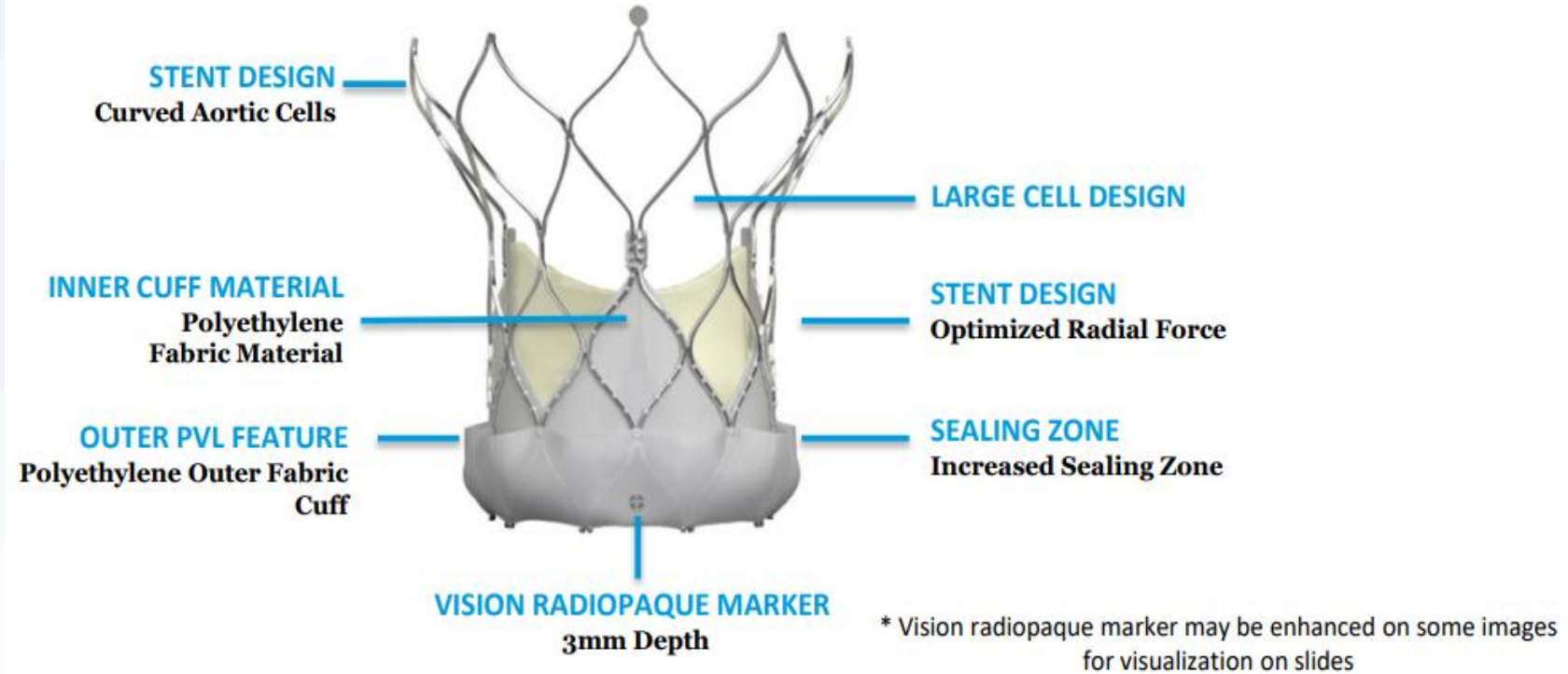
Design For Lifetime Management: Navitor Vision Is Here With 35 mm

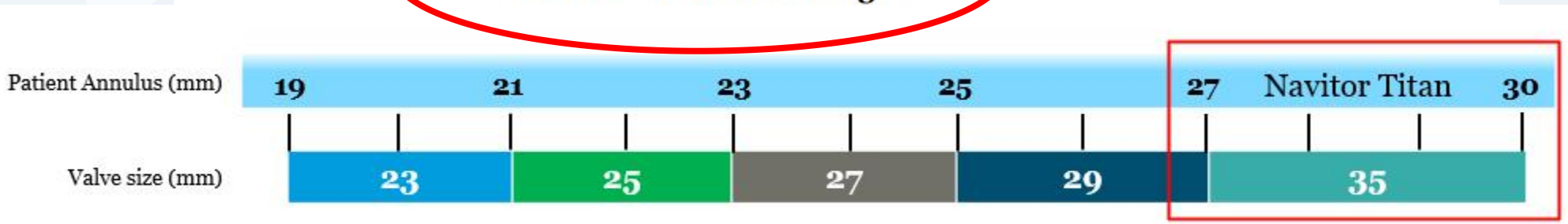
Ángel Sánchez Recalde
Hospital Universitario Ramón y Cajal

Navitor™ Vision Valve Design Features



* Vision radiopaque marker may be enhanced on some images for visualization on slides

VALVE DIMENSIONS
Annulus Treatment Range



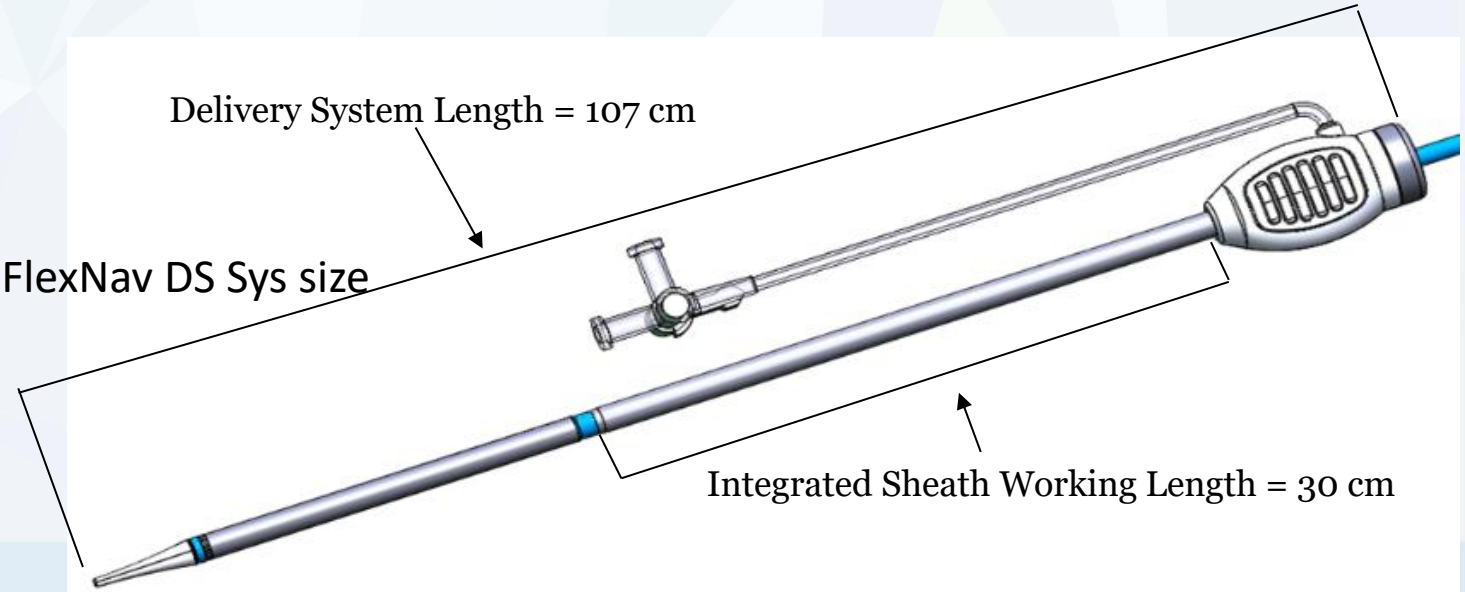
Navitor Titan™ Valve Designed for Use With FlexNav Delivery System

Table 3. FlexNav™ Delivery System Specifications

Delivery System Catalog Number	Equivalent Integrated Sheath Diameter	Valve Capsule Outer Diameter	Integrated Sheath Working Length	Delivery System Length	Minimum Vessel Diameter Requirement	Compatible Guidewire
FN-DS-SM-IDE	14F	6.0 mm	30 cm	107 cm	≥ 5.0 mm	0.035" (0.89 mm)
FN-DS-LG-IDE	15F	6.3 mm	30 cm	107 cm	≥ 5.5 mm	0.035" (0.89 mm)

