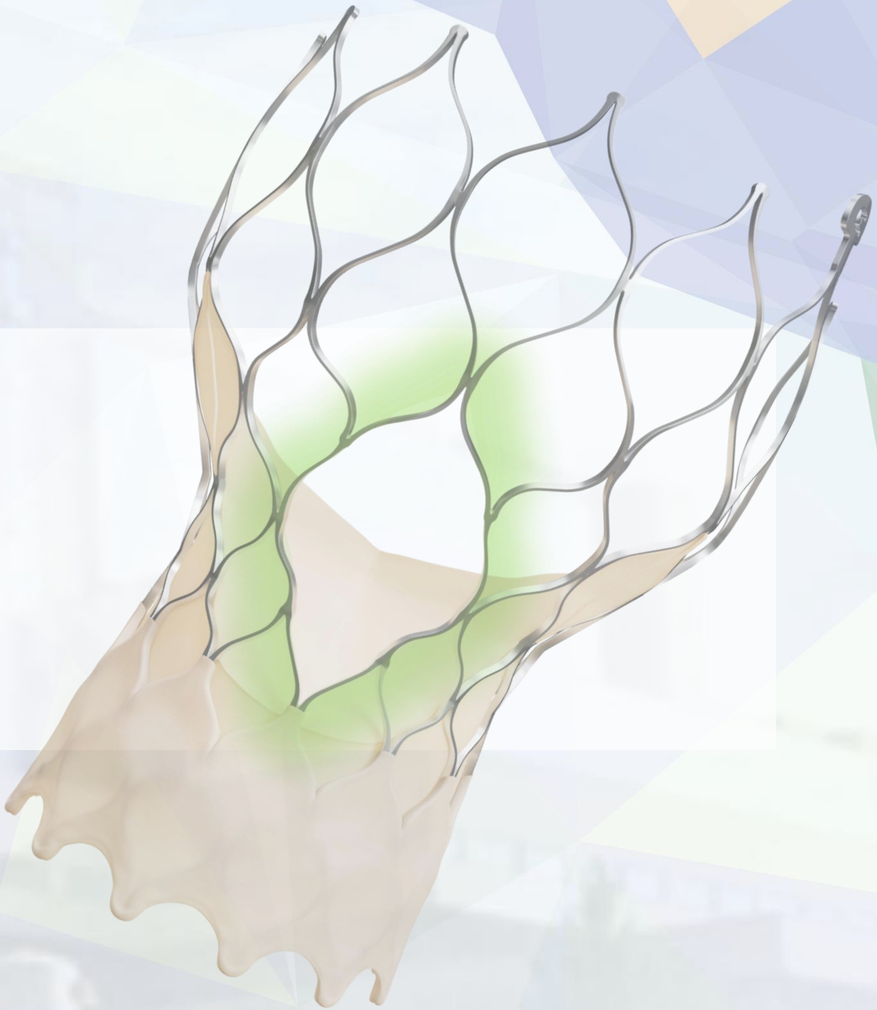
CSC 2024
CORONARY AND STRUCTURAL COURSE
CURSO CORONARIO Y ESTRUCTURAL
MADRID

10º ANIVERSARIO
6, 7 y 8 NOVIEMBRE
HOTEL RIU PLAZA DE ESPAÑA

SIMPOSIOS DE INNOVACION I

TAVI EVOLUTE FX plus la respuesta para ser polivalentes



Ramiro Trillo
Cardiologia Intervencionista
Santiago de Compostela

ÁREA SANITARIA
SANTIAGO DE COMPOSTELA
E BARBANZA

CARDIOCHUS

idis
INSTITUTO DE INVESTIGACIÓN SANITARIA
SANTIAGO DE COMPOSTELA

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Problemas y desafíos actuales para el reemplazo de la válvula aórtica transcatéter y los factores responsables relacionados

Patient-prosthesis mismatch

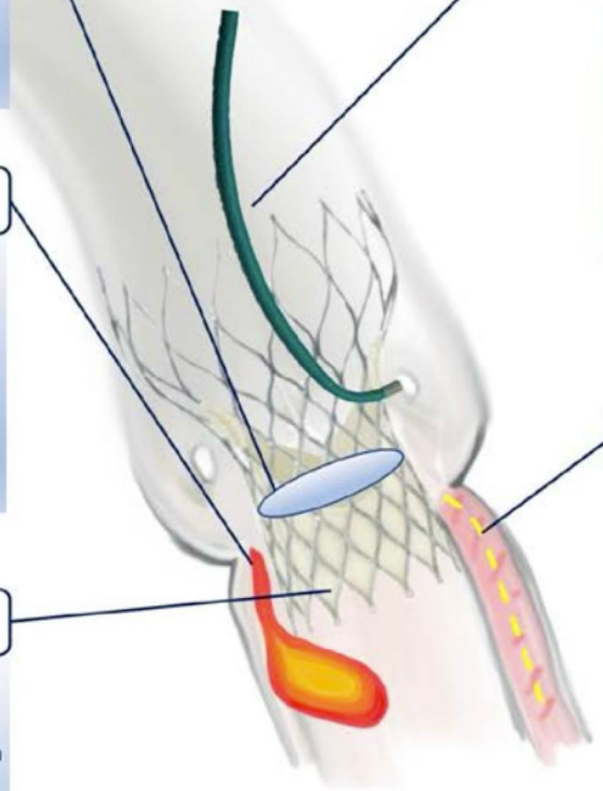
Patient	Prosthesis
Small annulus	Surgical
	Intra-annular

Paravalvular Leak

Patient	Prosthesis	Procedure
Cover Index	SE THV	Deep implant
LVOT-Ao Angle		
Calcification		

Durability

Patient	Prosthesis	Procedure
Age	SE (for PVL)	Balloon dilatation
	Leaflet/stent material	
	Crimping	



Coronary Reaccess

Patient	Prosthesis	Procedure
Small sino-tubular J	Supra-annular	V-i-V
Small sinus of Valsalva	High stent frame	Commissural alignment
Low coronary take-off	Small stent cells	Implantation height
Highly calcific annulus		

Permanent Pacemaker

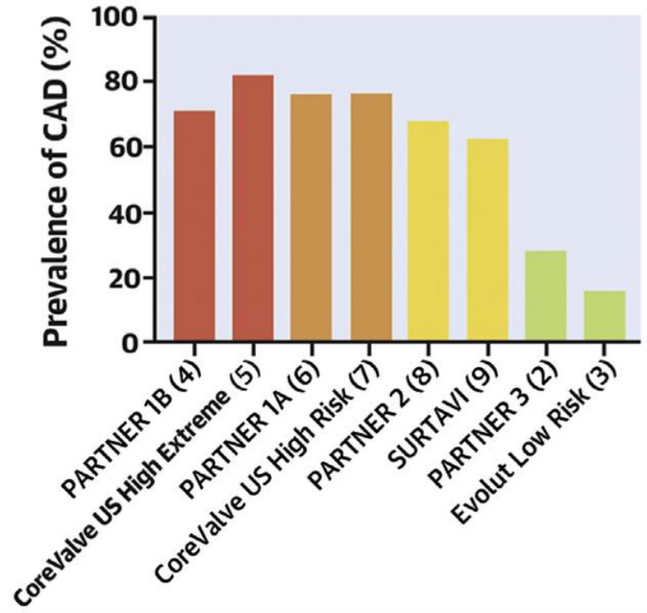
Patient	Prosthesis	Procedure
Age	SE THV	No cusp overlap
Conduction disturb		Deep implant
LVOT calcification		Balloon dilatation

Russo et al. Circ Cardiovasc Interv. 2022

Enfermedad coronaria

CAD Management Before TAVR

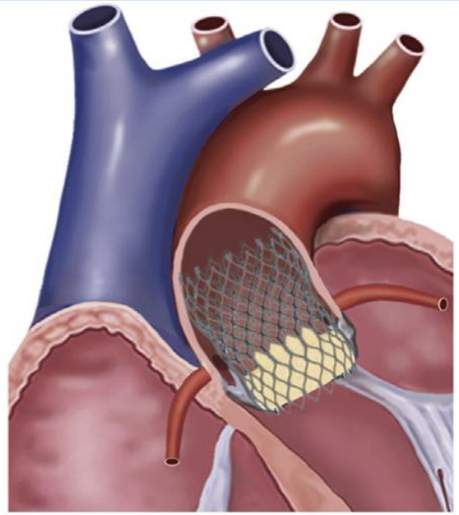
Prevalence of CAD in TAVR Recipients According to Surgical Risk



