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How I Treat a Failed Evolut: Case Example

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Disclosures

- Abbott Vascular: Consultant, Speakers Bureau
- Boston Scientific: Research Grant
- Edwards Lifesciences: Consultant, Proctor, Speakers Bureau
- Medtronic Inc: Consultant, Proctor, Speakers Bureau

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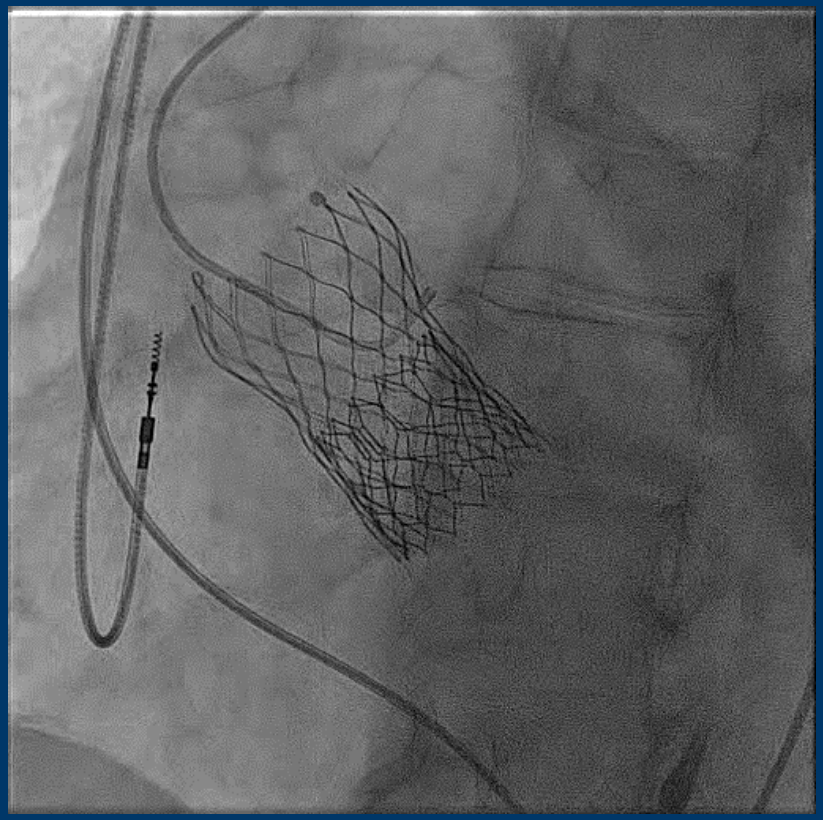
Sapien in Evolut



Procedural Goals

- Avoid Coronary Obstruction
- Preserve Coronary Access
- Ensure suitable Sapien function

Initial Considerations

- AS - position of second valve will need to treat the stenotic portion of the Evolut
- AR - less concern about Evolut leaflets as there is no obstruction to manage

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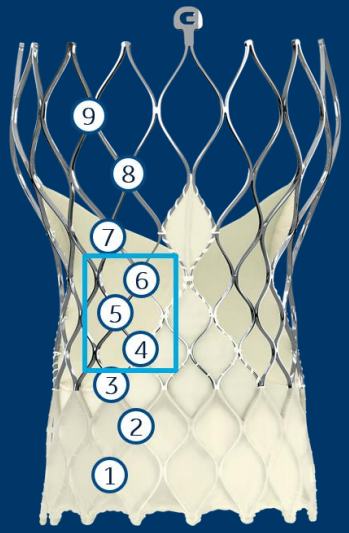
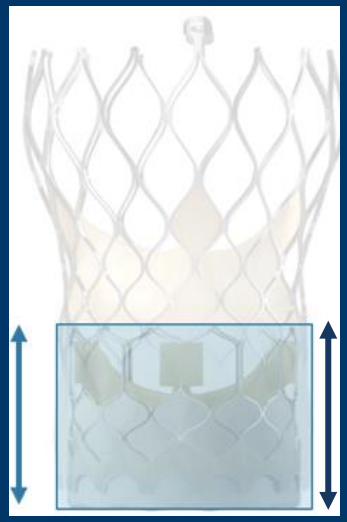
“Level” of Sapien and Neoskirt Height

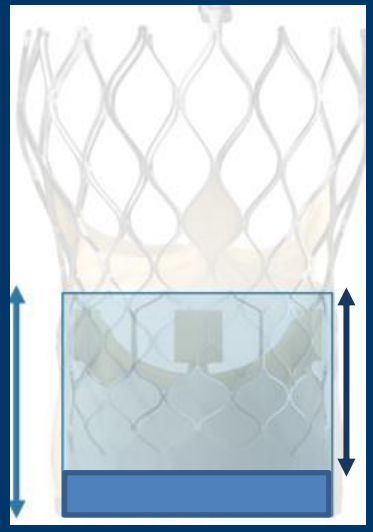
The completely sealed neoskirt will extend from the inflow of the index CV/Evolut THV valve to the outflow of the SAPIEN



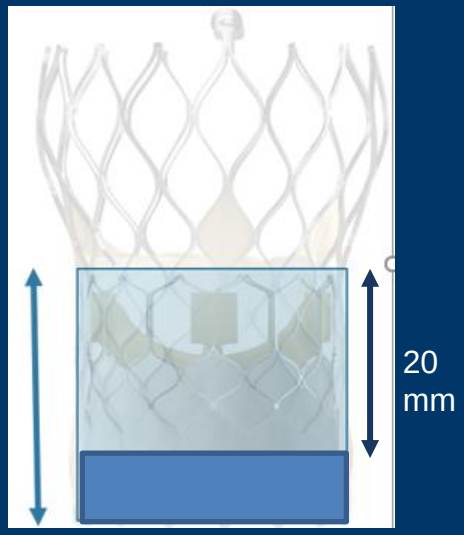
Outflow of S3 to:



Node 4



Node 5



Node 6

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Balloon-Expandable Valve for Treatment of Evolut Valve Failure

Implications on Neoskirt Height and Leaflet Overhang

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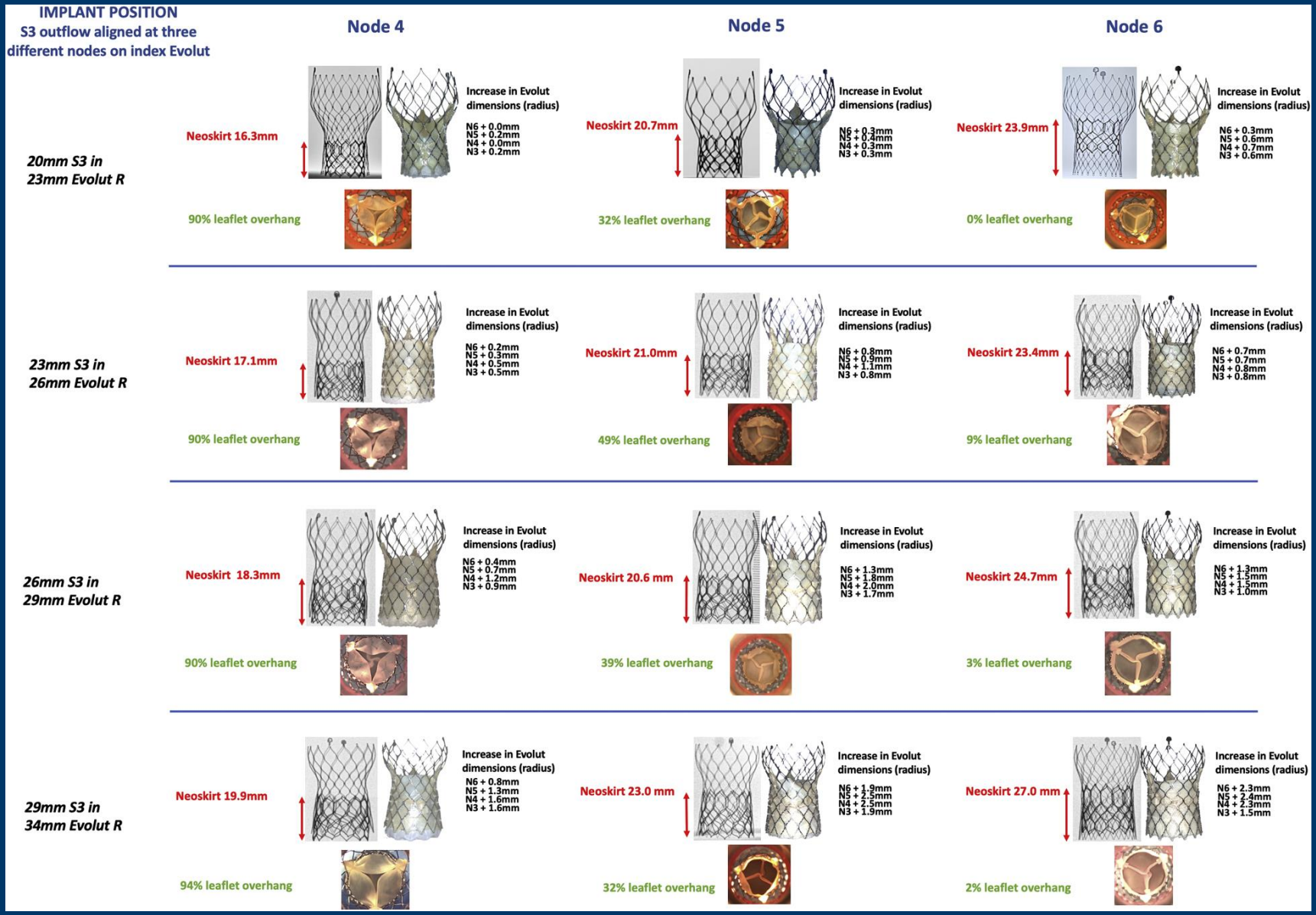

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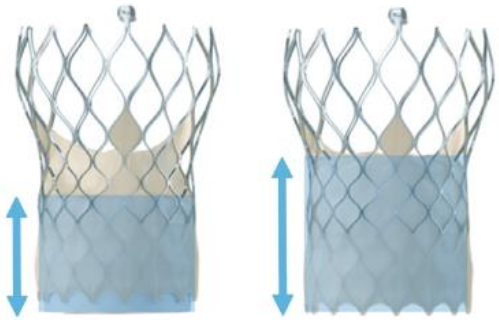
Akodad et al. *J Am Coll Cardiol Intv* 2022; 15:368-377.

Main Findings



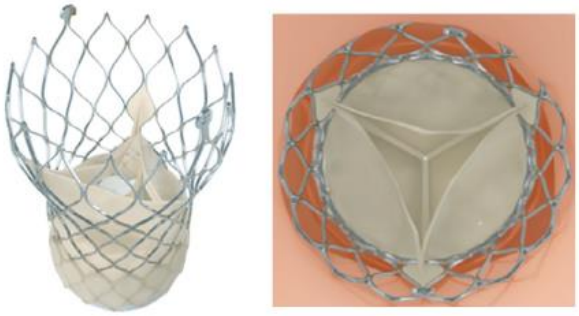
S3 Outflow at Node 4 **S3 Outflow at Node 6**

Higher S3 implantation associated with taller neo-skirt. Neo-skirt height can vary between **16.3-27 mm** with different implant positions and size combinations. A lower implant can reduce neo-skirt height by as much as **7.6 mm**.