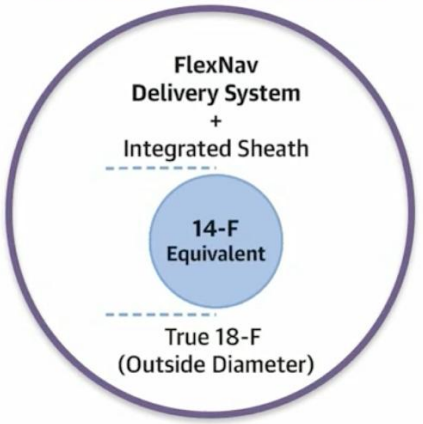
Compatible with Navitor Titan

Utilize same 15Fr Equivalent FlexNav DS Sys size



1. FlexNav™ : Excellent Deliverability

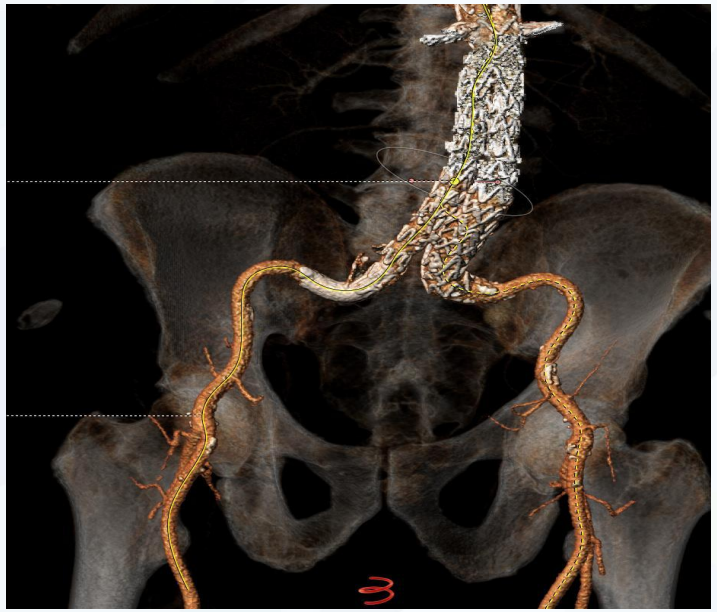
Vascular Complications

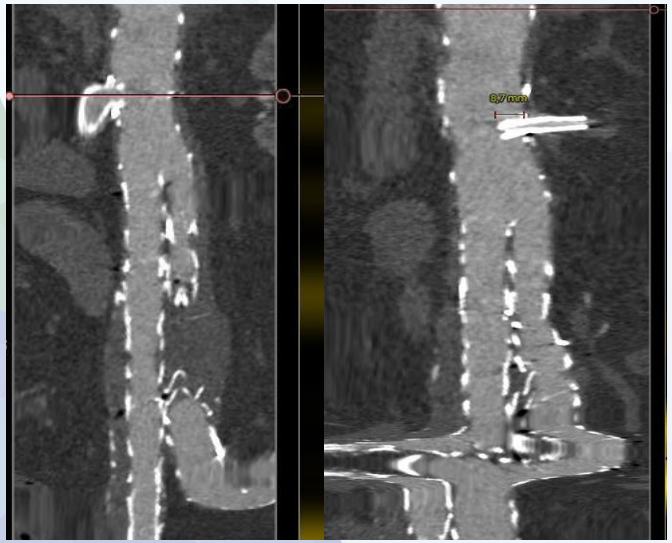


4.2%

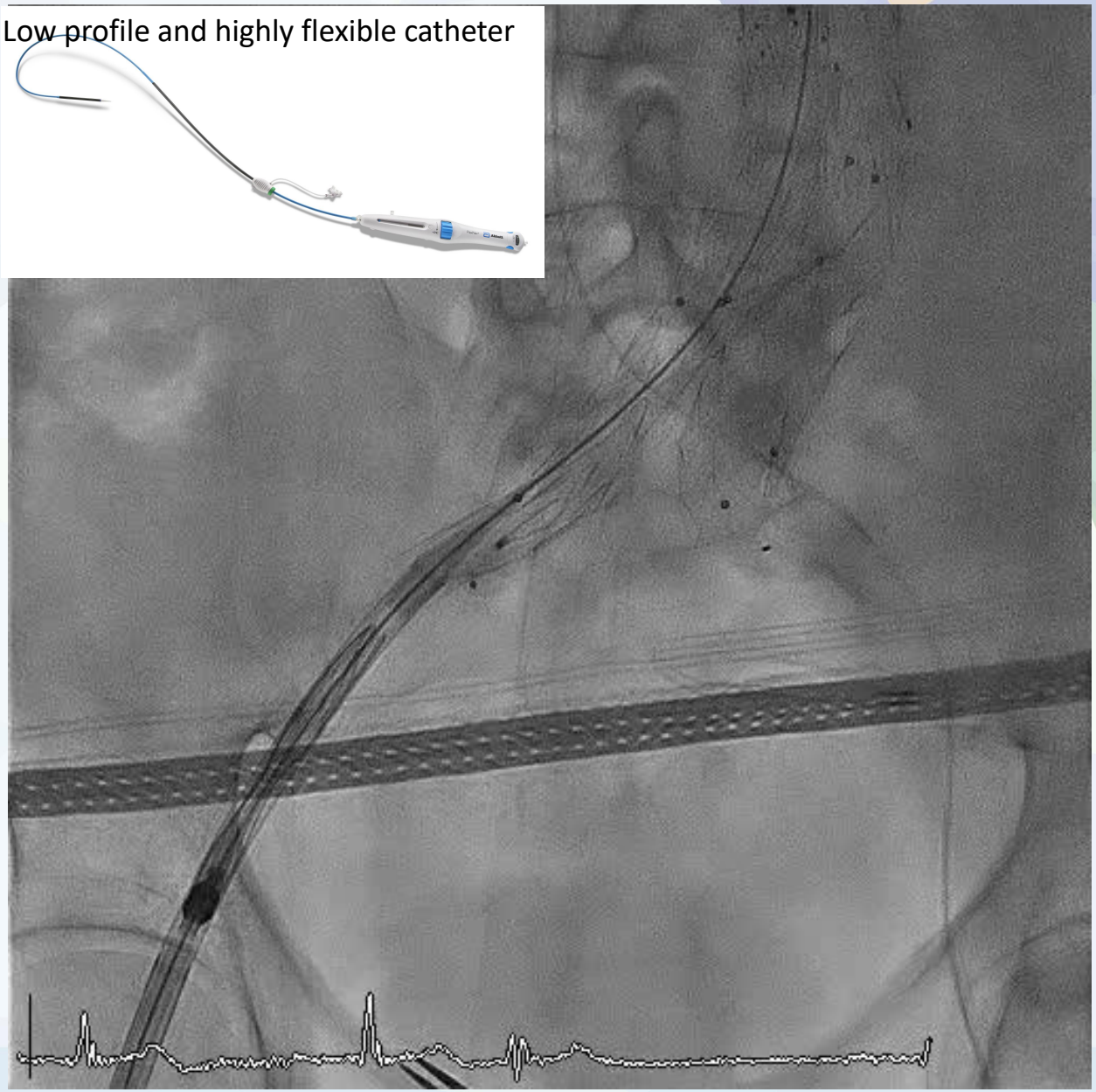
3.1% access site-related

1.2% non-access site-related



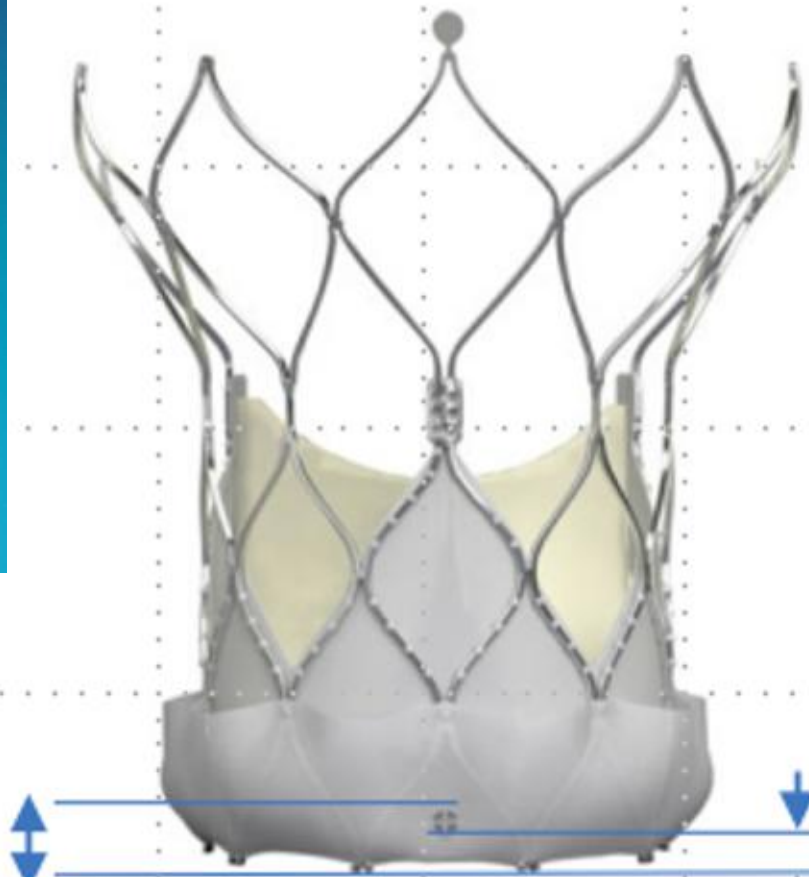


Low profile and highly flexible catheter



2. Precise Implant Depth Placement

Target implant depth: **3 mm**



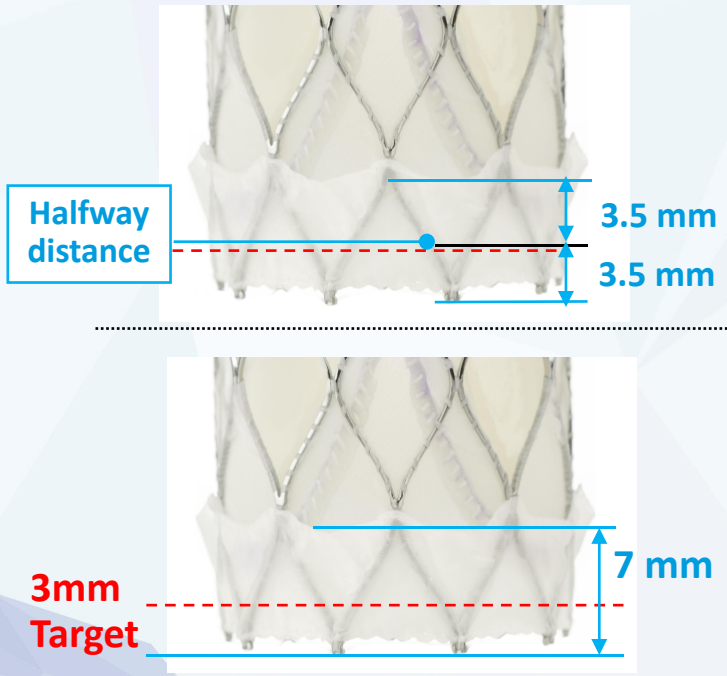
4.5mm - Valve inflow edge to the top of the marker(s)

3mm - Valve inflow edge to the bottom of the marker(s)

