

| | |
|----------------|------------|
| Patient | GREEN, IAN |
| Sex | Male |

| | |
|--------|----|
| Height | m |
| Weight | kg |

Physician Dr. Ravinay Bhindi
Hospital Royal North Shore Hospital
City Sydney
Country Australia

Received Date 29-May-2025
Reviewed Date 30-May-2025

Year Of Birth (Age) 1946 (78)

BMI
EOA needed to achieve
an iEOA > 0.85 cm²/m²

Clinical History

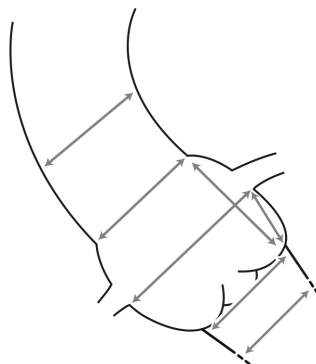
Case #: 31540520

Anticipated Implant Date: Not Provided

MEDTRONIC ANALYSIS

| ANNULUS | | | |
|----------------|-------|------------------|------|
| Diameter (mm) | 22.7 | x | 23.2 |
| | Min | | Max |
| Perimeter (mm) | 72.3 | , Derived Ø (mm) | 23.0 |
| Area (mm²) | 415.1 | , Derived Ø (mm) | 23.0 |

| LVOT | | | |
|----------------|-------|------------------|------|
| Diameter (mm) | 27.0 | x | 32.0 |
| | Min | | Max |
| Perimeter (mm) | 93.3 | , Derived Ø (mm) | 29.7 |
| Area (mm²) | 673.2 | , Derived Ø (mm) | 29.3 |



| | | | |
|------------------------------------|-------------|-------------|-------------|
| Max Ascending Aorta Diameter (mm) | <u>42.3</u> | | |
| Sinotubular Junction Diameter (mm) | <u>40.7</u> | x | <u>40.9</u> |
| | Min | | Max |
| Sinus of Valsalva Diameter (mm) | <u>45.9</u> | <u>41.1</u> | <u>45.3</u> |
| | LCC | RCC | NCC |
| Sinus of Valsalva Height (mm) | <u>36.6</u> | <u>32.3</u> | <u>34.8</u> |
| | LCC | RCC | NCC |
| Coronary Ostia Height (mm) | <u>21.1</u> | <u>23.6</u> | |
| | Left | Right | |

VIEWS

Cusp Overlap View RAO: 23°, Caudal: 19°

3 Cusp Coplanar View

Near Cusp Overlap View

RIGHT

CIA Min Diameter (mm)

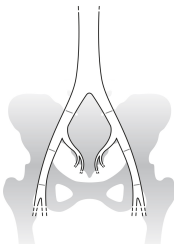
| | | |
|------|---|------|
| 14.8 | x | 15.7 |
|------|---|------|

EIA Min Diameter (mm)

| | | |
|------|---|------|
| 10.7 | x | 12.5 |
|------|---|------|

Femoral Min Diameter (mm)

| | | |
|-----|---|------|
| 8.8 | x | 10.3 |
|-----|---|------|



LEFT

CIA Min Diameter (mm)

$$\frac{14.2}{\text{---}} \times \frac{19.3}{\text{---}}$$

EIA Min Diameter (mm)

$$\frac{11.7}{\text{---}} \times \frac{13.2}{\text{---}}$$

Femoral Min Diameter (mm)

$$\frac{9.6}{\text{---}} \times \frac{11.1}{\text{---}}$$

Calcium: Mild ☐ Moderate ☐ Severe ☐

The diagram shows a central aorta with two branches extending upwards and outwards. The left branch is labeled 'LEFT' and the right branch is labeled 'RIGHT'. Below the 'RIGHT' label, the text 'Subclavian Min Diameter (mm)' is followed by a horizontal line with 'x' in the middle and dashes on either side. Below the 'LEFT' label, the text 'Subclavian Min Diameter (mm)' is followed by a horizontal line with 'x' in the middle and dashes on either side. Below the 'RIGHT' label, the text 'Annular Angulation' is followed by a horizontal line with '57°' in the middle.

VIV ADDITIONAL MEASUREMENTS

| | | |
|---------------------------------|--------|--------|
| Valve to Coronary Distance (mm) | --- | --- |
| | To LCA | To RCA |
| Valve to STJ Distance (mm) | --- | --- |
| | LCC | RCC |

Procedural Considerations

Chest and full body CT contains significant double image artifact and blurring - Difficult to determine anatomical and luminal borders - Please consider measurements **very gross** estimates

Site reports patient has a 25 mm Edwards Perimount 2800 surgical aortic valve (SAV) - Patient appears to have a radiopaque suture device near the SAV - Recommend obtaining Op report for specific SAV information

Possible LAA closure device - please verify with site

Dilated ascending aorta

Bend seen in descending thoracic aorta

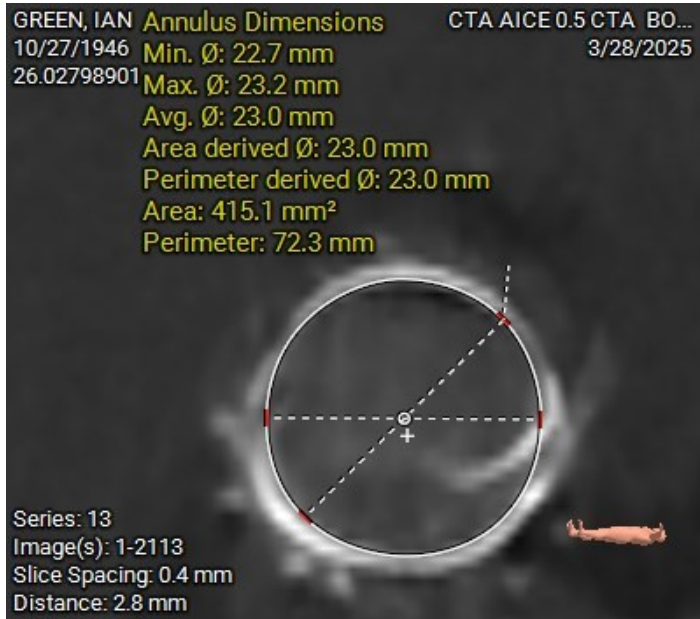
Bend seen in REI, LCI, and LEI

Possible bulging seen in LCI

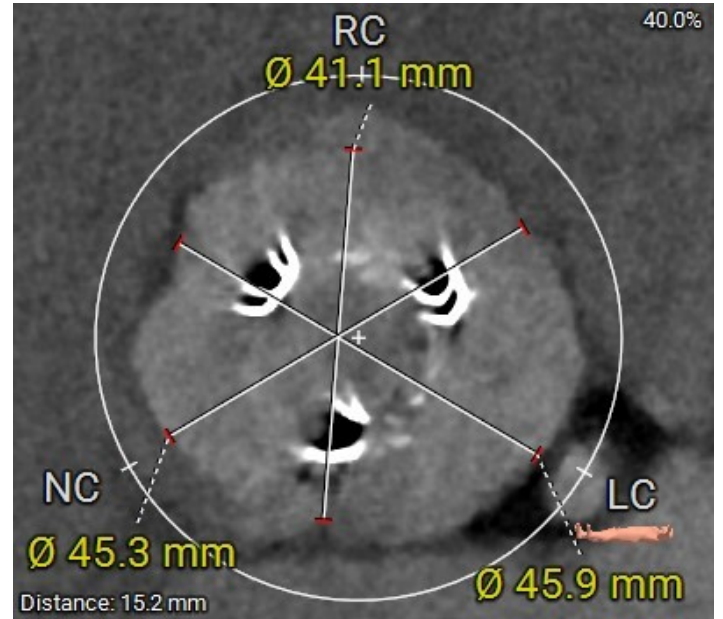
Artifact seen in LFA due to hip hardware

