

SAPIEN 3

Technology Overview

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship

Company

- | | |
|--|---|
| <ul style="list-style-type: none">● Consulting Fees/Honoraria● Proctoring-Training activities/Honoraria | <ul style="list-style-type: none">● Edwards Lifesciences● Edwards Lifesciences |
|--|---|

Edwards Balloon Expandable THV Evolution

2002-04



2005



2009



2012



Cribier Edwards

23mm



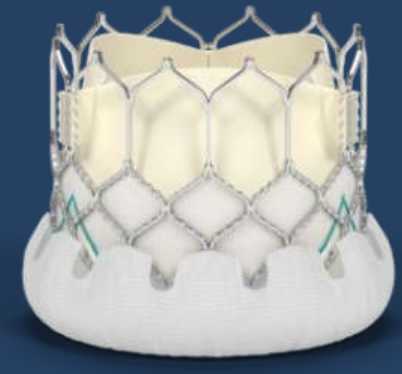
Edwards SAPIEN

23mm and 26mm



Edwards XT

20mm, 23mm, 26mm and 29mm



SAPIEN 3



Sheath compatibility for a 23mm THV size

The Edwards SAPIEN 3 is Designed to Achieve all Principles of Surgical Valve Replacement

Predictable Procedure



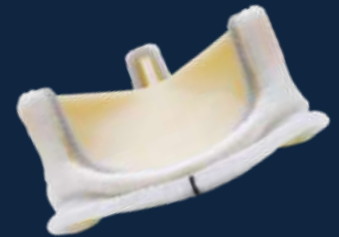
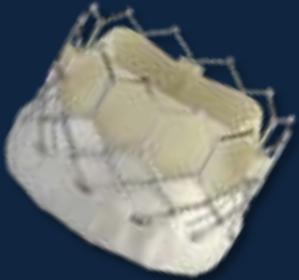
Optimal Haemodynamics



Low Rate of Complications



Durability



The SAPIEN 3 THV compares favorably to the surgical Carpentier Edwards Bioprosthesis