Future Perspectives

- CTA: Reasonable alternative to coronary angiography for the evaluation of CAD pre-TAVR
- FFR/iFR: Feasible and safe, promising preliminary results

CAD Management After TAVR



Coronary Access After TAVR

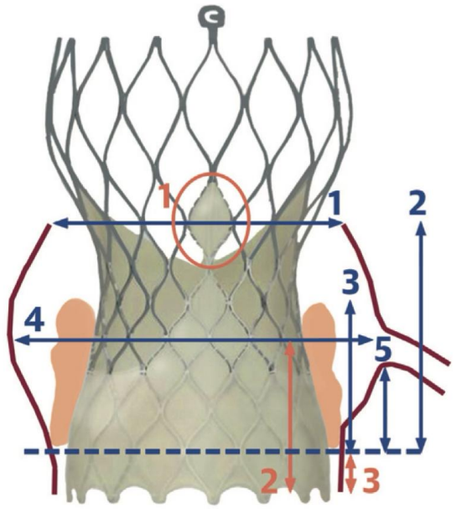
- No expected difficulties (in most cases) for coronary access (particularly valves with shorter stent frame/sealing skirt, larger stent cell size)
- Potential increased difficulties for coronary access (particularly RCA) in some cases (taller stent frame/sealing skirt, small sinus of Valsalva, low coronary height)

Poor Outcomes Associated With ACS Post-TAVR

Faroux L, et al. J Am Coll Cardiol. 2019 Jul 23;74(3):362-372

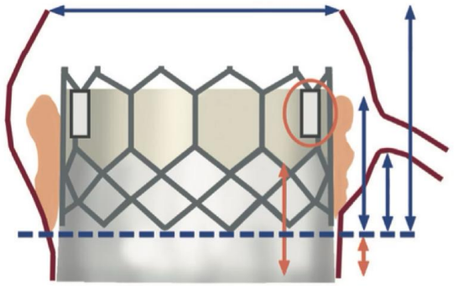
Acceso coronario

Factors Impacting Coronary Access



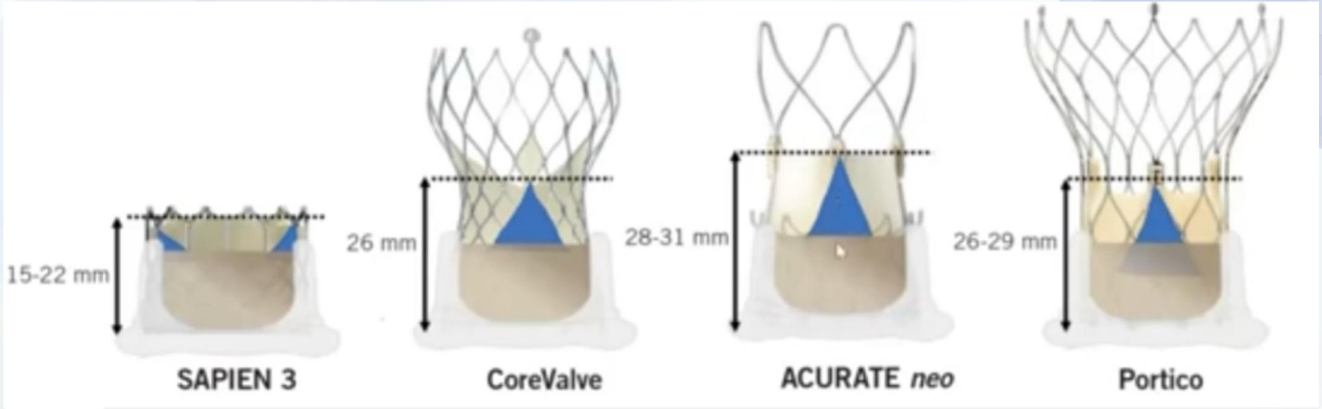
Anatomical

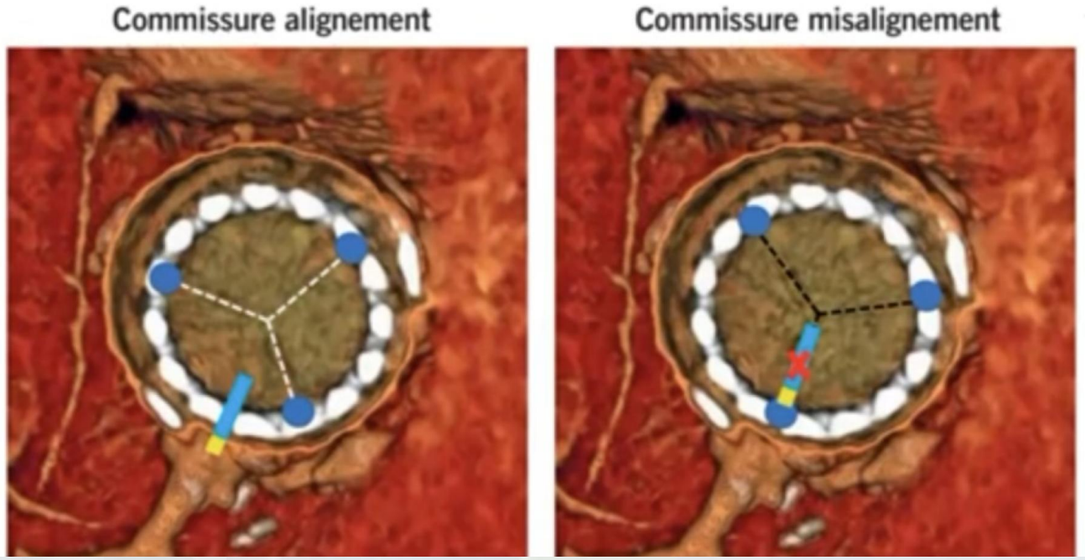
1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height



Device and Procedural

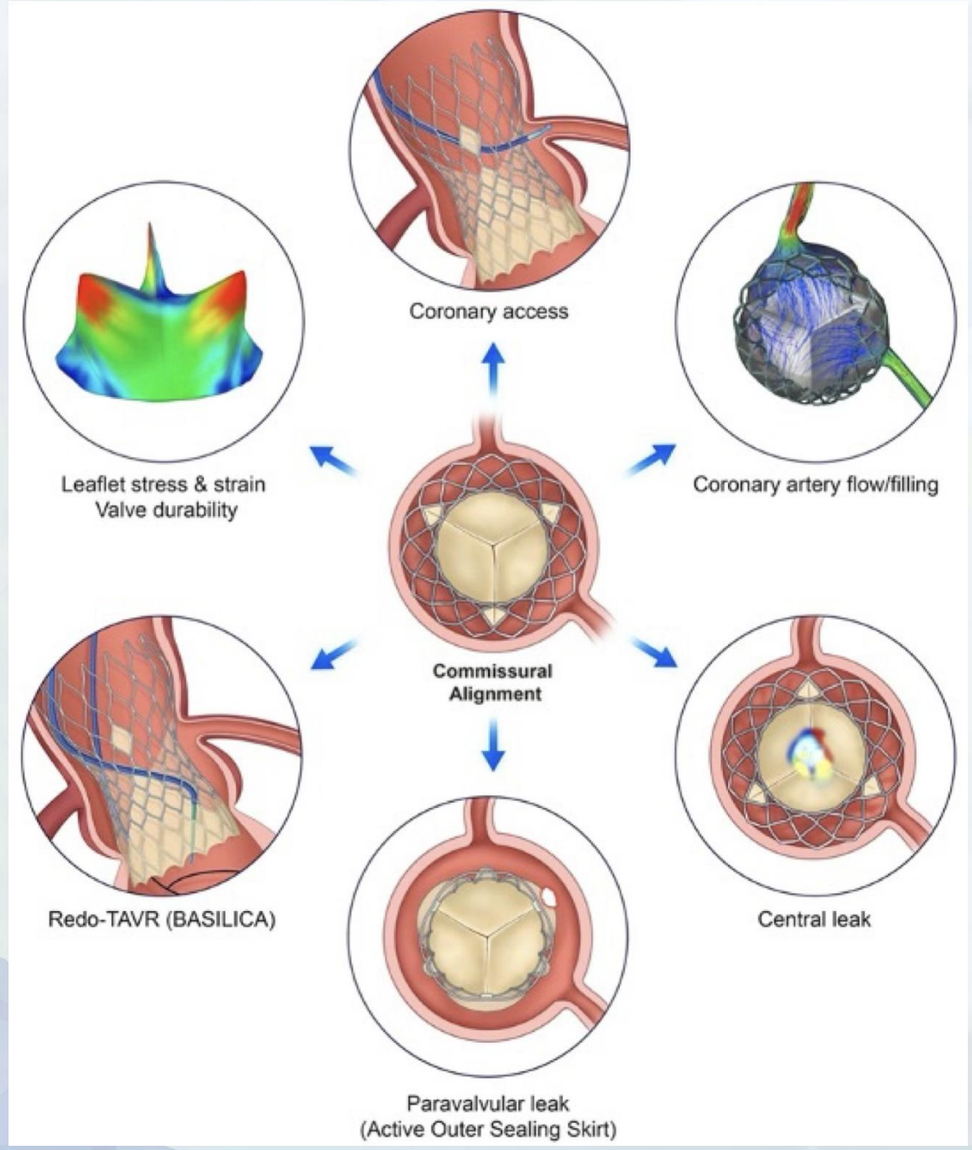
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth

