

# The Lotus Valve

Value of a Re-sheathable, Repositionable, Fully Re-capturable and Removable TAVR Device

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# Eberhard Grube, MD

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

<u>Physician Name</u>	<u>Company/Relationship</u>
Eberhard Grube, MD	Medtronic, CoreValve: C, SB, AB, OF Direct Flow: C, SB, AB Mitralign: AB, SB, E Boston Scientific: C, SB, AB Biosensors: E, SB, C, AB Cordis: AB Abbott Vascular: AB InSeal Medical: AB, E, Valtech: E, SB, Claret: SB Keystone: AB

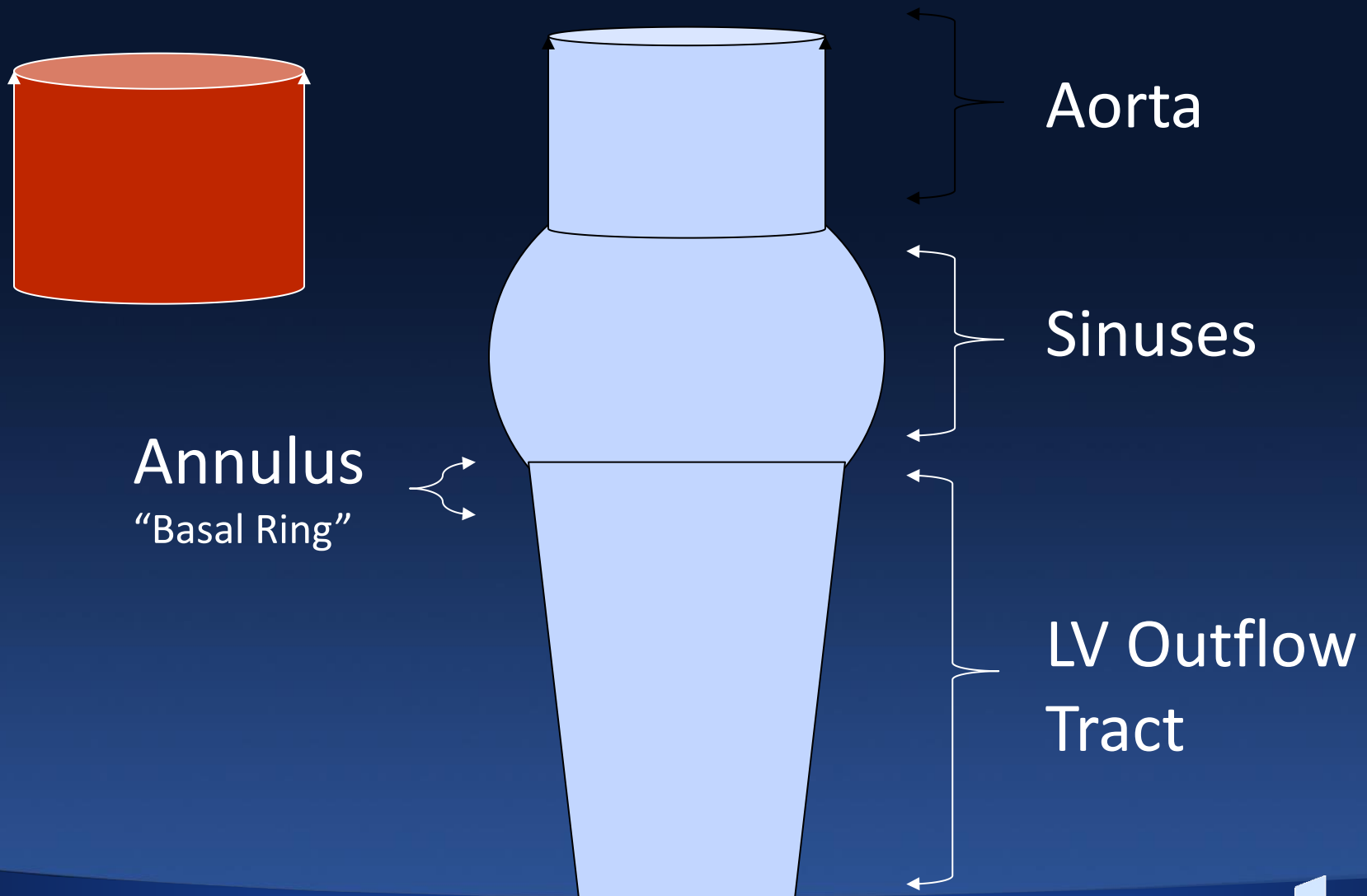
Key

G – Grant and or Research Support   E – Equity Interests   S – Salary, AB – Advisory Board  
C – Consulting fees, Honoraria   R – Royalty Income   I – Intellectual Property Rights  
SB – Speaker's Bureau   O – Ownership   OF – Other Financial Benefits<sup>1</sup>

# Consequence of Sizing Errors in TAVI Planning

- Paravalvular leak
- Valve embolization
- Conversion to high risk surgery
- Ectopic valve deployment
- Valve in Valve
  - Coronary occlusion
  - Pacemaker implantation
  - CVA

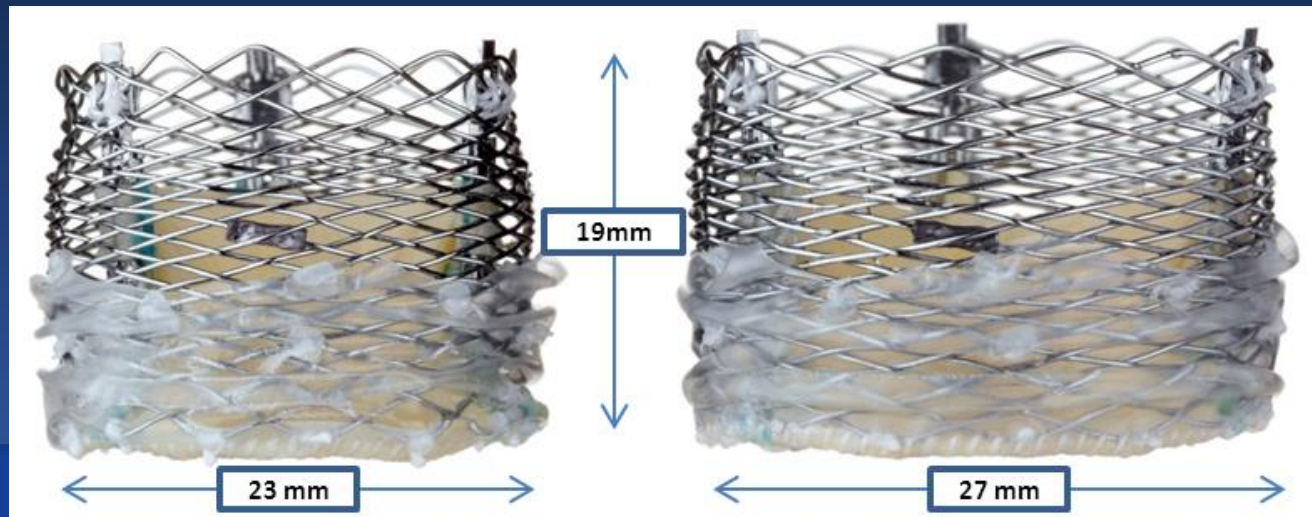
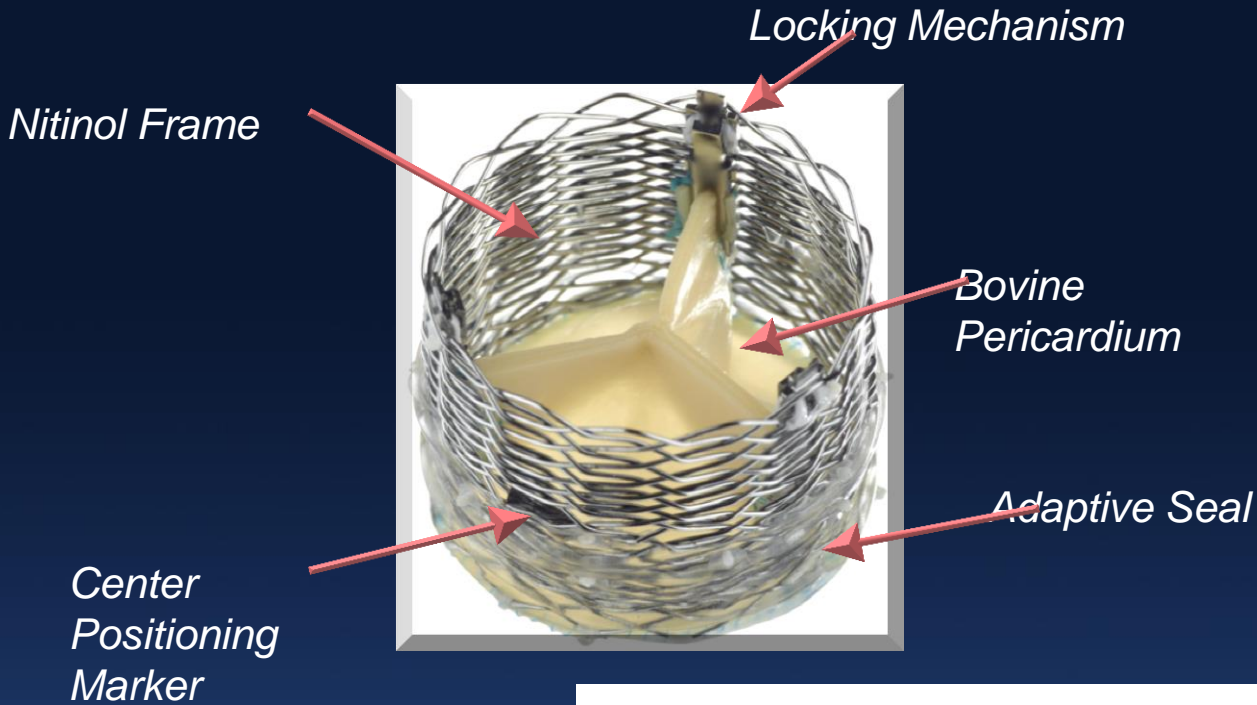
# Tips and Tricks in Aortic Valve Sizing



