



Report Details

Creation Date: 31/05/2025
Created By: RH
Received Date: 31/05/25
Reviewed Date:

Physician:
Hospital:
City: SYDNEY
Country: AUSTRALIA

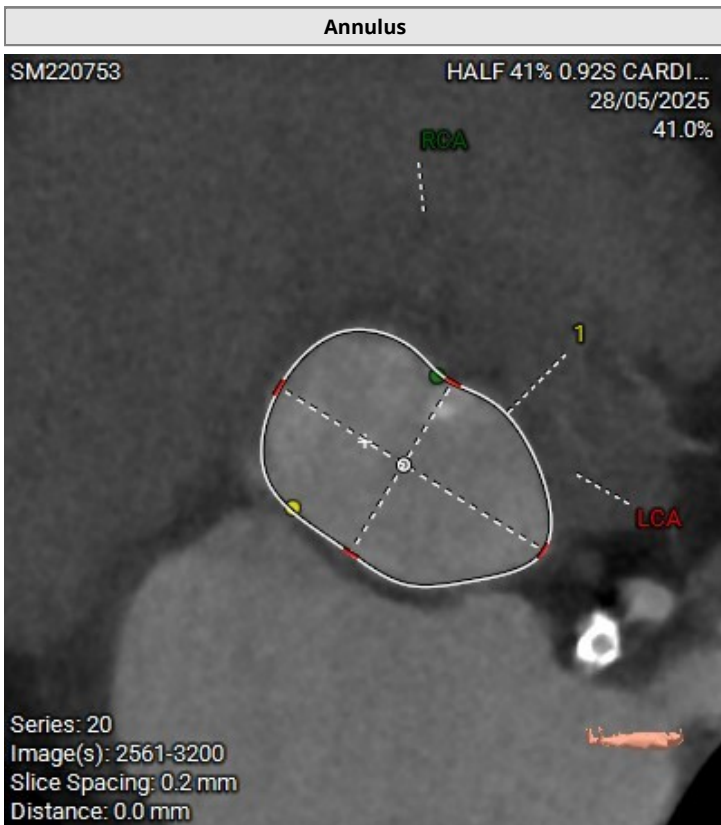
Patient Information

Name: SM220753
Sex:
Year Of Birth (Age):

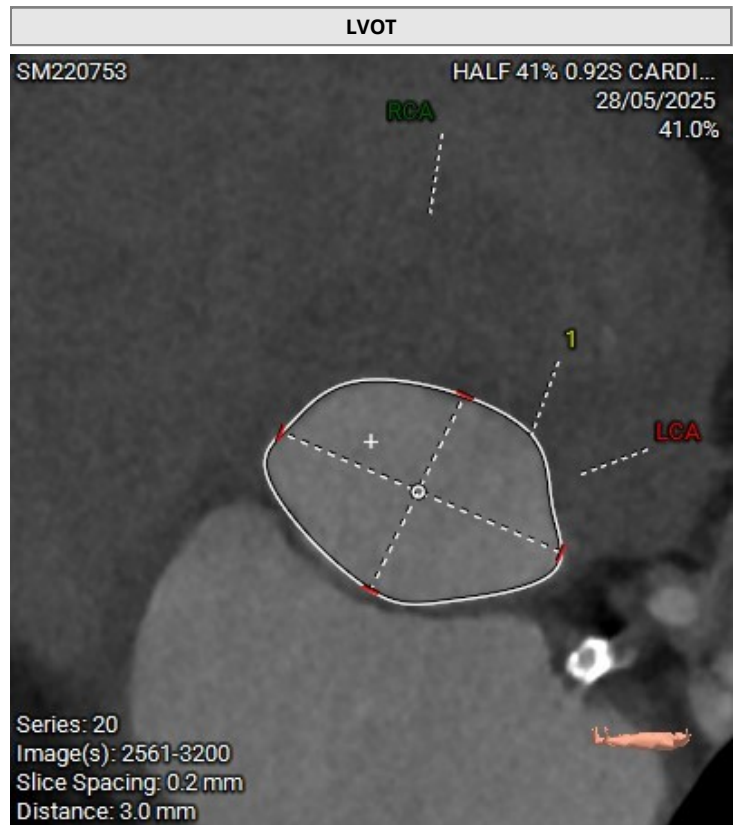
NYHA:
STS Score:

Comments: Virtual valve for demonstration only, not a sizing or placement recommendation.