SAPIEN 3 Transcatheter Heart Valve

Distinguishing Features

Low frame height

to respect the cardiac anatomy

Enhanced frame geometry for ultra-low delivery profile

Large upper cells for coronary access

Bovine pericardial tissue

.Optimized leaflet shape

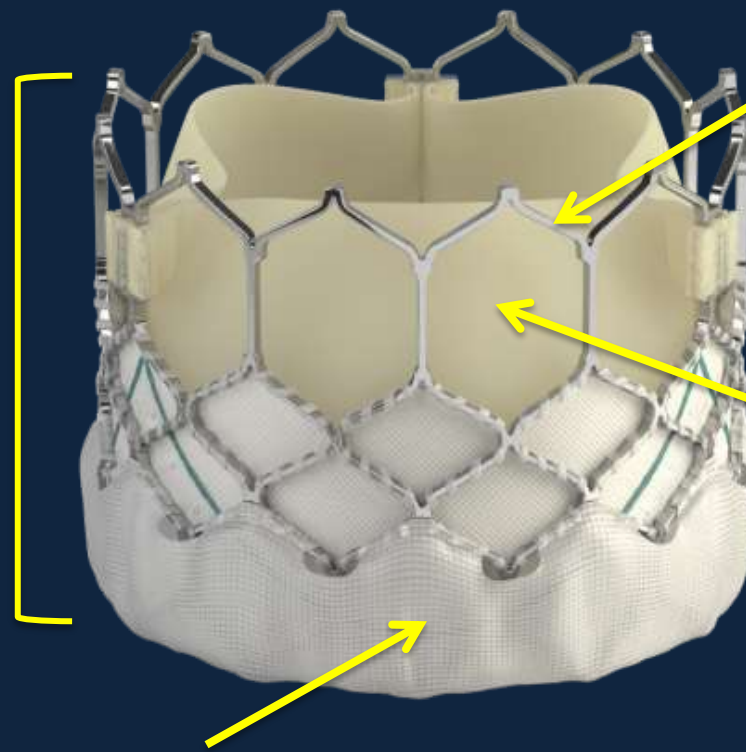
.Matching technology

.Carpentier-Edwards

Thermafix process

Outer skirt

to reduce PVL



SAPIEN 3 Transcatheter Heart Valve

Distinguishing Features

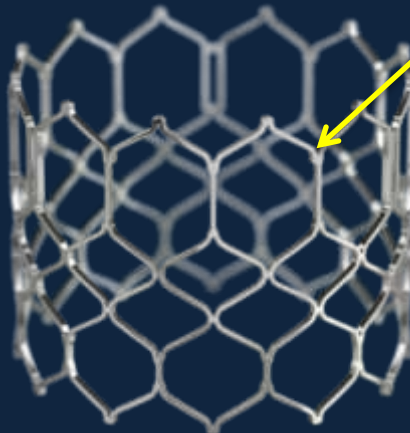
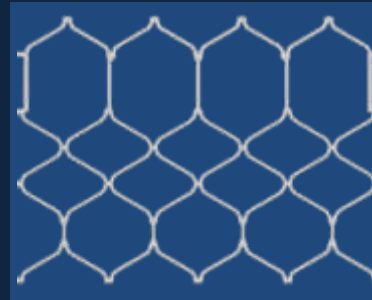
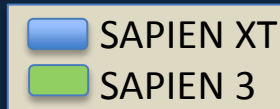
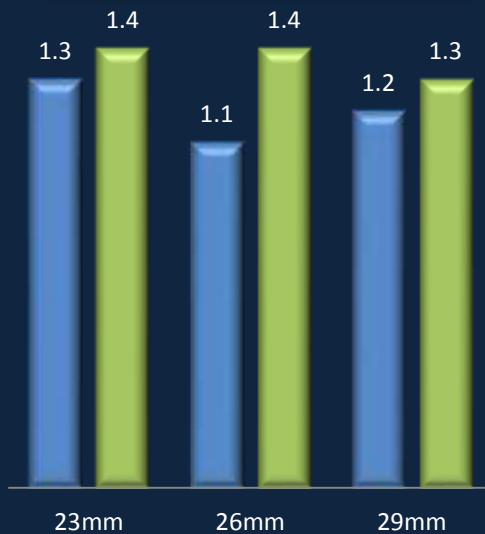
Cobalt-Chromium Alloy Frame

Designed changes while maintaining radial strength for circularity

Radial strength (bar)

