TAVR

Current Device & Future

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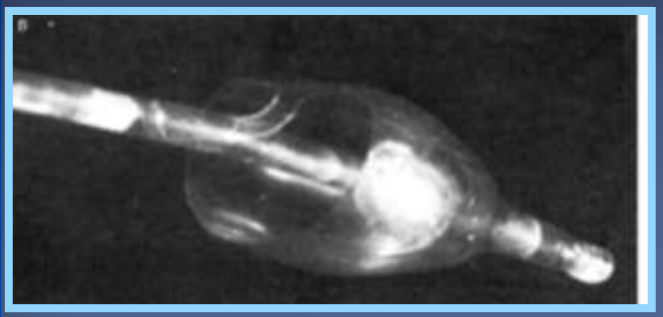
Asan Medical Center

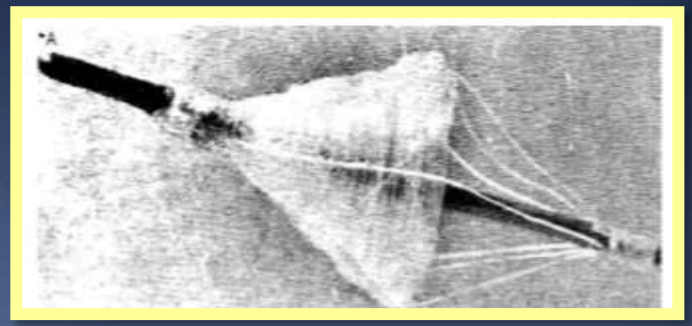
TAVR

PAST

History

- Transcatheter valvular interventions - exciting area for research since **1960**s.
- Initial animal investigations were performed by





Hywel Davies in 1965.
Moulopoulos in 1971
Phillips in 1976
Matsubara in 1992.
Temporary relief of aortic regurgitation.

- *Concept of balloon expandable valvular prosthesis from the endovascular stents.*
- In 1992, Andersen *et al*, porcine model, transluminal stented heart valve.

History

1992: Henning Andersen

First description of valve sutured in stent

Animal model(pig)

Encountered major limitations

Obstruction of coronary ostia

Handmade wire frame to which was sewn a porcine valve.

History

Alain Cribier: First Transcatheter Aortic Valve Implantation (TAVI) April 16, 2002

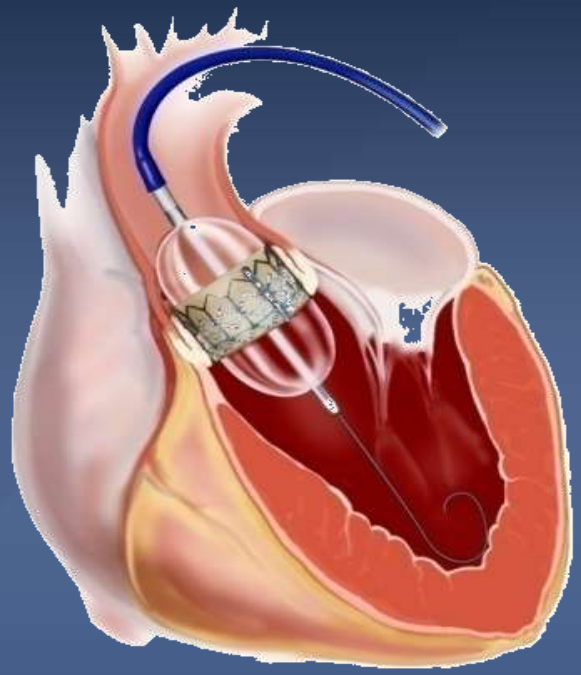
April 16 , 2002

8 days post implantation

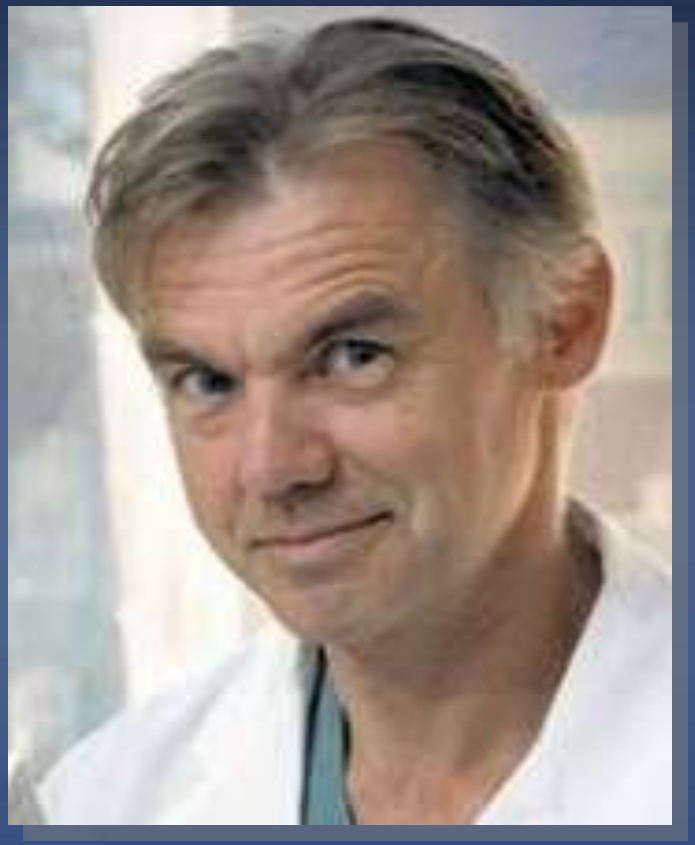
Approach

The first TAVI was undertaken from the right femoral vein, with a transseptal puncture required to access the left ventricle.[22] This higher risk and technically demanding procedure was soon replaced with arterial access.