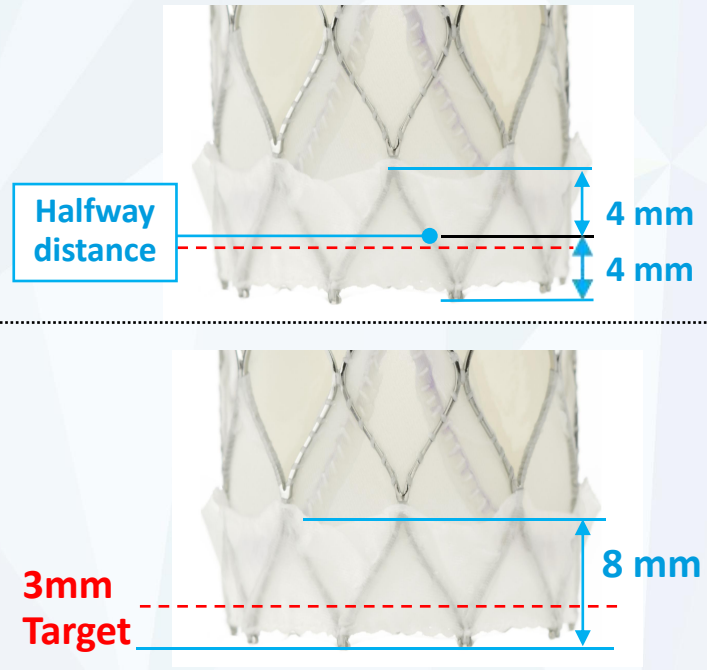
2. Implant depth placement

Target implant depth: **3 mm**

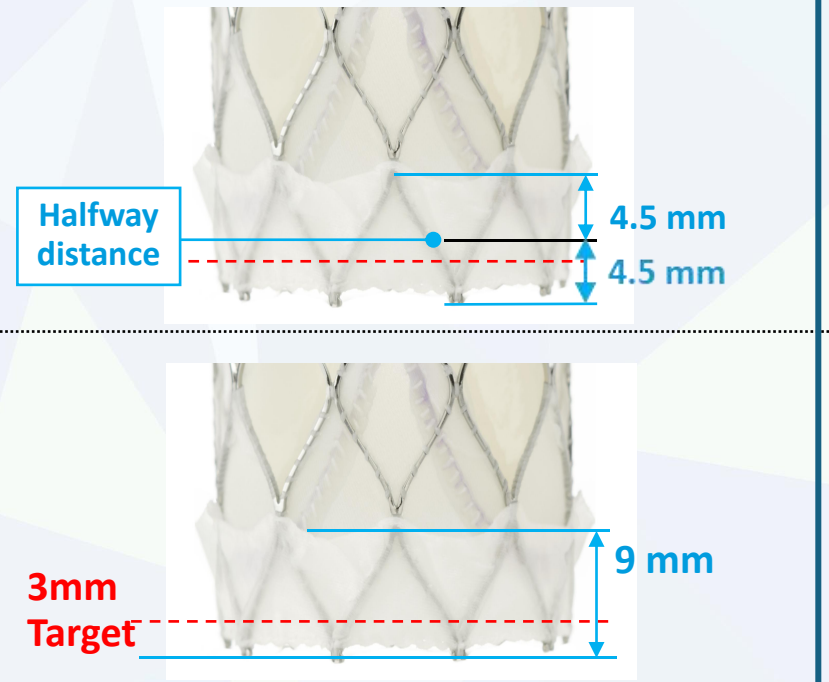
23-25 mm Navitor valves



27-29 mm Navitor valves

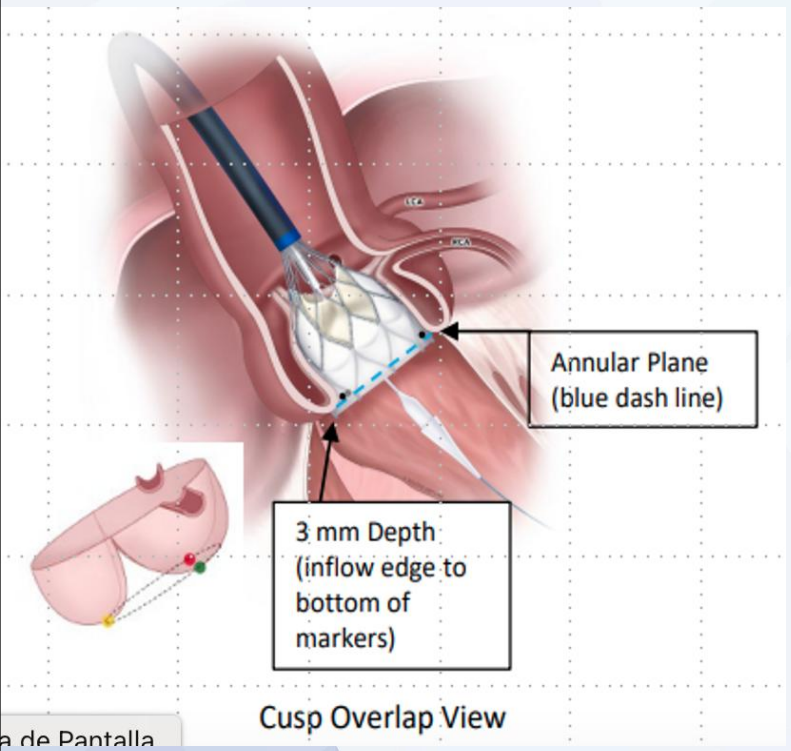


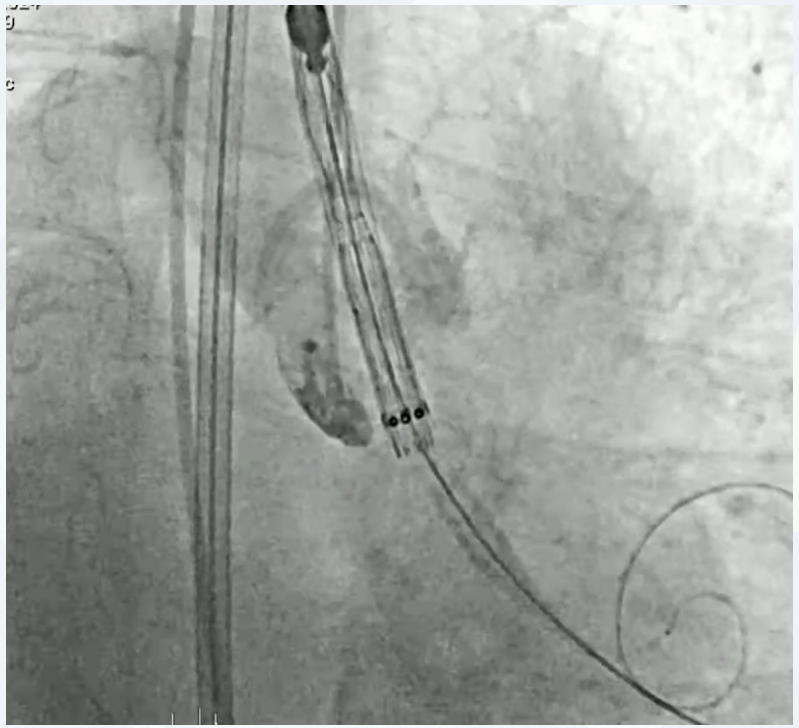
35 mm Navitor Titan



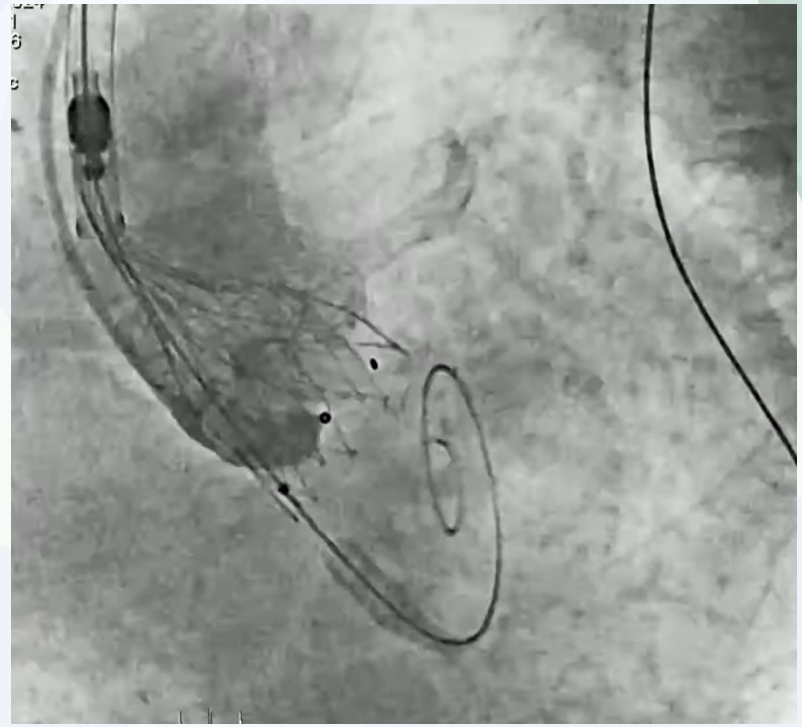
2. Precise Implant Depth Placement

Target implant depth: **3 mm**





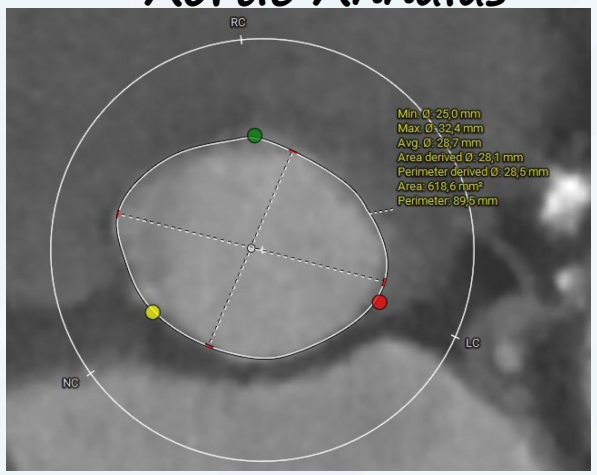
R-L Cusp overlap view