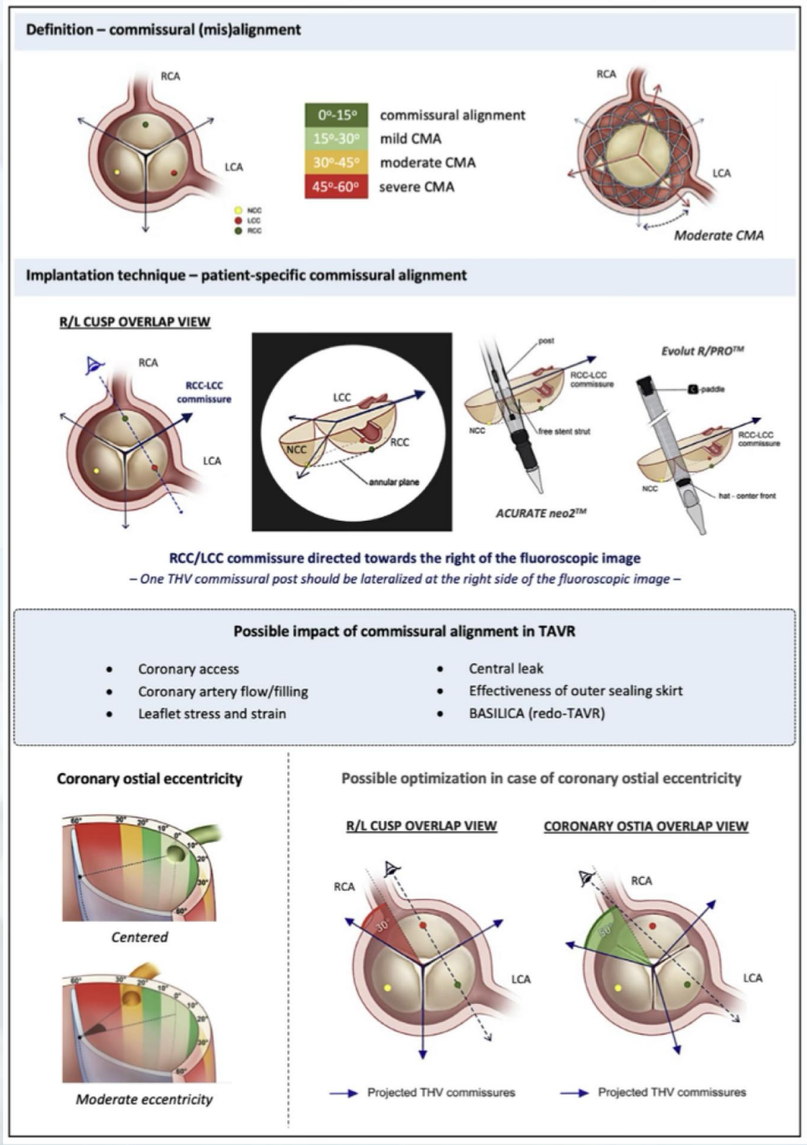




Yudi et al. JACC 2018

Alineamiento Comisural





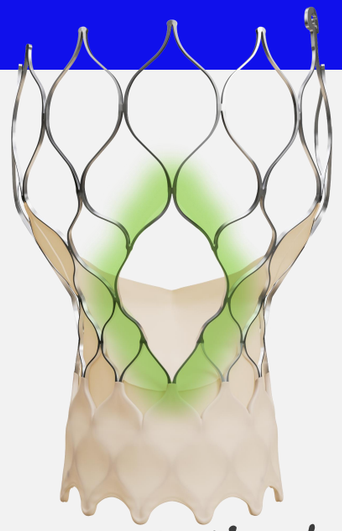
Tang, From the ALIGN-TAVR Consortium. JACC Cardiovasc Interv. 2022

Evolut FX+ System Overview

TAVI without Compromise

The Evolut FX+ System combines the FX delivery system for a more precise, predictable deployment with the Evolut FX+ TAV's with three coronary access windows to enable future coronary access.

Evolut FX+ TAV



4x Larger Windows to Enable Future Coronary Access[1]

Evolut FX DCS

Flexibility and Control for Precise, Predictable Deployment[2]

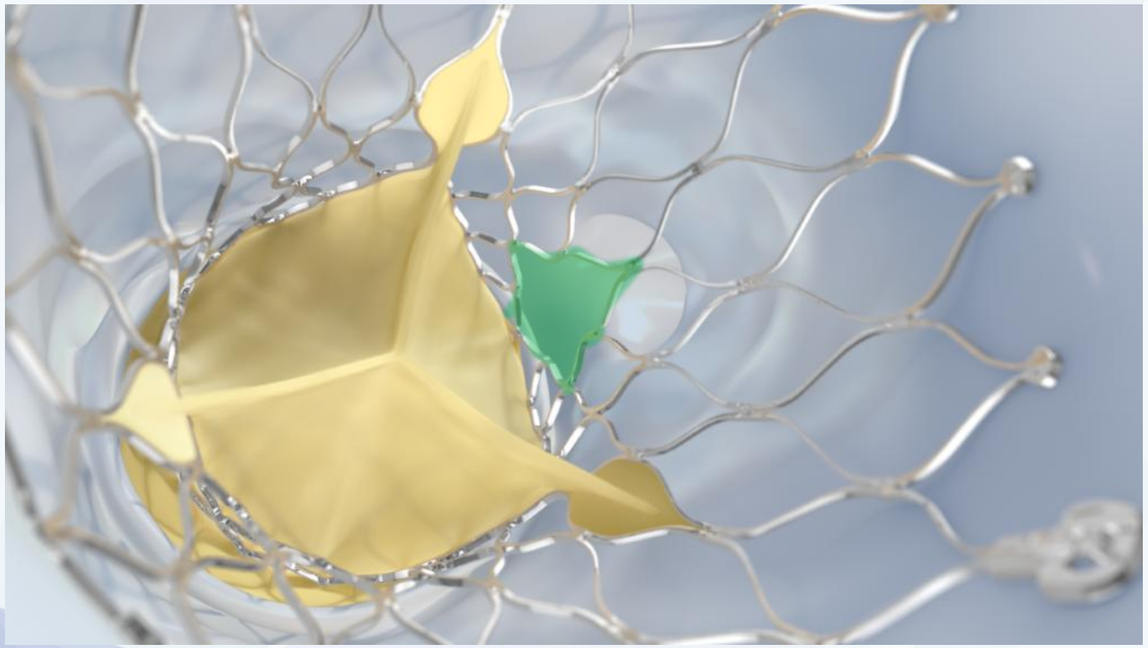
1. Medtronic computational data model on file compared to the Evolut platform. Computational model may not be indicative of clinical performance.
2. Zaid, S. et al., *JACC*: Cardiovascular Interventions, (16:13), 2023

