The Sapien 3 Valve: Next Generation Ballloon Expandable Valve Designed to Minimize PVL

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Disclosure Statement of Financial Interest

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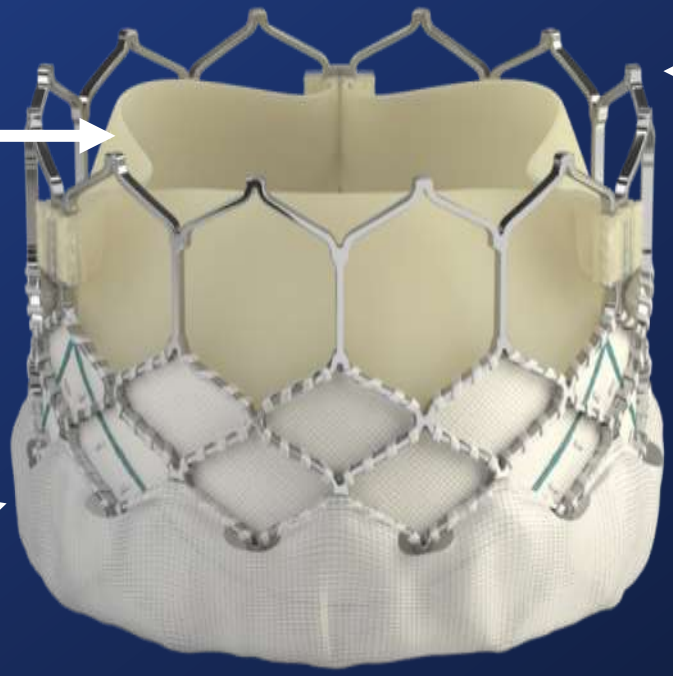
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Edwards Lifesciences
• Steering Committee	• Edwards Lifesciences, Claret Medical, Meril
• SAB	• Thubrikar Aortic Valve, Inc

SAPIEN 3 Transcatheter Heart Valve

Distinguishing Features

THE PARTNER II TRIAL



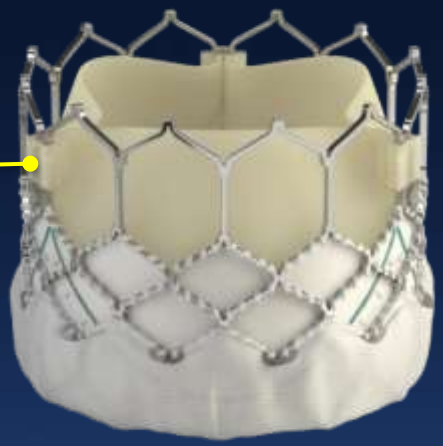
Bovine pericardial valve

Modified frame geometry

Overall lower profile design

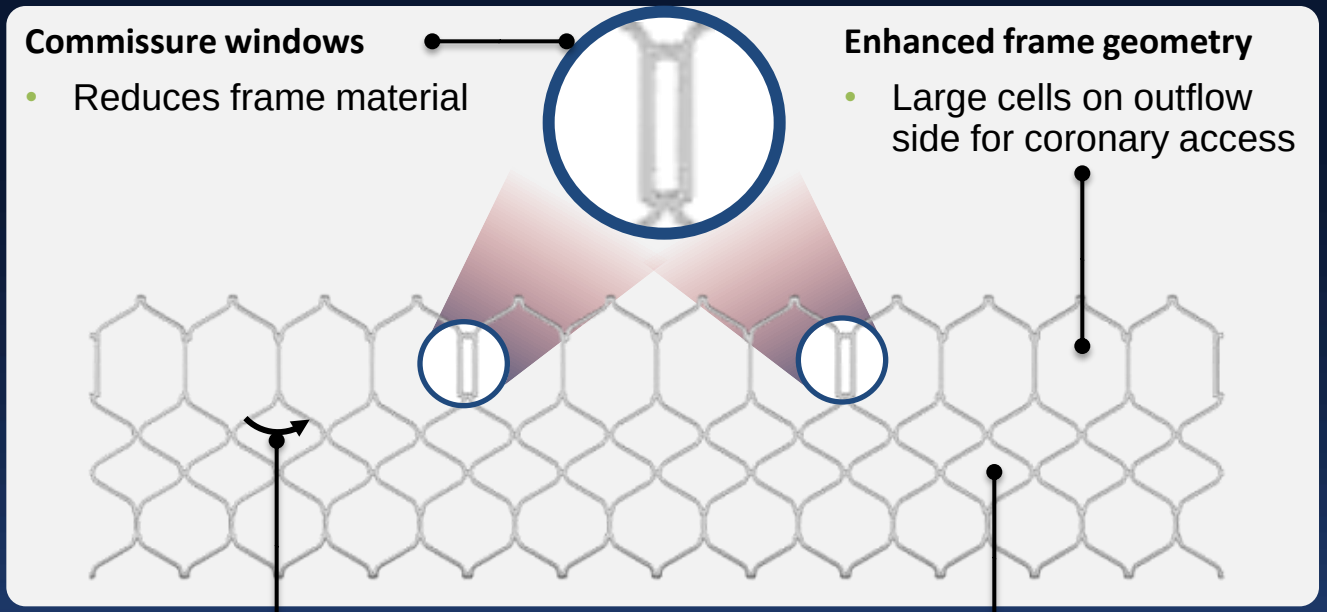
External skirt (to reduce PVL)

Design Changes Enable Reduce Profile



Commissure attachments

- Reduces leaflet material



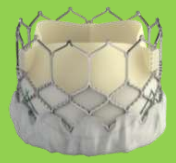
Wide strut angles

- For reduced crimp profile

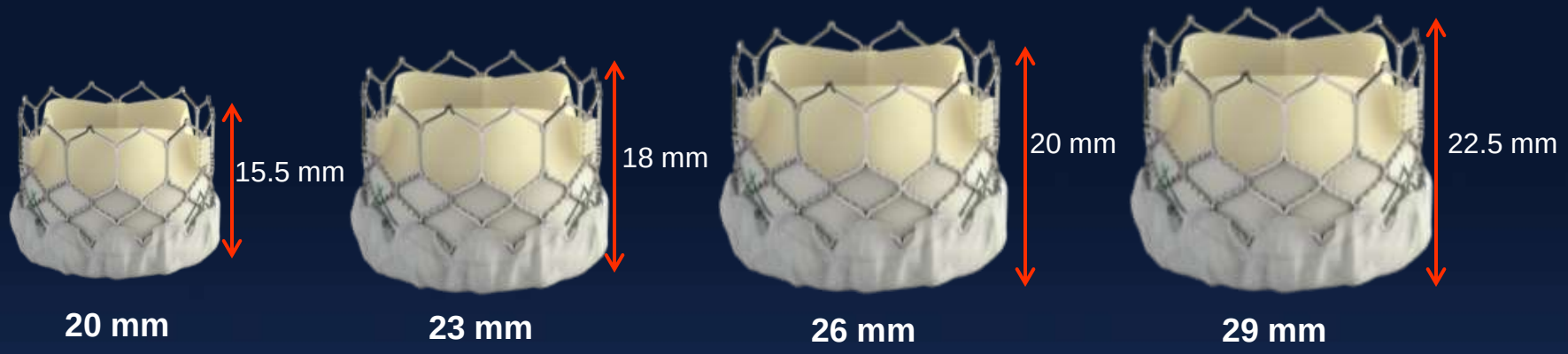
Enhanced frame geometry

- Small cells on inflow side to accommodate outer skirt

Sapien 3 Valve Size Matrix

	 20mm	 23 mm	 26 mm	 29 mm
Native annulus size by TEE	16-19 mm	18-22 mm	21-25 mm	24-28 mm
Native annulus area	273-345 mm^2	338-430 mm^2	430-546 mm^2	540-680 mm^2
Area-derived diameter	18.6-21.0 mm	20.7-23.4 mm	23.4-26.4 mm	26.2-29.5 mm
Nominal diameter (valve)	328 mm^2	406 mm^2	519 mm^2	649 mm^2

