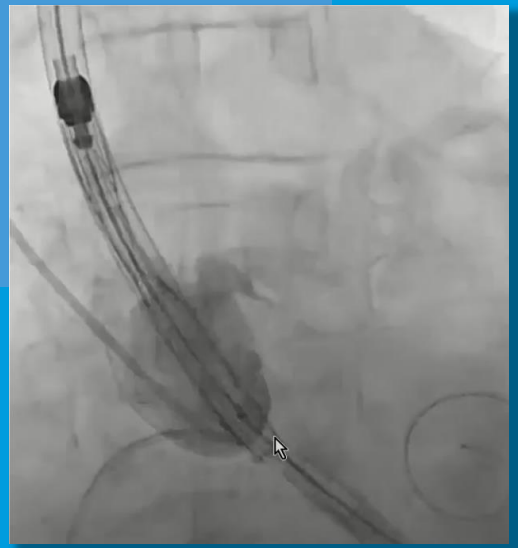
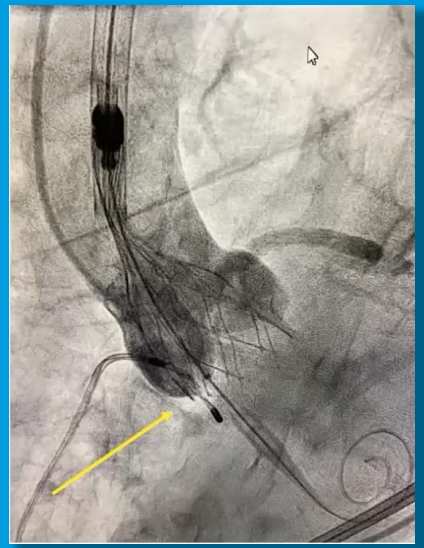
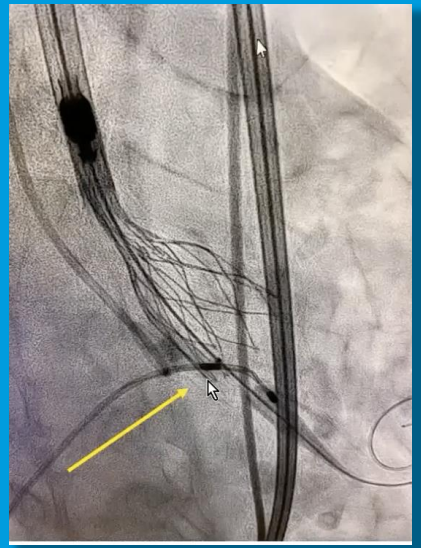
Valvula Navitor Abbott







Dr. PhD Carlos Fernandez Pereira.

Fellow American College Cardiology
Fellow European Society Cardiology
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Sistema de liberación Flexnav

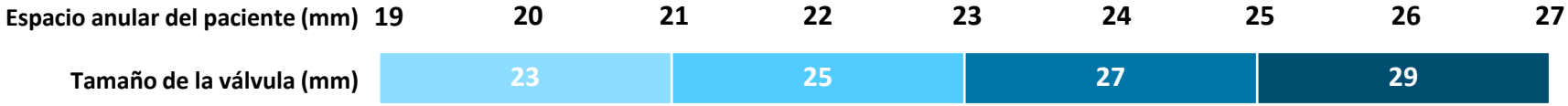
VÁLVULA PORTICO

- Celdas abiertas grandes que minimizan la obstrucción del flujo sanguíneo coronario y conservan el acceso coronario[1,2]
- Stent autoexpandible de nitinol: totalmente recapturable*, reposicionable* y recuperable*
- Funcionalidad temprana de la válvula que brinda estabilidad hemodinámica durante toda la liberación
- Más de 18.000 implantes realizados hasta la fecha con la válvula Portico

SISTEMA DE LIBERACIÓN FLEXNAV

- Sistema flexible en 3D y con capacidad de liberación y empuje a través de anatomías complicadas y complejas
- Bajo perfil, introductor integrado, equivalente a 14/15 French
- Capa de estabilidad para una colocación precisa
- El recubrimiento hidrofílico reduce la fricción en un 98 %

Portico Valve Size	Annulus Range (mm)	Area (mm^2)	Perimeter (mm)
23 mm	19-21	277-346	60-66
25 mm	21-23	338-415	66-73
27 mm	23-25	405-491	72-79
29 mm	25-27	479-573	79-85



RECUBRIMIENTO HIDRÓFILICO

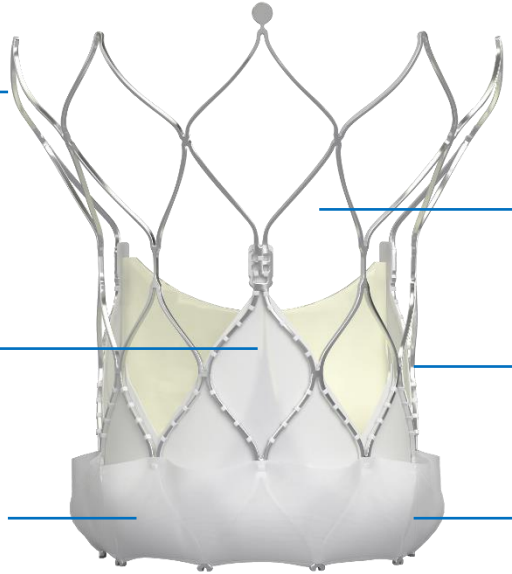
PUNTA ATRAUMÁTICA

Navitor™ Overview

Celdas con curvas
Reduce riesgo de daño estructures nativas

NaviSeal™ Cuff Interno
Mantiene el bajo perfil y mejora la durabilidad

NaviSeal Cuff Externo
sincroniza activamente con el ciclo cardiaco para sellar y mitigar leak



Diseño de Celdas Grandes
Minimiza obstruccion coronaria obstruction y mejora el acceso y flujo corornario

Fuerza radial Optima
expansion, anclaje, estabilidad y sellado

Zona de Sellado aumentado
Disminuye leak

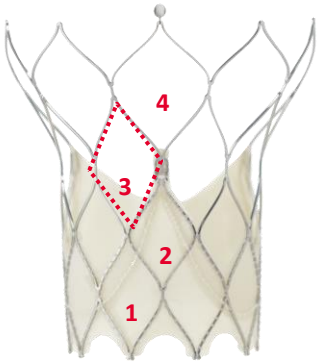
Rango de tratamiento del anillo
19 mm a 27 mm diametro del anillo

Preservación del **acceso coronario**

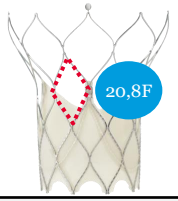
PORTICO/NAVITOR CELDAS GRANDES

- La celda de una válvula Portico™ tiene **un área que es aproximadamente un 573 %† mayor** que una celda de válvula Evolut‡ R/PRO[1]
- La celda de una válvula Portico™ tiene **un área que es aproximadamente un 56 %†† mayor** que el grupo de celdas de la válvula Evolut‡ R/PRO que rodea a la coronaria[1]
- El tamaño de la celda del stent de Portico es **20,8 F en comparación con 11,9 F** de la válvula Evolut R/PRO (tamaño de válvulas: 29 mm)[2]

Área de las celdas del stent

Válvula[1] Portico™ de 29 mm	Evolut‡ R/PRO[1] de 29 mm
	

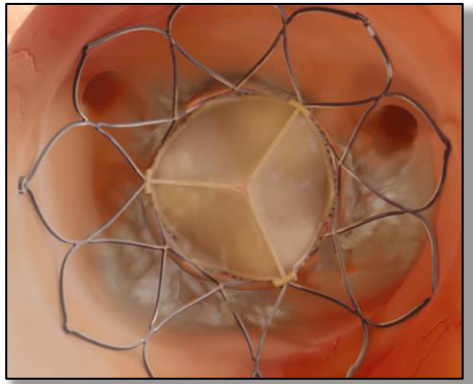
Número y tamaño de las celdas del stent

	Válvula[2] Portico™ de 29 mm	Evolut‡ R/PRO[2] de 29 mm
		
	• 36 celdas en total • 9 celdas en la sección del espacio anular del stent	• 135 celdas en total • 15 celdas en la sección del espacio anular del stent
	13,5 F (4,5 mm)	12,1 F (4,0 mm)
mm/26 mm	15,8 F (5,3 mm)	11,8 F (3,9 mm)
29 mm	20,8 F (6,9 mm)	11,9 F (4,0 mm)

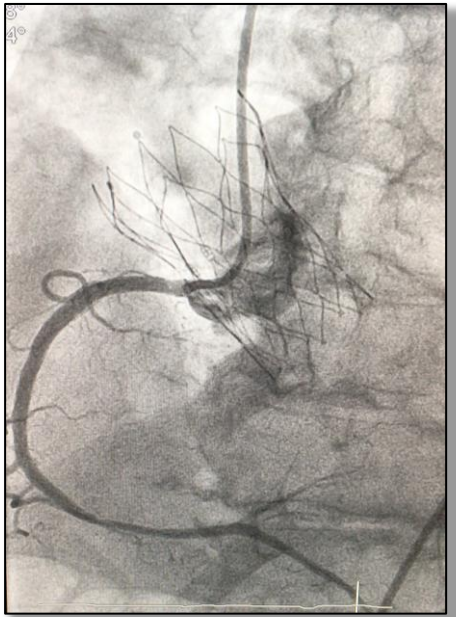
Conservación del acceso coronario

LA GEOMETRÍA DE CELDAS ABIERTAS DE GRAN TAMAÑO Y LA POSICIÓN DE LA VÁLVULA INTRAANULAR MINIMIZAN LA OBSTRUCCIÓN DEL FLUJO SANGUÍNEO CORONARIO PERMITE UN MEJOR ACCESO CORONARIO PARA INTERVENCIONES FUTURAS

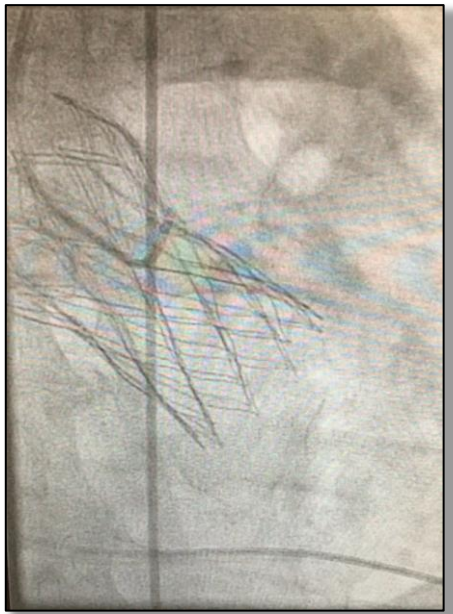
LOS GRANDES DIÁMETROS DE LAS CELDAS DEL STENT (DE 13,5 A 20,8 FRENCH) CONSERVAN EL ACCESO CORONARIO[3]