Medtronic

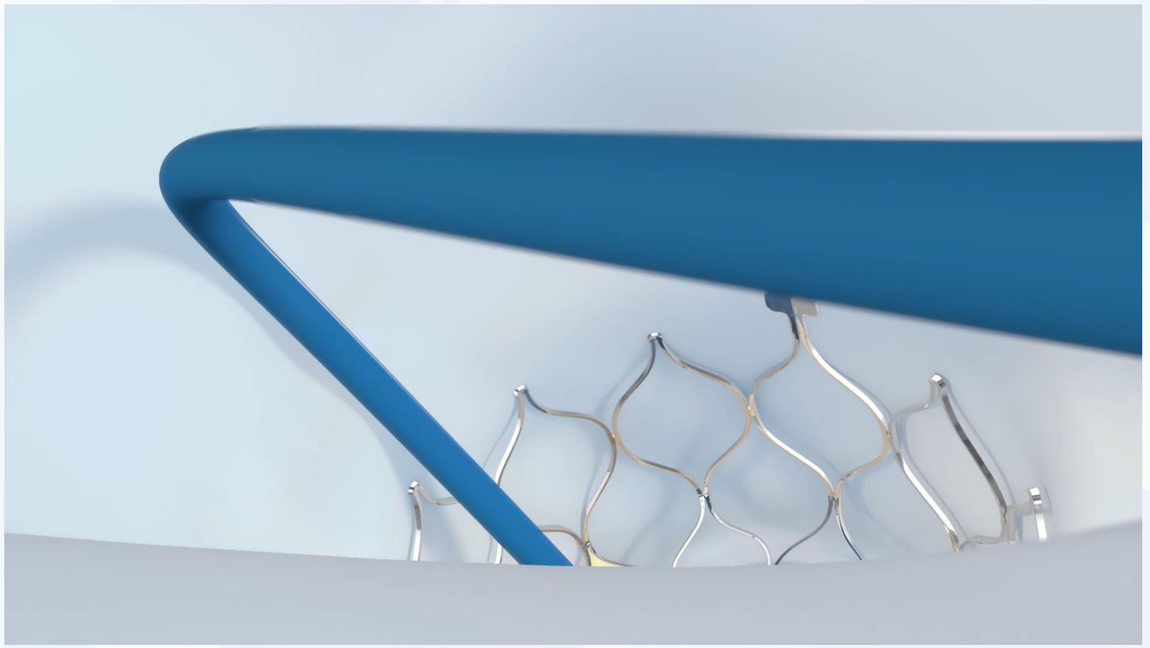
Evolut FX+ Design

The coronary access windows are designed to reduce frame obstruction and increase space for guide catheter maneuverability to enable coronary access.[1]

Reduced Potential for Frame Obstruction



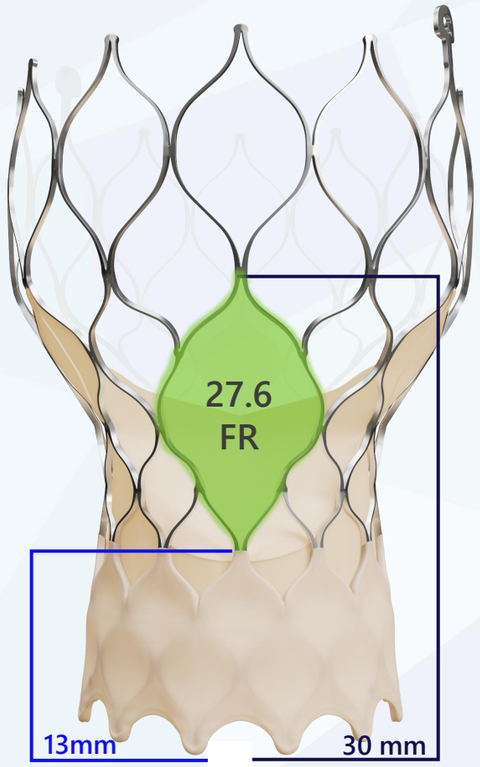
Increased Space for Guide Catheter Maneuverability



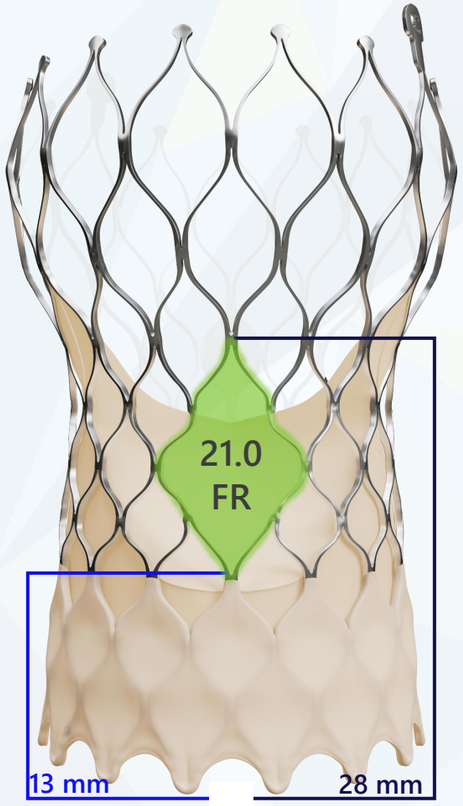
1. Medtronic computational data model on file compared to the Evolut platform. Computational model may not be indicative of clinical performance.