Sapien 3 foreshortens more than XT

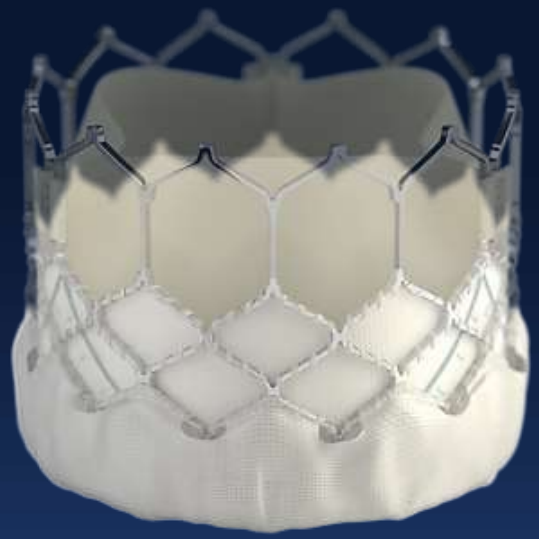


SAPIEN 3 Valve size	20 mm	23 mm	26 mm	29 mm
Crimped Height	21 mm	24.5 mm	27 mm	31 mm
Expanded Height	15.5 mm	18 mm	20 mm	22.5 mm
Foreshortening	5.5 mm	6.5 mm	7 mm	8.5 mm

Foreshortening occurs primarily from the ventricular side

Addition of Outer Skirt to Minimize PV Leak

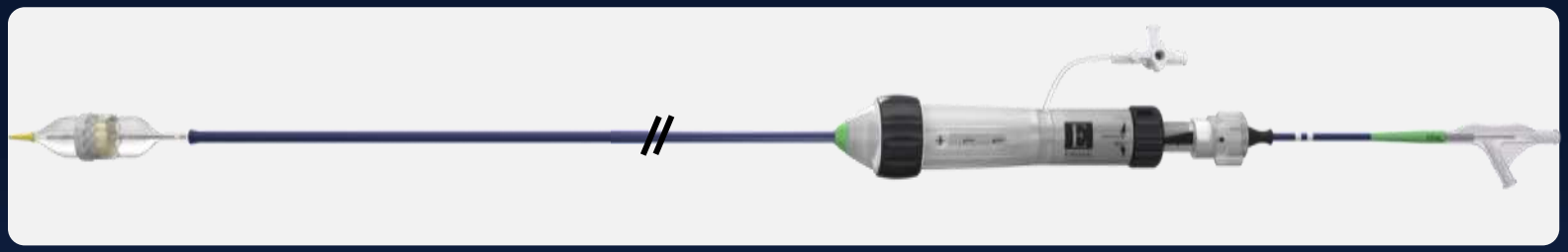
- **High radial strength cobalt-chromium frame**
  - **Full expansion for apposition at the annulus to minimize PV leak**
- **Inner skirt**
  - **Covers ~50% of valve**
- **Outer skirt**
  - **Covers ~1/3 of valve**



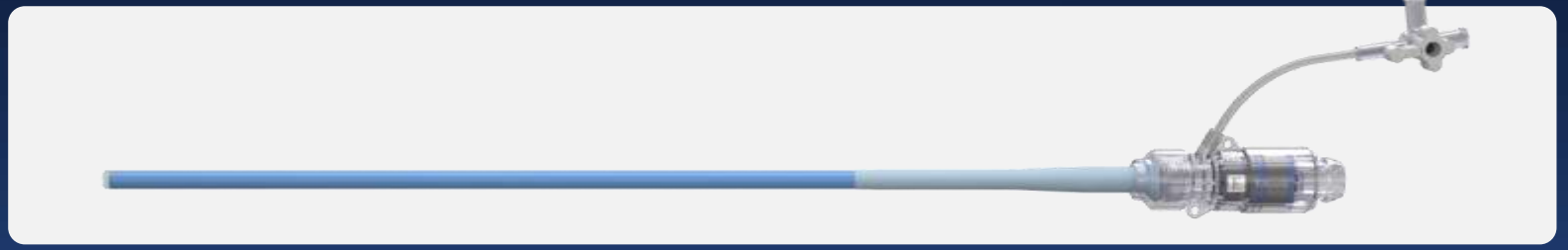
SAPIEN 3 Valve Size	Height of Valve	Inner Skirt Height	Outer Skirt Height
20 mm	15.5 mm	7.9 mm	5.2 mm
23 mm	18 mm	9.3 mm	6.6 mm
26 mm	20 mm	10.2 mm	7.0 mm
29 mm	22.5 mm	11.6 mm	8.1 mm

Edwards Commander Delivery System

- 14F eSheath compatible*



- Reduced minimum access vessel diameters

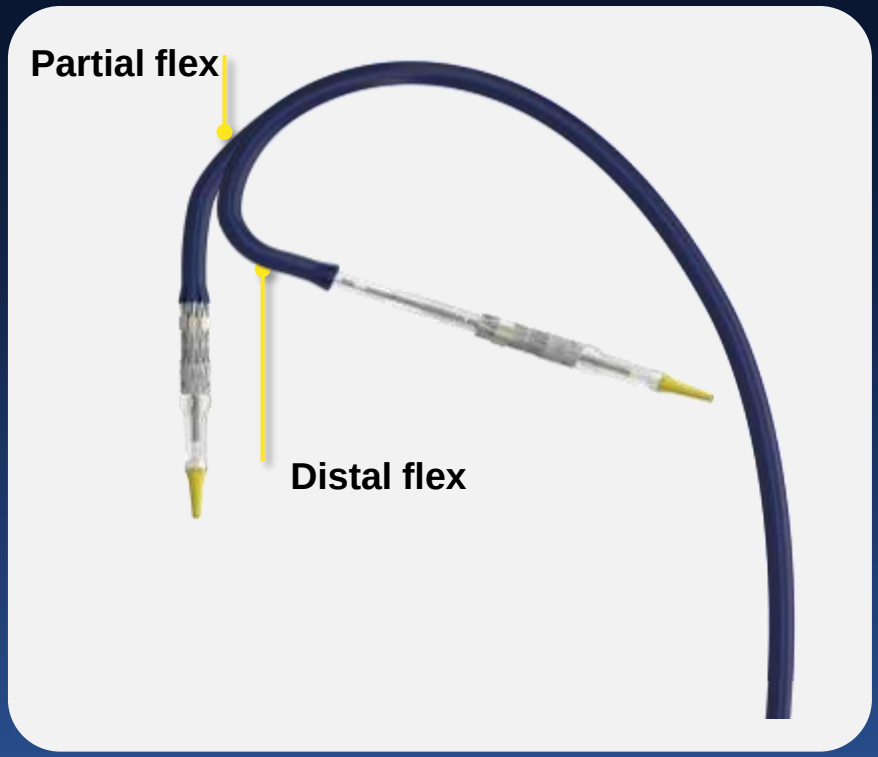


SAPIEN 3 Valve Size	20 mm	23 mm	26 mm	29 mm
Edwards eSheath Introducer Set	14F	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6.0 mm