Aorta

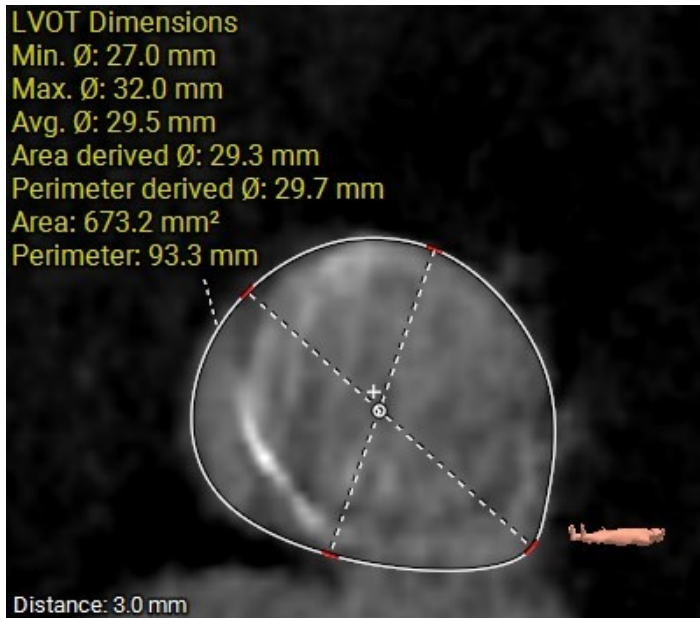
ANNULUS



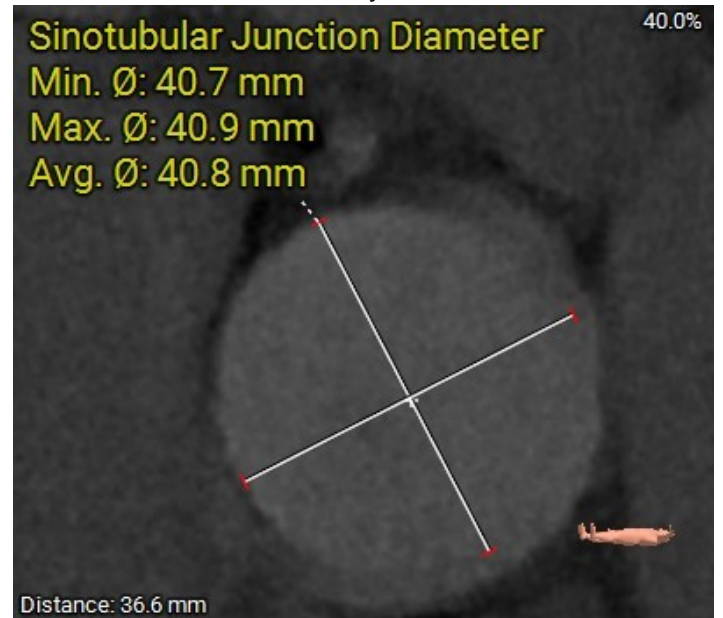
SOV DIAMETER



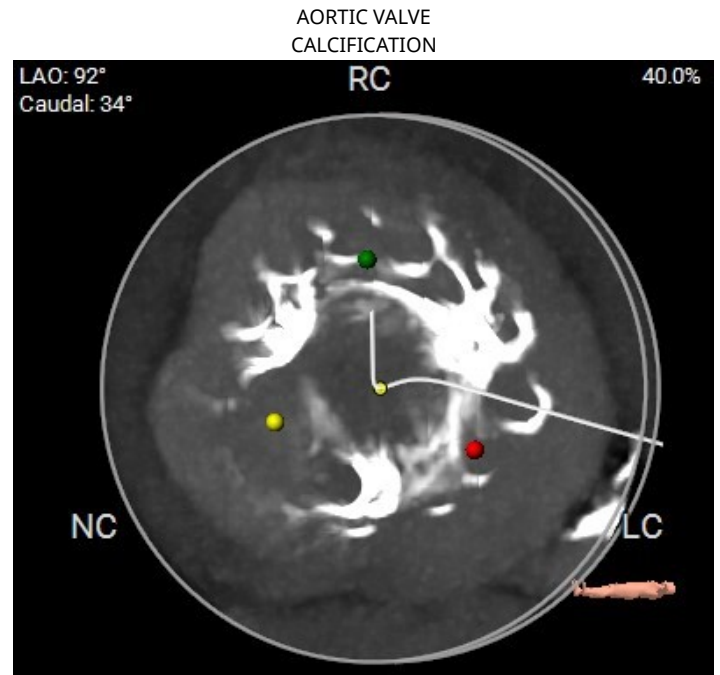
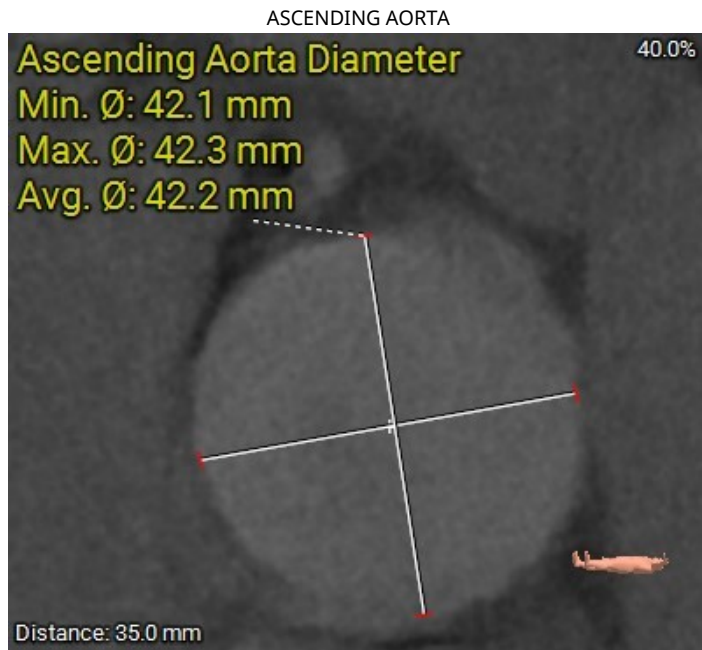
LVOT



