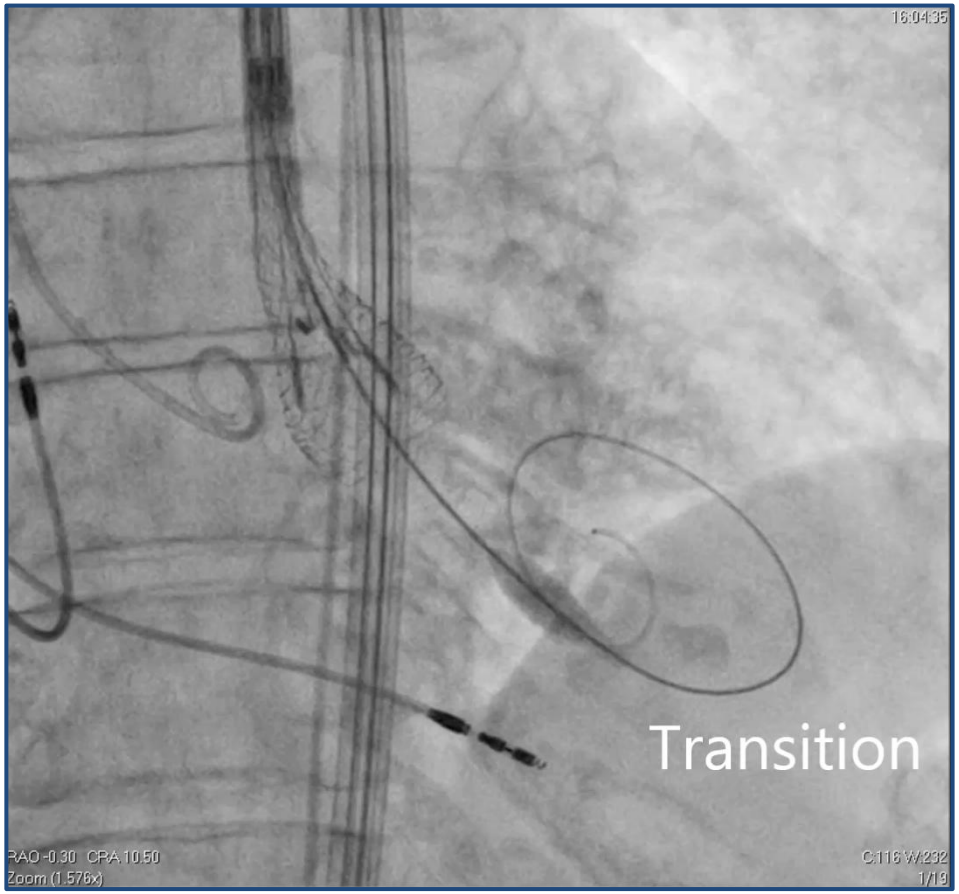
Avoid wire bias and resulting stress on ventricle

- Continuously monitor wire position, keep it “circular” and be ready to shorten wire, e.g., pull it back out of ventricle as nosecone goes forward to avoid accumulating wire in ventricle

Transition to Expansion

- Anticipate the transition phase – when the marker is close to the top of the pigtail
  - Apply **slight backward tension**, while continuing to unsheath the valve
- Allow the marker to land at the "Landing Zone" (approximately 5-6mm above the annular plane)



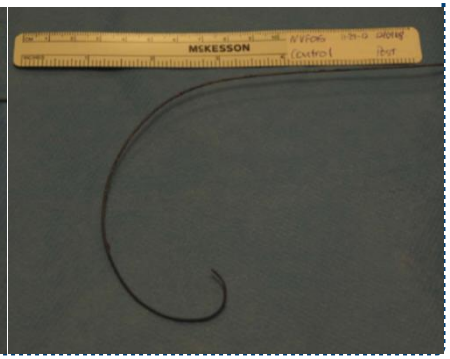


Review: Lotus Valve System

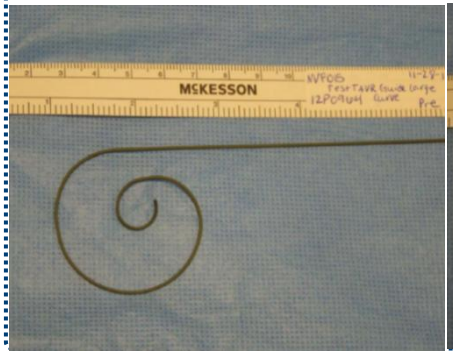
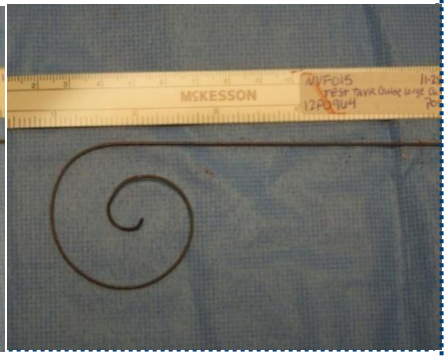
- Radiopaque marker in center of nitinol braid is used to position Lotus Valve
- Controlled mechanical expansion - as valve shortens in length, it expands in diameter
- Locking step is reversible - locked valve can be unlocked and resheathed

Safari™ Guidewire
Shape Retention Testing

Amplatz Super Stiff Wire

Before Use	After Use
	

Safari Pre-Formed Wire

Before Use	After Use
	

- Amplatz showed a 55% increase in diameter versus only 5% for Safari*
- Difference is evident even when using different shaping techniques

Safari Demonstrates Superior Shape Retention

*Shape retention study with Amplatz 260cm Super Stiff and Safari 260cm large curve guidewires, n=1 of each wire. Data on file.