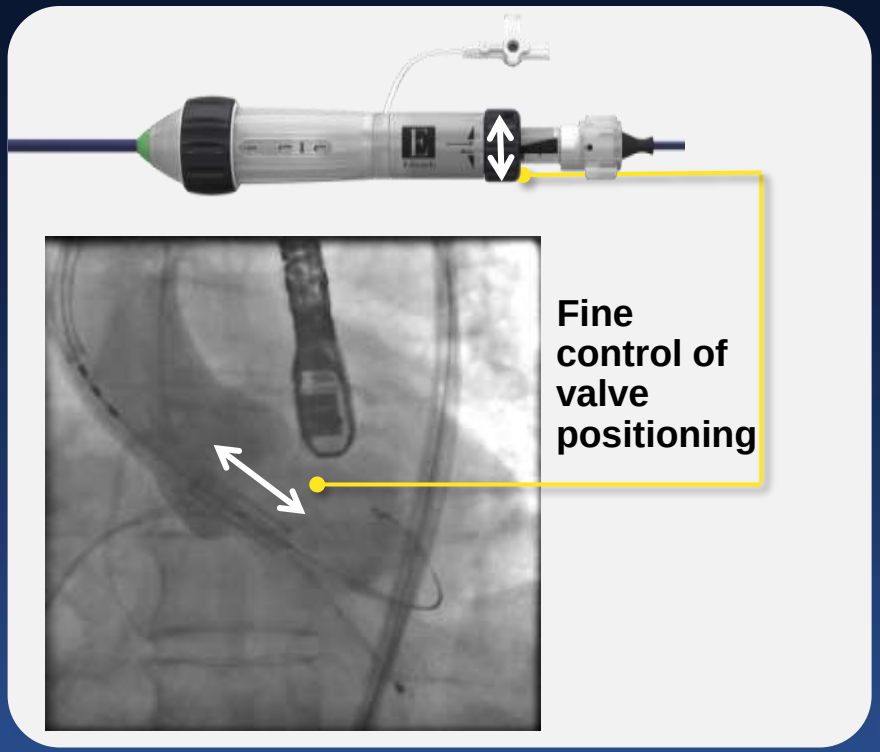
*14F eS

Edwards Commander delivery system

- Improved coaxial alignment



- Accurate positioning



Case History

Case Example #1

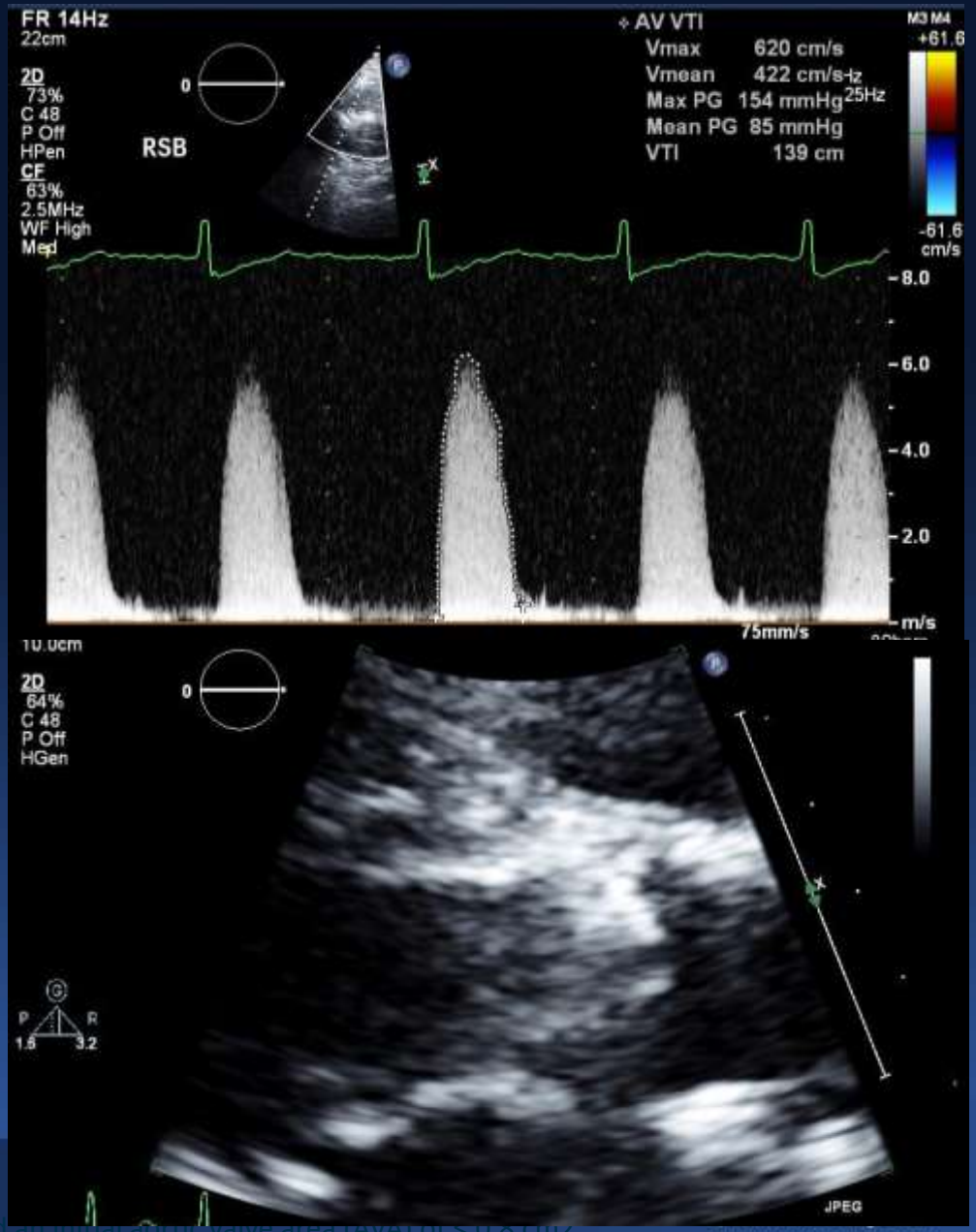
- **Relevant history**
  - 88 yo M (168 cm, 66 kg)
  - CHF, NYHA III
  - Hypertension
  - Creatinine 1.04 mg/dl
  - Admitted with NYHA Class IV symptoms

STS Score:

Procedure Name	AVRepl+CABG
Risk of Mortality	6.223%
Morbidity or Mortality	27.455%
Long Length of Stay	13.592%
Short Length of Stay	18.697%
Permanent Stroke	2.467%
Prolonged Ventilation	16.058%
DSW Infection	0.234%
Renal Failure	8.063%
Reoperation	11.334%

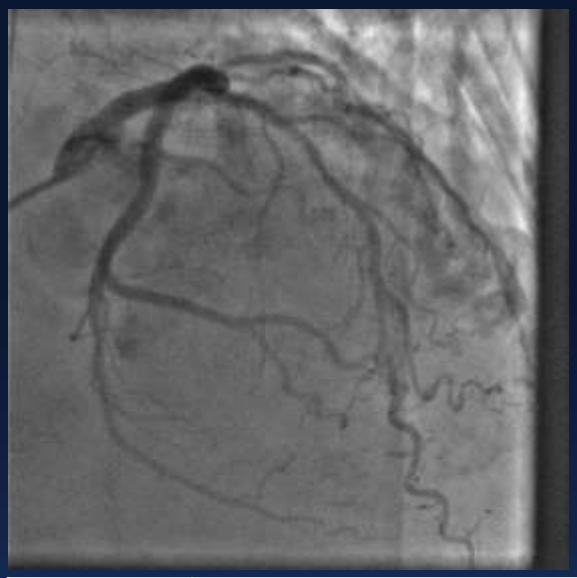
Baseline Echocardiogram

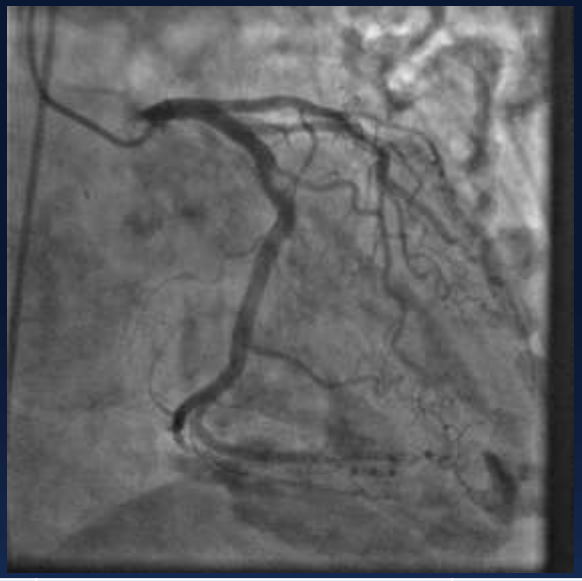
Echo Variable (TTE/TEE)	Measure
Trileaflet valve	Y
Peak Transaortic Vel	6.2 m/s
Mean transaortic Grad	85 mmHg
Calculated EOA	0.4 cm^2
Calculated iEOA	0.2 cm^2/m^2
Severity of AR	Mild
Severity of MR	Trace
Ejection Fraction	55%
TTE annulus diameter	22.7 mm
Is echo within window?	Y (5/19/14)
RV Pressures	51 mmHg
Dobutamine Resting EF Mcg used Peak Vel Mean Grad	N

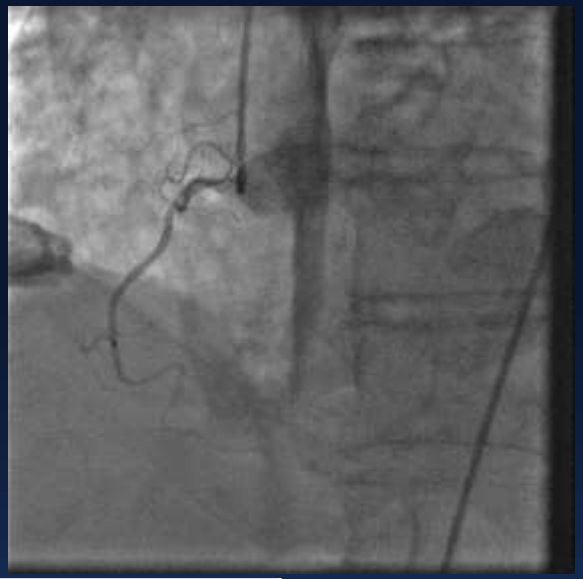


Mean gradient > 40 mmHg or jet velocity greater than 4.0 m/s and an initial aortic valve area (AVA) of ≤ 0.8 cm^2.