Screenshots



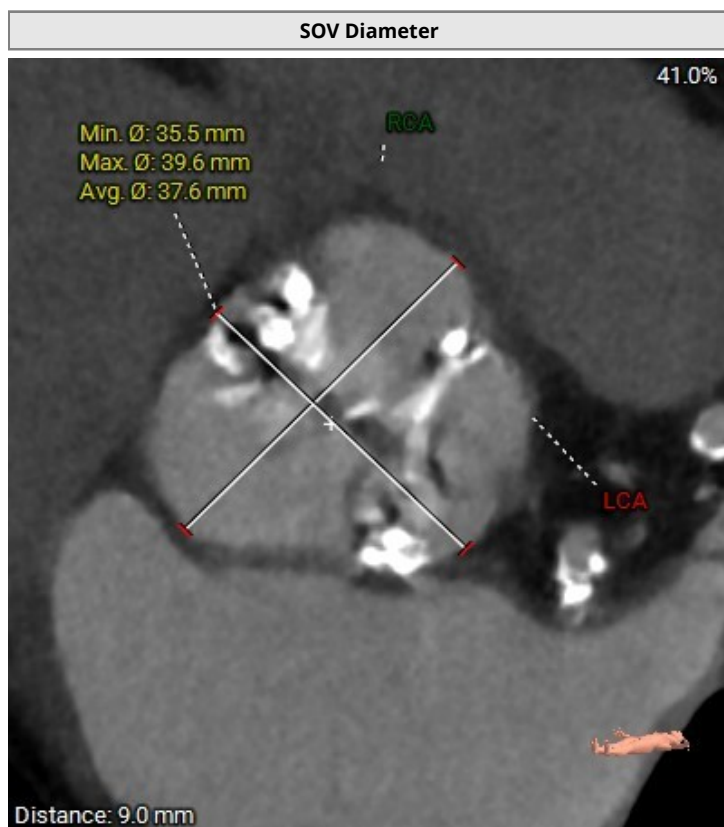
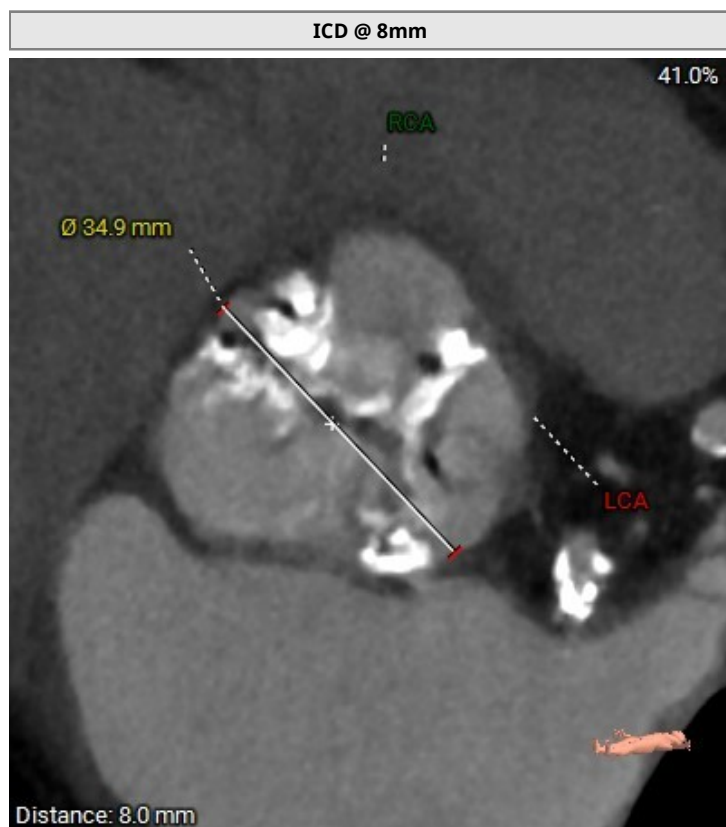
ID Type	Label	Value
1	Polygon Min. Ø	20.7 mm
	Max. Ø	32.2 mm
	Avg. Ø	26.5 mm
	Area	564.3 mm ²
	Perimeter	87.7 mm



ID Type	Label	Value
1	Polygon Min. Ø	22.4 mm
	Max. Ø	31.6 mm
	Avg. Ø	27.0 mm
	Area	537.8 mm ²
	Perimeter	85.3 mm

