



Simposio “Omnimédica”

Transcatheter pulmonary valve replacement using the Pulsta valve: initial experience

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Private and Children`s Hospital of Córdoba, Argentina.

November 30th, 2019. Bs As.

Lecture title:

***Transcatheter pulmonary valve replacement
using the Pulsta valve: initial experience***

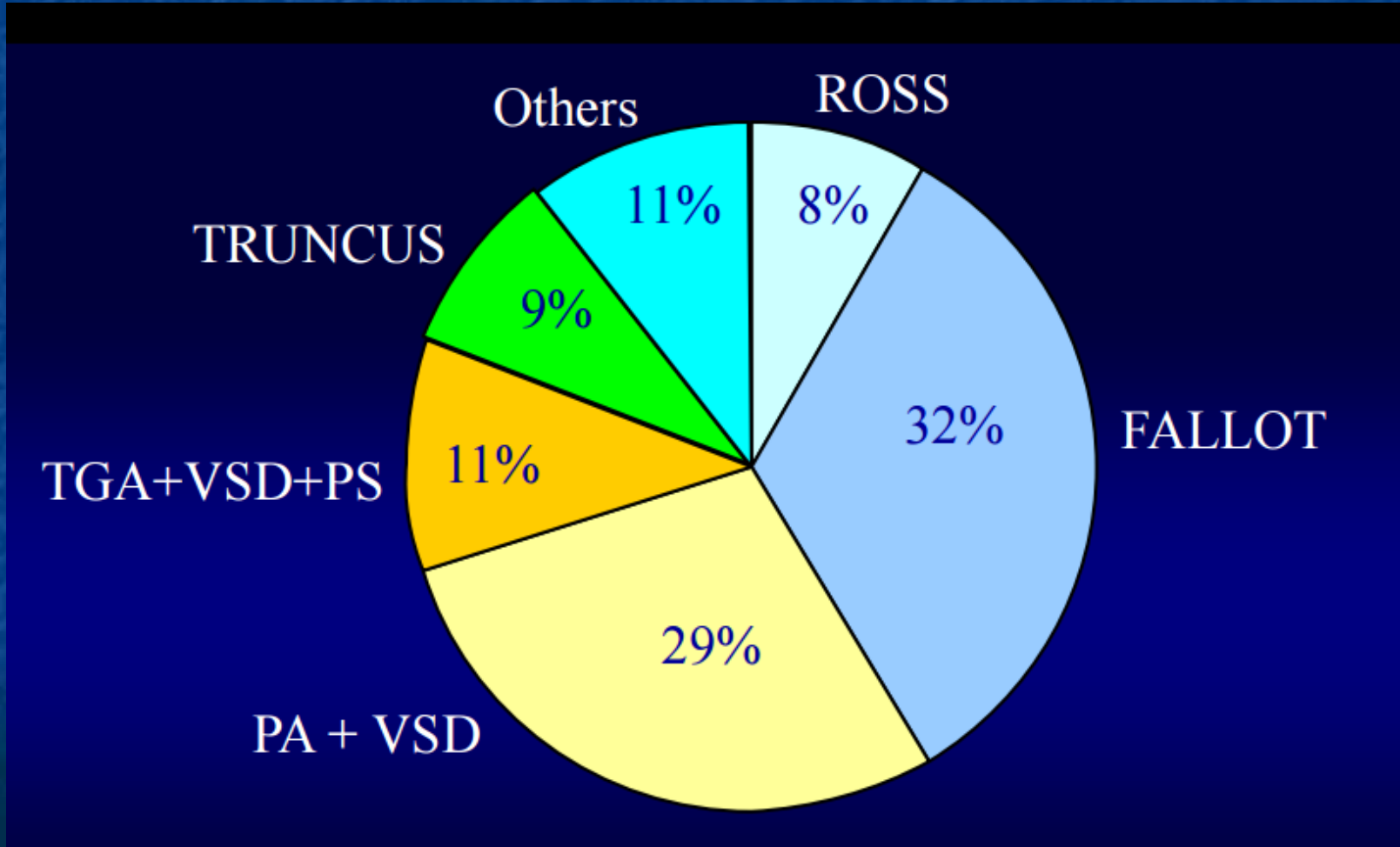
The following relationships exist related to this presentation:

Pulsta Valve (consultant)

Background: Pulmonary incompetence

- *Inevitable after transannular patching*
- *Incidence of 60 – 90% of pts*
- *Reduced exercise performance*
- *Progressive RV dilatation*
- *Arrhythmias*
- *? Sudden death*

RVOT dysfunction: Target population



PV replacement

RVOT anomalies (@ 20.1% of all CHD pts)

Tetralogy of Fallot

Truncus Arteriosus

d-TGA

Others

With PS

With PA

RV - PA Conduit

RV - PA Conduit

RV - PA Conduit

RV - PA Conduit

Surgical correction of RVOT (non-conduit)

Virtually all pts will require future procedure(s) to replace the conduit or the PV

~85% of dysfunctional RVOT pts

~15% of dysfunctional RVOT pts

RVOT dysfunction: Surgical repair


Valved conduit, homograft and bioprosthetic valve repair:


■ <i>North America (USA and Canada)</i>	<i>>50%</i>
■ <i>South America</i>	<i><10%</i>
■ <i>Europe</i>	<i><25-30%</i>
■ <i>Asia-Pacific</i>	<i><1%</i>

Transannular patch repair:

■ <i>North America (USA and Canada)</i>	<i><1%</i>
■ <i>South America</i>	<i>>90%</i>
■ <i>Europe</i>	<i>>70-75%</i>
■ <i>Asia-Pacific</i>	<i>>99%</i>

Recommendations for optimal timing of PVR based on pre-operative MRI parameters

<i>RV EDV index</i>	<i>Therrien et al (2004):</i>	<i>170 ml/m²</i>	
	<i>Oosterhov et al (2007):</i>	<i>160 ml/m²</i>	
	<i>Beuchel et al (2016):</i>	<i>150 ml/m²</i>	

<i>RV ESV index</i>	<i>Therrien et al (2004):</i>	<i>90 ml/m²</i>	
	<i>Geva et al (2010):</i>	<i>85 ml/m²</i>	
	<i>Bokma et al (2016):</i>	<i>80 ml/m²</i>	

Current indications

- *Asymptomatic pts with ≥ 2 of the following criteria:*

- *RV EDV index >150 mL/m² or Z score $> +4$*
- *RV ESV index >80 mL/m²*
- *RV EF $<47\%$ - LV EF $<55\%$*
- *QRS duration >160 ms – Sustained tachyarrhythmia*
- *Large RVOT aneurysm*
- *RVOT obstruction with RV systolic pressure >0.7 systemic*
- *\geq moderate TR*

Current indications

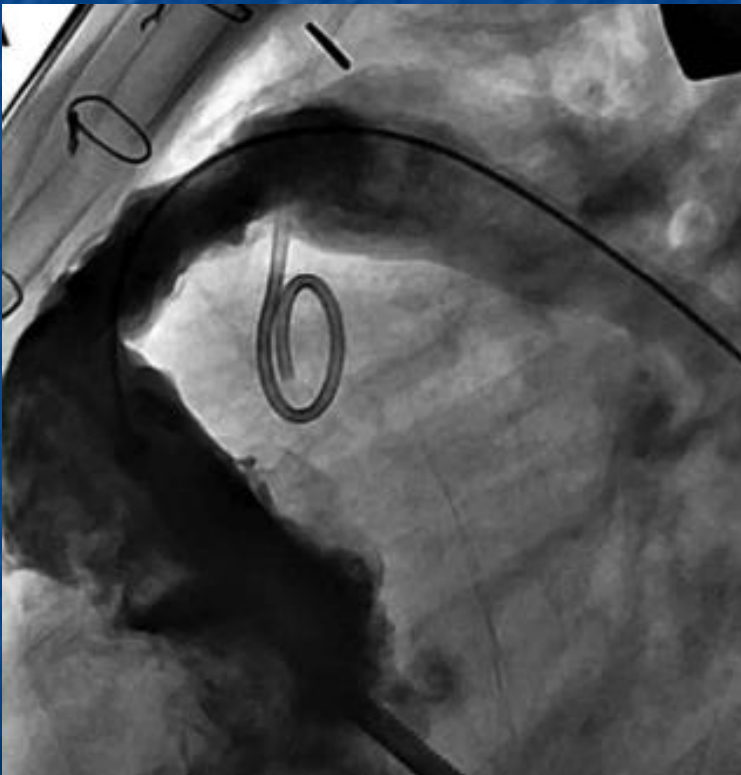
- *Symptomatic pts with ≥ 1 of the quantitative criteria plus:*

- *Exercise intolerance not explained by extra-cardiac causes ($\leq 70\%$ predicted peak Vo_2)*
- *Signs and symptoms of heart failure*
- *Syncope attributable to arrhythmia*

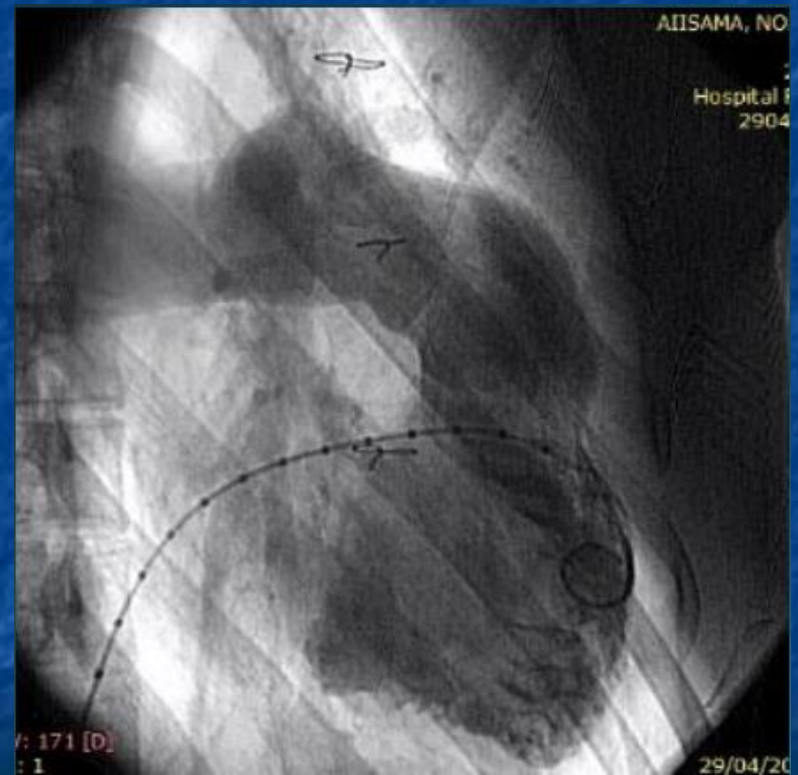
- *Special considerations with ≥ 1 of the quantitative criteria:*

