2016 ASE State of the Art Echocardiography Course | Tucson, AZ

How Do I Evaluate a Patient Being Considered for TAVR?

Sunday, February 14, 2016 | 11:00 – 11:25 PM | 25 min

NYU SCHOOL OF MEDICINE

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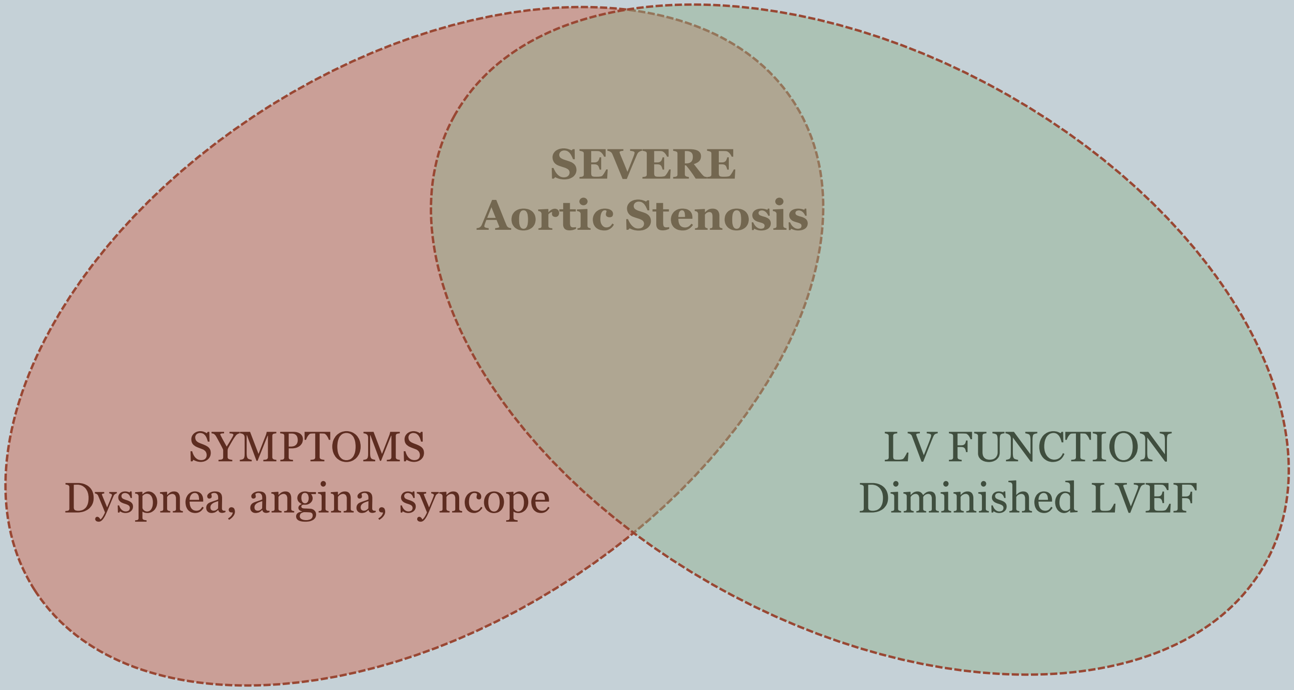
Disclosures

Speakers Bureau

Philips, Medtronic

Treatment Options for Aortic Stenosis

Primary indications for surgical treatment of aortic stenosis



Severe symptomatic AS irrespective of LVEF

Severe AS with diminished LVEF irrespective of symptoms

Valve Replacement Options for Aortic Stenosis

SAVR Surgical Aortic Valve Replacement
(Traditional surgical AVR)

TAVR Transcatheter Aortic Valve Replacement

same as

TAVI Transcatheter Aortic Valve Implantation

TAVR: Primary Indications

(1) **Preferred treatment** for inoperable patients (ineligible for SAVR) with severe symptomatic aortic stenosis

(2) **Alternative treatments** for patients with severe symptomatic aortic stenosis who have high SAVR risk

History of TAVR

It took a decade to translate the TAVR concept from an animal experiment to a human implant…

… it took another decade to validate TAVR concept in clinical trials

1992 — Proof of TAVR Concept in Animals

2002 — First TAVR in Humans

2010 — PARTNERS Trial of TAVR published

2015 — TAVR is routine clinical practice

History of TAVR | First Human Implantation in 2002

Alain Cribier
(b. 1945)
French
Interventional Cardiologist

Performed first
TAVR in 2002

(Also first to report
percutaneous aortic balloon
valvuloplasty in 1986)

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD;
Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD;
François Laborde, MD; Martin B. Leon, MD

***Background*—**The design of a percutaneous implantable prosthetic heart valve has become an important area for investigation. A percutaneously implanted heart valve (PHV) composed of 3 bovine pericardial leaflets mounted within a balloon-expandable stent was develo… implantation was performed in a 57-year… and other associated noncardiac dise… valvuloplasty had been performed with…

***Methods and Results*—**With the use of an … diseased native aortic valve, with accura… or of the mitral valve function, and a… implantation, valve function was excell… of 4 months, the valvular function rema… and there was no recurrence of heart… progressive worsening of the leg ischemi… after PHV implantation.

***Conclusions*—**Nonsurgical implantation o… midterm hemodynamic and clinical imp… confirmatory clinical implantations, PH… selected patients with nonsurgical aortic…

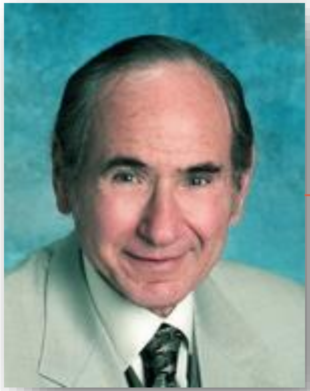
This first human TAVR:

(1) Would not meet current standard indication criteria (Patient had bicuspid aortic valve).

(2) Was performed in a manner not performed now (It was done using transvenous, transseptal approach across the mitral valve).

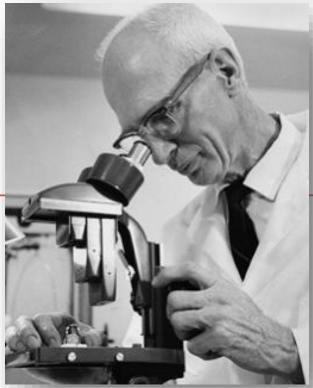
Surgical Prosthetic Valve development

Trained at Bellevue Hospital,
now part of NYU Medical Center



Albert Starr
(b. 1926 in New York)

1960
Starr-Edwards
mechanical valve



Miles Lowell Edwards
(1898-1982)

1972
Carpentier-Edwards
bioprosthetic valve

Alain Carpentier
(b. 1933 in Toulouse)

SAVR & TAVR Valve development

History of TAVR | First Animal Implantation in 1992

European Heart Journal (1992) **13,** 704–708

Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs

H. R. Andersen*, L. L. Knudsen* and J. M. Hasenkam†

*Departments of *Cardiology, †Thoracic and Cardiovascular Surgery, and the Institute of Experimental Clinical Research, Skejby University Hospital, Aarhus, Denmark*

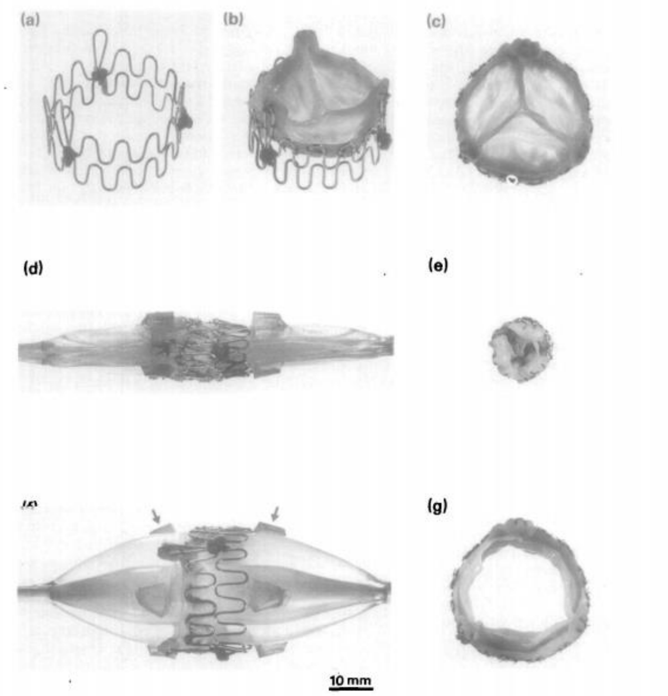
KEY WORDS: Expandable stent–valve, transluminal implantation, prosthetic heart valve, pigs.

A new artificial aortic valve prosthesis was developed for implantation by the transluminal catheter technique without thoracotomy or extracorporeal circulation. The new heart valve was prepared by mounting a porcine aortic valve into an expandable stent. Before implantation, the stent–valve was mounted on a balloon catheter and compressed around the deflated balloon. The stent–valve mounted balloon catheter was then advanced retrogradely to the ascending aorta or the aortic root in anaesthetized pigs. Implantation was performed by balloon inflation which expanded the stent–valve to a diameter exceeding the internal diameter of the vessel — thus ensuring a stable fixation against the vessel wall. A total of nine implantations were performed in seven 70 kg closed chest pigs. Sub- and supracoronary implantation was performed in two and three pigs, respectively, while implantation in both positions was done in two. Angiographic and haemodynamic evaluation after implantation revealed no significant stenosis (≤ 16 mmHg) in any of the nine valves and trivial regurgi- ... l flow in three animals. This ... nals by transluminal catheter

This first animal TAVR:

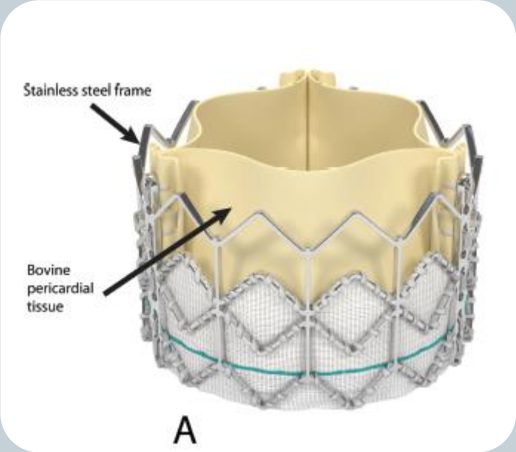
(1) Was the basis for subsequent balloon-expandable Sapien valve used in humans
(2) Was performed in the same manner used in humans now (It was done using transarterial retrograde approach).

Implantation of artificial heart v



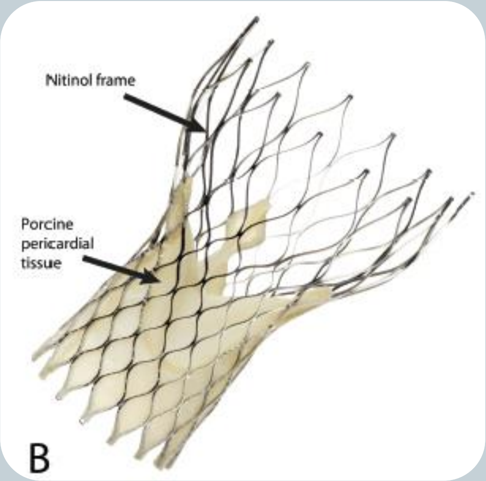
TAVR: The First Wave of Valves

TAVR Prostheses Used in United States



Edwards
Sapien Valves

Balloon-expandable
bovine pericardial aortic valve prosthesis



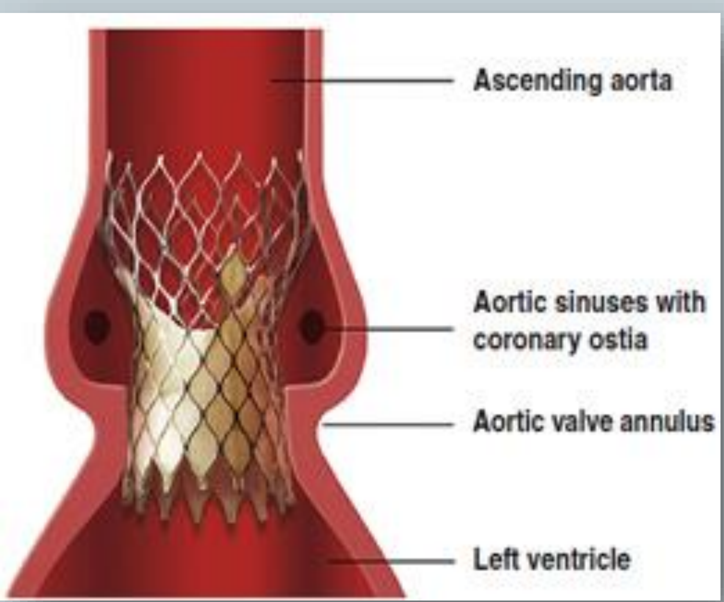
Medtronic
CoreValves

Self-expandable
porcine pericardial aortic valve prosthesis

TAVR Prostheses Used in United States

Edwards
Sapien Valve

Anchoring in the aortic annulus



Medtronic
CoreValve

Anchoring in ascending aorta and LVOT.