Successful development of RetroFlex™ system for t he Transfemoral access

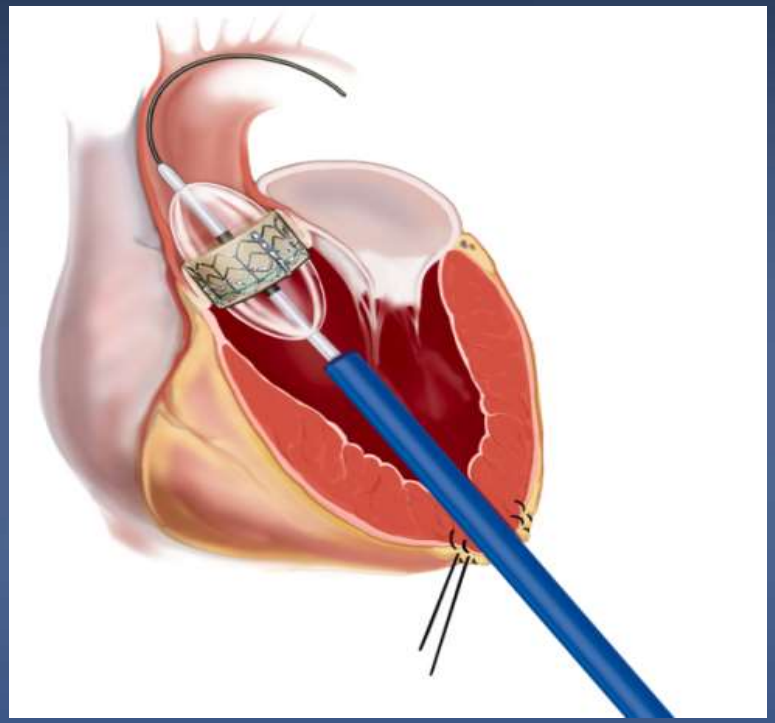


2004



John Webb

Successful development of Ascendra™ system for the Transapical access



2005

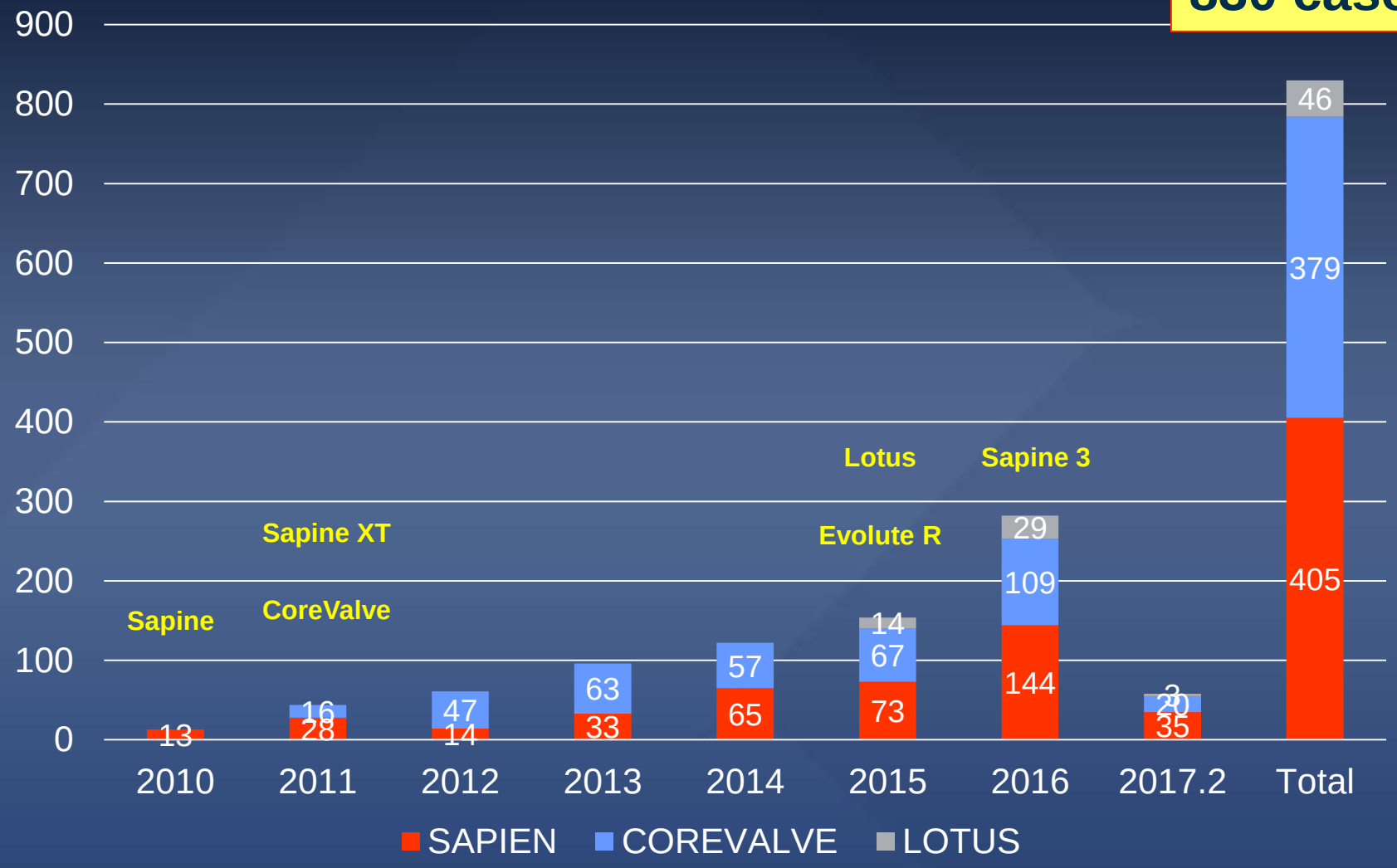
Friedrich Mohr

Michael Mack

TAVR Status in KOREA

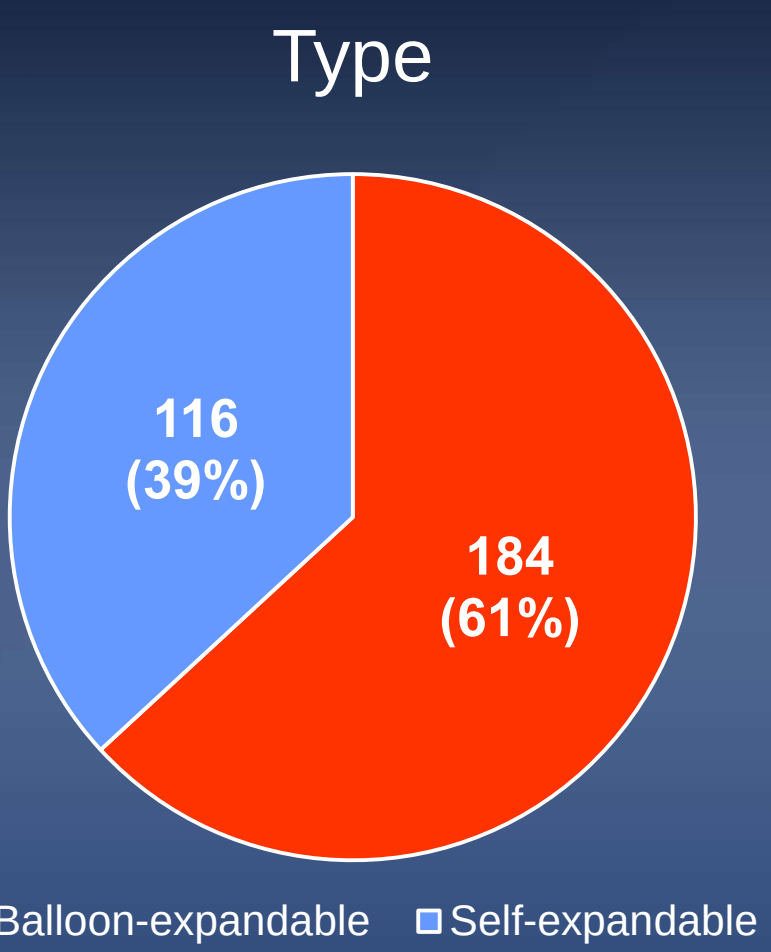
All TAVR (2010~2017.2)

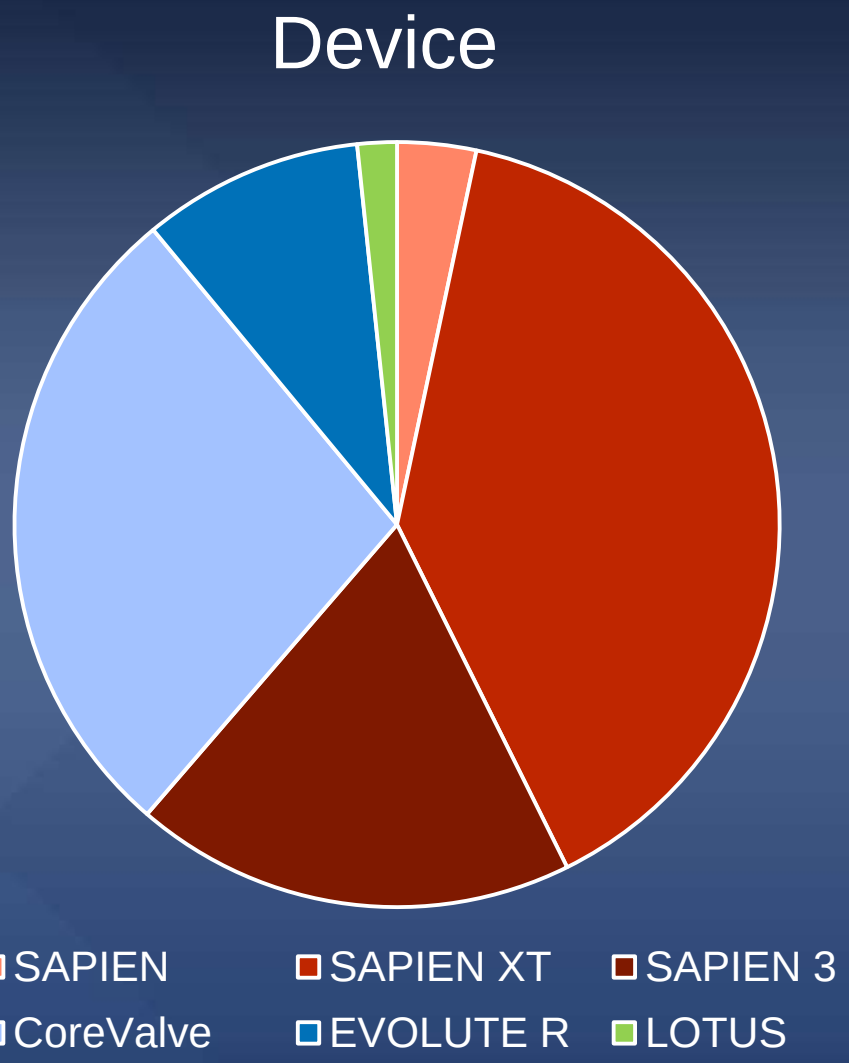
Total 830 cases



TAVR in Asan Medical Center (N=312)

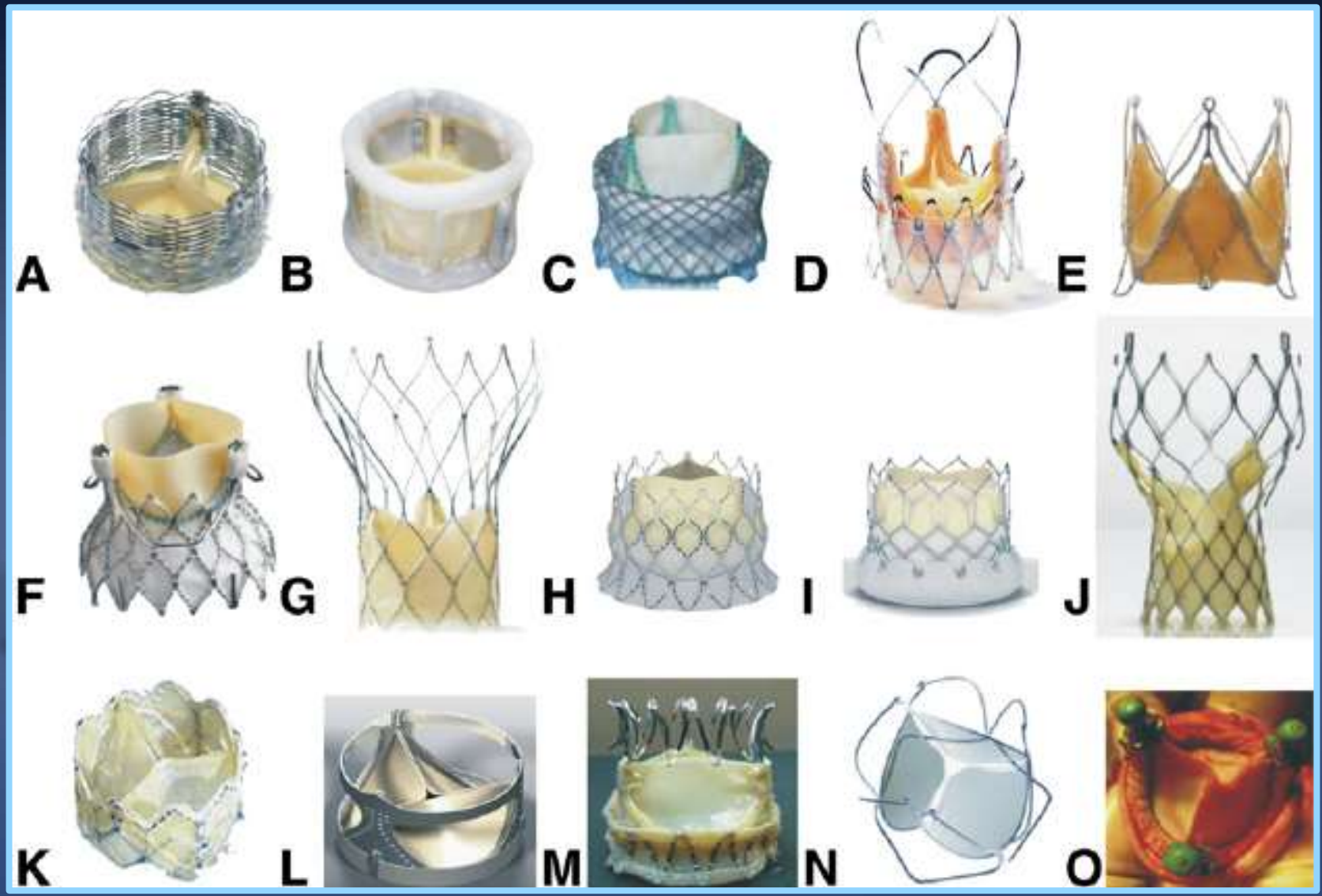
TAVR Device Proportion





Current

TAVR Devices in Korea



Device specification

- Tissue Type
- Valve Size
- Deployment Method
- Approach
- Delivery Catheter
- Function
- Skirt & Seal