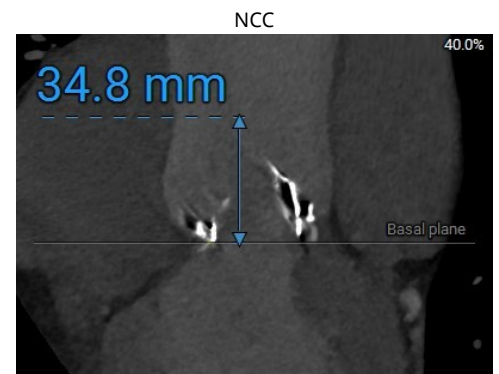
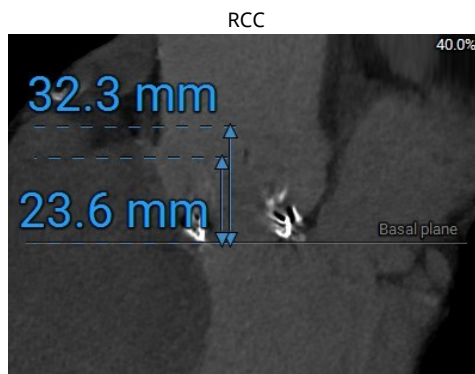
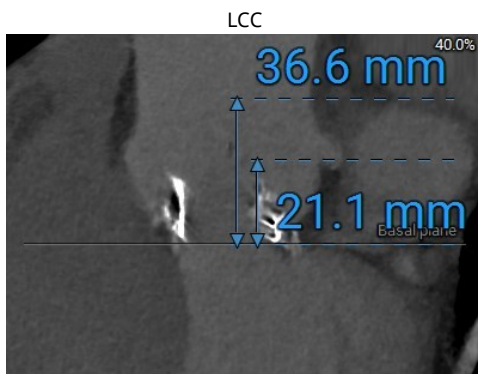
STJ