Evolut FX+ Design

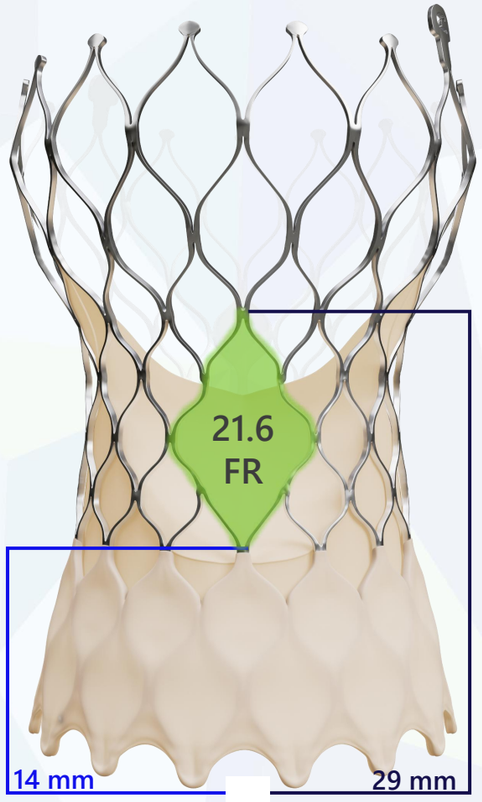
Window Heights & Dimensions



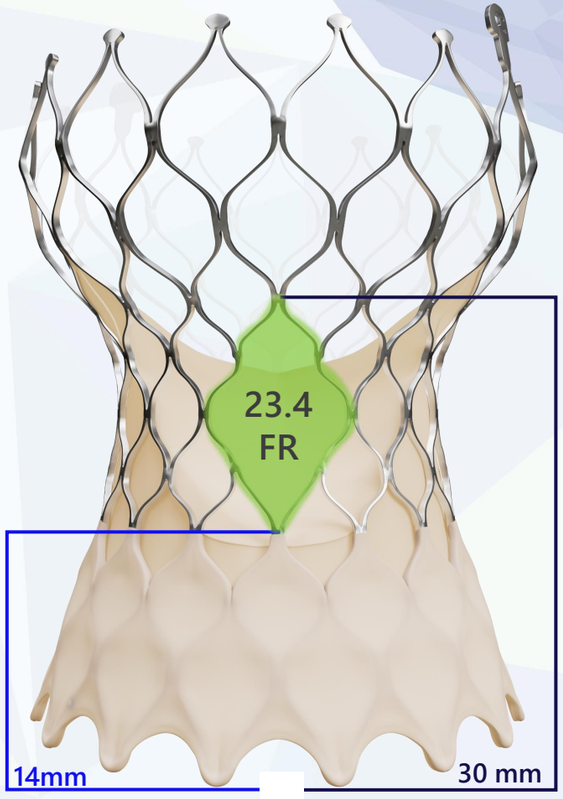
Evolut FX+
23 mm TAV



Evolut FX+
26 mm TAV



Evolut FX+
29 mm TAV

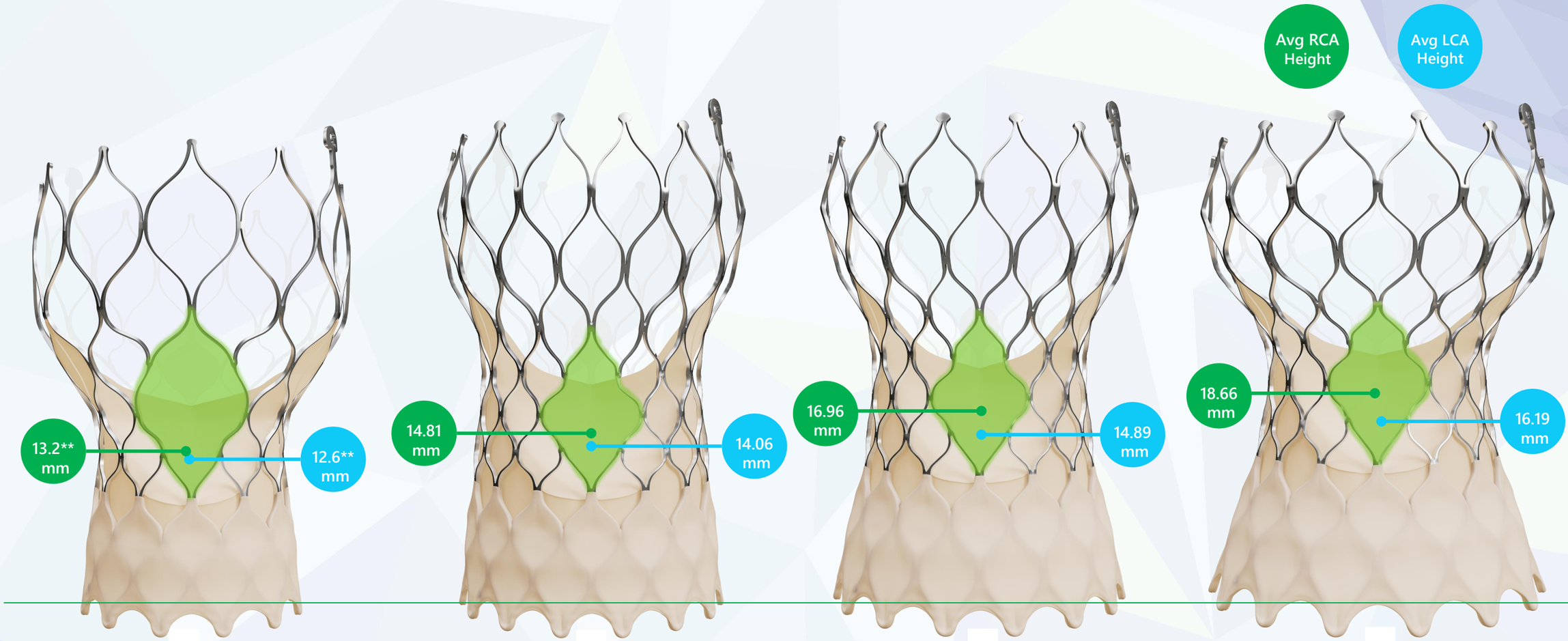


Evolut FX+
34 mm TAV

Note: Measurements provided are approximate based on engineering specifications.

Evolut FX+ Design

Average Coronary Heights*



Evolut FX+
23 mm TAV

Evolut FX+
26 mm TAV

Evolut FX+
29 mm TAV

Evolut FX+
34 mm TAV

*Average coronary takeoff height data for TAV sizes 26, 29, and 34 obtained from the Evolut Low Risk clinical trial; image heights are based on a target implant depth of 3 mm.
**Due to minimal data set for the 23 mm TAV average coronary heights taken from Cavalcanti, et. al., Arq. Bras. *Cardiol.* 81 (4) Oct 2003

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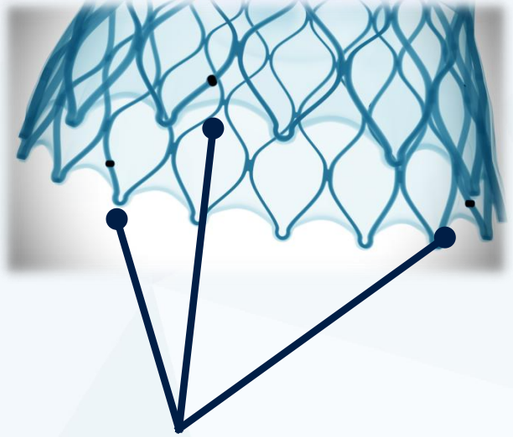
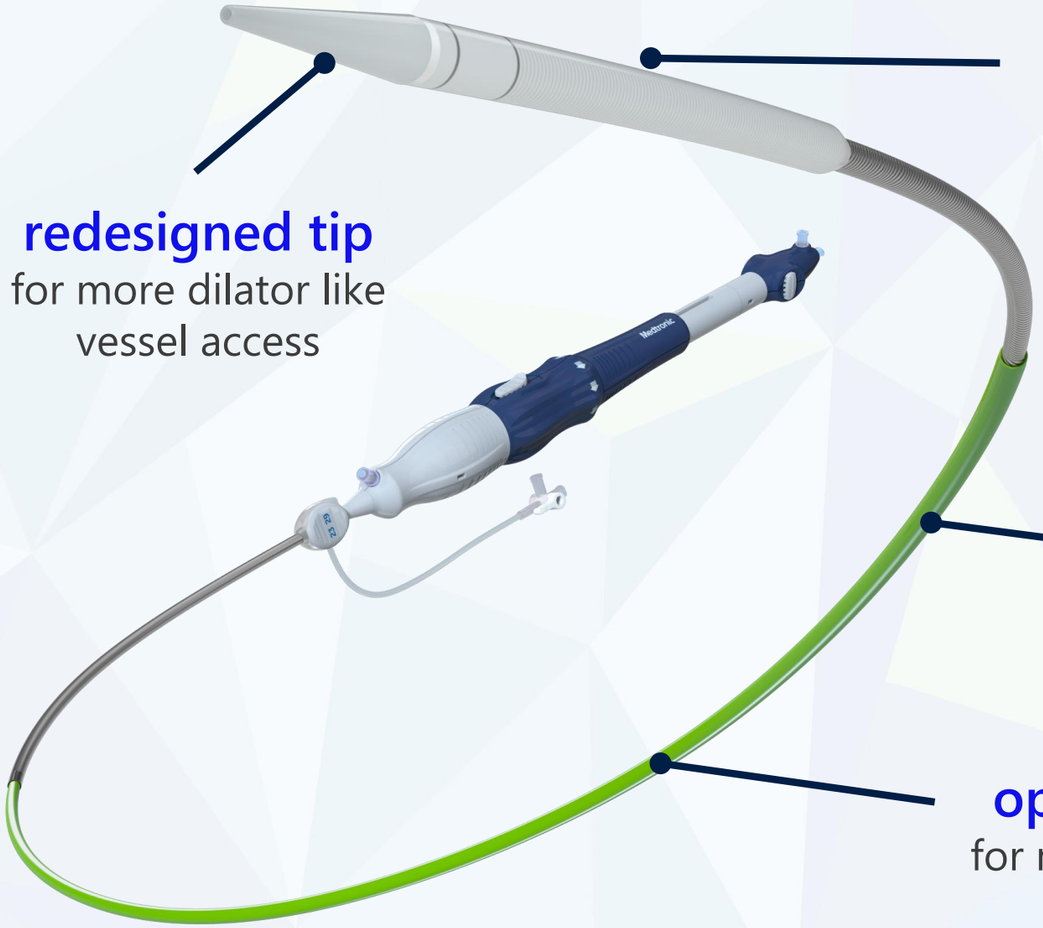
Evolut™ FX DCS

The Evolut FX+ TAV uses the Evolut FX delivery system for a predictable and stable deployment.



enhanced visualization
with radiopaque TAV markers to identify depth and commissures



redesigned tip
for more dilator like vessel access

redesigned capsule
for increased flexibility

single spine shaft
for greater shaft flexibility and improved deliverability

optimized stability layer
for more predictable deployment

Performance as compared to Evolut™ PRO+ system in bench testing. Bench testing may not be indicative of clinical performance.