3 Cusp coplanar view

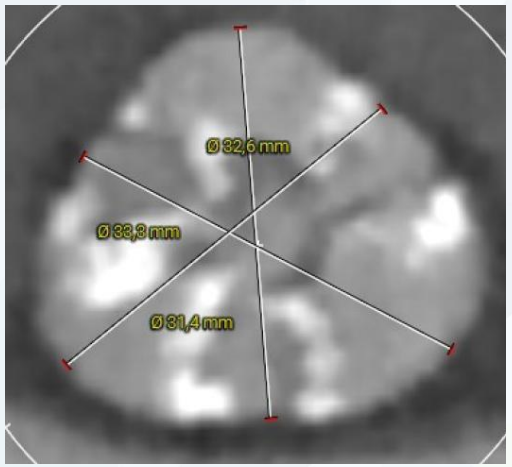
TITAN

Aortic Annulus



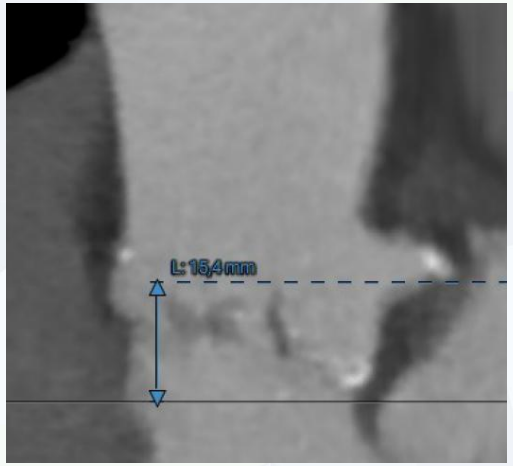
MinxMax D: 25x32 mm
Perimeter 89.5 mm (deriv. 28.5)

Sinus of valsalva

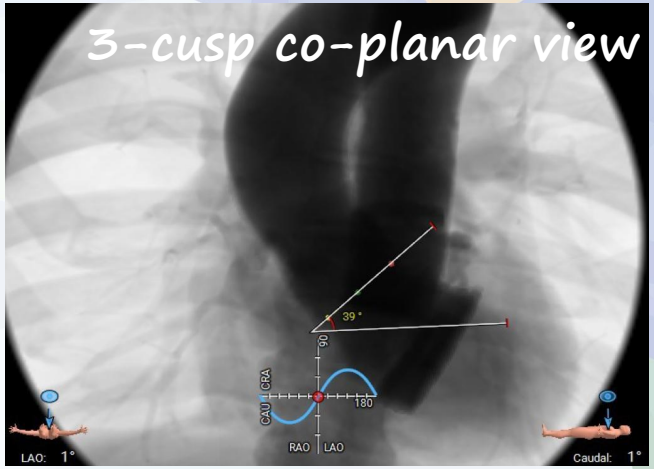


33x32x31 mm

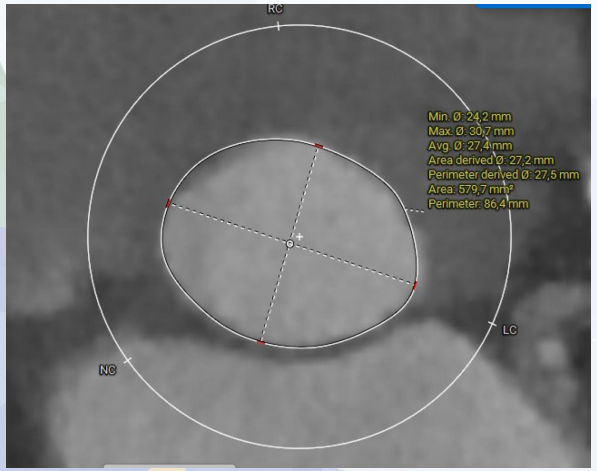
LCA height



15.4 mm

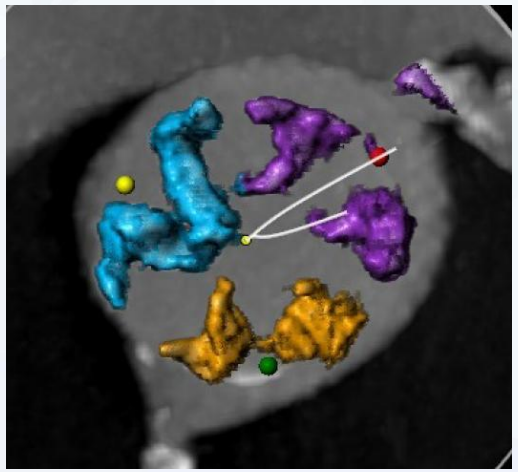


LVOT



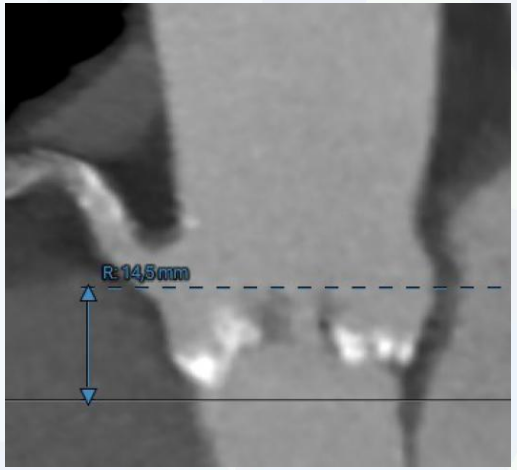
MinxMax D: 24x30.7 mm
Perimeter 86.4 mm (deriv. 27.5)