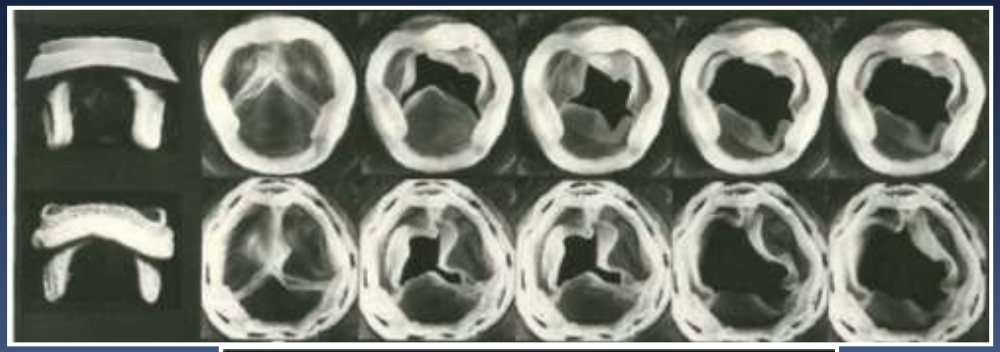
Tissue Type

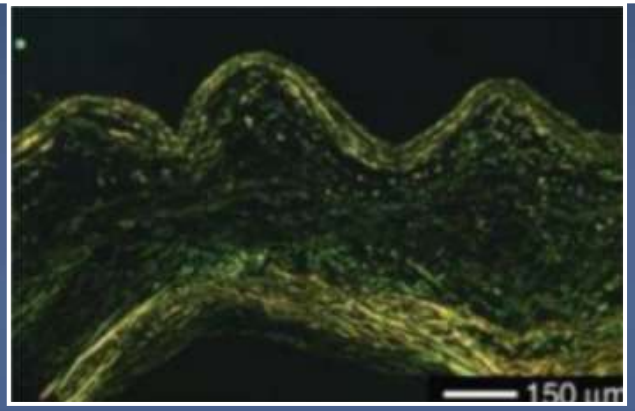
Bioprosthesis Valve

Porcine Pericardium

Bovine Pericardium

Porcine VS Bovine

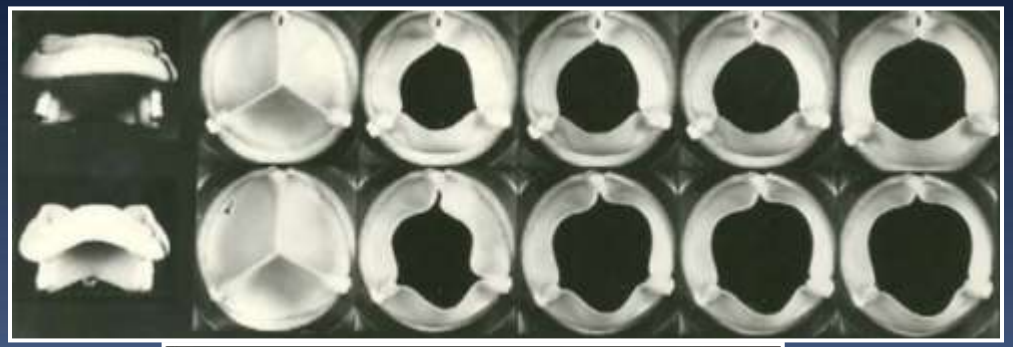


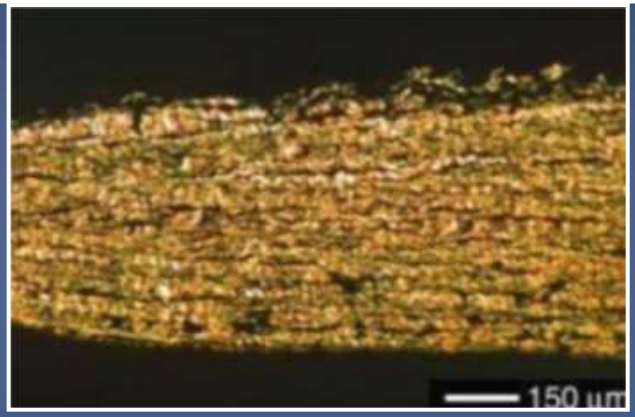


Porcine Pericardium

Low Profile

Tear





Bovine Pericardium

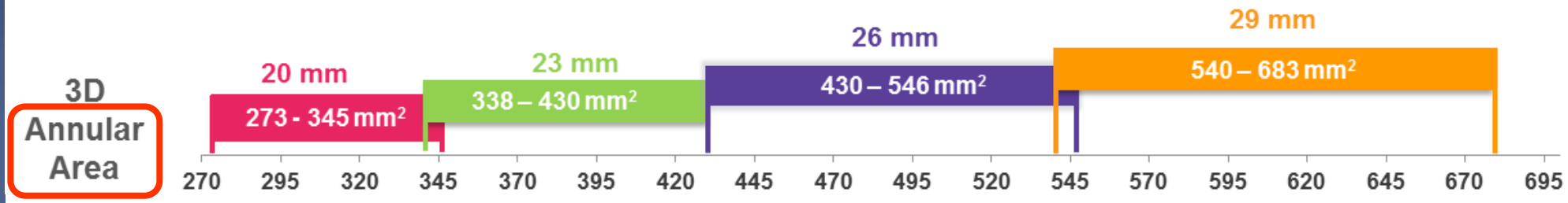
Better Durability

Calcification

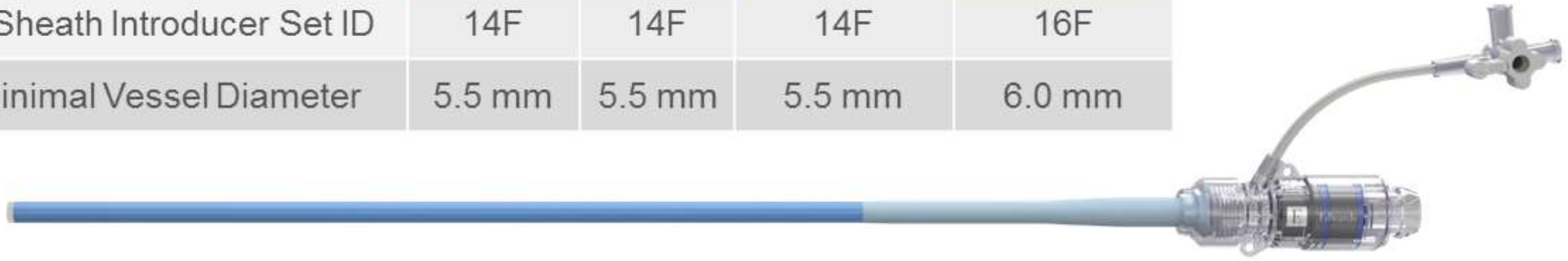
Valve Size

Sapien 3

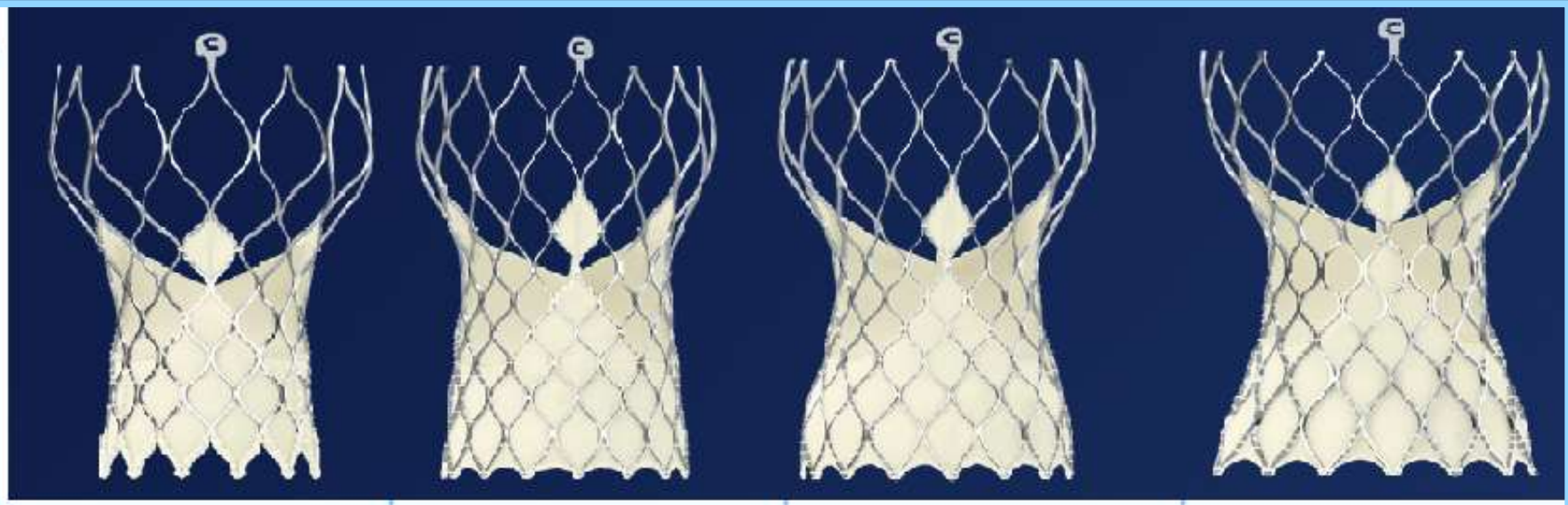
Specifications		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size	Area	273–345 mm²	338–430 mm²	430–546 mm²	540–683 mm²



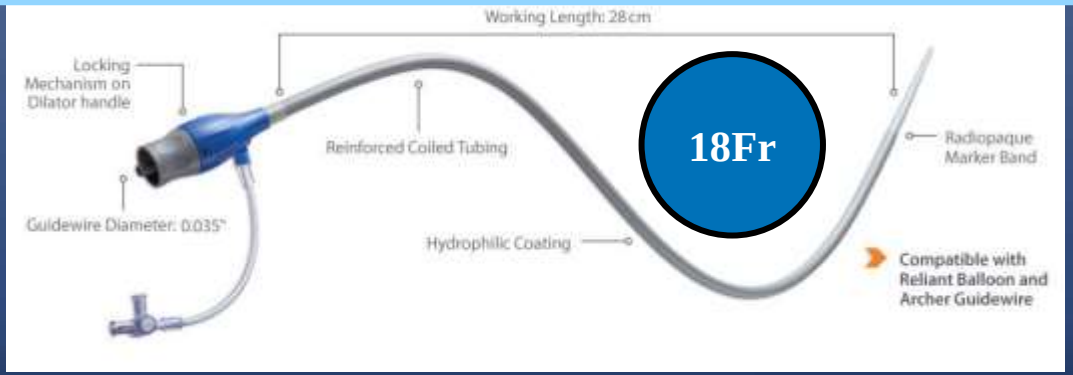
SAPIEN 3 Valve	20 mm	23 mm	26 mm	29 mm
eSheath Introducer Set ID	14F	14F	14F	16F
Minimal Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6.0 mm



Core Evoult R



	23 mm	26 mm	29 mm	31 mm
Size				
Annulus Diameter	18-20 mm	20-23 mm	23-26 mm	26-29 mm
Annulus Perimeter†	56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-91.1 mm



Lotus

	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

Lotus Introducer for 23 mm

- LIS - (Lotus Introducer Sheath – Small
- Access vessels 6.0 mm or larger
- Review IFU prior to use