Evolut in Evolut **S3 Outflow at Node 5**

S3 implantation into an Evolut valve increases the dimensions of the index Evolut valve. Increase in radius can vary between **0-2.5 mm**. This is not seen in Evolut in Evolut redo TAVR.

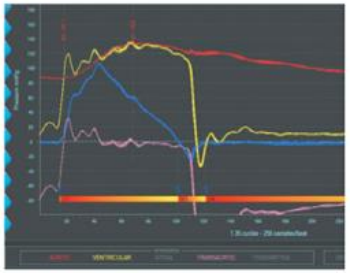
LEAFLET OVERHANG OF INDEX EVOLUT LEAFLETS



S3 Outflow at Node 4

Lower S3 implantation associated with greater leaflet overhang. Leaflet overhang can vary between **0%-94%** with different implant positions.

VALVE PERFORMANCE



Hydrodynamic function was acceptable at all tested implant positions, except for a 29-mm S3 implanted with the outflow at node 4 and 6 in a 34-mm Evolut where the regurgitant fraction was >20%.

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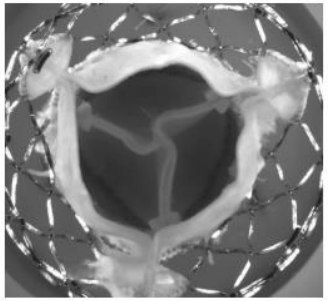
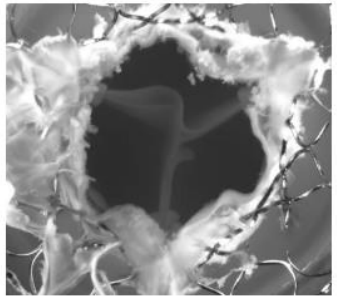
Akodad et al. *J Am Coll Cardiol Intv* 2022; 15:368-377.

Results: Redo-TAVR Sapien 3 performance

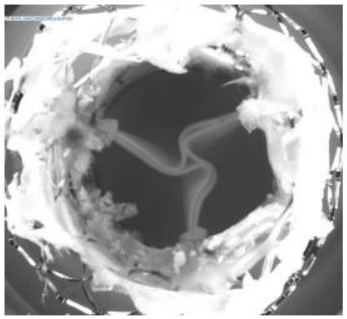
20mm Sapien 3 in 23mm Evolut R



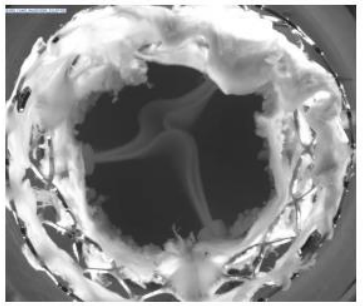
26mm Sapien 3 in 29mm CoreValve



26mm Sapien 3 in 29mm Evolut PRO



29mm Sapien 3 in 34mm Evolut R



	EOA (cm^2)			Mean Gradient (mmHg)		Peak Velocity (m/s)		Regurgitant Fraction (%)
	Pre Redo-TAVR	Post Redo-TAVR	ISO accepted	Pre Redo-TAVR	Post Redo-TAVR	Pre Redo-TAVR	Post Redo-TAVR	Post Redo-TAVR
20mm S3 in 23mm Evolut R	0.82	1.17	0.95	56.3	28.5	5.0	3.4	7.9
26mm S3 in 29mm CoreValve	1.10	2.16	1.60	32.7	9.5	3.8	1.9	18.9
26mm S3 in 29mm Evolut PRO	0.85	2.07	1.60	41.4	10.2	4.6	1.9	12.3
29mm S3 in 34mm Evolut R	0.66	2.54	2.10	76.6	6.9	6.2	1.6	25.8 *

Evolut/CoreValve leaflet overhang was <40% and calcified leaflets were pinned open and remained stationary (<10% change) through the cardiac cycle

* ISO accepted: <20% (additional studies on-going)

TCT.23, October 23-26, San Francisco

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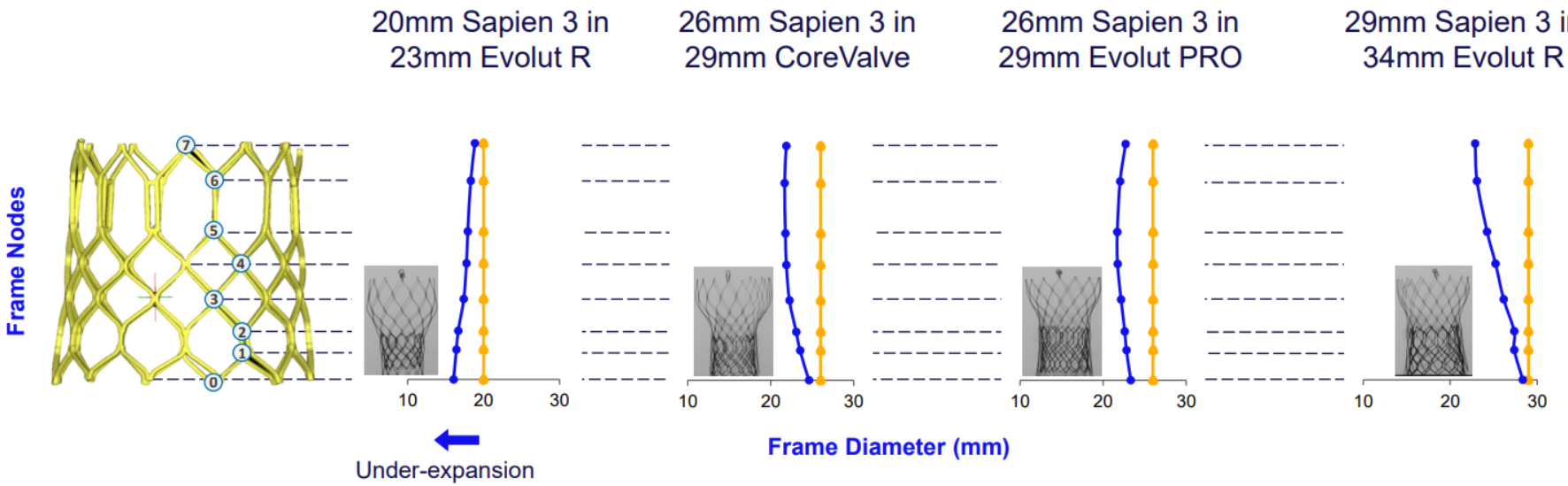
Sellers, S, Meier, D, Nigade, A. et al. TCT-396 Calcification Patterns in TAVR Explants: Informing Durability and Implications for Reintervention. *JACC.* 2023 Oct, 82 (17_Supplement) B158.**https://doi.org/10.1016/j.jacc.2023.09.404**