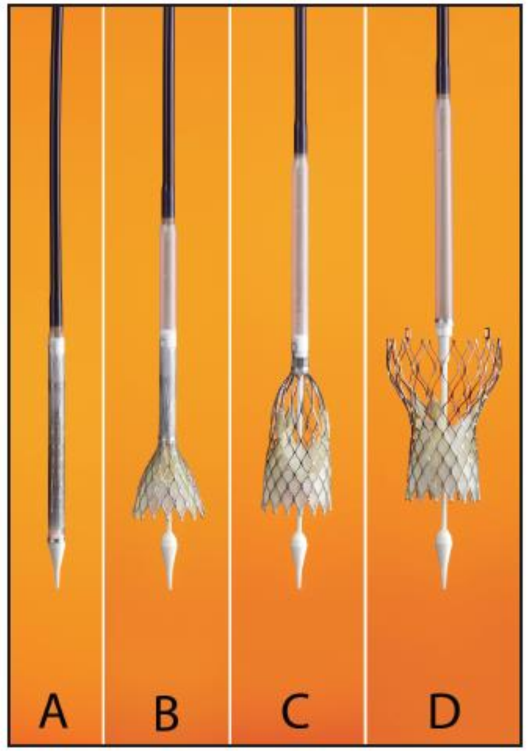
TAVR Prostheses Used in United States

Video 1

Edwards
Sapien Valve

Balloon Expandable

Video 2

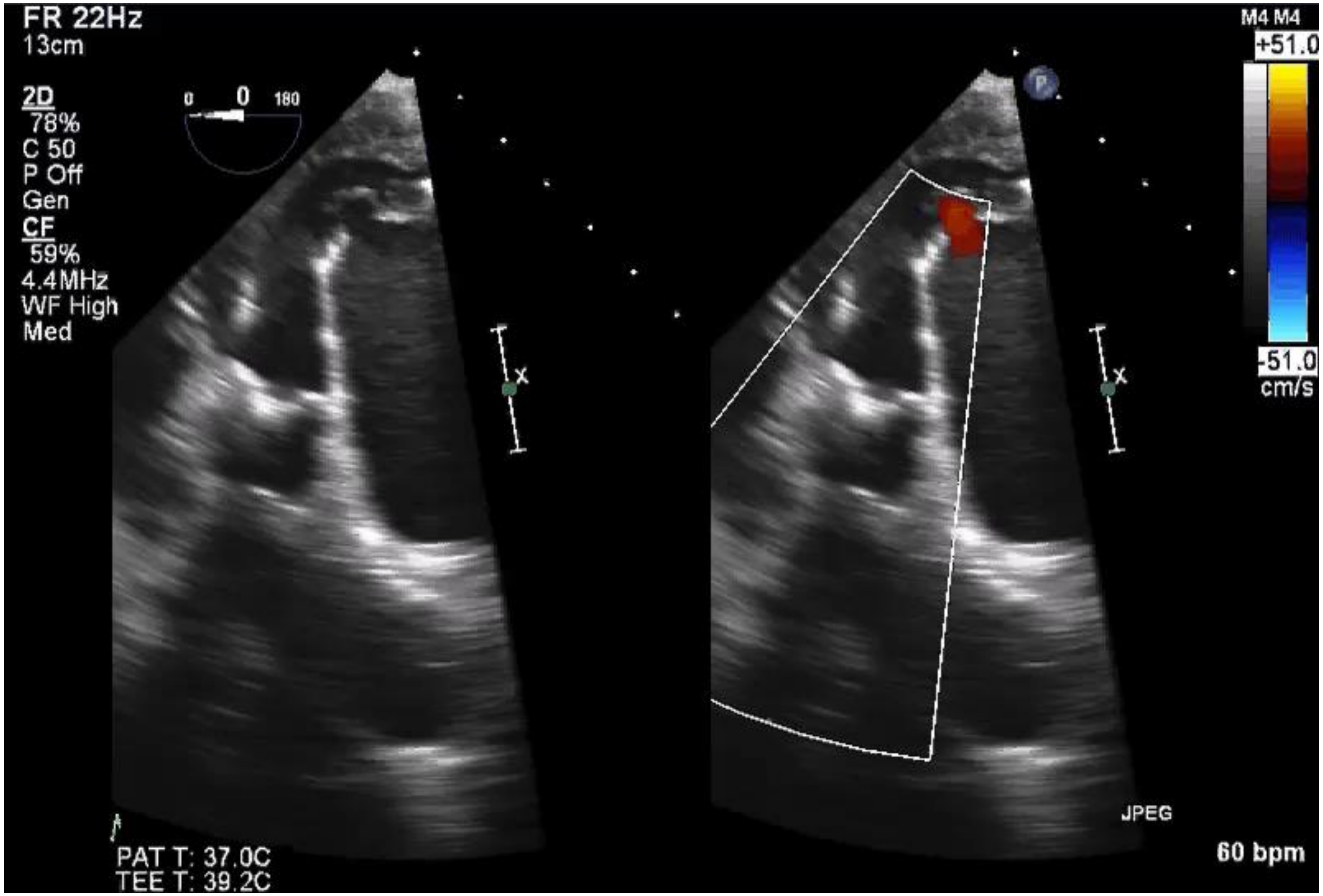


Medtronic
CoreValve

Self Expanding

1st Wave: What We Have Accomplished

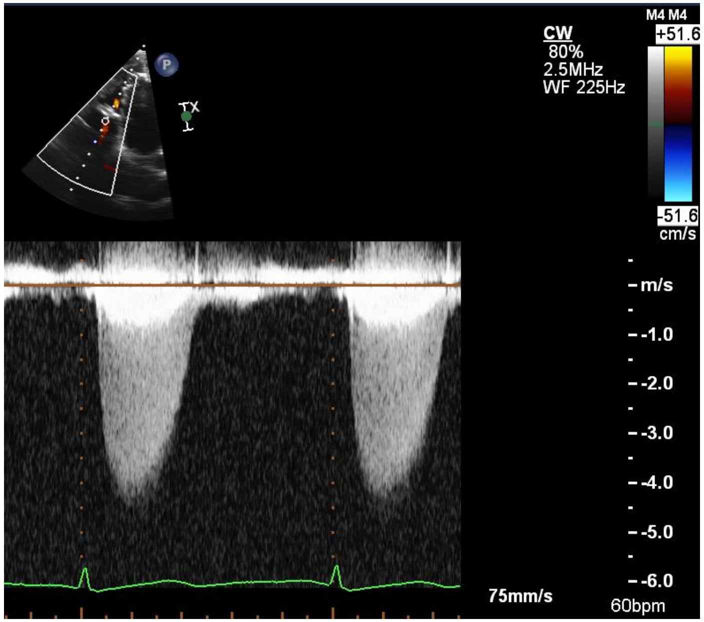
Severe Aortic Stenosis



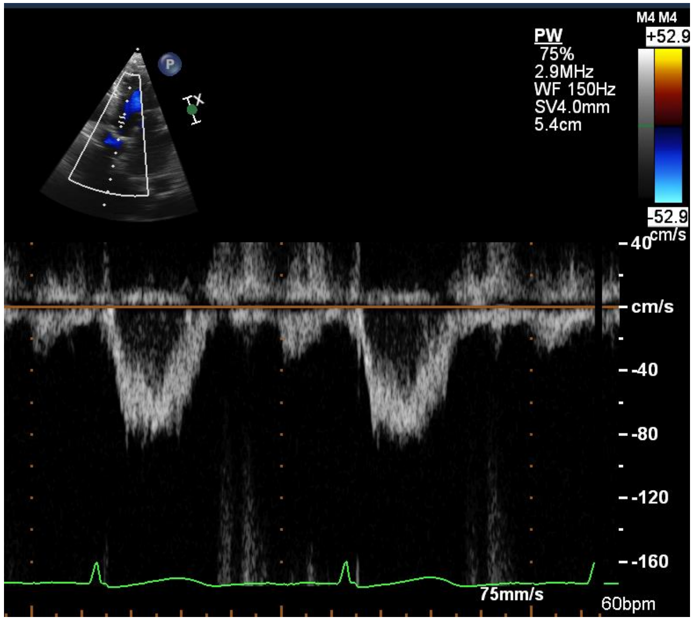
TEE: Transgastric View

Severe Aortic Stenosis

Continuous Wave (CW) Doppler



Pulsed Wave (PW) Doppler



Aortic Valve

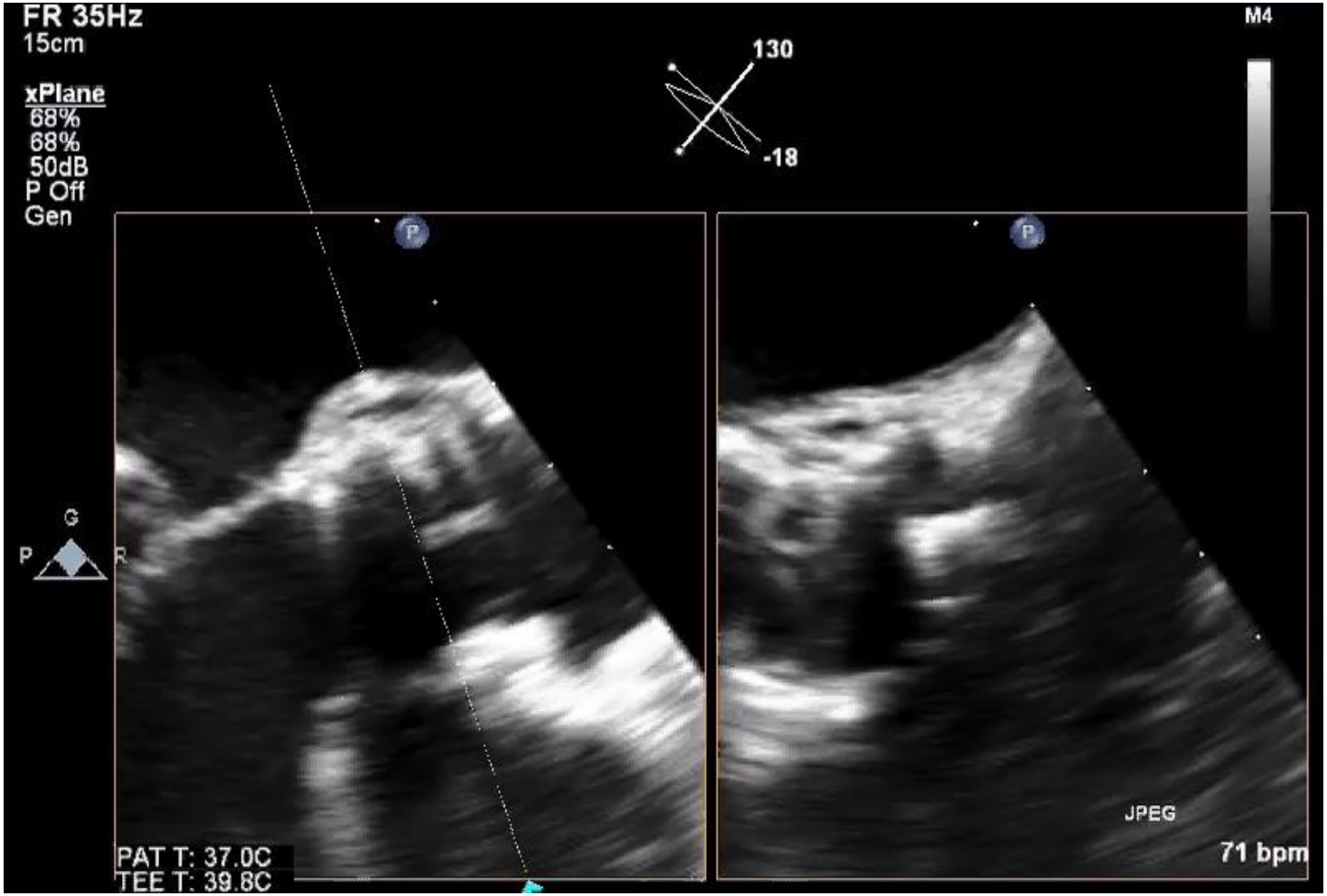
VTI = 134 cm
Vmax = 4.3 m/sec
Peak/Mean Gradient 74/43 mm Hg

LVOT

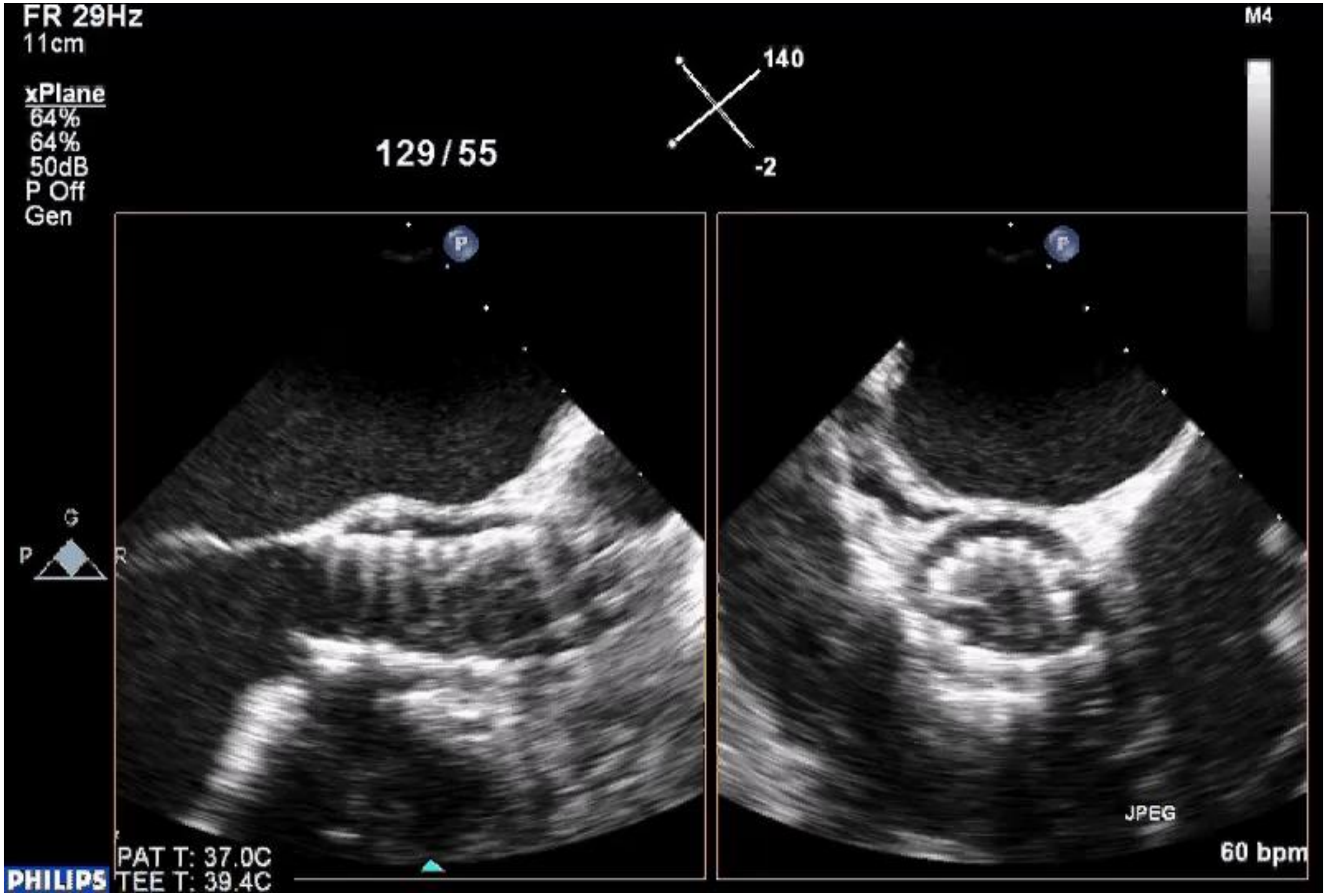
VTI = 24 cm
Vmax = 0.8 m/sec
Area 3.14 cm^2

Dimensionless Index = 24 / 134 = 0.18 | **Aortic Valve Area = 0.6 cm^2**

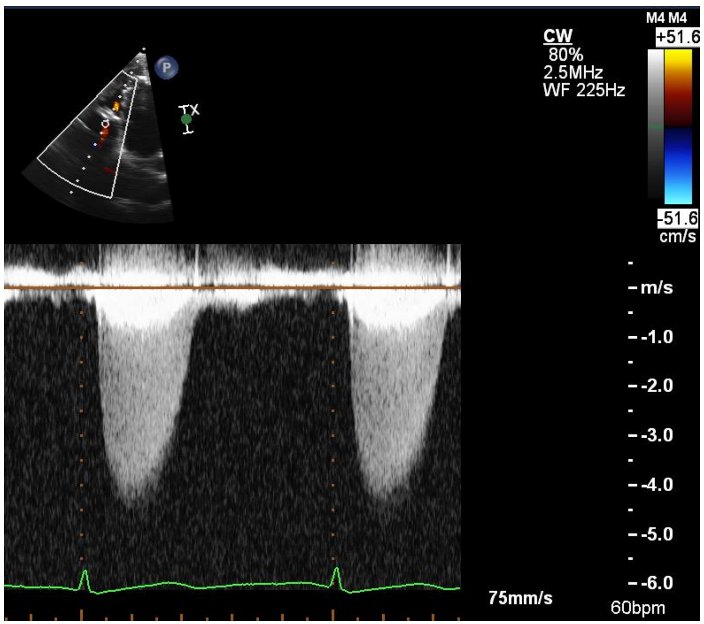
Severe Aortic Stenosis | Treated with Sapien TAVR



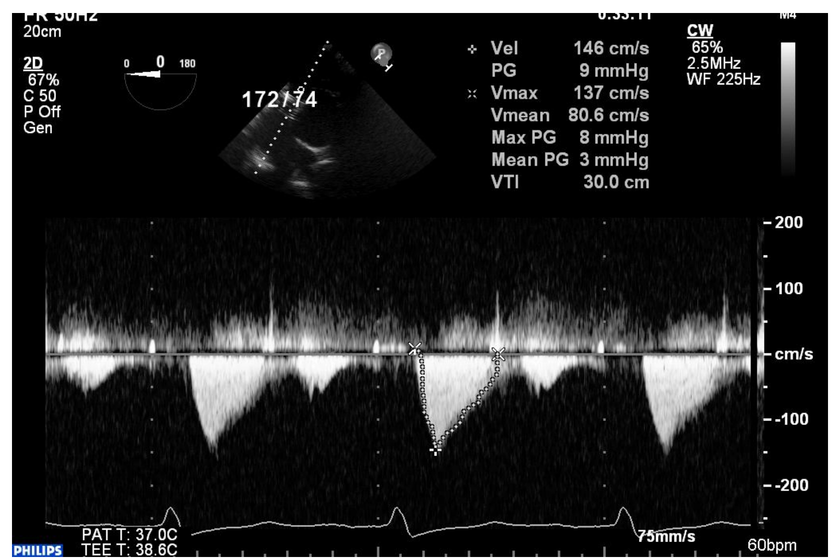
Severe Aortic Stenosis | Treated with CoreValve TAVR



Aortic Valve Gradients | Pre & Post TAVR



Before TAVR
(Severe native valve stenosis)



After TAVR
(Minimal aortic valve gradients)

TAVR | Treatment Outcomes

Natural History Symptomatic Severe AS	
	Mortality
2-year	50%
5-year	80%

Prognosis of severe symptomatic stenosis treated medically is abysmal.

					1-year All-Cause Mortality		
			N	STS	Medical	SAVR	TAVR
Sapien	Partner B	Inoperable	358	Very high	50.7%	[> 50%]	30.7%
	Partner A	High Risk	699	≥ 10		26.8%	24.2%

					1-year All-Cause Mortality		
			N	STS	Medical	SAVR	TAVR
CoreValve	Pivotal	Inoperable	489	Very high	36.5%	[> 50%]	26.5%
	Pivotal	High Risk	795	≥ 10		19.1%	14.2%

1^{ST} Wave of TAVR: What Else Have We Accomplished?

Simplified anesthesia management during TAVR

INITIAL TAVR EXPERIENCE	SUBSEQUNT TAVR EXPERIENCE
General anesthesia	Moderate sedation
Endotracheal intubation	No endotracheal intubation
TEE guidance	TTE guidance

JACC: CARDIOVASCULAR IMAGING
VOL. 8, NO. 3, 2015

ISSN 1936-878X/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcmg.2015.01.003

iFORUM

DEBATES IN IMAGING

Optimal Imaging for Guiding TAVR: Transesophageal or Transthoracic Echocardiography, or Just Fluoroscopy?

Itzhak Kronzon, MD, Vladimir Jelnin, MD, Carlos E. Ruiz, MD, PhD, Muhamed Saric, MD, PhD, Mathew Russell Williams, MD, Albert M. Kasel, MD, Anupama Shivaraju, MD, Antonio Colombo, MD, Adnan Kastrati, MD
Section Editor: Partho P. Sengupta, MD

THE FOLLOWING iFORUM DEBATE FEATURES 3 VIEWPOINTS related to the most practical and effective imaging strategy for guiding transcatheter aortic valve replacement (TAVR). Kronzon, et al. provide evidence that enhanced analysis of aortic valve anatomy and improved appreciation of complications mandate the use of transesophageal echocardiography as front-line imaging modality for ALL patients undergoing TAVR. On the other hand, Saric and colleagues compare and contrast the approach of performing TAVR under transthoracic guidance. Lastly, Kasel and co-workers provide preliminary evidence that TAVR could be performed under fluoroscopic guidance without the need for additional imaging technique. Although the use of less-intensive sedation or anesthesia might reduce the procedural time, we need more randomized data to establish the most cost-effective approach in guiding TAVR.

NYU TAVR Team

Mathew Williams, MD, prepares to insert the compressed replacement valve into the catheter. Dr. Williams has performed more TAVRs than any surgeon in the U.S.

Using 3-D echocardiography, Muhamed Saric, MD, PhD (left), guides the positioning and deployment of the replacement valve in real time.

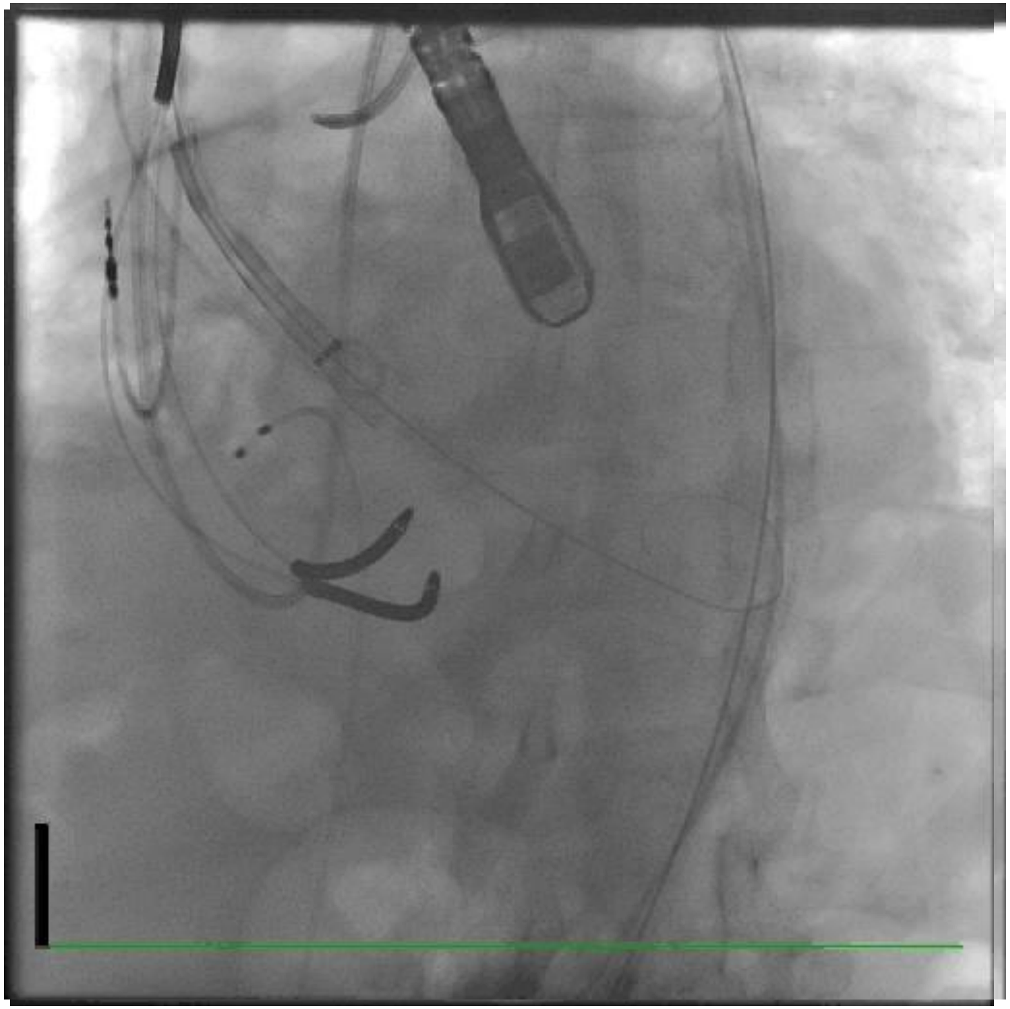
Guided by X-ray fluoroscopy, interventional cardiologist James Slater, MD, the Robert and Marc Bell Professor of Cardiology, inserts a catheter in an artery in the groin and threads it up into the heart.

