Edwards Lifesciences

Report Details

Creation Date:	2/06/2025	**Physician:**	
Created By:	D'Ettorre M	**Hospital:**	North Shore Private Hospital
Received Date:		**City:**	
Reviewed Date:		**Country:**	

Patient Information

Name:	SM220753 Femorals	**NYHA:**	
Sex:		**STS Score:**	
Year Of Birth (Age):			

Comments:

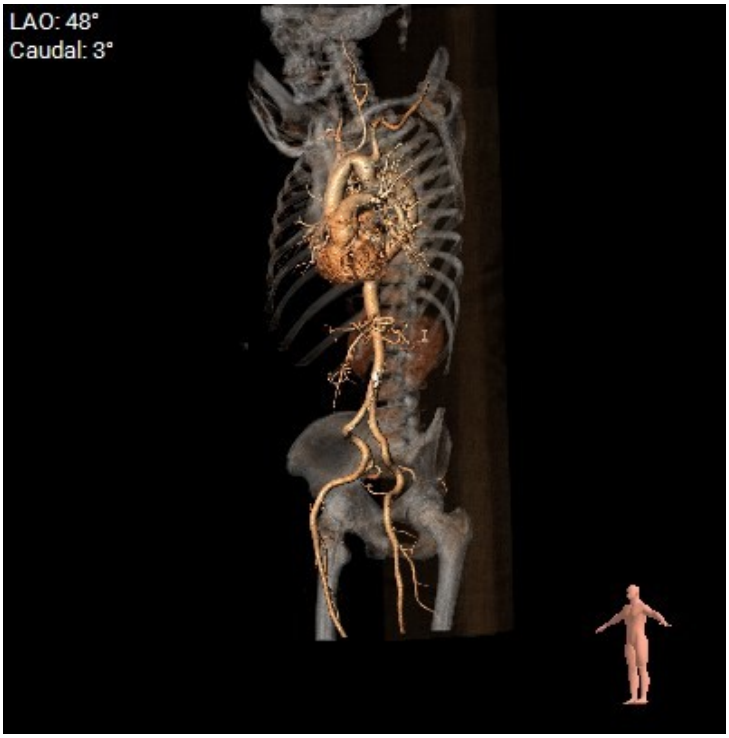
Aortic Valve

Annulus Area	
Area Derived Diameter	
Annulus Perimeter	
Perimeter Derived Diameter	
Annulus Min Diameter	
Annulus Max Diameter	

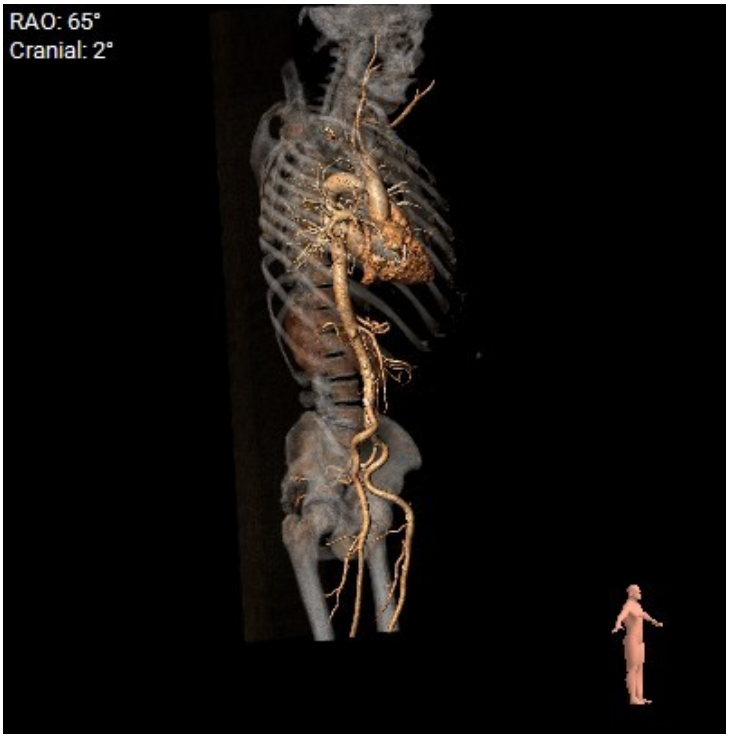
Sinus of Valsalva Diameter	
Sinotubular Junction Diameter	
LCA Height	
RCA Height	
Sinotubular Junction Height	