Aortic valve



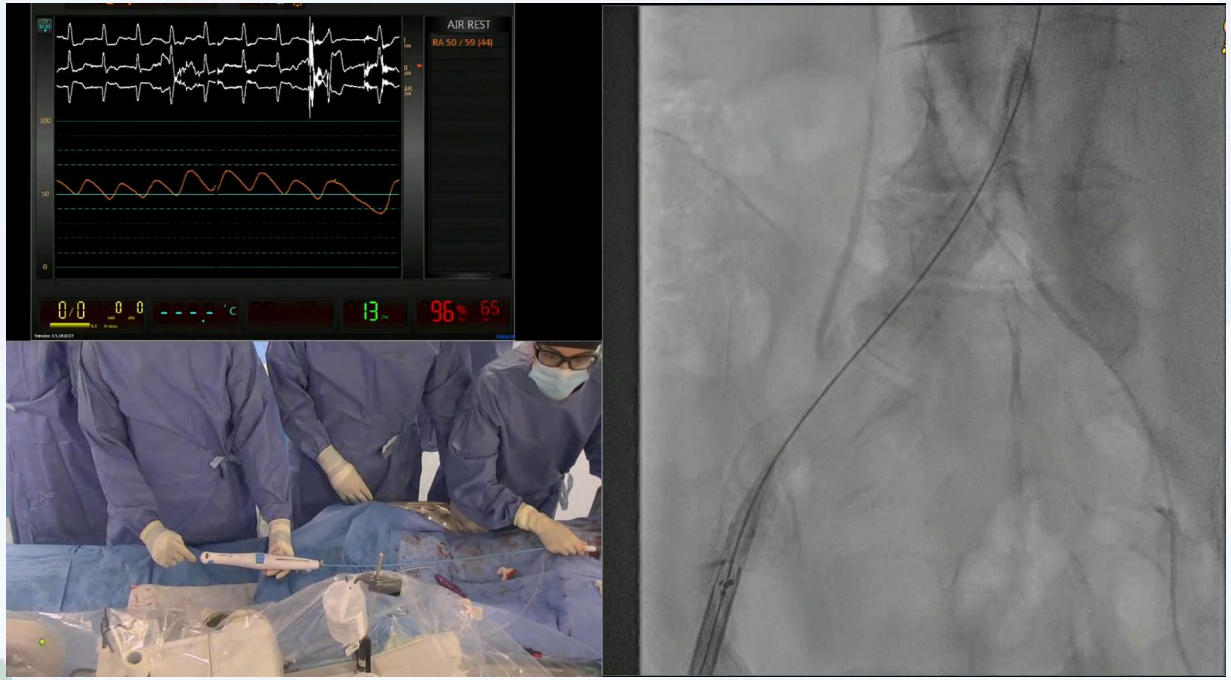
Moderate calcific

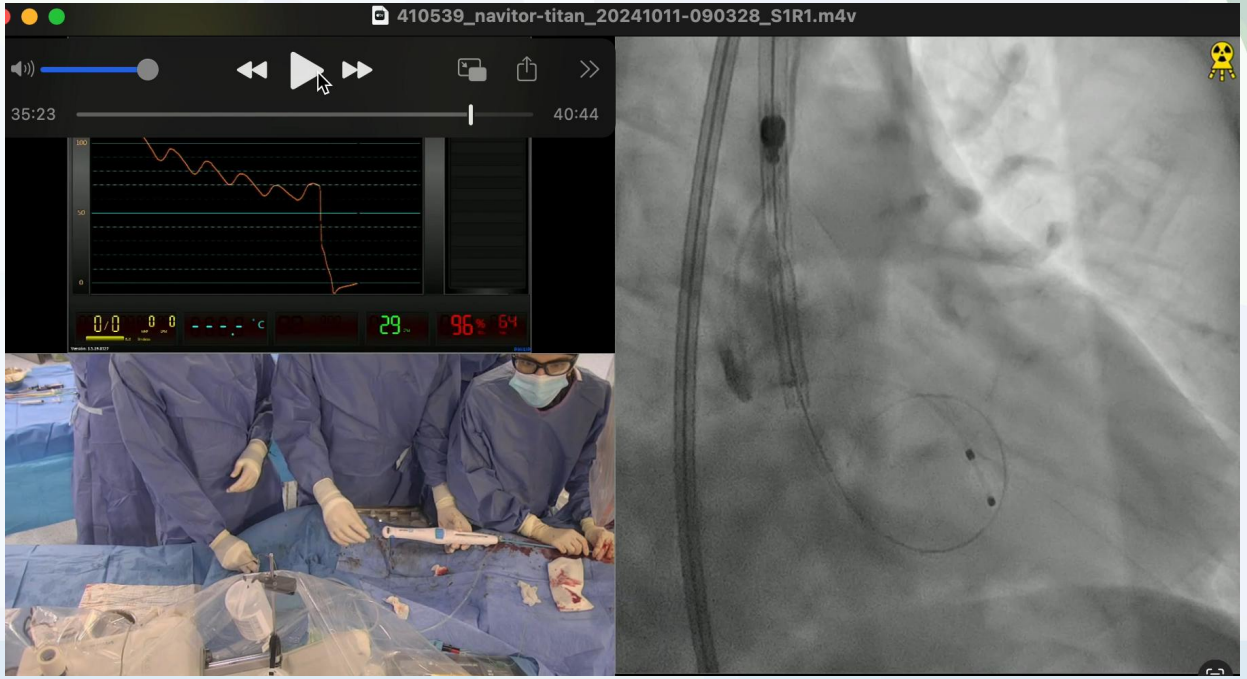
RCA height



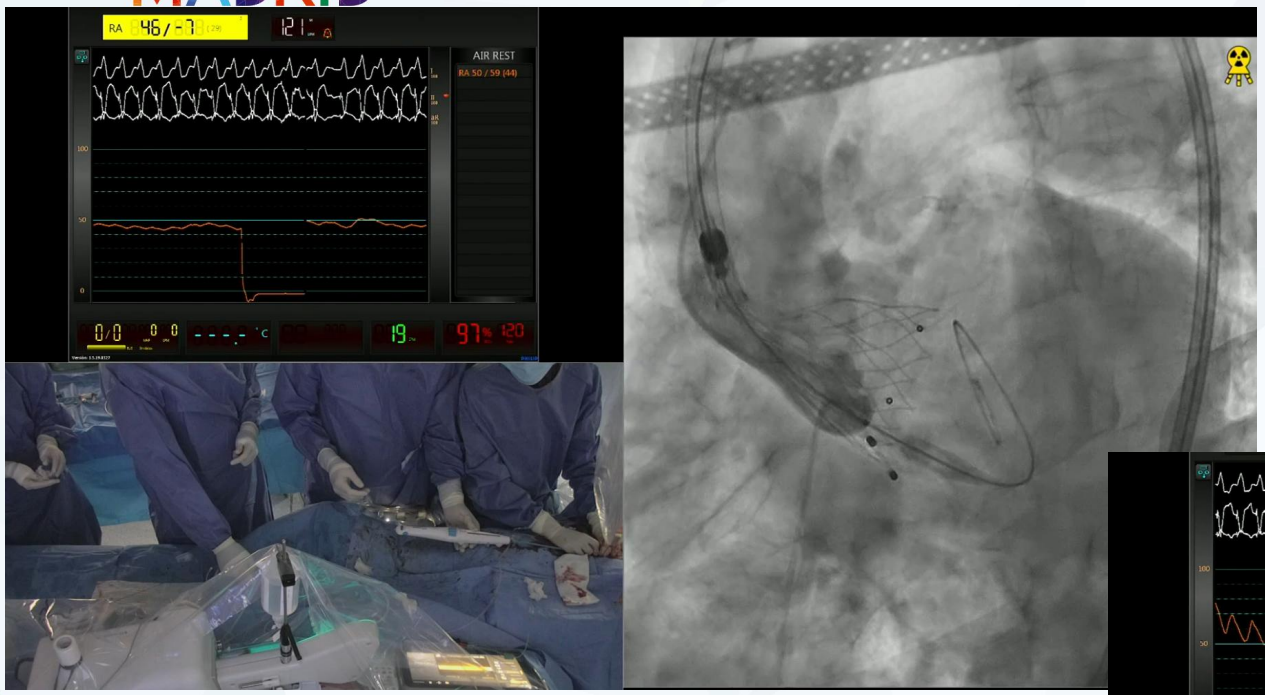
14.5 mm

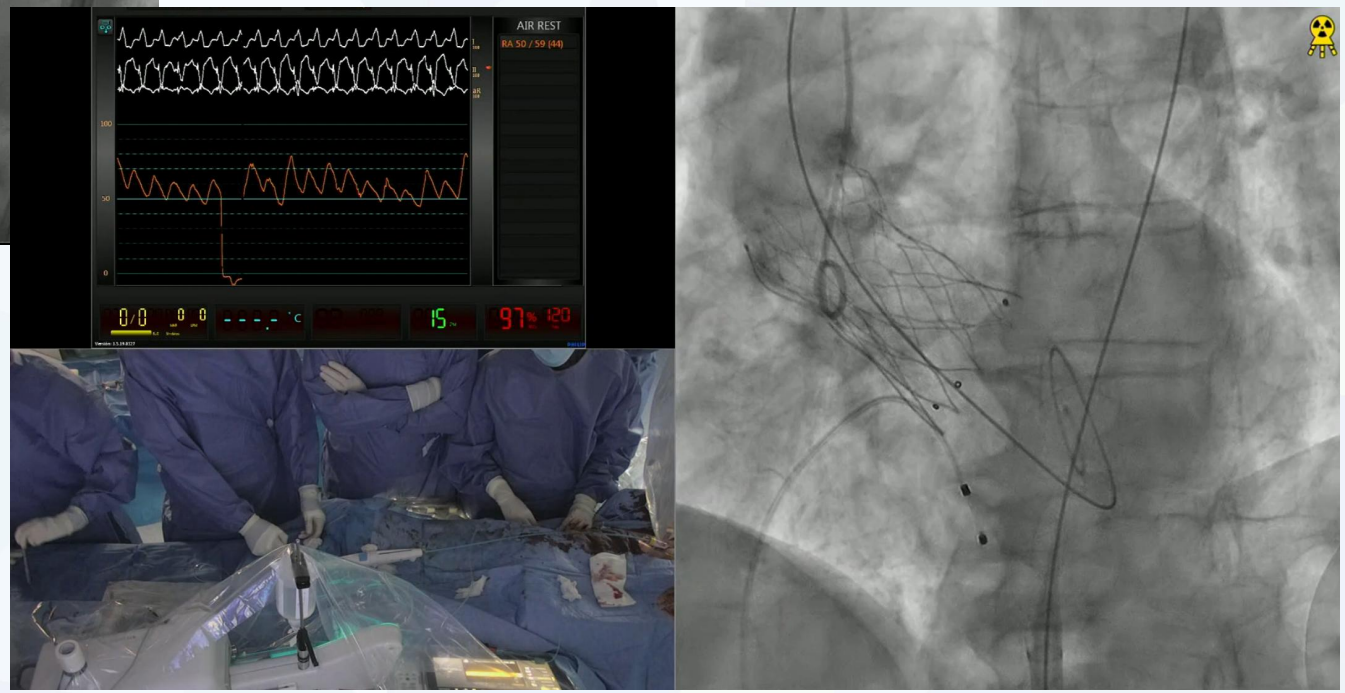
3. Expanding Annulus Range from 27 to 30 mm: TITAN





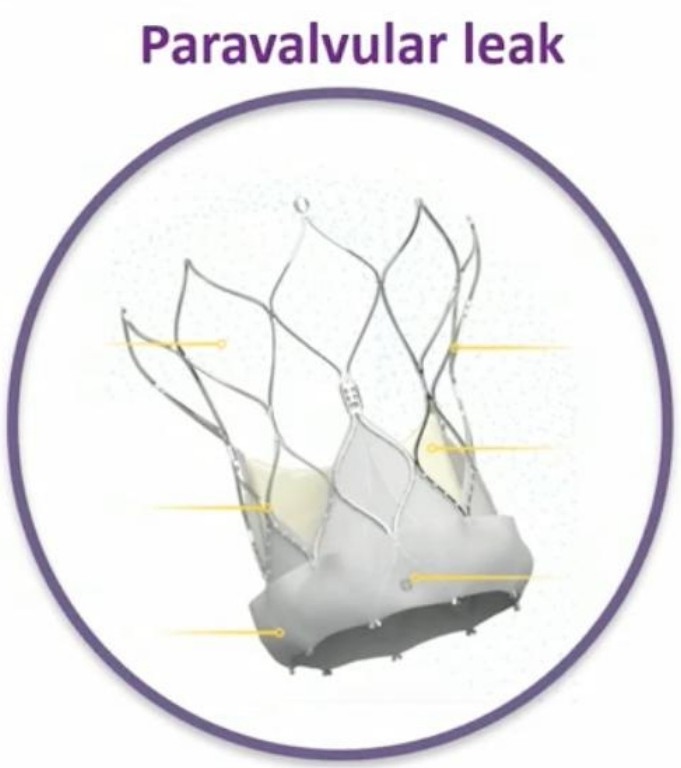