A Team Approach for Replacing Heart Valves

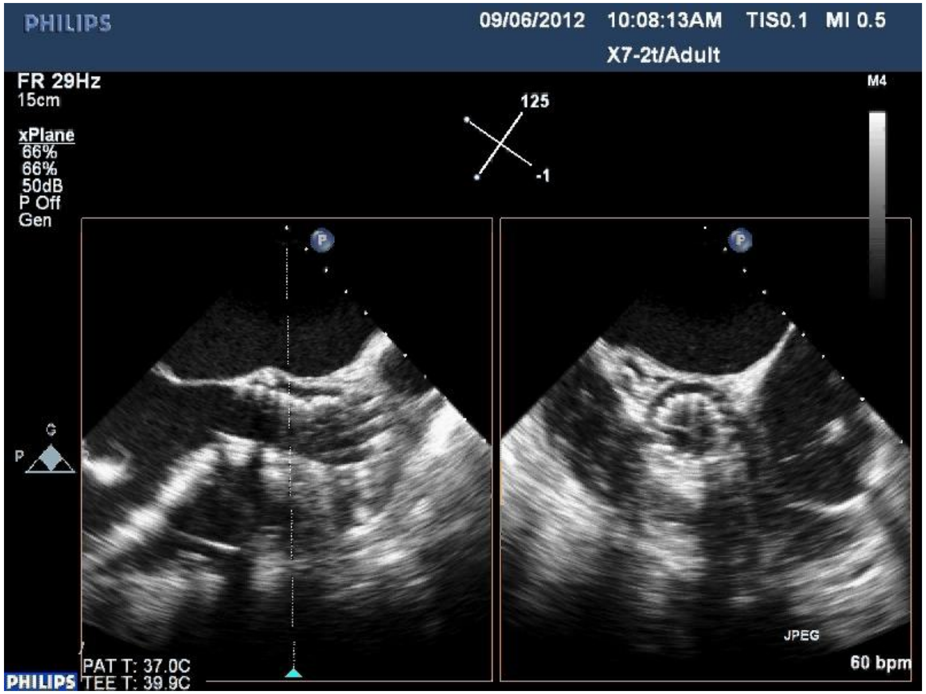
One of the procedures made possible by NYU Langone Medical Center's state-of-the-art hybrid OR—equipped for both surgery and catheterization—is transcatheter aortic valve replacement (TAVR). TAVR allows a narrowed, stiffened valve to be replaced through a catheter, a minimally invasive approach requiring moderate sedation and two small incisions. About 250,000 Americans are estimated to suffer from severe aortic stenosis, which limits blood flow from the heart. Without a valve replacement, half will not survive more than two years after the onset of symptoms.

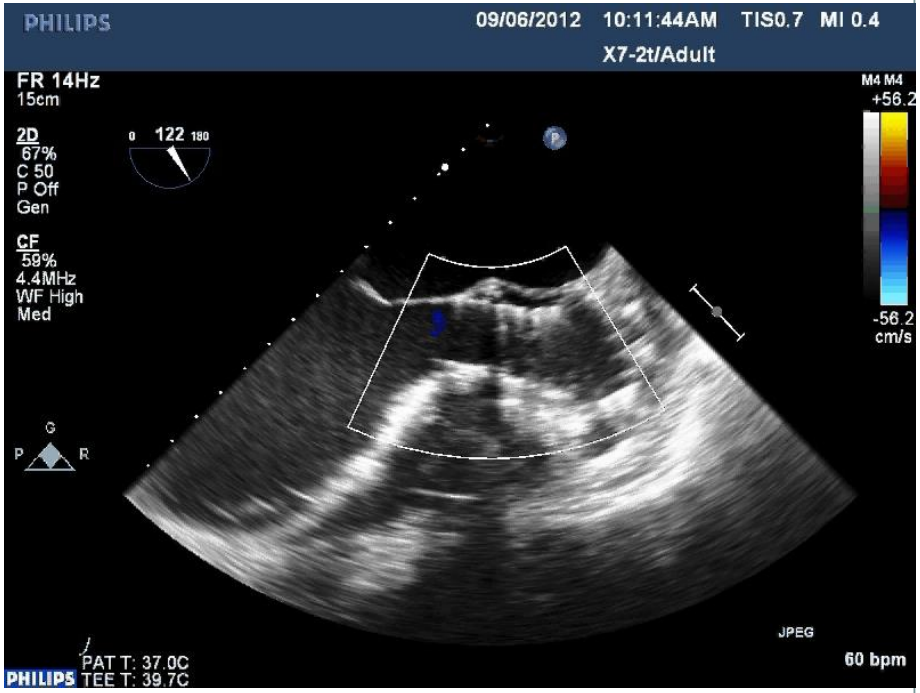
The artificial valve, enveloped in a metal scaffold, or stent, collapses to the width of a pencil, allowing it to fit inside an artery.

CoreValve Deployment

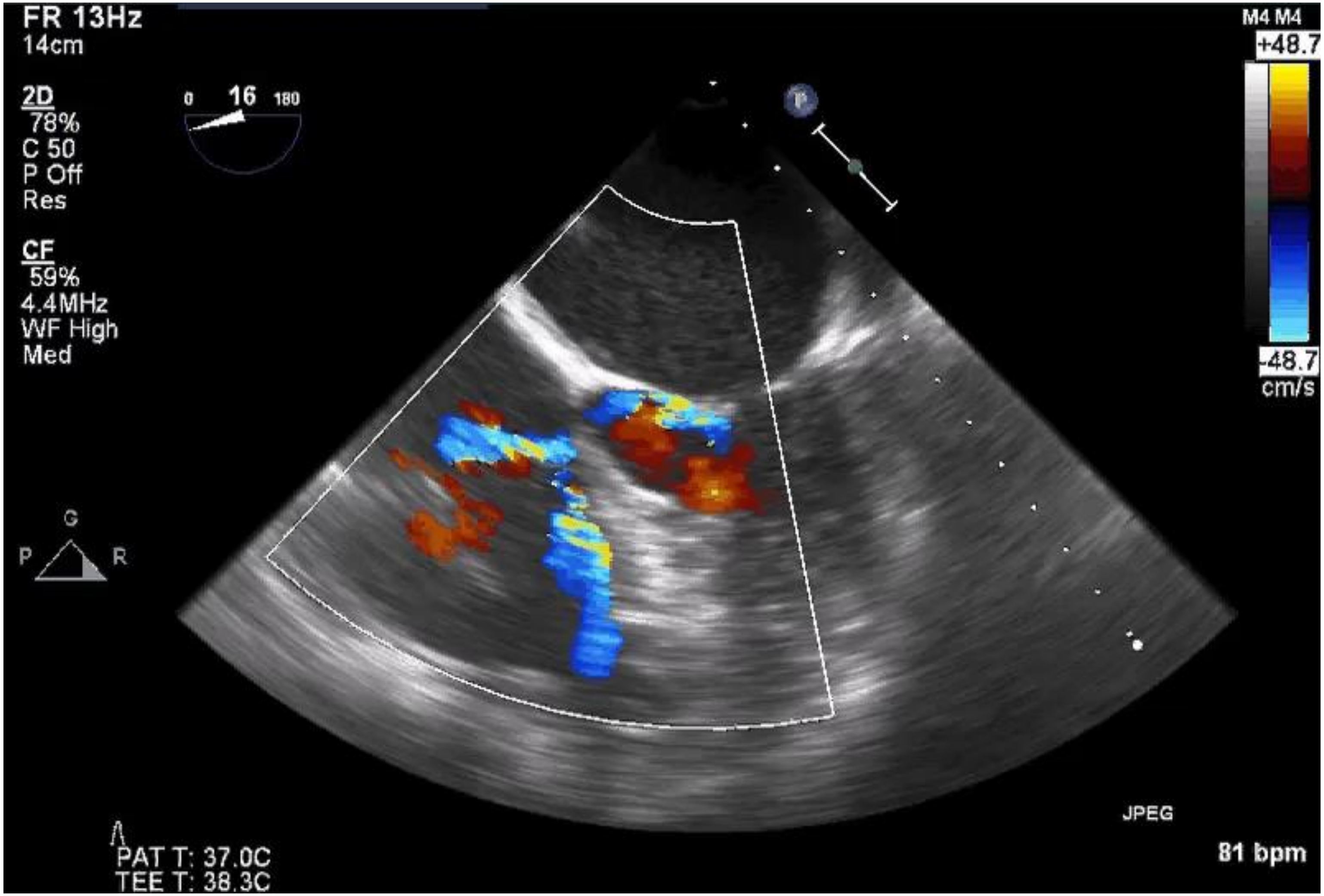


CoreValve Deployed

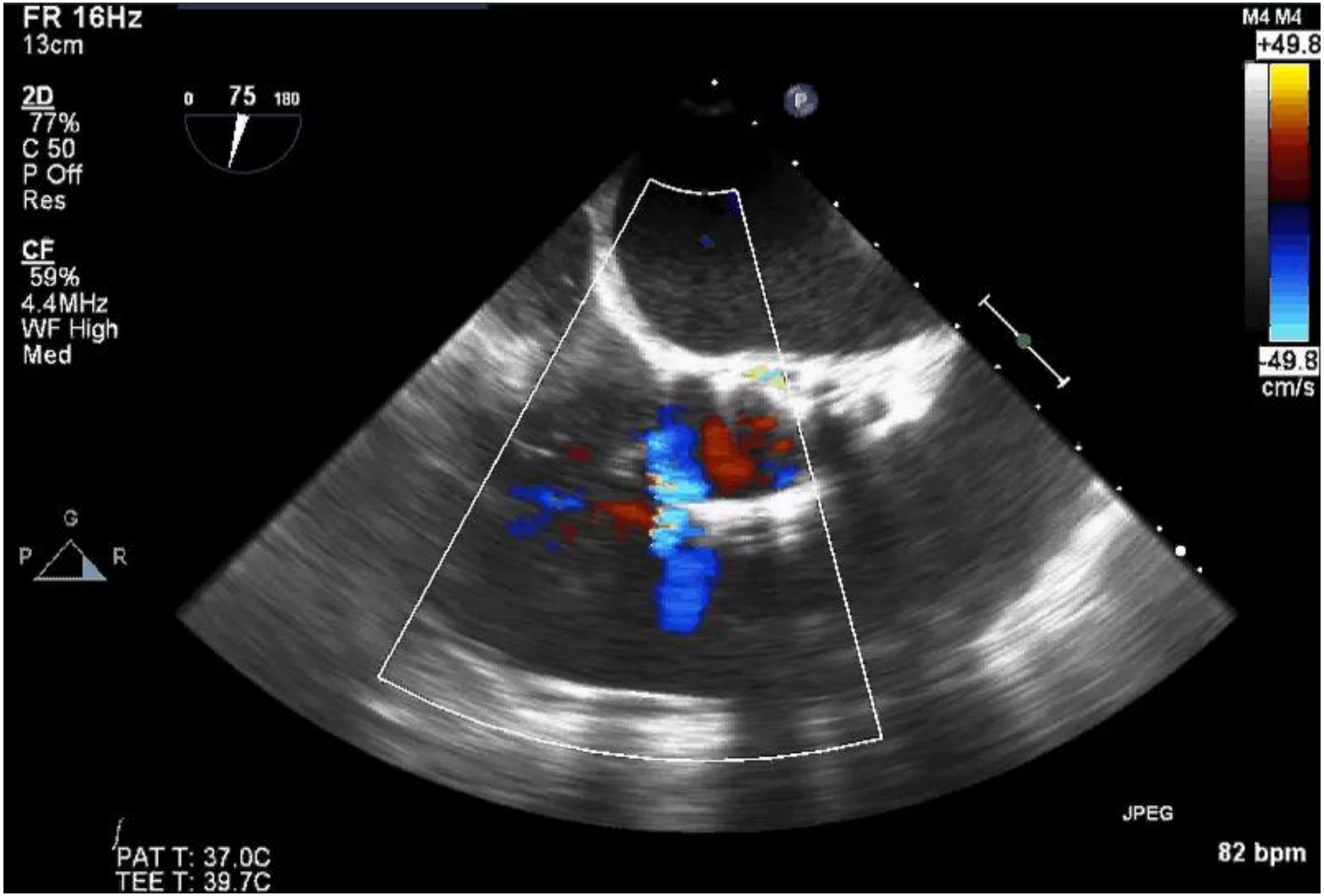




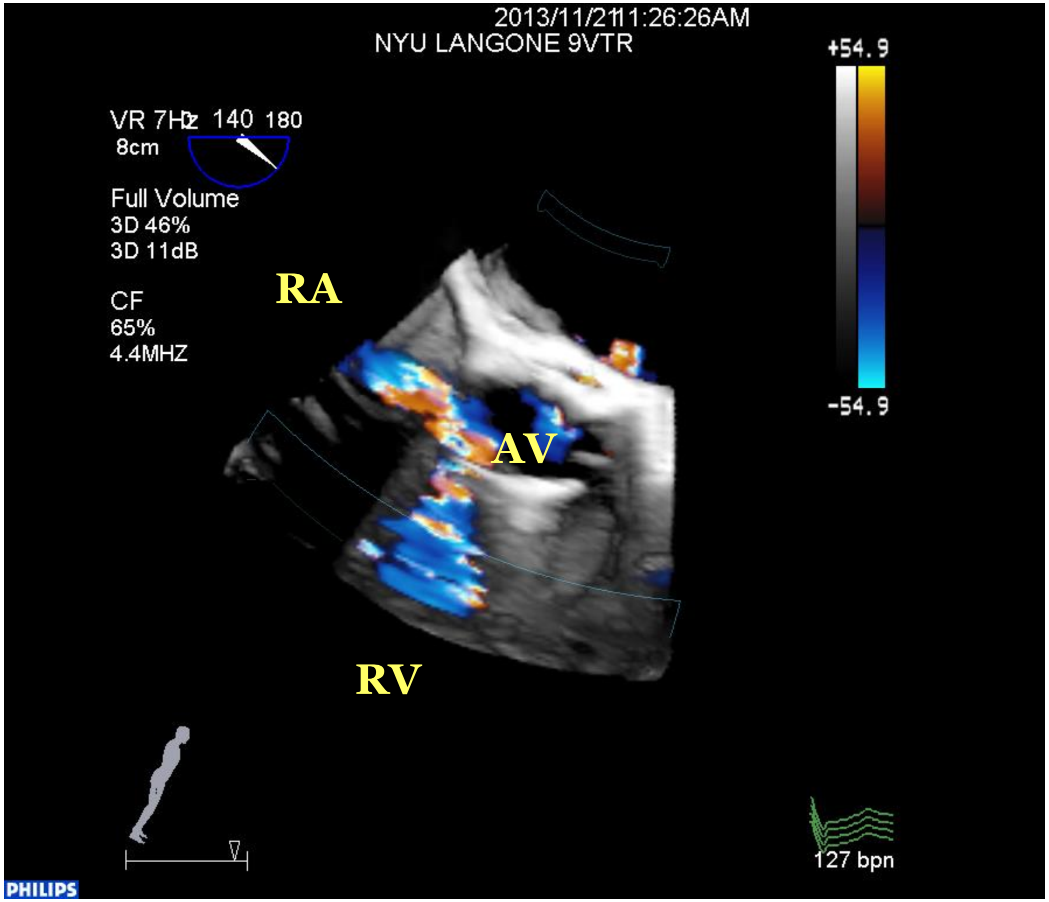
Post TAVR Complication: VSD + Gerbode Defect