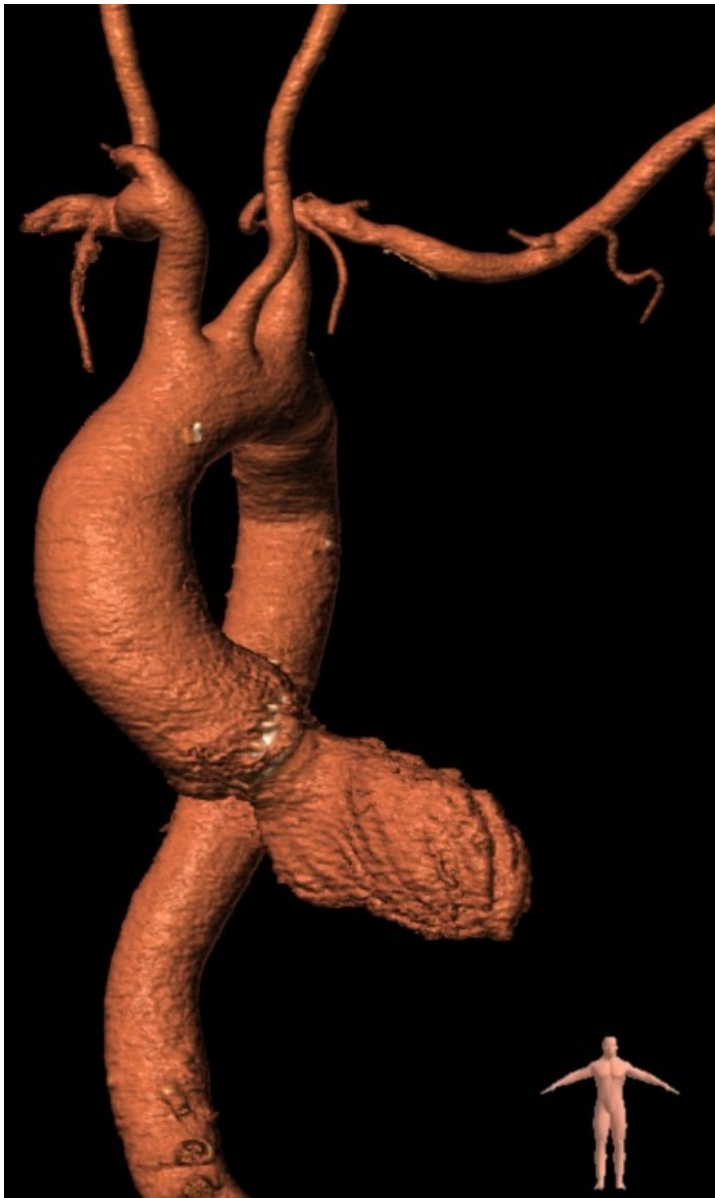
Aorta



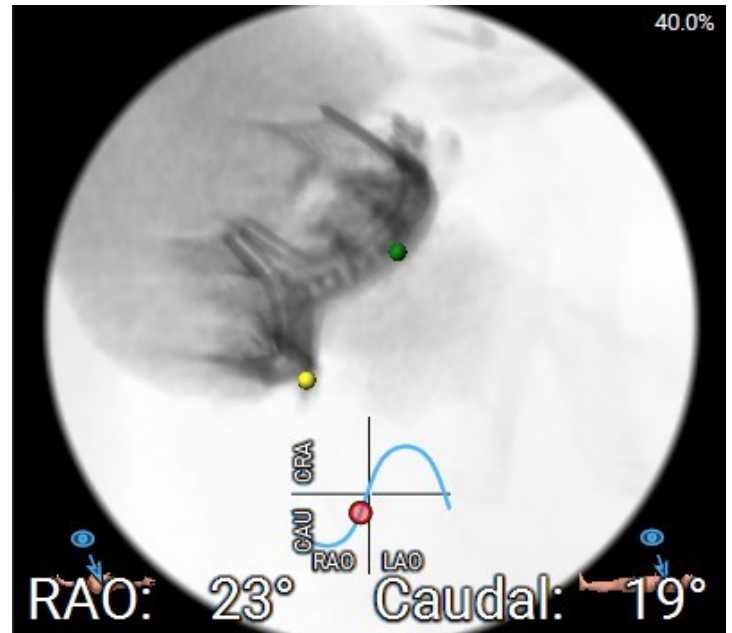
SINUS HEIGHT



AORTIC ROOT

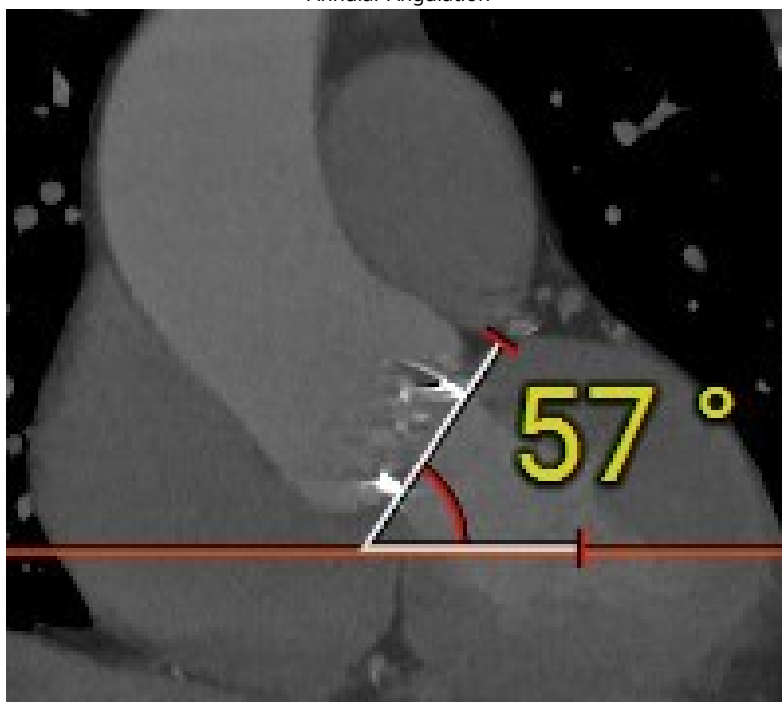


IMPLANTER'S VIEW

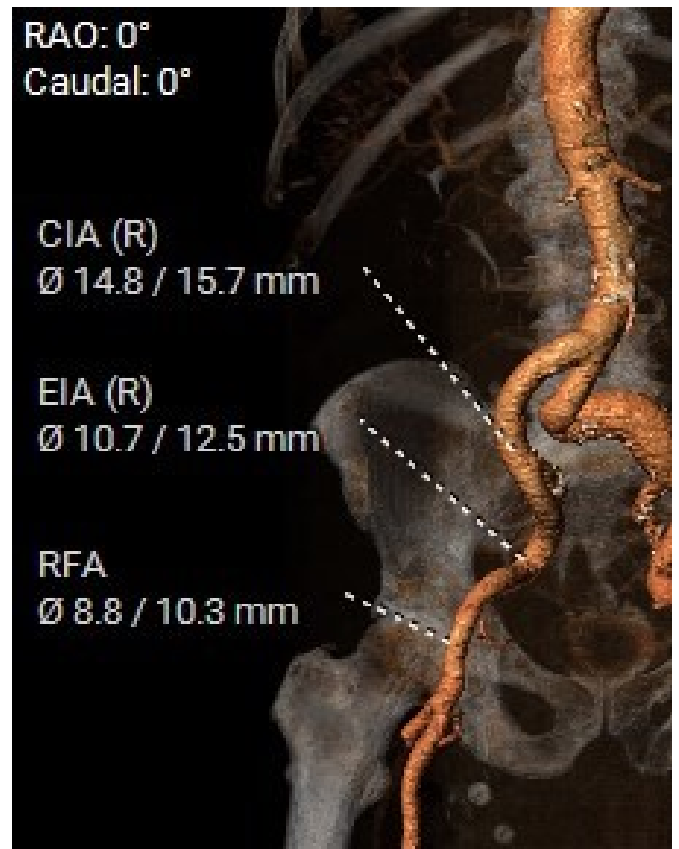
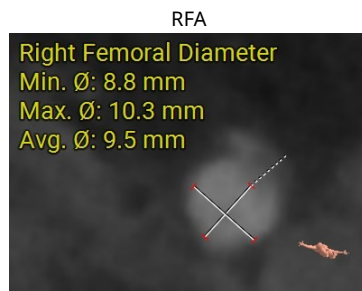
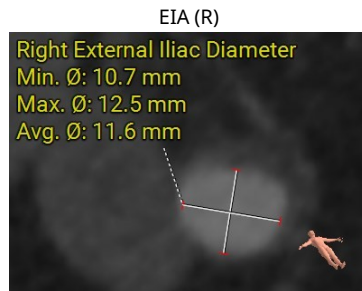
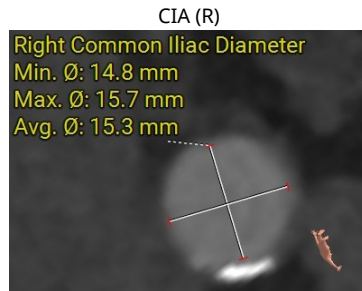
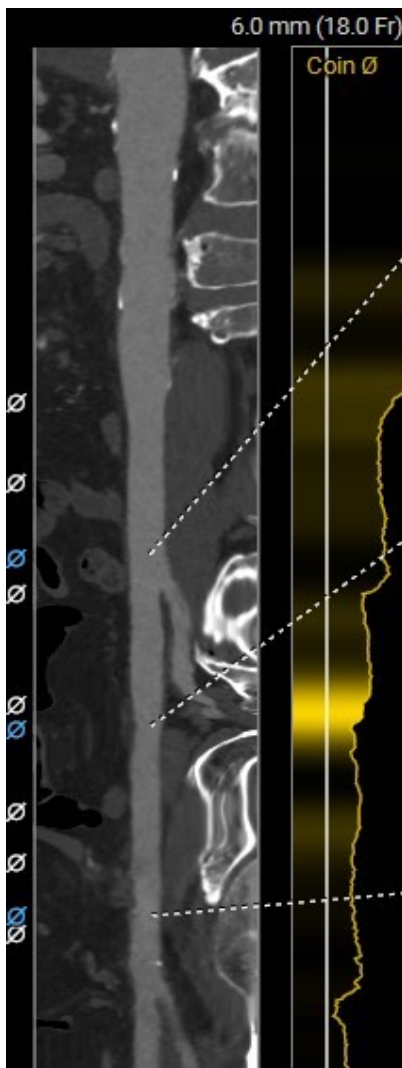