ACCESO CORONARIO DERECHO



ACCESO CORONARIO IZQUIERDO



Estudios Clinicos

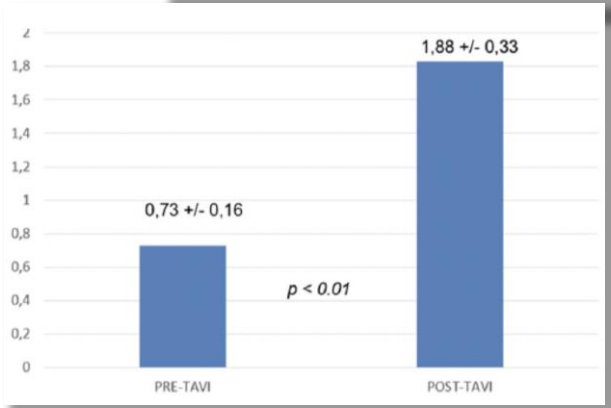
Experiencia con el implante valvular aórtico con la válvula autoexpandible Portico: resultados hospitalarios, a 30 días y en el seguimiento alejado de una serie consecutiva de pacientes

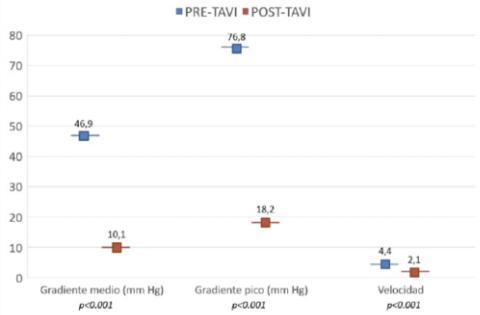
Experience with aortic valve implantation with the Portico self-expanding valve: in-hospital results, 30 days and long term follow-up of a consecutive series of patients

Carlos Fernández-Pereira[1,3,4], Juan Mieres[1,2], Hernán Pavlovsky[1,3], A. Matías Rodríguez-Granillo[1,3,4], Diego Azcarrunz-Catoretti[1,2], Carolina Salvatori [7], Norberto G. Allende[6], Valeria Curotto[5], Ricardo Pérez de la Hoz[5], Alfredo E. Rodríguez[1,2,3,4]

Eventos intrahospitalarios (procedimiento y 30 días de seguimiento) n=40	
	% (n)
Muerte de cualquier causa, %	7,5 (3/40)
Muerte cardiovascular, %	7,5 (3/40)
Accidente cerebrovascular (ACV) menor, %	5,0 (2/40)
Complicaciones vasculares severas, %	15,0 (6/40)
Taponamiento cardíaco, %	5,0 (2/40)
MACE, %	25 (10/40)
Nuevo bloqueo completo de rama izquierda, %	27,5 (11/40)
Requerimiento de marcapasos transitorio, %	20,5 (8/40)
Requerimiento de marcapasos definitivo, %	12.5 (5/40)

Variable	N
Número de pacientes	40
Edad, años	80,9±7,8
Abordaje femoral, %	97,5
Valve-in-valve, %	3
Número de válvula 23, %	20,0
Número de válvula 25, %	25,0
Número de válvula 27, %	22,5
Número de válvula 29, %	32,5
Posdilatación, %	5,02
Cantidad de contraste utilizado, ml	226±65
Creatinina preprocedimiento, mg/dl	1,1±0,3
Creatinina posprocedimiento (48 hs), mg/dl	1,2±0,8
Tiempo de fluoroscopia, min	29,3±12,6
Días de internación	5,8±6,1
Implante exitoso, %	100



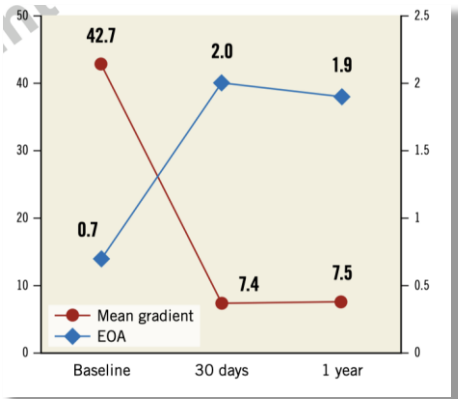


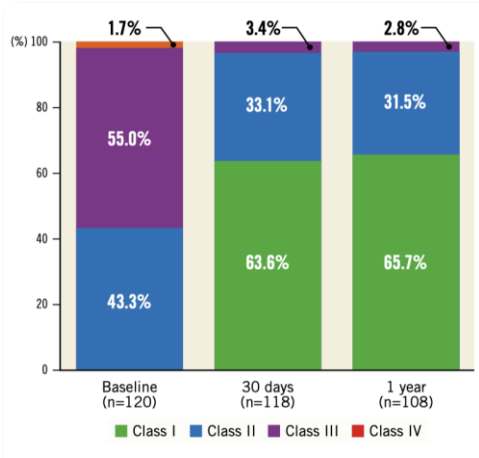
Revista Argentina de Cardioangiología Intervencionista 2021;12(4):213-217.

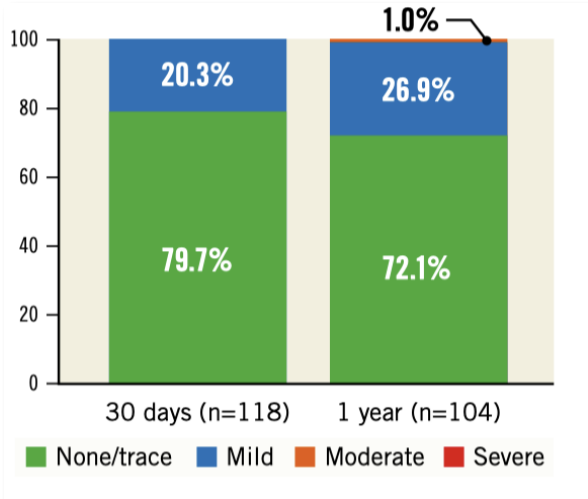
Thirty-day and one-year outcomes of the Navitor transcatheter heart valve in patients with aortic stenosis: the prospective, multicentre, global PORTICO NG Study

Lars Sondergaard[1]*, MD; Antony S. Walton[2,3], MD; Stephen G. Worthley[4], MD; Dave Smith[5], MD; Bassem Chehab[6], MD; Ganesh Manoharan[7], MD; Gerald Yong[8], MD; Francesco Bedogni[9], MD; Nicholas Bates[10], PhD; Michael J. Reardon[11], MD

Procedural outcomes	N=120
Procedural success[a]	97.5%
Procedural mortality	0.0%
TAVI-in-TAVI	2.5%
Conversion to surgical aortic valve replacement	0.0%
No TAVI valve implanted	0.0%







Eurointervention 2023;18 march 2023

Study Overview

The PORTICO NG study is a prospective, multi-center, global, investigational study evaluating the safety and effectiveness of the Navitor™ transcatheter aortic valve in patients with symptomatic severe aortic stenosis and high or extreme surgical risk.

Subjects were enrolled at sites in the US, Europe and Australia

Follow-up visits at discharge, 30 days, 1 year and annually through 5 years

Primary endpoints

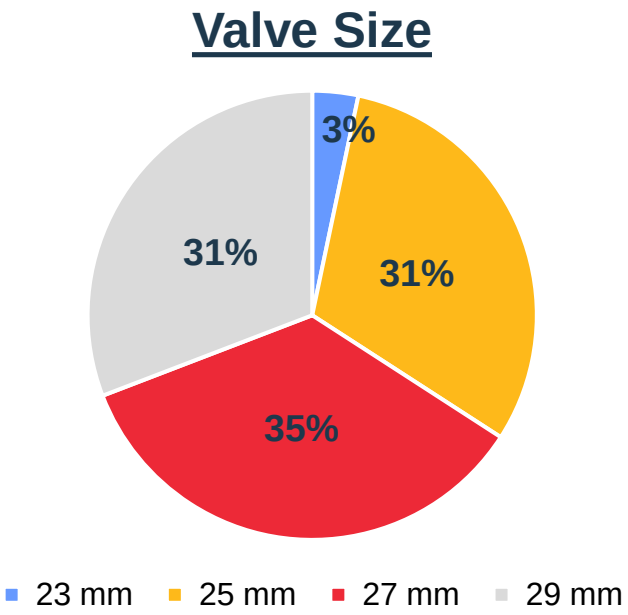
- All-cause mortality at 30 days
- Moderate or greater PVL at 30 days

Echoes are assessed by an independent core laboratory

Adverse events are adjudicated by a Clinical Events Committee

Baseline Demographics and Valve Size

Baseline Characteristics	N=120
Age (Years)	83.5
Gender (Female)	58.3%
NYHA class III and IV	56.7%
STS score	4.0%
Extreme Risk	18.3%
≥1 Frailty Factor	83.3%
Mean Gradient (mmHg)	42.7
Effective Orifice Area (cm^2)	0.7