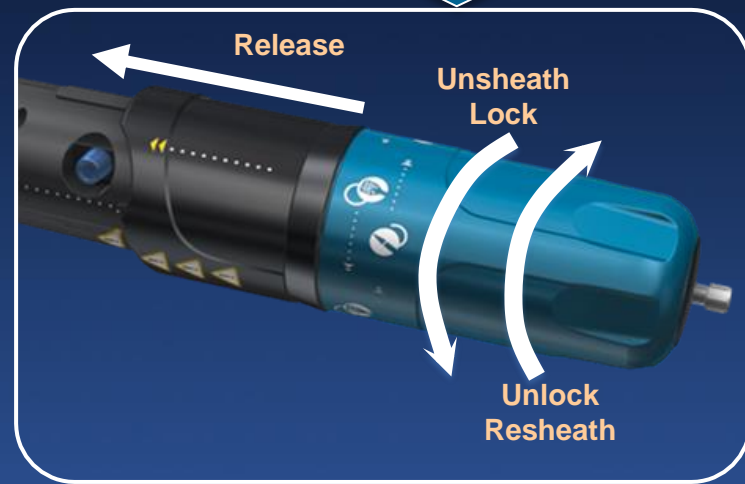
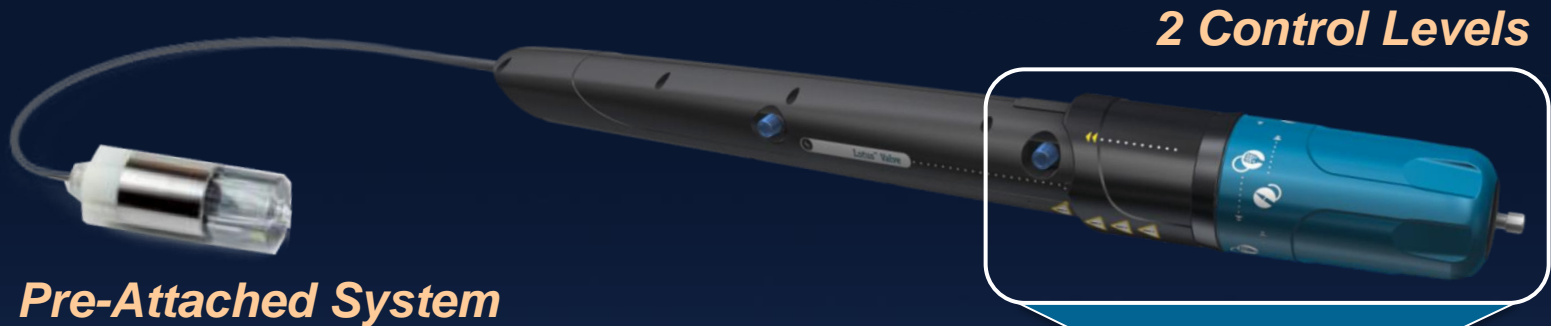
# Tips and Tricks in Aortic Valve Sizing



# Boston Scientific Lotus Device



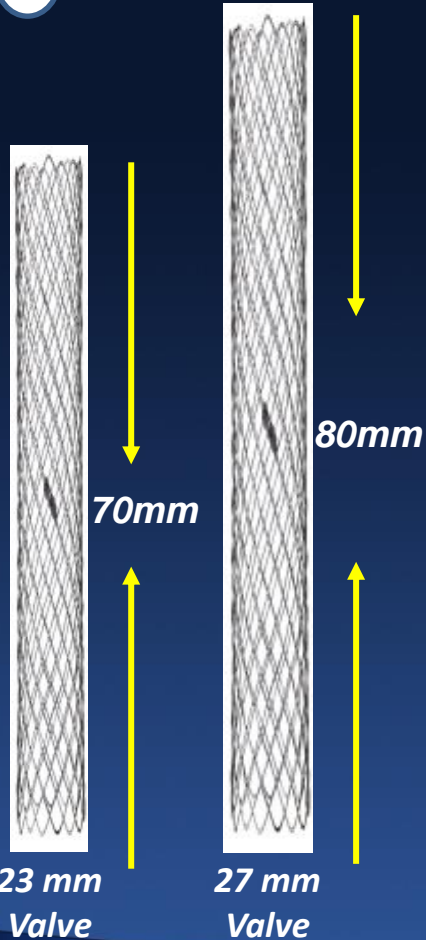
# Lotus Valve System Design Features



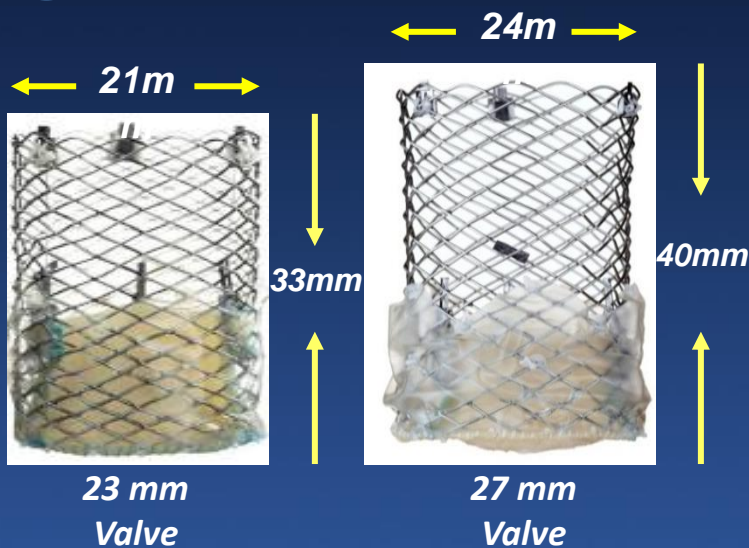


# Lotus Valve System Deployment Phases

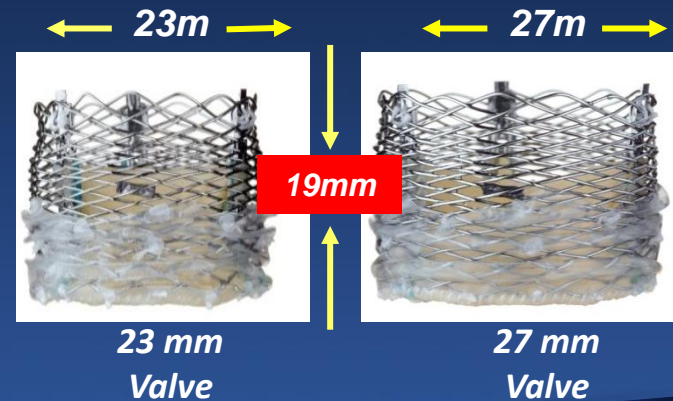
## 1 Elongated Configuration (for Delivery)



## 2 Intermediate Configuration

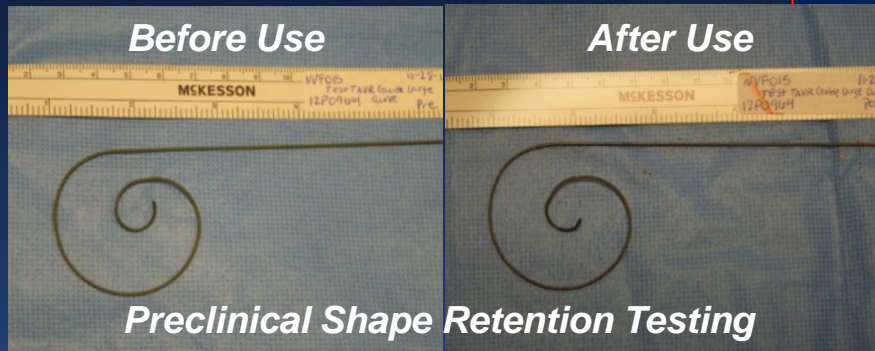
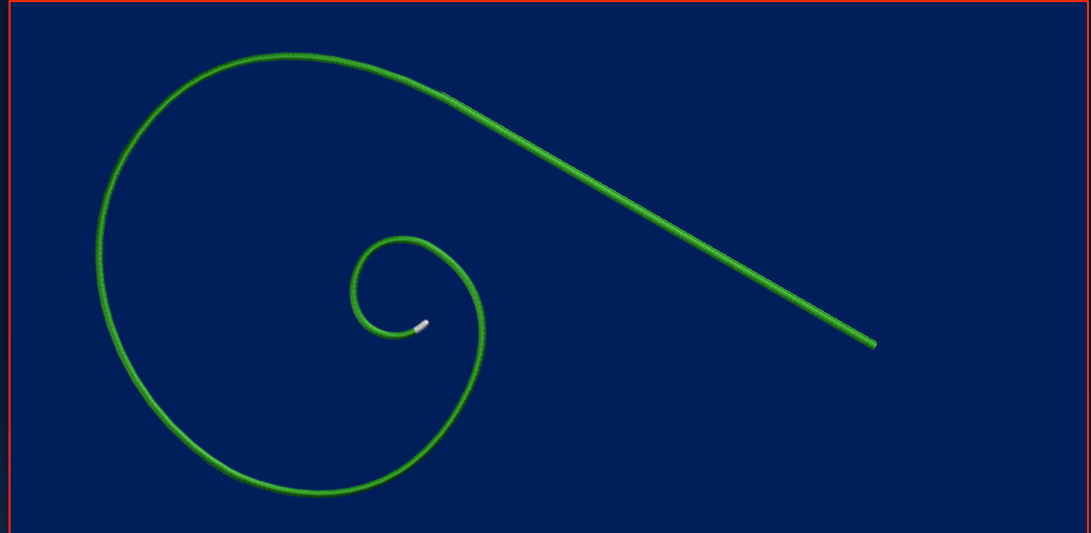
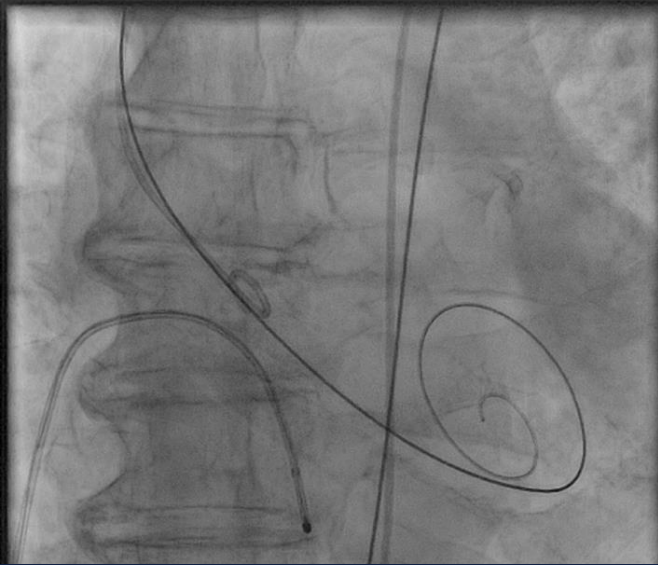


## 3 Final Locked Configuration

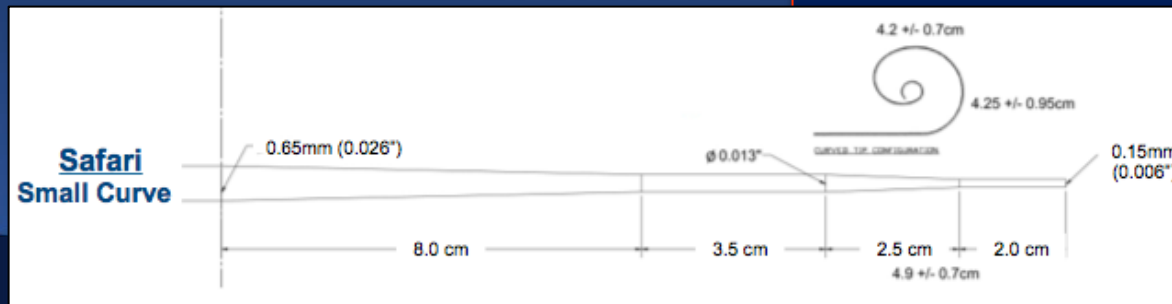




# Safari Guidewire



- **Pre-shaped architecture designed for consistent, reliable performance**
- **Double curve designed to facilitate stable, atraumatic placement**
- **PTFE coating allows for less force during device delivery**