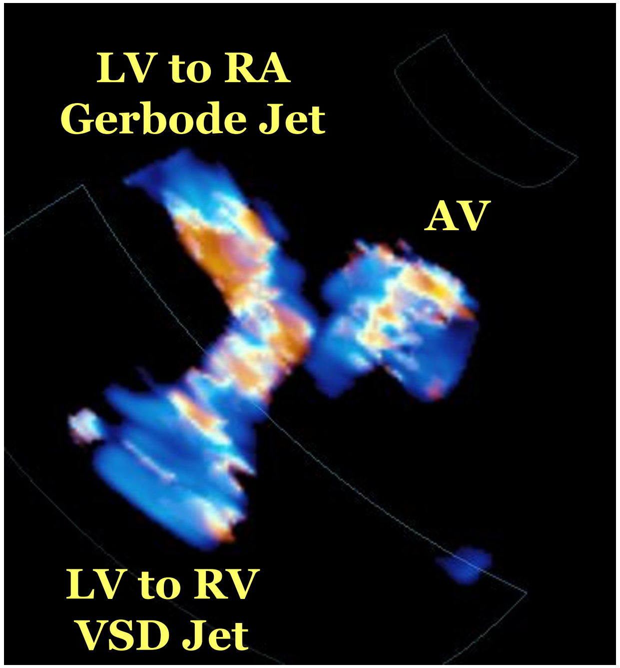


POST TAVR COMPLICATION: VSD + GERBODE DEFECT



Post TAVR Complication: VSD + Gerbode Defect

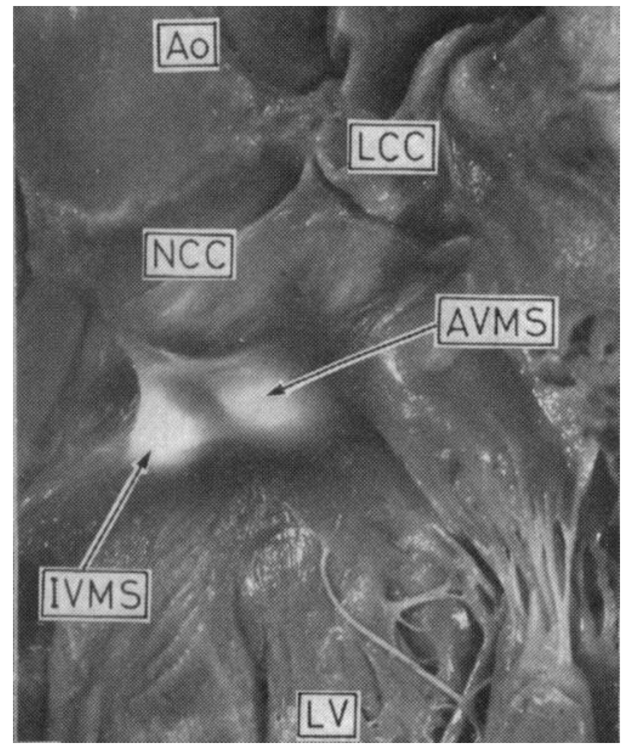




Post TAVR Complication: Membranous VSD + Gerbode Defect

Frank Gerbode
(1907-1984)
American Cardiac Surgeon

Membranous Septum



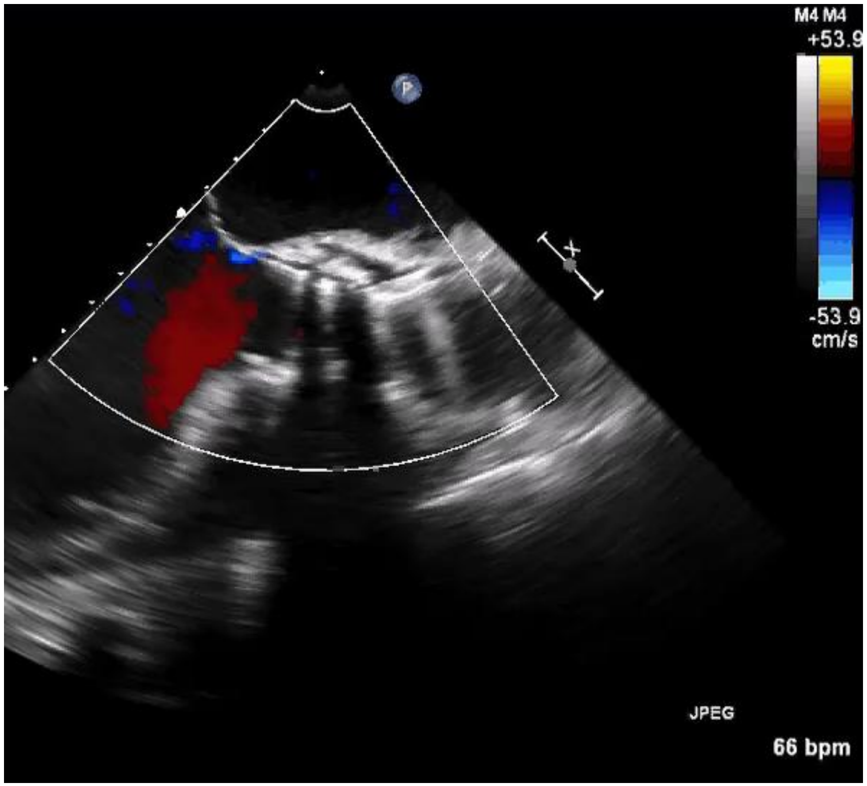
1^{ST} Wave TAVR

We have accomplished a lot…

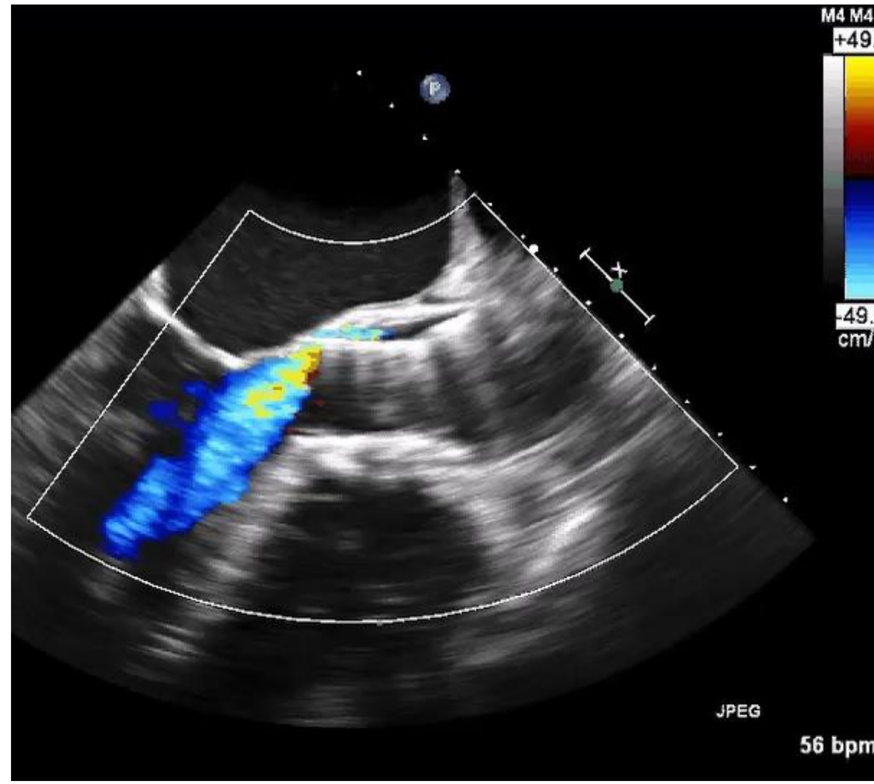
…so what's the problem?

Paravalvular Aortic Regurgitation Post TAVR

Trivial PVL



Marked PVL



Potential for Hemolytic Anemia

Potential for Hemodynamic Compromise

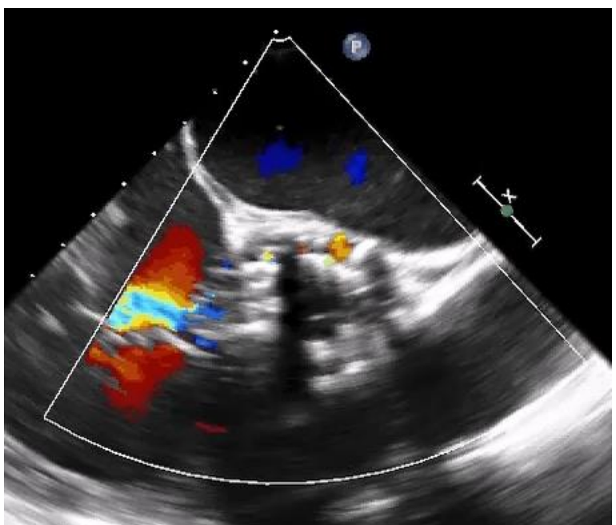
PARAVALVULAR AORTIC REGURGITATION POST TAVR

No easy way to grade it

Table 4 VARC II Recommendations for Evaluation of Aortic and/or Paravalvular Regurgitation After TAVR

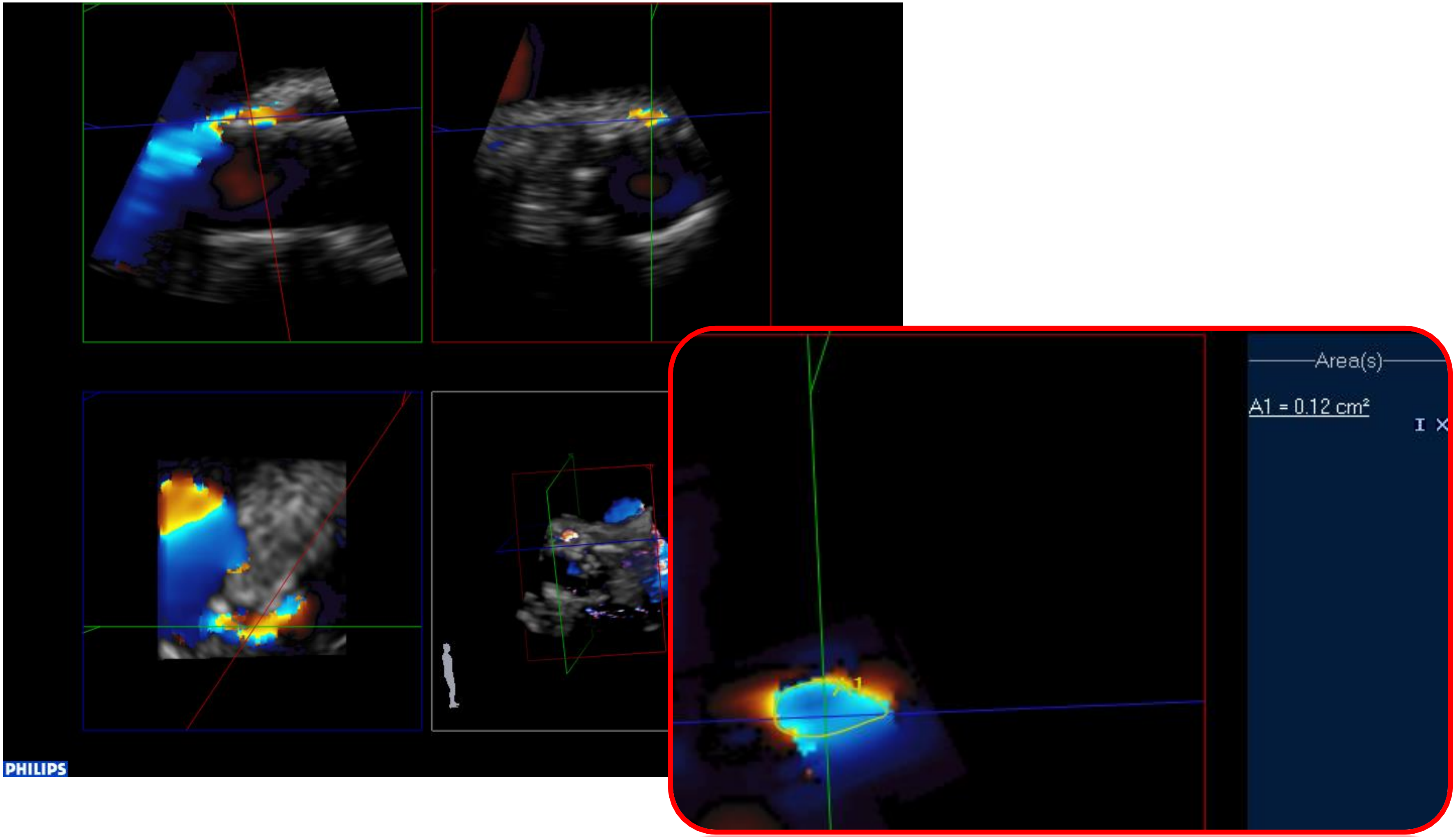
	Mild	Moderate	Severe
Semiquantitative parameters			
Diastolic flow reversal in the descending aorta—pulsed wave	Absent or brief early diastolic	Intermediate	Prominent, holodiastolic
Circumferential extent of prosthetic valve paravalvular regurgitation (%)*	<10	10–29	≥30
Quantitative parameters†			
Regurgitant volume (ml/beat)	<30	30–59	≥60
Regurgitant fraction (%)	<30	30–49	≥50
Effective regurgitant orifice area (cm^2)	0.10	0.10–0.29	≥0.30

*Not well validated and may overestimate severity compared with quantitative Doppler. †For LVOT >2.5 cm, significant stenosis criteria is <0.20. Adapted with permission from Kappetein et al. (66). VARC = Valve Academic Research Consortium; other abbreviations as in Table 1.



VARC II Criteria
An expert consensus
without empiric validation

Paravalvular AR Post TAVR | EROA By 3D Echo



PARAVALVULAR AR POST TAVR | IMPACT ON SURVIVAL

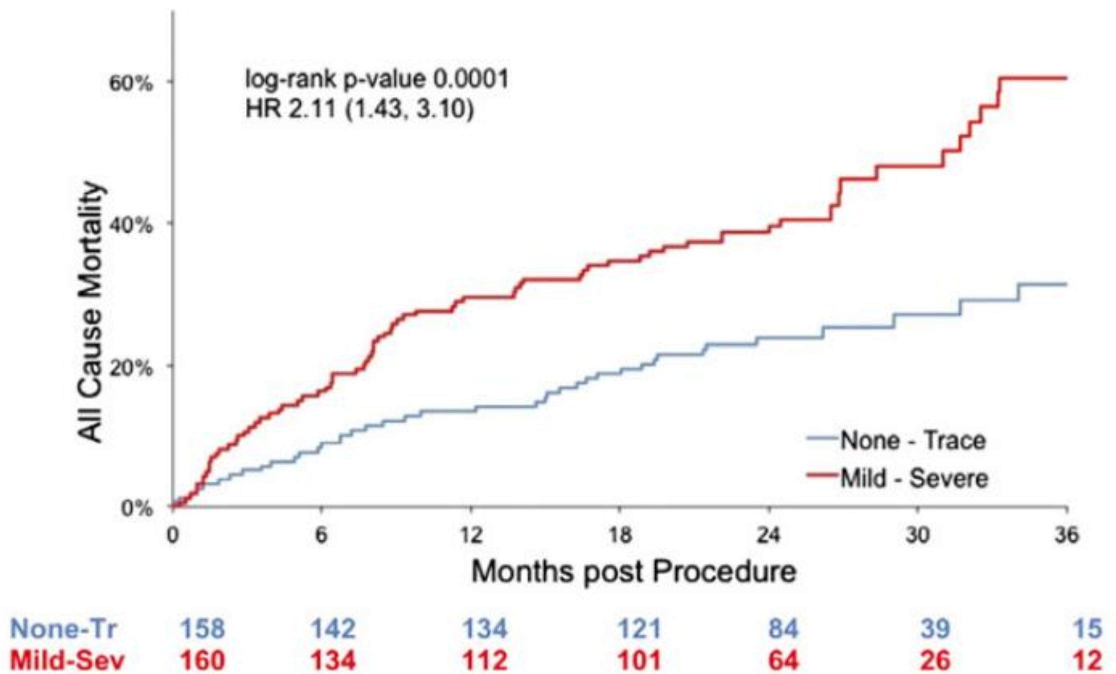


Figure 2 Impact of Paravalvular Leak on 2-Year All-Cause Mortality

Reprinted with permission from Kodali et al. (8). HR = hazard ratio.

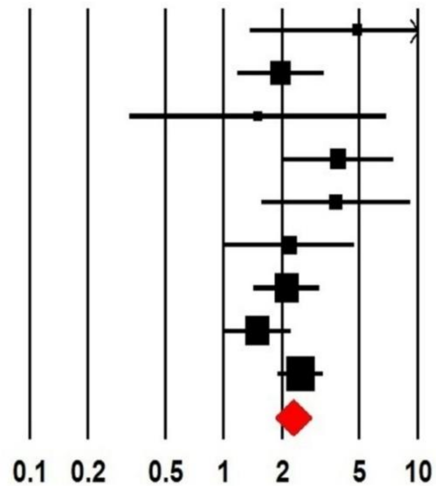
Higher grades of paravalvular AR portend worse prognosis.

Even mild paravalvular AR portends worse prognosis.

PARAVALVULAR AR POST TAVR | IMPACT ON SURVIVAL

Study name	Statistics for each study				
	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos*	4.900	1.367	17.570	2.439	0.015
Hayashida	1.970	1.187	3.271	2.621	0.009
Amabile	1.500	0.329	6.829	0.524	0.600
Sinning	3.890	2.020	7.491	4.063	0.000
Tamburino	3.785	1.572	9.112	2.969	0.003
Fraccaro	2.190	1.023	4.686	2.020	0.043
Kodali	2.110	1.433	3.107	3.783	0.000
Moat	1.490	1.002	2.215	1.971	0.049
Gilard	2.490	1.909	3.248	6.728	0.000
All (N=4791)	**2.273**	**1.840**	**2.808**	**7.609**	**0.000**

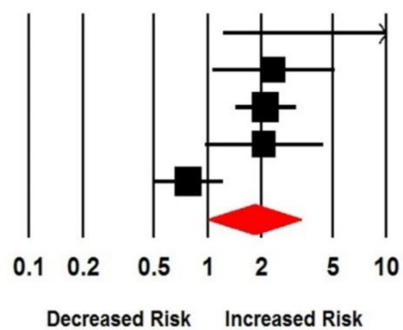
Hazard ratio and 95% CI



Moderate/Severe
paravalvular AR

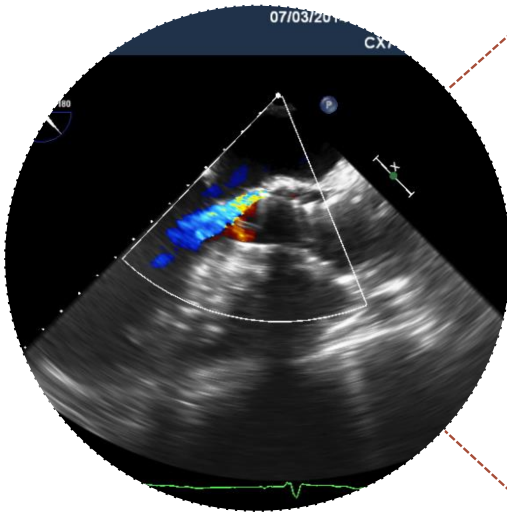
Study name	Statistics for each study				
	Hazard ratio	Lower limit	Upper limit	Z-Value	p-Value
Lemos	10.080	1.229	82.673	2.152	0.031
Sinning	2.342	1.066	5.145	2.119	0.034
Kodali	2.110	1.433	3.107	3.782	0.000
Fraccaro	2.064	0.968	4.400	1.876	0.061
Tamburino	0.780	0.499	1.218	-1.092	0.275
All (N=1620)	**1.829**	**1.005**	**3.329**	**1.975**	**0.048**

Hazard ratio and 95% CI



Mild
paravalvular AR

Paravalvular AR Post TAVR | Mechanisms



Undersized TAVR Valve	*Meticulous annular sizing pre-TAVR minimizes this risk.*
Maldeployed TAVR Valve	*Reposition existing TAVR or do valvuloplasty or place valve-in-valve TAVR*
Excessive Aortic Root Calcium	*New TAVR prosthesis designs*

Annular Sizing

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PUBLISHED BY ELSEVIER INC.