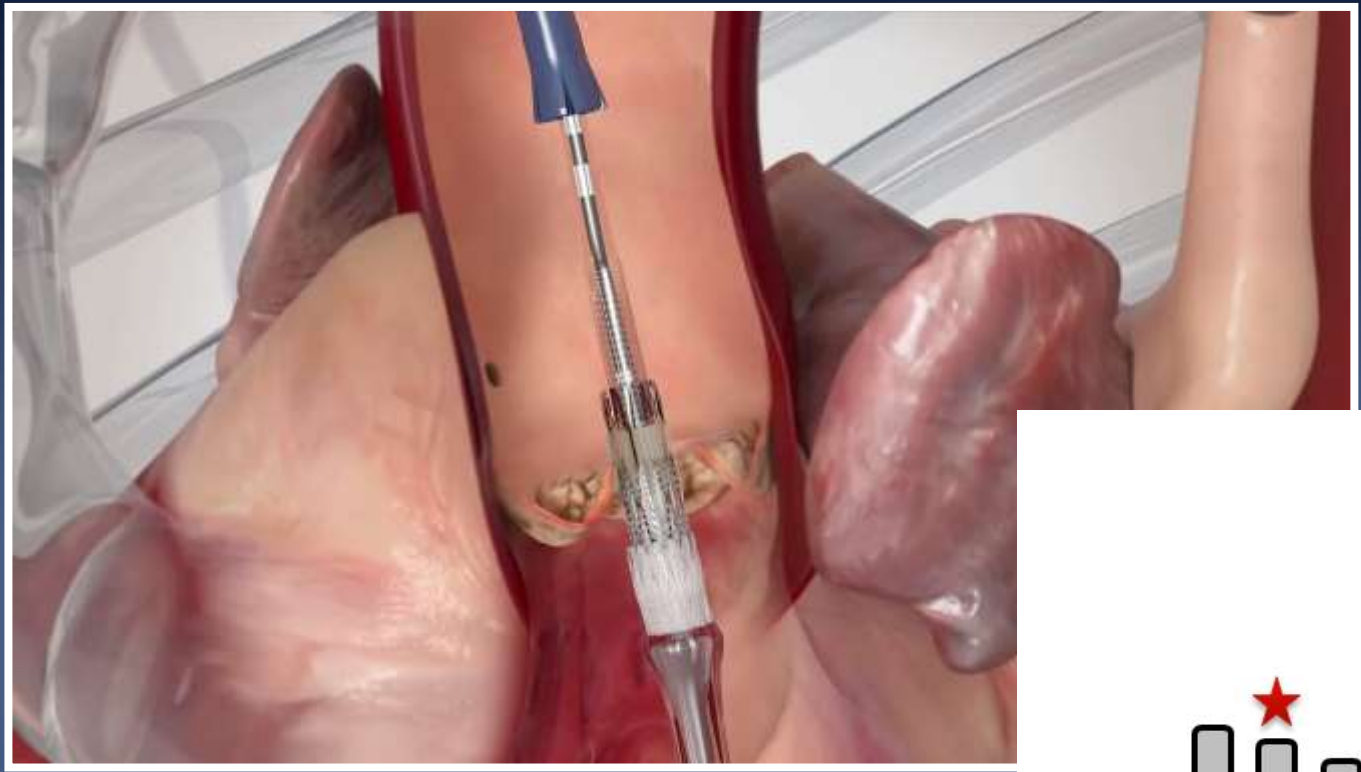
Lotus Introducer for 25 mm and 27 mm

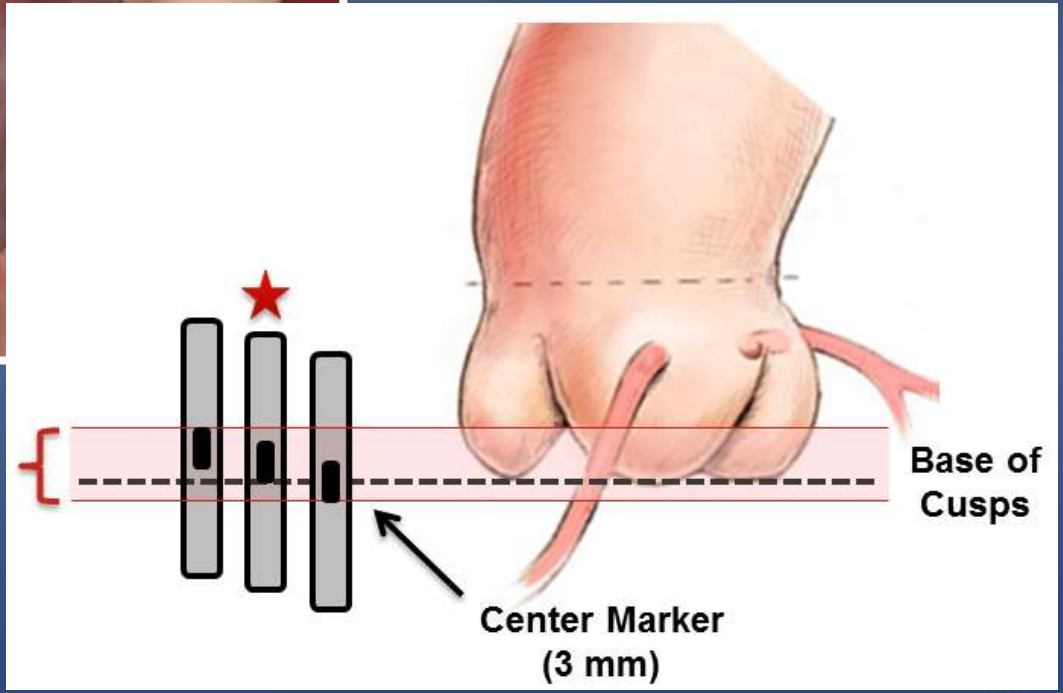
- LIS - (Lotus Introducer Sheath – Large
- Access vessels 6.5 mm or larger
- Review IFU prior to use

Deployment Method

Balloon Expandable
Self Expandable

Sapien 3

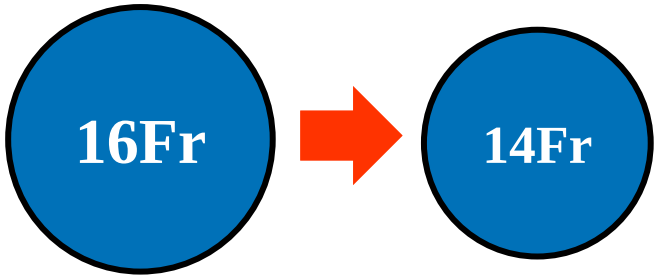


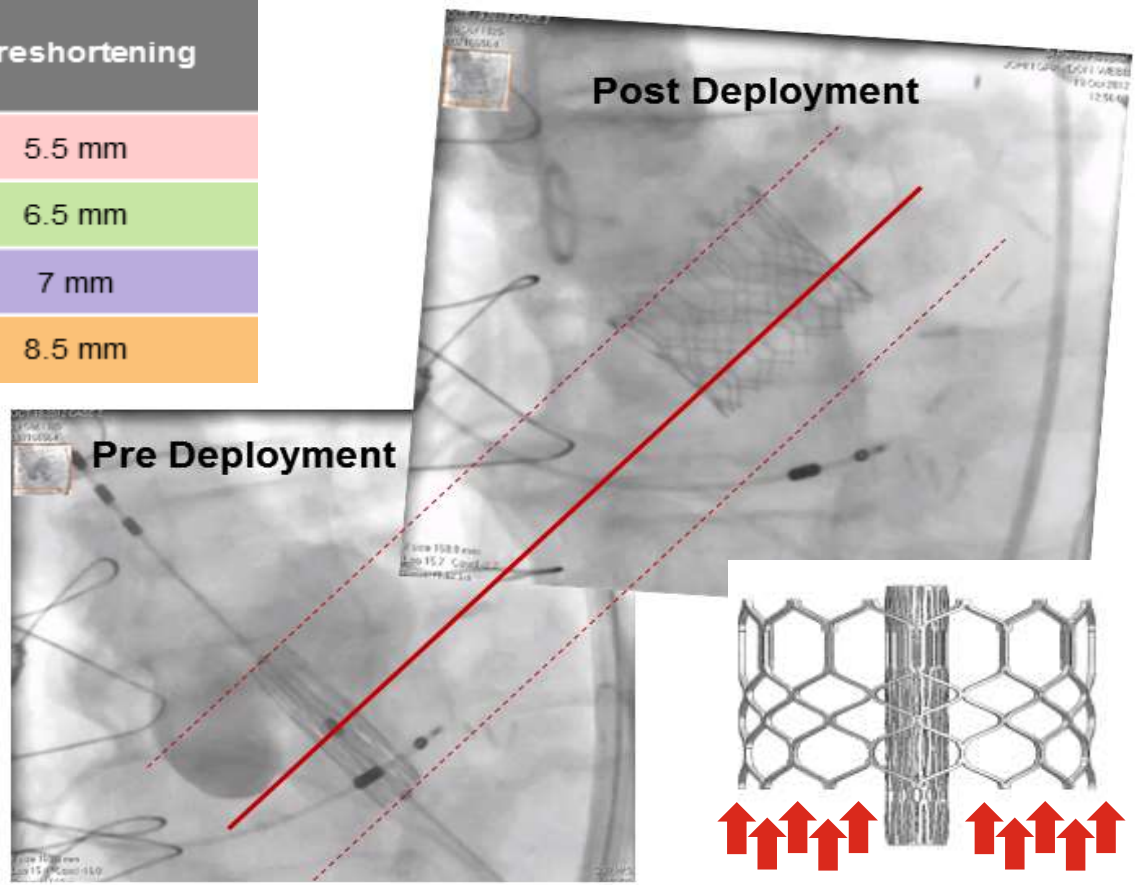


Sapien 3 Position - Foreshortening

THV Size	Crimped Height[1]	Expanded Height	Foreshortening
20 mm	21 mm	15.5 mm	5.5 mm
23 mm	24.5 mm	18 mm	6.5 mm
26 mm	27 mm	20 mm	7 mm
29 mm	31 mm	22.5 mm	8.5 mm