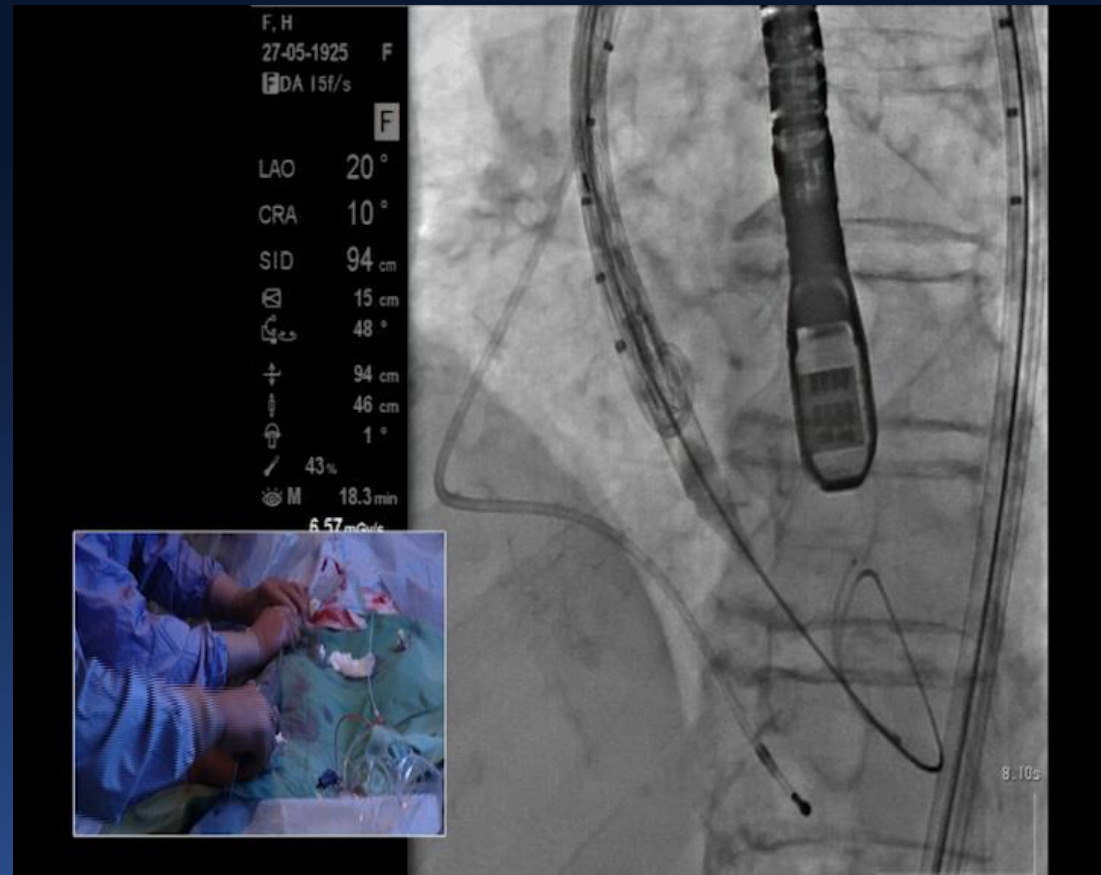


- **Two curve sizes accommodate varying anatomies and systolic contractions of left ventricle**

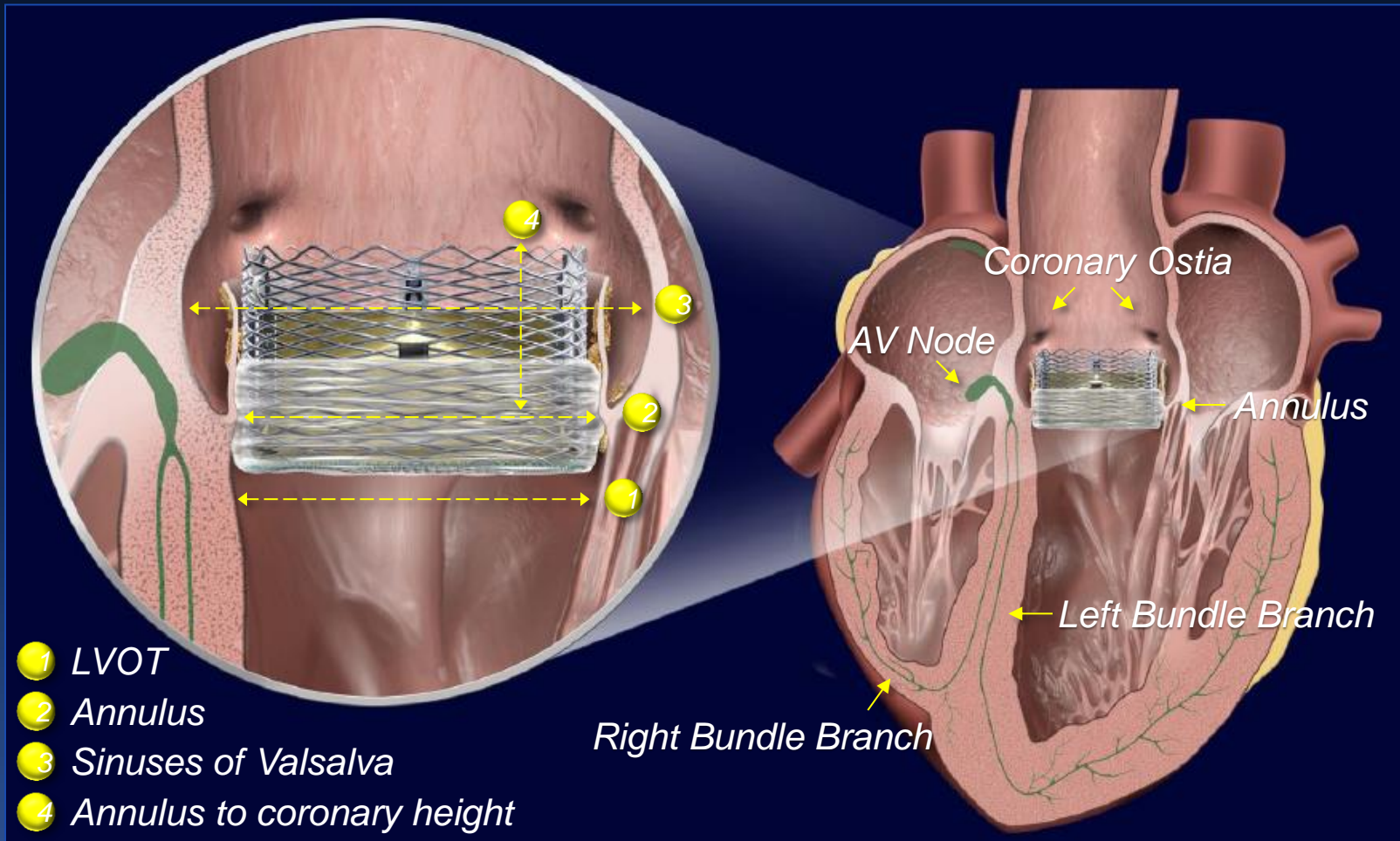
# Lotus Valve System

## Controlled Mechanical Expansion

- *Valve deployed via controlled mechanical expansion.*
  - ➔ *Neither balloon expandable nor self-expanding.*
- *No rapid pacing during deployment*
- *Valve functions early*
- *No valve movement on release*



# LOTUS Valve In Situ



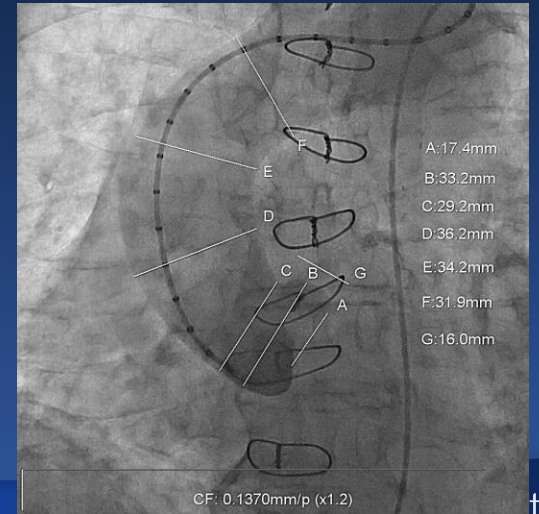
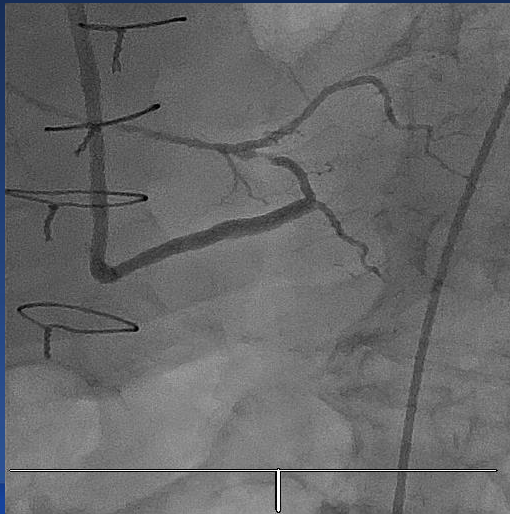
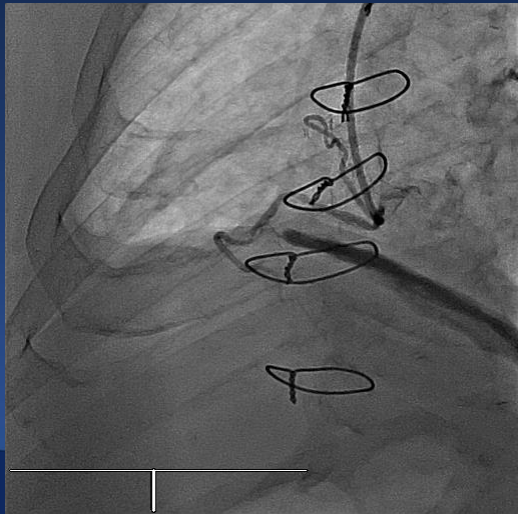
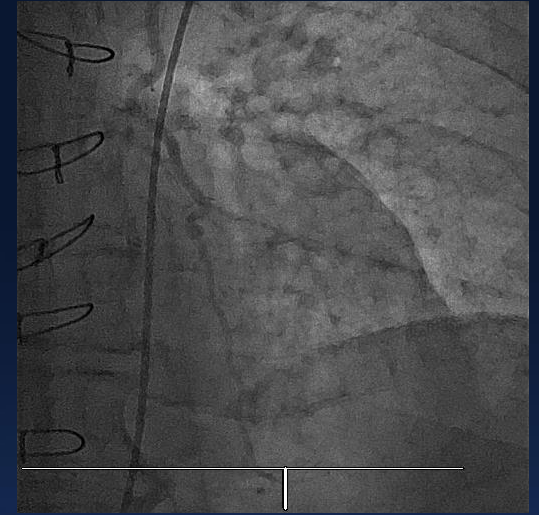
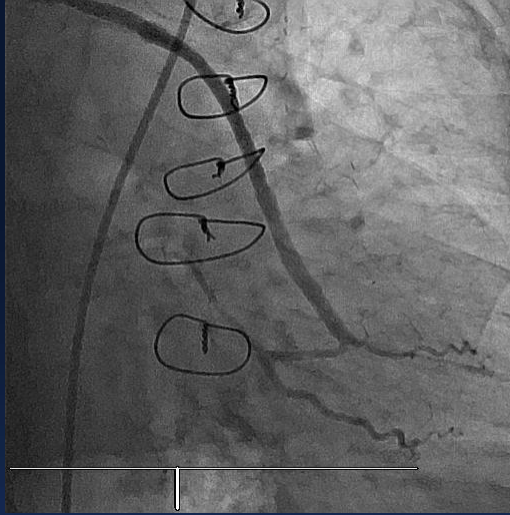
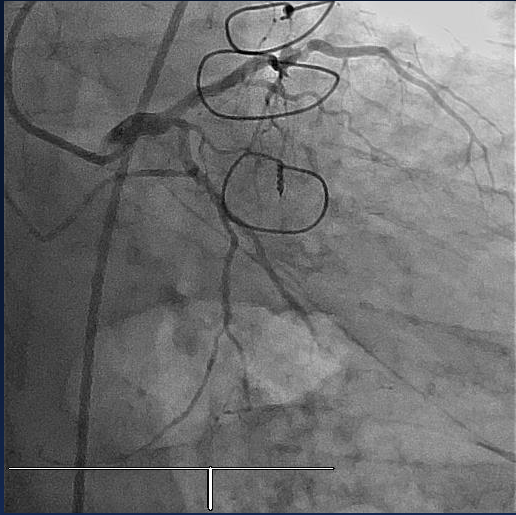
# Case History

- **83-year-old male with severe aortic stenosis**
  - Height/Weight (metric units): 163 cm, 72 kg, BMI 27.1
  - NYHA class III
  - Aortic valve area 0.35 cm<sup>2</sup>/m<sup>2</sup>, Mean gradient 50 mmHg
  - Previous CABG
  - Open Prostatectomy, HT, Hyperlipidaemia
- **Deemed high surgical risk by the Heart Team**
  - STS Mortality 6.8%, EuroSCORE II 7.14%
  - Frail (5 meter gait speed 8.2 sec, Hand grip 12.8 kg)



# Routine Investigations

## Angiographic Screening & Measurements



# Routine Investigations

## Angiographic Screening & Measurements



- R Femoral percutaneous access.