3. Expanding Annulus Range from 27 to 30 mm: TITAN

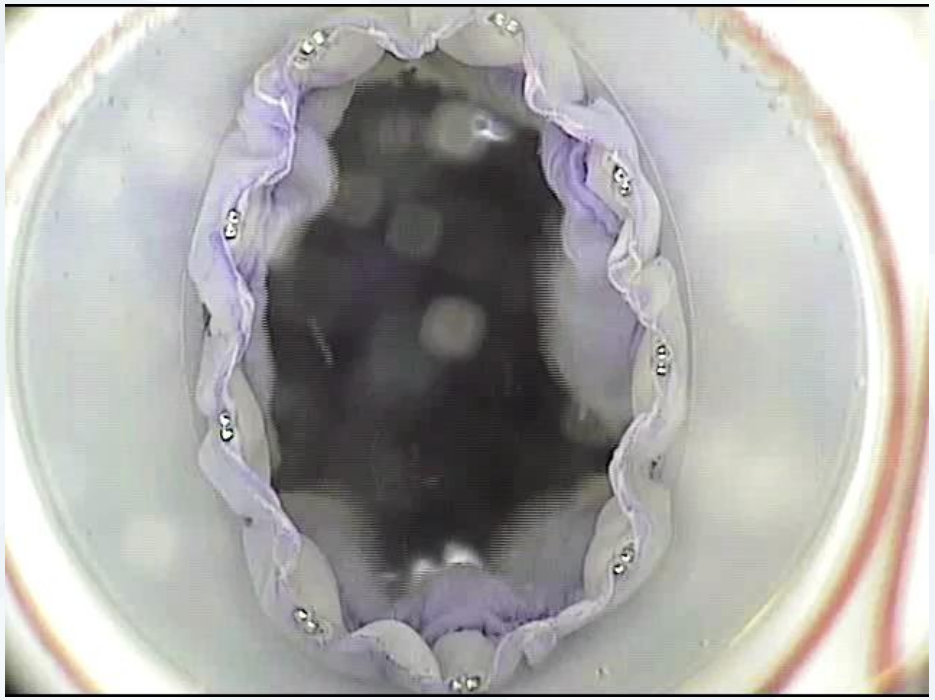


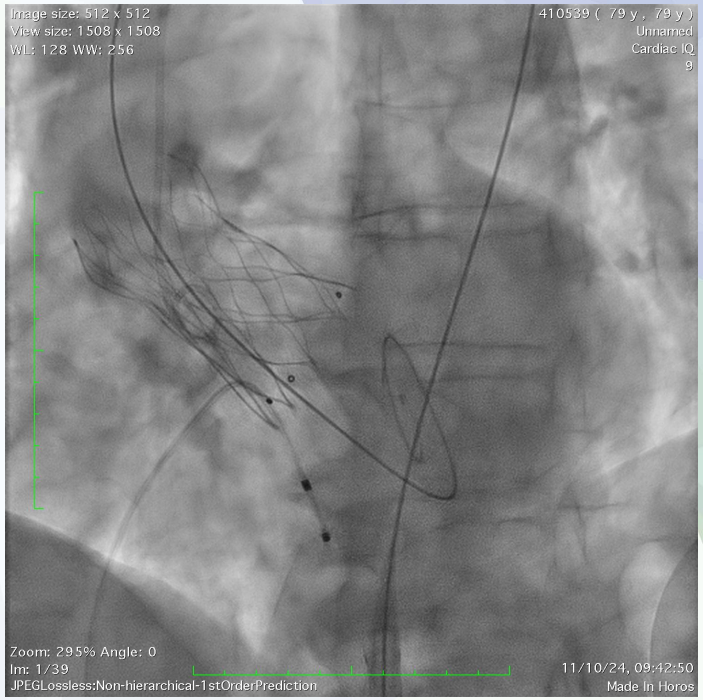


- Achieve similar radial force profile to the other Navitor valve sizes
- Same predictable overall performance of the other sizes

4. Paravalvular leak







SMART SEALING MITIGATES PVL

30-DAY ECHO CORE LAB DATA[1]