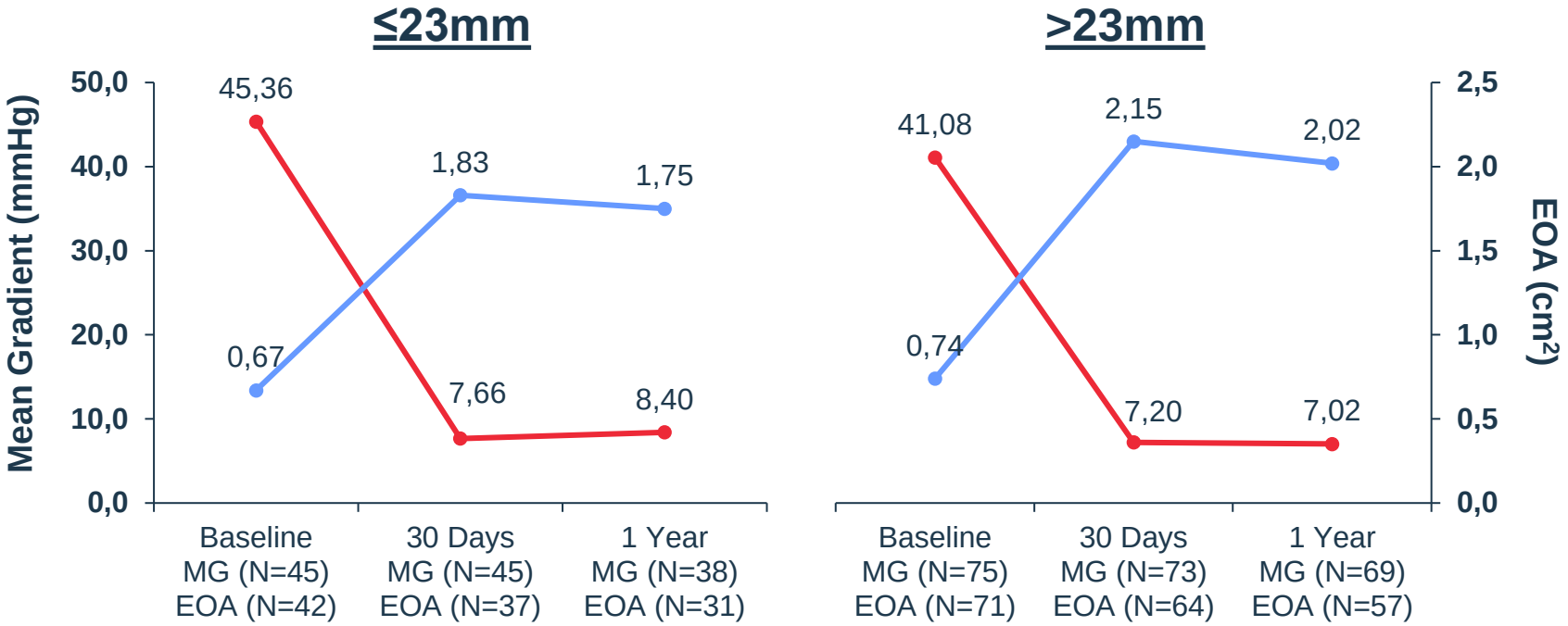
Smith, D. One-year outcomes from a next generation TAVI device with an active sealing cuff. Presented at EuroPCR 2022. May 17, 2022.

Key Outcomes

Key Outcomes	30-day	1-year
All-cause mortality	0.0%	4.2%
Disabling stroke	0.8%	0.8%
Life-threatening bleeding	2.5%	5.0%
Major vascular complications	0.8%	0.8%
Acute kidney injury (stage 2/3)	1.7%	1.7%
New pacemaker implantation	15.0%	16.8%
Mean Gradient (mmHg)	7.4	7.5
Effective Orifice Area (cm^2)	2.0	1.9

Smith, D. One-year outcomes from a next generation TAVI device with an active sealing cuff. Presented at EuroPCR 2022. May 17, 2022.

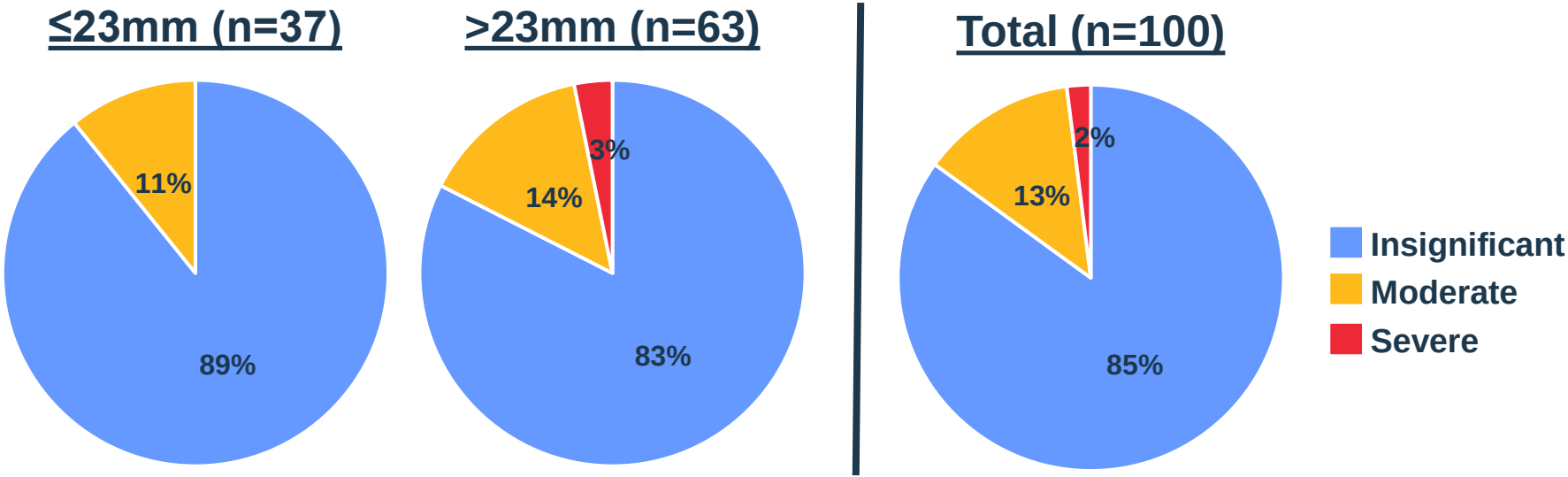
Hemodynamics by Native Annular Diameter



Single-digit mean gradients and large EOAs are observed in both small and large aortic annuli

Hemodynamics by Valve Size

Prosthesis-Patient Mismatch by Native Annular Diameter



No severe PPM observed in small aortic annuli; low incidence of severe PPM in large aortic annuli

Prosthesis-patient mismatch is calculated according to VARC-3 definitions.

Limitations

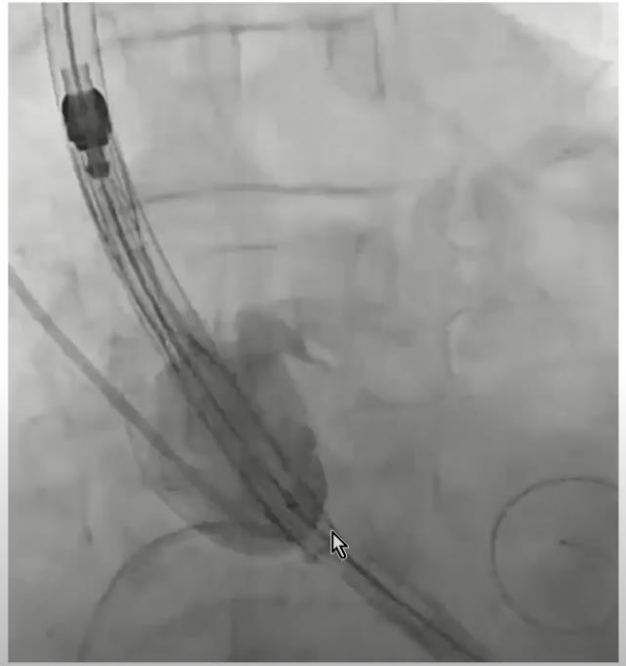
- Limited sample size for the 23mm valve
- Subjects included in the study were at high or greater surgical risk based on study inclusion and exclusion criteria

Conclusions

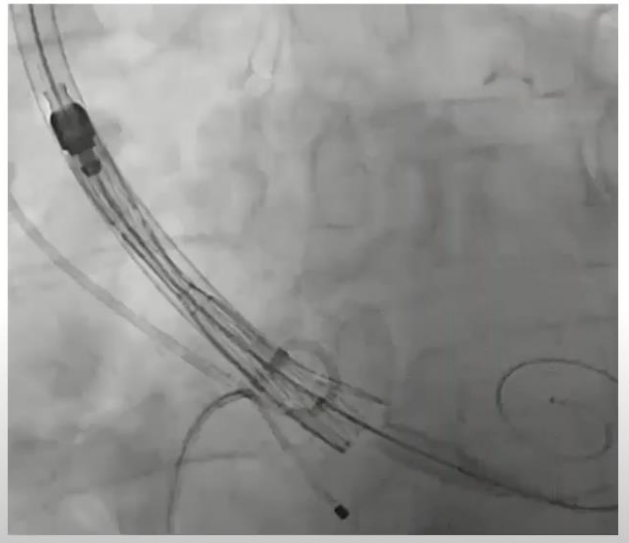
- The Navitor™ self-expanding, intra-annular THV demonstrated excellent hemodynamics through 1 year
  - Single-digit mean gradients and large EOAs in small and large native aortic annuli and across all valve sizes are observed
- Low incidence of prosthesis-patient mismatch (PPM) across both small and large annuli
  - No severe PPM observed in subjects with small native aortic annuli