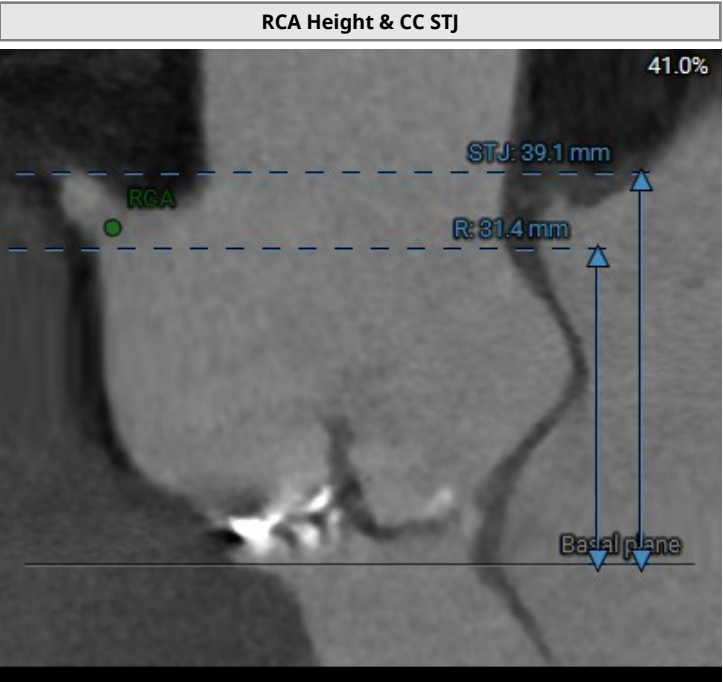
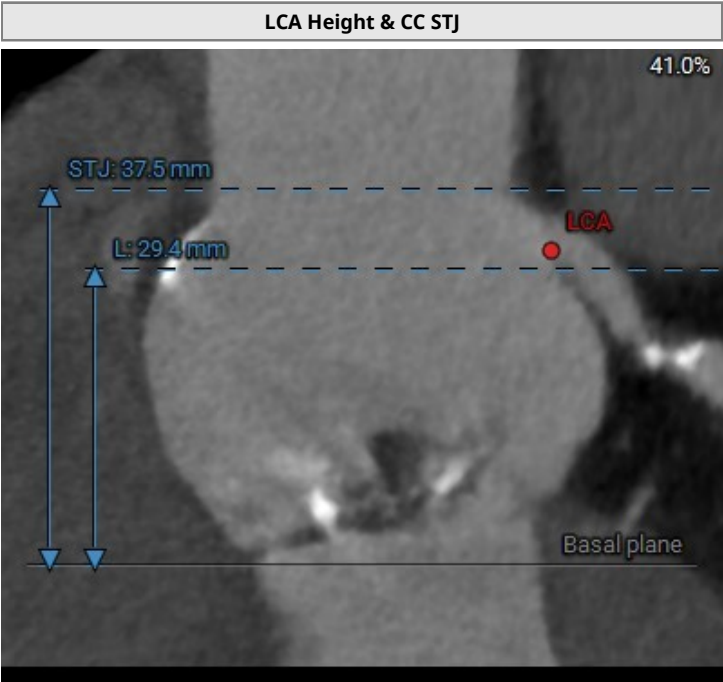
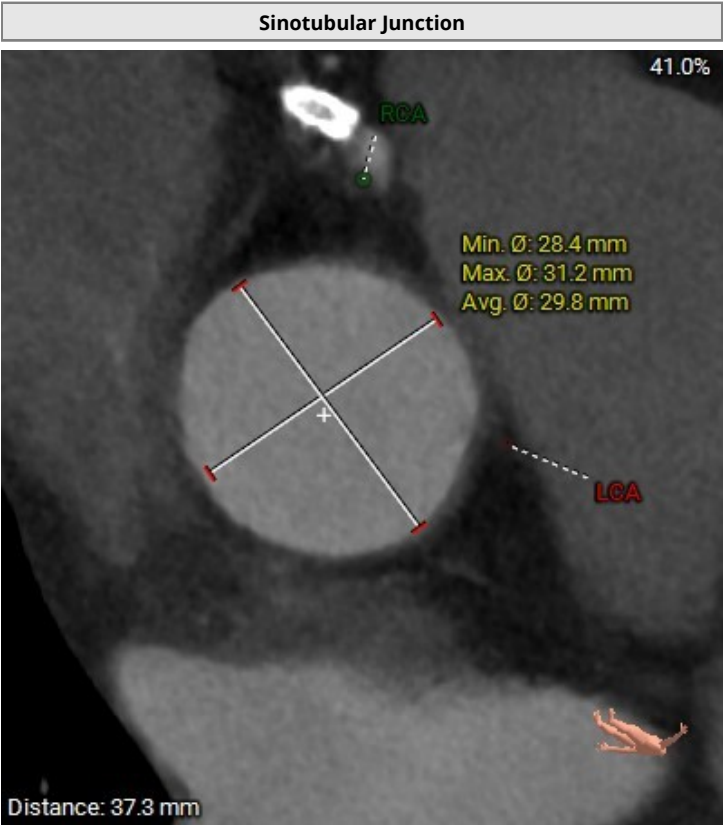
Case Report

Note: The intended use of this report is to provide an adjunctive case planning resource and should not be used for diagnostic purposes.