80%	20%	0%	0%
NONE/TRACE	MILD	MODERATE	SEVERE

5. Hemodynamics: Design

Hemodynamics

Mean Gradient (mm Hg)	7.4
EOA (cm^2)	2.0

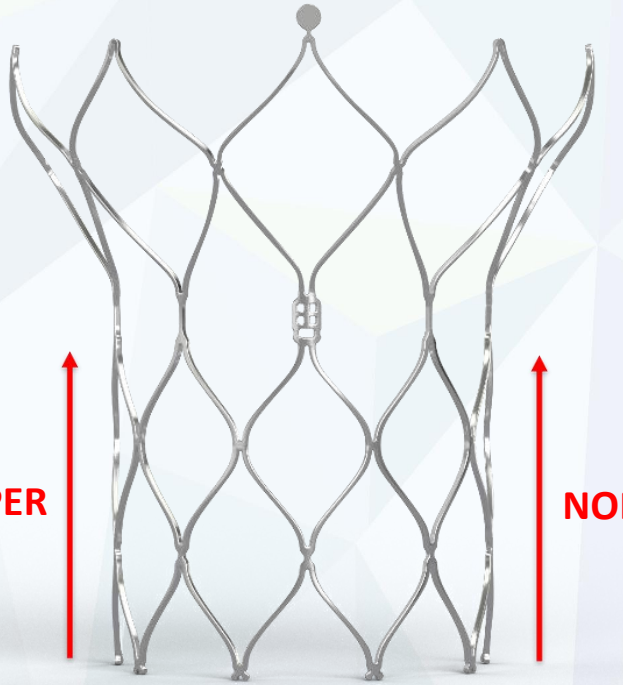
Fully opening Intra-annular leaflets

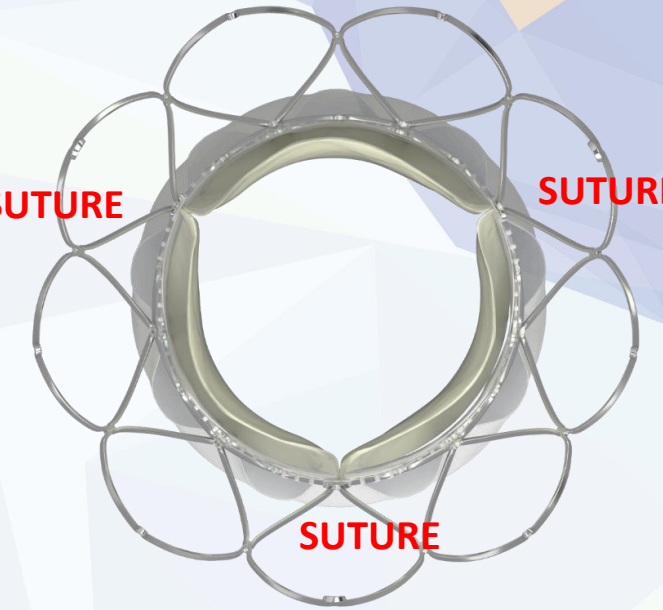
- Max orifice area
- Single digit mean gradient

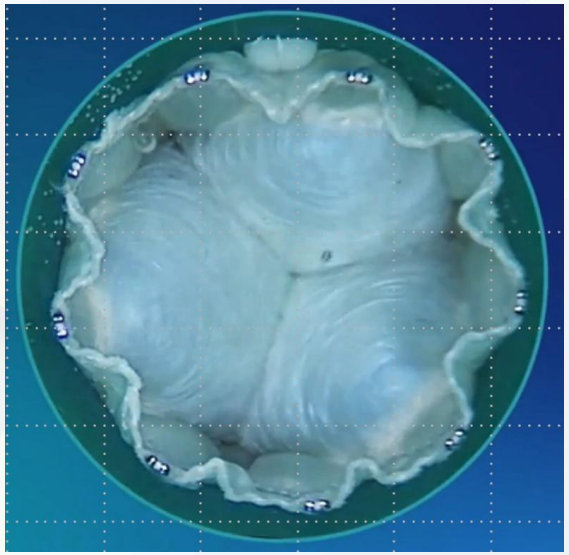
Inflow Diameter*

=

Outflow Diameter*



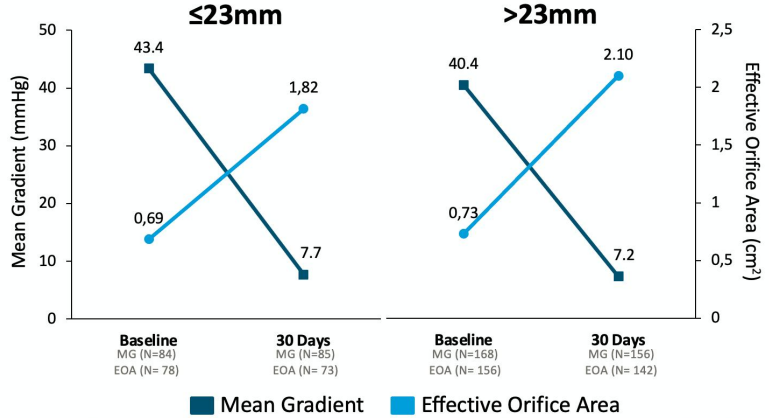




NAVITOR™VISION
VALVE
CYLINDRICAL VALVE

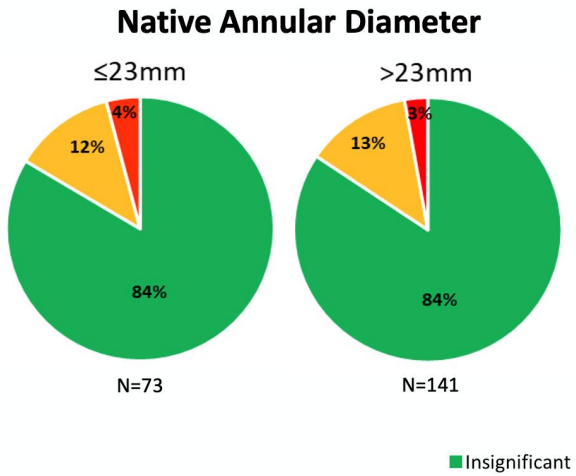
5. Hemodynamics

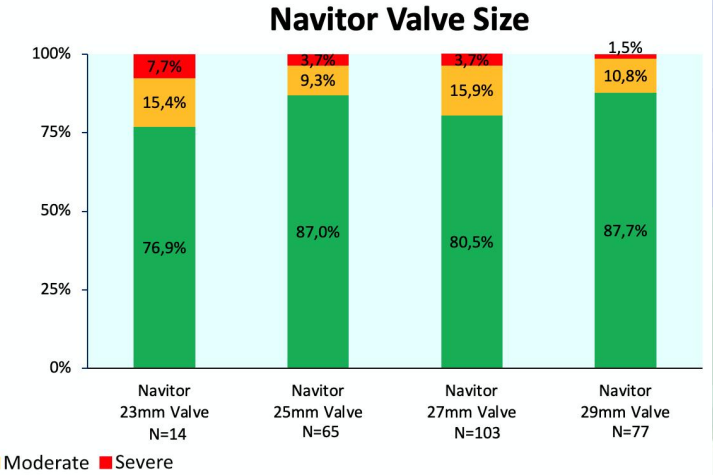
Single-Digit Gradients,Large EOAs across anular diameters

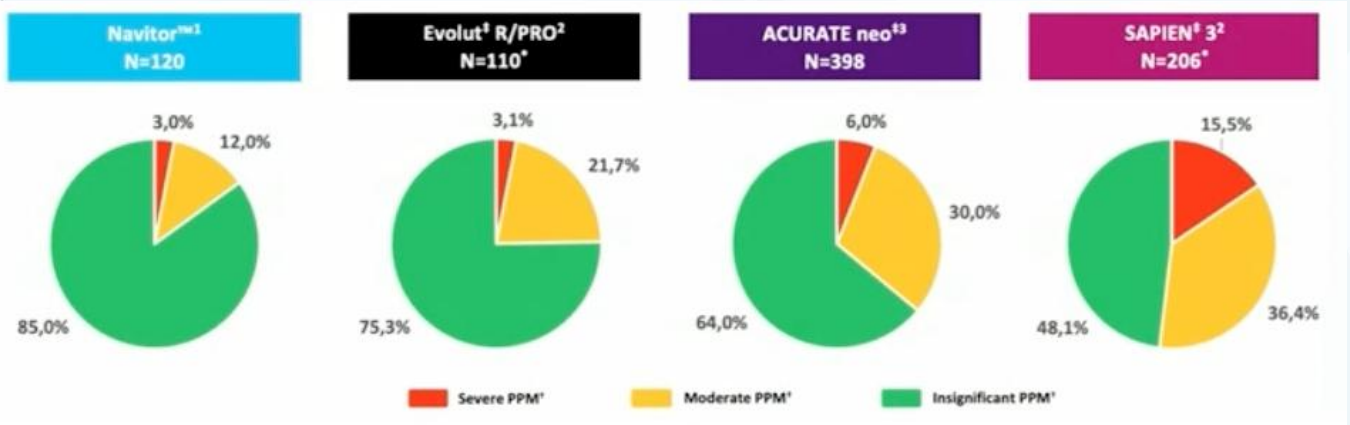


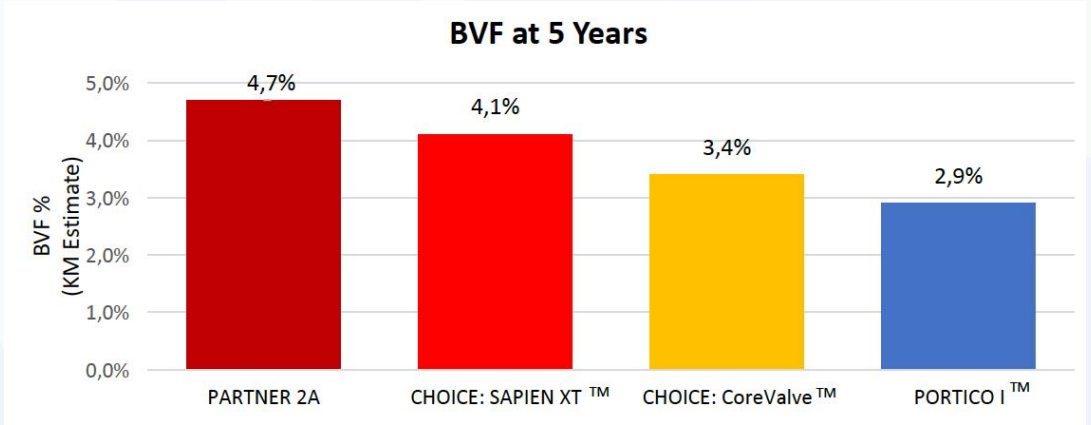
Mahoney, P. Assessment of Hemodynamics and Patient-Prosthesis Mismatch by Valve Size for an Intra-Annular Self-Expanding Transcatheter Heart Valve in the PORTICO NG Study. Presented at CRT 2023; February 27, 2023.