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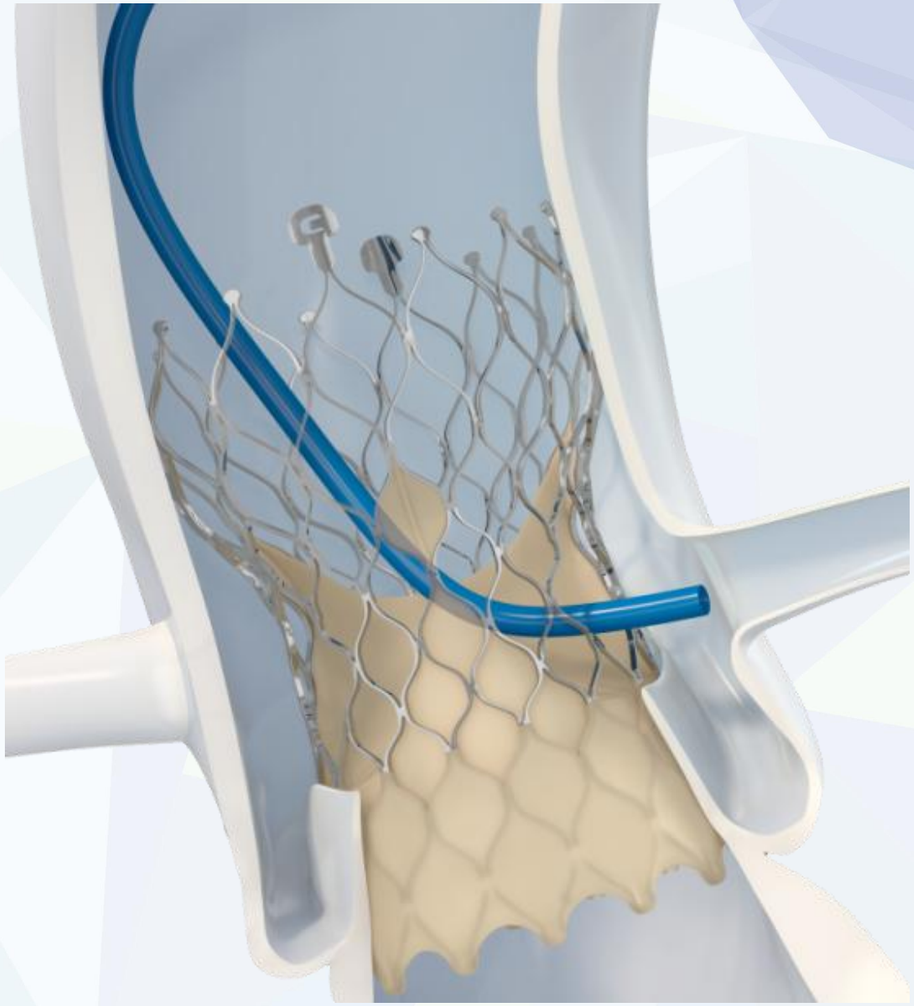
Commissure Alignment

When following commissure alignment best practices, the Evolut FX system can achieve

96.5% favorable commissure alignment*

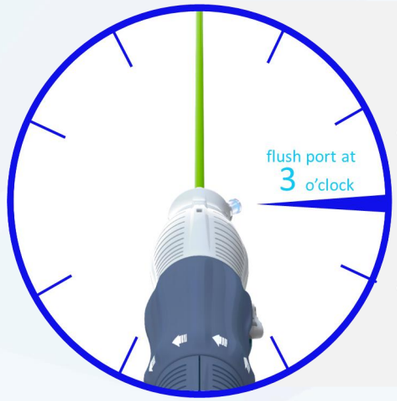


*TAV commissures located within 0 – 30° from native commissures.

Zaid, S. et al., *JACC*, 16:13, 2023.

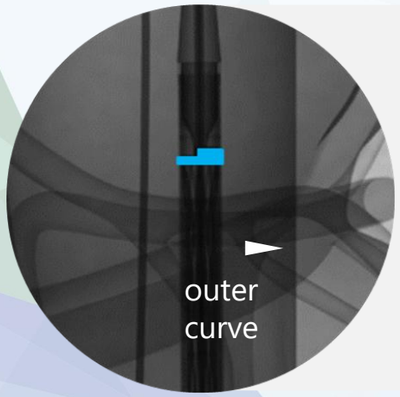
Commissure Alignment

Adjusting Flush Port and Hat Marker in Descending Aorta†



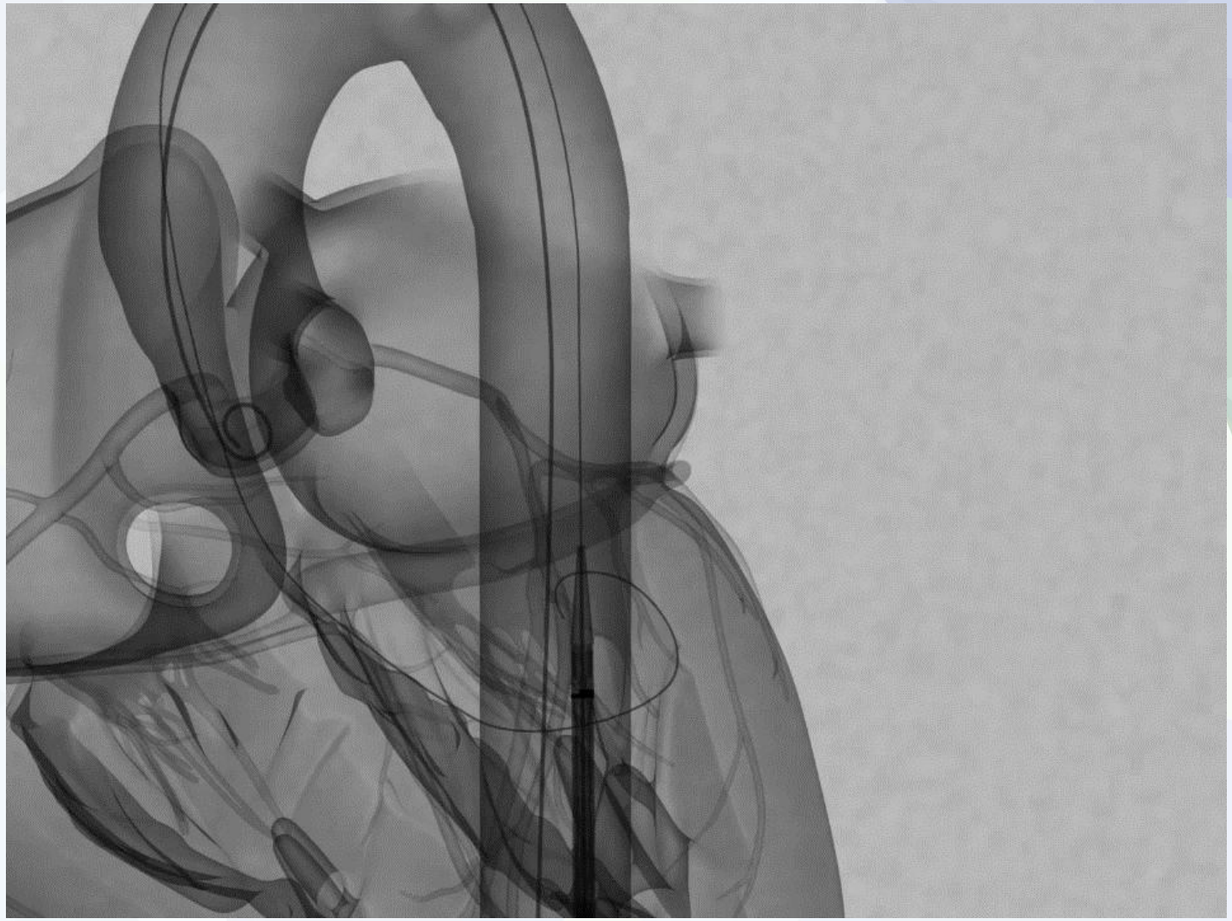
Flush Port Orientation Check

- Prior to capsule entering the aortic arch confirm flush port orientation is at 3 o'clock in the descending aorta
- If needed, adjust flush port orientation by rotating the handle (up to a ¼ turn).*