- *TOF repair at ≥ 3 years of age*
- *Pre-pregnancy PVR*

Typical RVOT anatomical features



RVOT s/p RV- PA conduit



RVOT s/p transannular patch repair

Available transcatheter heart valves

- ***Melody® transcatheter pulmonary valve
(Medtronic, Minneapolis, Minnesota)***
- ***Sapien and Sapien XT® transcatheter heart valve system
(Edwards Lifesciences, Irvine, California)***
 - ***Venus P-Valve®
(Venus Medtech, Shanghai, China)***

Available transcatheter heart valves

- *Harmony® transcatheter pulmonary valve
(Medtronic, Minneapolis, Minnesota)*
- *Pulsta Valve®
(TaeWoong Medical Co., Seoul, Korea)*

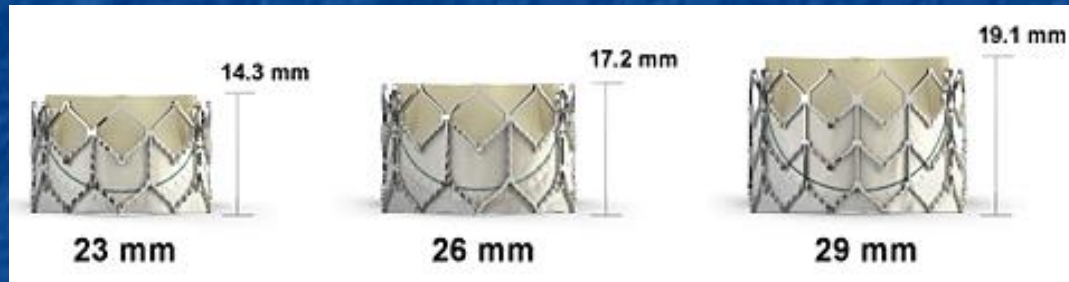
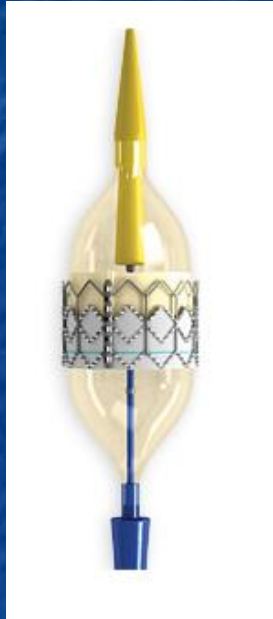
Medtronic Melody® Pulmonary Valve



- *18 mm Contegra modified-bovine jugular vein with valve segment*
- *CP Platinum Iridium Numed stent 34 mm in length*
- *Catheter BIB (balloon in balloon): 18 mm, 20 mm and 22 mm.*
- *Ensemble® 22F delivery system*

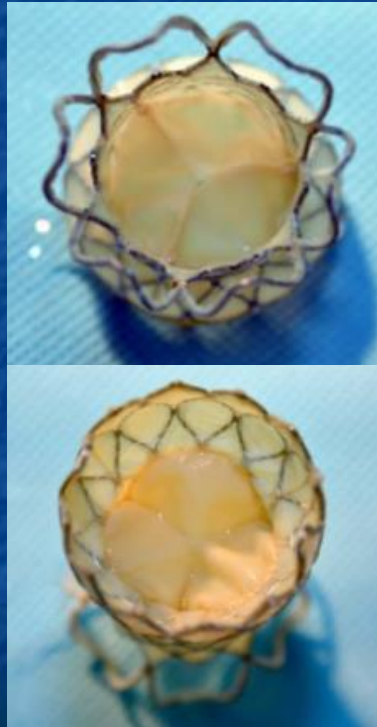
PV replacement

Sapien and Sapien XT® Transcatheter valves



- *Trileaflet bovine pericardial tissue. PET fabric skirt. 22 – 24F delivery sheath.*
- *Balloon-expandable cobalt –chromium stent design*
- *Sapien Valve: 23 and 26 mm. Used with Retroflex I or III delivery system*
- *Sapien XT Valve: 23, 26 and 29 mm. Used on the NovaFlex delivery system*

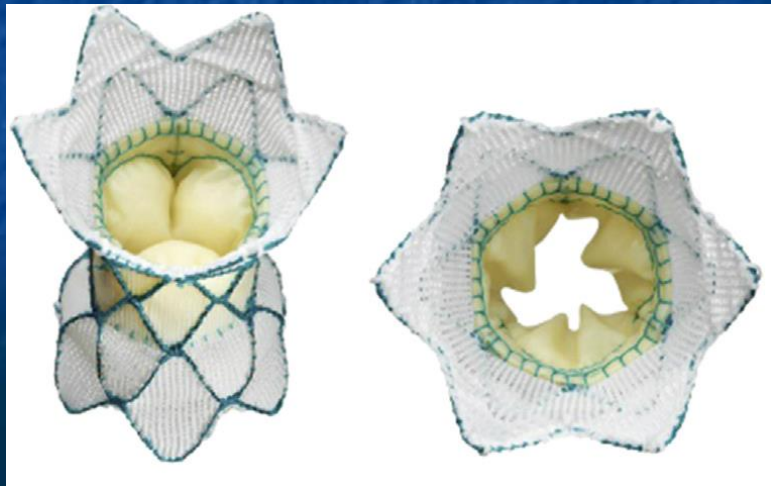
Venus P-Valve®



- *Self-expandable Nitinol multi-level support frame.*
- *Trileaflet porcine pericardial tissue.*
- *22–24 Fr catheter delivery system.*
- *Stent valve diameters range from 20 to 32 mm (in 2 mm increments) with each diameter available in 20 , 30 and 35 mm straight sections lengths.*

PV replacement

Harmony® transcatheter pulmonary valve



- *Porcine pericardial tissue valve*
- *Self-expanding nitinol frame*
- *Outer diameter 23.5 mm*
- *Length 55 mm*
- *Outflow diameter 34 mm*
- *Inflow diameter 42 mm*
- *25 F delivery sheath*

Lessons learned: Practical algorithm

Dysfunctional RVOT

*RV-PA conduit or
Bioprosthesis*

*Transannular patch
or native tracts*

*16 – 22 mm
Conduit/Bioprosthesis
Native??*

*21 – 28 mm
Conduit /Bioprostheis
Native??*

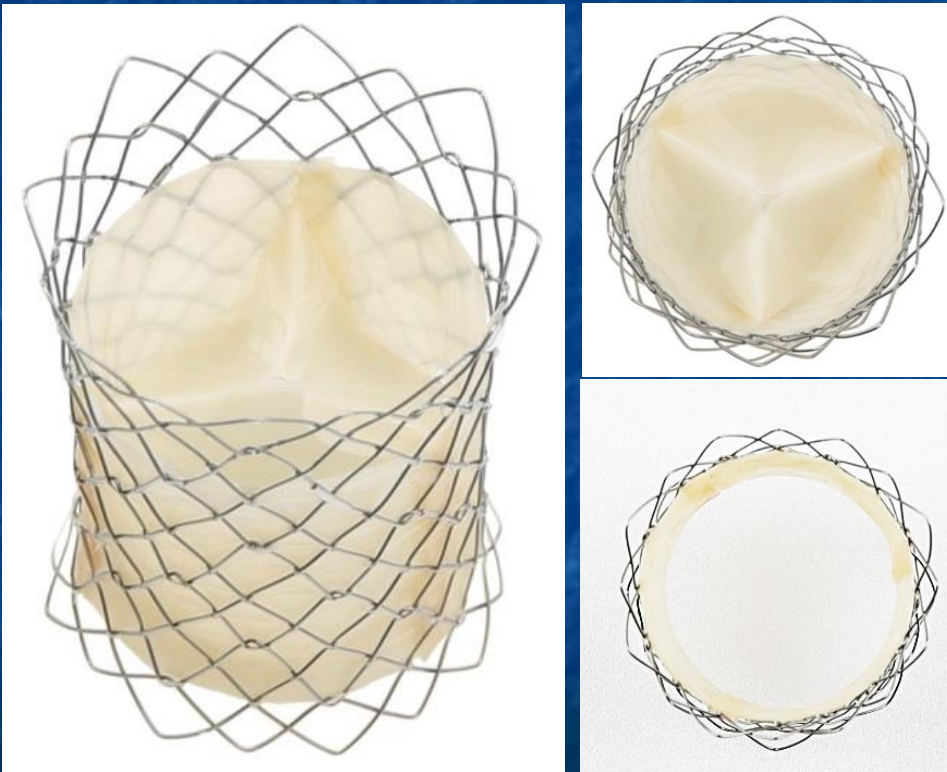
*18– 32 mm
PV annulus*

Melody®

Sapien XT®

*Venus-P Valve®
Harmony®
Pulsta®*

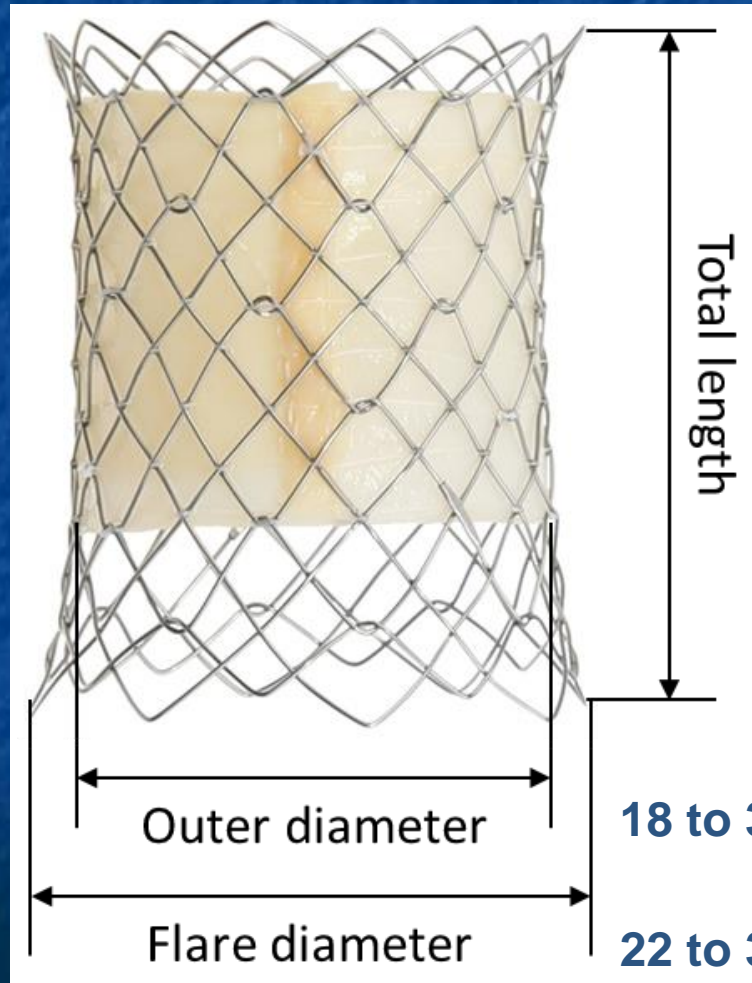
Pulsta Valve®



- **Self-expandable knitted Nitinol support frame.**
- **Trileaflet porcine pericardial tissue.**
- **18–20 Fr catheter delivery system.**
- **Outer diameter 18 mm to 32 mm.**
- **Flare diameter 22 mm to 34 mm.**
- **Length 38 mm.**
- **Stent valve diameters range from 18 to 32 mm in 2 mm increments.**