Low Incidence of Severe PPM at 30 days









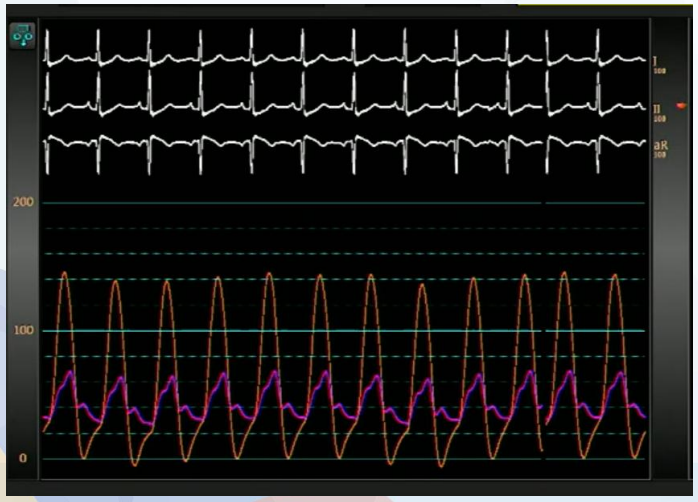
Mahoney, P. Assessment of Hemodynamics and Patient-Prosthesis Mismatch by Valve Size for an Intra-Annular Self-Expanding Transcatheter Heart Valve in the PORTICO NG Study. Presented at CRT 2023; February 27, 2023.

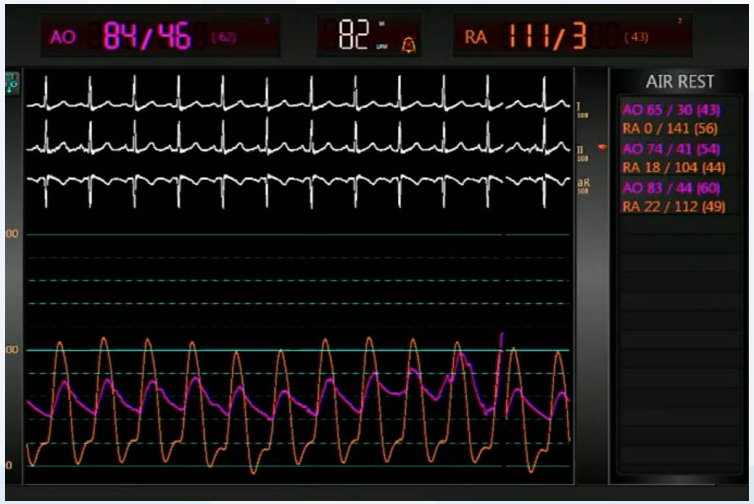
5. Hemodynamics

Trifecta 21

Non-fracturable

True-ID 19 mm

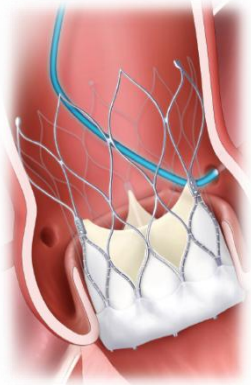




6. Coronary Access Post-TAVI

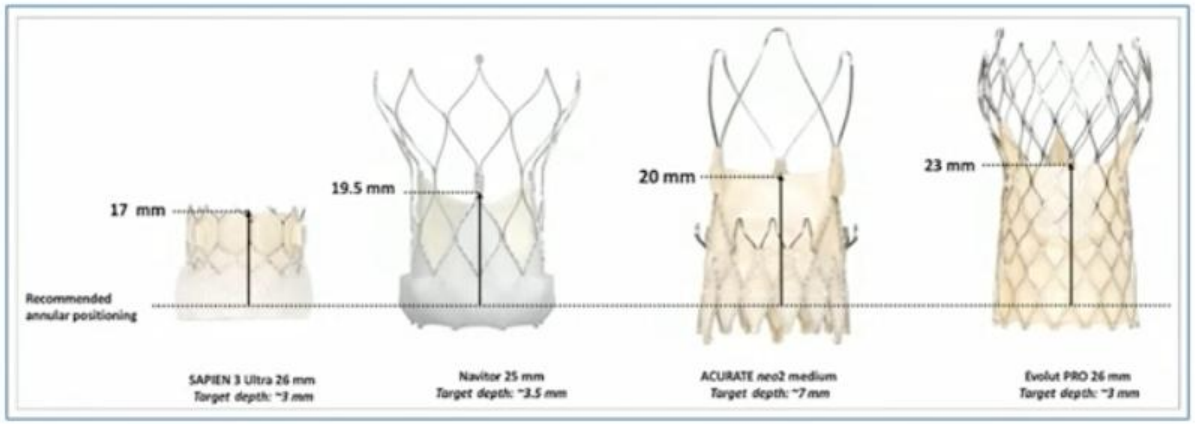
Optimizing the procedure for future coronary access – factors to take into consideration:

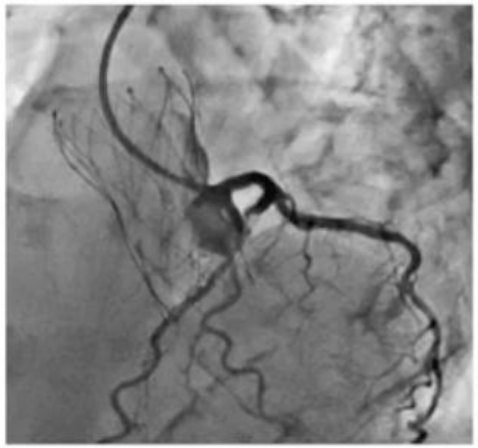
Patient	THV design	Implantation/operator-related
• Coronary height • Sinus of Valsalva dimensions	• Self-expandable | Balloon expandable • Neoskirt height	• Implant depth • Commisural alignment



Large cell geometry and intra-annular valve design preserve coronary access for future interventions

* For 29 mm Navitor Vision valve.
** Based on Abbott coronary access testing





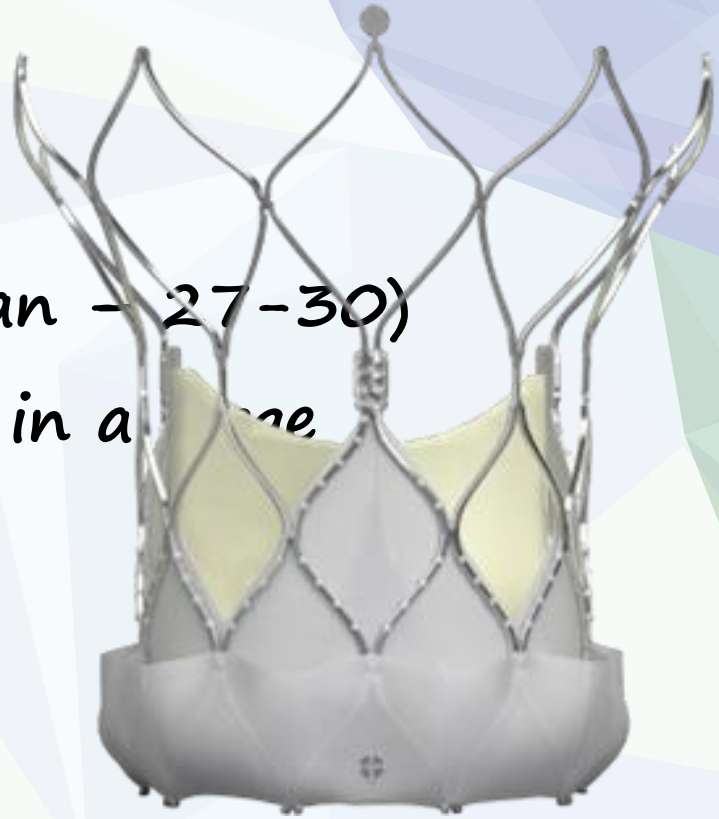
LOWEST NEOSKIRT HEIGHT[1]

- Among commercially available self-expanding valves, Abbott's TAVI system offers the lowest neoskirt height.

Conclusion

1. Best deliverability
2. Precise Implant Depth Placement - PM rate
3. Annulus treatment range from 19 – 30 mm (Titan – 27-30)
4. Titan 35 mm offers flexibility, accuracy & stability in a[illegible]e plataform

1. No Paravalvular leak
2. Best hemodynamic profile (design) – intraannular
3. Coronary access post-TAVI
4. Future TAV-in-TAV



Navitor™ TAVI System
Navitor Vision valve