- **Severe IHSS including septal hypertrophy:**
  THV movement aortic



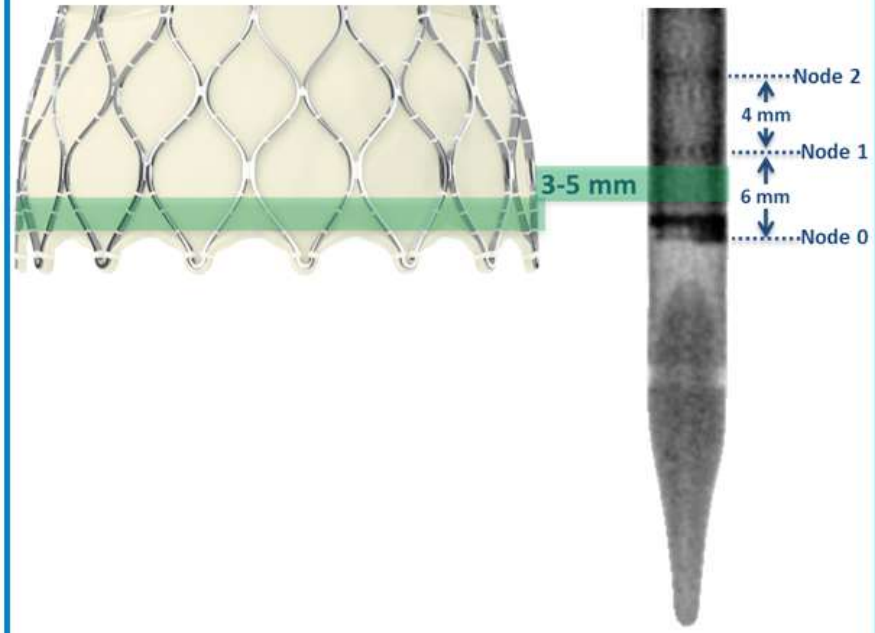


Core Evolut R

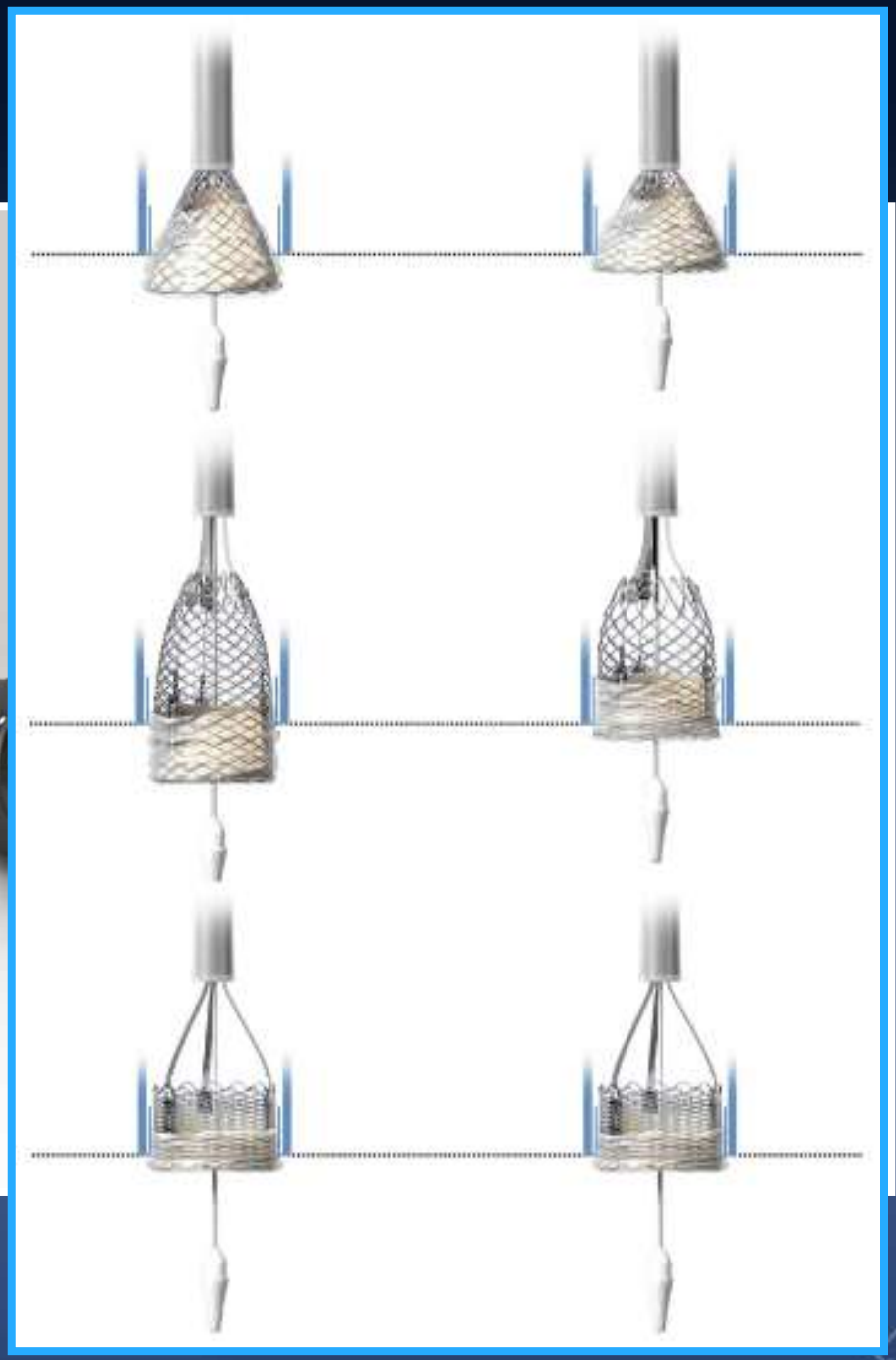
Evolut R

Target implant depth is **3 - 5 mm**

Midway between nodes 0 and 1 to just below node 1



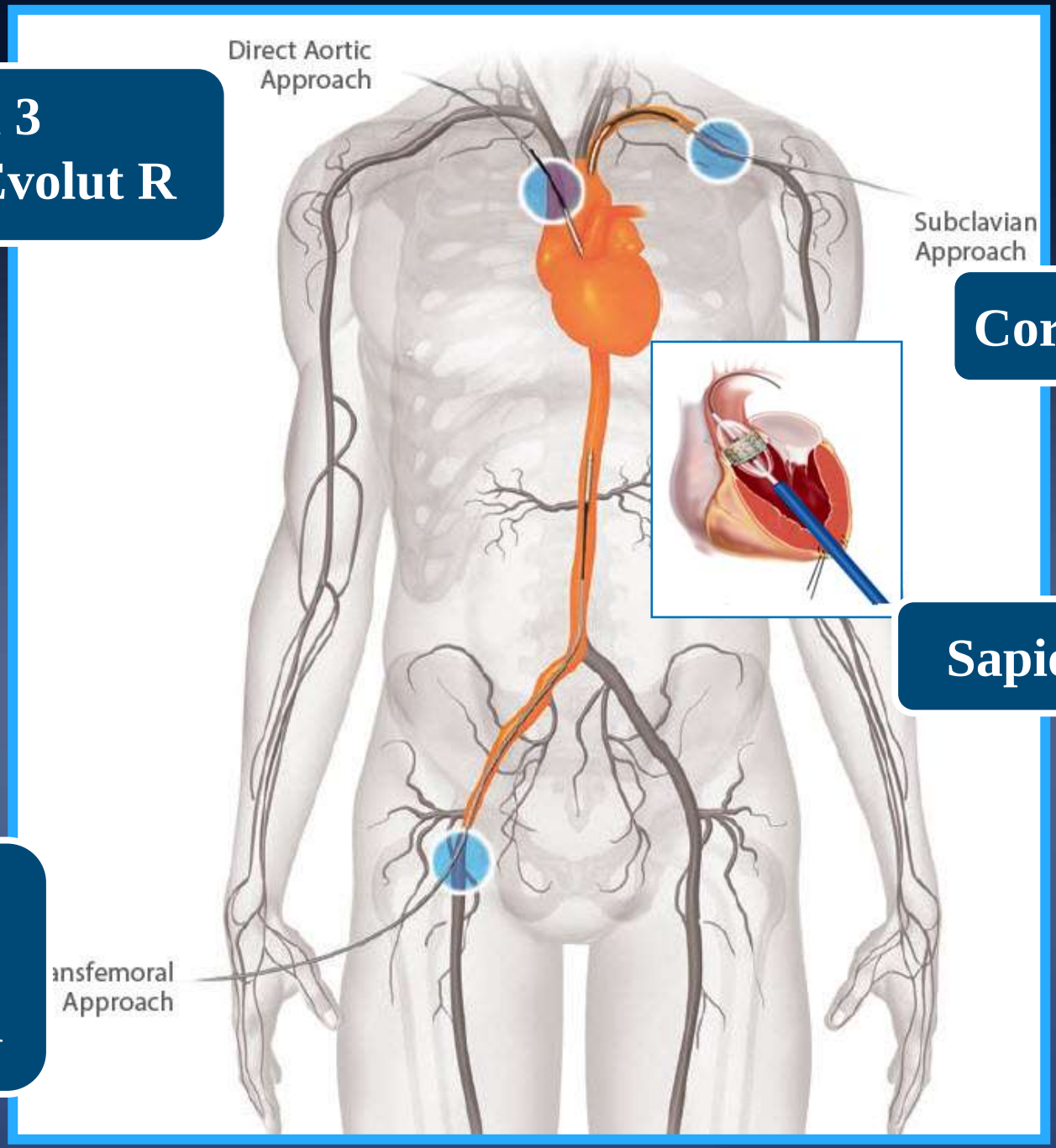
Lotus



Complete repositionability

Approach

Sapien 3
Core Evolut R



Core Evolut R

Sapien 3

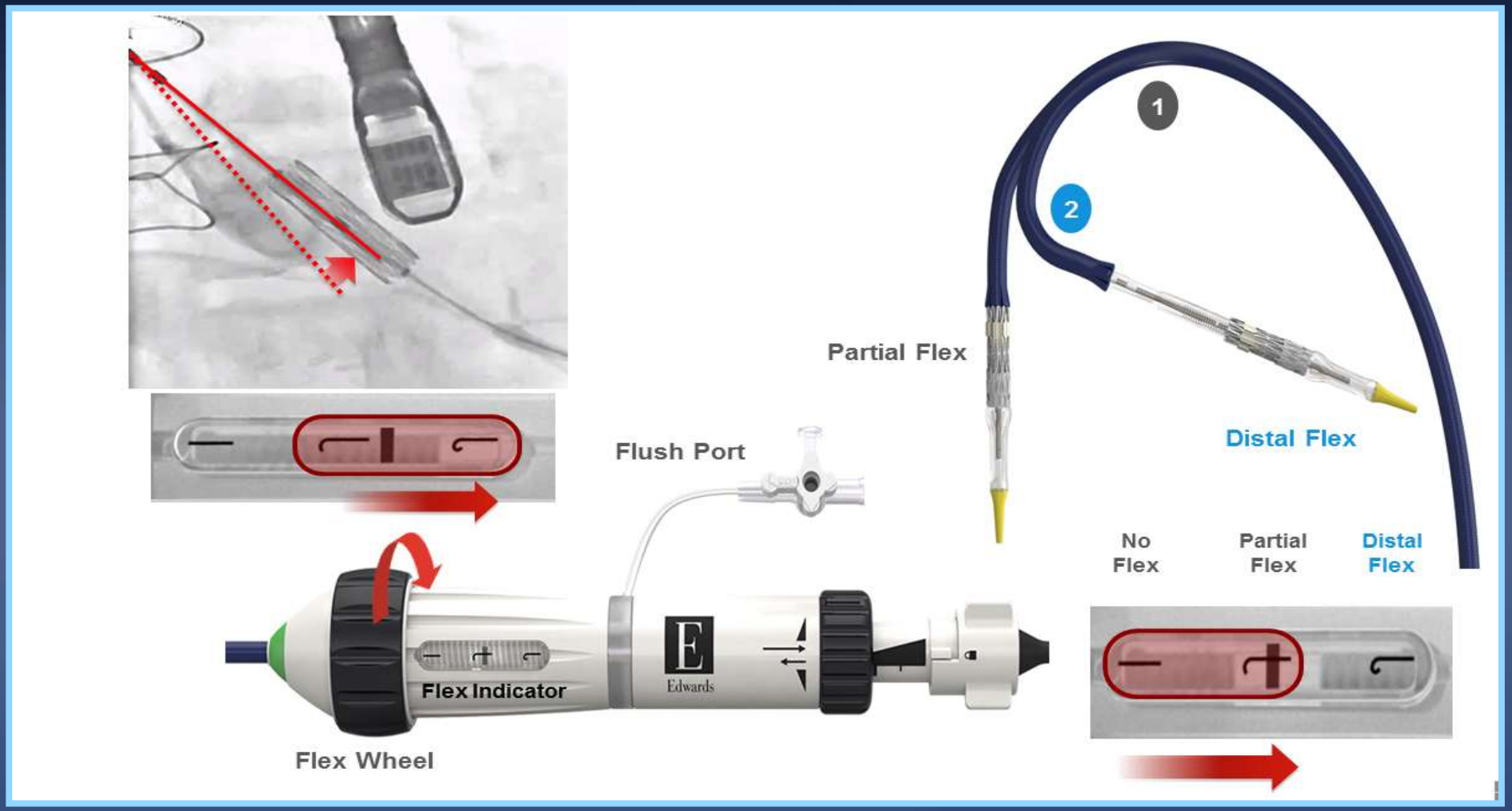
Lotus
Sapien 3
Core Evolut R

Minimum Vessel Diameter

	SAPIEN 3		Lotus	Evolut R
				
Valve Size (mm)	20, 23, 26	29	23, 25, 27	23, 26, 29
Indicated Vessel Diameter (mm)	5.5	6.0	6.0	5.0

Delivery Catheter

S3 Commander - Dual Articulation



S3 Commander - Fine Tuning

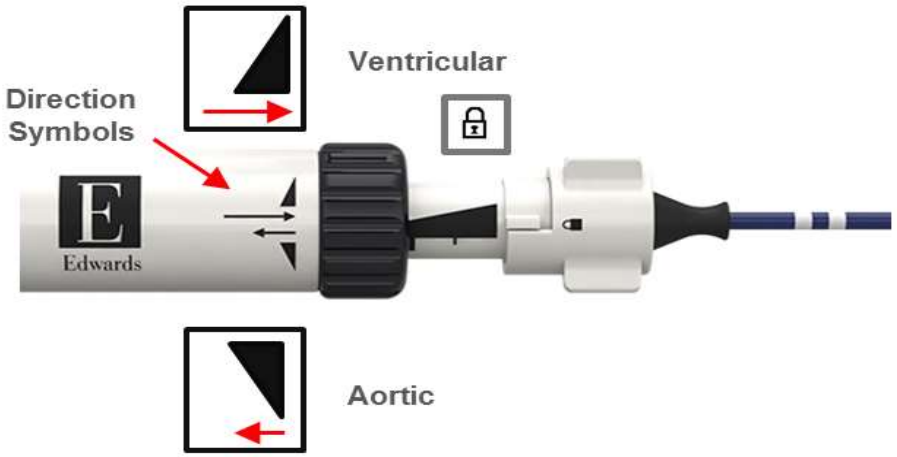
THV Positioning: Fine Positioning

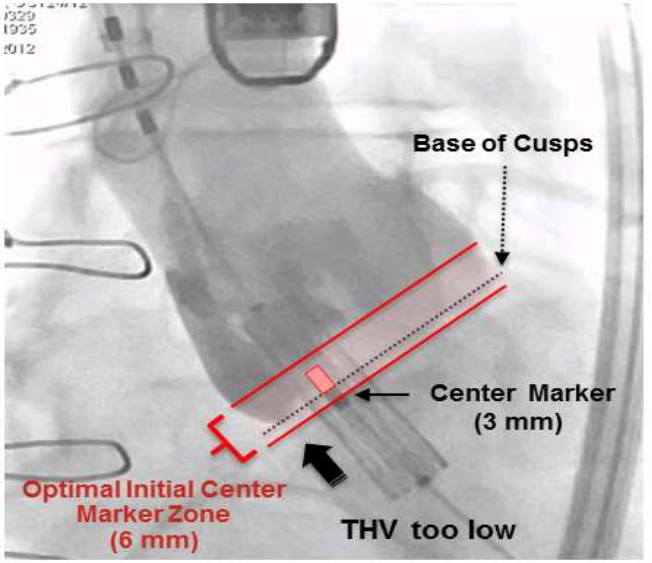
Use Fine Adjustment Wheel to Control Fine Positioning