PV replacement

Pulsta Valve®



Low profile delivery catheter

18 Fr. (18~28 mm Ø)

20 Fr. (30, 32 mm Ø)

38 mm

18 to 32 mm

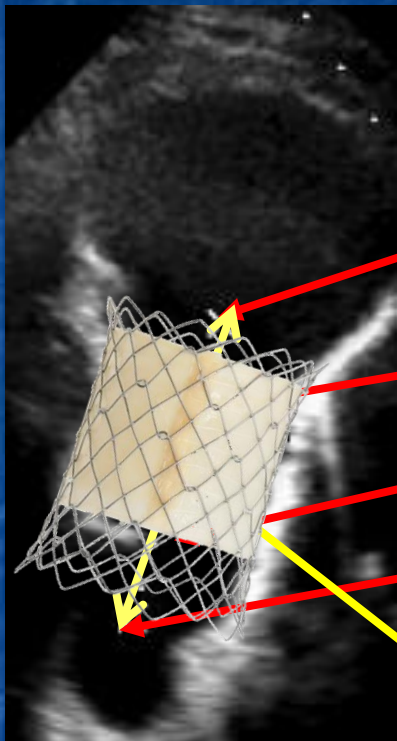
22 to 36 mm

Flare Ø 4 mm > than outer Ø

Pulsta Valve® sizes

Model name	Outer diameter (mm)	Flare diameter (mm)	Total length (mm) ±Tolerance(5%)	Expansion force (gf) ±Standard deviation	Compression force (gf) ±Standard deviation
TPV1828	Ø18	Ø22	28 ± 1.4	600 ± 21	1705 ± 22
TPV2028	Ø20	Ø24		-	-
TPV2231	Ø22	Ø26	31 ± 1.55	-	-
TPV2431	Ø24	Ø28		-	-
TPV2633	Ø26	Ø30	33 ± 1.65	-	-
TPV2833	Ø28	Ø32		480 ± 23	1694 ± 27
TPV1838	Ø18	Ø22	38 ± 1.9	630 ± 22	1102 ± 115
TPV2038	Ø20	Ø24		-	-
TPV2238	Ø22	Ø26		-	-
TPV2438	Ø24	Ø28		-	-
TPV2638	Ø26	Ø30		-	-
TPV2838	Ø28	Ø32		-	-
TPV3038	Ø30	Ø34		-	-
TPV3238	Ø32	Ø36		526 ± 26	1336 ± 134

Valve size selection



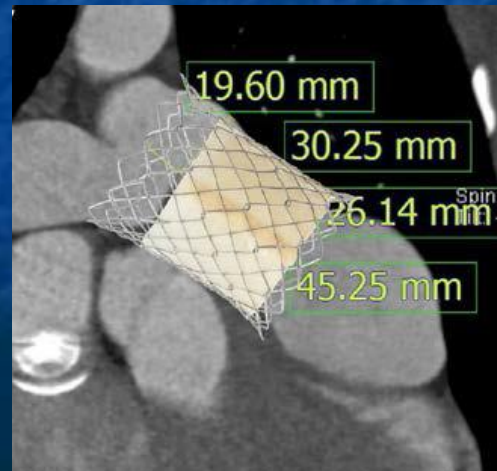
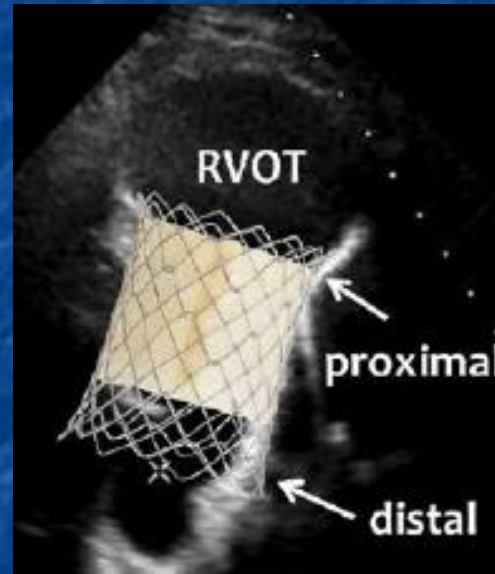
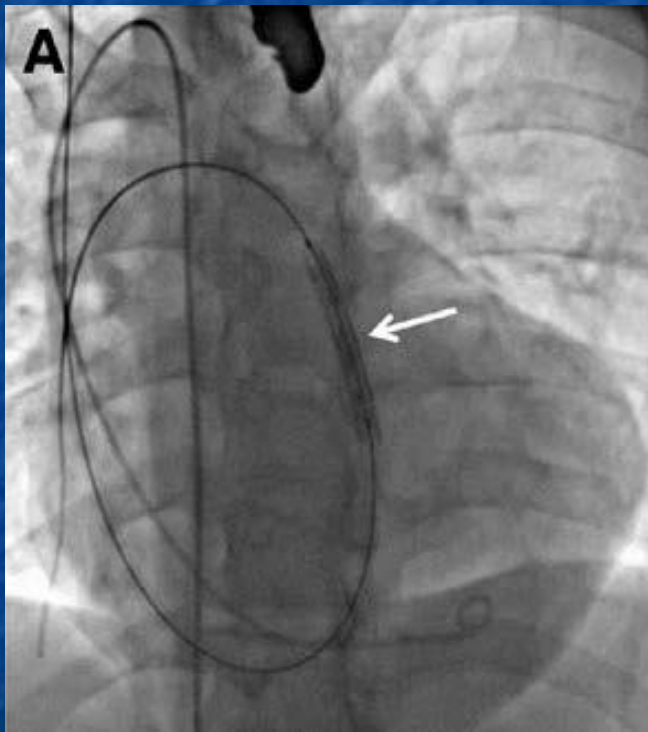
Main PA, mm	EchoCG, mm	CT, mm	MRI, mm	Cine angio., mm	Mean, mm
Proximal	30.7	32.5*30.6	30.3	30.2	30.9
Mid	27.3	26.5*30.1	26.7	27.6	27.9
narrowest	17	20.9*19.6	20.2	18.1	19.1
Distal bifurcation	26.5	23.2*37.8	27.8	30.8	30.7
length	39.9	43.2	36.1	38.6	39.5

→ 28 mm Ø, 38 mm length

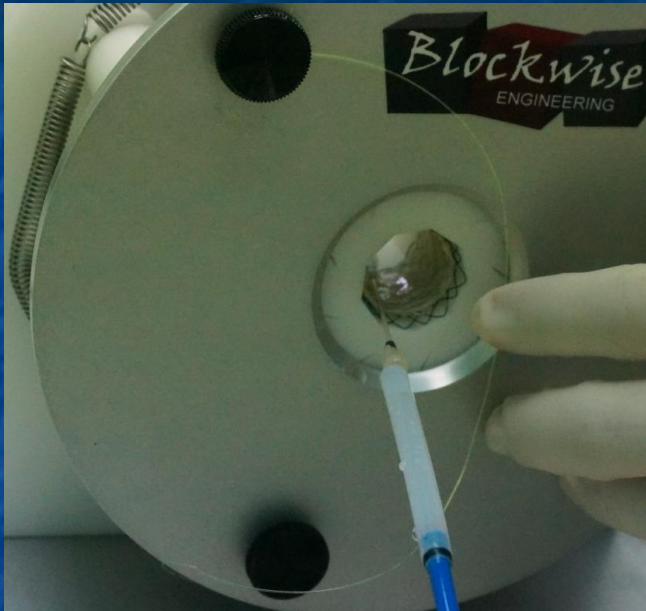
- *Multiple image modalities*
- *≥ 1~2 mm larger valve than overall main PA diameter*