Results: Sapien 3 frame deformation



Nominal frame diameter *

Post Redo-TAVR frame diameter *

* Micro-CT area-derived outer diameter

Sapien 3 under-expansion was common following Redo-TAVR and may be affected by calcium location and TAV sizes **

** Balloon post-dilatation not performed

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Sellers, S, Meier, D, Nigade, A. et al. TCT-396 Calcification Patterns in TAVR Explants: Informing Durability and Implications for Reintervention. *JACC.* 2023 Oct, 82 (17_Supplement) B158.**https://doi.org/10.1016/j.jacc.2023.09.404**

Case

- 58 y/o male, LVEF 15%, CKD, pulm HTN
- 34 mm Evolut in 2019 not at our hospital, moderate AS/moderate AI
- Cardiogenic shock, inotropes, IABP
- Concern that AI will worsen after LVAD
- Can we do combined LVAD + TAV in TAV?

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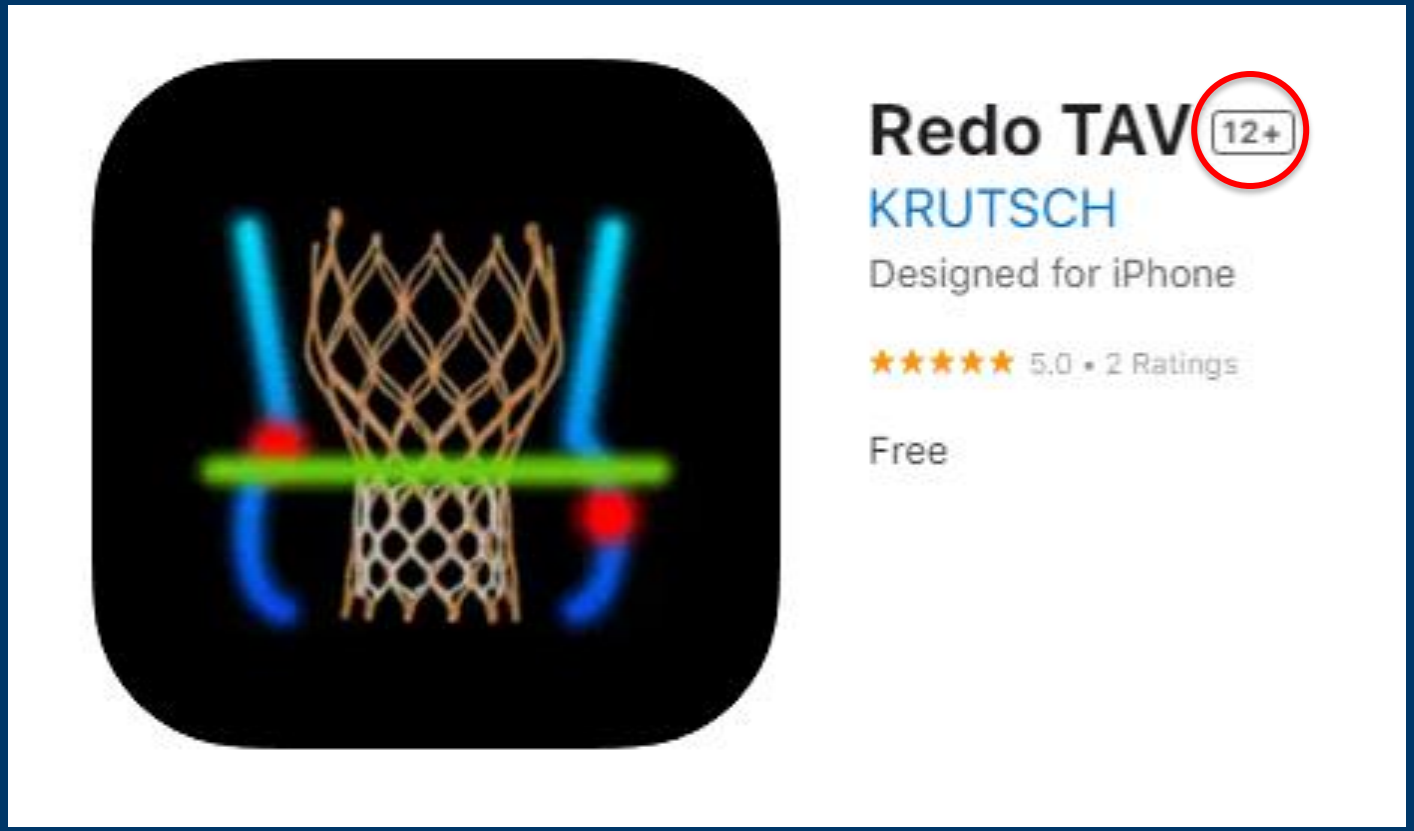
TAV in TAV APP



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CT Planning

Step 1: Index TAV & Measurements

TAV Selection

Pre-Index TAV CT Data

Available | Not Available

Native Valve: Select...