4 rows and columns between each commissure for high radial strength

Circularity



Wide strut angles



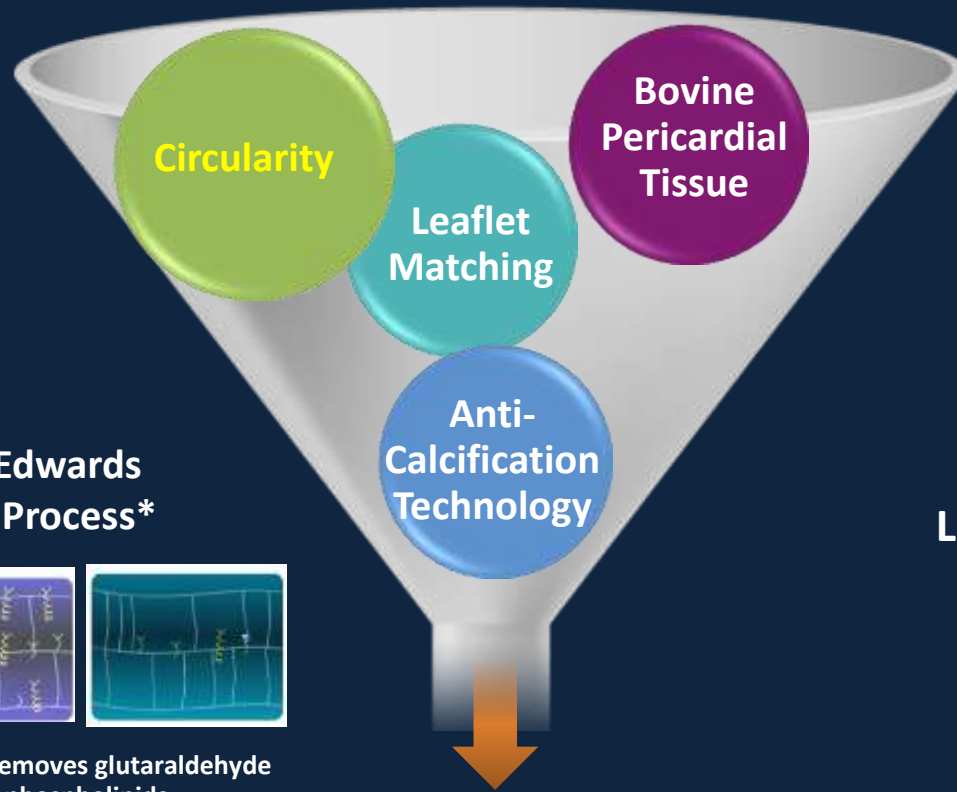
To reduce crimped profile



SAPIEN 3 Transcatheter Heart Valve

All critical features for durability

Circularity at annulus level



Bovine Tissue

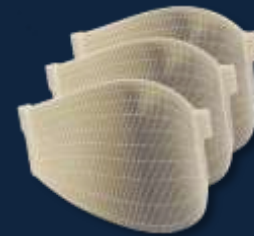


Carpentier-Edwards
ThermaFix™ Process*



Patented chemical treatment removes glutaraldehyde molecules and 98% of phospholipids

Leaflet Matching



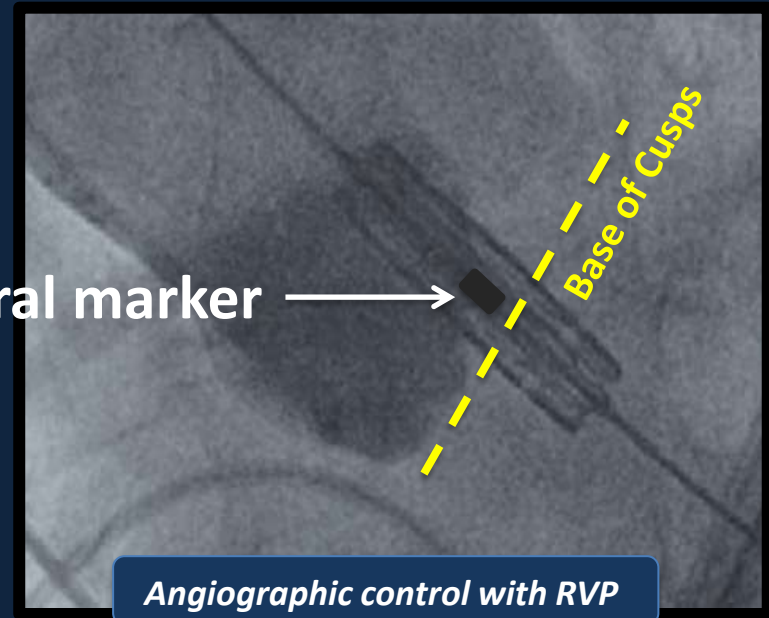
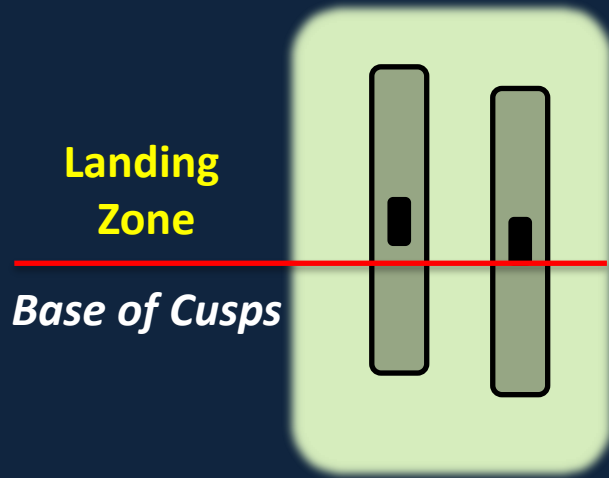
Durability

SAPIEN 3: Expanded Size Coverage and Sizing Recommendations

	 23 mm	 26 mm	 29 mm
Native Annulus Size By TEE	18-22 mm	21-25 mm	24-28 mm
Native Annulus Area	338-430 mm ²	430-546 mm ²	540-680 mm ²
Area-derived Diameter	20.7-23.4 mm	23.4-26.4 mm	26.2-29.5 mm