Coronary Artery Evaluation



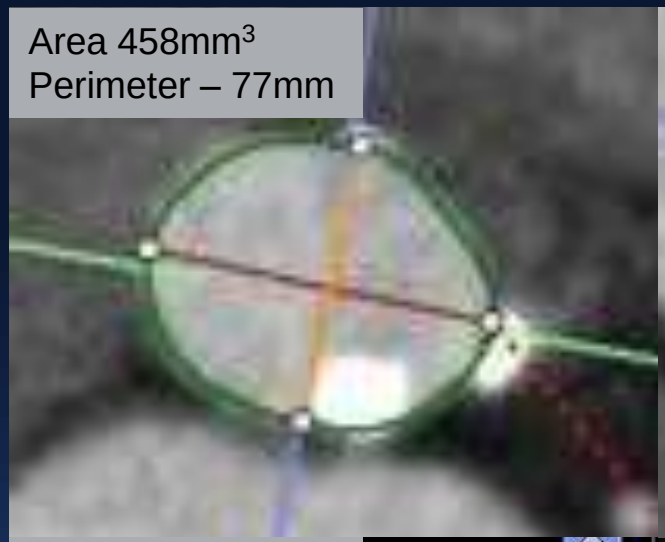




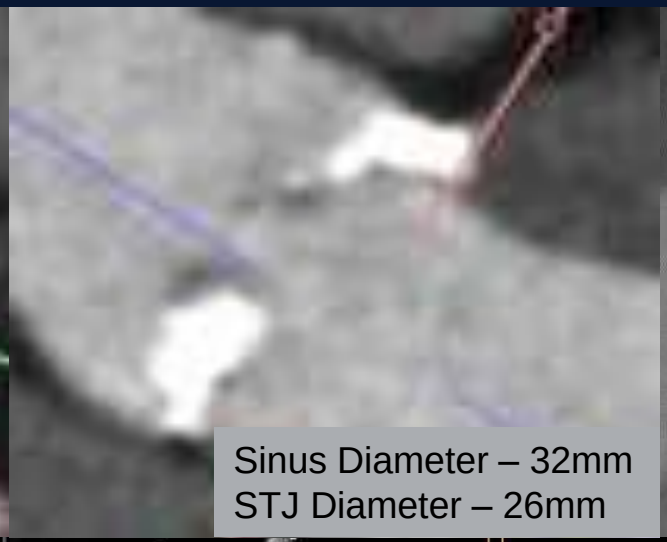
	% stenosis	Location (prox/mid/distal)	Revascularization (Y/N)
LM	Luminal irregularities		N
LAD	80%	mid	Y
LCx	Luminal irregularities		N
RCA	Luminal irregularities		N