Native AV Calcification: Select...

Select Index TAV

TAV: Evolut FX

Size: 34

Next

1:24

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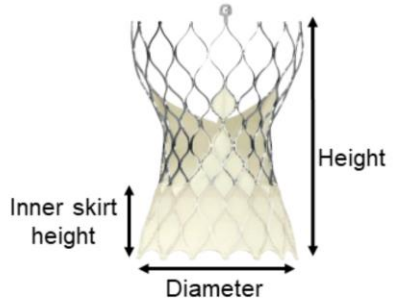
CT Planning

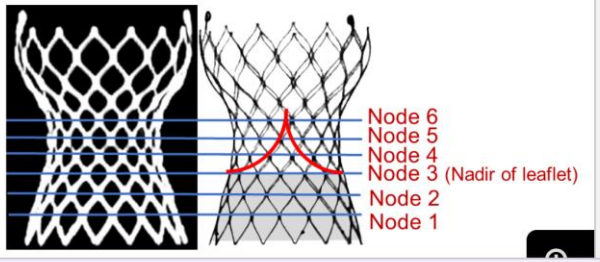
Step 1: Index TAV & Measurements

Medtronic Evolut FX 34



Height:	45
Diameter:	34
Inner Skirt Height:	14
Native Annulus Perimeter:	81.7-94.2

Reference Levels for Redo-TAV



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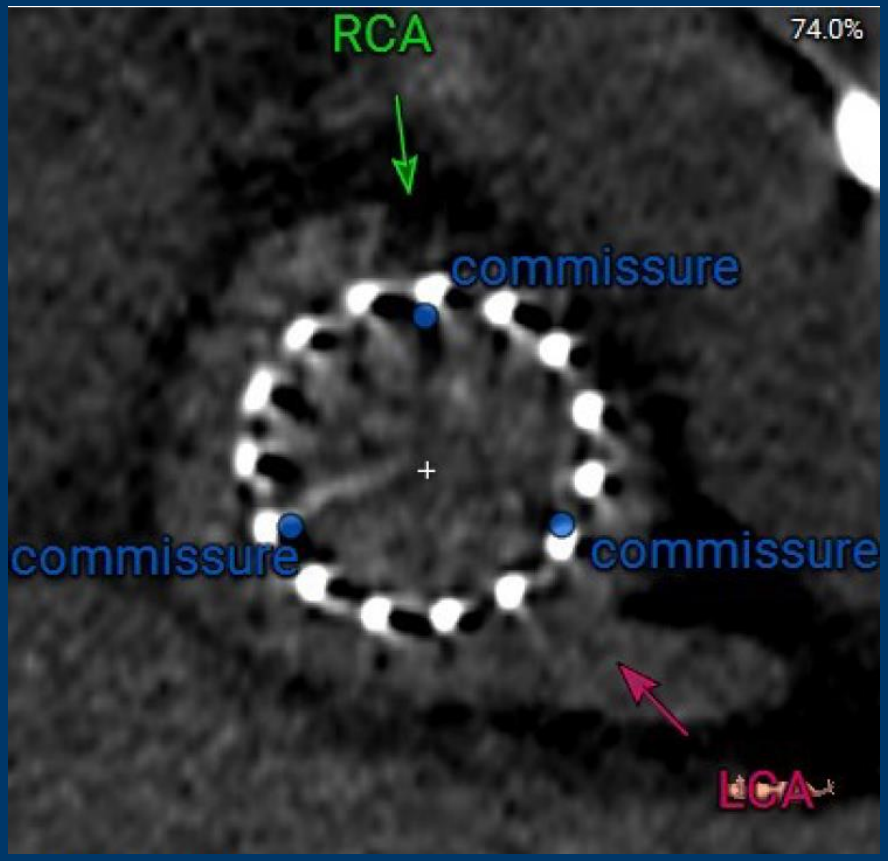

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1:25

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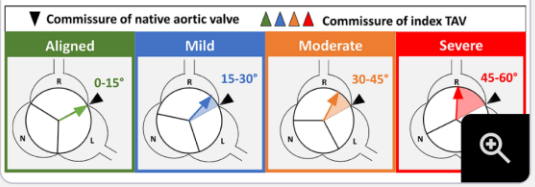
CT Planning

Step 1: Index TAV & Measurements

Index TAV Measurements

Index TAV Failure Mechanism: AR

Commissure Alignment



Commissure Alignment of Index TAV

Commissure: Severely Misaligned

Next

1:25

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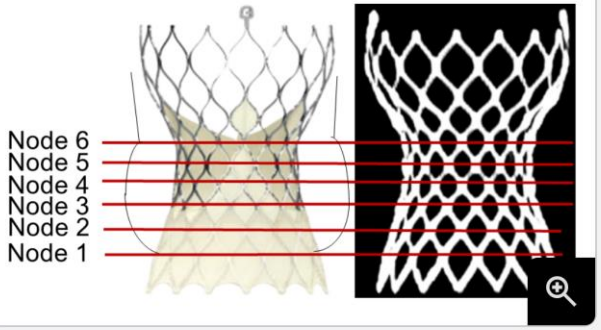
CT Planning

Step 1: Index TAV & Measurements

Where & How to Measure Index TAV

Where to Measure Index TAV



How to Measure Index TAV

Enter Area and/or Perimeter

Reset

Step 2

1:26

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CT Planning

Step 1: Index TAV & Measurements

Where & How to Measure Index TAV

Area and perimeter can be entered simultaneously.