The outer skirt allows minimal (< 10%) or no oversizing

SAPIEN 3: Accurate valve positioning



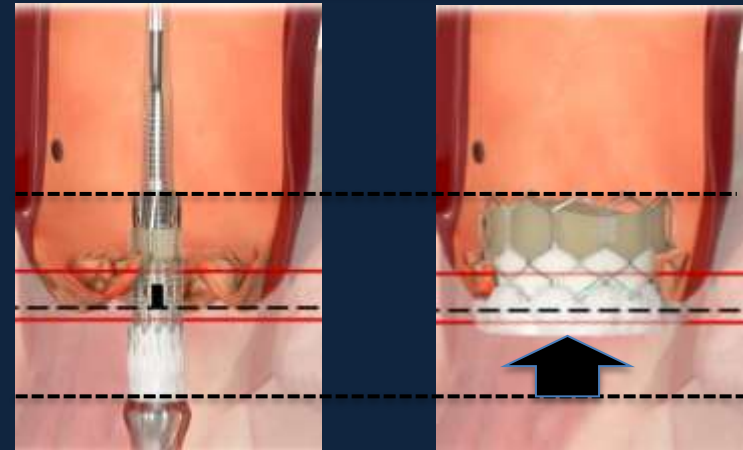
Recommended THV positioning
to limit the rate of new PPM

Foreshortening during inflation:
from ventricular side



THV Size	Crimped	Deployed	Shortening
23mm	24.5mm	18mm	6.5mm
26mm	27mm	20mm	7mm
29mm	31mm	22.5mm	8.5mm

SAPIEN 3 Height



Ideal THV Position
75% to 80% in Aorta

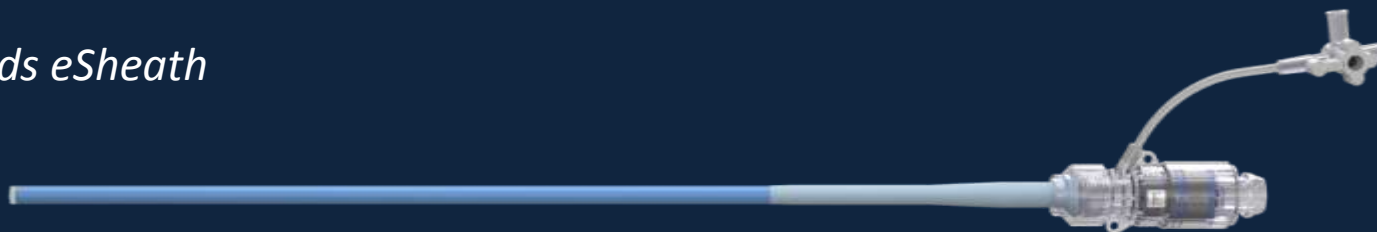
SAPIEN 3: The Edwards Commander Delivery system for TF-TAVR