PV replacement

Pulsta Valve®



Pulsta Valve® loading



Delivery system

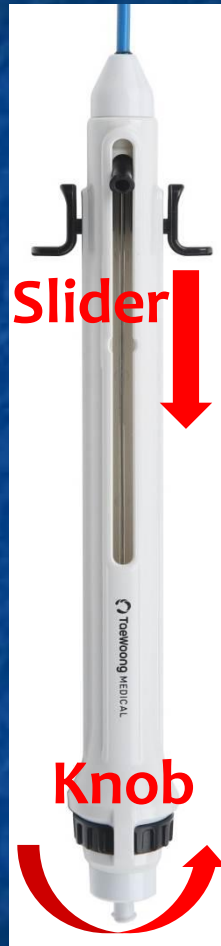


Delivery catheter
Useable length: **110 cm**



**Hook
block**

Head



Slider

Knob

Handle

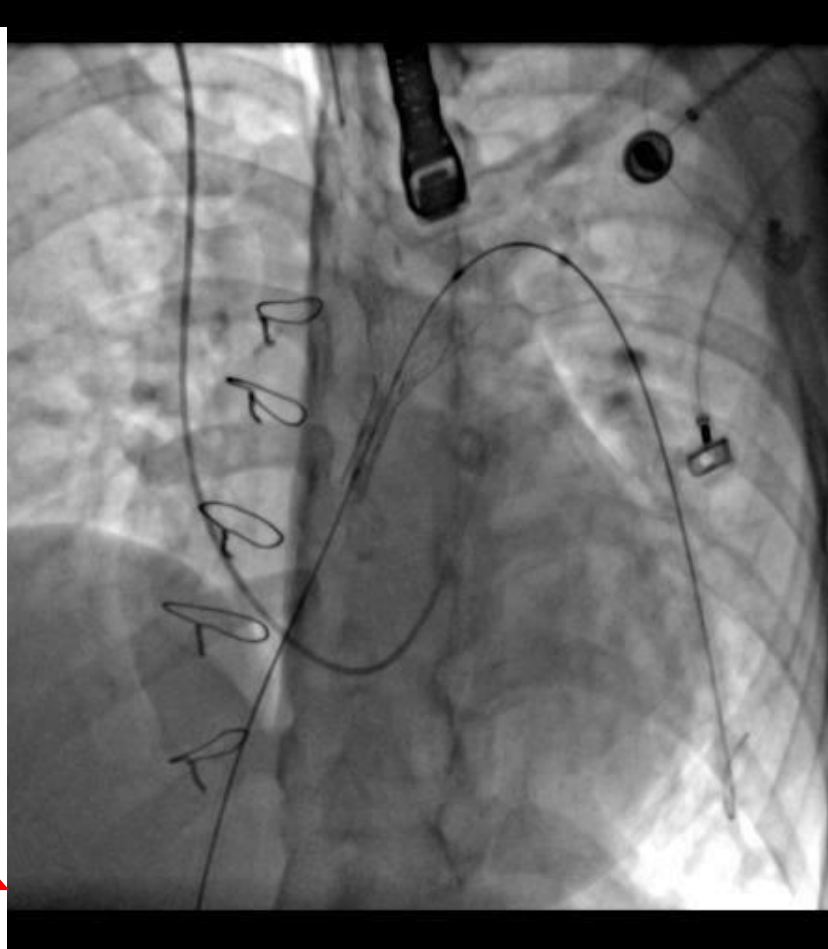
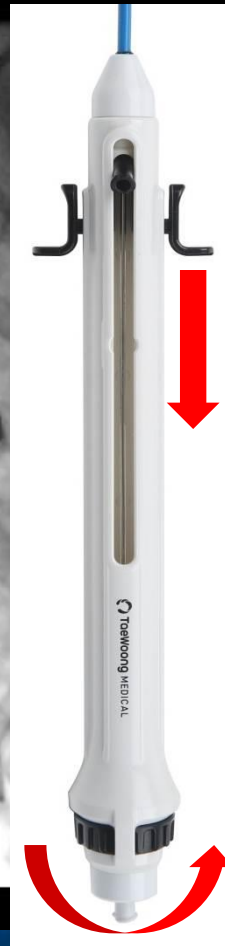
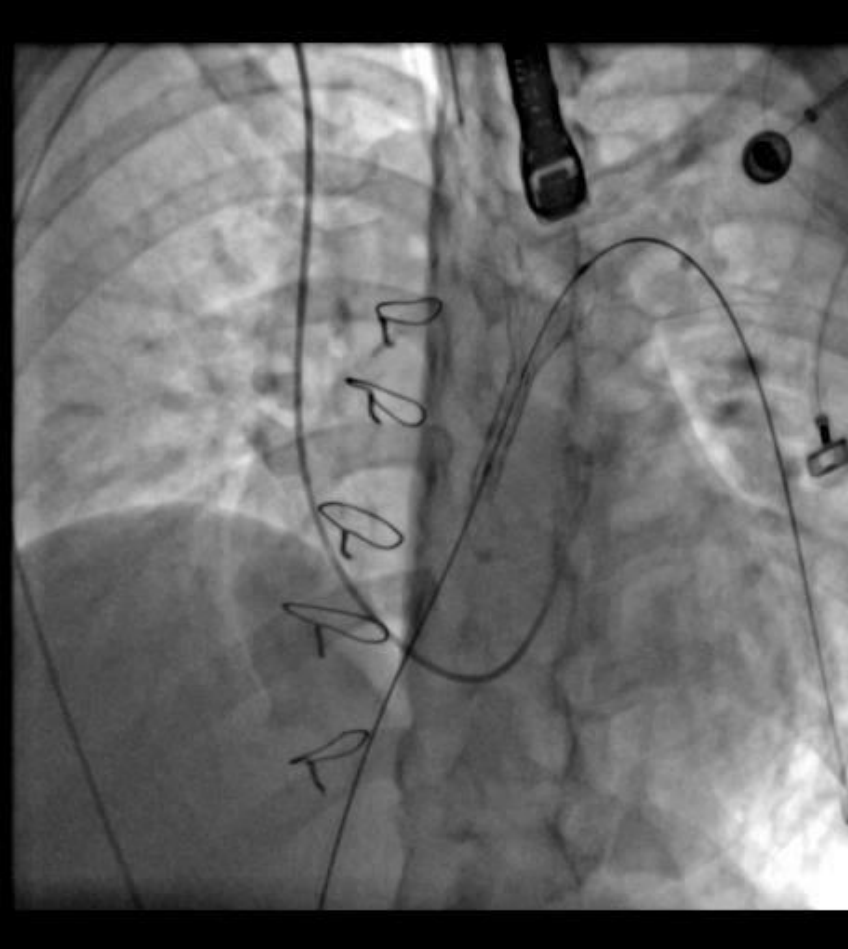


18F.
(up to 28
mm valve)

20F.
(up to 32
mm valve)

12F. shaft

Deployment of Pulsta Valve

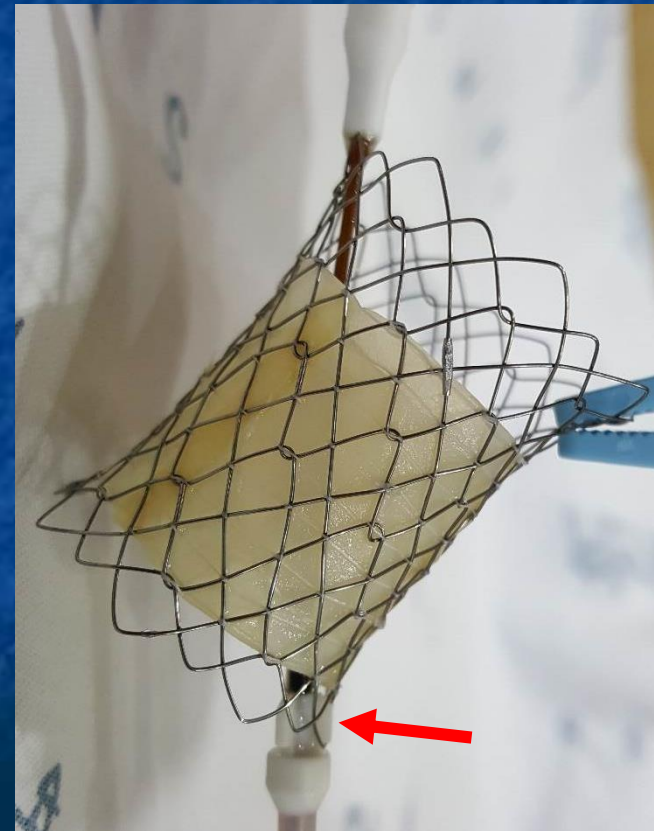
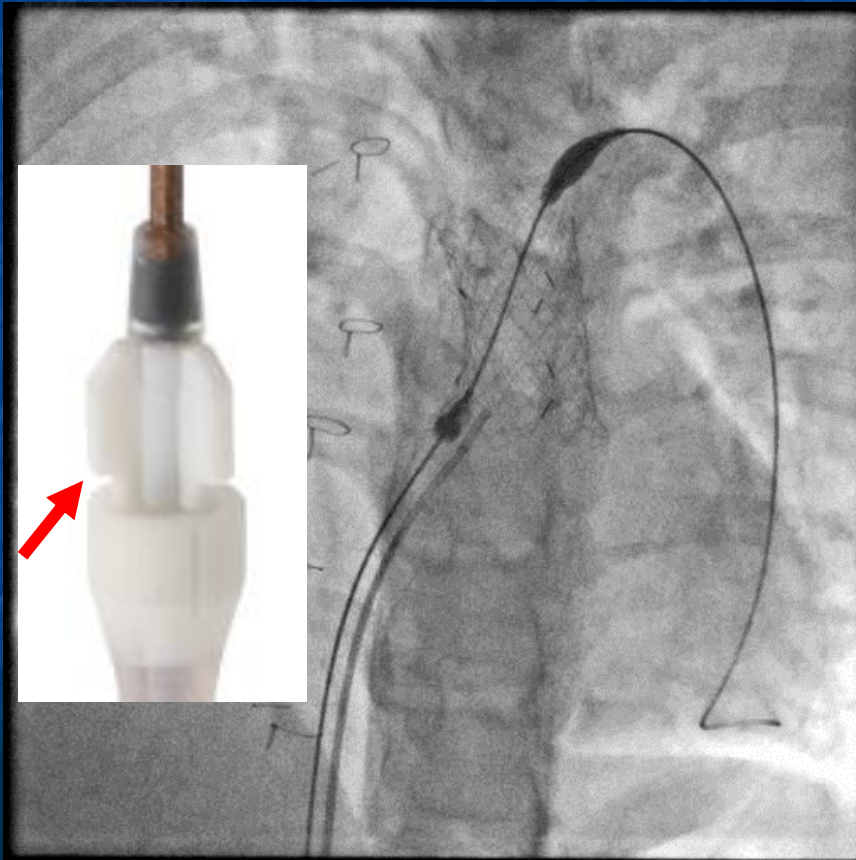


*Distal unsheath of valve
and **re-positioning***

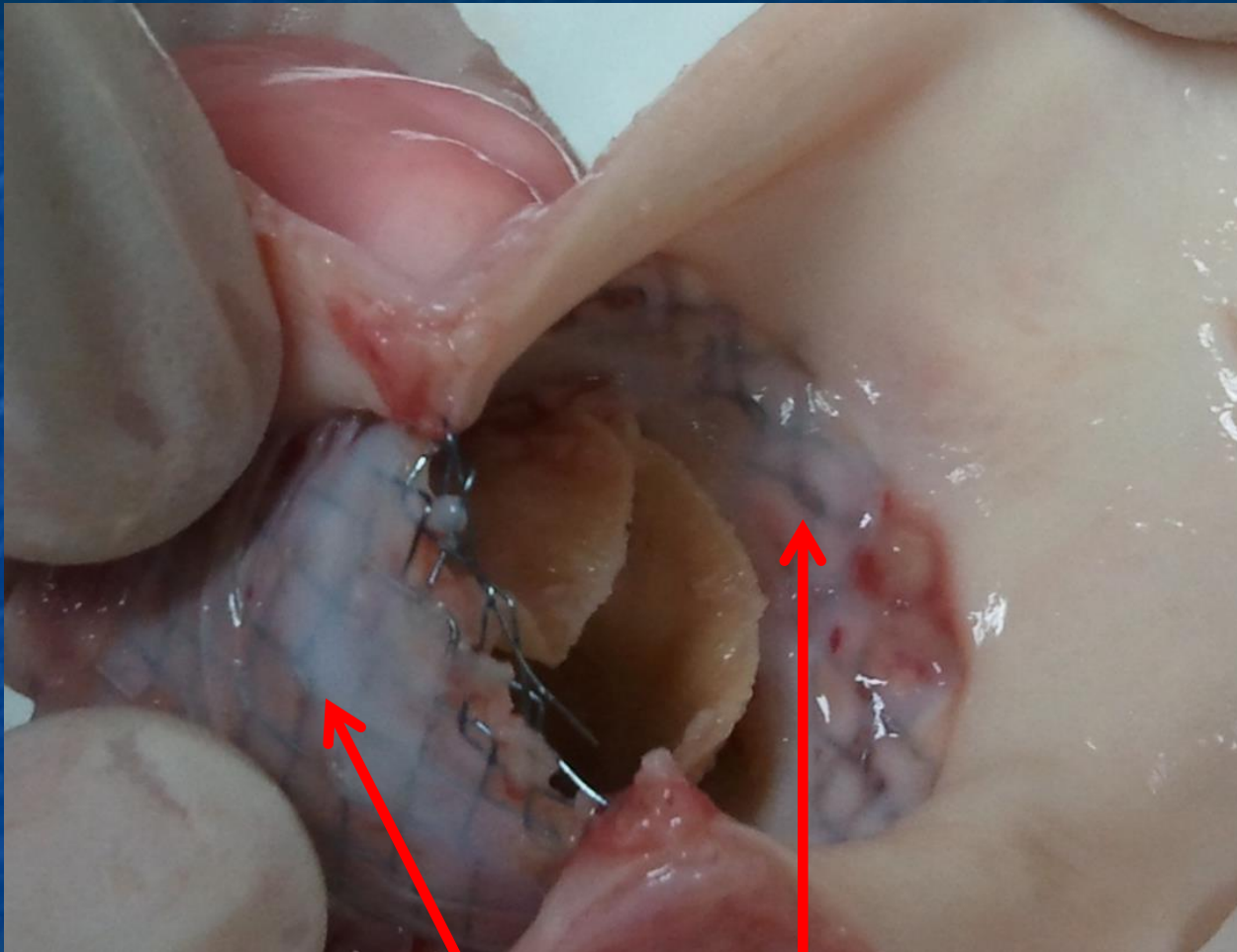
Full deployment

Watch for hook block detachment

- ***Wait for spontaneous release firstly***
- ***Gentle push of delivery catheter forward secondly***
- ***Wire selection to RPA is best method to prevent***