Sistema de liberación Navitor

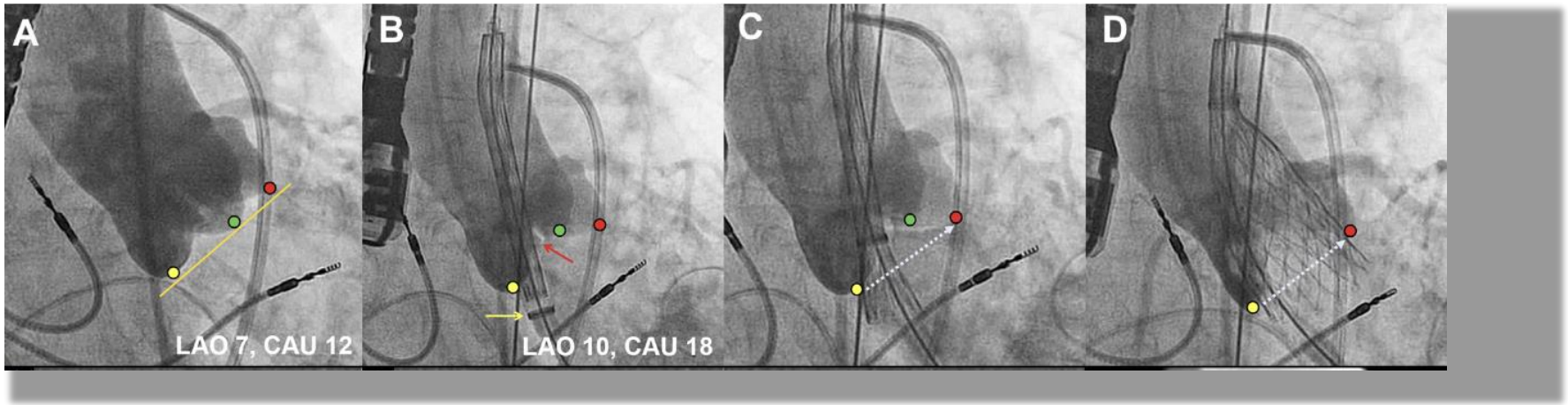
Good starting position



Starting position too low



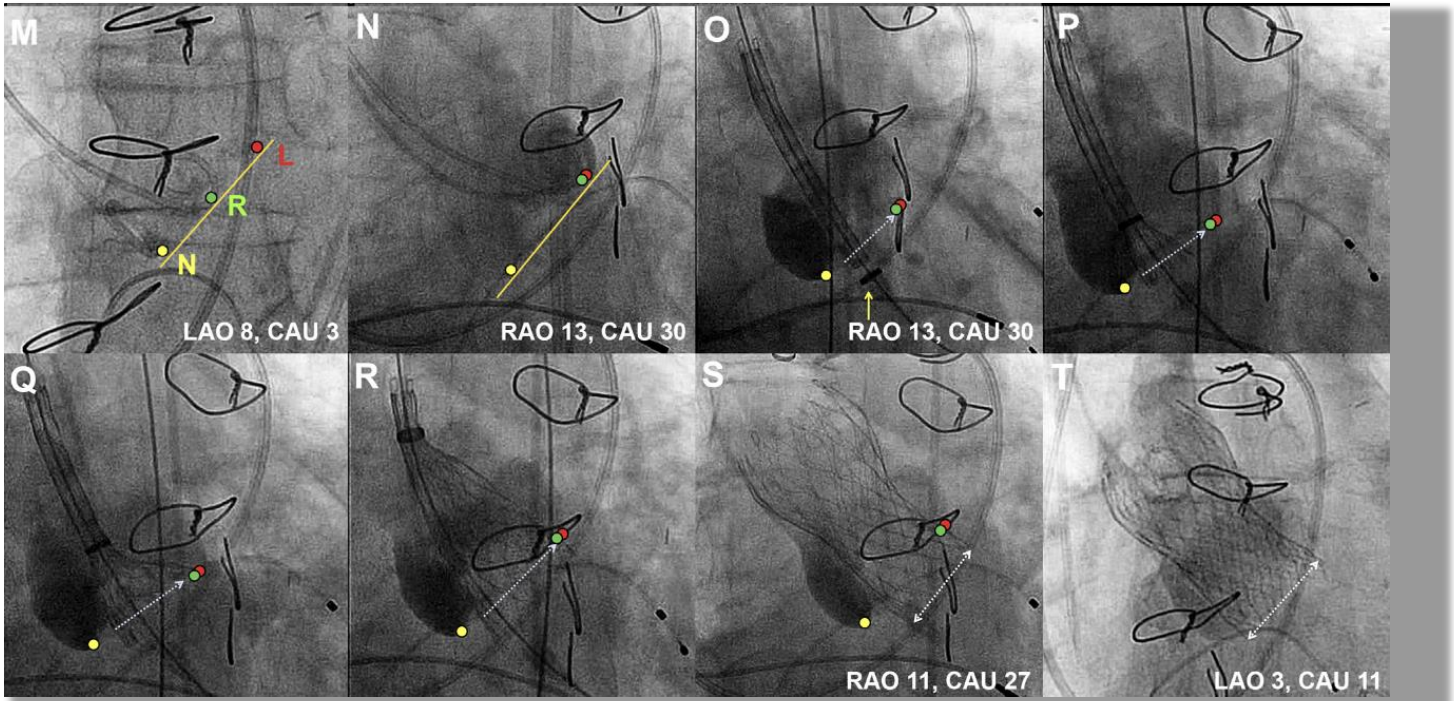
“Cusp-Overlap” View Simplifies Fluoroscopy-Guided Implantation of Self-Expanding Valve in Transcatheter Aortic Valve Replacement



“We believe this rule may simplify implantation of certain self-expanding valves, such as the Evolut R CoreValve and Portico”

Tang G et al. JACC: CARDIOVASCULAR INTERVENTIONS.VOL.11,16,2018 Letters.AUG 27,2018:1658–67.1663

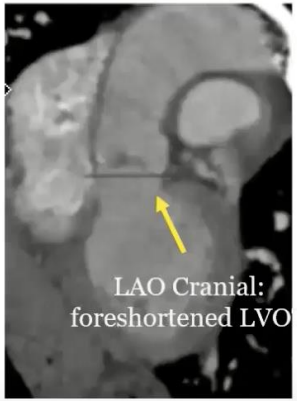
“Cusp-Overlap” View Simplifies Fluoroscopy-Guided Implantation of Self-Expanding Valve in Transcatheter Aortic Valve Replacement

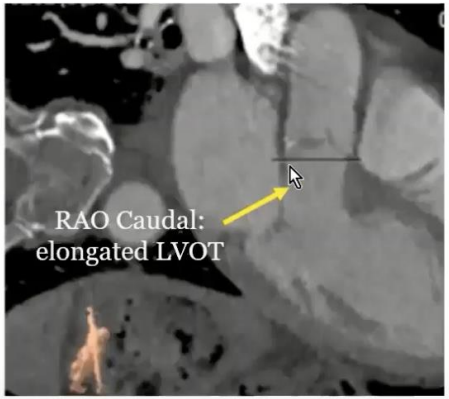


Tang G et al.J A C C : C A R D I O V A S C U L A R I N T E R V E N T I O N S V O L . 1 1 , N O . 1 6 , 2 0 1 8 Letters.A U G U S T 2 7 , 2 0 1 8 : 1 6 5 8 – 6 7.1663

Sistema de liberación Cusp over lap+OAI

Elongating LVOT in RAO Caudal (Cusp Overlap) View

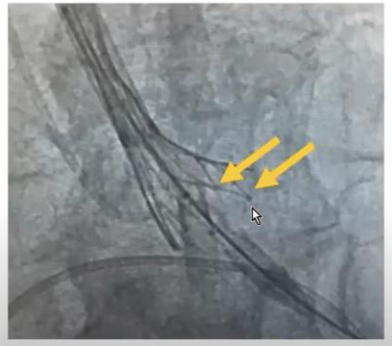




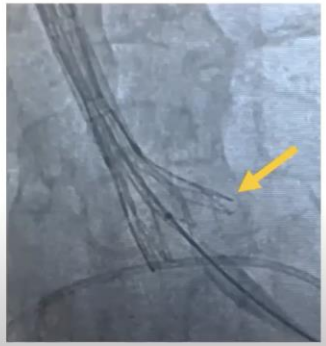
The LAO view can make the Valve appear higher than what it really is because it is foreshortened.

Align the Struts at every step, to know the real DEPTH

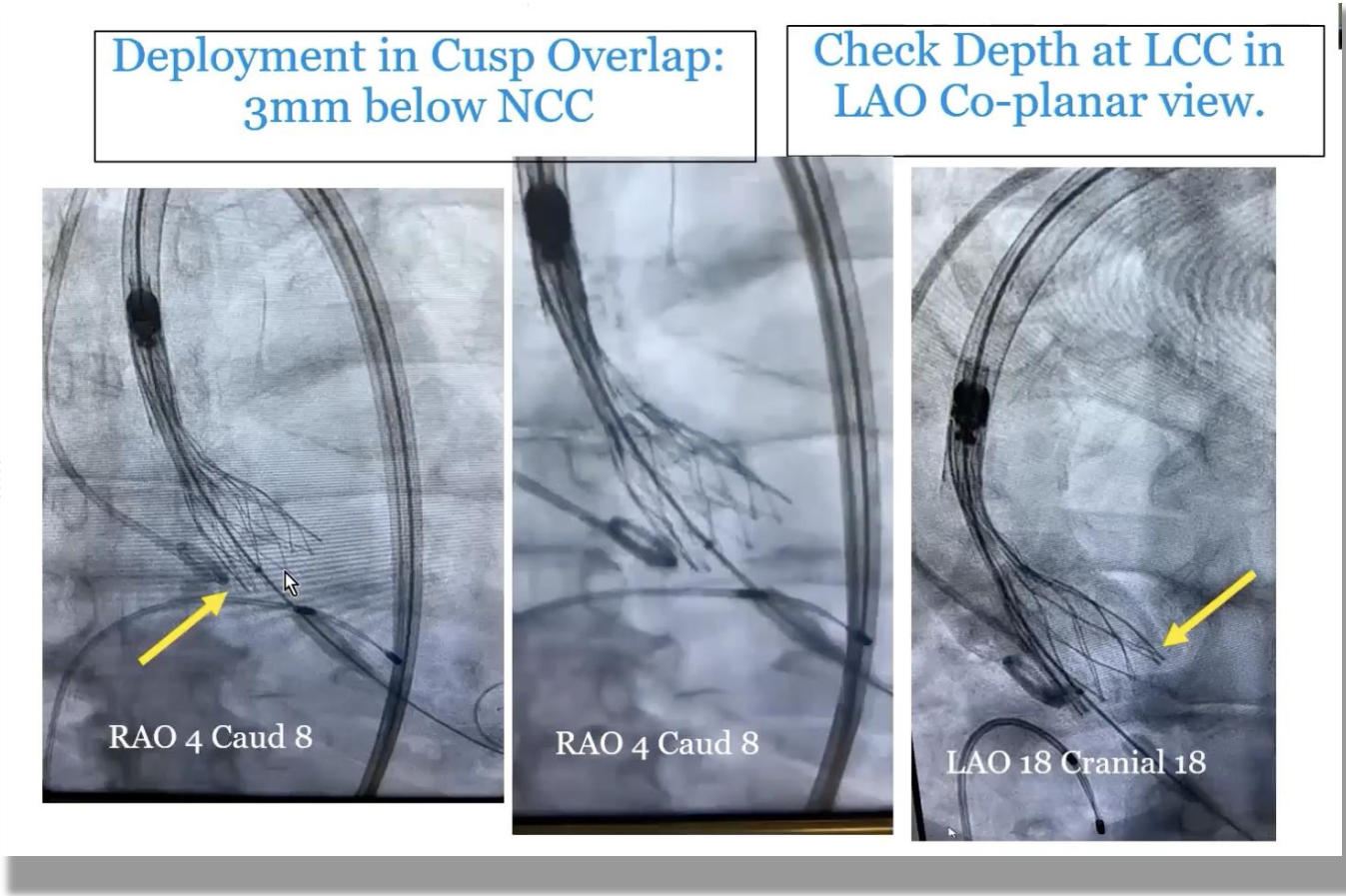
Struts not aligned



Struts aligned

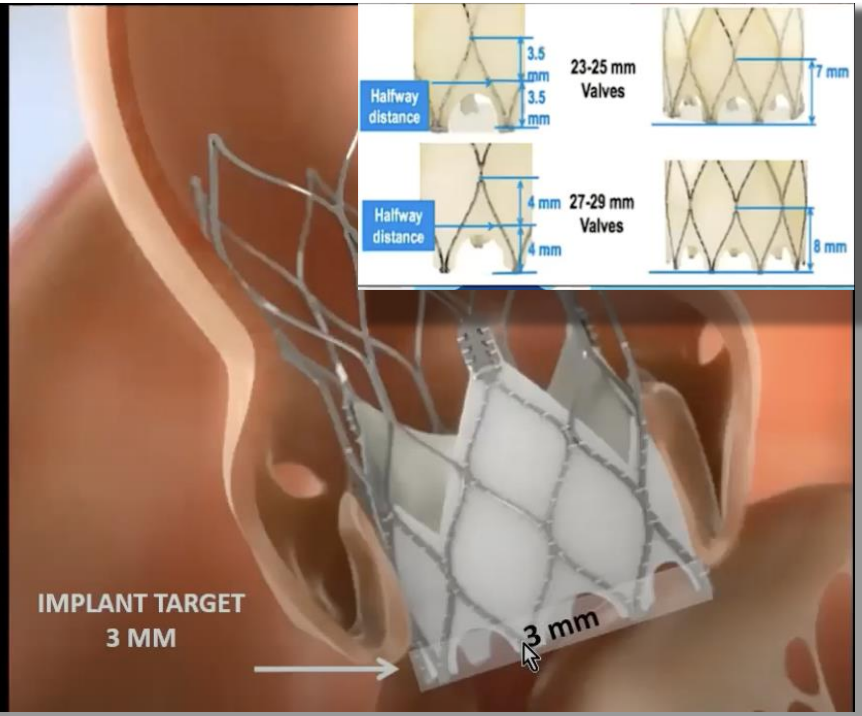


Sistema de liberación Navitor



Navitor :profundidad de liberacion

	VALVE SIZE	
	23/25 mm	27/29 mm
Ventricular Half-cell Height*[1]	7 mm	8 mm
Halfway Distance of Ventricular Half-cell Height	3.5 mm	4 mm
Implant Target Depth Below Annulus[1]	3 mm	3 mm