# Routine Investigations

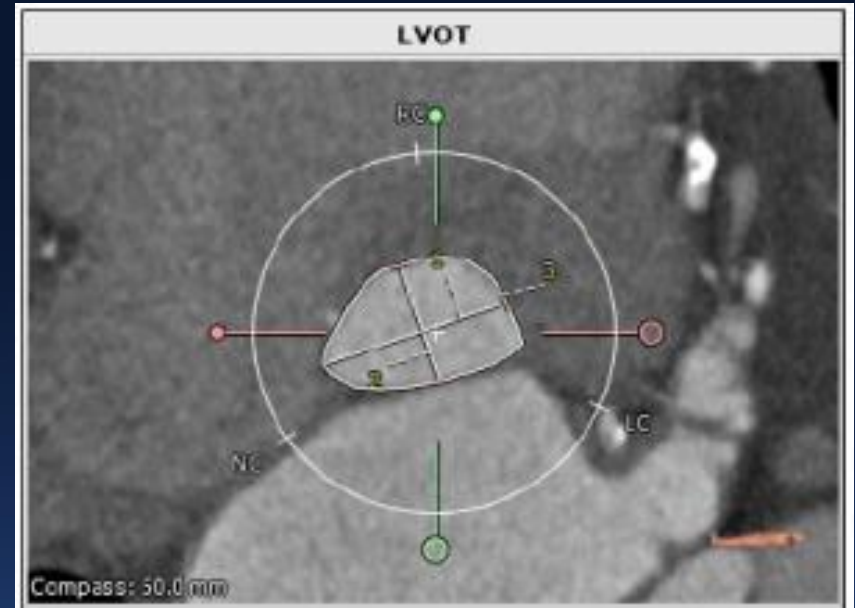
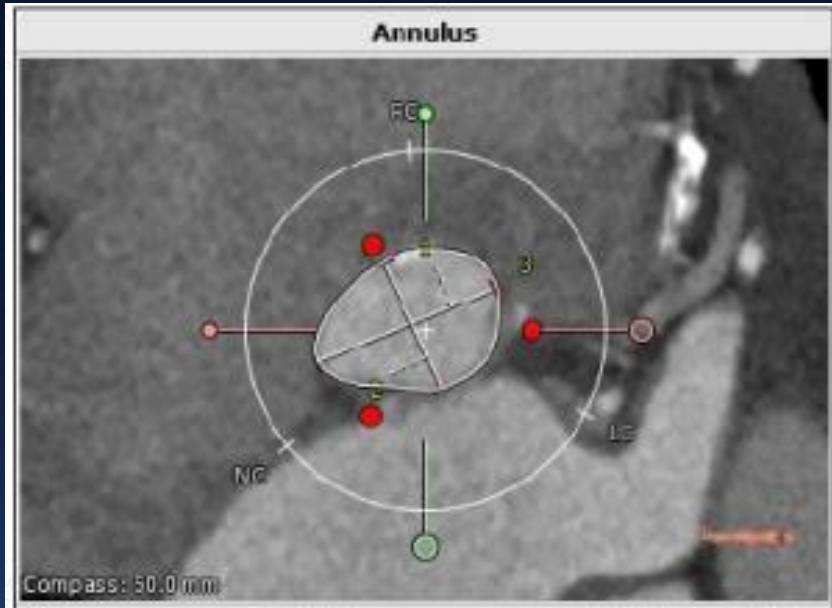
## Echocardiogram Screening Measurements

Echocardiographic data:	
Aortic Valve Area	0.6 cm <sup>2</sup> 0.35 cm <sup>2</sup> /m <sup>2</sup>
Mean and Peak Pressure Gradient	50 mmHg 102 mmHg
Peak Velocity	5.0 m/s
LVEF	60%
AR/MR/TR	Mild AR Mild MR Mild TR

# Routine Investigations

## CTA Screening & Measurements

### 3Mensio Annulus and LVOT Measurements



#### Basal Ring Diameter

Maximum	26.7 mm
Minimum	19.1 mm
Perimeter	22.9 mm (72.0 mm)
Area	22.1 mm (383.5 mm <sup>2</sup> )

#### Left Ventricular Outflow Tract Diameter

Maximum	26.2 mm
Minimum	16.8 mm
Perimeter	22.8 mm (71.7 mm)
Area	21.4 mm (358.5 mm <sup>2</sup> )

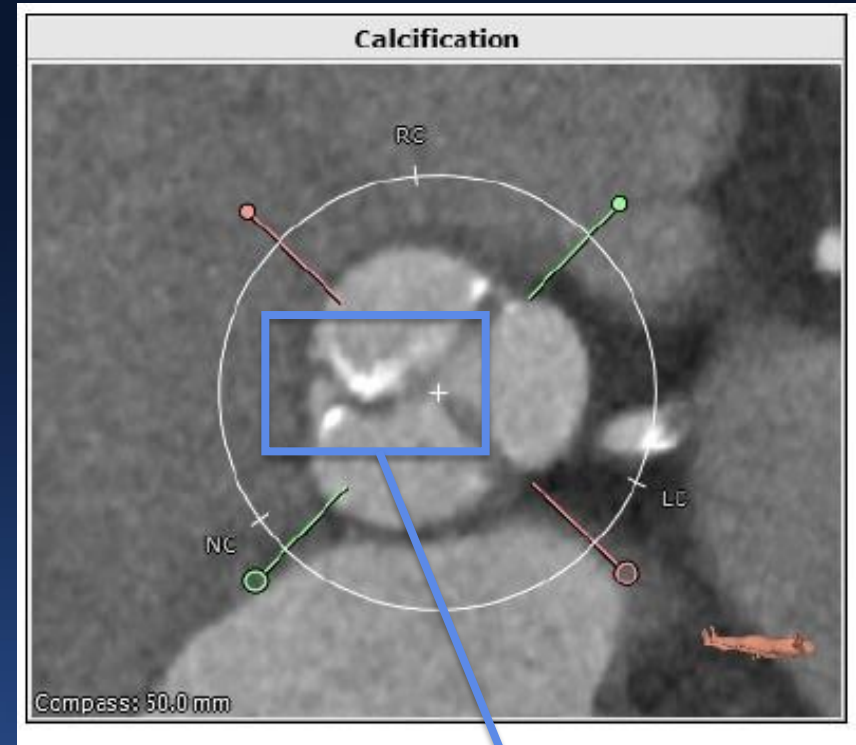
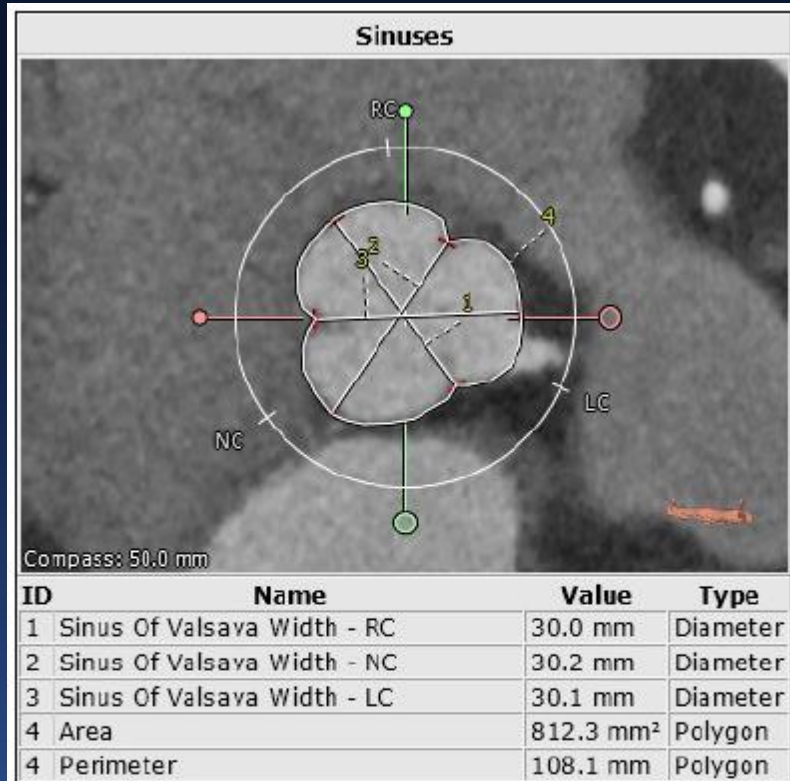
# Sizing Guidelines

CT Measuring for Patient Screening		Ideal 23mm case	"Grey Zone"	Ideal 27mm case
Actual Lotus valve	Diameter (mm)	23		27
	Perimeter (mm)	72.3		84.8
	Area (mm <sup>2</sup> )	415.5		572.5
Annulus	Diameter (mm)	20 ≤ ideal < 23.5	≥ 23.5 to < 25	25 ≤ ideal ≤ 27
	Perimeter (mm)	66 < ideal < 74	≥ 74 to < 78	78 ≤ ideal < 85
	Area (mm <sup>2</sup> )	350 < ideal < 420	≥ 420 to < 480	480 ≤ ideal < 580
LVOT	Diameter (mm)	19 < ideal < 22	≥ 22 to < 25	25 ≤ ideal < 27
	Perimeter (mm)	65 < ideal < 72	≥ 72 to < 78	78 ≤ ideal < 85
	Area (mm <sup>2</sup> )	340 < ideal < 420	≥ 420 to < 460	460 ≤ ideal < 550
	<b>Area of caution</b>	caution < 300 possibly unsuitable < 280		caution > 600 unsuitable > 650
SOV	<b>Concern? too small</b>	< 540		< 650
	Ideal area (mm <sup>2</sup> )	600 - 800		800 - 1000
	Generous area (mm <sup>2</sup> )	800 - 1000		1000 - 1200
	<b>Concern? too large</b>	> 1100		> 1300
Annulus to Coronary Height	Ideal > 10mm	ideal > 12mm but the larger the sinus area, the less concerning this metric becomes		ideal > 10mm but could be marginally less if sinus capacity is large
Choosing in the "Grey Zone" between 23mm and 27mm	Annulus	← SMALLER	Annulus → LARGER →	
	LVOT metrics	← SMALLER	LVOT Size → LARGER →	
	SOV metrics	← SMALLER	Sinus Size → LARGER →	
	Burden of calcium	← MORE CALCIFIED	Calcium → LESS CALCIUM →	