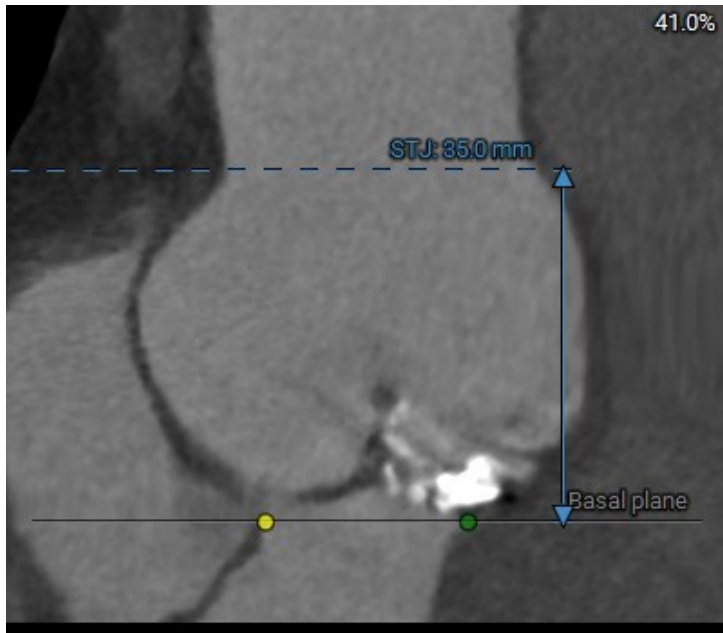


Case Report

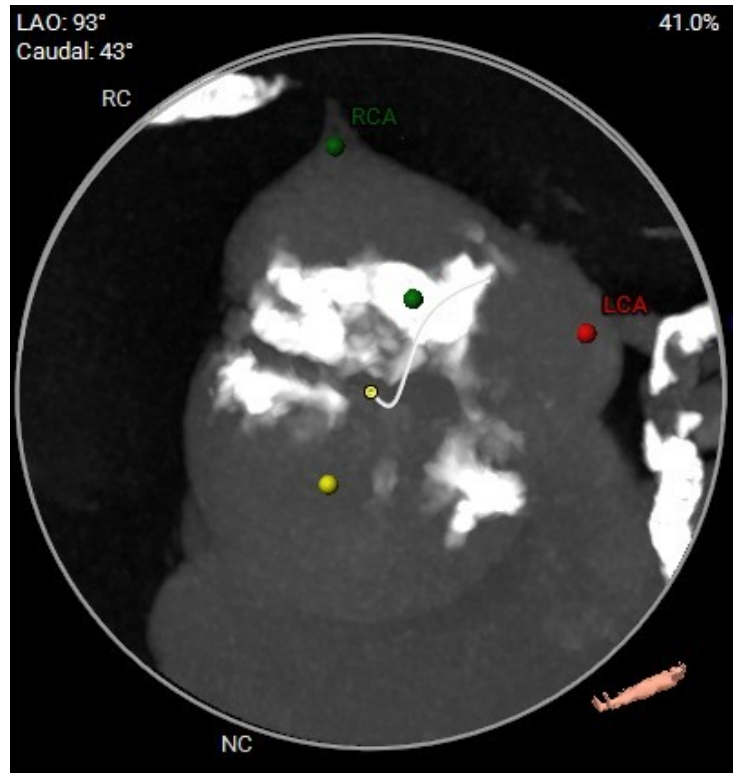
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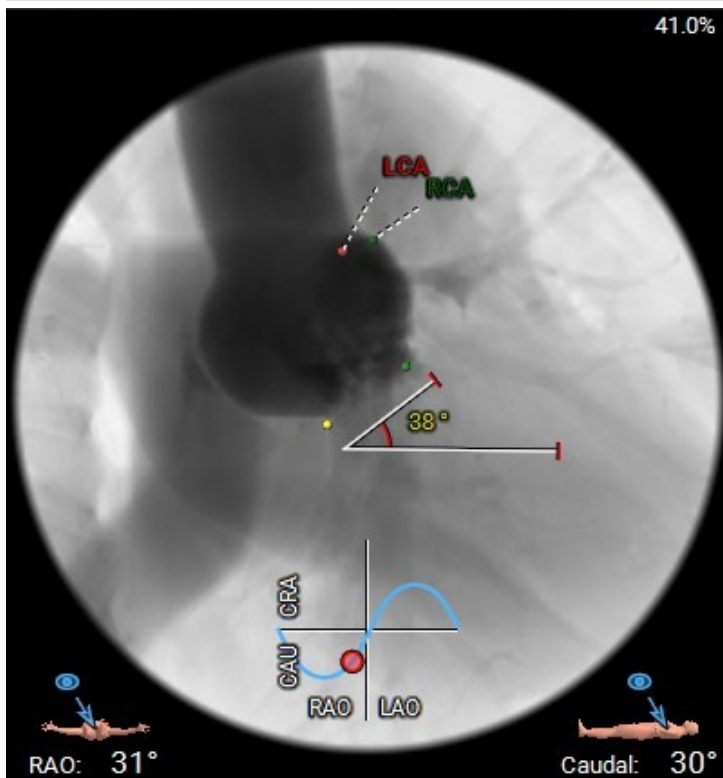
Sinus Height NCC