Cusp overlap view

Annular Angulation

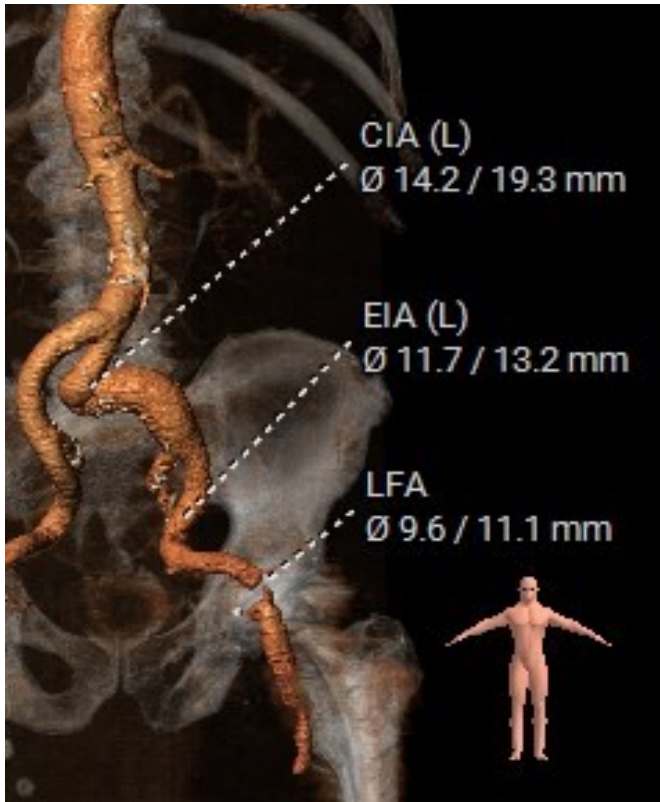


Femoral Access - Right

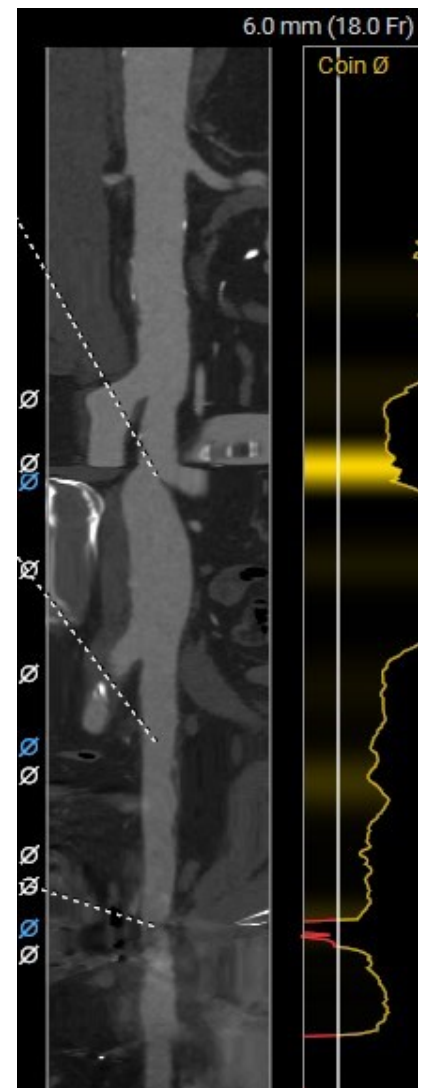
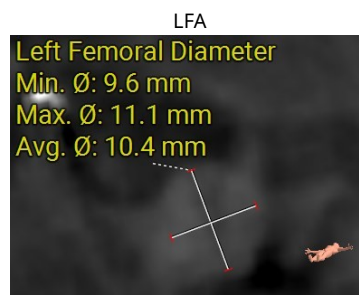
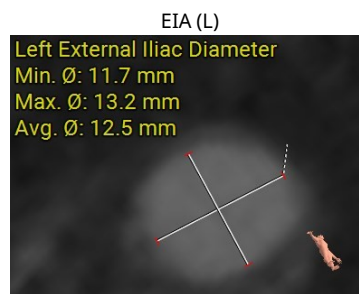
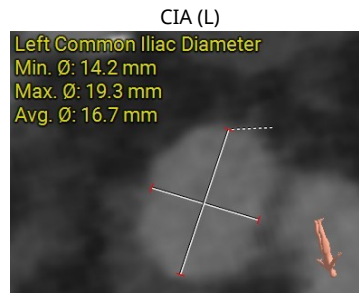


Bend seen in REI

Femoral Access - Left



- Bend seen in LCI and LEI
- Artifact seen in LFA due to hip hardware



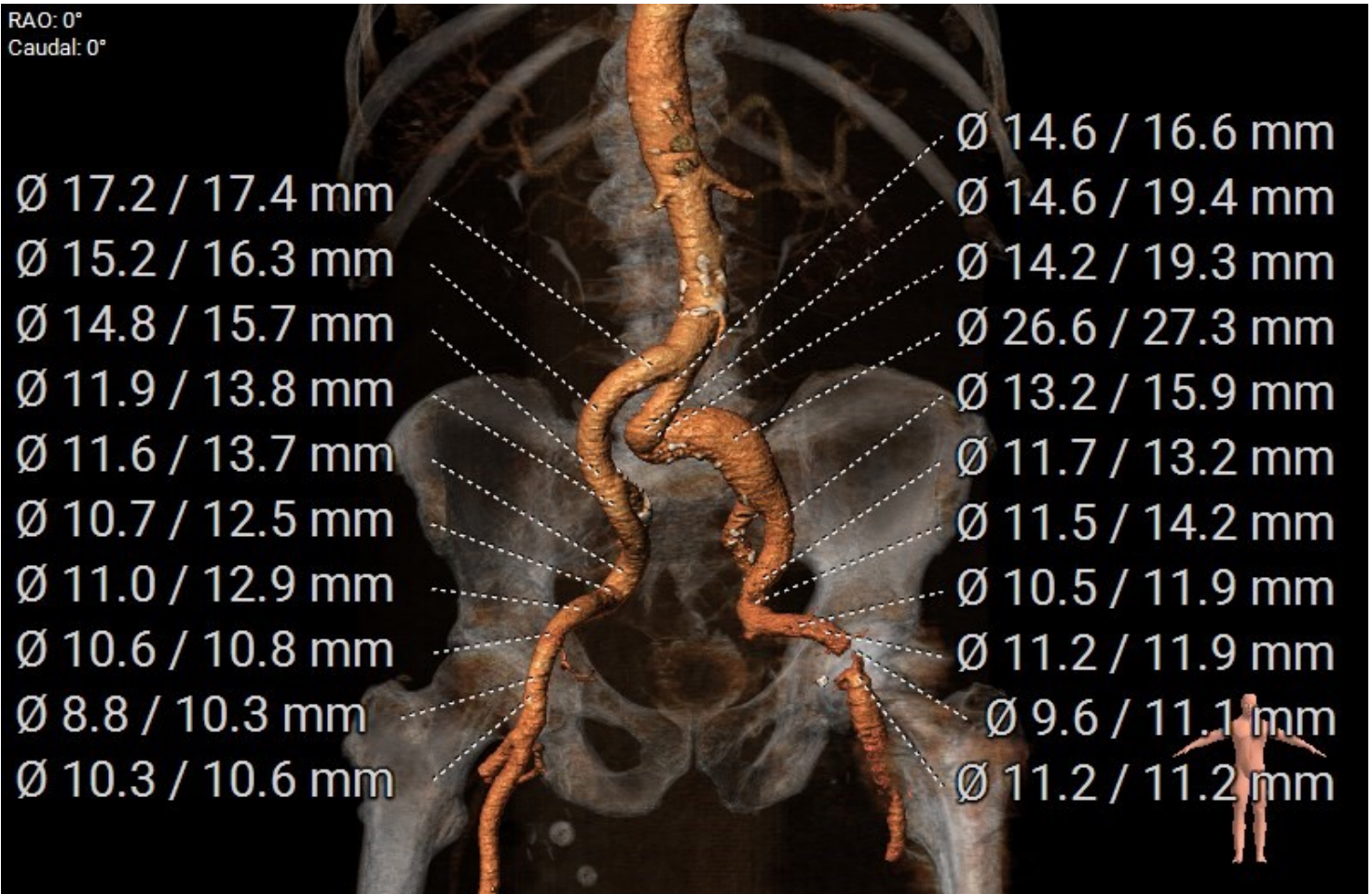
Possible bulging seen in LCI

Additional Femoral Images



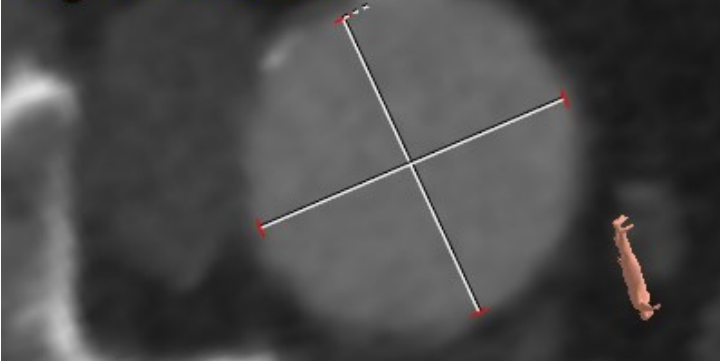
Possible bulging seen in LCI

RAO: 0°
Caudal: 0°



Perpendicular Plane (L)