# Routine Investigations

## CTA Screening & Measurements

### *Further Anatomic Considerations*



*Minimal calcification*

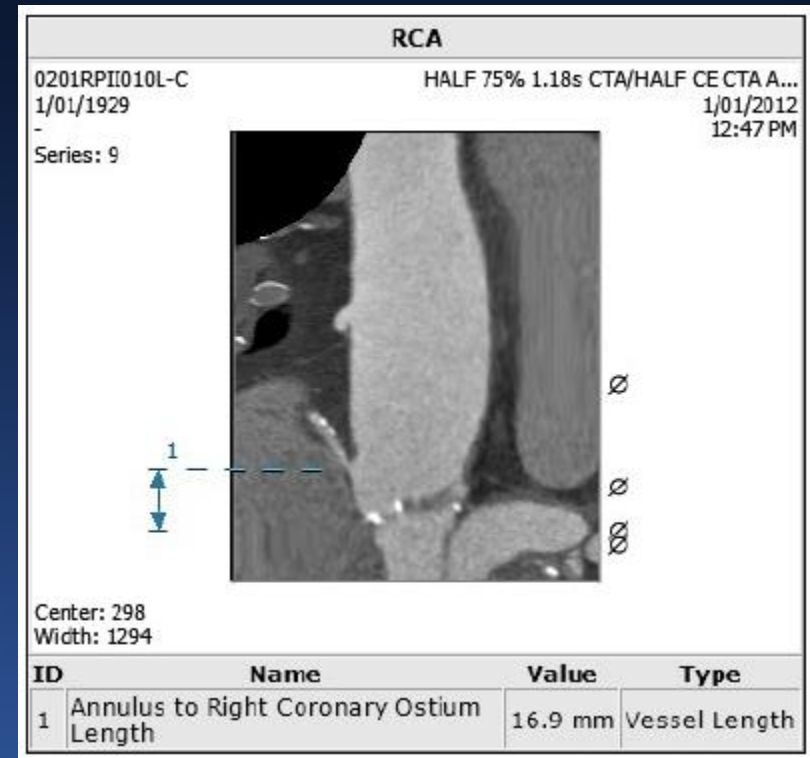
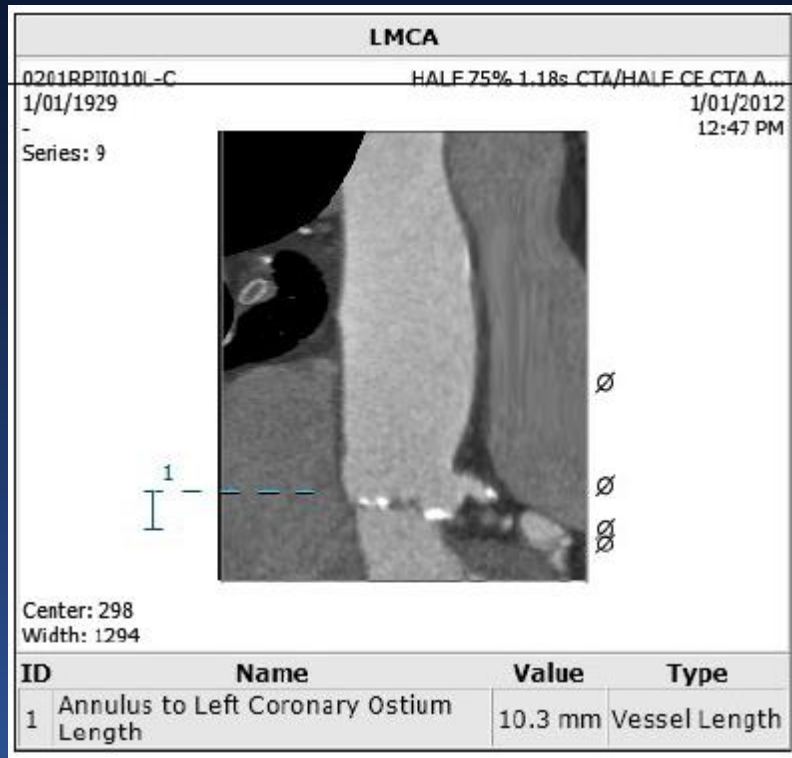
# Routine Investigations