Screenshots

Dimmed background



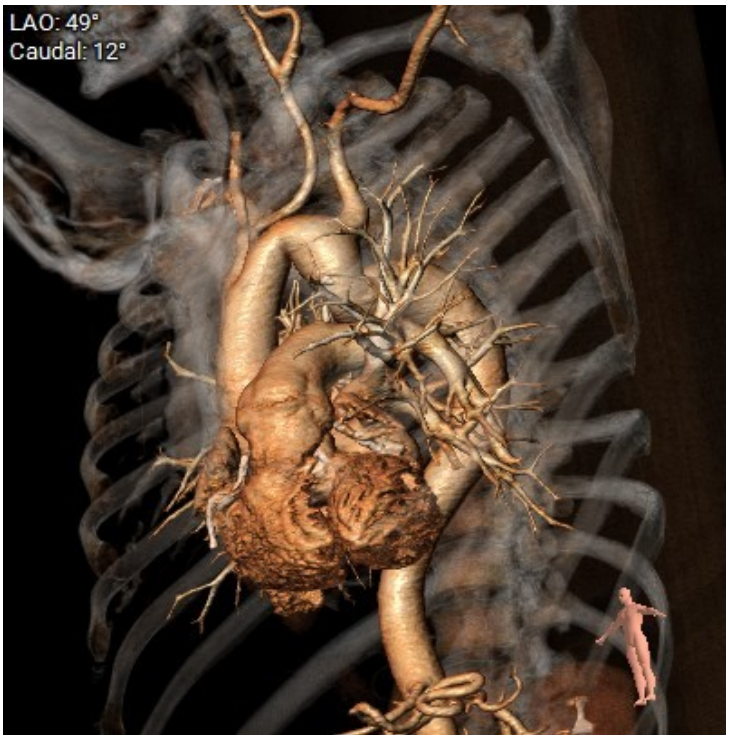
Dimmed background



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.