Ultra-low Profile 14F eSheath Compatible*



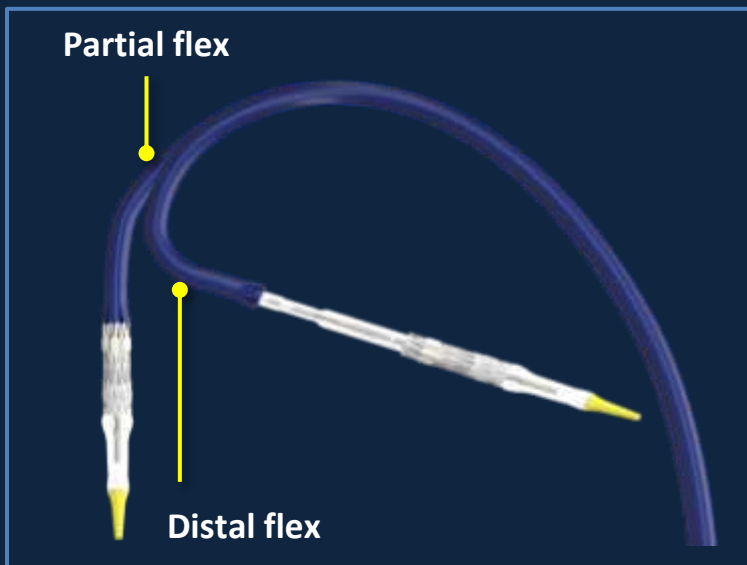
Reduced Minimum Access Vessel Diameters

Edwards eSheath



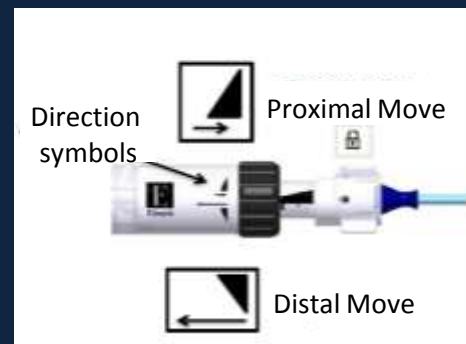
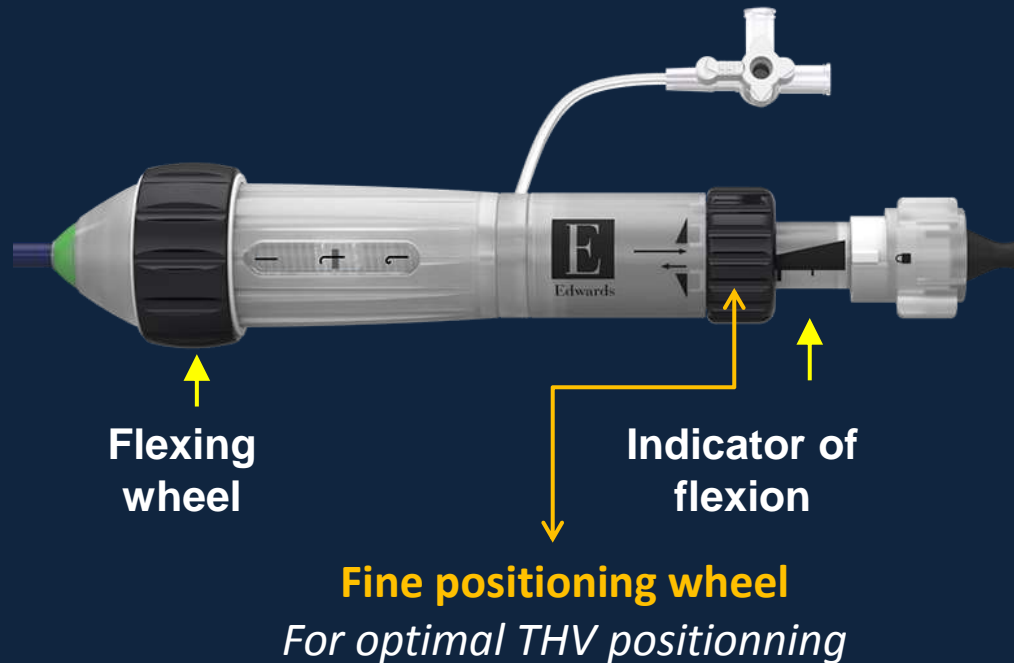
SAPIEN 3 Valve Size	23 mm	26 mm	29 mm
Edwards eSheath Introducer Set	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	6.0 mm