## CTA Screening & Measurements

### Annulus to Coronary Heights

Height from Annulus to Lowest edge of Left Coronary Ostium = 10.3 mm

Height from Annulus to Lowest edge of Right Coronary Ostium = 16.9 mm



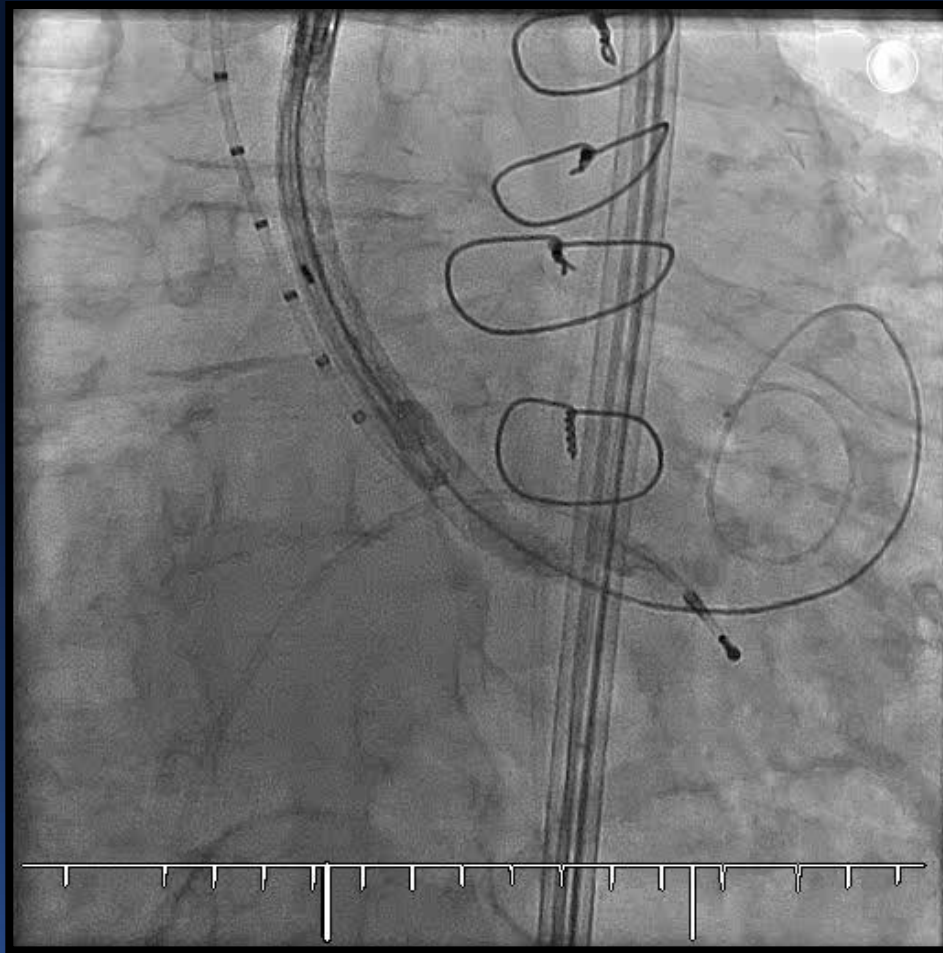
# Routine Investigations

## CTA Screening & Measurements





# 23 mm Lotus Deployment

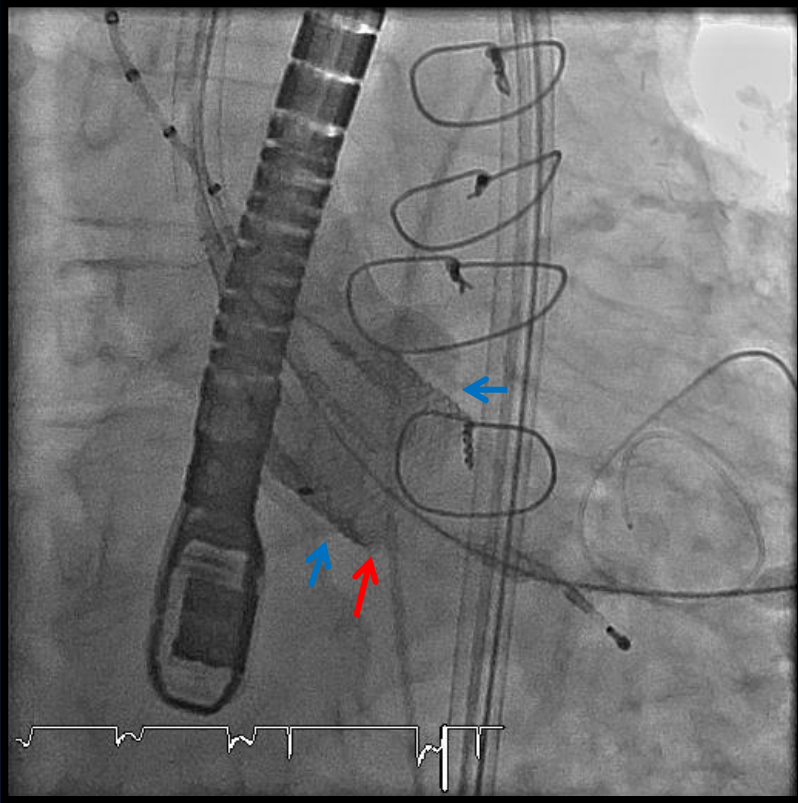


*Intuitive Handle Design*

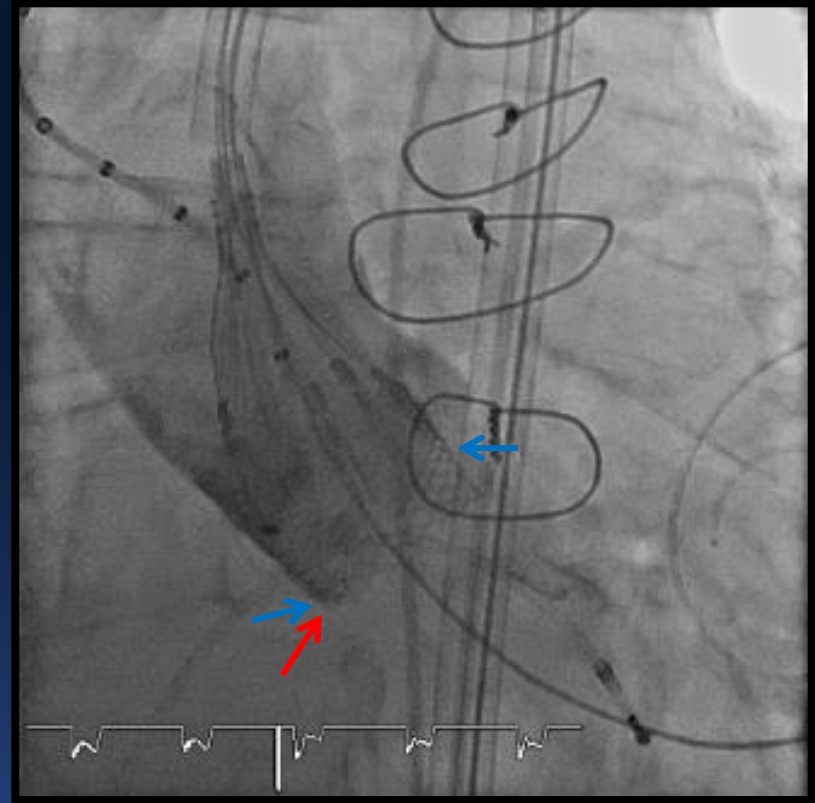
**2 Controls**



# 23 mm Lotus Deployment

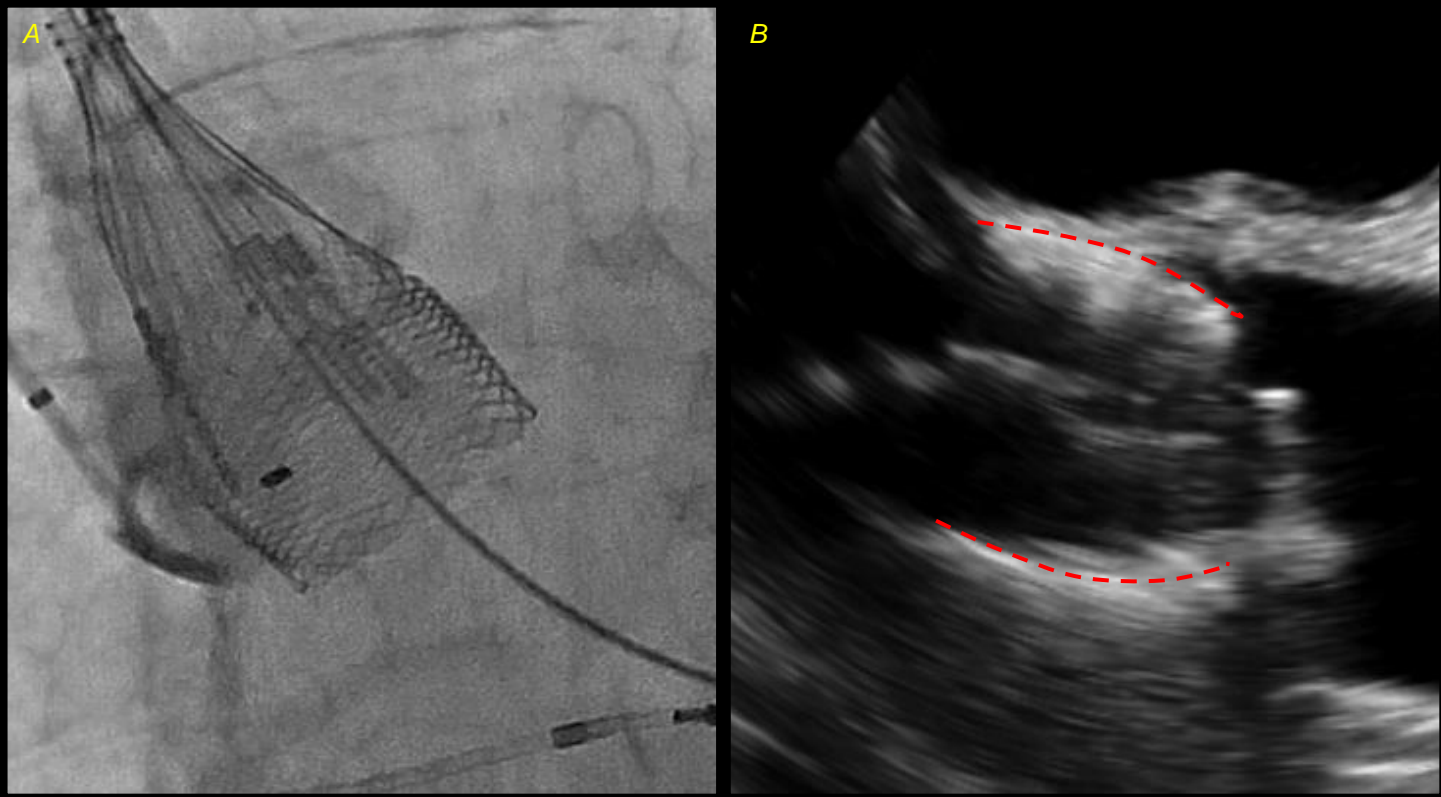


Despite only trivial AR the 23 mm valve did not form a waist



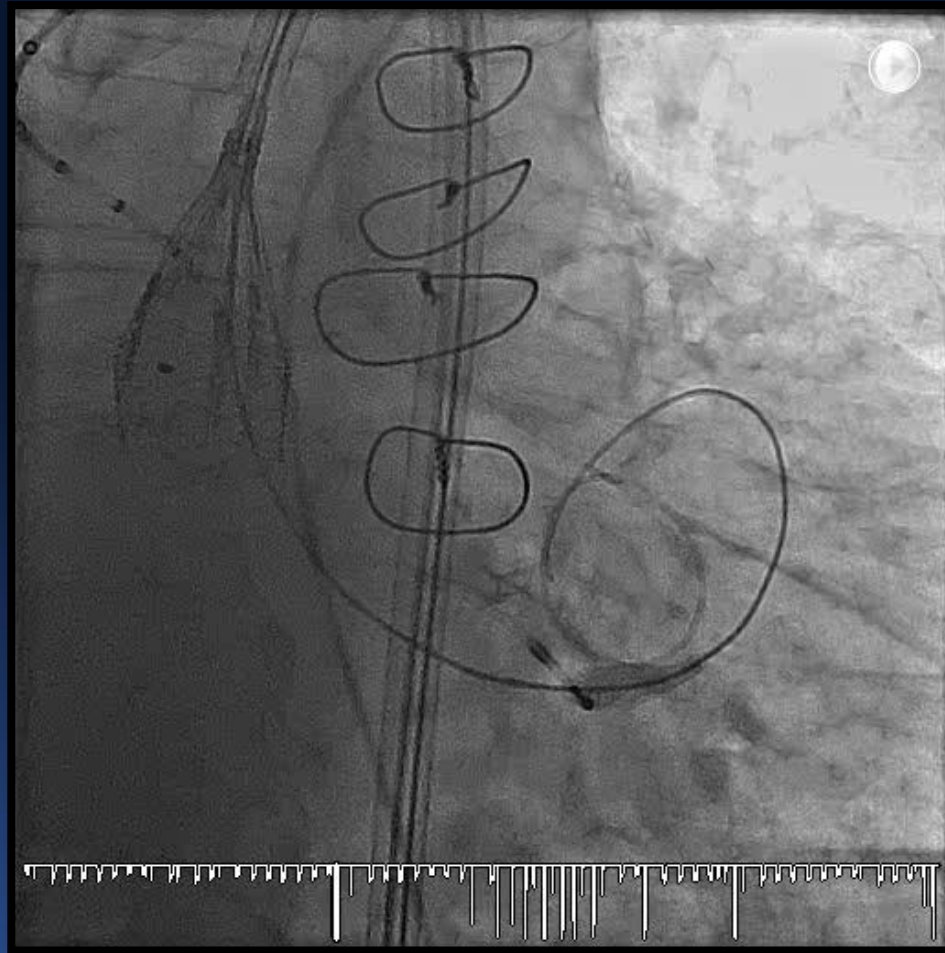
*With minimal tension on the delivery catheter the valve dislodged on the non-coronary side*