Hat Marker Orientation Check

- In the **descending aorta, open-arch LAO view** confirm the hat marker is facing the outer curve (right side of screen).
- If an inner curve hat marker position is observed, adjust orientation by rotating the handle (up to a ¼ turn).*



†Commissure alignment steps beyond initial insertion of delivery system with flush port oriented at 3 o'clock are only applicable to the Evolut FX system.
* Rotation should occur before capsule enters arch. Stop rotating handle if resistance is encountered or capsule does not respond to rotation under fluoroscopic visualization.

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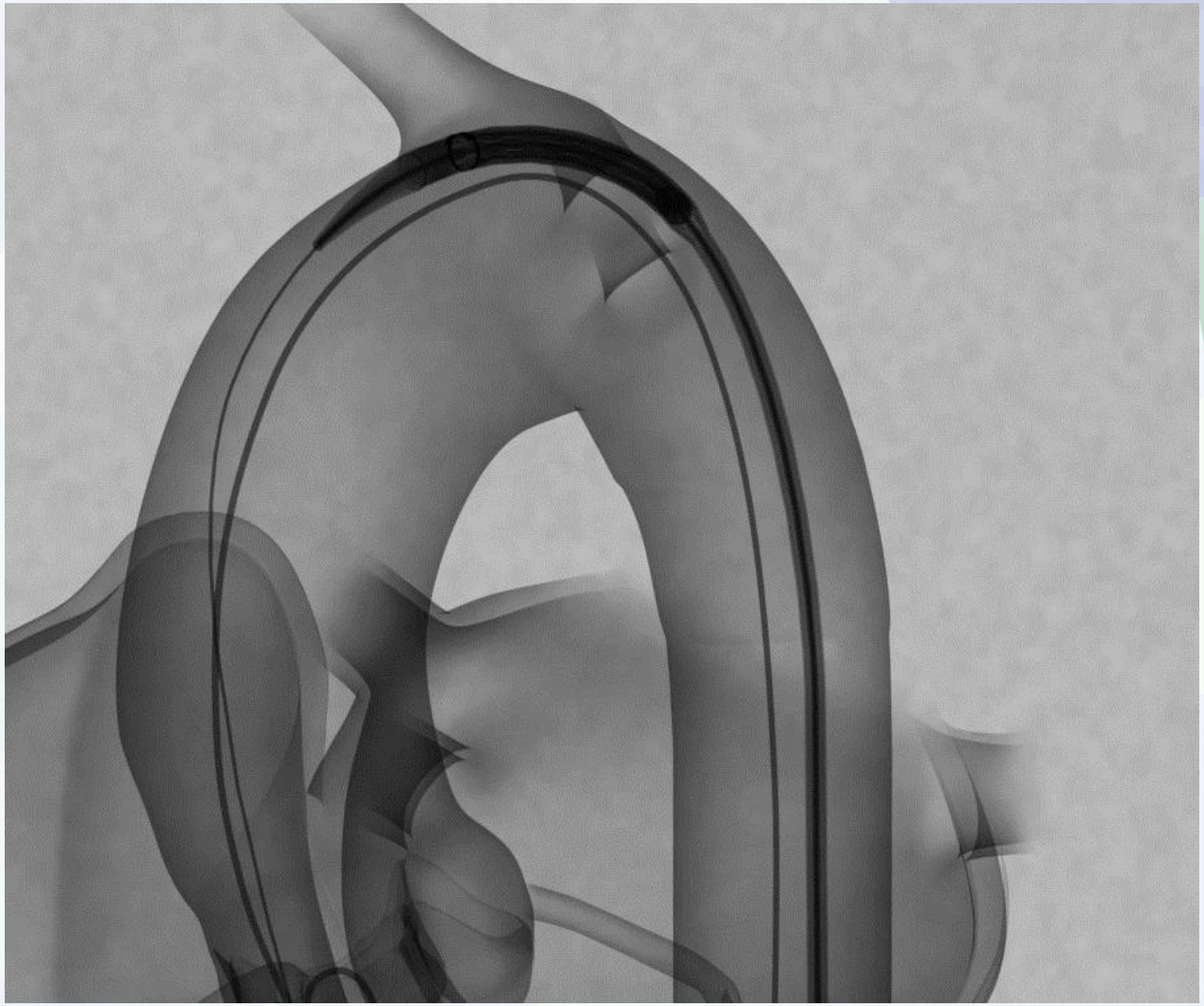
Commissure Alignment

Adjusting for Inner-Curve Hat Marker Orientation in Ascending Aorta

Verify hat marker position on the outer curve in an LAO view when nearing the annulus.

Inner curve hat marker position may occur infrequently due to arch anatomy.

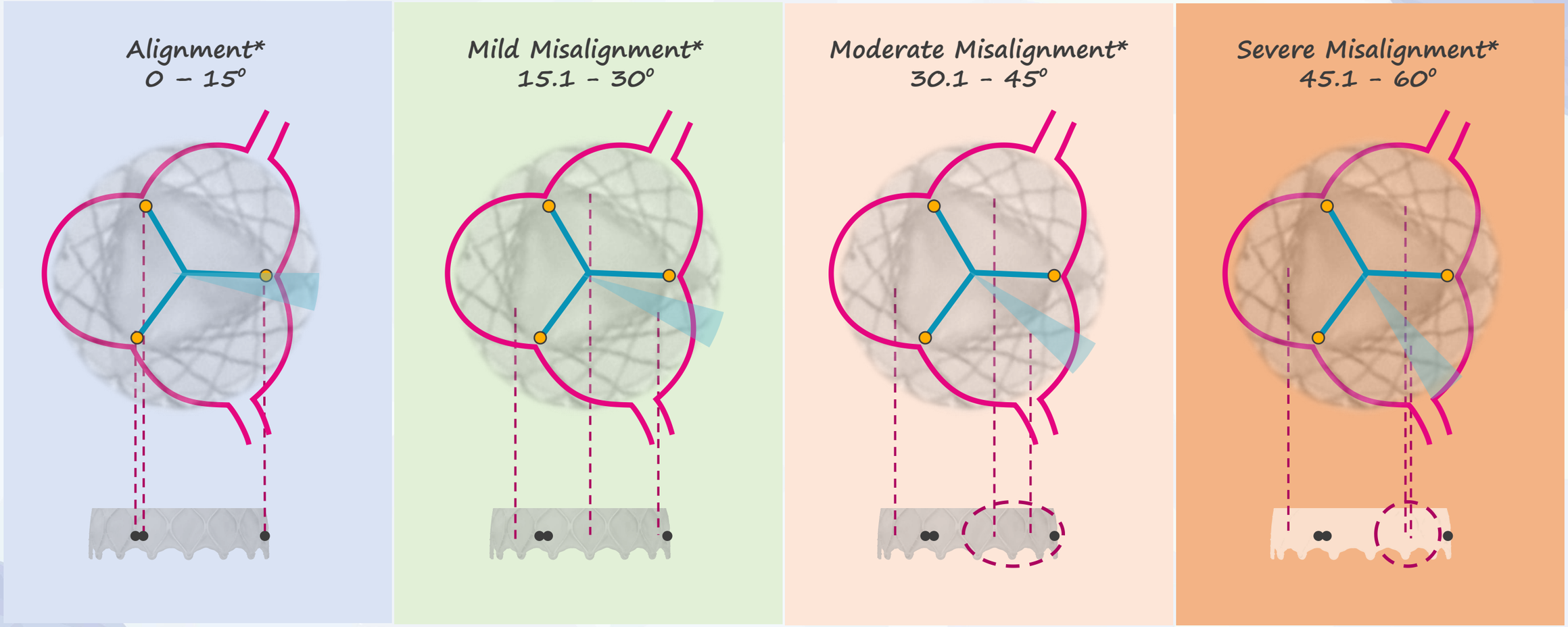
- *If needed, adjust alignment by withdrawing the system to the descending aorta and rotating the flush port to **2 o'clock** before readvancing.**