Min. Ø: 26.6 mm
Max. Ø: 27.3 mm
Avg. Ø: 26.9 mm



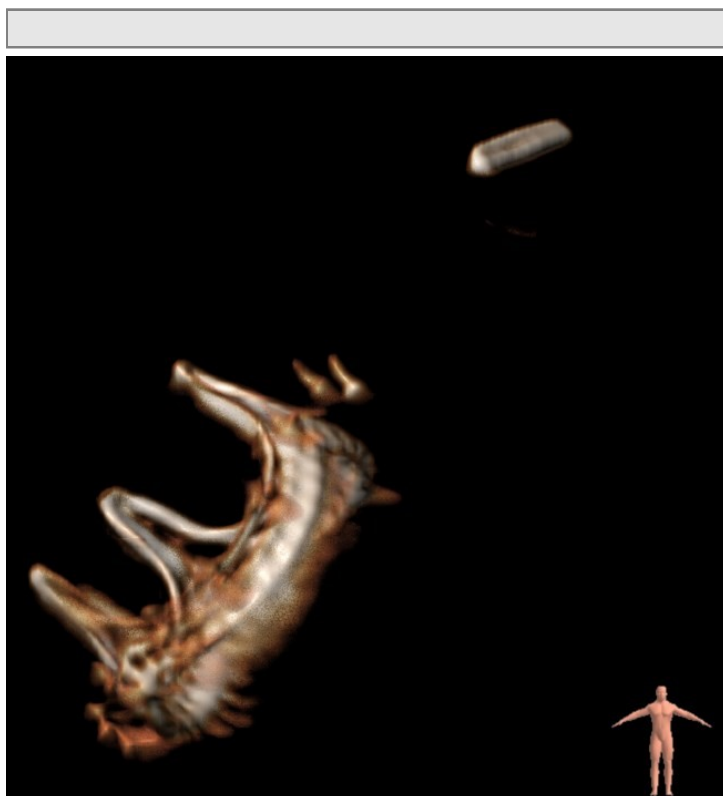
Possible bulging seen in LCI

Additional Images

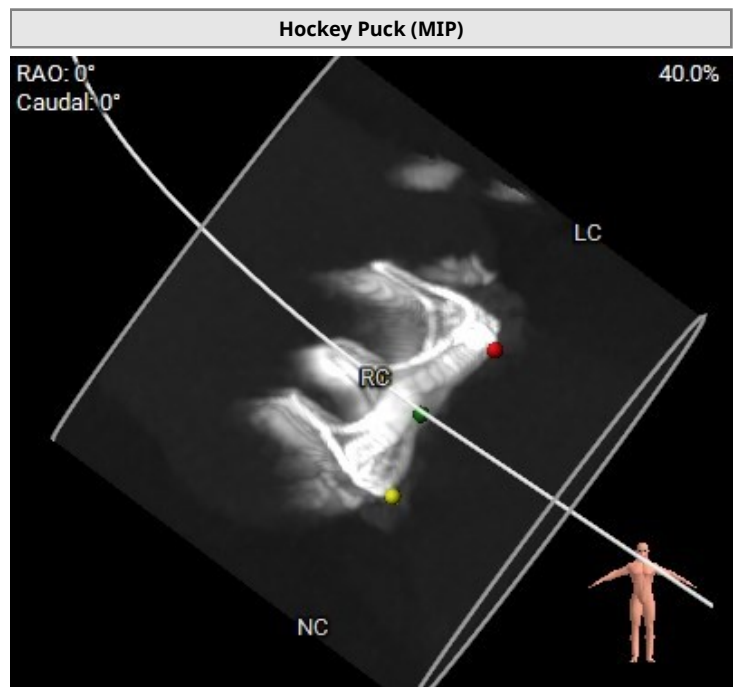
Perimount RSR 2800 Valve,⁸ Magna 3000 Valve⁹

|  | Surgical Valve Size | 19 mm | 21 mm | 23 mm | 25 mm | 27 mm | 29 mm | 31 mm |  |
|---|-----------------------------|-------|-------|-------|-------|-------|-------|-------|---|
| | Inner Diameter [†] | 18 | 20 | 22 | 24 | 26 | 28 | - | |
| | Height | 14 | 15 | 16 | 17 | 18 | 19 | - | |

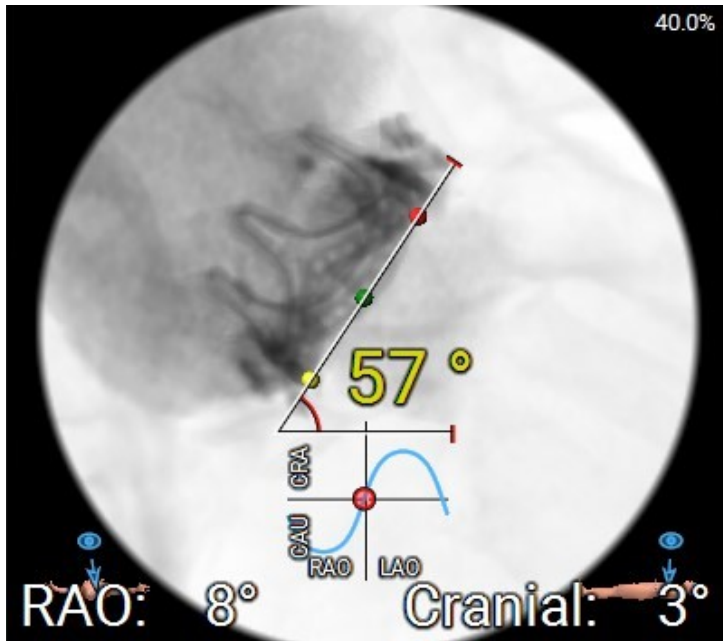
Site reports patient has a 25 mm Edwards Perimount 2800 surgical aortic valve (SAV) - Patient appears to have a radiopaque suture device near the SAV - Recommend obtaining Op report for specific SAV information



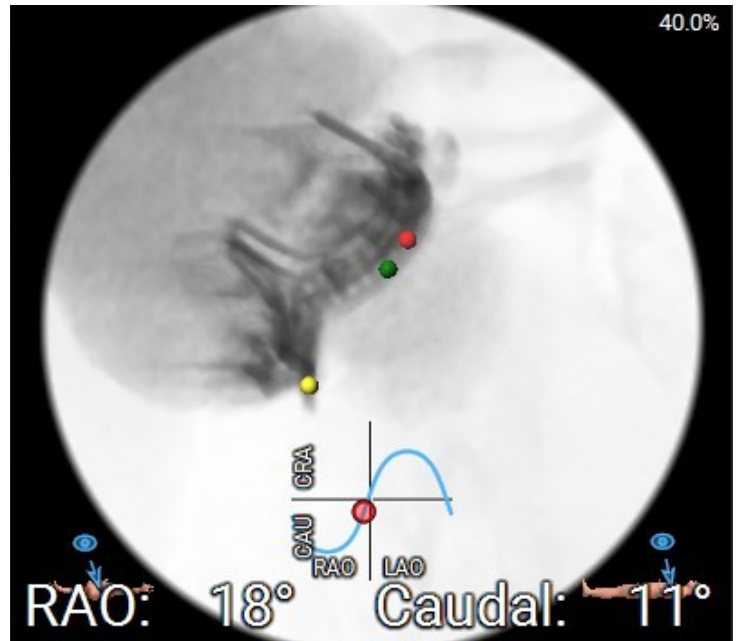
Possible LAA closure device - please verify with site