# TOE Appearance



- Barrel shaped without any waisting

# Retrieval of the 23 mm Device

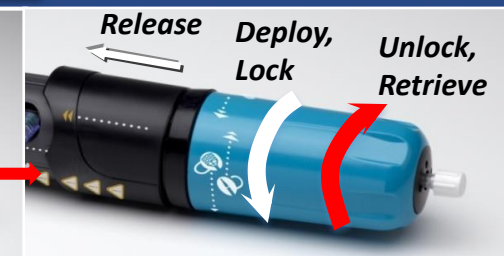


*Intuitive Handle Design*

**2 Controls**

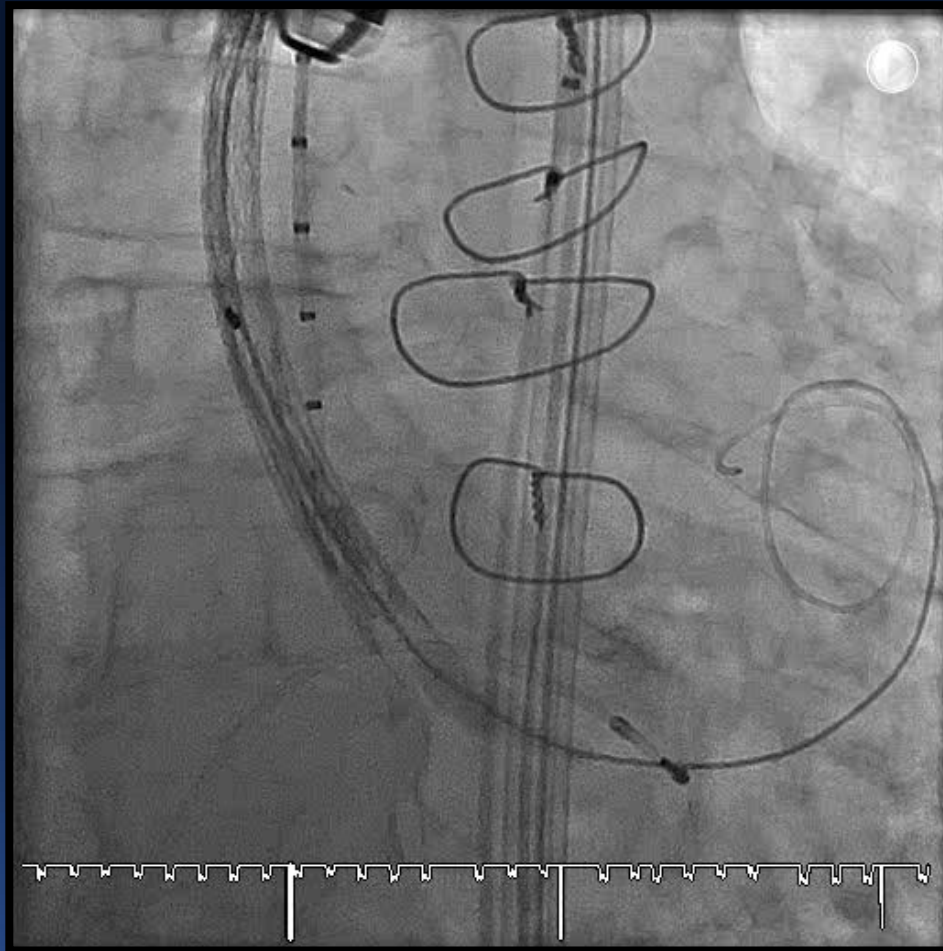


*Release*    *Deploy, Lock*    *Unlock, Retrieve*

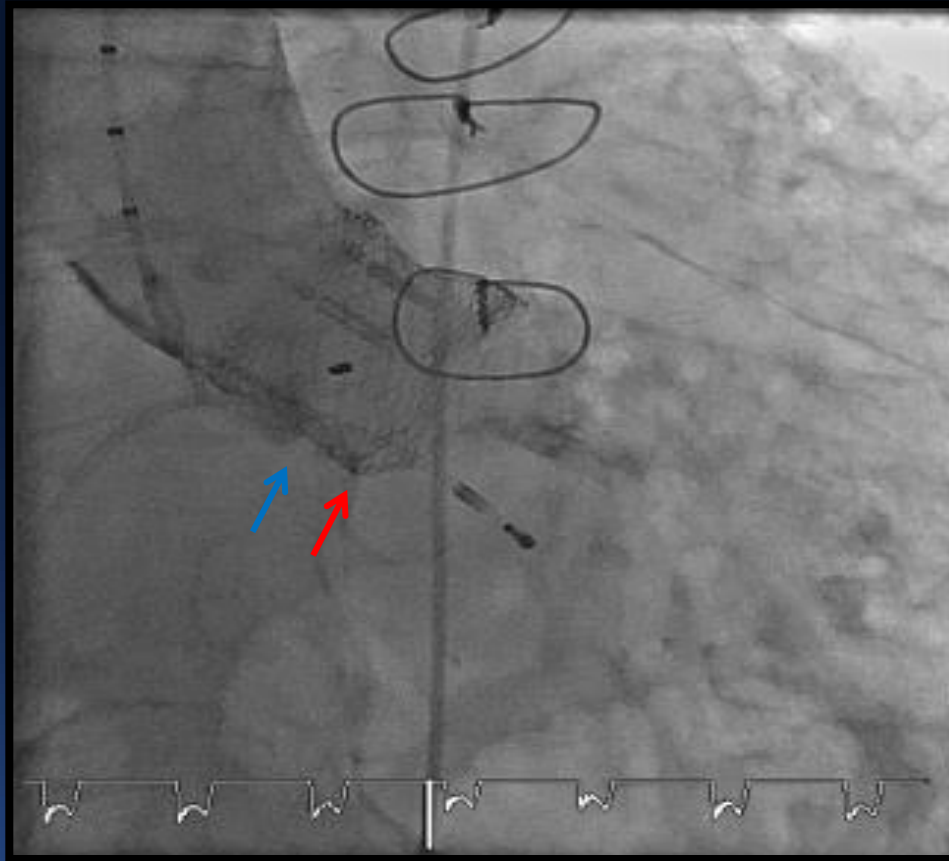




# 27 mm Lotus Deployment



# 27mm Lotus Final Position



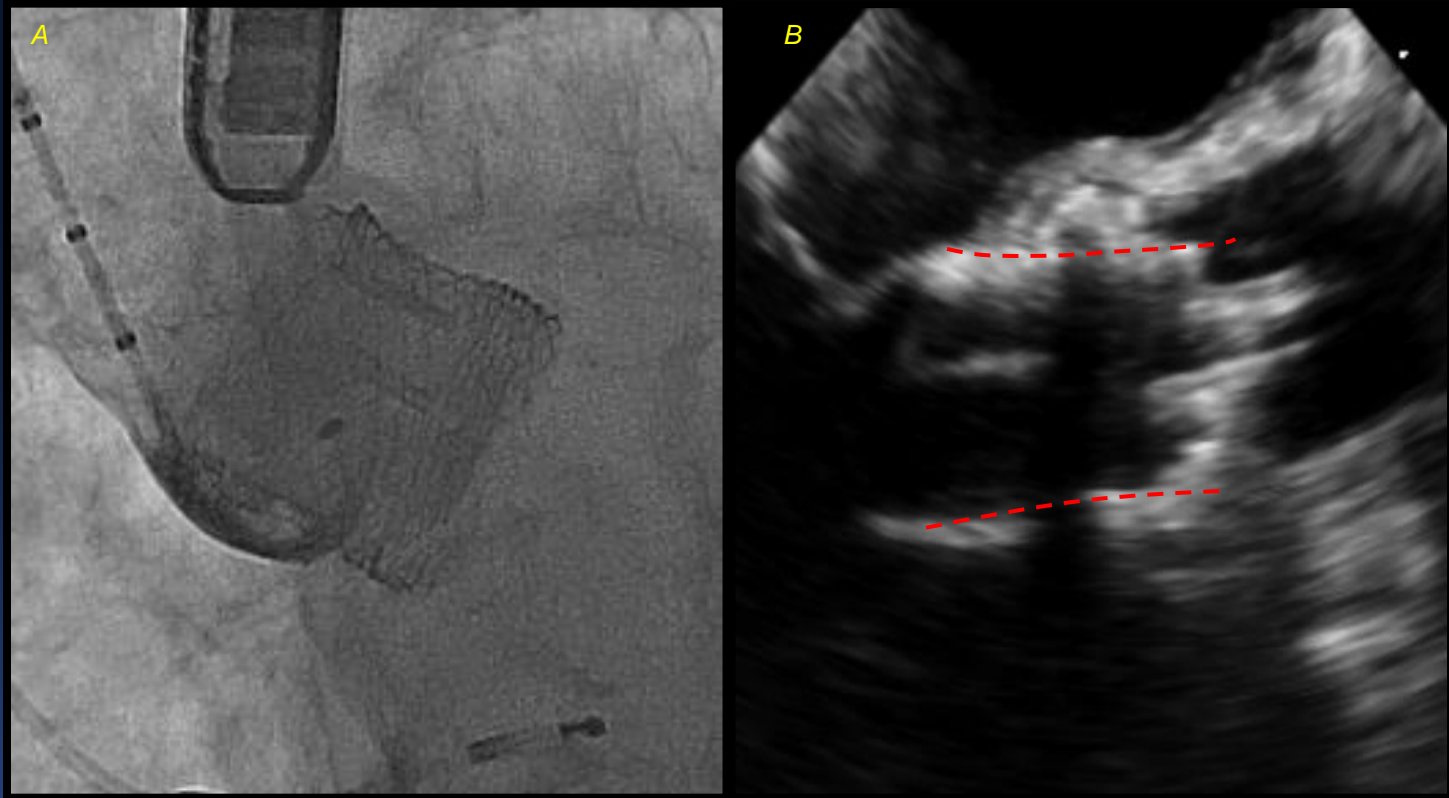
- Successful placement of a 27 mm SADRA Lotus device
- Slight “waist” with no AR



# Lotus Valve System: Fully Deployed



# TOE Appearance



- Mild waist at mid frame

# Lotus Clinical Program

## REPRISE I

*Feasibility Study; Acute Safety & Performance (Extreme/High Risk)*  
N=11; single arm; 23mm valve size  
Primary Endpoint: Device success (VARC-1) without MACCE  
Meredith et al, EuroIntervention 2014 Mar 20;9(11):1264-70

## REPRISE II

*CE Mark Study; Safety & Performance (Extreme/High Risk)*  
N=120; single arm; 23 & 27mm valve sizes  
Primary Device Performance Endpoint: Mean pressure gradient at 30d  
Meredith et al, JACC 2014; In Review

## REPRISE II Extension

*Safety & Performance Study (Extreme/High Risk)*  
N=130; single arm; 23 & 27mm valve sizes  
Primary Safety Endpoint: All-cause mortality at 30d  
Enrollment Complete

## RESPOND

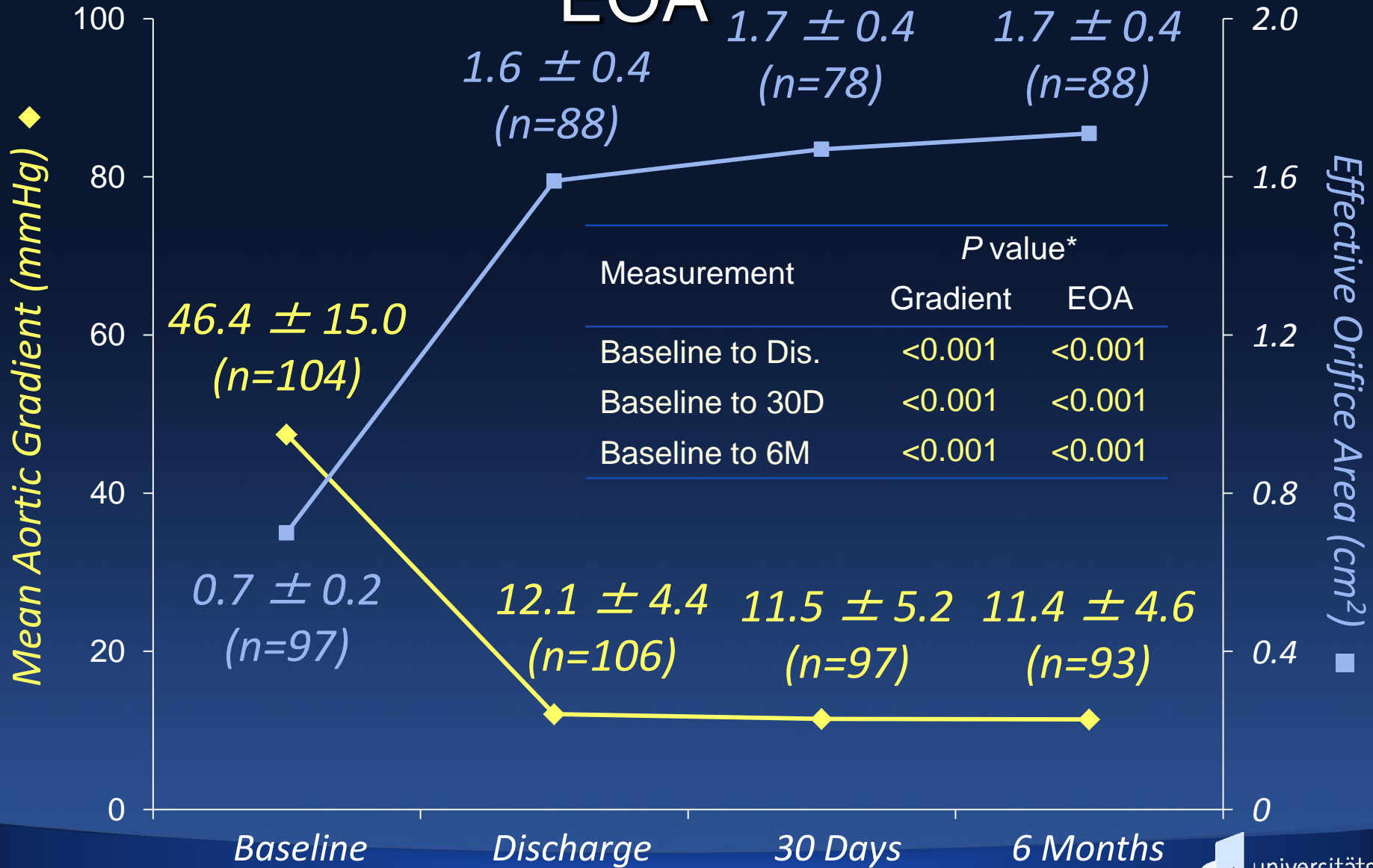
*Post Market Safety & Performance Study (Real World)*  
N=1000; single arm; 23, 25 & 27mm valve sizes  
Primary Endpoint: All-cause mortality at 30d & 1y  
Currently Enrolling

## REPRISE III

*FDA Approval Study; Safety & Efficacy (Extreme/High Risk)*  
N~1000; Global RCT vs. comparator; 23, 25 & 27mm valve sizes  
Anticipated start: 2H 2014