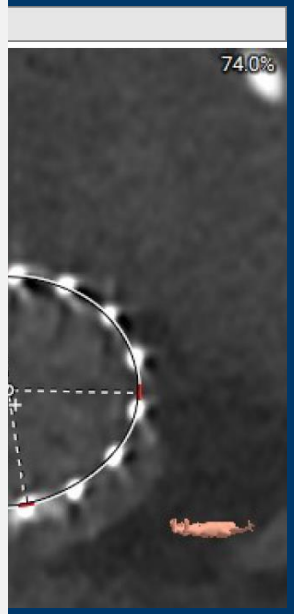
Area | Perimeter

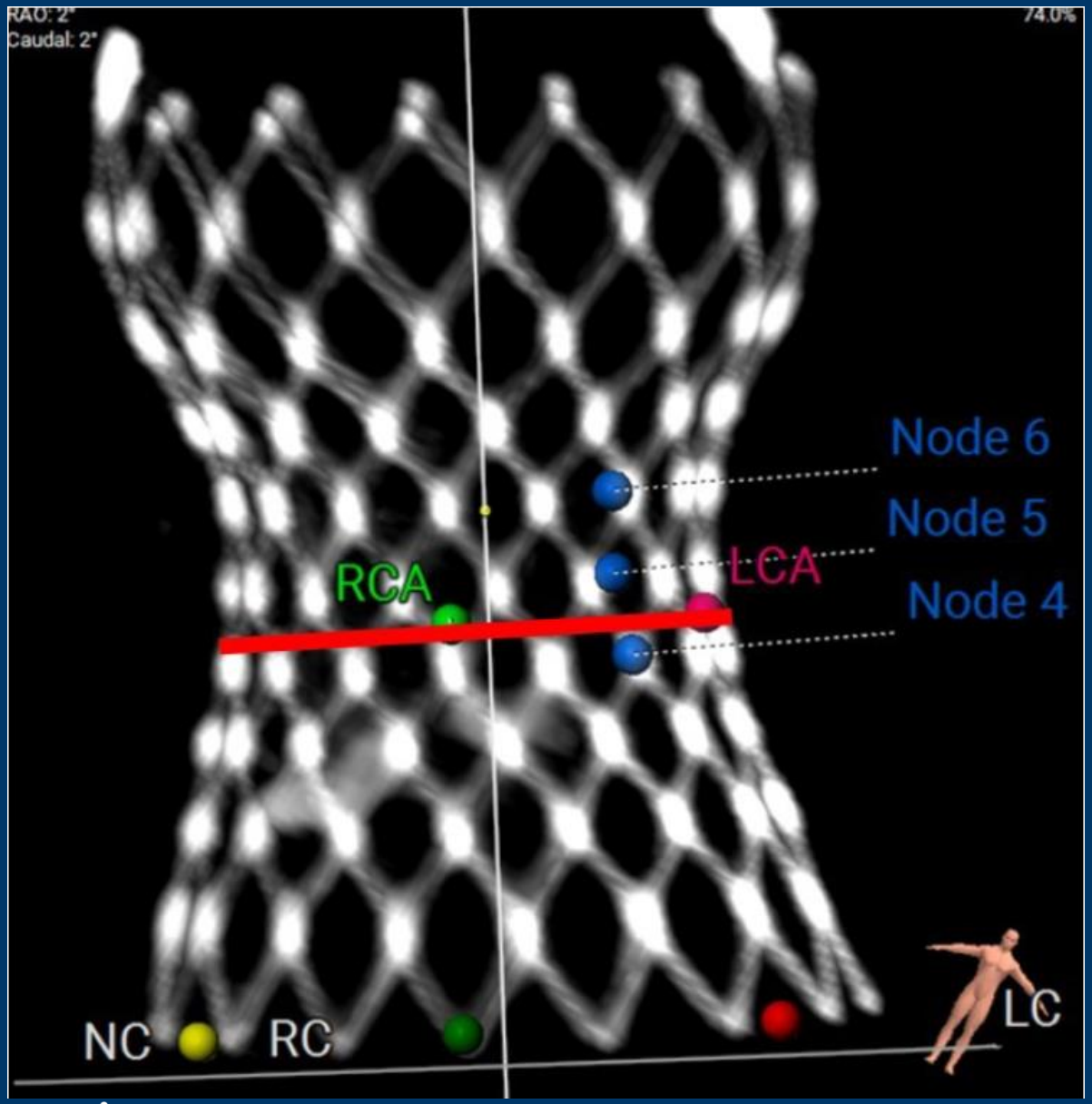
Node 6:	418	mm²
Node 5:	411	mm²
Node 4:	413	mm²
Node 3:	479	mm²
Node 2:	570	mm²
Node 1:	656	mm²

Where & How to Measure Index TAV

Reset

Step 2





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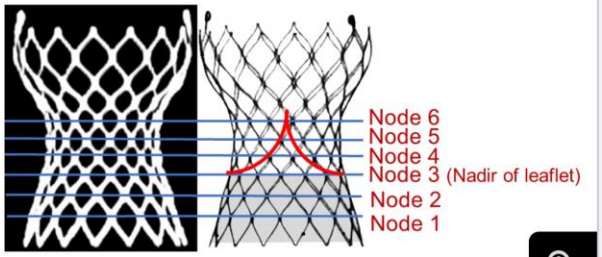
CT Planning

Step 2: Identify Coronary Risk Plane

Mark bottom of both coronaries in relation to the reference levels

Reference Levels for Redo-TAV



Bottom of RCA & LCA Ostiums

RCA: Node 4

LCA: Node 4

Coronary Risk Plane (Lowest Level of Coronaries)