3 Cusp Coplanar



Near Cusp Overlap

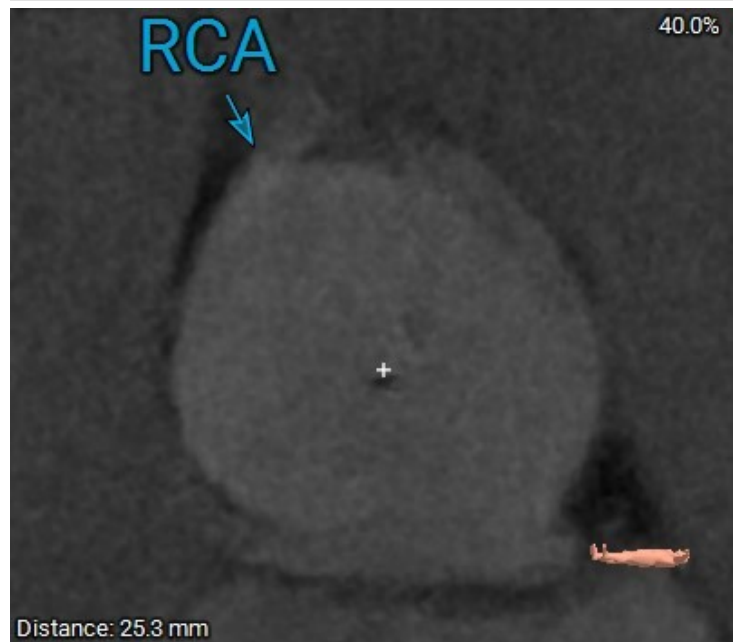


Perpendicular Plane

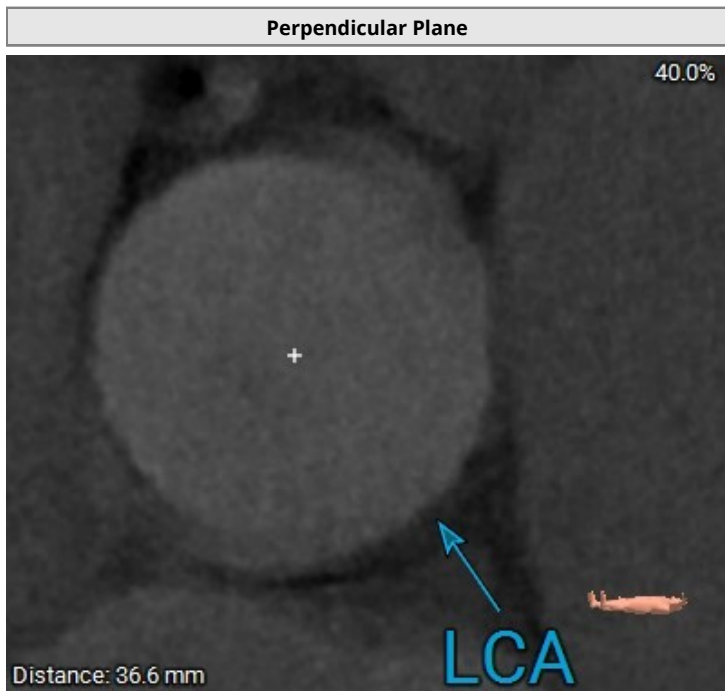


LCA appears to originate above SAV stent posts

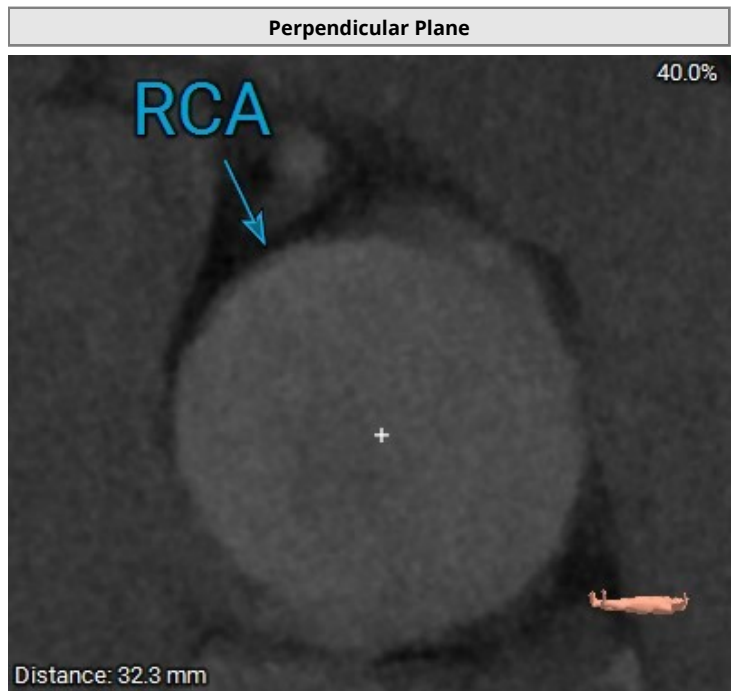
Perpendicular Plane



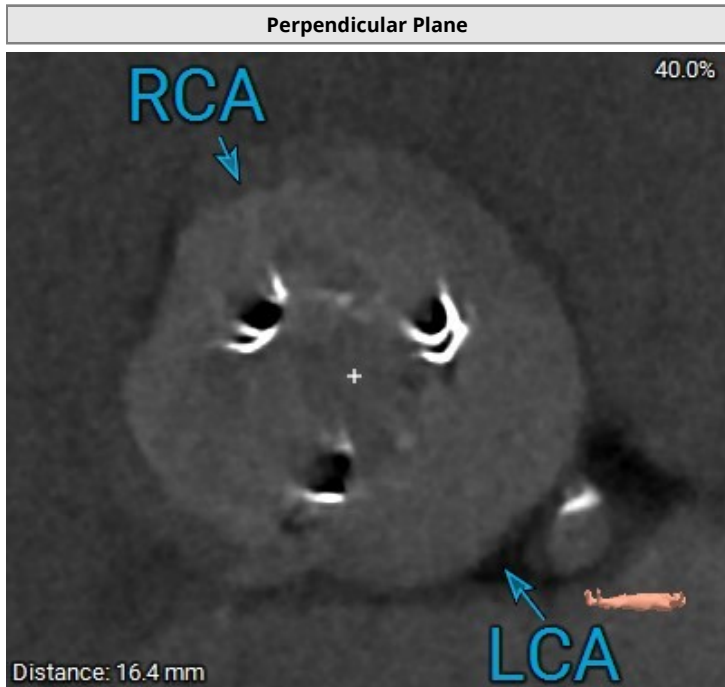
RCA appears to originate above SAV stent posts



LCC - VTSTJ not provided as the top of LCC is > 2 mm from the top of SAV stent



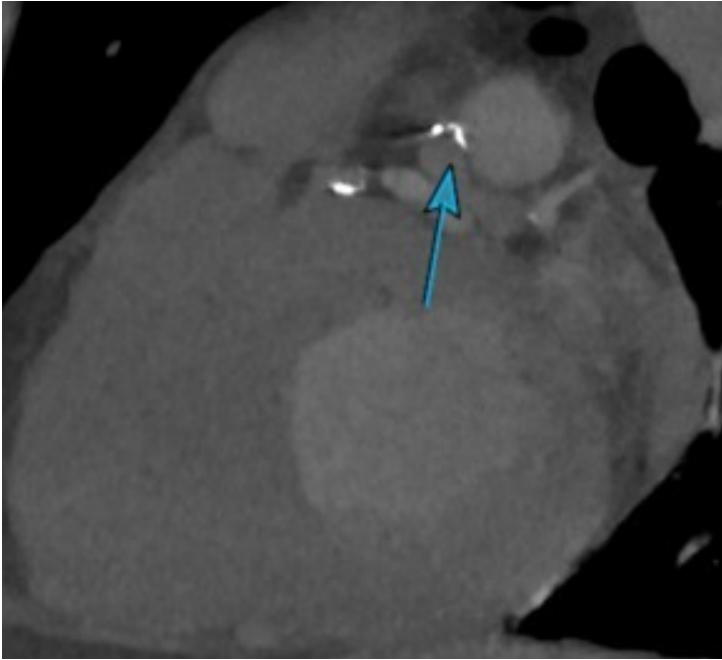
RCC - VTSTJ not provided as the top of RCC is > 2 mm from the top of SAV stent