Dimmed background



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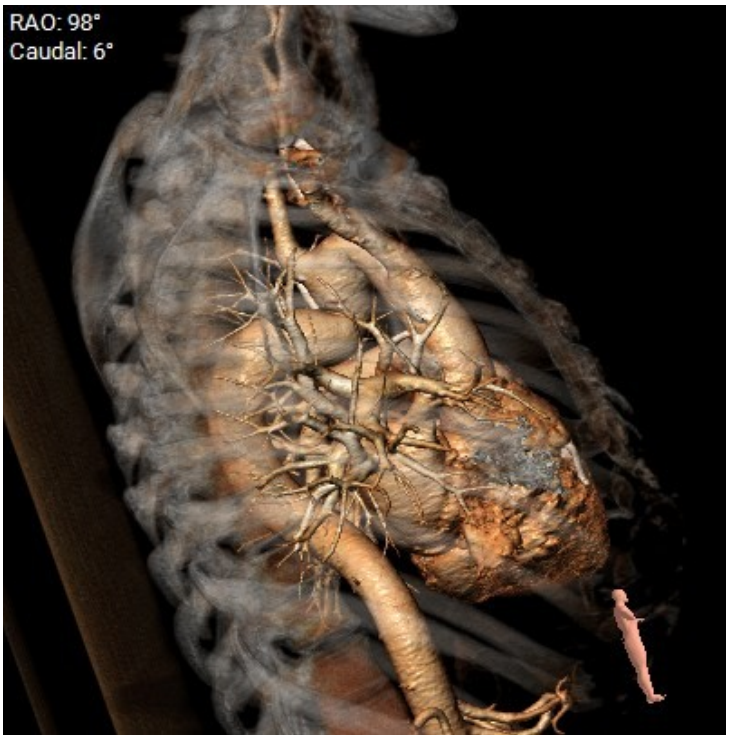
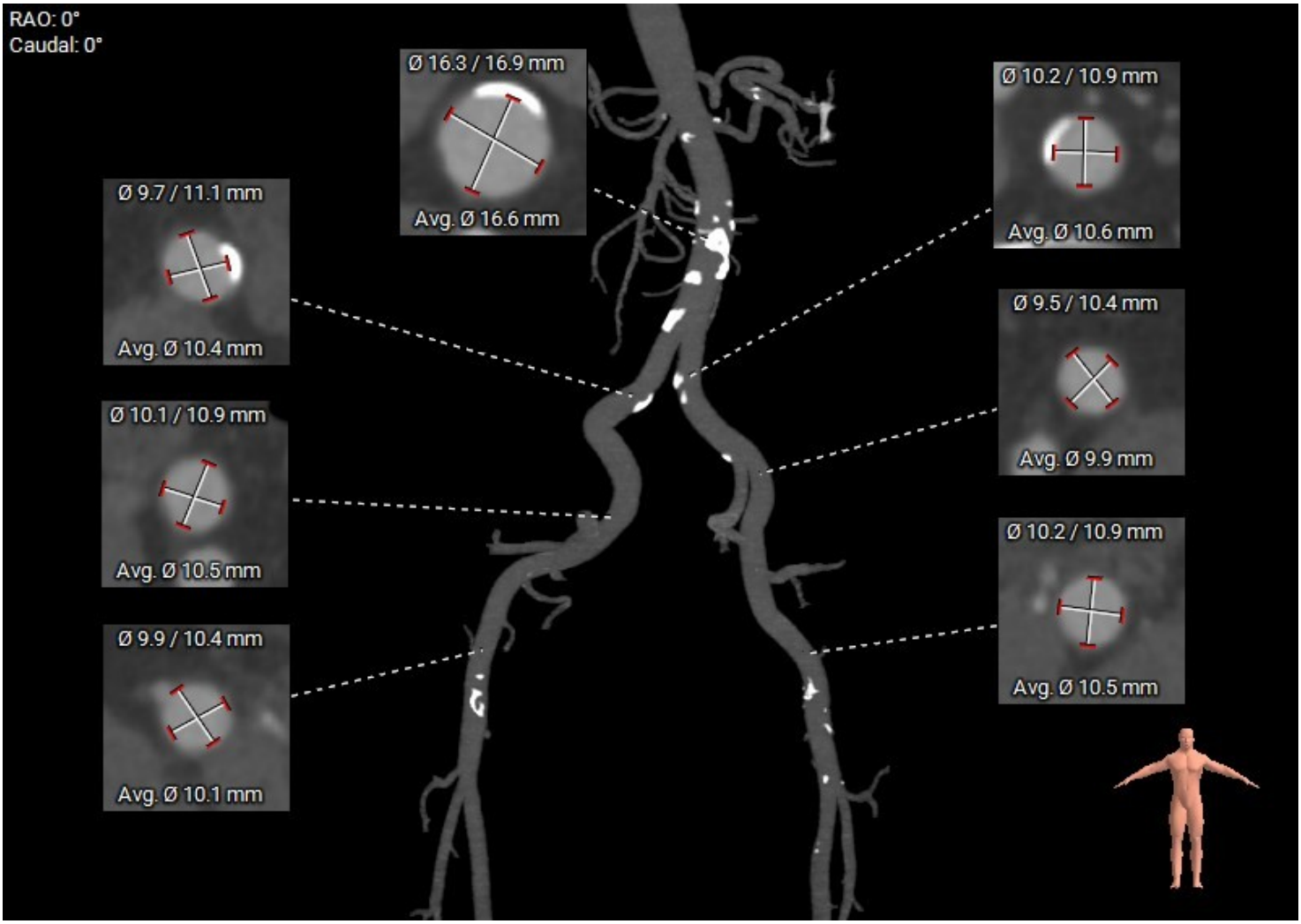