VOL. 6, NO. 2, 2013
ISSN 1936-878X/$36.00
http://dx.doi.org/10.1016/j.jcmg.2012.12.005

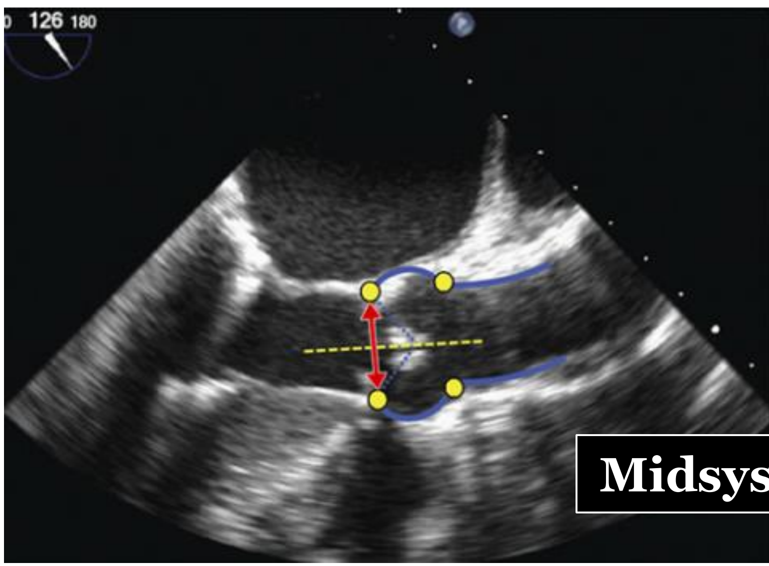
iREVIEWS

STATE-OF-THE-ART PAPER

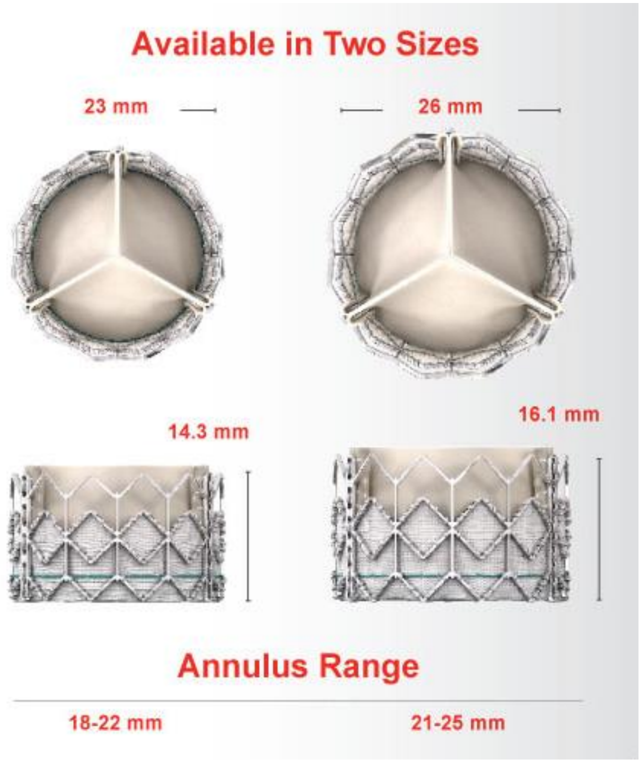
Standardized Imaging for Aortic Annular Sizing

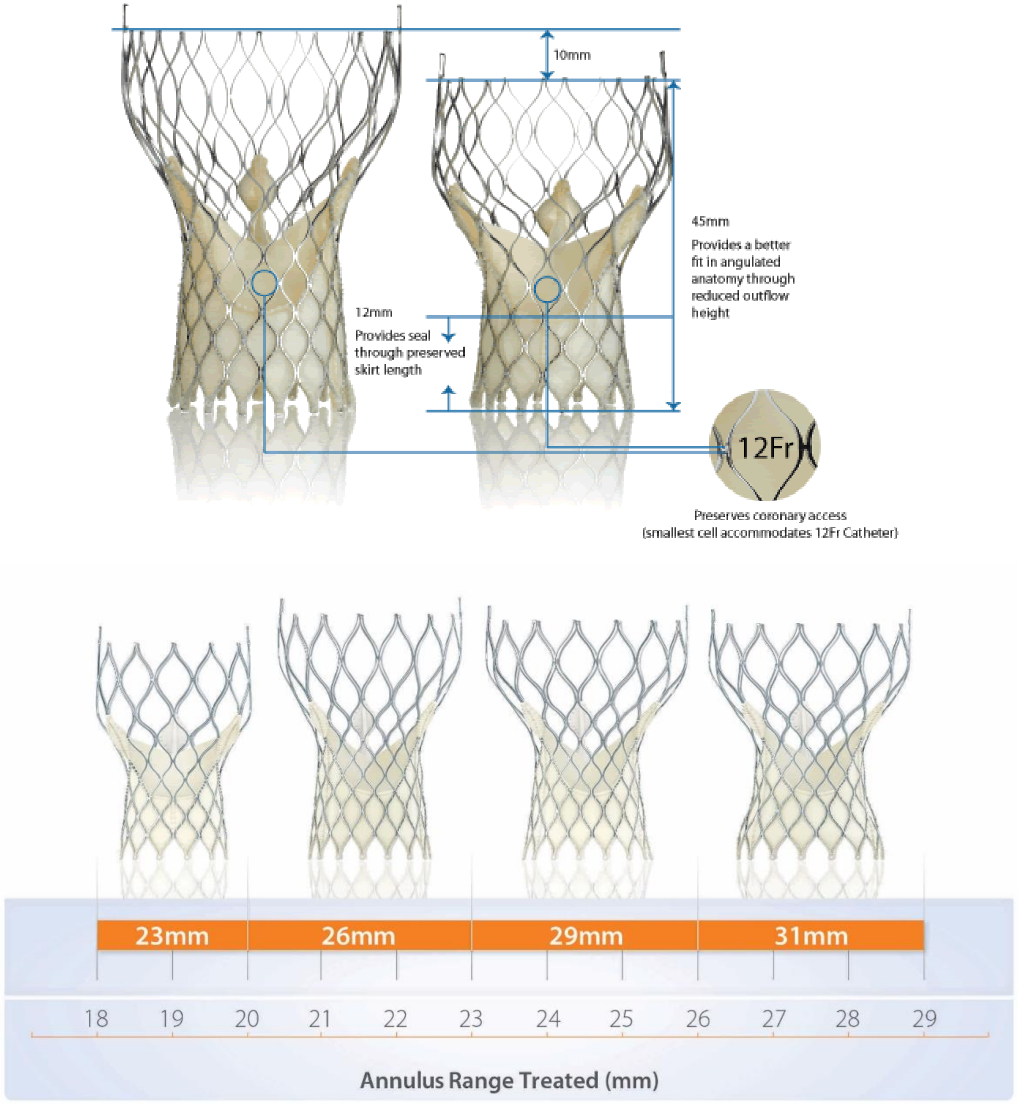
Implications for Transcatheter Valve Selection

Albert M. Kasel, MD,* Salvatore Cassese, MD,* Sabine Bleiziffer, MD,†
Makoto Amaki, MD, PhD,‡ Rebecca T. Hahn, MD,§ Adnan Kastrati, MD,*
Partho P. Sengupta, MD‡
Munich, Germany; and New York, New York



Midsystolic Frames





1º Generation Edwards Sapien

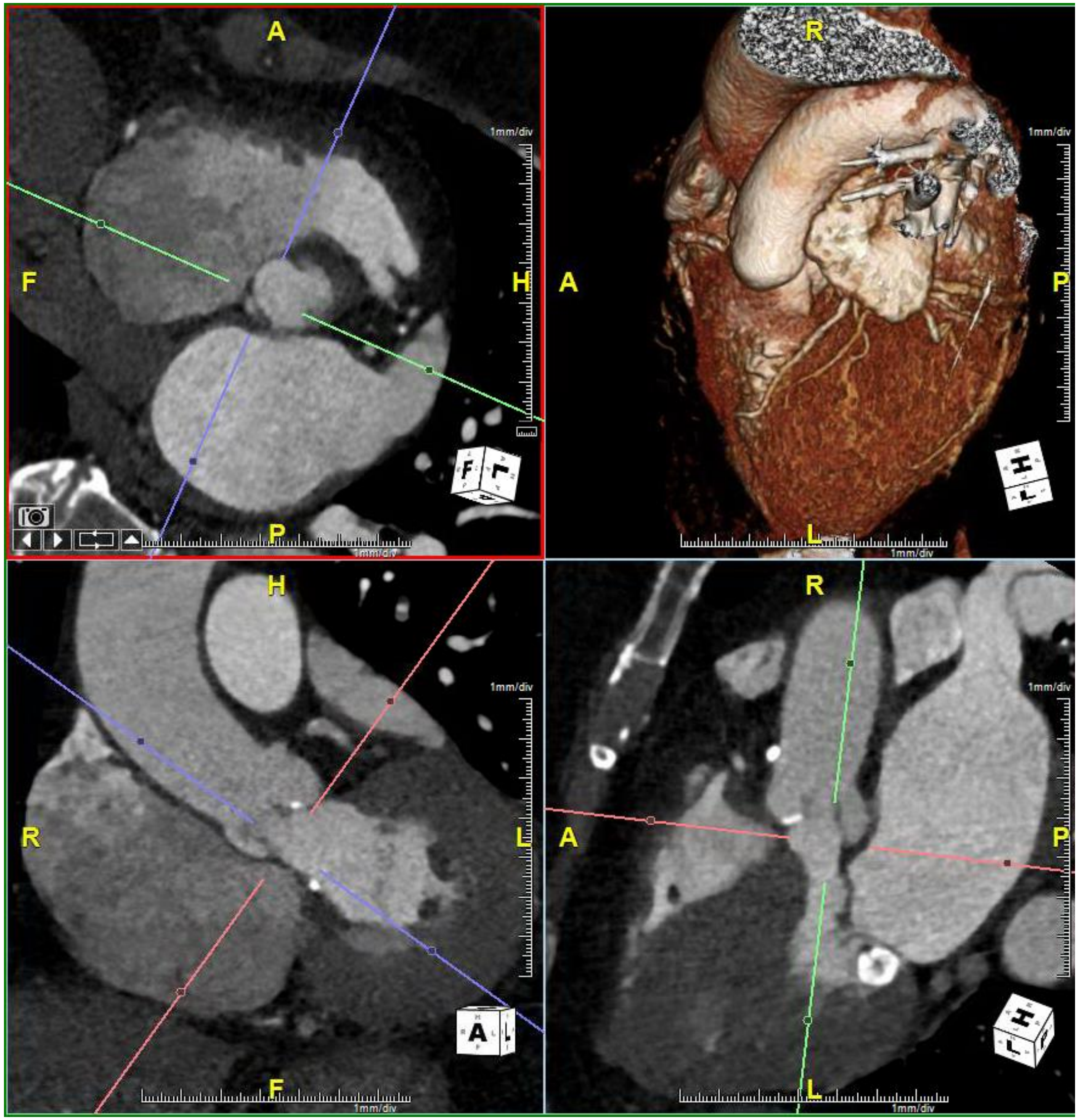
1º Generation Medtronic CoreValve

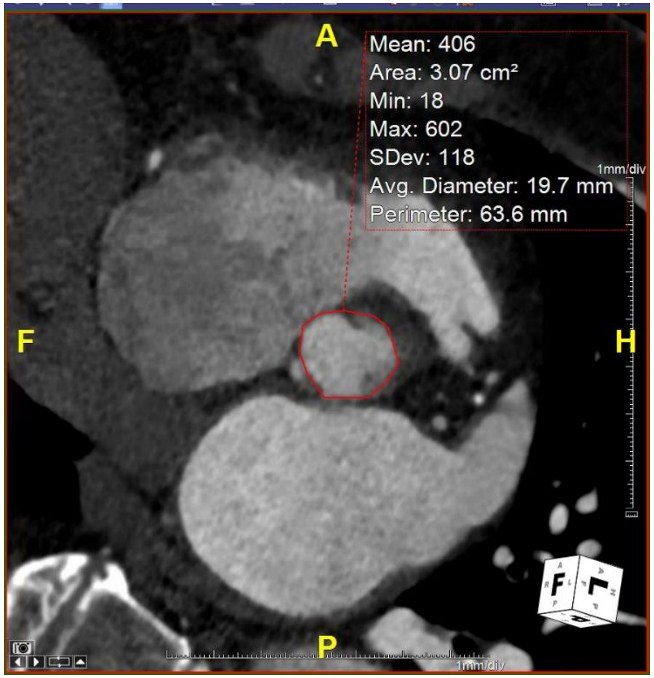
TAVR-related Aortic Root Measurements

Some interventionalists prefer **CT measurements** of aortic root over echocardiographic measurements…

…because calcifications interfere with echo but not CT imaging.