Sapien 3 Case Example

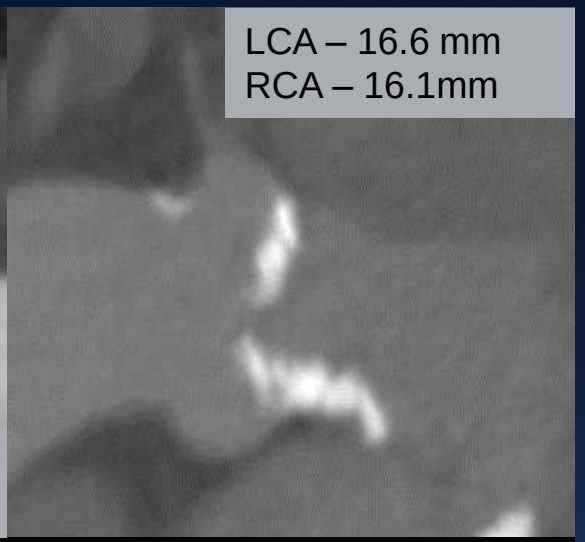
Aortic Valve Complex



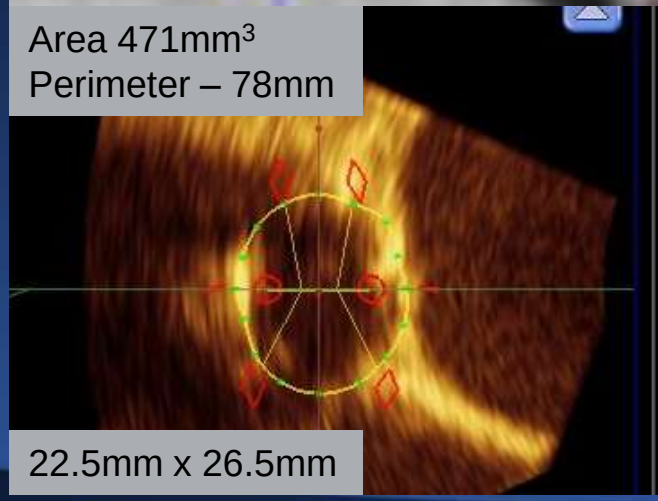
Area 458mm^3
Perimeter – 77mm



Sinus Diameter – 32mm
STJ Diameter – 26mm

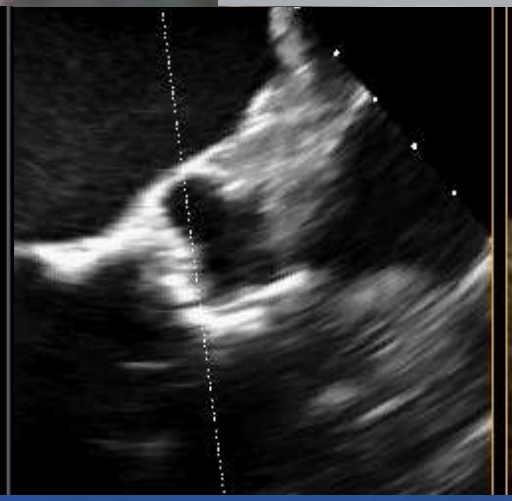


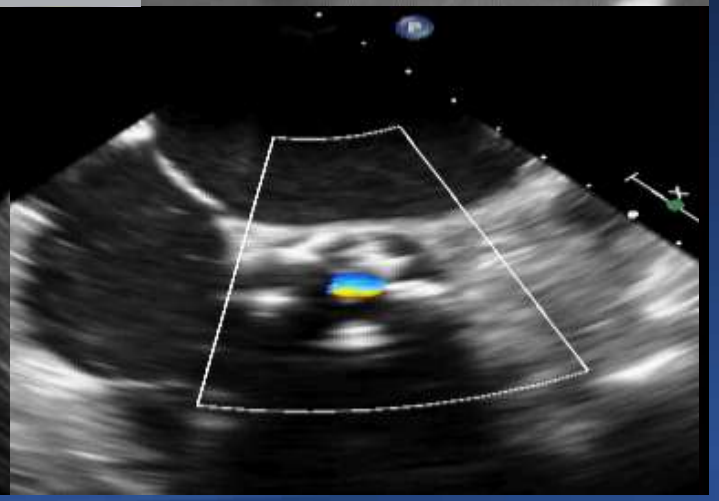
LCA – 16.6 mm
RCA – 16.1mm



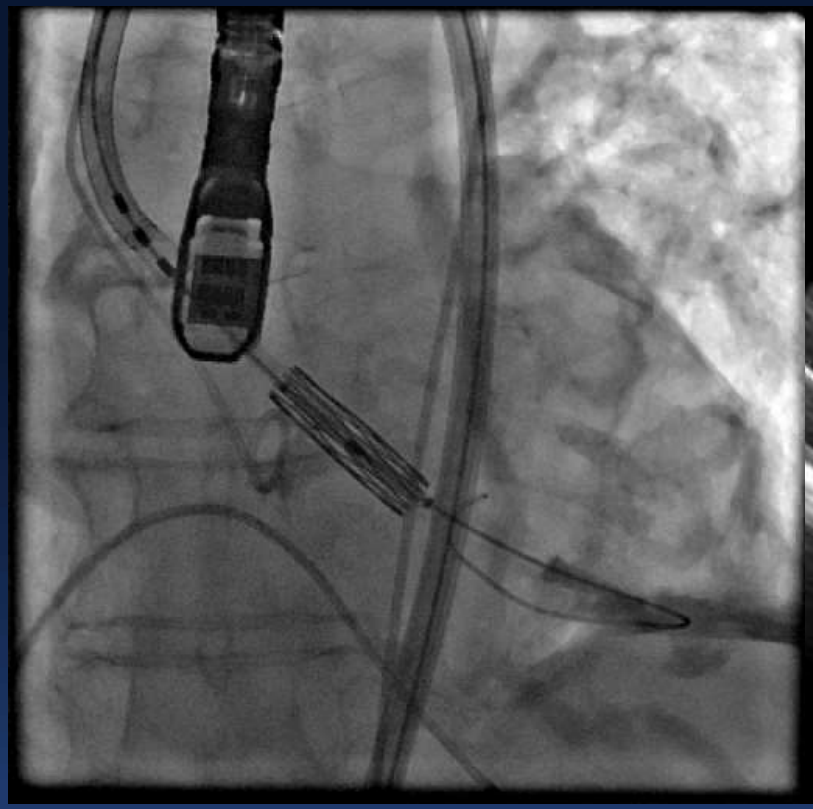
Area 471mm^3
Perimeter – 78mm

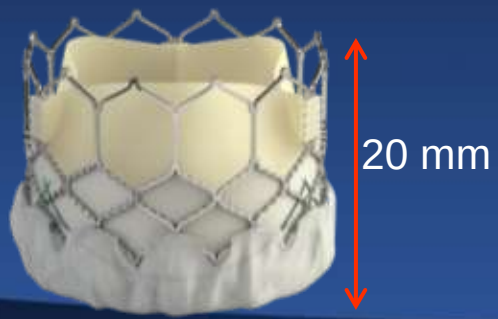
22.5mm x 26.5mm





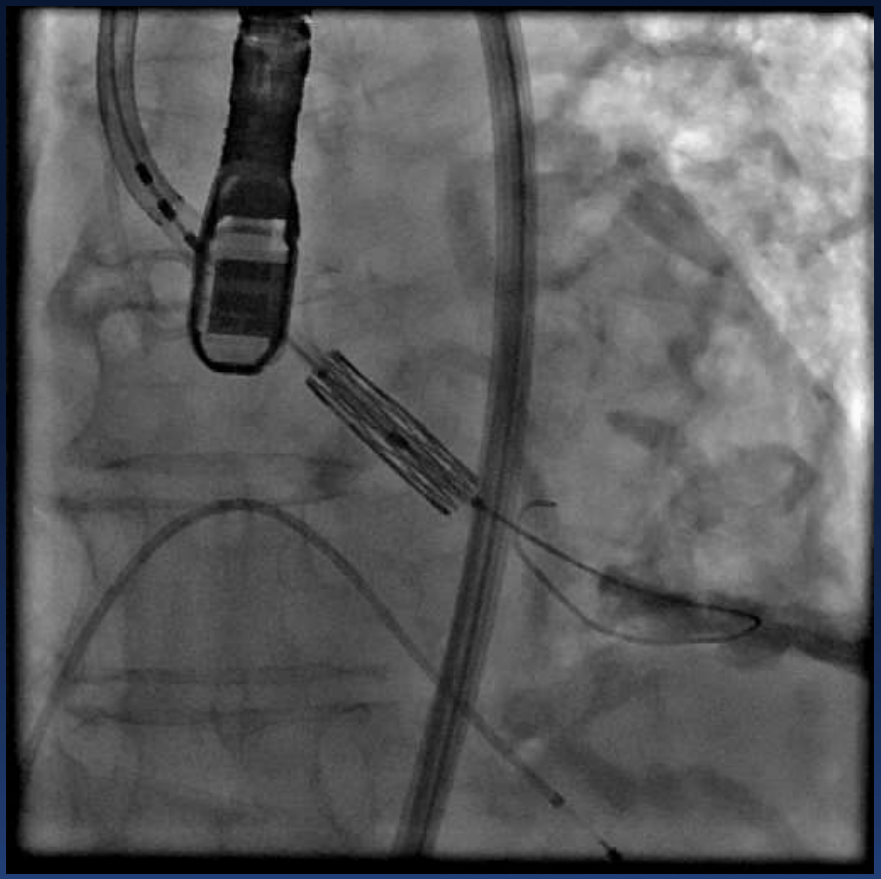
26mm Sapien 3 Positioned

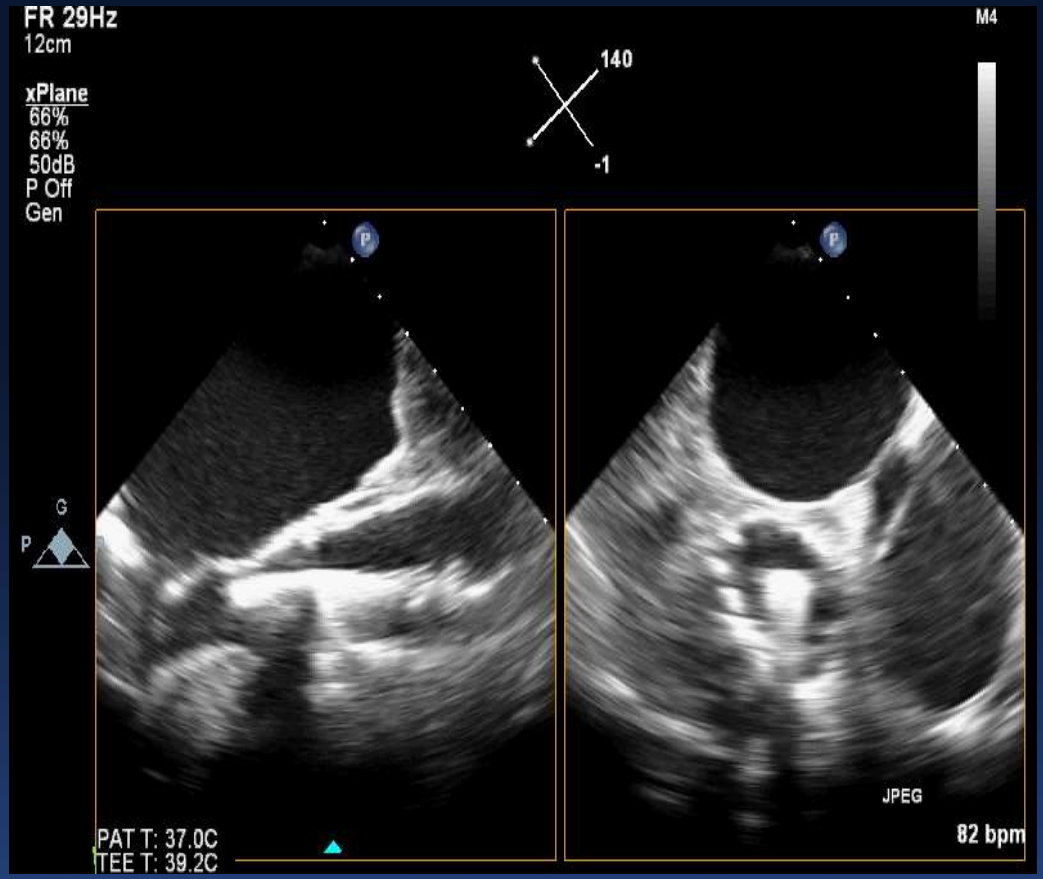




Crimped Height – 27mm
Foreshortening – 7mm

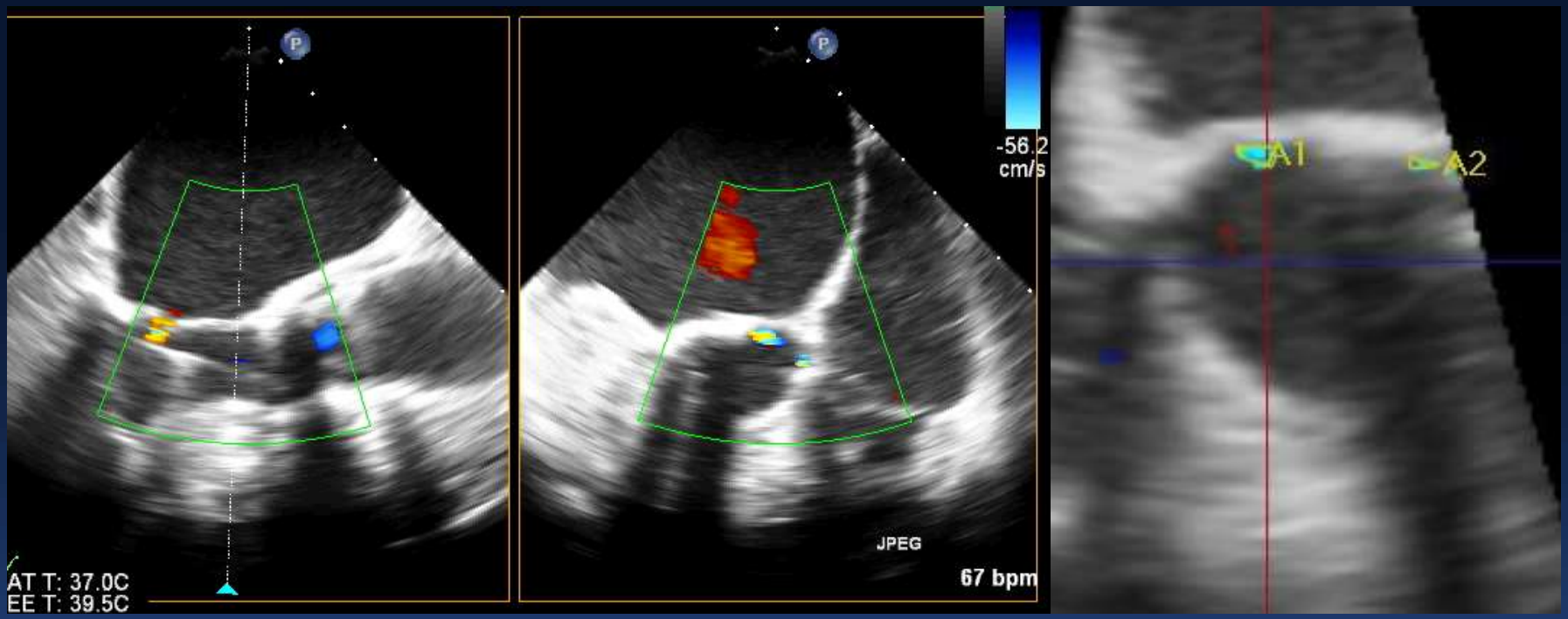
Sapien 3 Deployed





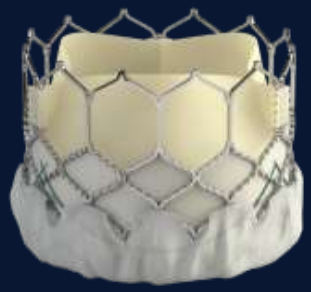
Slow, continuous inflation for valve deployment

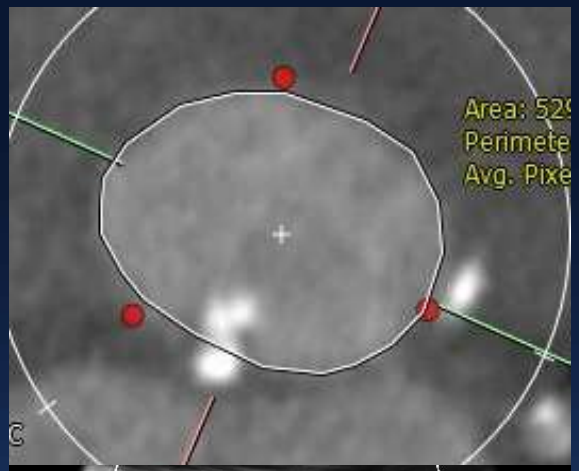