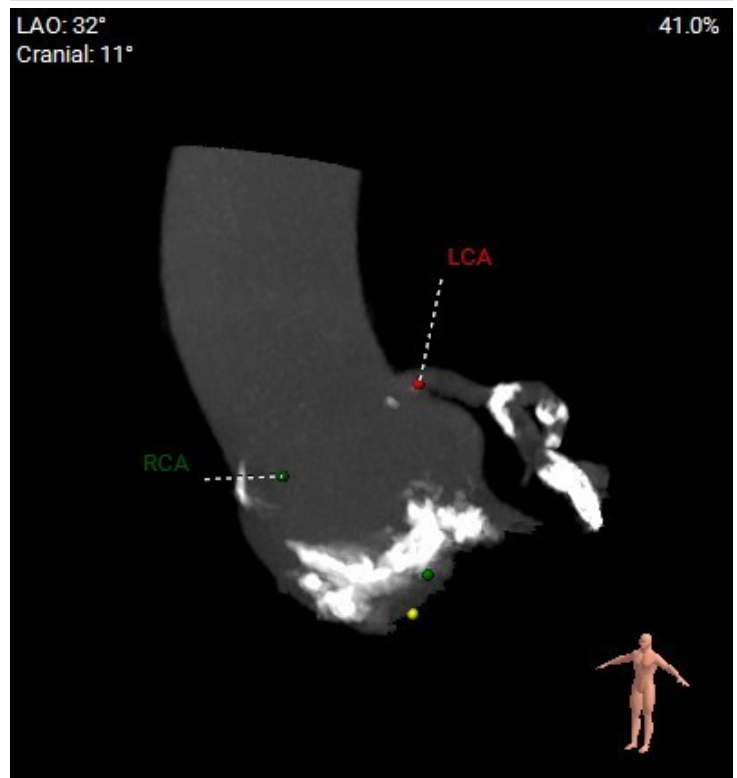
Hockey Puck (MIP)



Angio



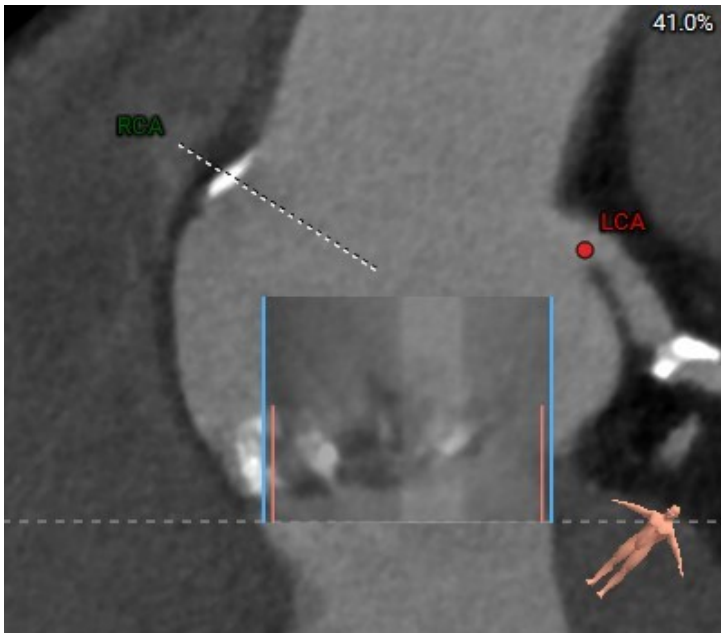
Calcifications



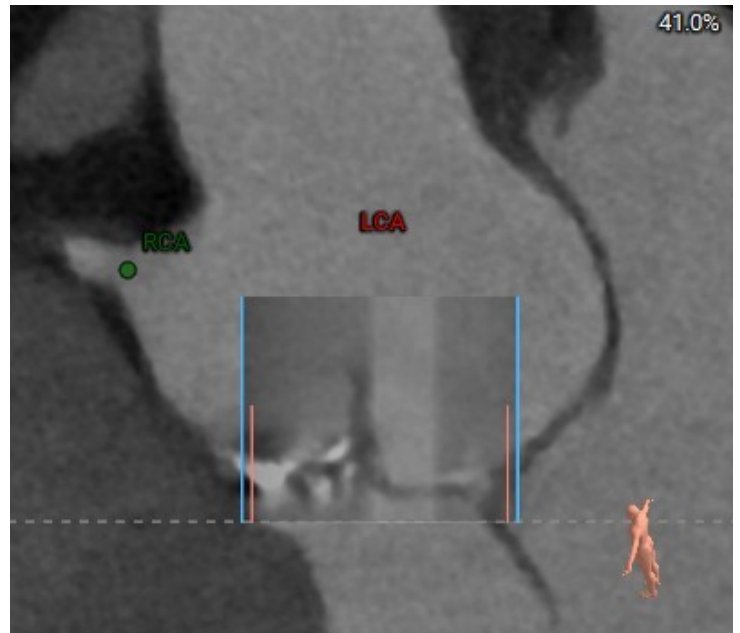
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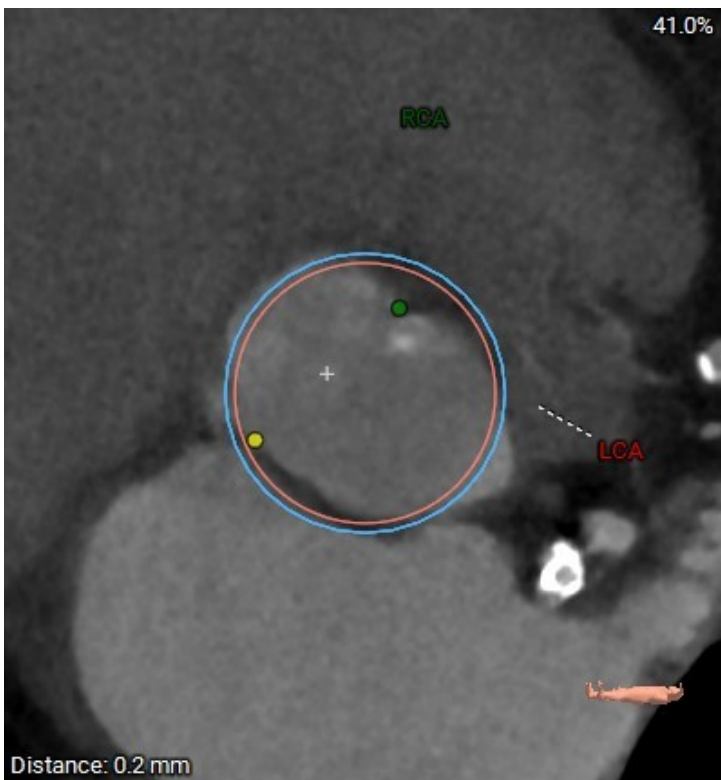
29mm THV to LCA