Calcifications



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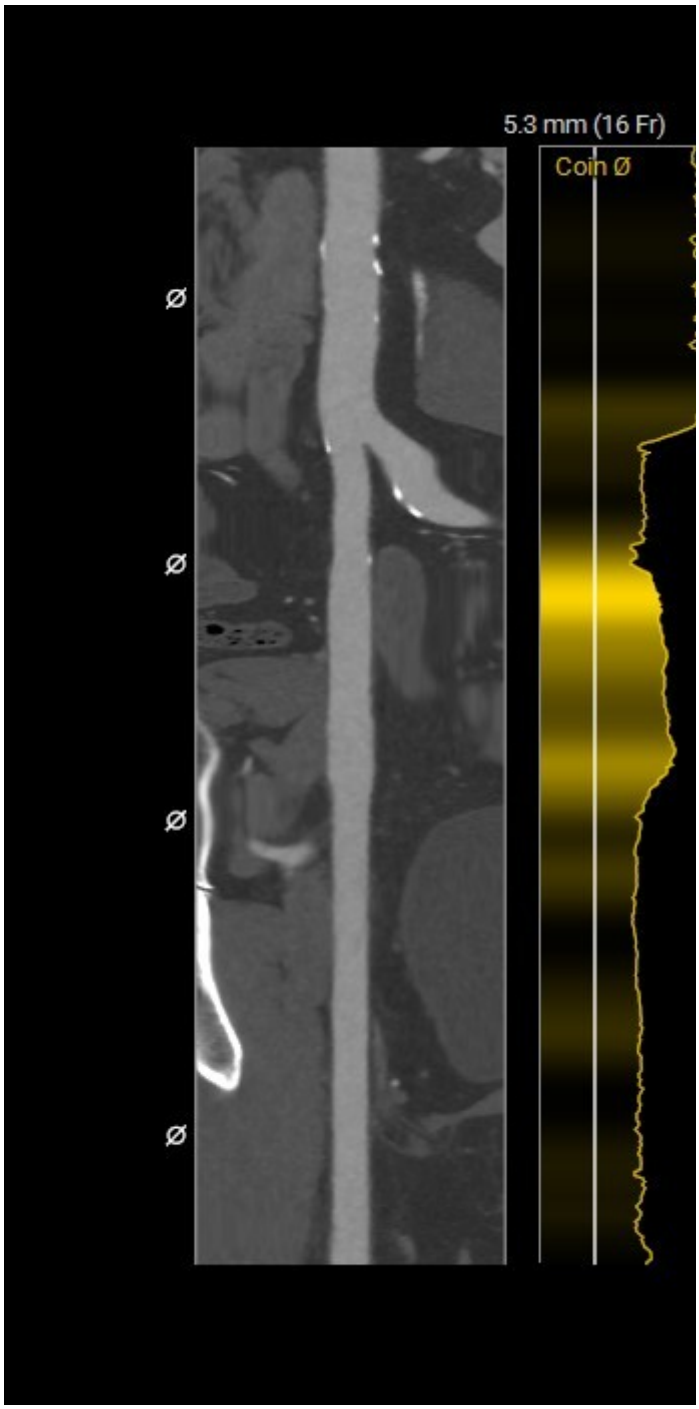
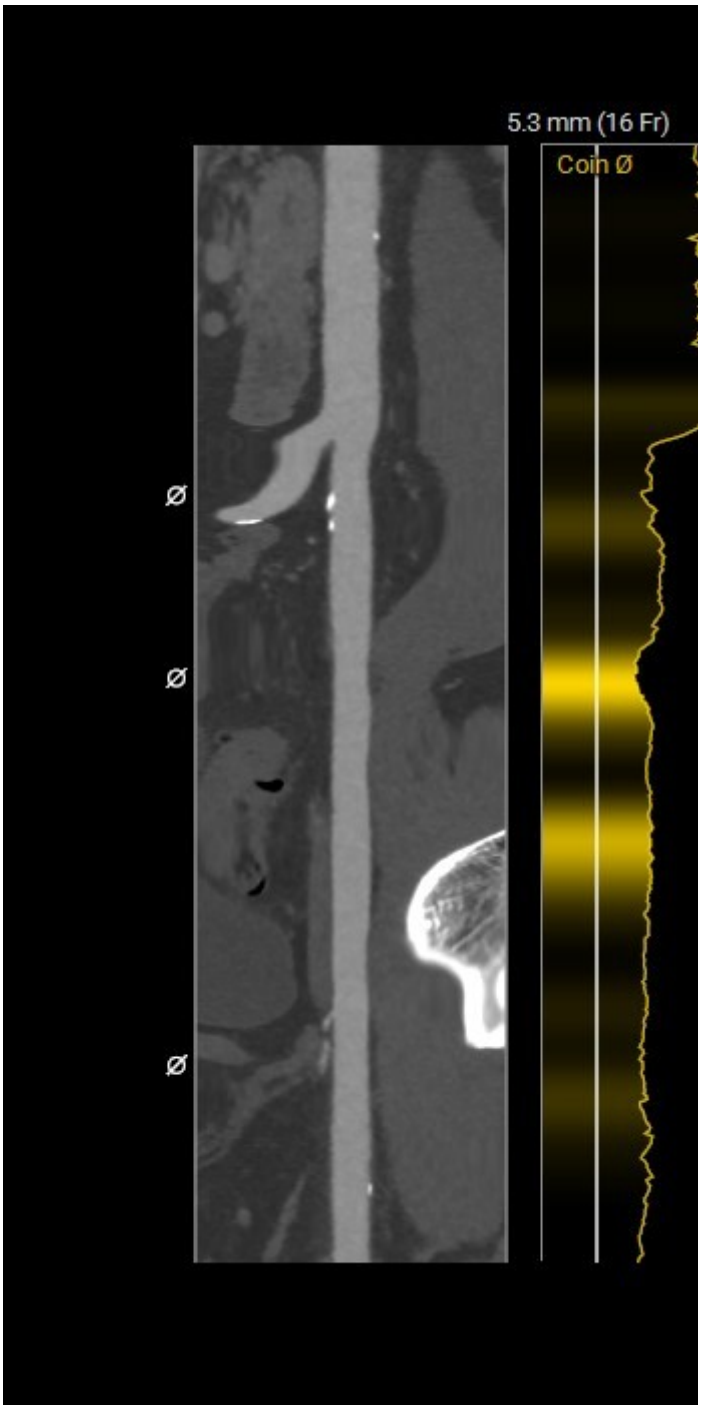
Stretched Vessel - Right Iliac	Stretched Vessel - Left Iliac