# REPRISE II Mean Aortic Gradient &

## EOA



# REPRISE II Trial

## 6-Month Safety Results

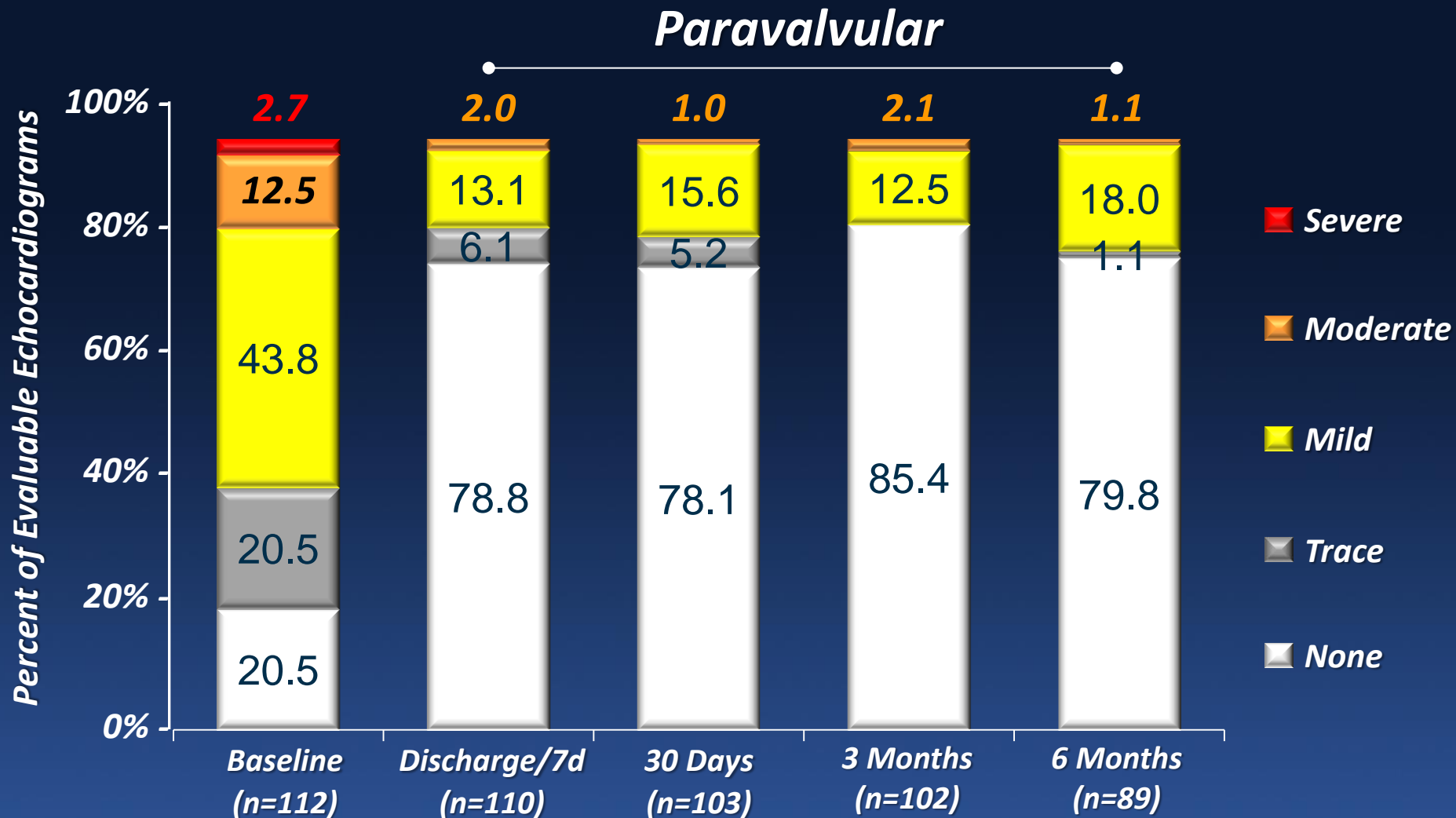
	Patients (N=119*)
All-cause mortality (Primary Safety Endpoint at 30 days)	8.4% (10/119)
Disabling stroke <sup>†</sup>	3.4% (4/119)
Myocardial infarction	3.4% (4/119)
Life-threatening or disabling bleeding	5.0% (6/119)
Major vascular complication	2.5% (3/119)
New permanent pacemaker	29.4% (35/119)
LVOT overstretch $\geq 10\%$	57.1% (20/35)
Annulus overstretch $\geq 10\%$	40.0% (14/35)

Ian Meredith AM, MBBS, PhD at EuroPCR 2014

TAVI Summit 2014

# REPRISE II Aortic Regurgitation

## Paravalvular Aortic Regurgitation Over Time

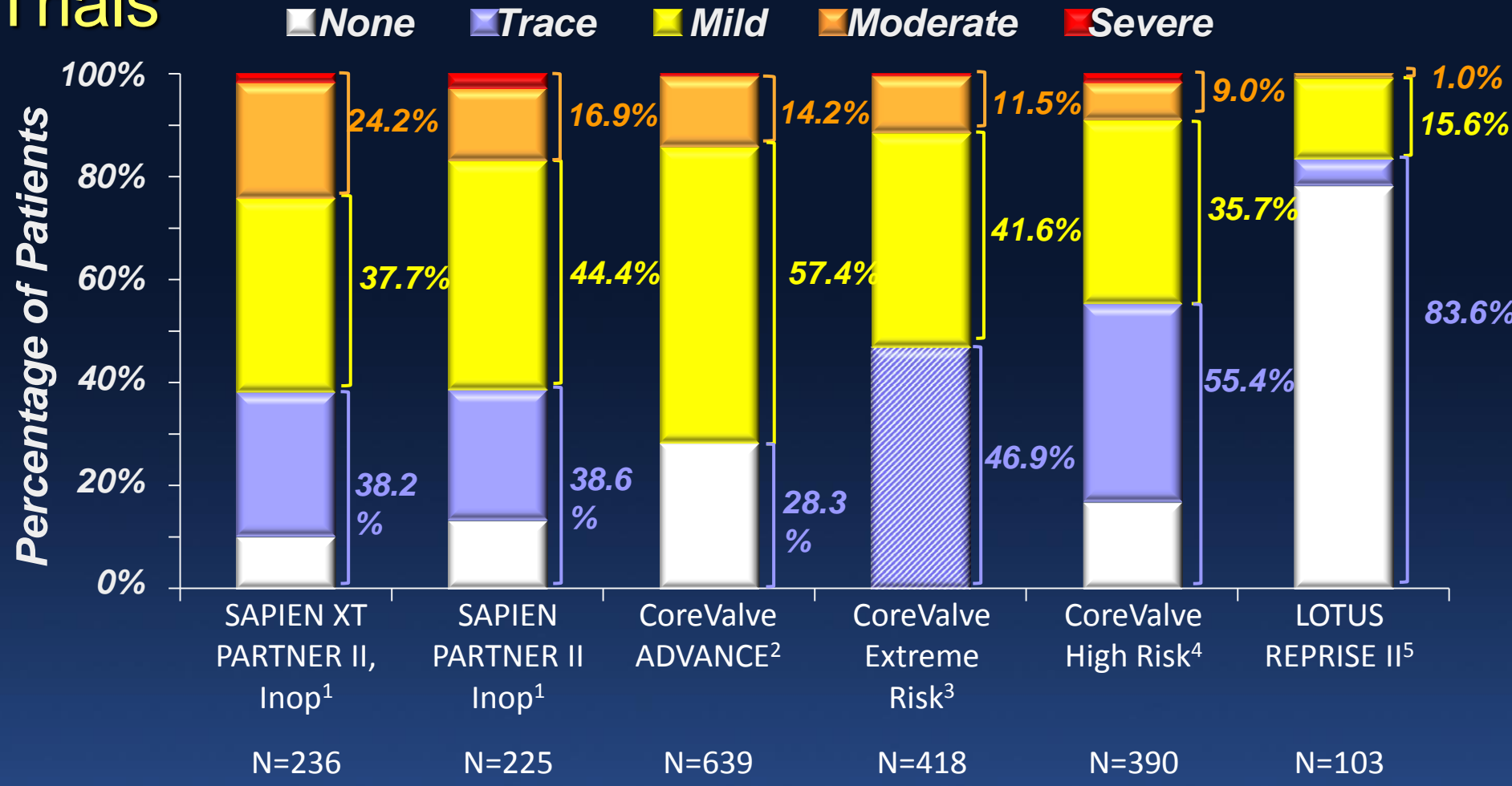


*No severe paravalvular aortic regurgitation post-implantation*



# 1-Month PVL in Core-Lab Adjudicated Clinical Trials

## Trials



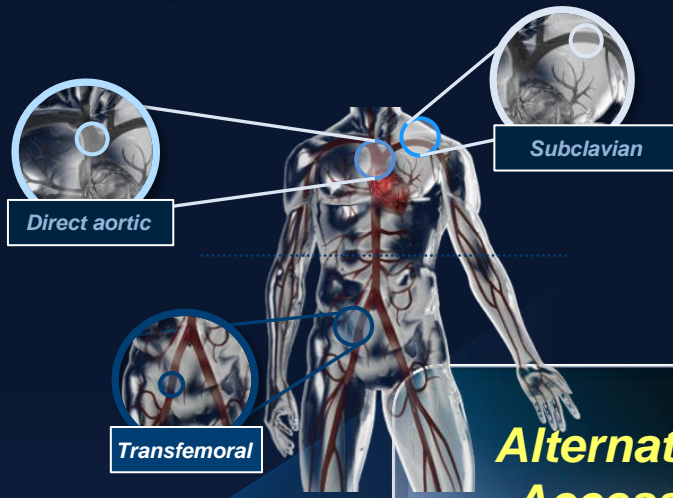
Mod & Sev PVL	SAPIEN XT	SAPIEN PARTNER II Inop <sup>1</sup>	CoreValve ADVANCE <sup>2</sup>	CoreValve Extreme Risk <sup>3</sup>	CoreValve High Risk <sup>4</sup>	LOTUS REPRISE II <sup>5</sup>
	24.2%	16.9%	14.2%	11.5%	9.0%	1.0%

# Boston Scientific Future TAVI Pipeline



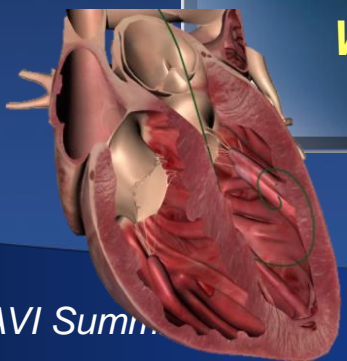
**Complete Size Matrix**

**FUTURE PIPELINE**

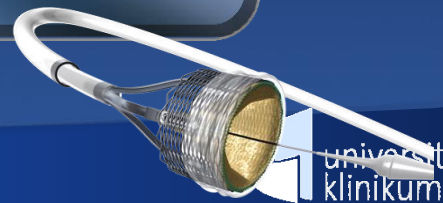


**Alternate Access Routes**

**TAVI-Dedicated Wires**



**Enhanced Delivery System**



# Take Home Message

- Annular measurements alone may not predict or guarantee valve stability especially if there is minimal annular or leaflet calcification
- Greater appreciation of the overall Aorto-valvular complex three dimensionally including distribution, burden and patterns of calcification necessary
- Valve specific sizing algorithms
- The Lotus TAVI prosthesis facilitates easy repositioning, full retrieval and change of device size if required