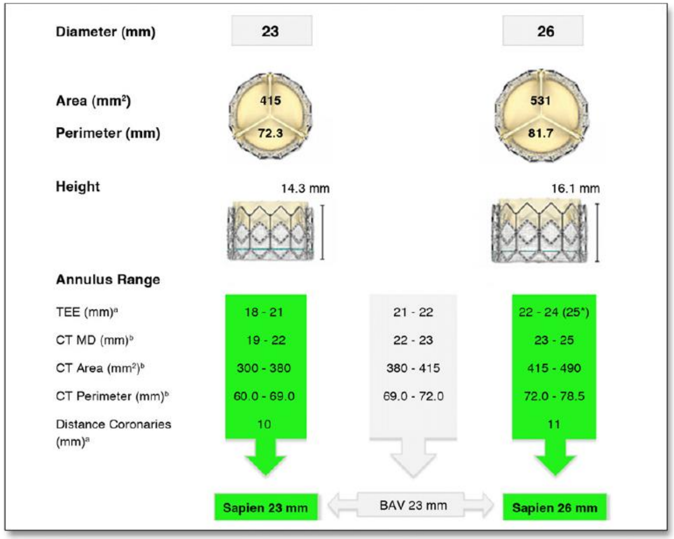
Aortic Annular Sizing | CT



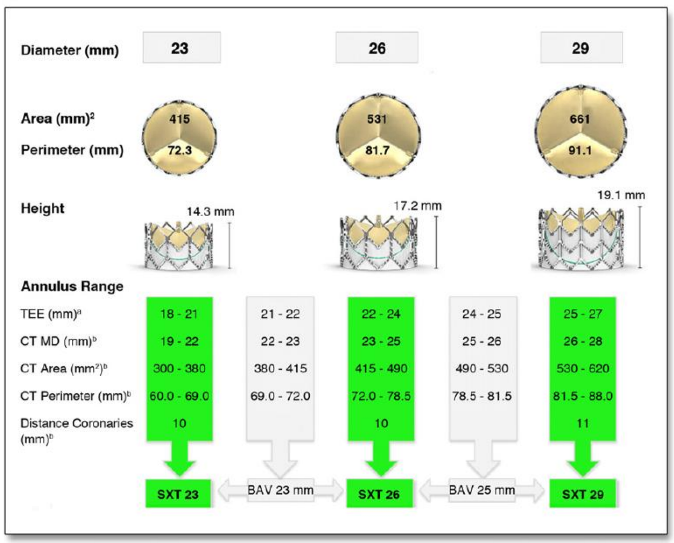


*Aortic annular **perimeter** by CT*

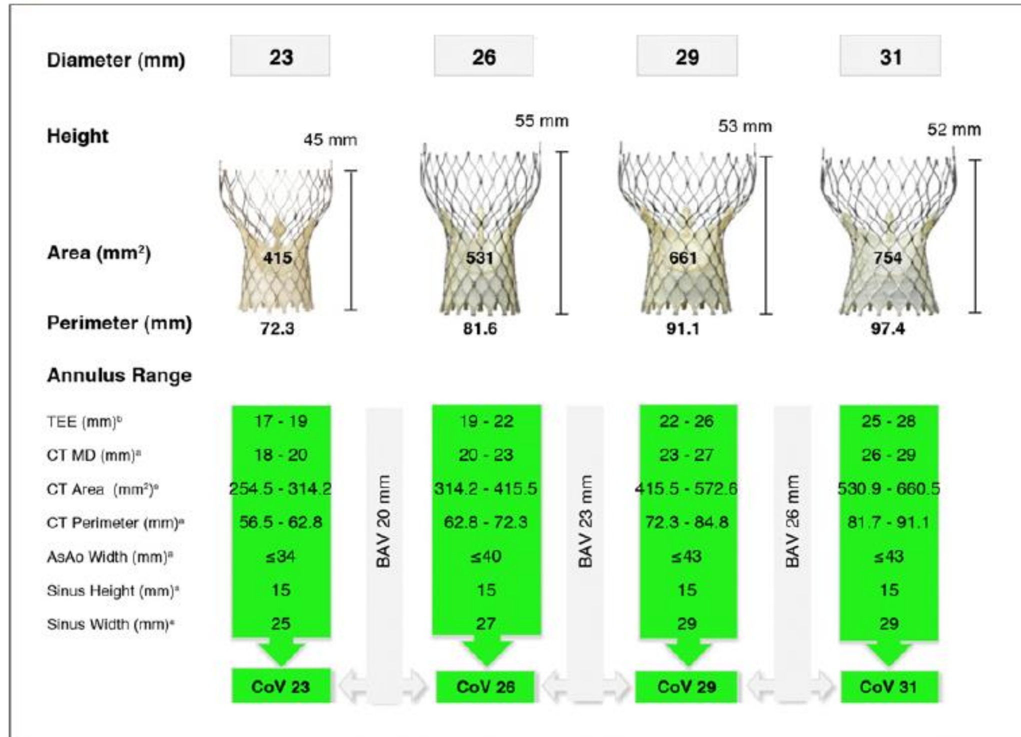
A



B



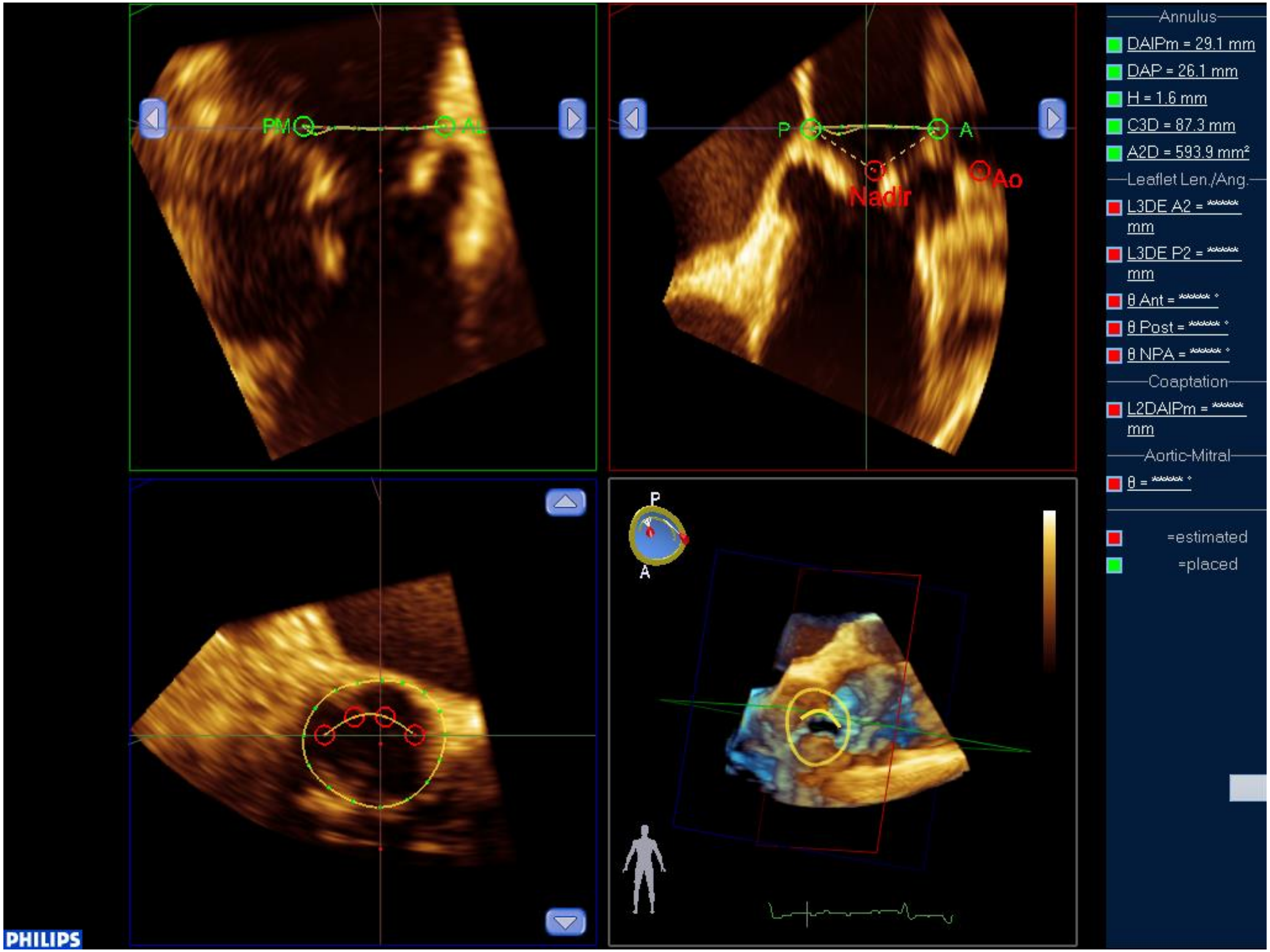
C



Edwards Sapien & Sapien XT

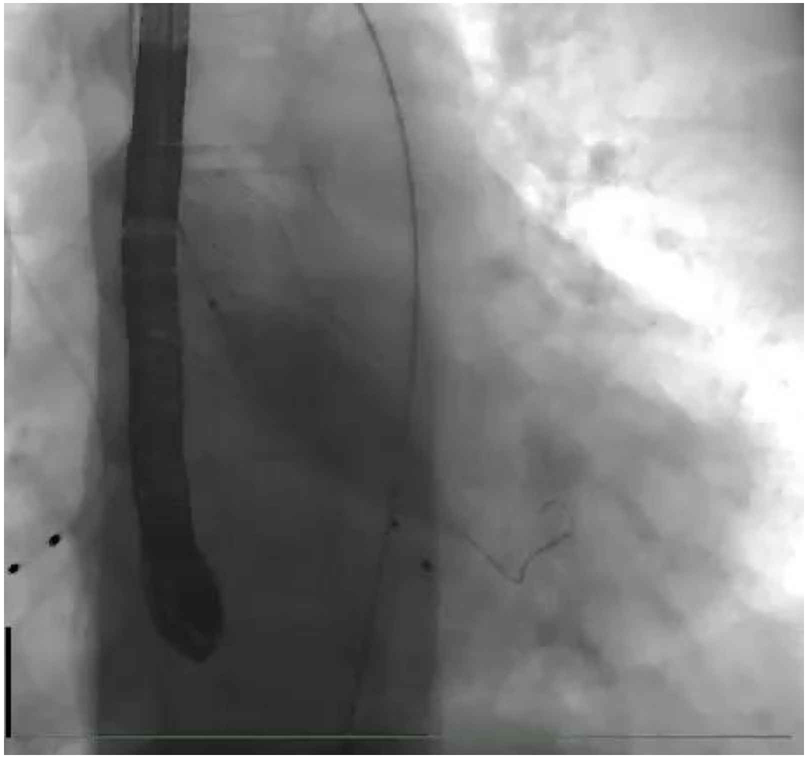
Medtronic CoreValve

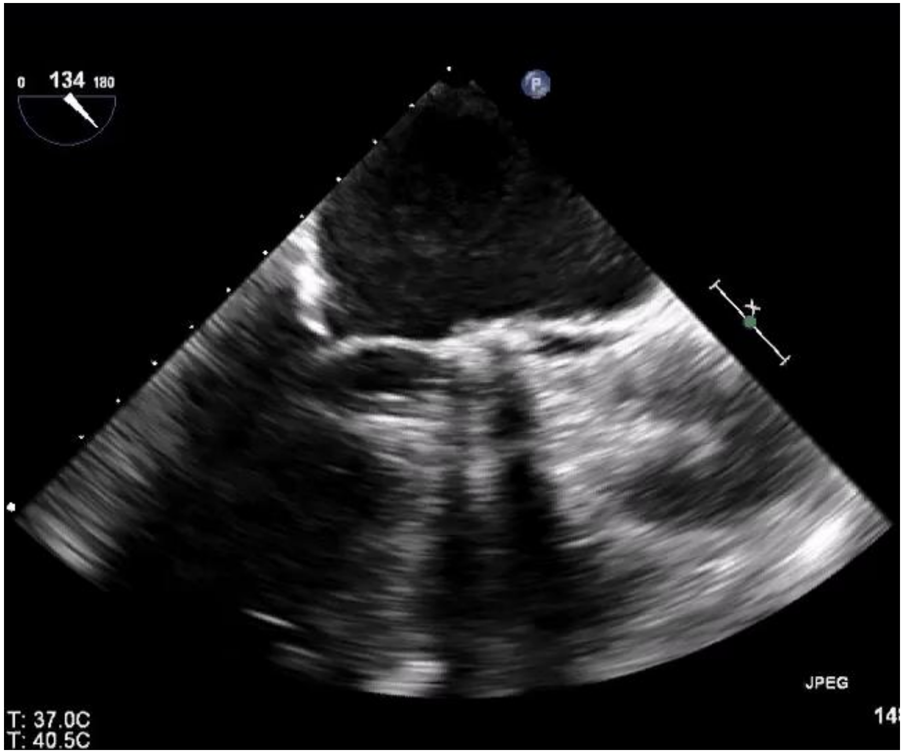
Aortic Annular Sizing | 3D TEE



Post Dilation for TAVR PVL

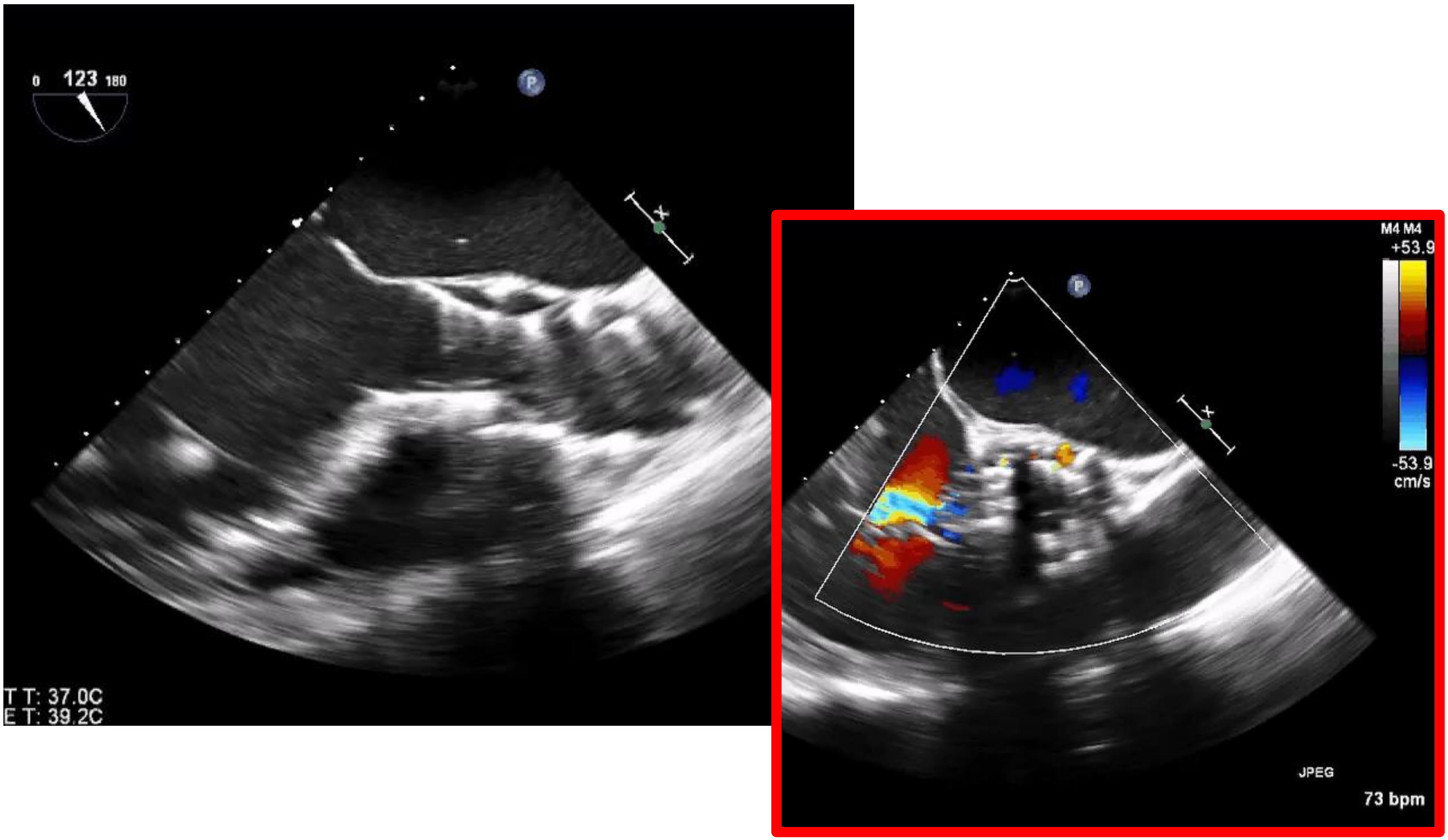
Balloon Post Dilatation | Accented Means of Reducing PVL