Final Assessment



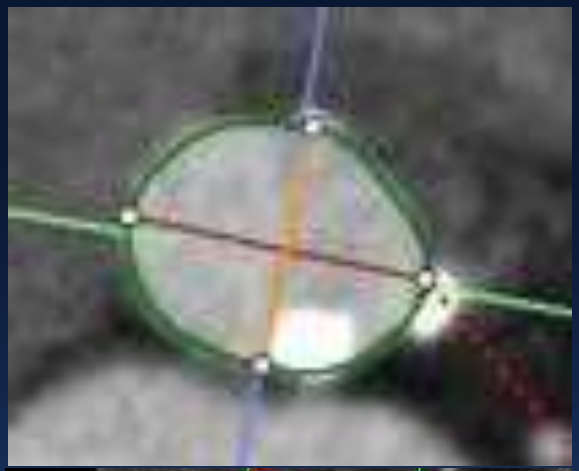
Trace to Mild PVL with EROA – 5mm^2

Sapien XT vs. Sapien 3





Preoperative
CT with severe
LVOT Calcium



Post TAVR
AR Assessment

Case History

Example #2

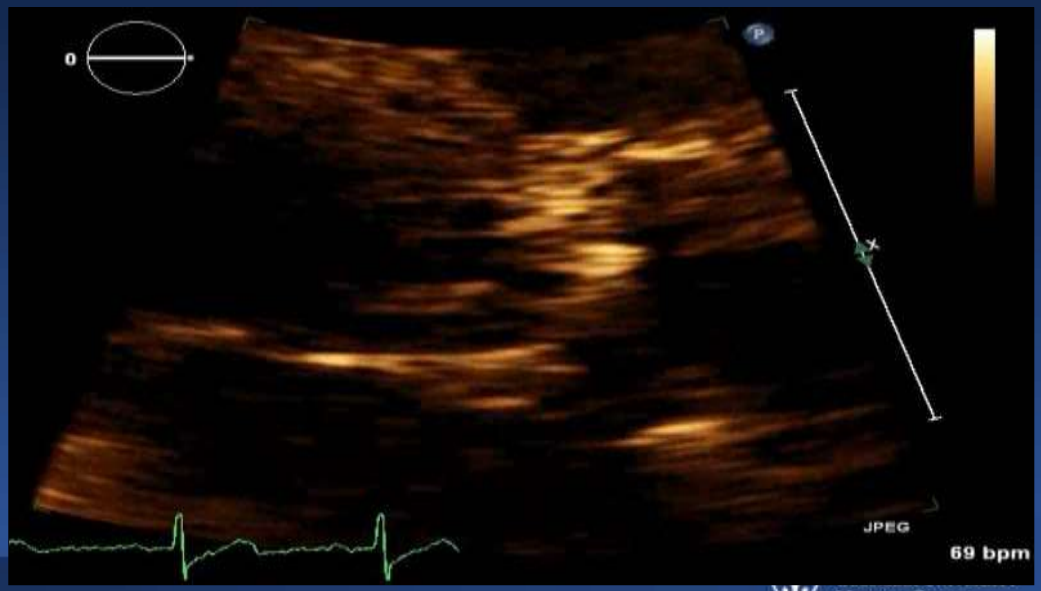
- **82 year-old male**
  - **Severe symptomatic AS**
  - **NYHA Class III symptoms**
  - **CAD**
  - **HTN**
  - **Moderate COPD (FEV1 55% pred)**
  - **Stage 2 CKD (Cr 1.0)**
  - **h/o CVA 2010 (no residual deficits)**
  - **Recent admission for CHF**

Procedure Name	AVRepl+CABG
Risk of Mortality	4.156%
Morbidity or Mortality	25.805%
Long Length of Stay	15.131%
Short Length of Stay	18.949%
Permanent Stroke	2.752%
Prolonged Ventilation	17.030%
DSW Infection	0.536%
Renal Failure	6.332%
Reoperation	10.518%