Endothelialization

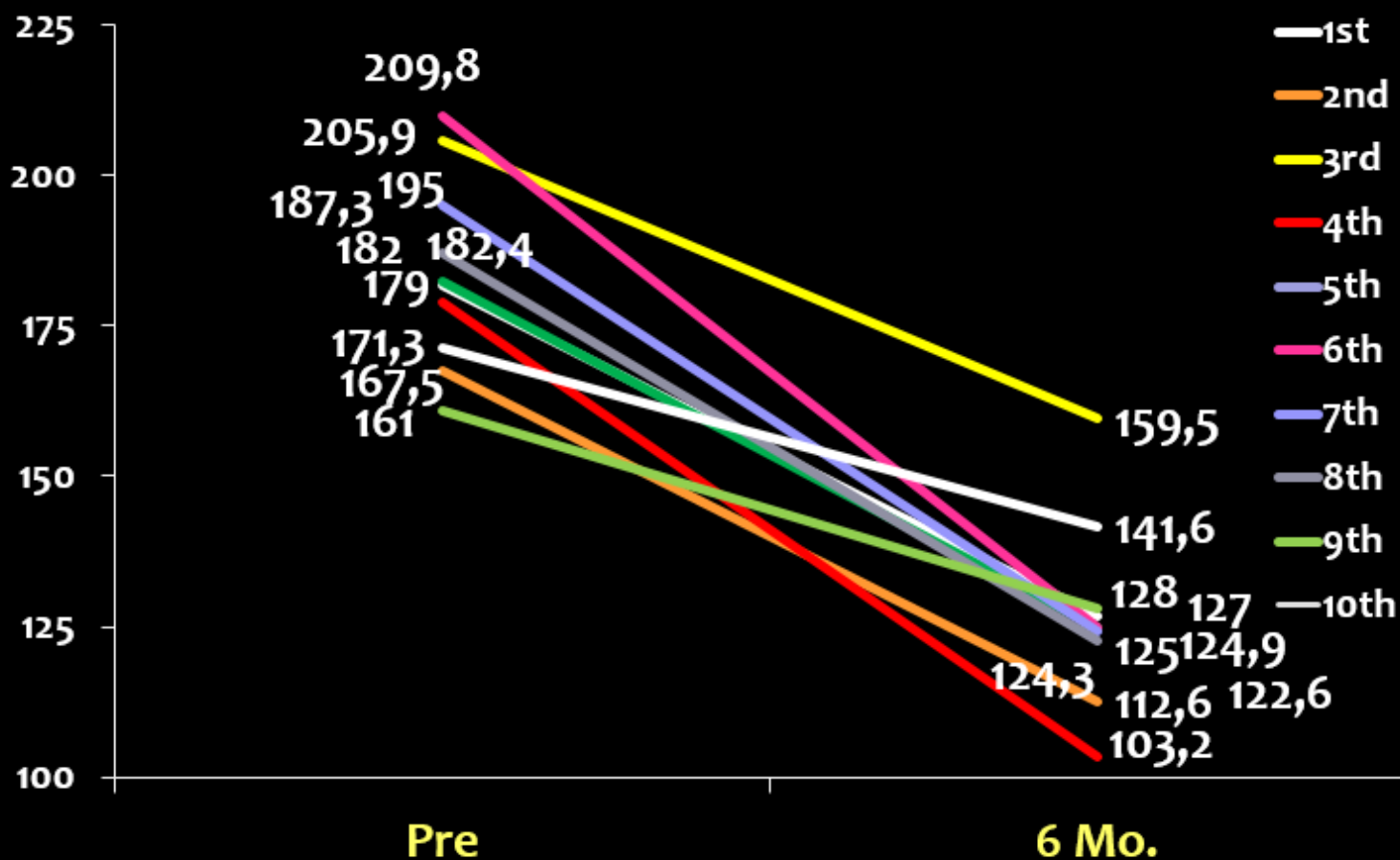


Full endothelialization after 3 months

RV indexed end-diastolic volume from MRI

Follow-up – 10 patients

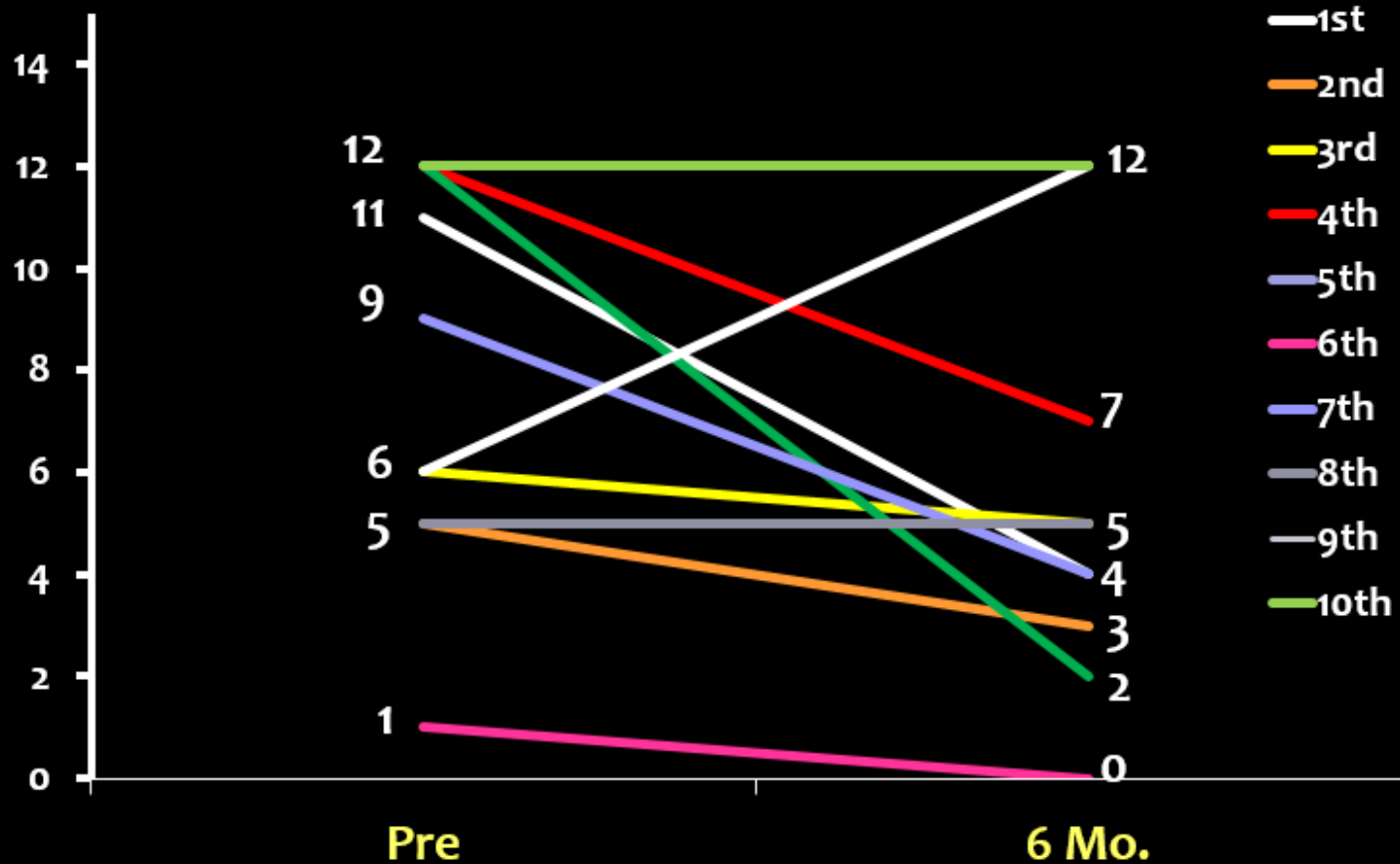
mL/m²



RV-PA peak pressure gradient from cath.

Follow-up – 10 patients

mmHg



Adverse Events: Total 25 patients

- ***No device related serious adverse event***
- ***No device movement or embolization***
- ***No stent fracture***
- ***No infective endocarditis***