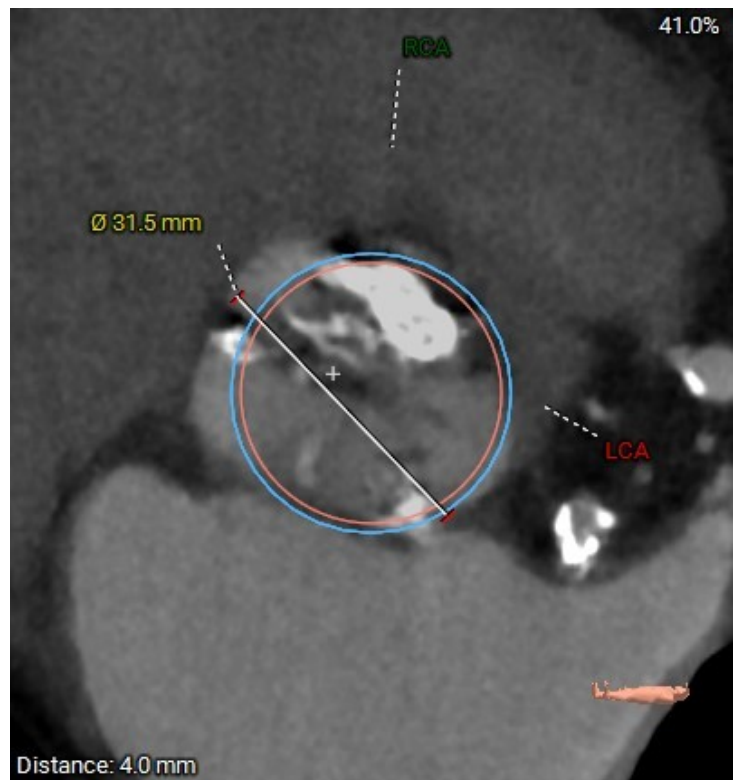
29mm THV to RCA



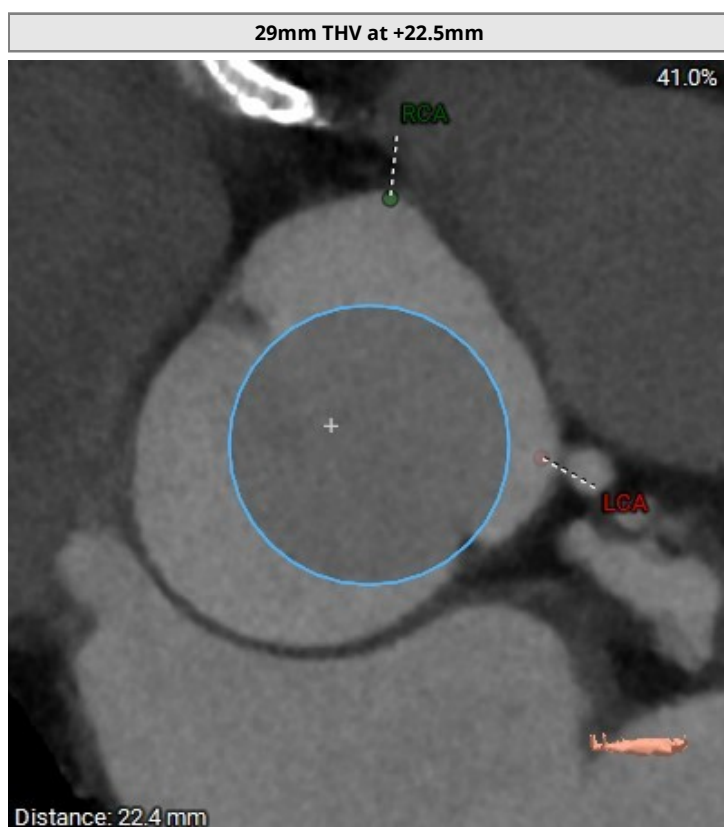