Ensure the **Flex Tip is pulled back to the middle of the Triple Marker**

Ensure the **Balloon Lock is Locked**

Turn the Fine Adjustment Wheel to finely control the THV position in either direction





Lotus Delivery System

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

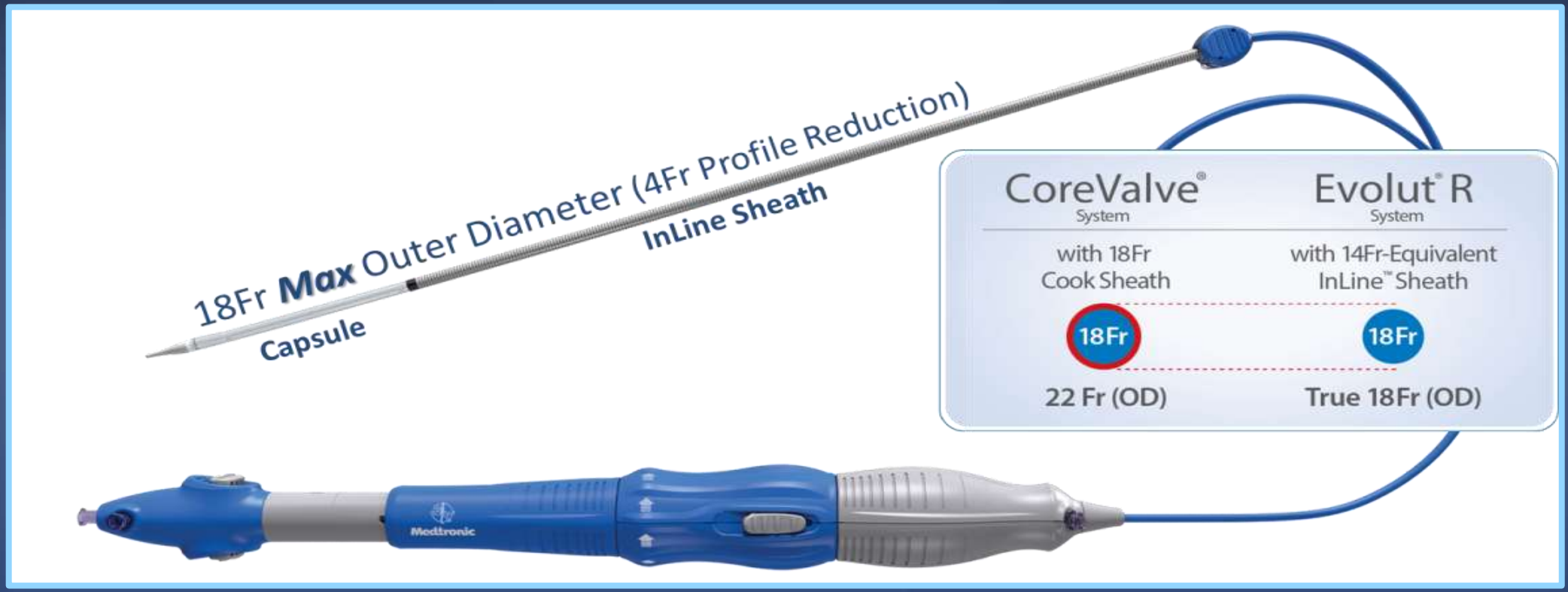
20Fr

18Fr

Pre-Shaped

Core Evolut R Delivery System

14Fr-Equivalent System with InLine Sheath
Minimum Transarterial Access Vessel Diameters ≥ 5.0 mm



Function

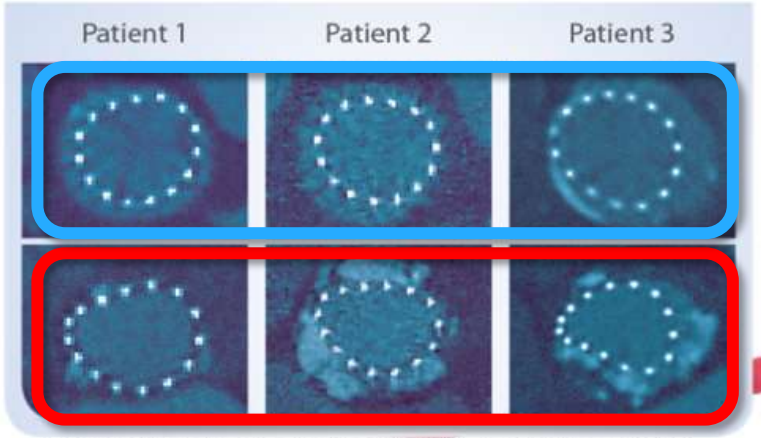
Intra-annular Valve
Supra-annular Valve

Supra-annular Valve : Evolut R

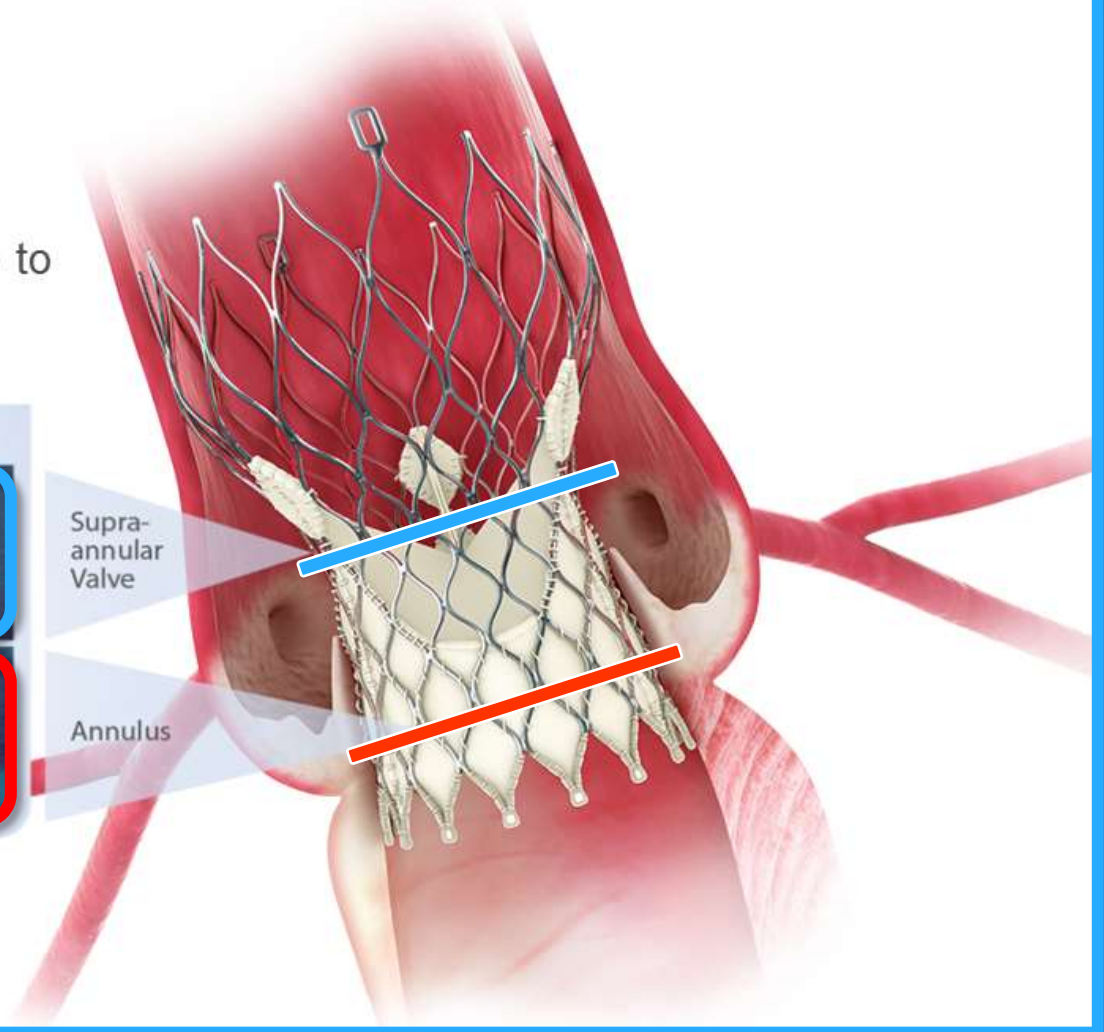
PRODUCT DESIGN:

Conforming Frame

The nitinol frame conforms and seals to the non-circular annulus.



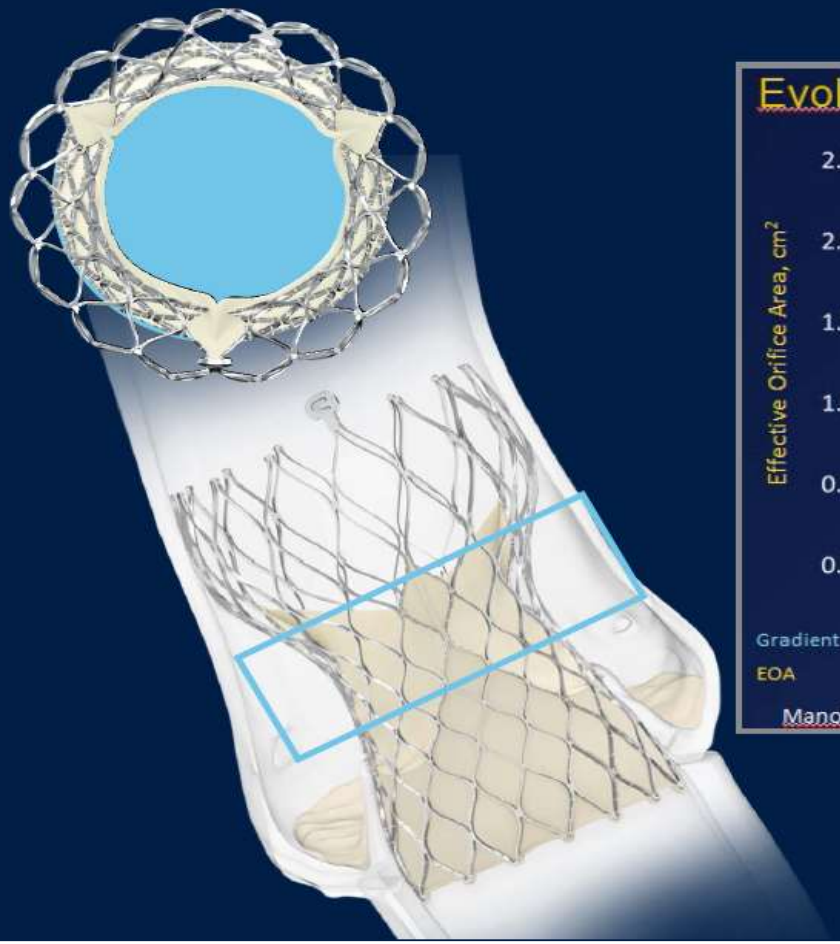
Images courtesy of Drs. De Jaegere and Schultz, Erasmus MC, Rotterdam, The Netherlands