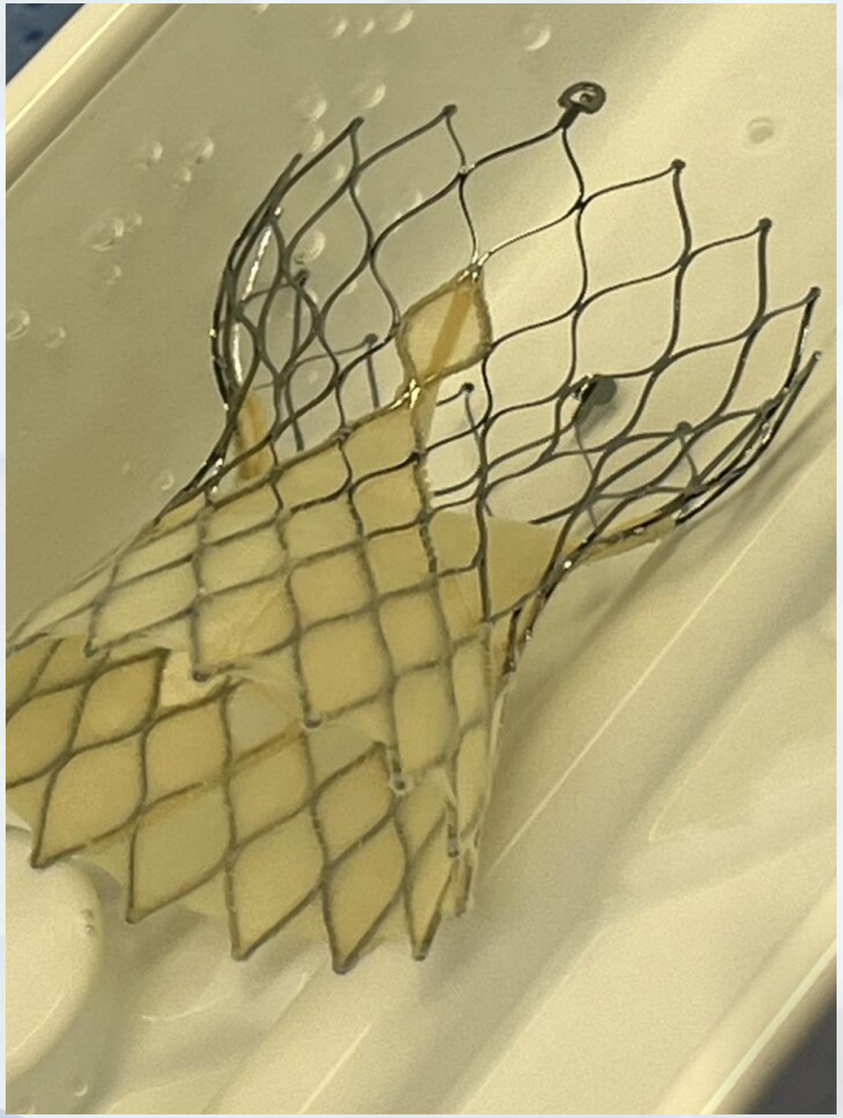
*Consider individual patient characteristics along with potential risks and benefits to determine if alignment adjustment is needed.

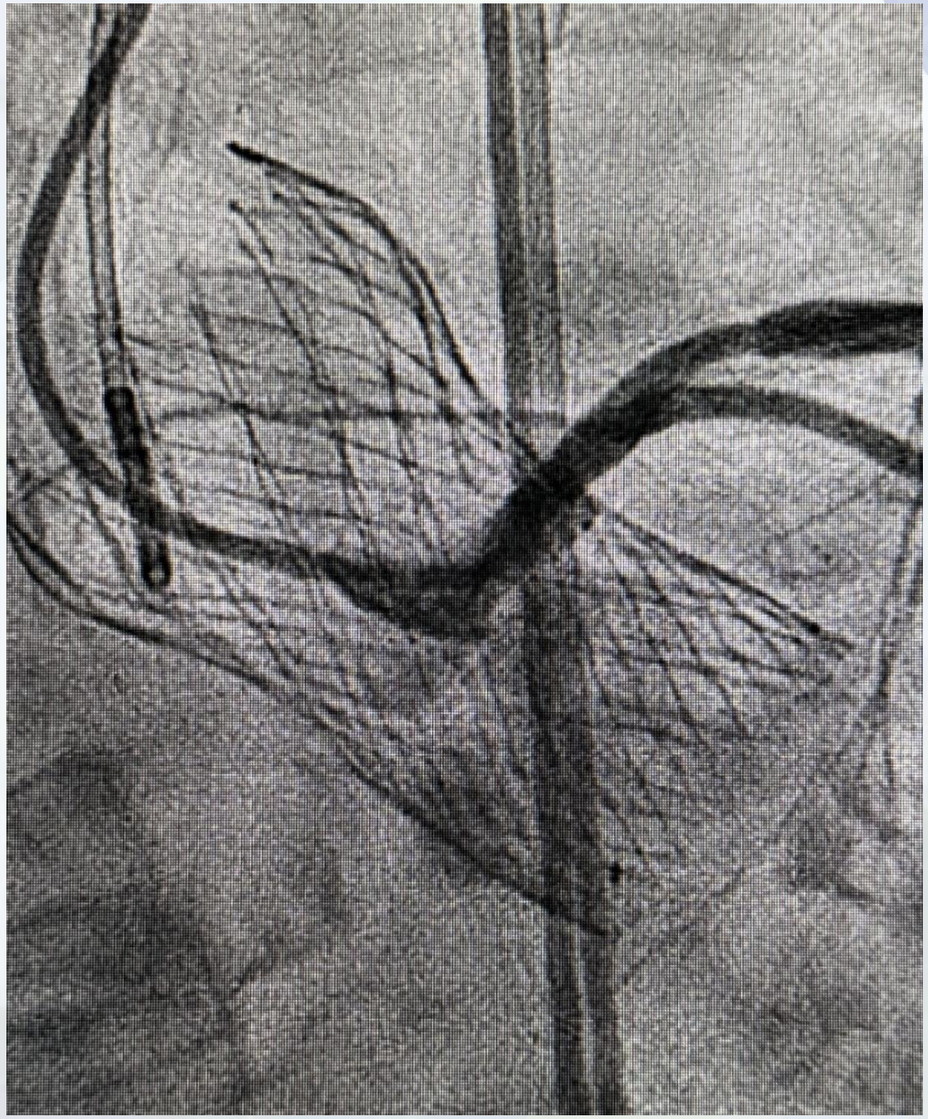
Commissure Alignment – Cusp Overlap View

Frame Marker Orientation Demonstrated



*Definitions of alignment taken from Tang, G. et al., *JACC: Cardiovasc Interv.* 2022 Aug 8;15(15):1497-1518.
PowerPoint animation created by Frank Schmidt.



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Evolut™ FX+
Transcatheter Aortic Valve
34 mm
Medtronic
First case with
Evolut™ FX+
Congratulations!
Built for durability, designed for access
FX+


Medtronic
Evolut FX taxi


Medtronic
Evolut FX Taxc

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