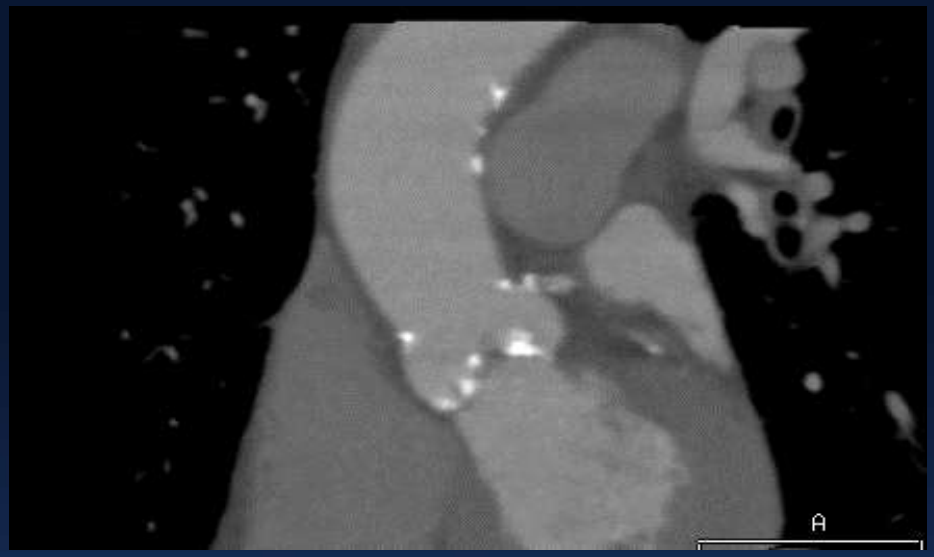
Exclusion: active upper GI bleeding within 3 months prior to procedure. Clinically or neuroimaging confirmed stroke or TIA within 6 months

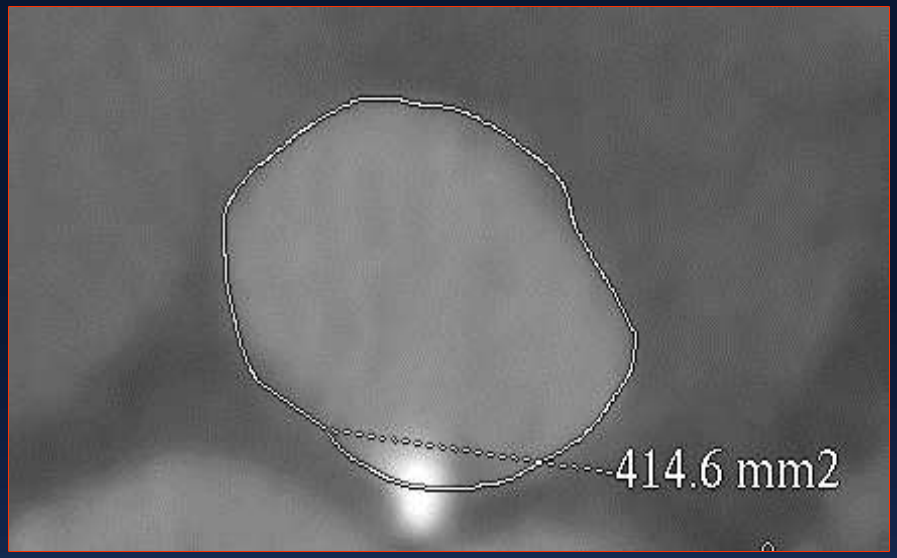
Baseline Echocardiogram

Echo Variable (TTE)	Measure
Trileaflet valve	Y
Peak Transaortic Vel	4.2 m/sec
Mean transaortic Grad	43 mmHg
Calculated EOA	0.7 cm^2
Calculated iEOA	0.3 cm^2/m^2
Severity of AR	Trace
Severity of MR	Mild
Ejection Fraction	55%
TTE annulus diameter	23.0 mm
Is echo within window?	Y
RV Pressures	N/A – inadequate TR jet
Dobutamine Resting EF Mcg used Peak Vel Mean Grad	N



Aortic Valve Complex

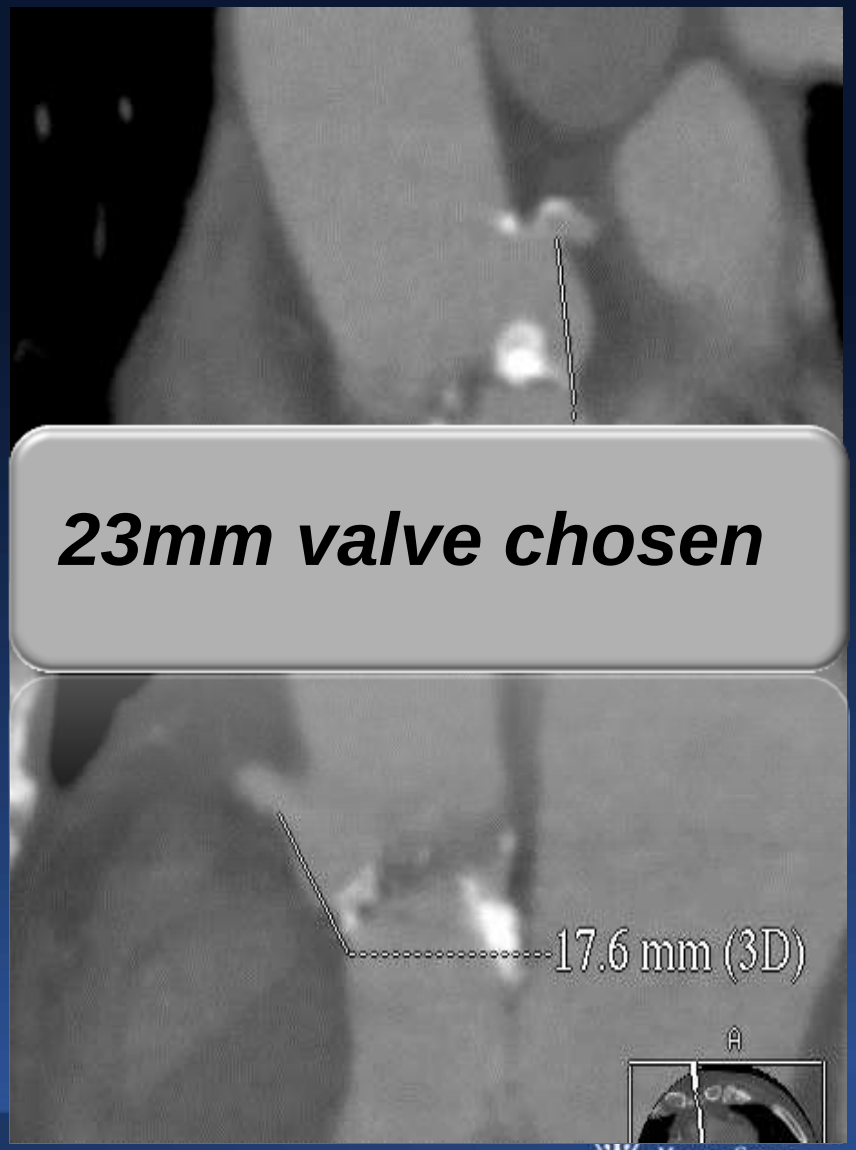




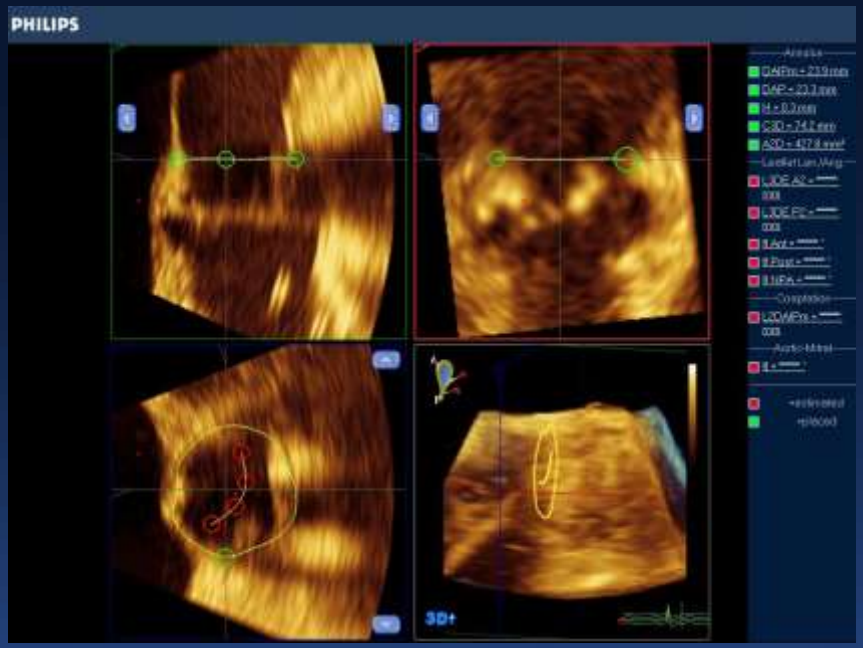
Annulus by CT (5/6/14)	Measure
Short Annulus Diameter	21.7 mm
Long Annulus Diameter	26.2 mm
Annular Perimeter	73.4 mm
Annular Area	415 mm^2
% Area Oversizing	-2.2%
Planned Valve Size	23 mm