SAPIEN 3: The Edwards Commander Delivery system for TF-TAVR

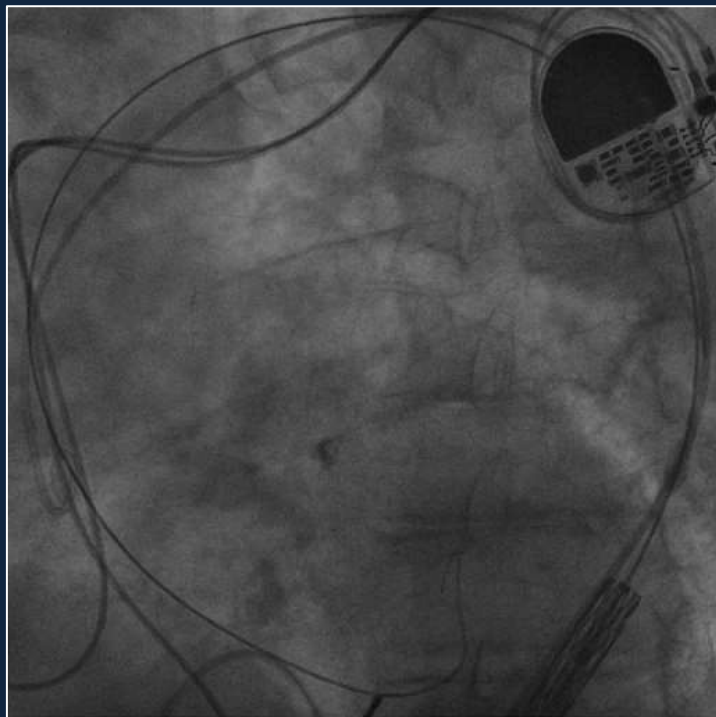


Dual articulation:

- *Partial* for safe aortic arch crossing
- *Distal* for intra-annulus coaxiality