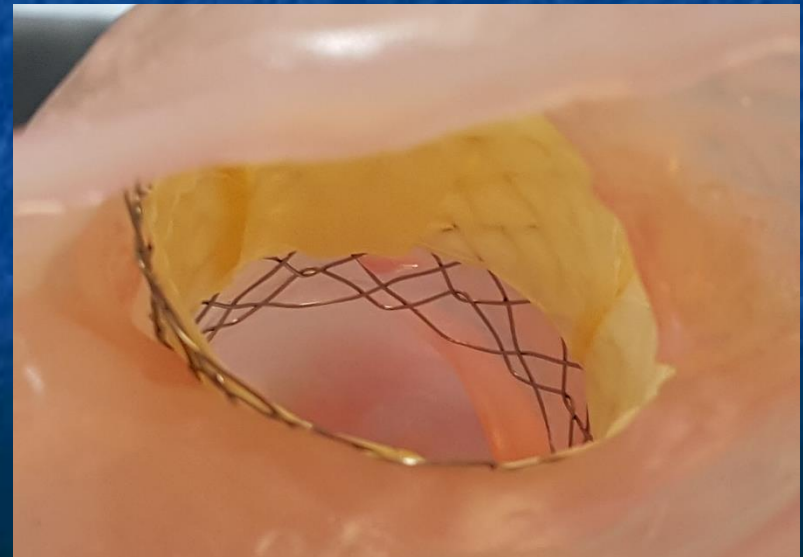
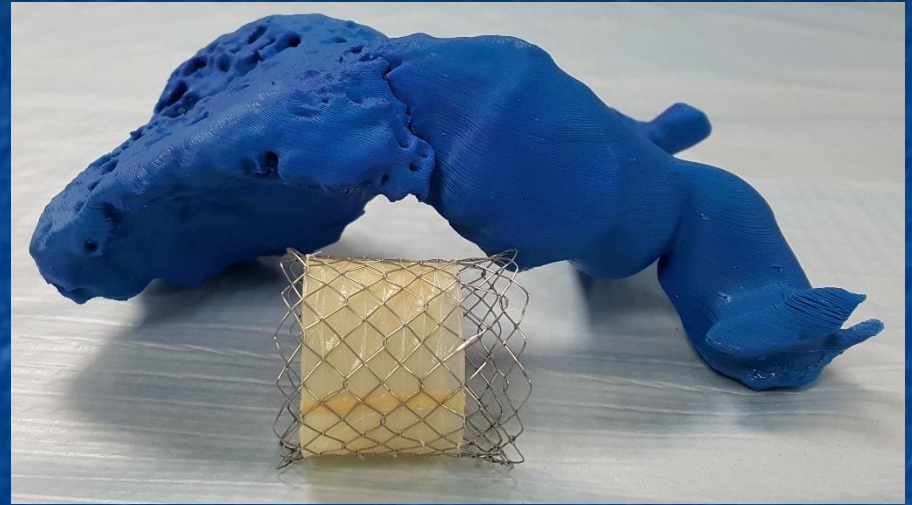
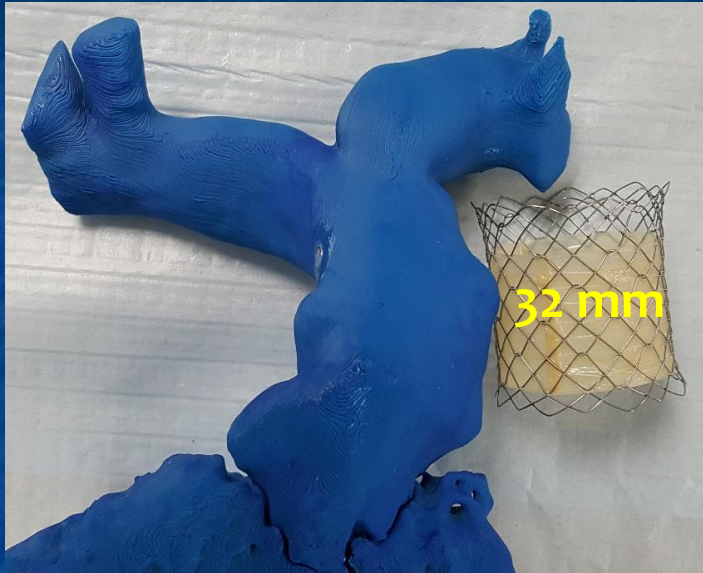
Pulsta Valve, CE approval study

Country	Center
Italy	1 site
S. Korea	3 sites
Spain	2 sites
Germany	1 site
Netherlans	2 sites
Turkey	2 sites



- **6 countries, 11 centers**
- **PI: Dr. Mario Carminati**
- **Factory CRO (Netherland)**
- **First investigator meeting** : Nov. 26th. 2018 (At Rome, Italy)
- **Under review** from each country's **Competent Authorities** and **Ethics Committee**

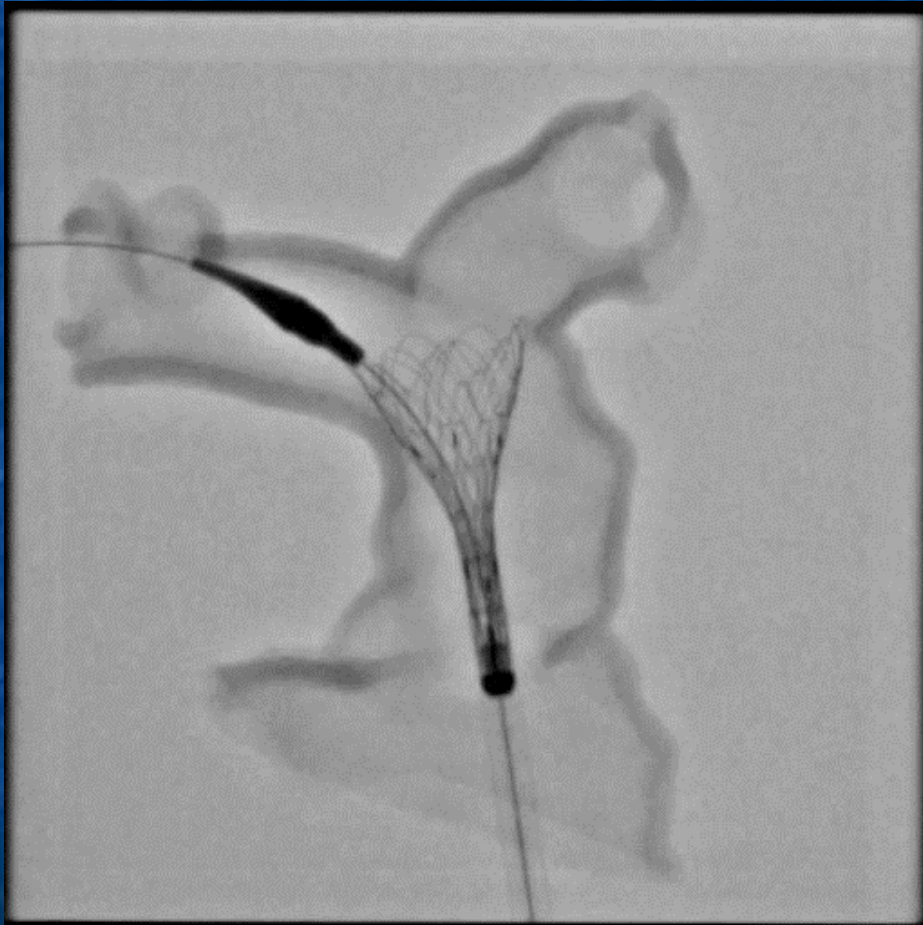
Valve implantation simulation using 3D printing model



Valve implantation simulation using 3D printing model



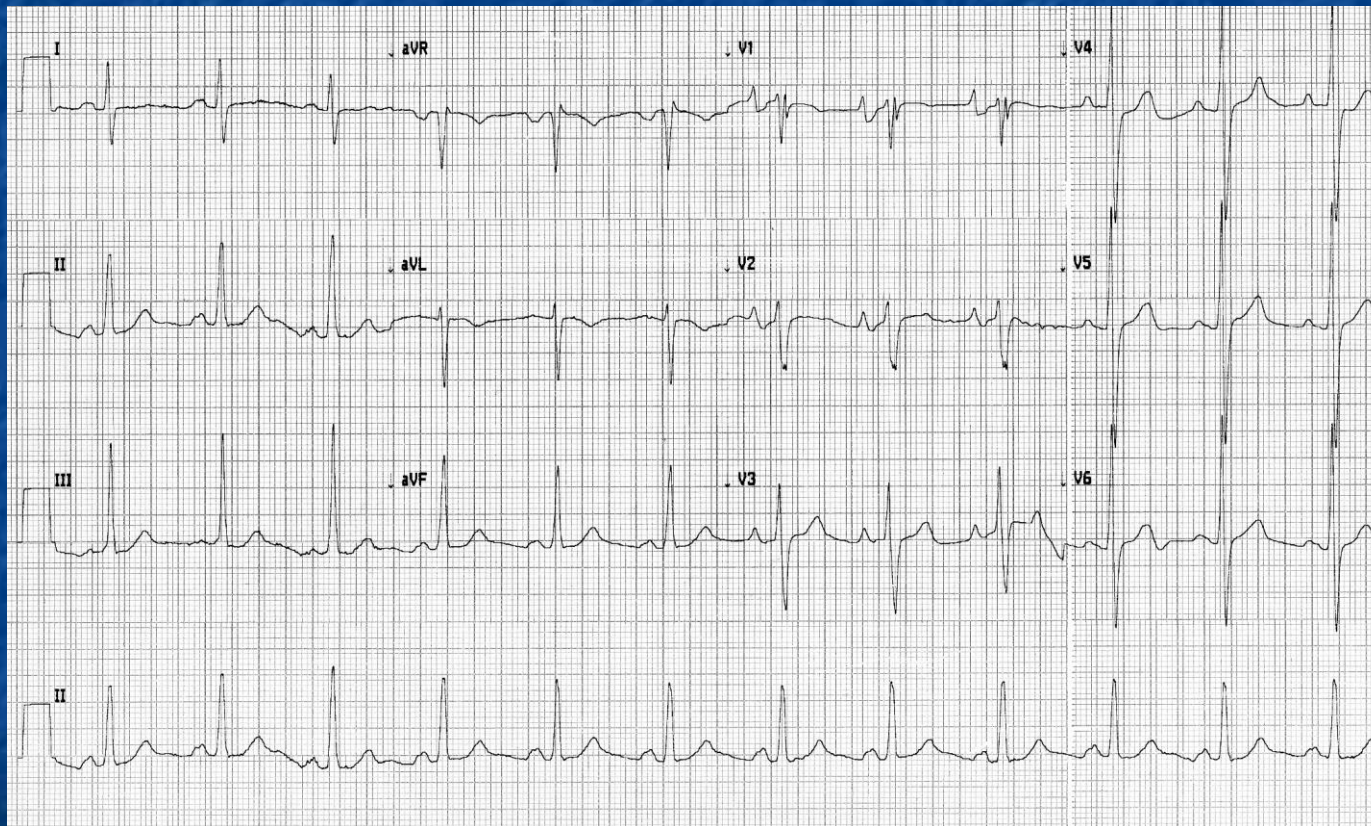
Valve implantation simulation using 3D printing model