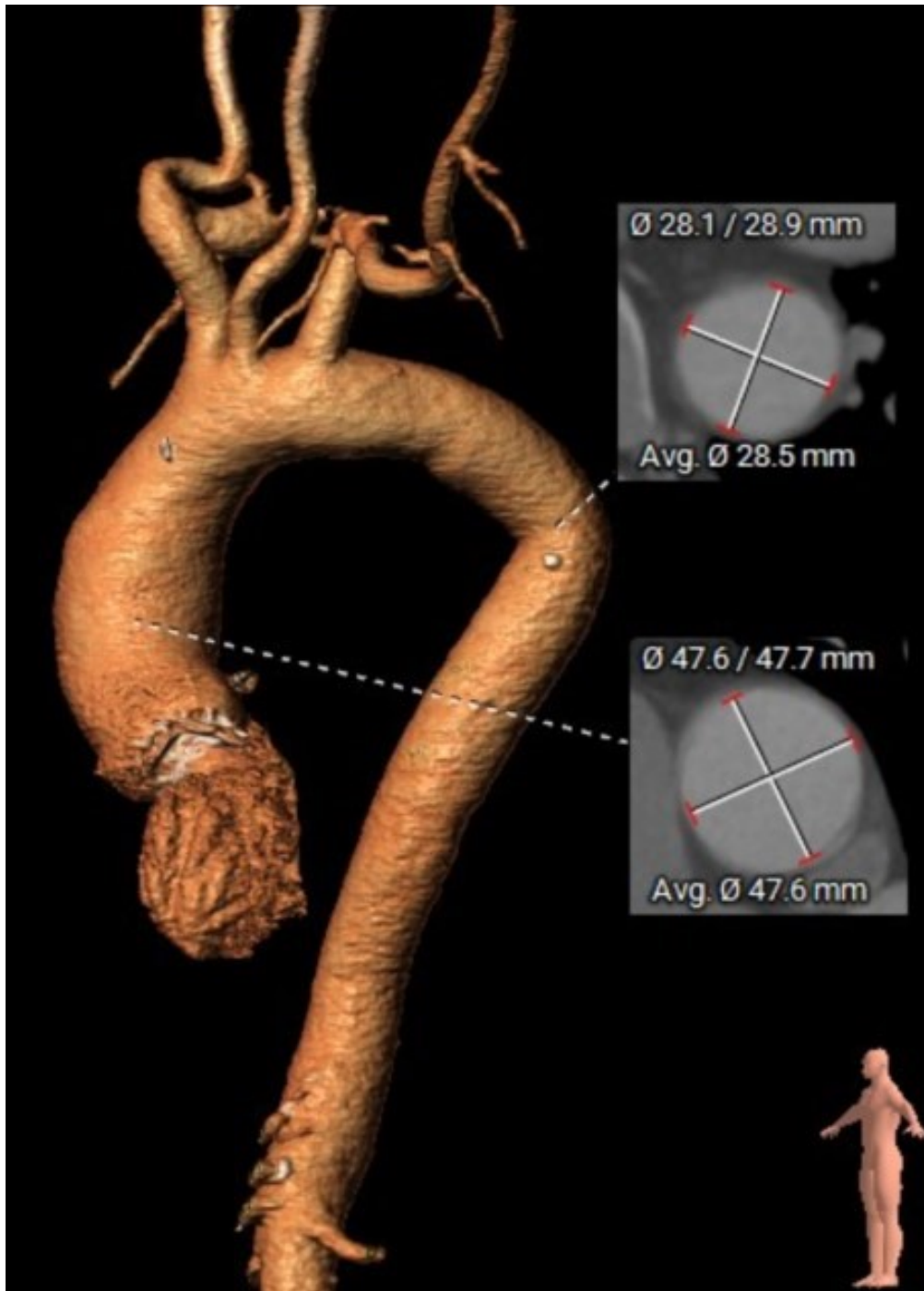
LCC and RCC - VTA not provided as LCA and RCA originates above SAV stent posts



Possible LAA closure device - please verify with site



Possible LAA closure device - please verify with site



- Dilated ascending aorta
- Bend seen in descending thoracic aorta

Patient valve selection criteria

Evolut FX bioprosthesis valve size selection

| Size | | 23 mm | 26 mm | 29 mm | 34 mm |
|---------------------------------------|---------|--------------|--------------|--------------|--------------|
| Annulus diameter (A) | 23.0 mm | 18–20 mm | 20–23 mm | 23–26 mm | 26–30 mm |
| Annulus perimeter† | 72.3 mm | 56.5–62.8 mm | 62.8–72.3 mm | 72.3–81.7 mm | 81.7–94.2 mm |
| Sinus of Valsalva diameter (mean) (B) | 44.1 mm | ≥ 25 mm | ≥ 27 mm | ≥ 29 mm | ≥ 31 mm |
| Sinus of Valsalva height (mean) (C) | 34.5 mm | ≥ 15 mm | ≥ 15 mm | ≥ 15 mm | ≥ 16 mm |
| Oversizing Percentage | | 0% | 13% | 26% | 48% |

†Annulus perimeter = annulus diameter x π .

Selection criteria

Access consideration by MSCT

Minimum transarterial access vessel diameter

Aortic root angulation, femoral access

Aortic root angulation, left subclavian

Aortic root angulation, right subclavian

Vascular access location, direct aortic access

IFU guidance by MSCT

Evolut FX 23/26/29 mm TAVs ≥ 5.0 mm

Evolut FX 34 mm TAV ≥ 6.0 mm

Not recommended if > 70 degrees.

Not recommended if > 70 degrees.[§]

Not recommended if > 30 degrees.[§]

Ascending aorta access site ≥ 60 mm from basal plane.[¶]

[§]Patients with a patent LIMA or RIMA graft must present with access vessel diameters that are either ≥ 5.5 mm when using model D-EVOLUTFX-2329 or ≥ 6.5 mm when using model D-EVOLUTFX-34.

[¶]For direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.

Note the position of any SVGs

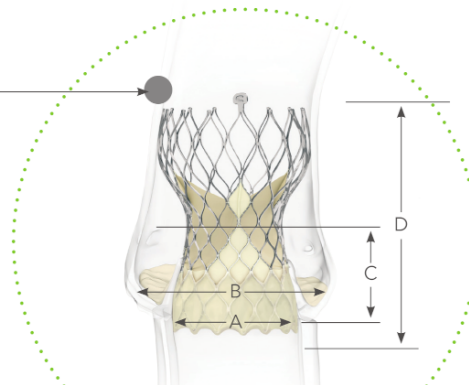
(A) Annulus diameter

(B) Sinus of Valsalva diameter

(C) Sinus of Valsalva height

(D) Frame height (≈ 45 mm, not including paddles)

Illustration not to scale.



CAUTION: For distribution only in markets where CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, Evolut™ PRO+, Evolut™ FX Systems and Evolut™ FX+ Systems are approved. See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+, the Evolut™ FX and the Evolut™ FX+ device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu. For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, the commercial name of the Evolut™ PRO+ device is Medtronic CoreValve™ Evolut™ PRO+ System, the commercial name of the Evolut™ FX device is Medtronic Evolut™ FX System and the commercial name of the Evolut™ FX+ device is Medtronic Evolut™ FX+ System.

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See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+ device and the Evolut™ FX device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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Notes:

Conclusion:
Reviewer Name: #36
Review Date: 30-May-2025