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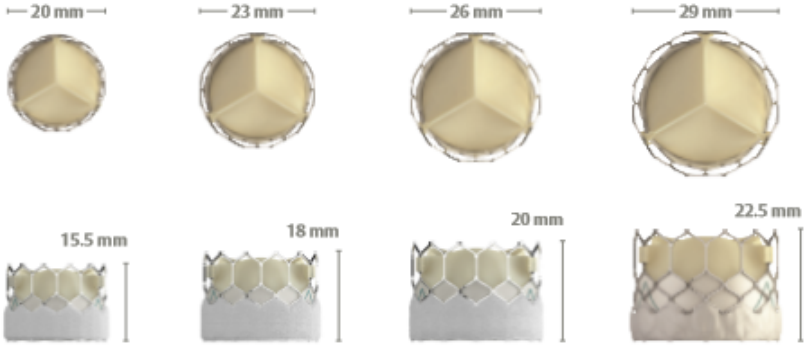
Edwards SAPIEN 3 and SAPIEN 3 Ultra
Transcatheter Heart Valve System

Annulus Sizing And Vascular Access

Complete Range of Valve Sizes Expands the Treatable Patient Population

SAPIEN 3 Ultra valve shown



SAPIEN 3 valve shown

	20 mm	23 mm	26 mm	29 mm
Inflation Volume	11 mL	17 mL	23 mL	33 mL
Area (CT)	273 - 345 mm²	338 - 430 mm²	430 - 546 mm²	540 - 683 mm²
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.

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon • Switzerland edwards.com

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