CRP Level: Node 4

Examples

Example 1 Example 2

Step 3

1:26

CT Planning

Step 3: Select Second TAV

Choose Second TAV Device

- ACURATE neo2
- Allegra
- Evolut FX — USE WITH CAUTION
- Evolut PRO+ — USE WITH CAUTION
- MyVal
- Navitor
- SAPIEN 3 (selected)
- SAPIEN 3 Ultra

Use With Caution

Next

4:42

CT Planning

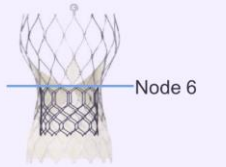
Step 4: Choose NSP & Assess NSP/CRP

Coronary Risk Plane (Lowest Level of Coronaries)

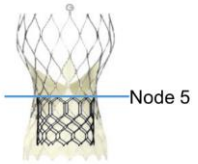
CRP Level: Node 4

Assess at All Levels When and Why

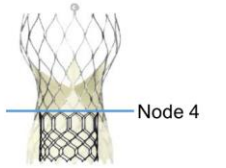
Select NSP Level



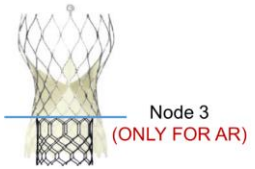
Node 6



Node 5



Node 4



Node 3 (only for AR)

Step 5

4:43

CT Planning

Step 5: Second TAV Sizing

Select Relevant Values

Select 4 Relevant Areas and/or Perimeters

Area | Perimeter

Include Perimeter? ☐

Node 6:	418 mm²	☑
Node 5:	411 mm²	☑
Node 4:	413 mm²	☑
Node 3:	479 mm²	☑
Node 2:	570 mm²	☐
Node 1:	656 mm²	☐
Additional Area:	Enter... mm²	☐

Relevant Values

Reset | Calculate

4:43

CT Planning

Step 5: Second TAV Sizing

Choose Second TAV Size

Selected Second TAV Device:	SAPIEN 3
Average Area:	430.3 mm²
Average Perimeter:	N/A
Area Derived Diameter:	23.4 mm
Perimeter Derived Diameter:	N/A

Choose the second TAV size using the measured values and sizing table.

View Sizing Guide

View Sizing Table

Index TAV

TAV:	Evolut FX	Size:	34

Second TAV

TAV:	SAPIEN 3	Size:	26 ⌄

Step 6 →

4:46

CT Planning

Step 6: Coronary Risk Assessment

Enter VTA Values

NSP: Node 6

Bottom of RCA & LCA Ostiums

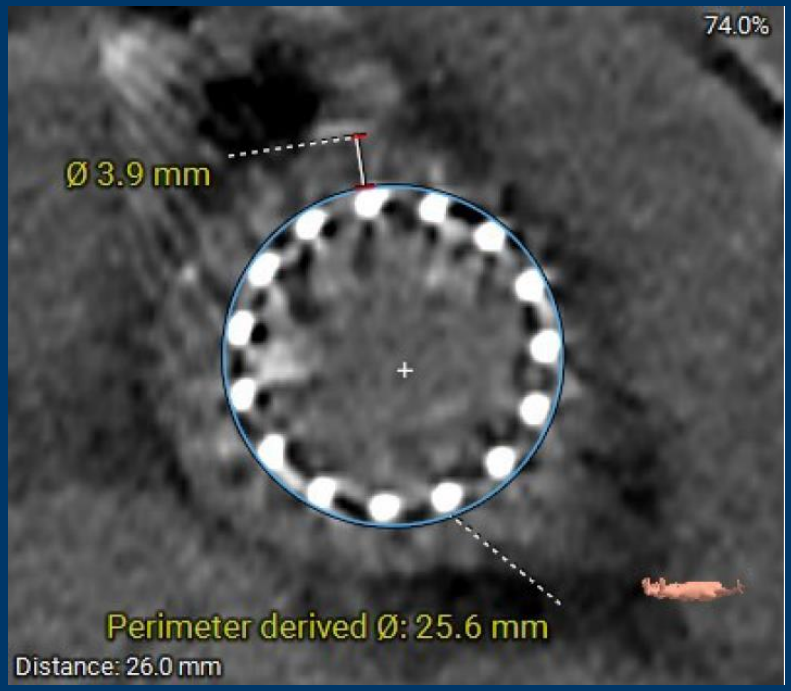
RCA: Node 4

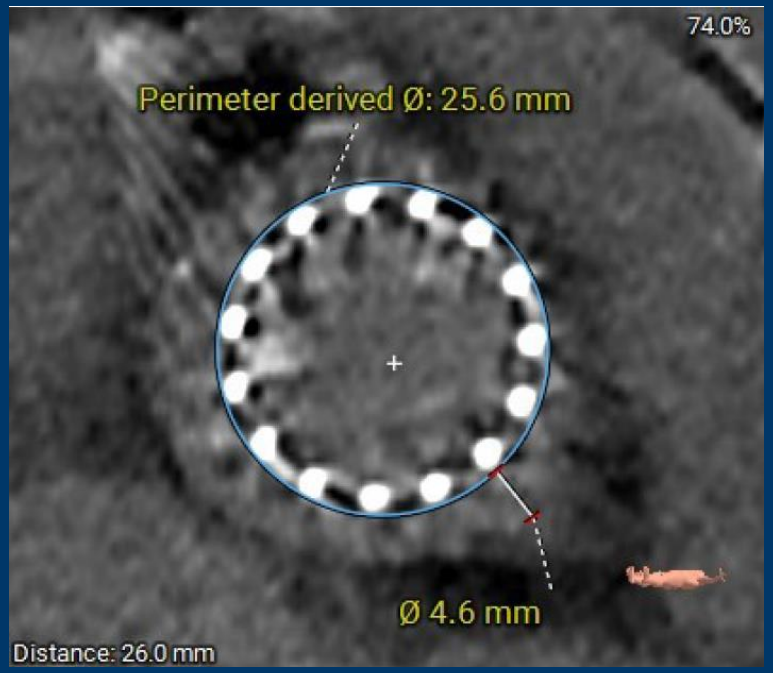
LCA: Node 4

RCA	LCA
NSP Above/Below RCA?	NSP Above/Below LCA?
Above / Below	Above / Below
NSP Above/Below STJ?	NSP Above/Below STJ?
Above / Below	Above / Below
Enter VTA Measurements	Enter VTA Measurements
VTSTJ: N/A	VTSTJ: N/A
VTAoS: Enter... mm	VTAoS: Enter... mm
VTC: 3.9 mm	VTC: 5.3 mm