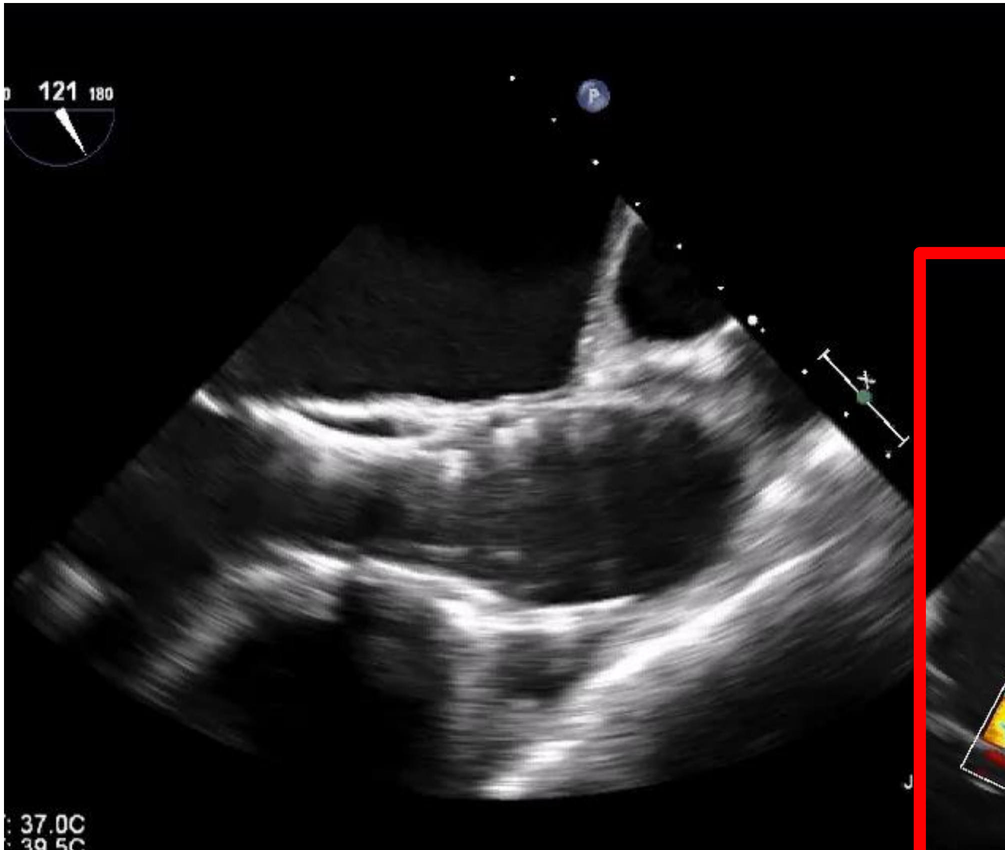


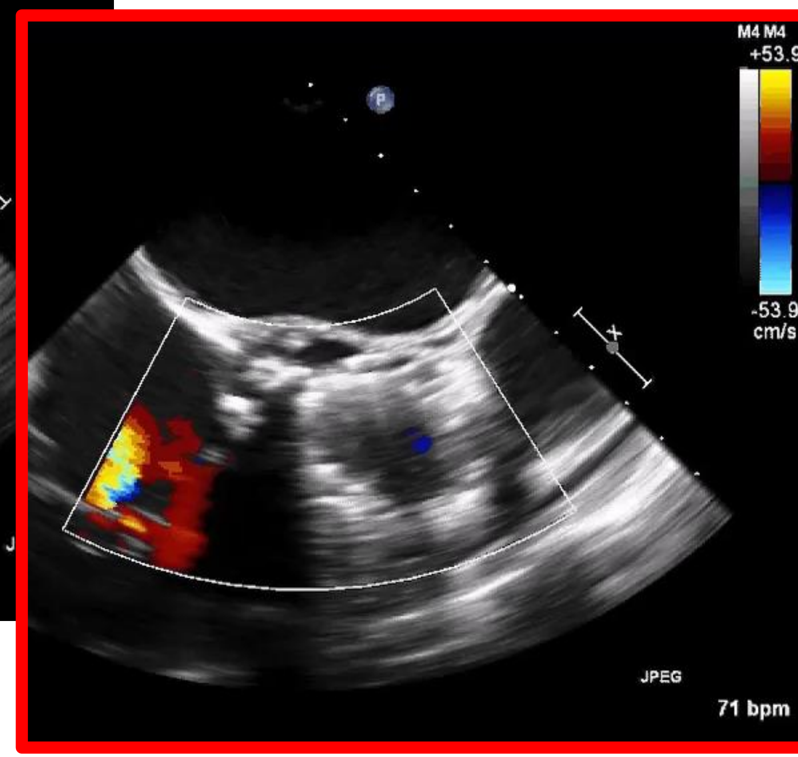
Valve-in-Valve For TAVR PVL

1ST COREVALVE MALPOSITIONED >> PARAVALVULAR AR



2ND CoreValve Placed ViV >> No More Paravalvular AR





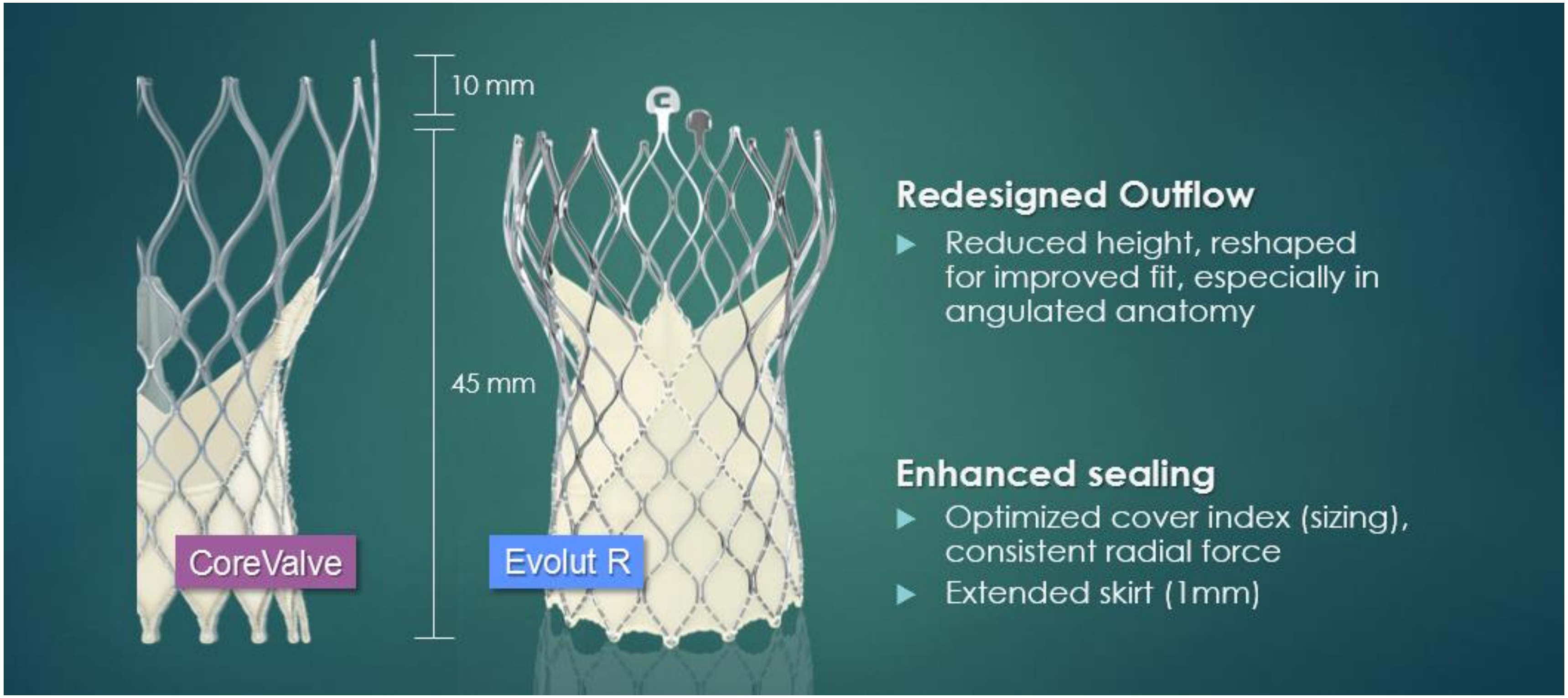
New Generation of TAVR Valves

New Wave of TAVR Valves

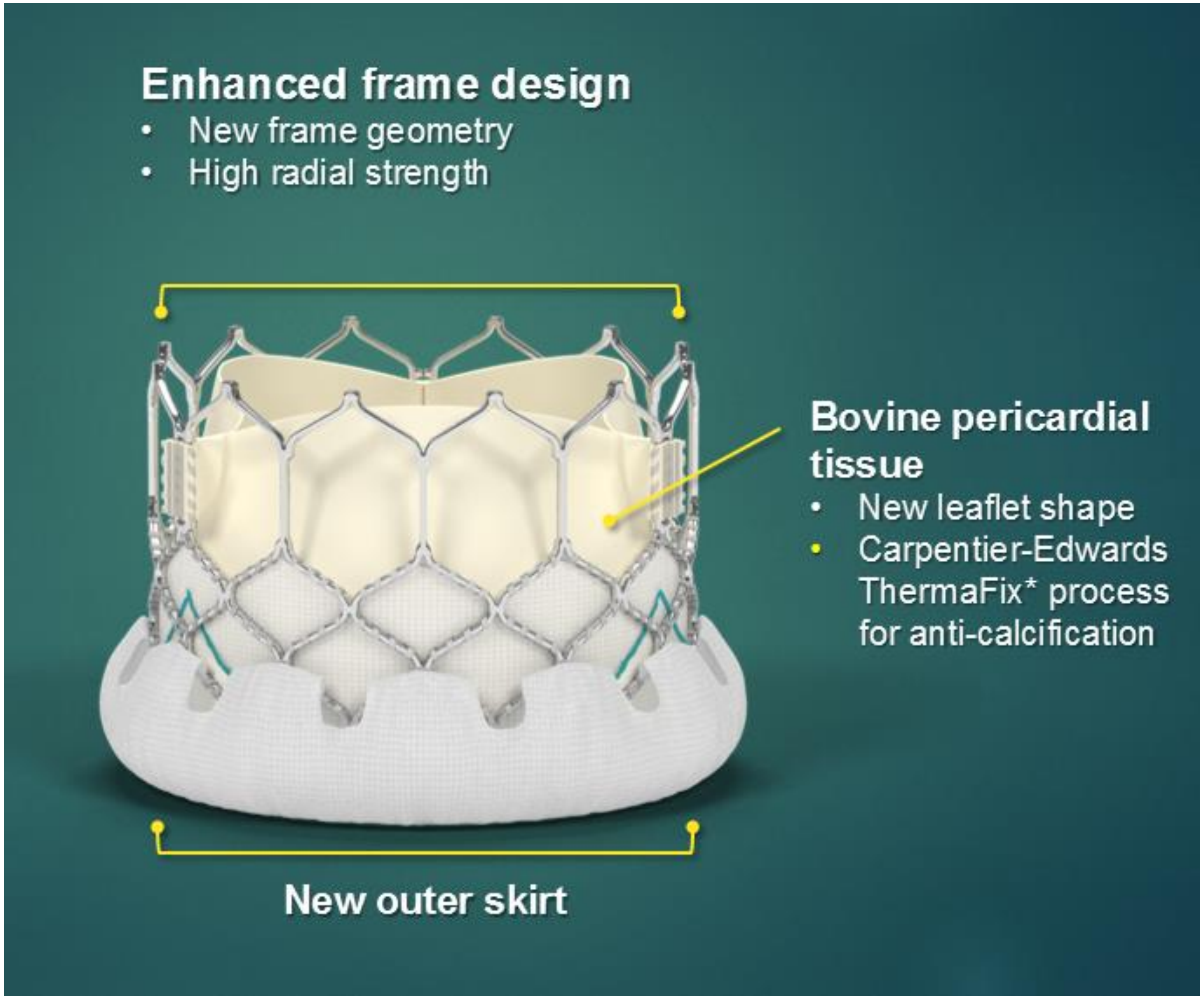
(1) **Repositionable** during delivery

(2) Special proximal prosthetic **skirt design** to prevent PVLs

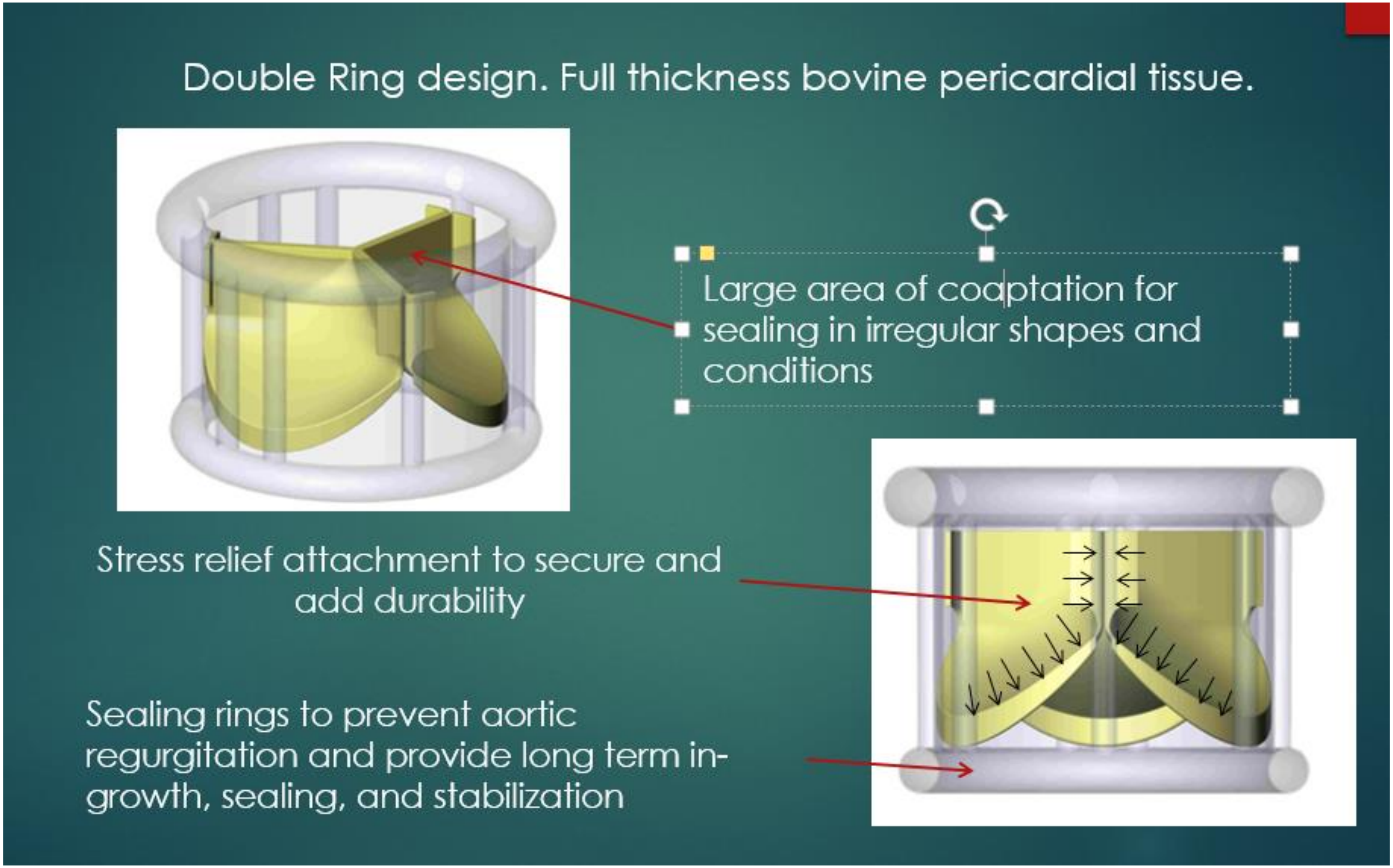
CoreValve Evolut R



Sapien 3

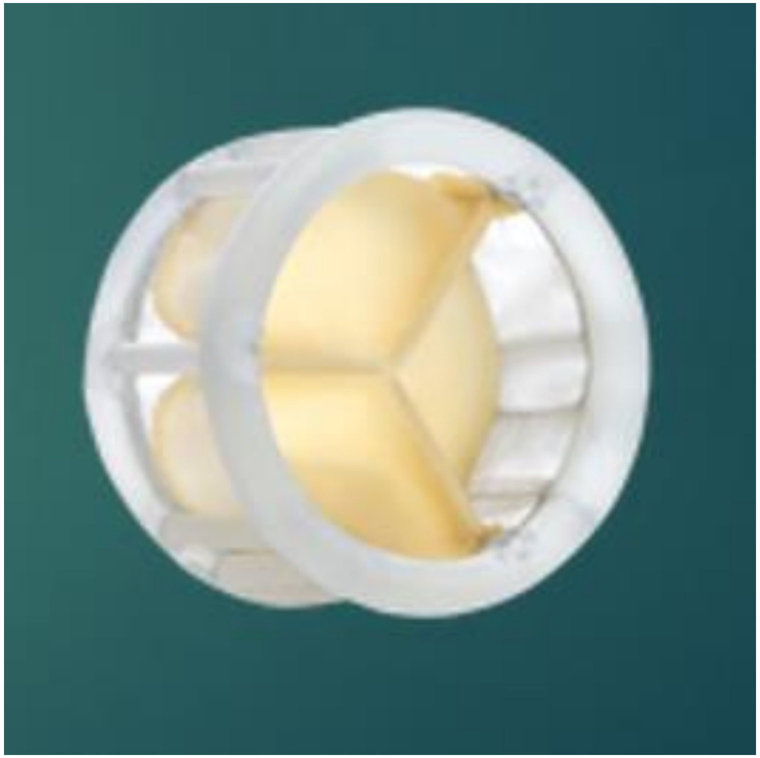

Enhanced frame design
• New frame geometry
• High radial strength
Bovine pericardial tissue
• New leaflet shape
• Carpentier-Edwards ThermaFix* process for anti-calcification
New outer skirt

DIRECT FLOW

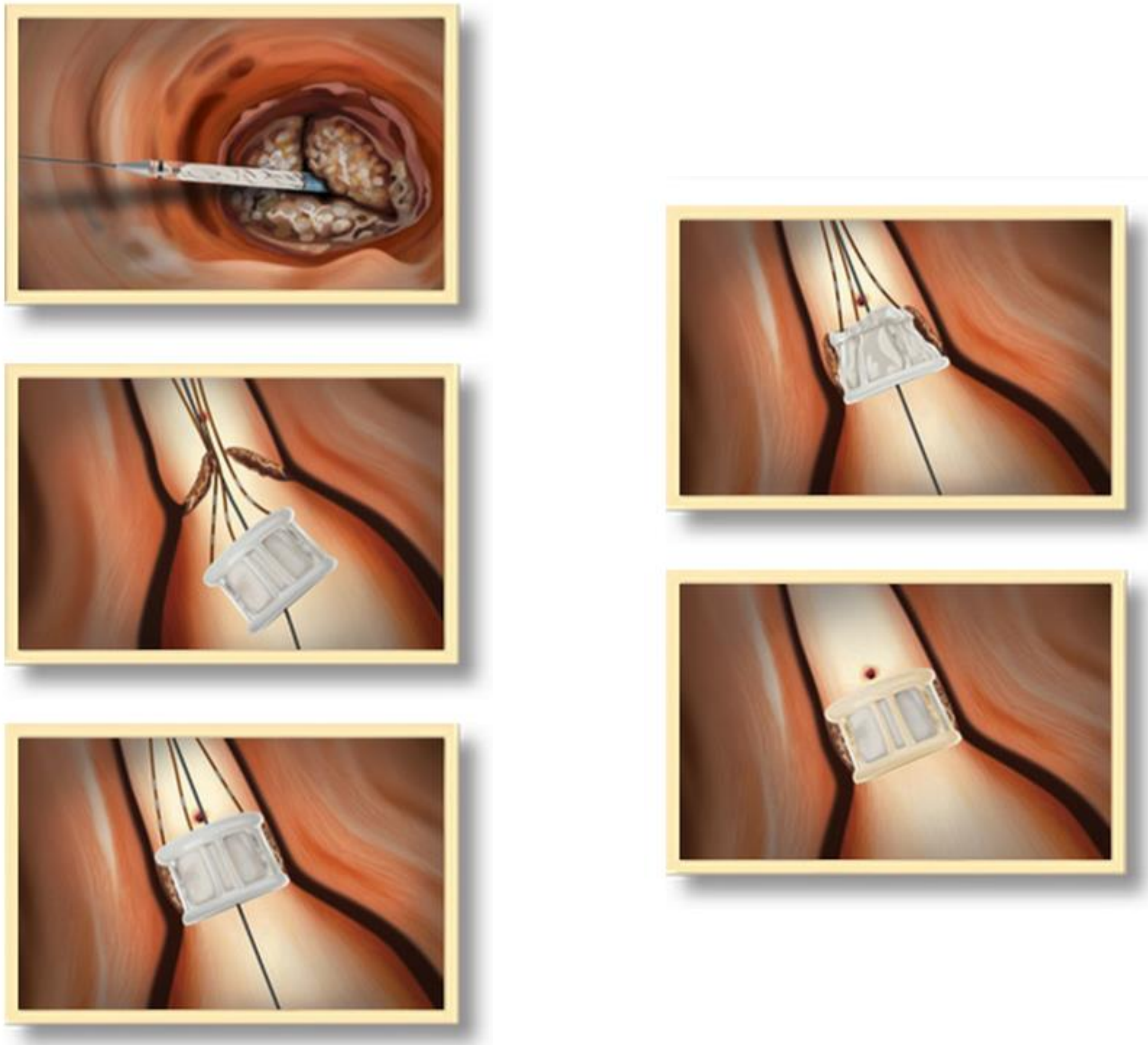


Double Ring design. Full thickness bovine pericardial tissue.
Large area of coaptation for sealing in irregular shapes and conditions
Stress relief attachment to secure and add durability
Sealing rings to prevent aortic regurgitation and provide long term in-growth, sealing, and stabilization