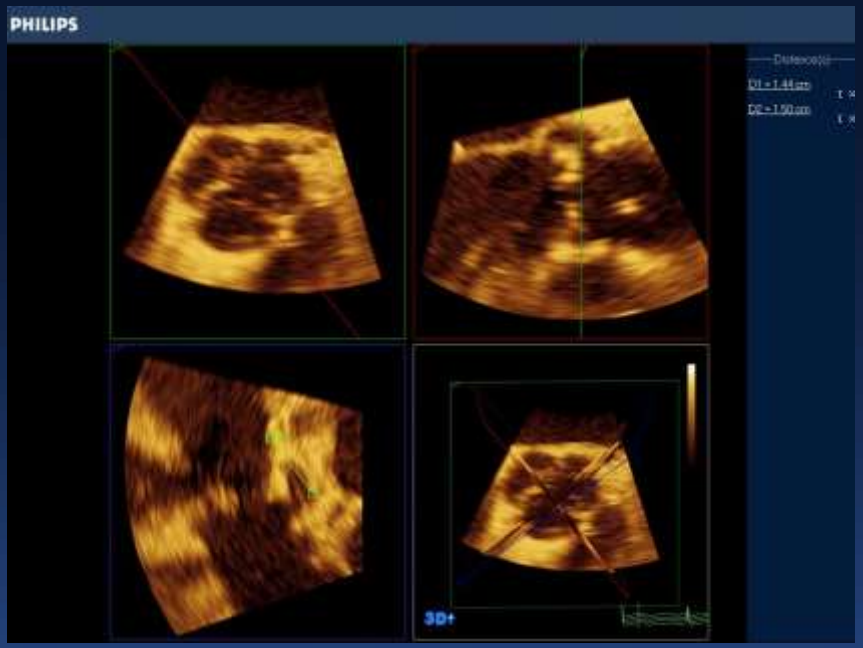
Aortic Valve Complex

Annulus by CT (5/6/14)	Measure
Short Annulus Diameter	21.7 mm
Long Annulus Diameter	26.2 mm
Annular Perimeter	73.4 mm
Annular Area	415 mm^2
% Area Oversizing	-2.2%
Aortic Root by CT (5/6/14)	**Measure**
LVOT calcification	Mild
Sinus of Valsalva Diameter	32.2 mm
Sinotubular Junction Diameter	26.0 mm
Left Coronary Height	16.7 mm
Right Coronary Height	17.6 mm



Echo Assessment of Annulus

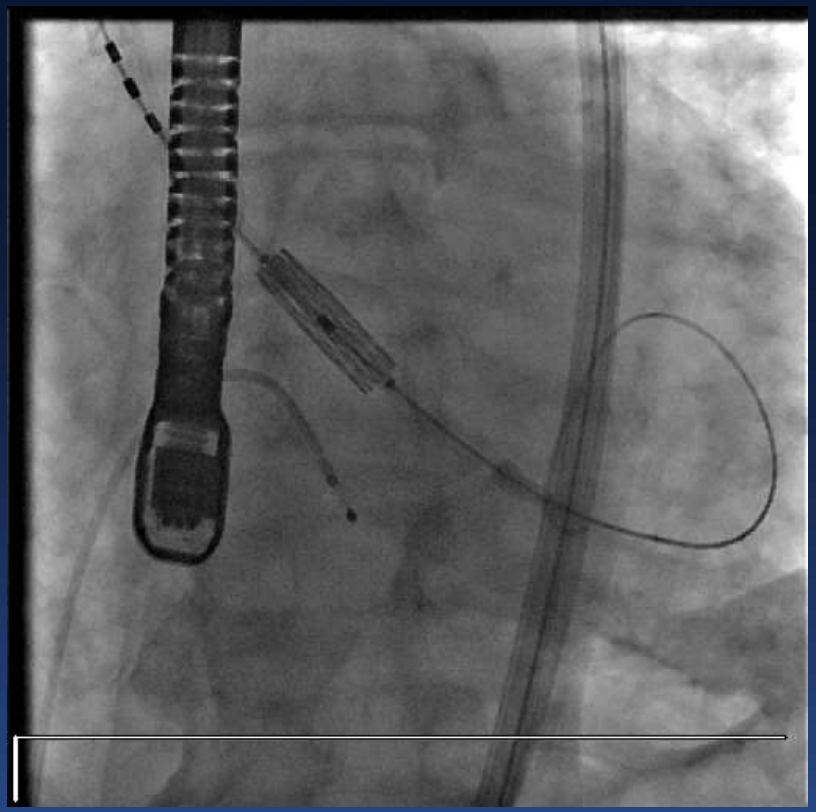


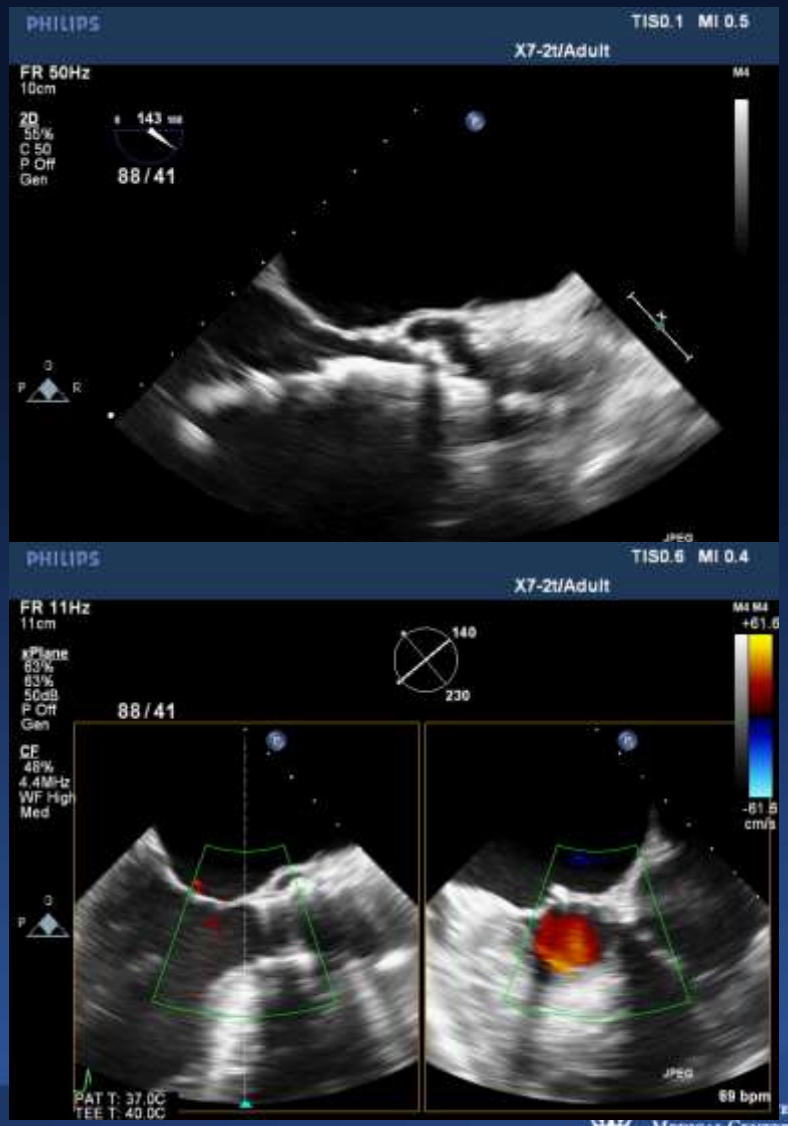


Annular Area = 428 mm^2
Max/min = 23.9 and 23.3 mm
(nearly circular)

Left main = 14 mm
LCC length = 15 mm

Sapien 3 Deployment





Final Assessment