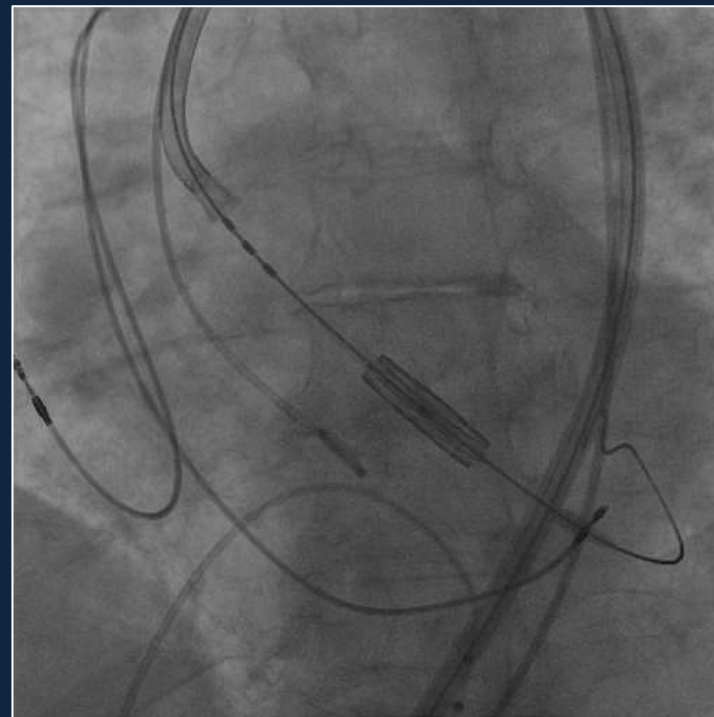


SAPIEN 3: The Edwards Commander Delivery system for TF-TAVR



Half flexion

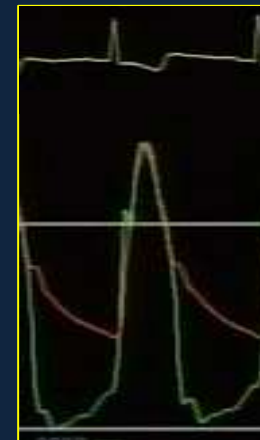
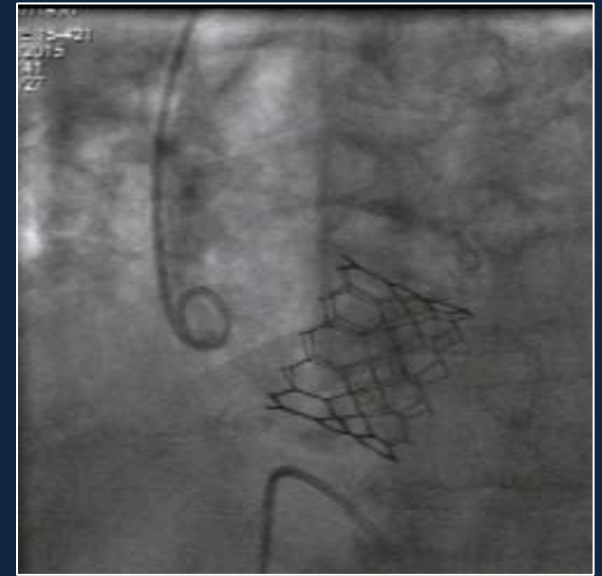
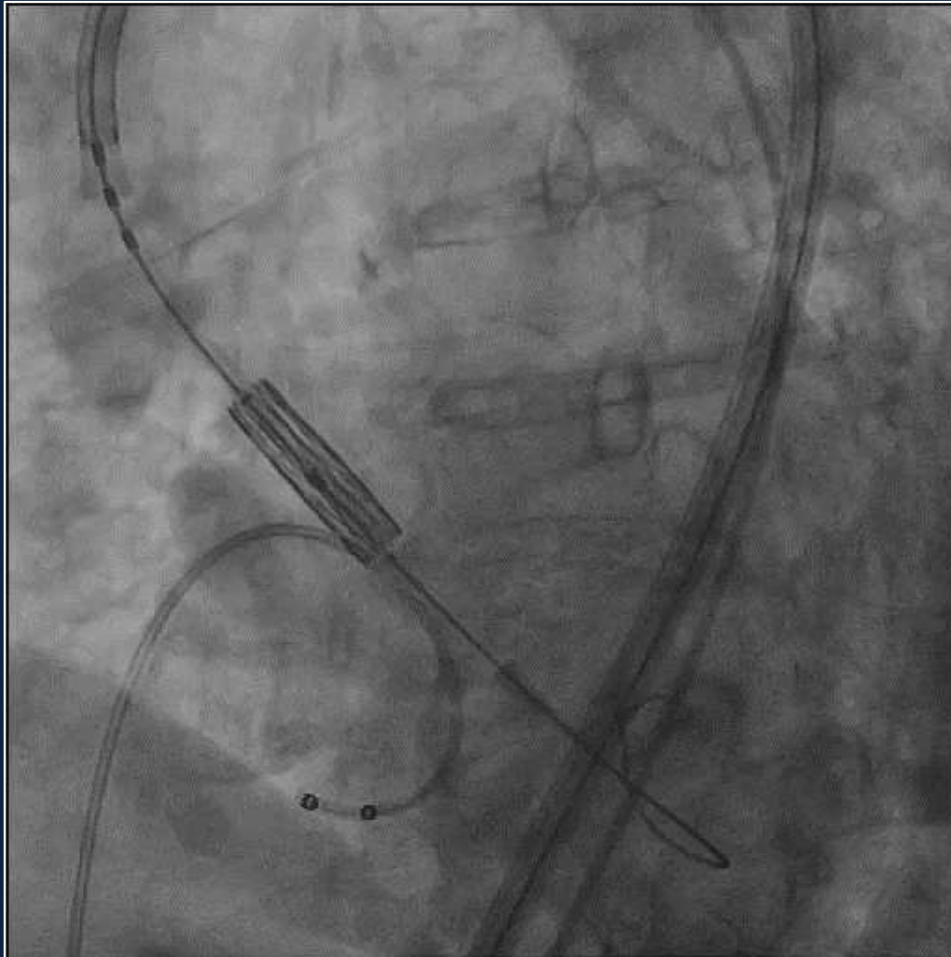
(2 full rotation) for safe crossing of the aortic arch, even in severe tortuosity



Full flexion, + traction on wire

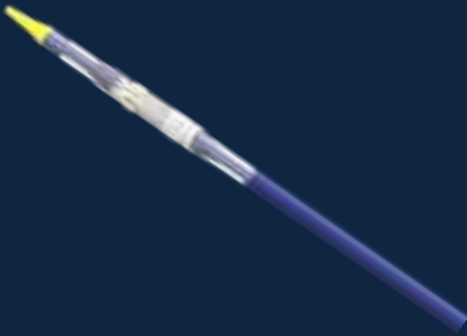
for coaxial crossing of the native valve even in major AO angulation