DIRECT FLOW

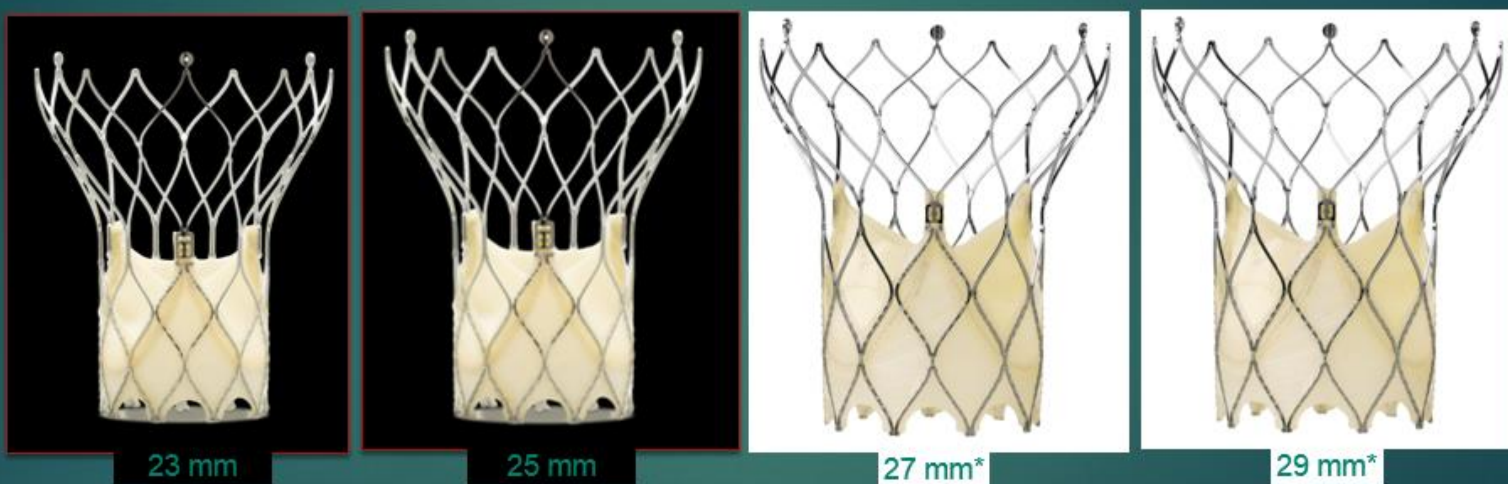


Direct Flow



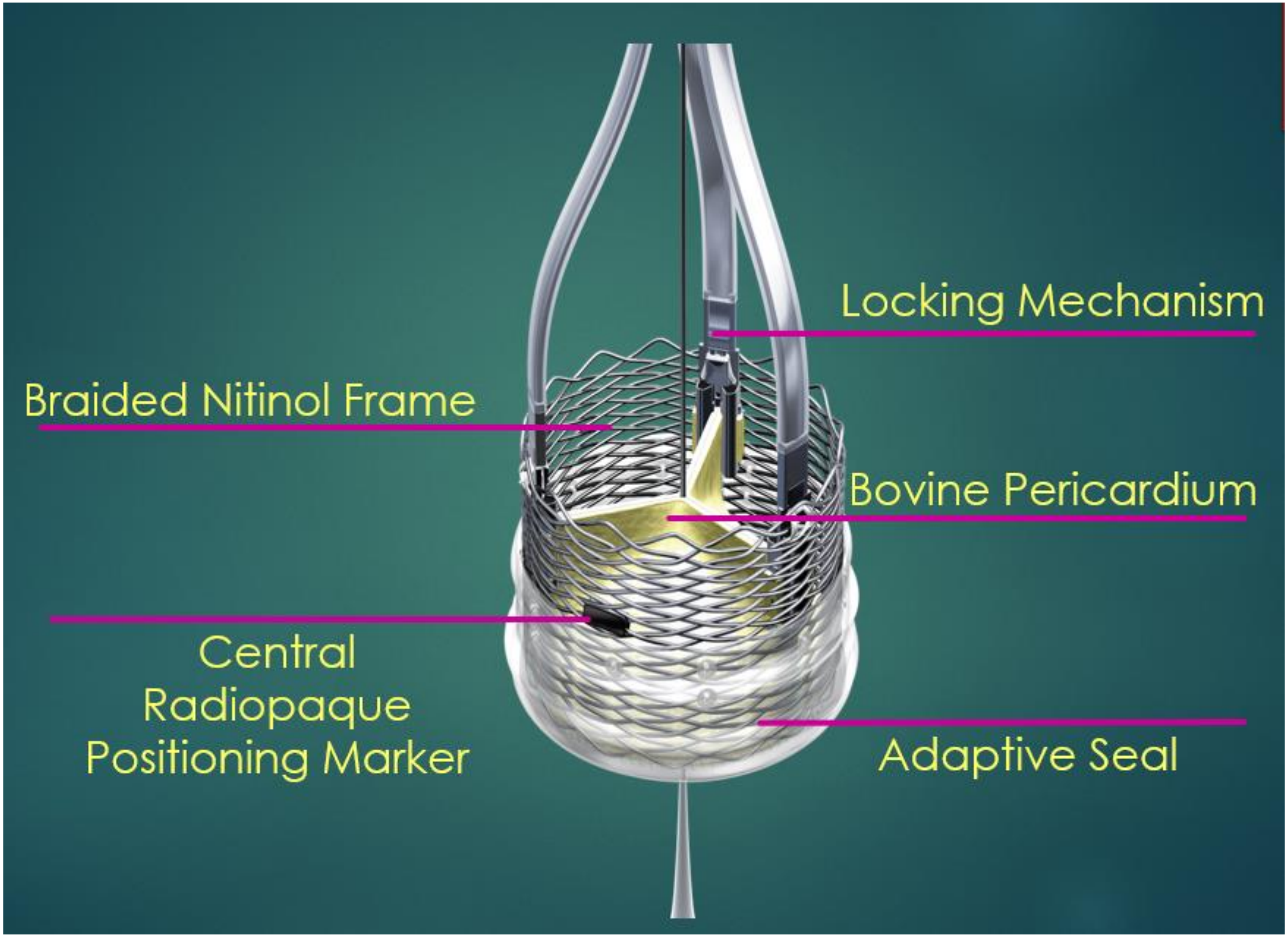
PORTICO

- Treats annulus range from 19-27 mm*
- Bovine pericardial valve with porcine cuff
- Fully retrievable, repositionable and resheathable

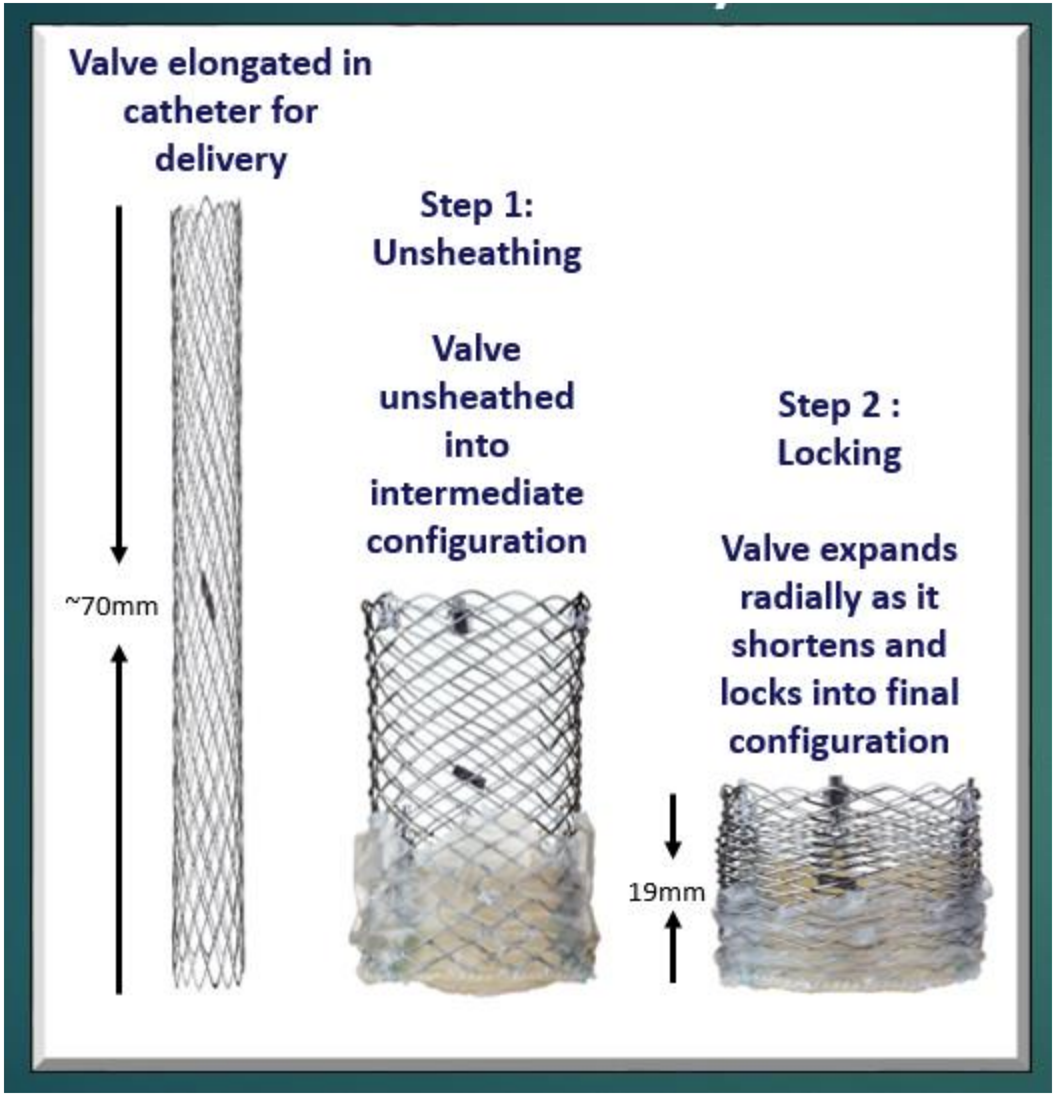


Patient Annulus (mm)	19	20	21	22	23	24	25	26	27
Use Range (mm)	23		25		27		29		

Lotus


Locking Mechanism
Braided Nitinol Frame
Bovine Pericardium
Central
Radiopaque
Positioning Marker
Adaptive Seal

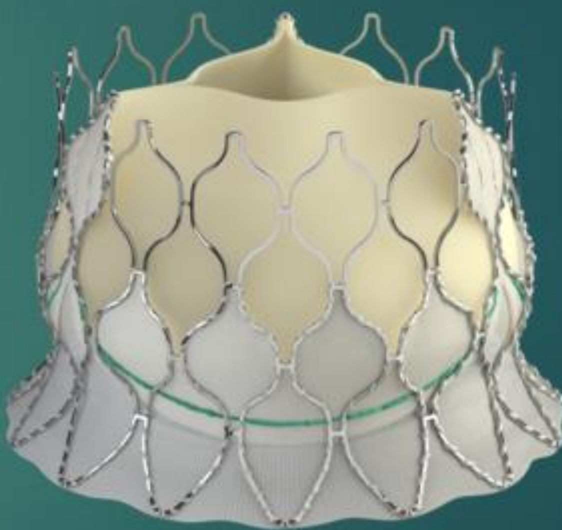
Lotus



Valve elongated in catheter for delivery
~70mm
Step 1: Unsheathing
Valve unsheathed into intermediate configuration
Step 2 : Locking
Valve expands radially as it shortens and locks into final configuration
19mm

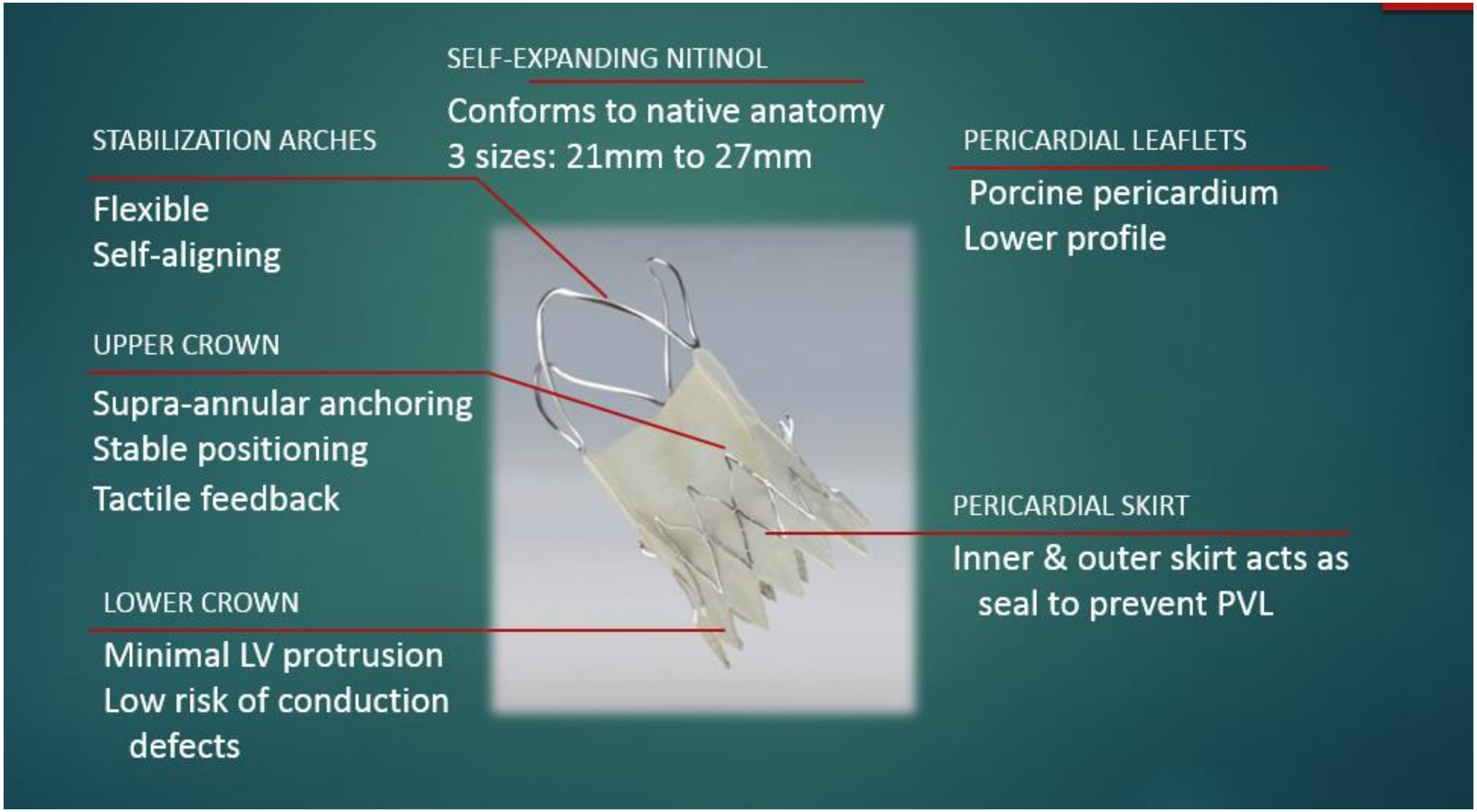
EDWARDS CENTERA

- Self-expanding nitinol frame
- Treated bovine pericardium
- Contoured frame designed for optimal seating and sealing in the annulus
- Low frame height designed to minimize conduction disturbances
- Repositionable
- 23 mm, 26 mm, 29 mm sizes



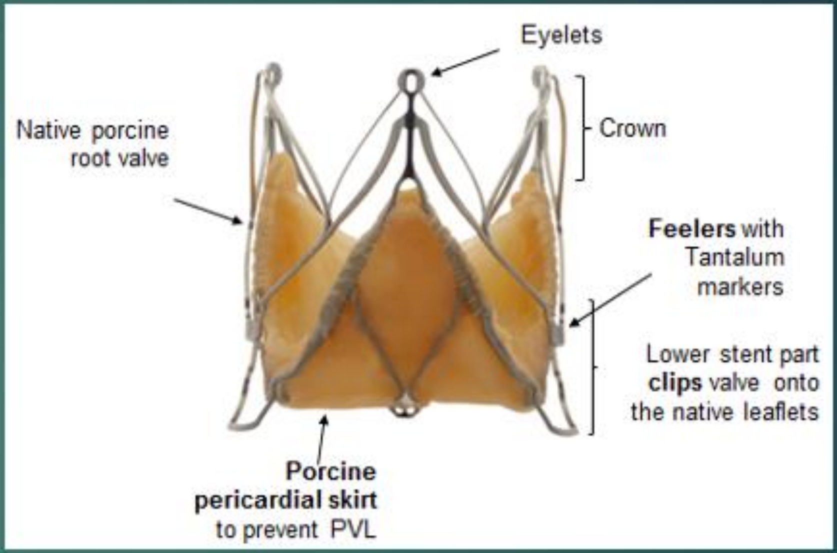
Engager

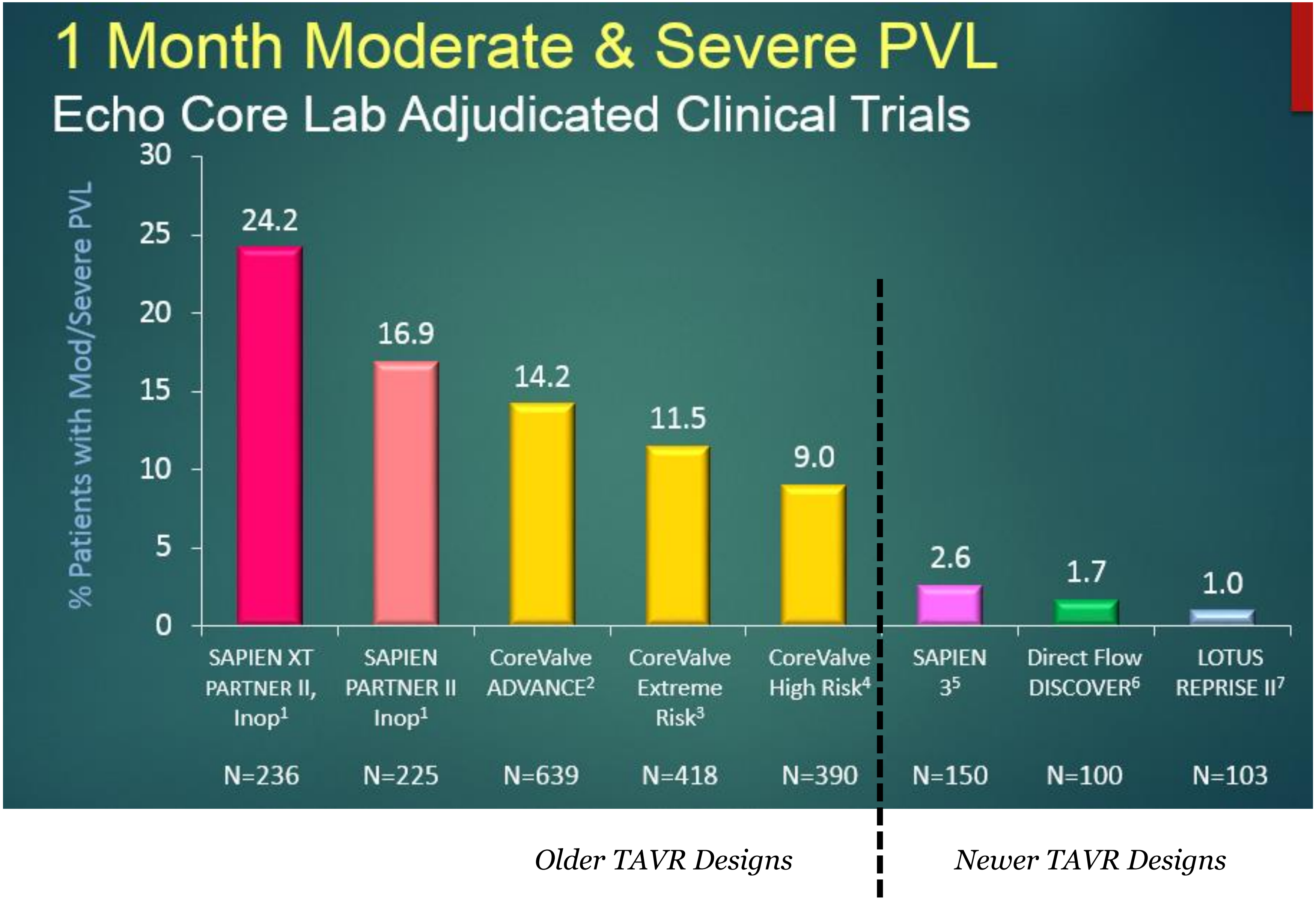
Symetis Acuarate



JENA VALVE

Access Route	Transapical
Deployment	Self Expanding
Stent Material	Nitinol Stent
Valve Material	Native Porcine Valve
Skirt Material	Porcine Pericardium
Sizes	23, 25, 27 mm
Annuli Range	21-27 mm
CE Approval	CE-Mark for treatment of AS and AR




1 Month Moderate & Severe PVL
Echo Core Lab Adjudicated Clinical Trials
% Patients with Mod/Severe PVL
30
25
20
15
10
5
0
24.2
16.9
14.2
11.5
9.0
2.6
1.7
1.0
SAPIEN XT PARTNER II, Inop1
SAPIEN PARTNER II Inop1
CoreValve ADVANCE2
CoreValve Extreme Risk3
CoreValve High Risk4
SAPIEN 35
Direct Flow DISCOVER6
LOTUS REPRISE II7
N=236
N=225
N=639
N=418
N=390
N=150
N=100
N=103
Older TAVR Designs
Newer TAVR Designs

Thank You!

New York University Medical Center