Navitor™ Valve caso 1 Argentina

Aortic Valve

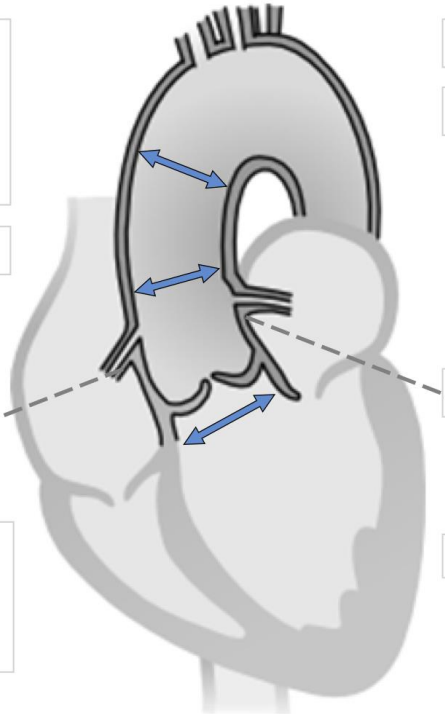
Aortic Annulus

Perimeter:	77.3	mm
Perimeter Derived Ø:	24.6	mm
Area:	467.7	mm²
Area Derived Ø:	24.4	mm

LVOT Ø: 24.0 mm

Asc. Aorta Ø: 36.6 mm

STJ Ø: 32.2 mm



RCA Height: 18.1 mm

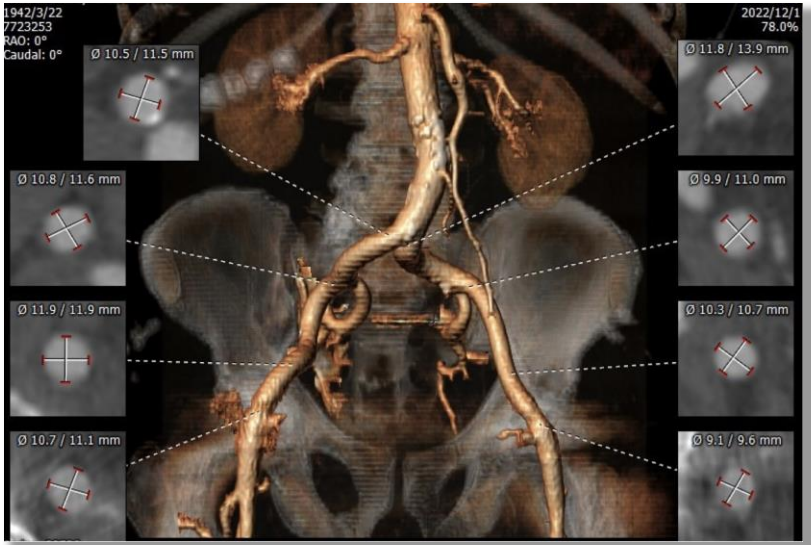
LCA Height: 15.7 mm

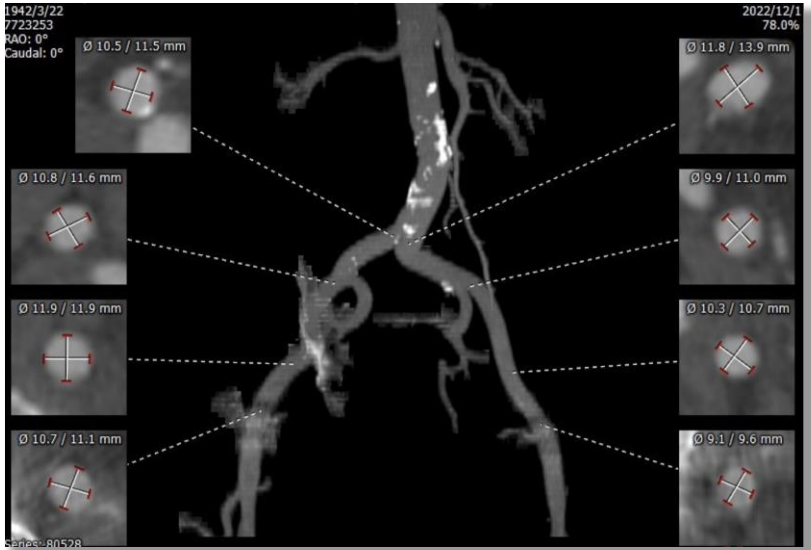
Sinus Of Valsalva Diameters:

Left:	36.9	mm
Right:	33.9	mm
Non:	34.3	mm

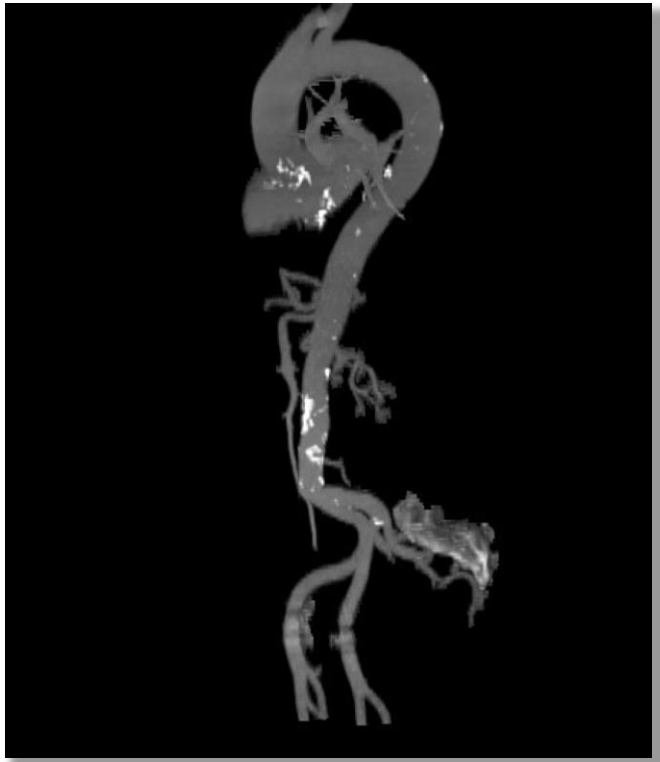
Aortic Valve Calcification: Mild

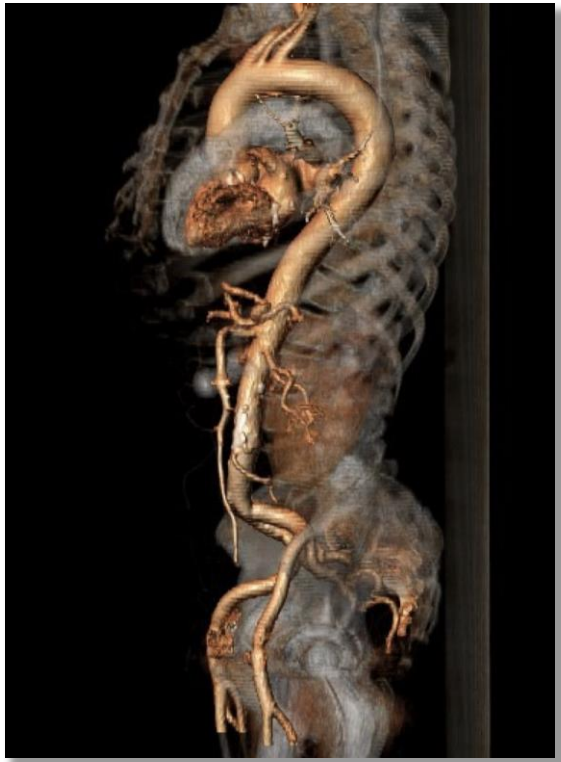
Navitor™ Valve caso 1 Argentina



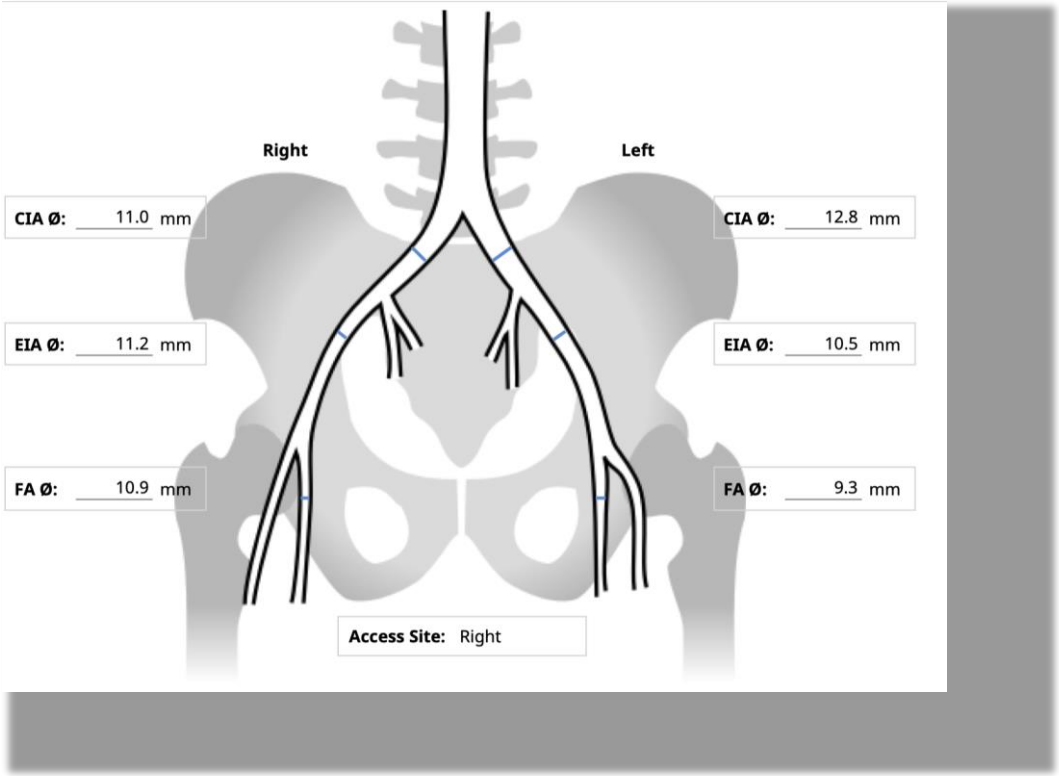


Navitor™ Valve caso 1 Argentina

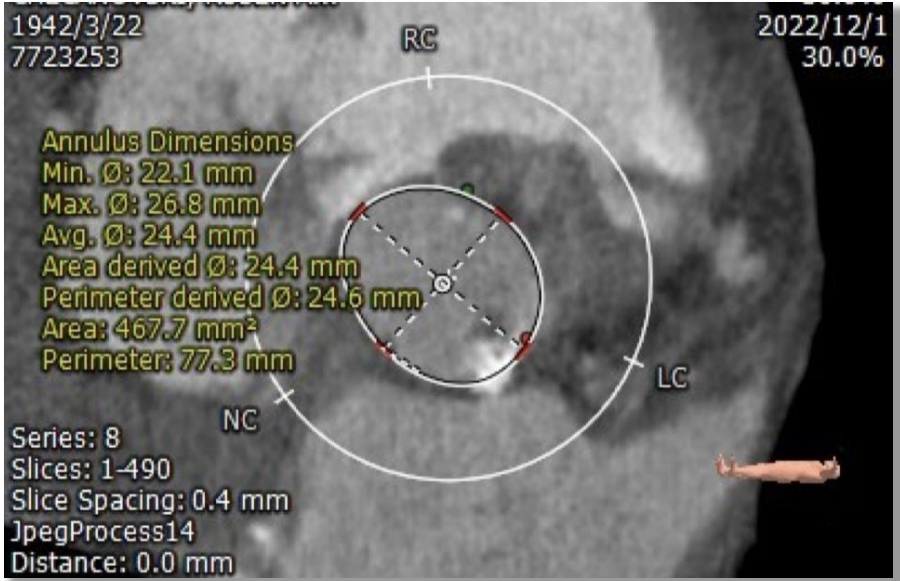


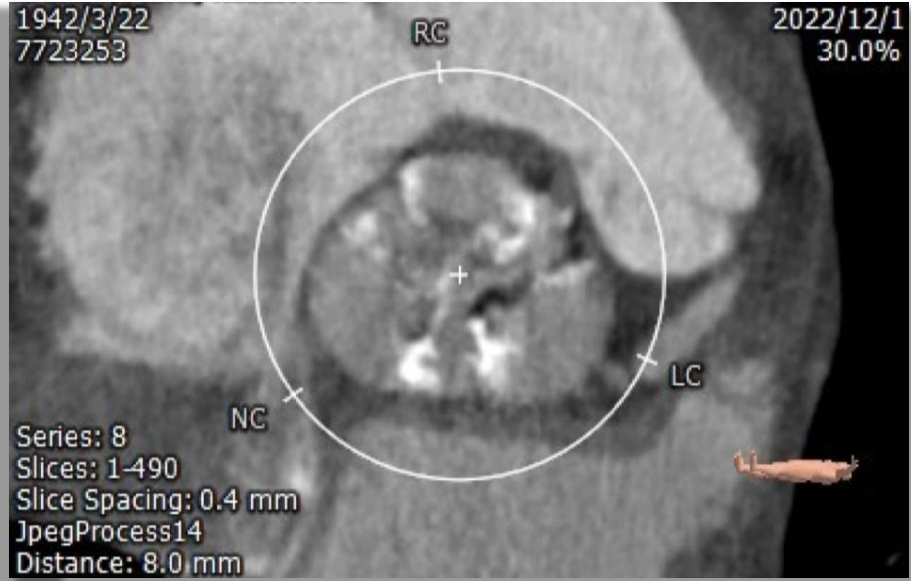


Navitor™ Valve caso 1 Argentina

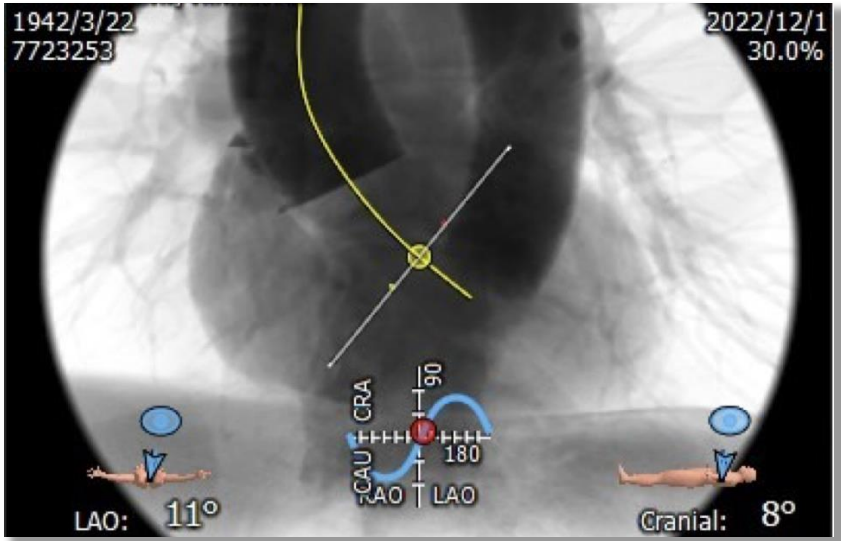


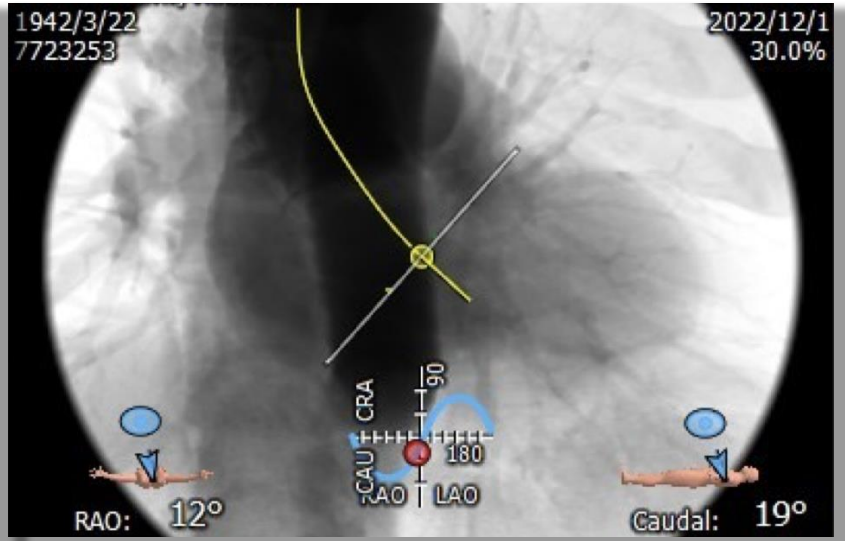
Navitor™ Valve caso 1 Argentina





Navitor™ Valve caso 1 Argentina





Navitor™ Valve caso 1 Argentina

Gender:	Male	**Weight:**	**kg**	**EuroSCORE II:**	**%**
Year Of Birth (Age):	1942 (80)	**BMI:**		**STS Score:**	**%**

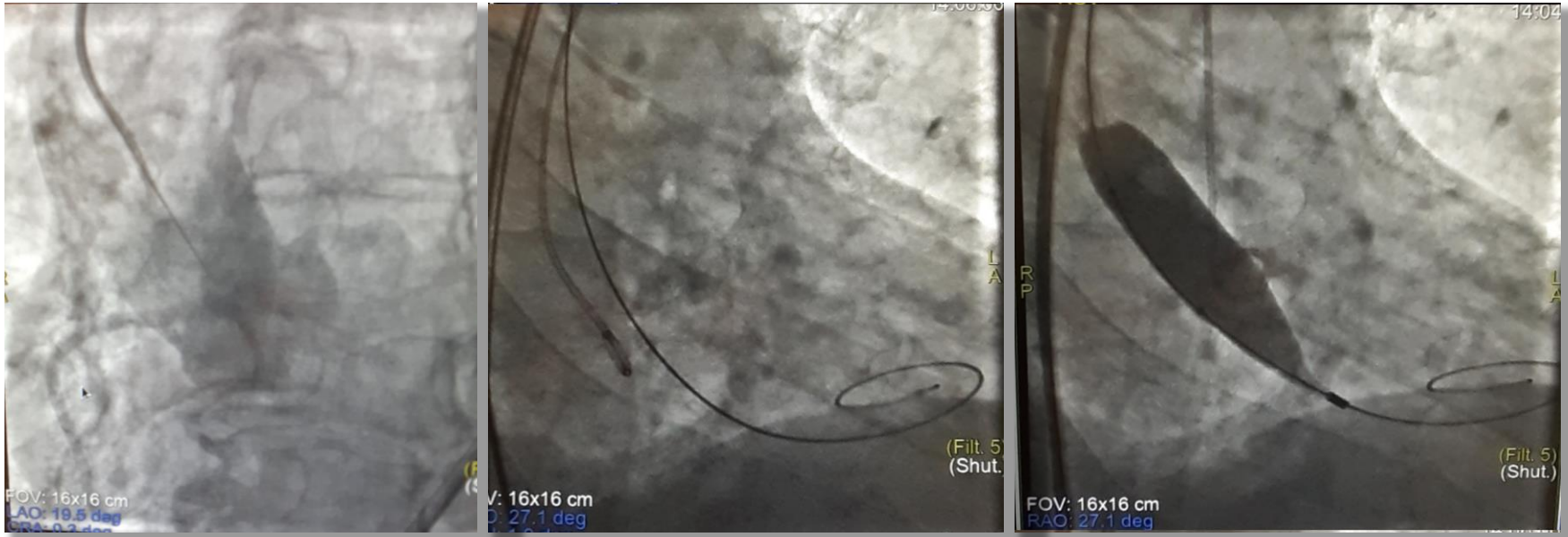
Comments: Systolic period

Aortic valve calcification：mild
The annulus perimeter: 77.3mm, the average diameter: 24.6mm.
LVOT perimeter: 74.7mm, the average diameter: 23.8mm.
22mm balloon and TAV27 valve is recommended.