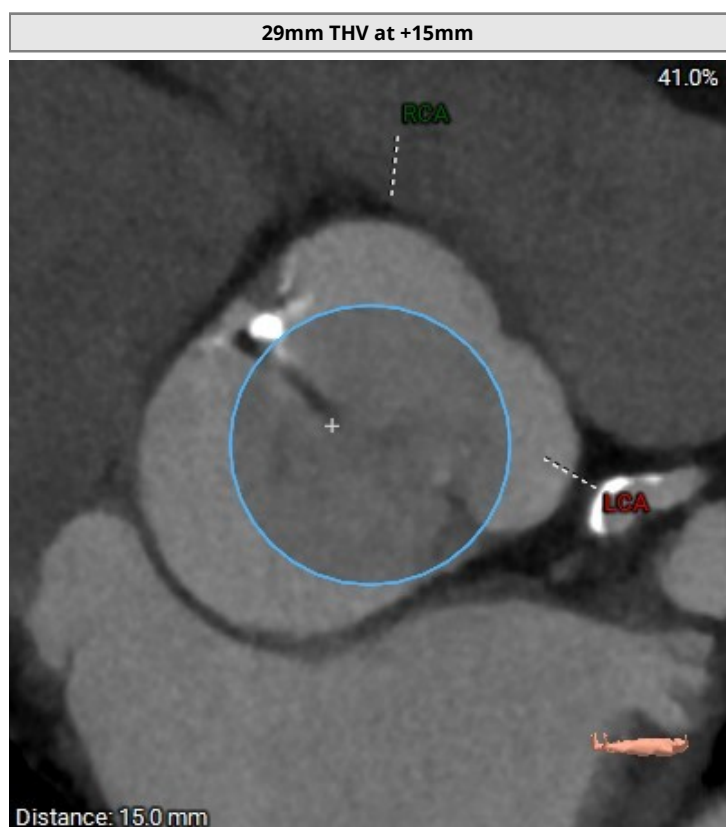
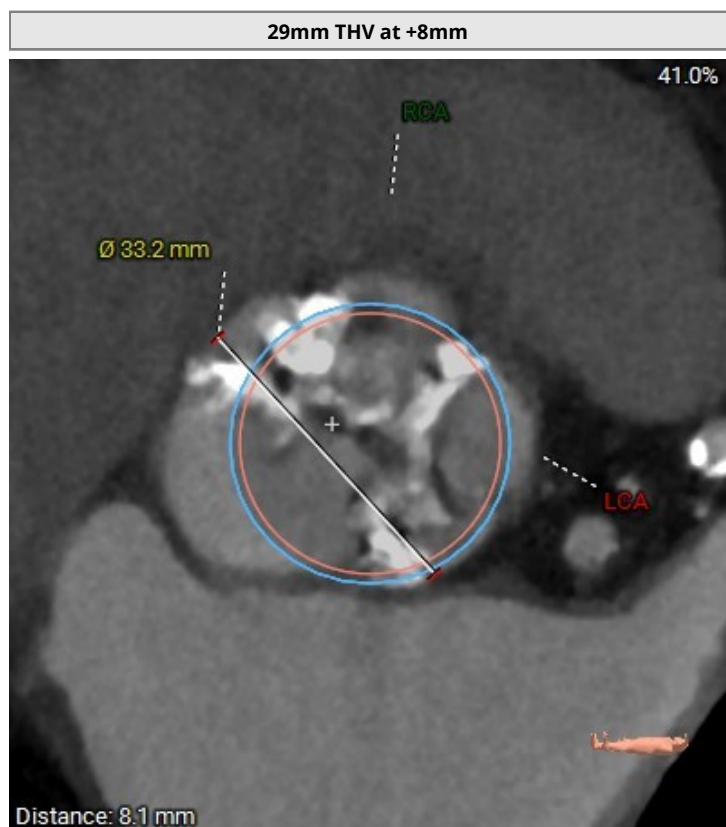
29mm THV at Annulus