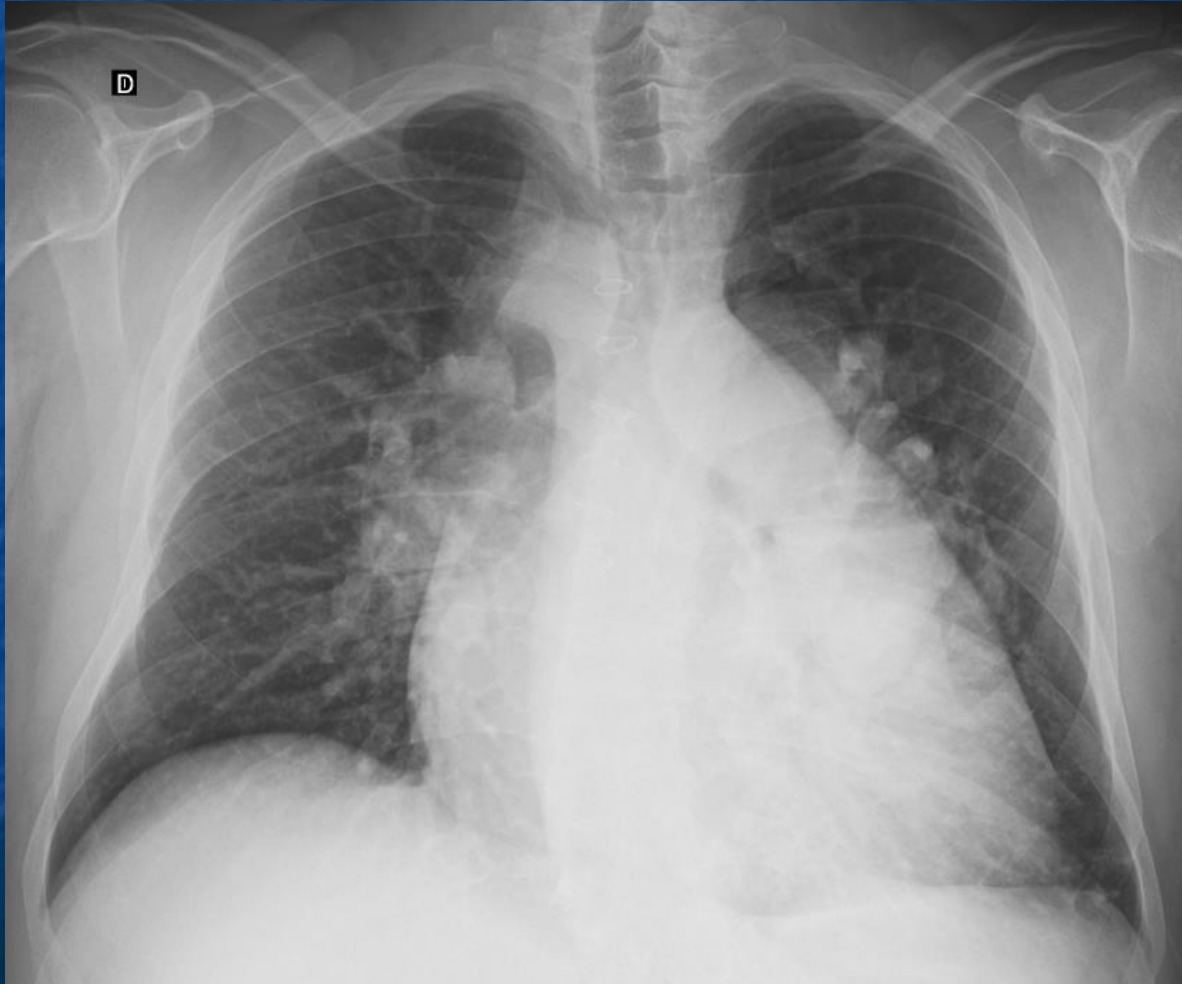
PULSTA VALVE SCREENING

- ***GN, 40 yo, 85 kg, 1.65 mts, BSA 31.***
- ***TOF***
- ***Surgical Hx: 5 yo complete repair.***
- ***FC II-III. Pronounced SOB. Frequent palpitations.***
- ***Current meds: carvedilol, amiodarone.***
- ***EKG: SR, complete RBBB, premature ventricular beats, QRS duration 160 msec***

EKG:



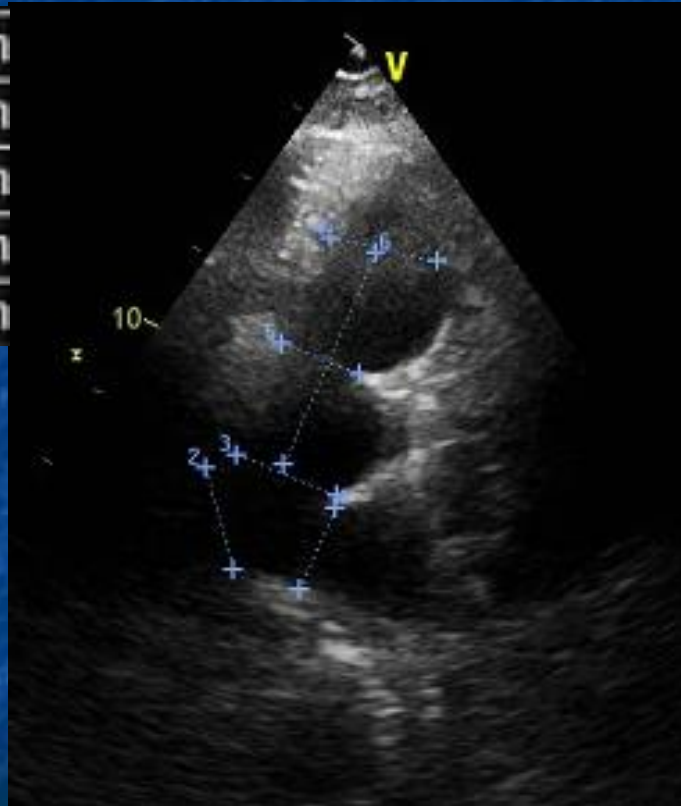
Chest X-Ray:



PULSTA VALVE SCRENNING

ECHO measurments (difficult windows!)

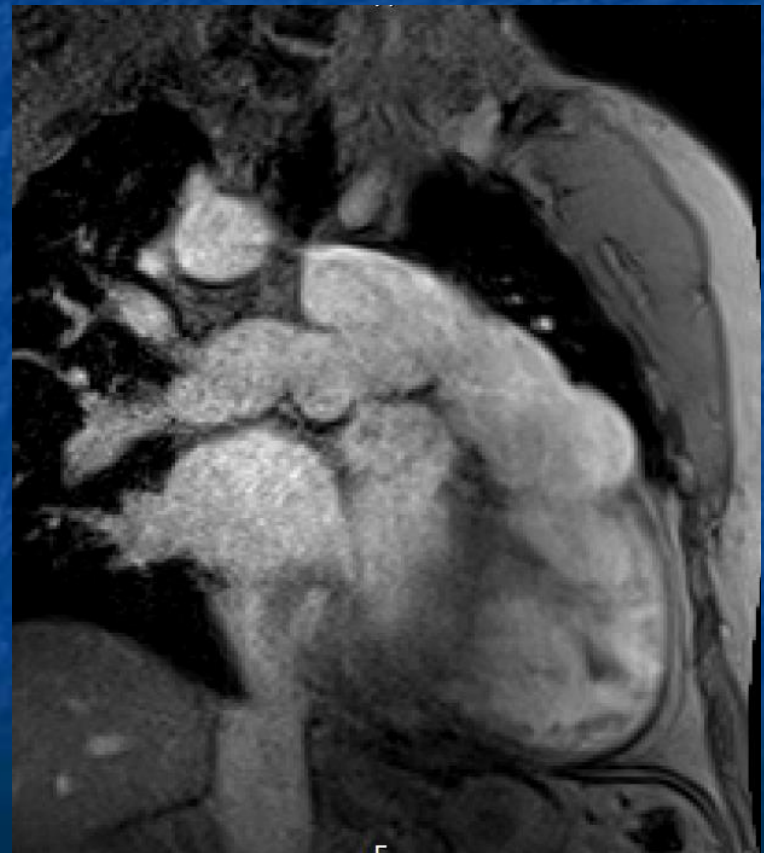
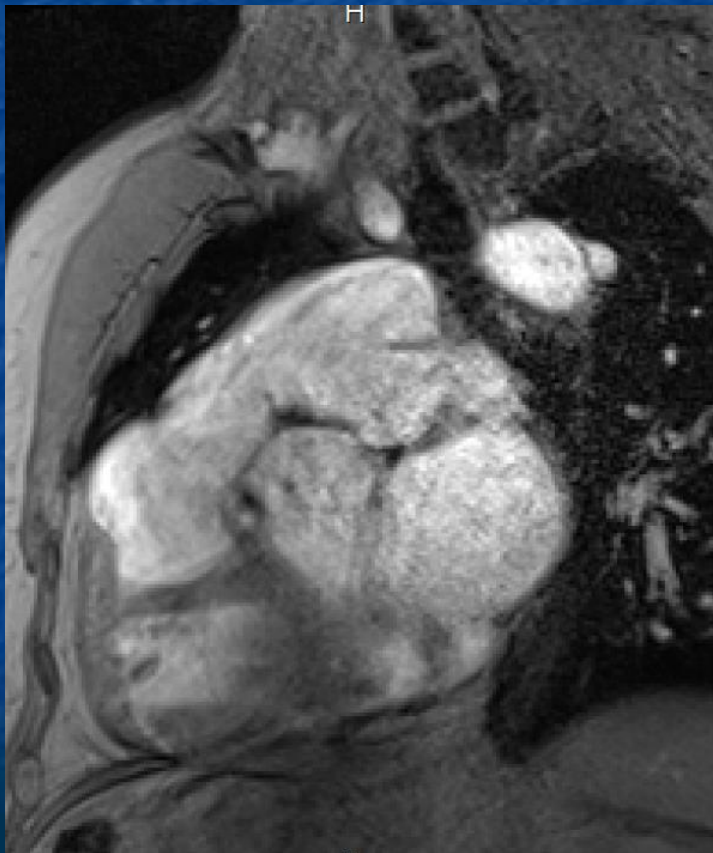
5 L	2.4 cm
4 L	3.1 cm
3 L	3.1 cm
2 L	3.0 cm
1 L	2.5 cm



- **PV level: 31 mm**
- **Mid PA trunk: 24 mm**
- **Distal PA trunk: 31 mm**
- **RPA: 25 mm**
- **LPA: 30 mm**