SAPIEN 3: Easy, stable, predictable THV deployment and results



SAPIEN 3: The Edwards CERTITUDE Delivery system for TA/TAO-TAVR

Integrated Pusher



Articulation Feature



Ergonomic Handle



SAPIEN 3 Valve Size

23 mm

26 mm

29 mm

Edwards Certitude Introducer Sheath

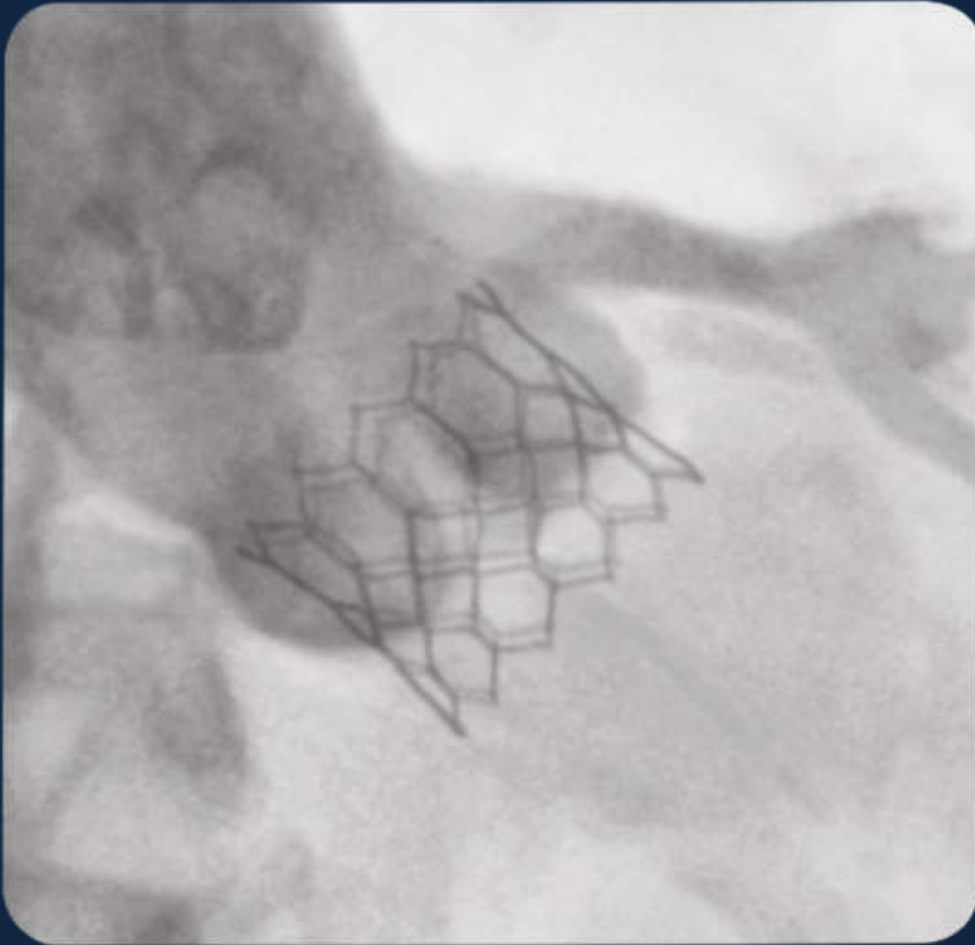
18F

18F

21F

- Ultra-low profile system – 18F Certitude sheath compatible*
- Integrated pusher
- Articulation feature for ease of coaxial positioning
- Ergonomically designed handle

SAPIEN 3: Predictable Results



TF-TAVR in > 85%

**No or mild PVL
in > 95%**

**Low rate of
complication**

Excellent outcome

Summary and Conclusions

The SAPIEN 3 is an optimal transcatheter valve

- **All characteristics of a surgical bioprosthesis:**
 - Sub coronary position or easy access to coronary arteries
 - Treated bovine pericardium valve
 - Circular frame opening
 - Protection of adjoining structures
 - Low rate of major complications (PVL –almost gone)
- **Friendly technique, predictable implantation, adapted to the vast majority of patients**
- **Compatible with TF minimalist approach in nearly 90% of cases**
- **Many advantages that will catalyze, following the positive results of PARTNER 2 S3, a broad expansion of TAVR to lower risk patients**