29mm THV at +4mm

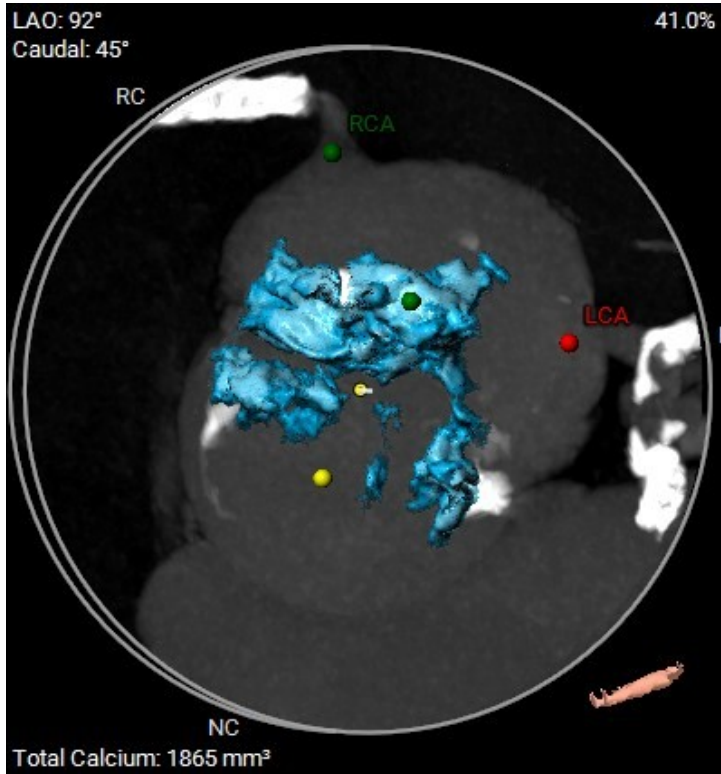
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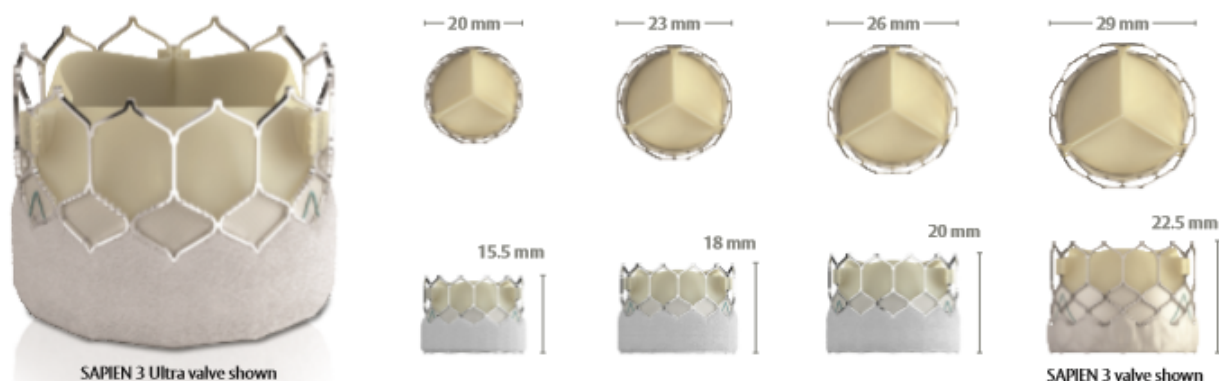
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Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System

Annulus Sizing And Vascular Access

Complete Range of Valve Sizes Expands the Treatable Patient Population



	20 mm	23 mm	26 mm	29 mm
Inflation Volume	11 mL	17 mL	23 mL	33 mL
Area (CT)	273 - 345 mm ²	338 - 430 mm ²	430 - 546 mm ²	540 - 683 mm ²
Area-derived Diameter (CT)	18.6 - 21.0 mm	20.7 - 23.4 mm	23.4 - 26.4 mm	26.2 - 29.5 mm
Crimped Height*	21 mm	24.5 mm	27 mm	31 mm
Expanded Height	15.5 mm	18 mm	20 mm	22.5 mm
Foreshortening	5.5 mm	6.5 mm	7 mm	8.5 mm
Inner Skirt Height†	7.9 mm	9.3 mm	10.2 mm	11.6 mm
Outer Skirt Height - SAPIEN 3 THV	5.2 mm	6.6 mm	7.0 mm	8.1 mm
Outer Skirt Height - SAPIEN 3 Ultra THV*	7.3 mm	9.0 mm	9.7 mm	

Transcatheter heart valve size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during the transcatheter heart valve size selection. Risks associated with undersizing and oversizing should be carefully considered.

Low Profile Access Demonstrates Significant Reduction in Major Vascular Complications[‡]



Access Vessel Sizing	20 mm	23 mm	26 mm	29 mm
Edwards eSheath Introducer Set	14F (4.6 mm)	14F (4.6 mm)	14F (4.6 mm)	16F (5.3 mm)
Minimum Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6 mm

*Rounded to the nearest 0.5 mm †Measured at bottom of zig-zag

‡The PARTNER II S3i Trial intermediate-risk SAPIEN 3 valve cohort (VARC II) versus the PARTNER IIA Trial intermediate-risk SAPIEN XT valve cohort (VARC I) 30-day unadjusted results.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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