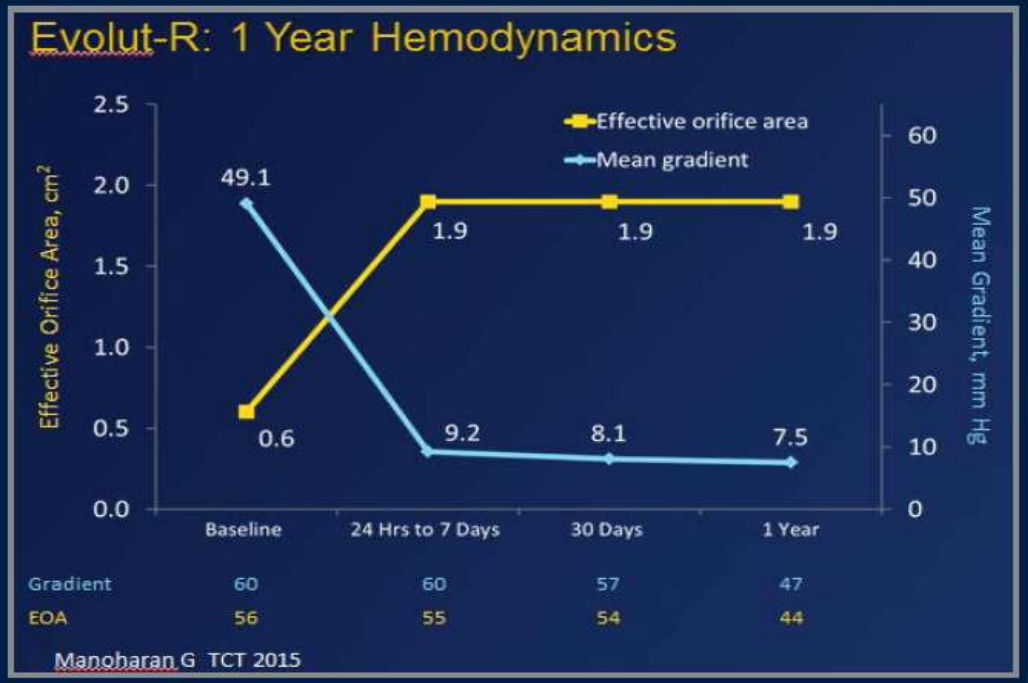


Supra-annular Valve : Evolut R

EXCEPTIONAL HEMODYNAMICS

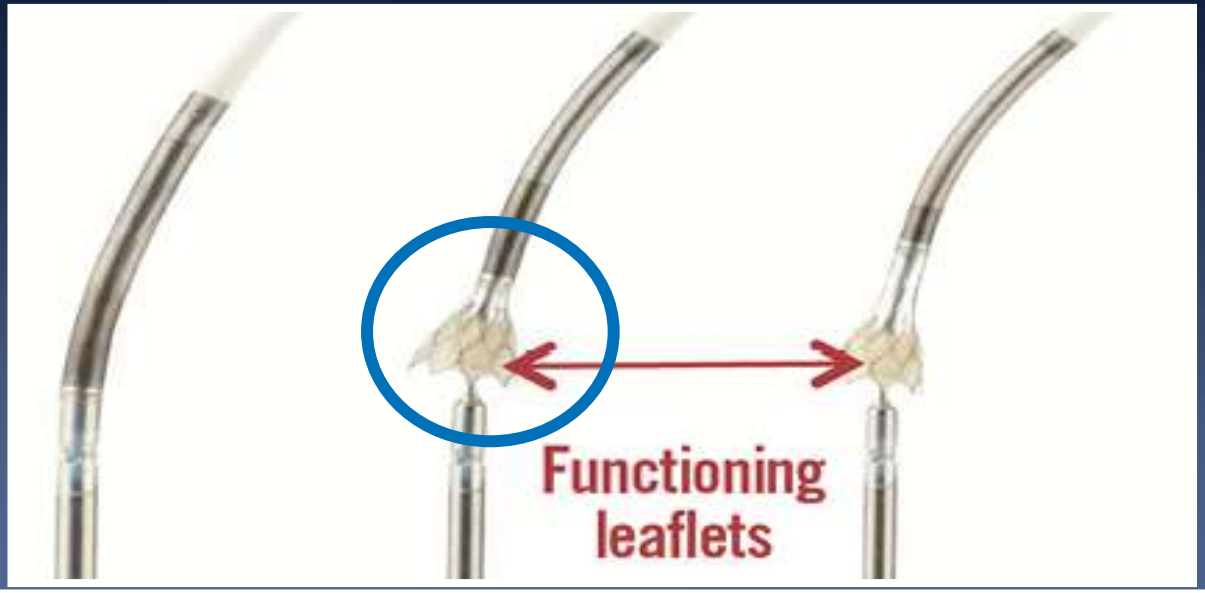
SUPRA-ANNULAR VALVE DESIGN MAXIMIZES ORIFICE AREA





Hemodynamic Compromise During Implantation

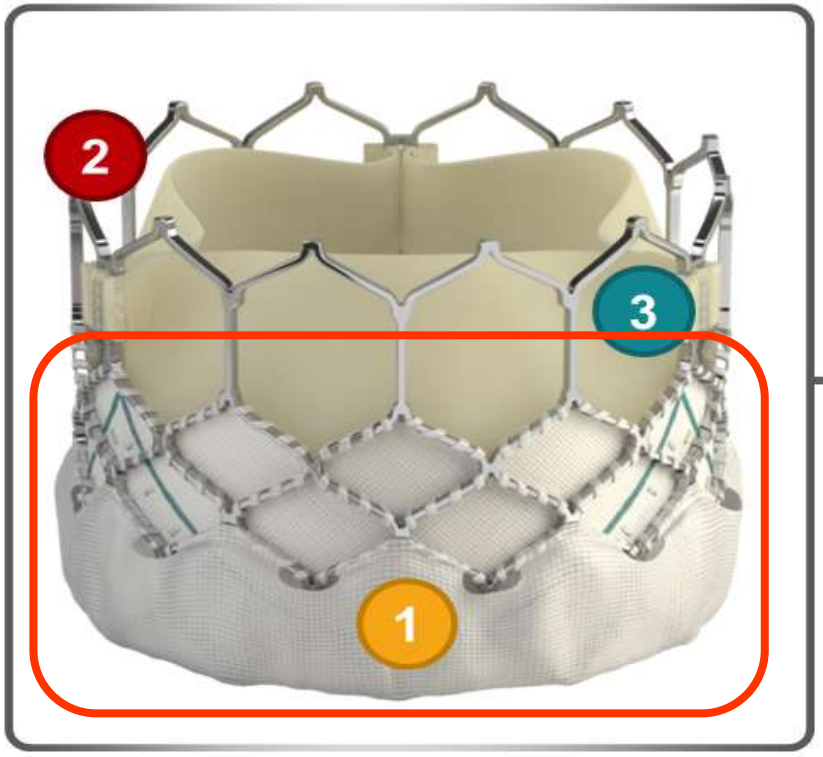
Intra-annular Valve



Supra-annular Valve

Skirt & Seal

Sapien 3 - Sealing Skirt



1

Outer Sealing Skirt

- Designed to minimize paravalvular leak

2

Frame Design

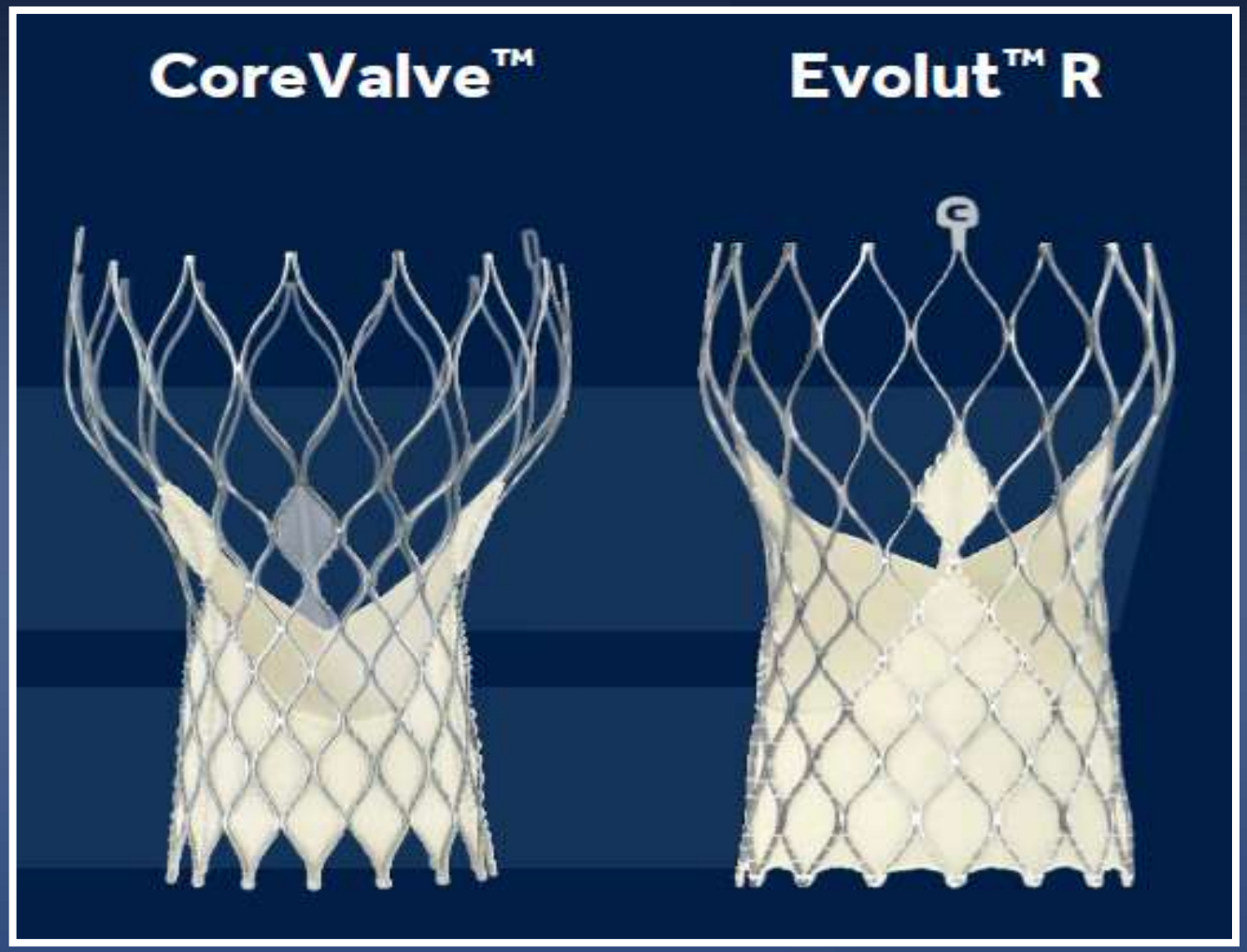
- Enhanced frame geometry for low delivery profile
- Cobalt-chromium frame for high radial strength