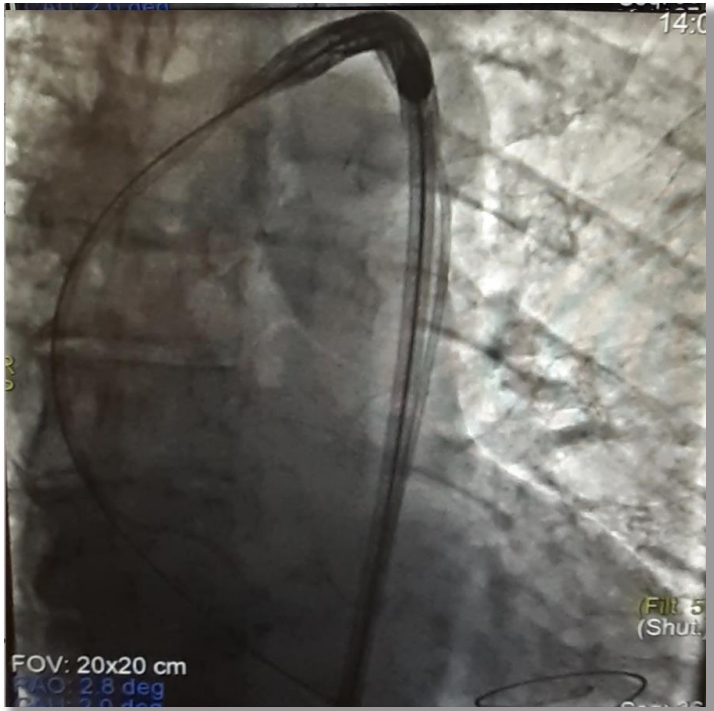
The min internal diameter of left femoral artery is 9.3mm. The min internal diameter of right femoral artery is 10.9mm.
The right femoral artery is recommended.
Integrated catheter sheath (for 2nd generation delivery system) is recommended.

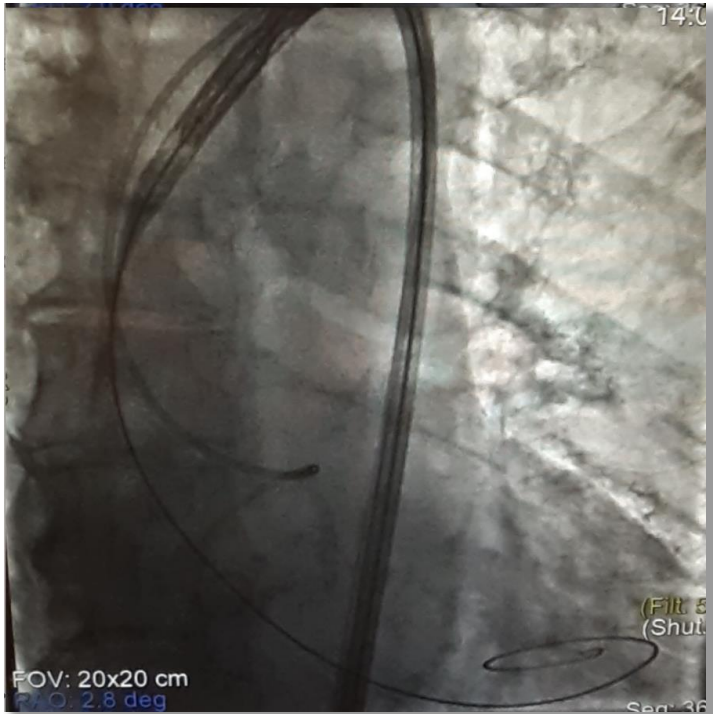
Risk:
1.The height of the LCA is good, the length of the leaflet is long the sinus width is good.
The height of the RCA is good, the length of the leaflet is good, the sinus width is good.
LCA and RCA has low risk.
2.Calcification extends from the annulus to the LVOT: 8.2mm. The risk of annulus rupture exists. Small balloon to predilate is recommended.

Navitor™ Valve caso 1 Argentina

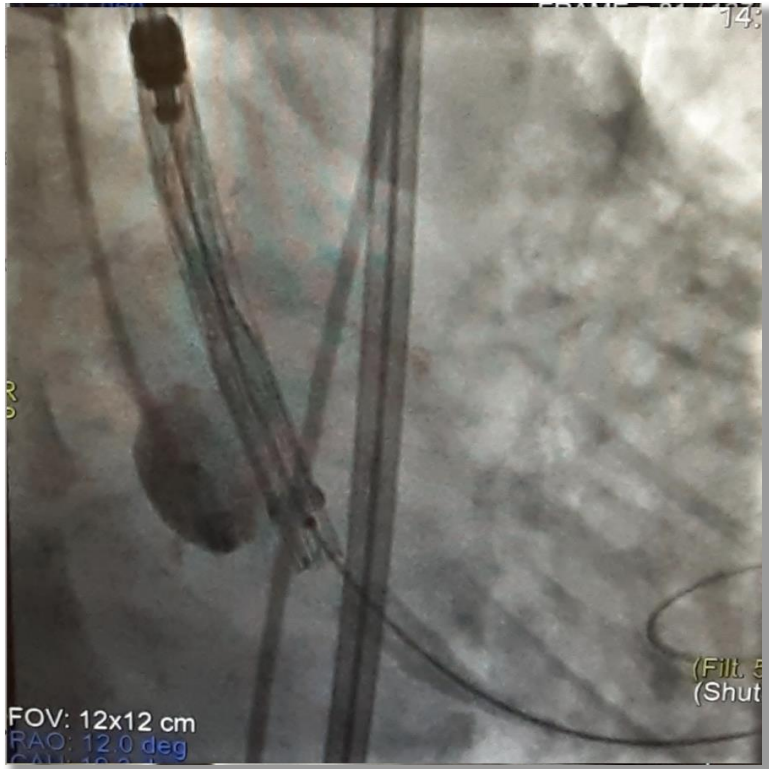


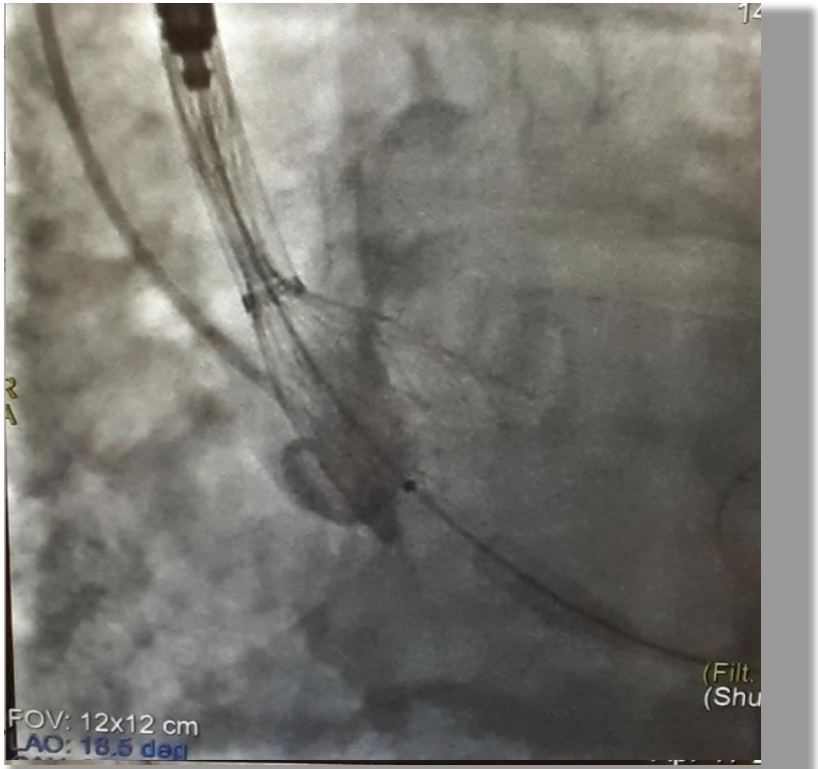
Navitor™ Valve caso 1 Argentina





Navitor™ Valve caso 1 Argentina





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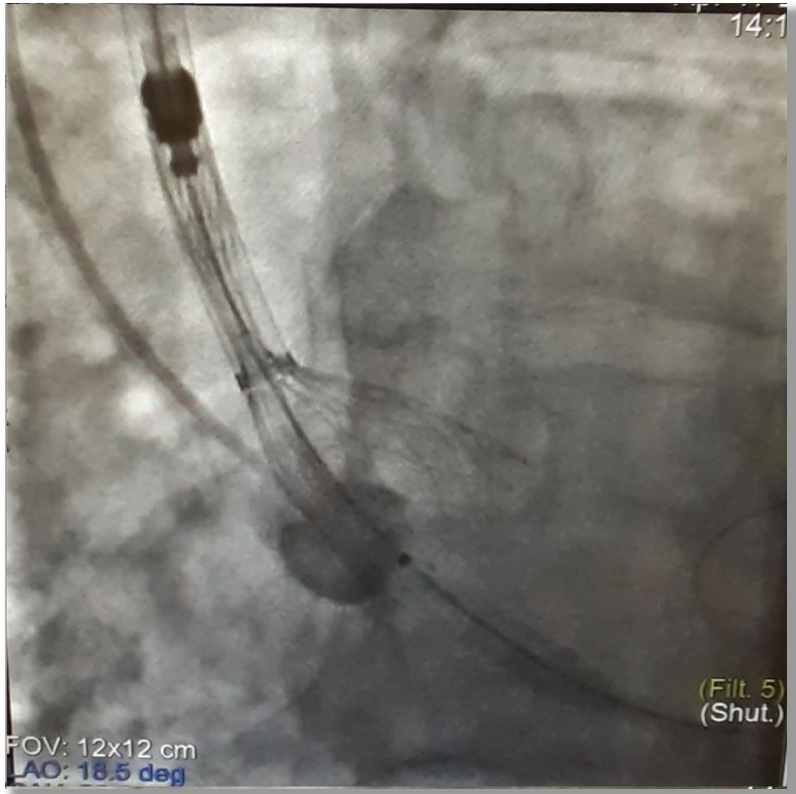