Narrowest VTA Values

Next





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CT Planning

Step 7: Summary Report

Area & Perimeter According to In-Vivo Sizing Algorithm

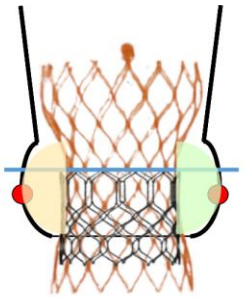
Area:	430.3 mm^2	Perim:	N/A

Index TAV Failure Mechanism: AS+AR

CRP: Node 4

NSP: Node 6

Summary - Not to Scale



Narrowest VTA Values

RCA:	3.9 mm
LCA:	5.3 mm

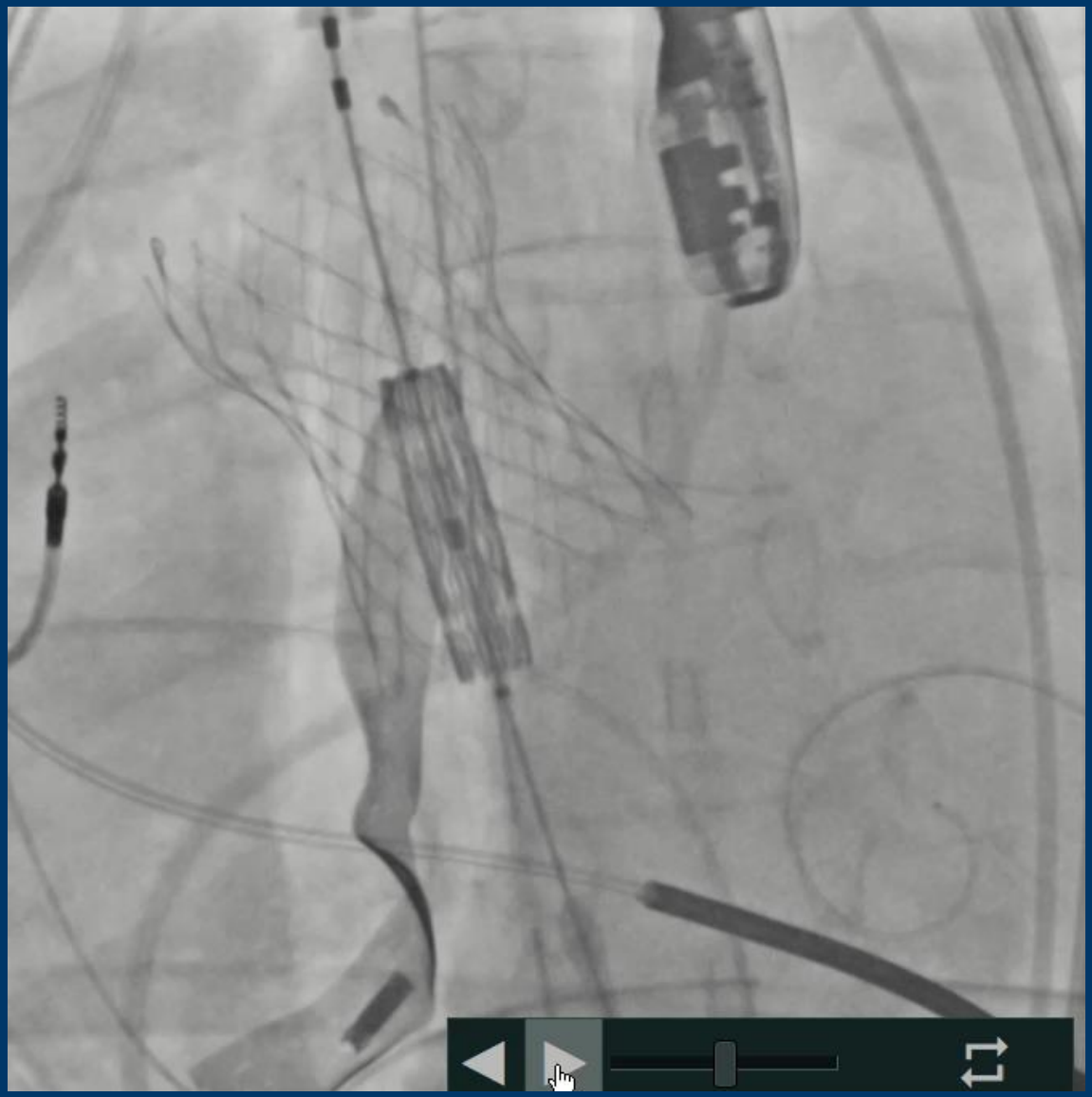
Caution

Consider coronary protection if in doubt

Intermediate risk to coronaries

Screenshot

Next



Conclusions

- The feasibility of TAV in TAV involves thorough analysis of the aortic root, coronary and STJ anatomy
- The algorithm to assess coronary risk is not as complicated as you might think
- Devices/techniques to facilitate precise device positioning will help to facilitate TAV in TAV procedures

Thank You