3

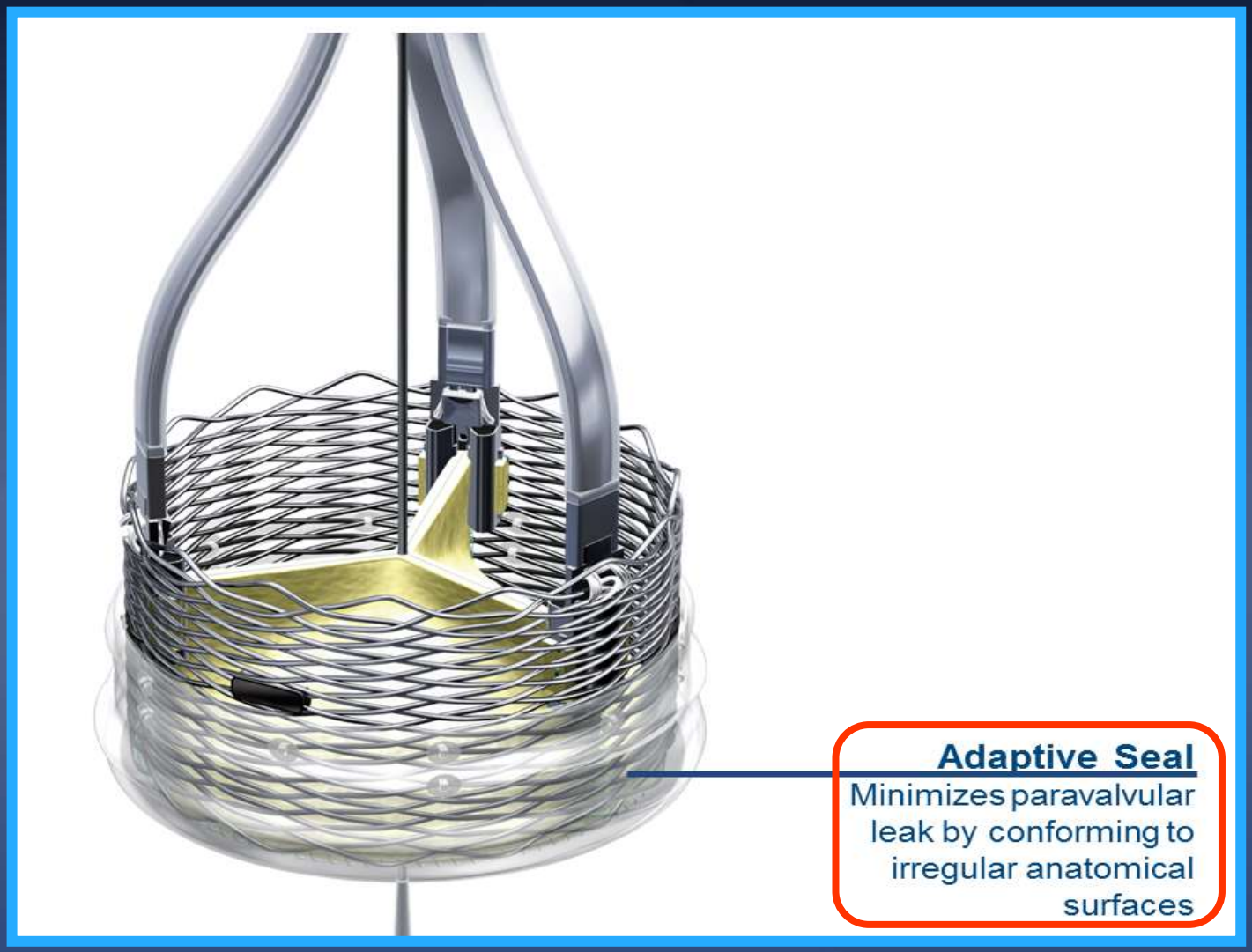
Proven Valve Tissue

- Same bovine pericardial tissue and processes as Edwards surgical valves

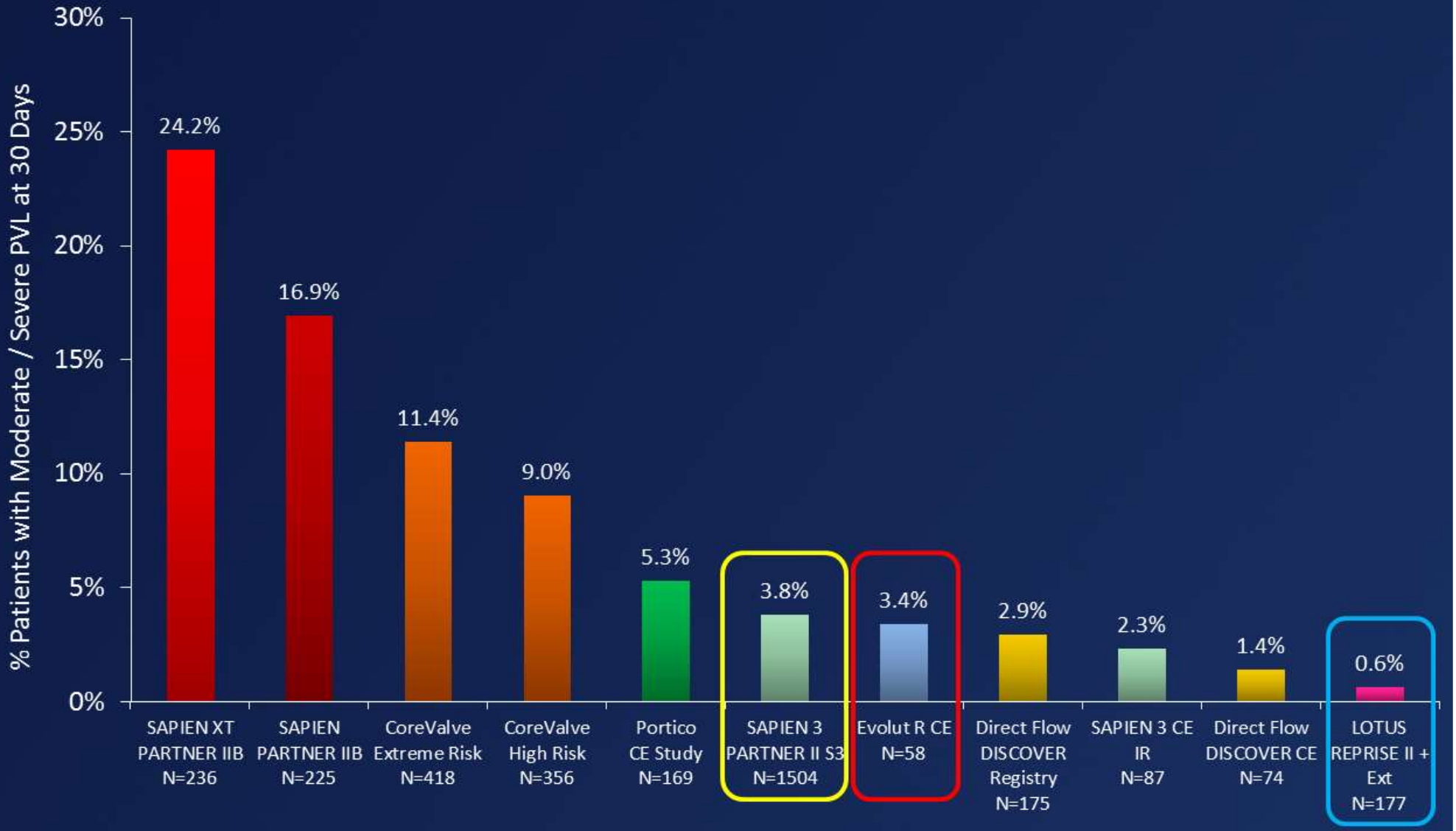
Core Evoult R



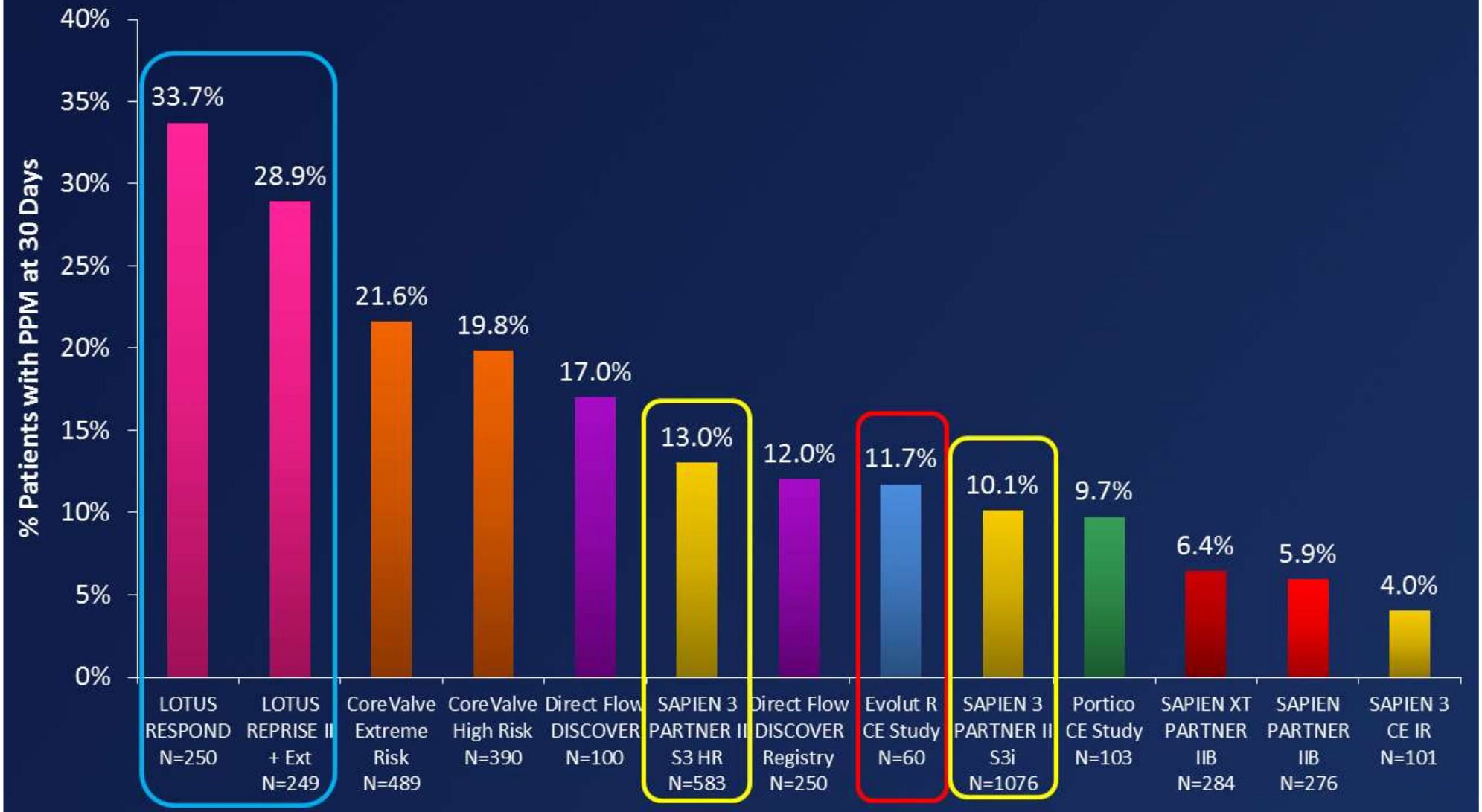
Lotus - Adaptive Seal



30 Day Moderate and Severe PVL



30 Day Permanent Pacemaker Rate



Future

- **Low Profile**
- **Various Sizes**
- **Long-term Durability**
- **No Paravalvular Leak**
  - Skirt & Seal
- **No Conduction Disturbance**
  - Shallow Target Depth
- **Complete Control**
  - Steerable Catether
  - Repositionability