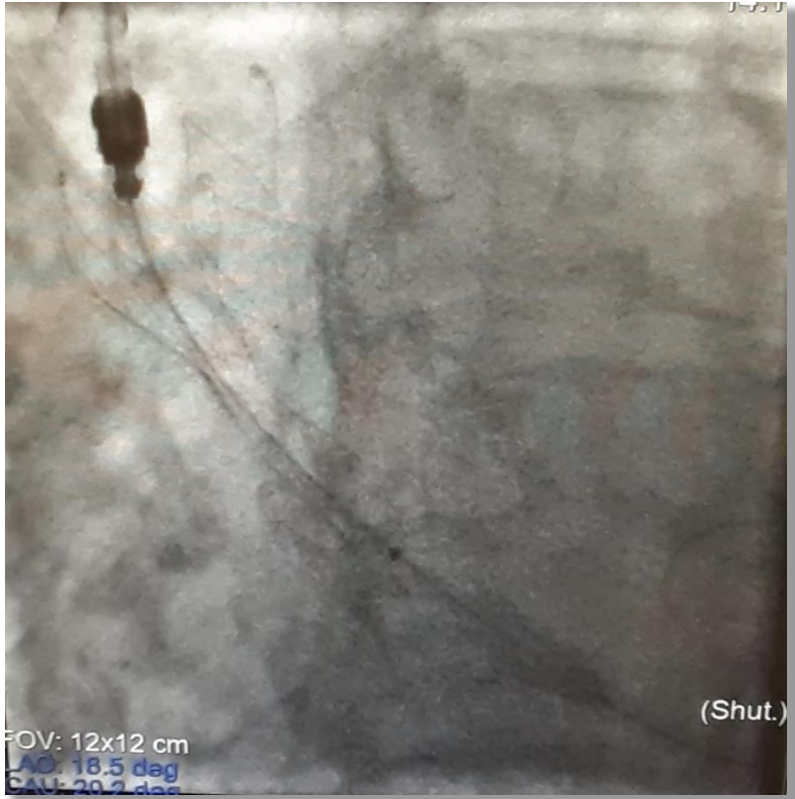

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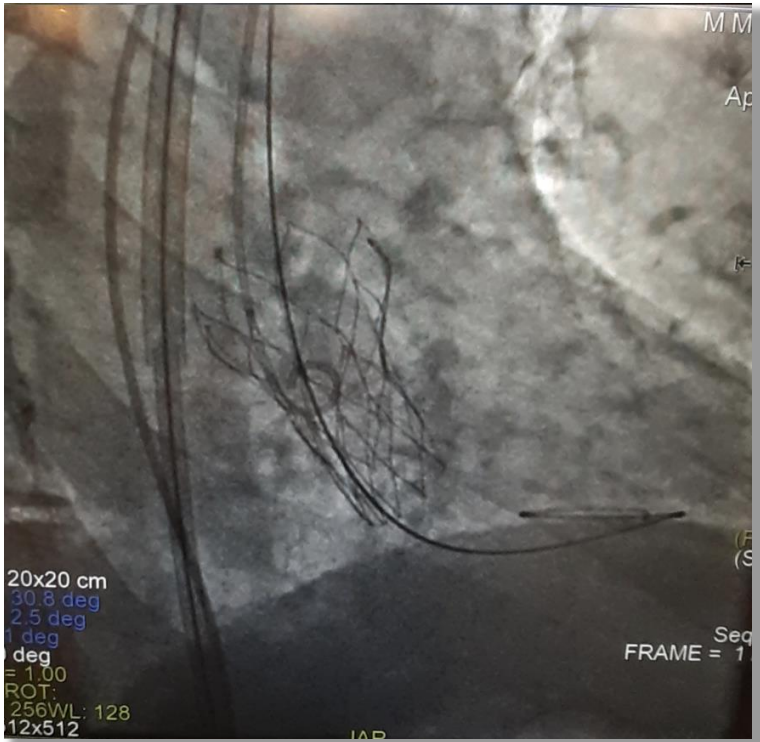

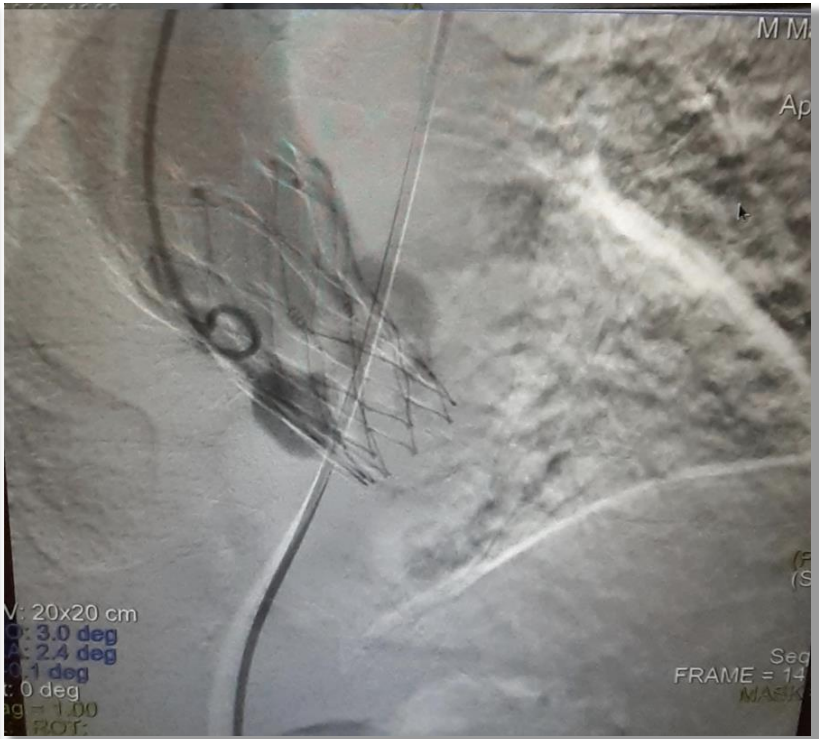

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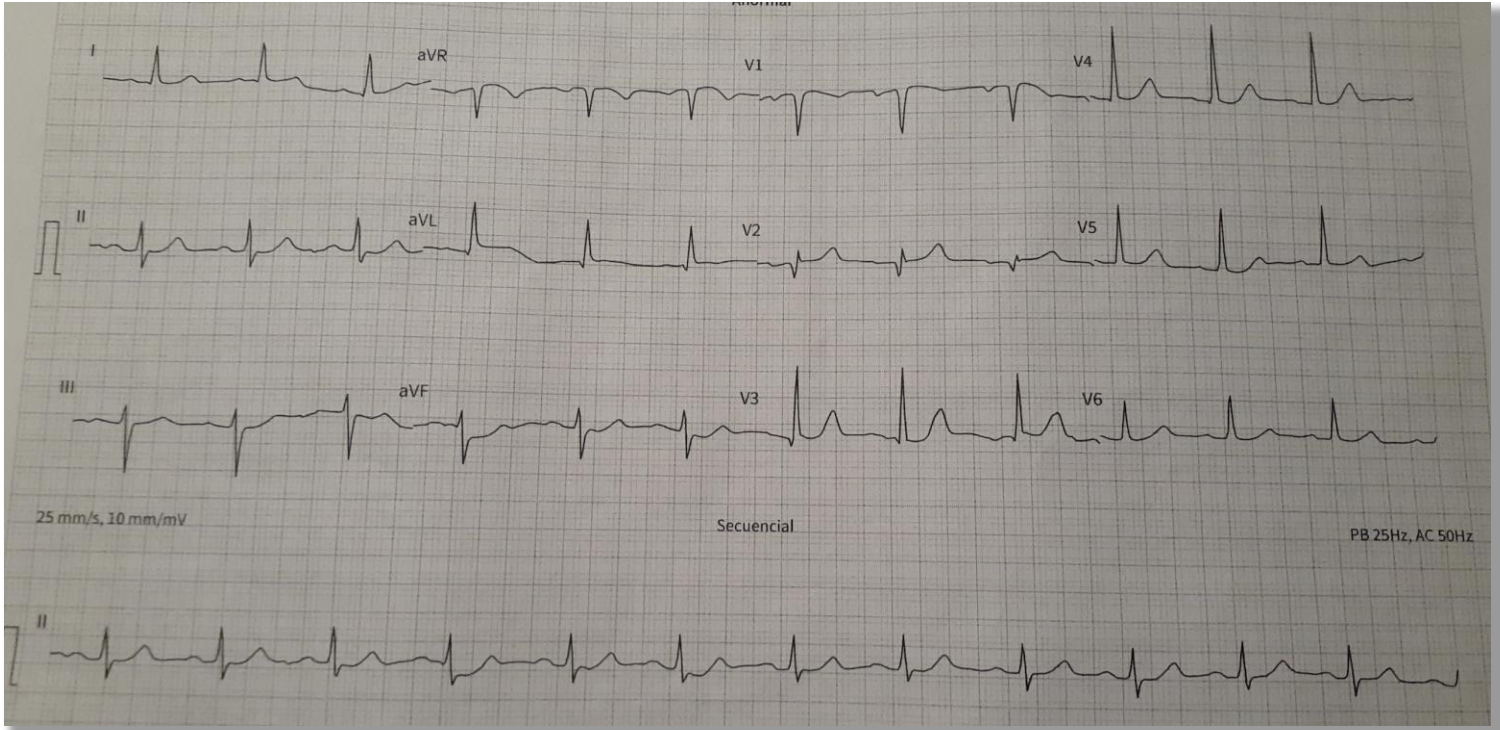
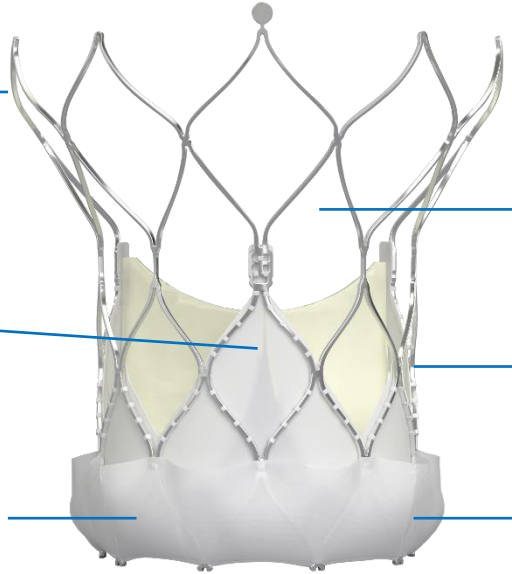


MUCHAS GRACIAS!



Celdas con curvas
Reduce riesgo de daño pared aortica

NaviSeal™ Cuff Interno
bajo perfil y durabilidad

NaviSeal Cuff Externo
para sellar y mitigar leak

Diseño de Celdas Grandes
Minimiza obstruccion coronaria y mejora el acceso y flujo corornario

Fuerza radial Optima
expansion, anclaje, estabilidad y sellado

Zona de Sellado aumentado
Disminuye leak

Rango de tratamiento del anillo
19 mm a 27 mm -diametro del anillo-