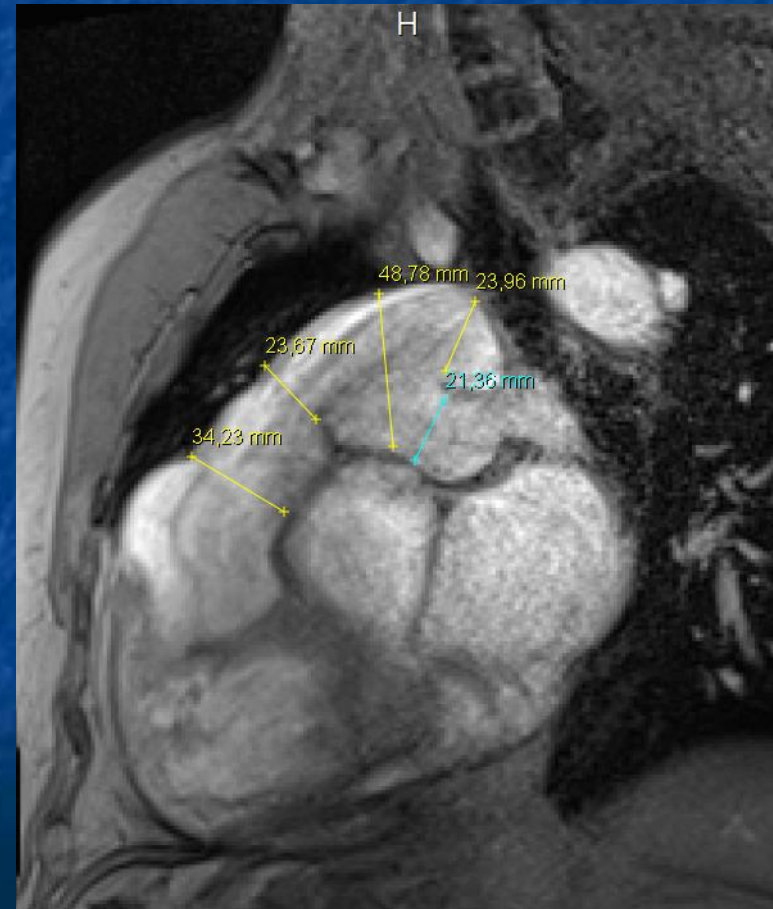
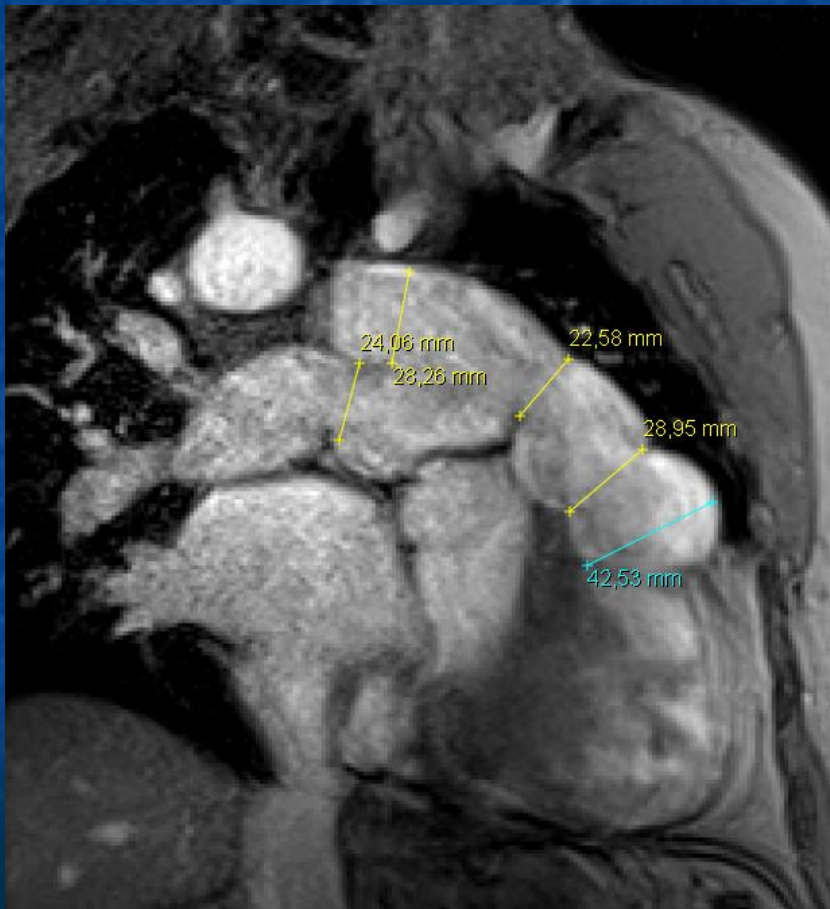
PULSTA VALVE SCRENNING

MRI views



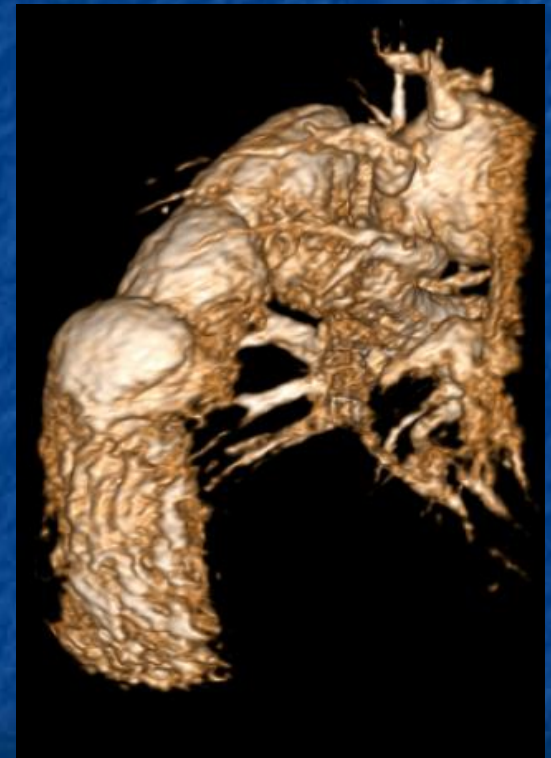
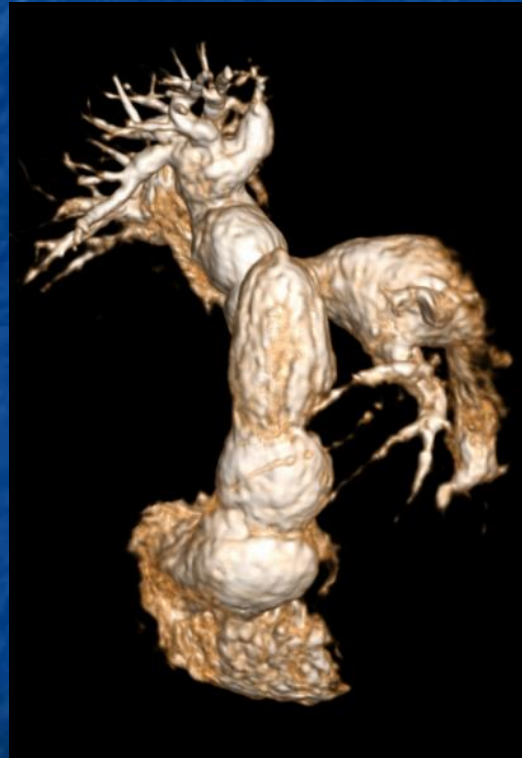
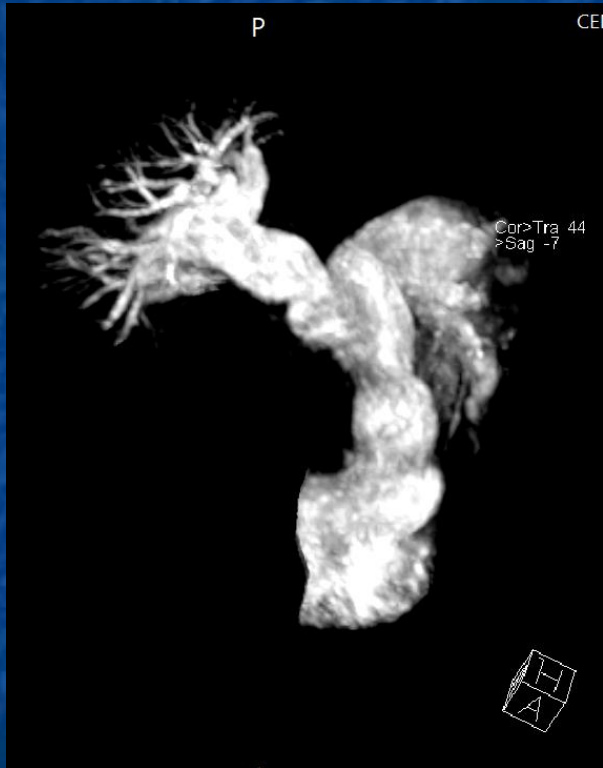
PULSTA VALVE SCREENNING

MRI measurments



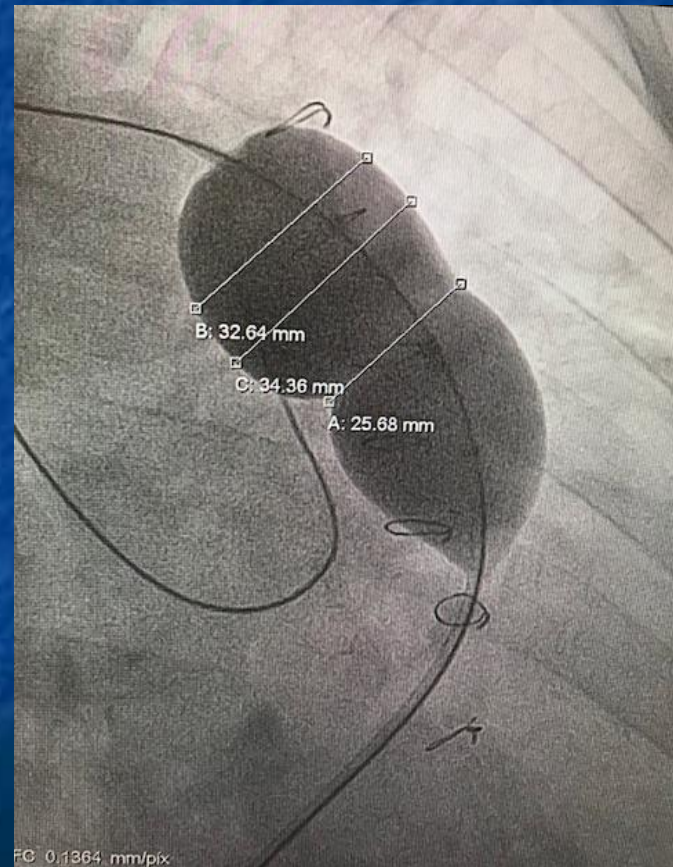
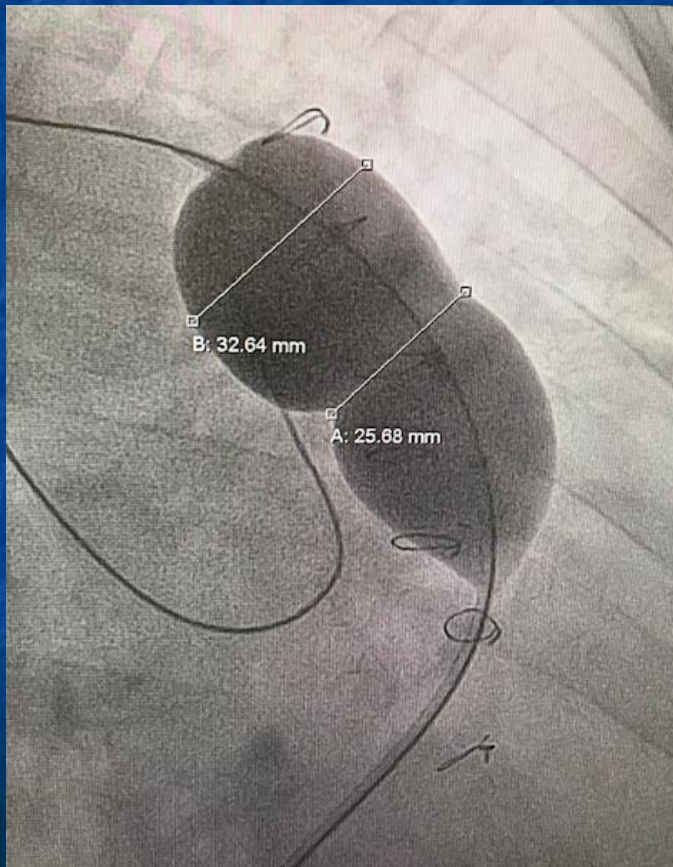
PULSTA VALVE SCREENING

MRI reconstruction



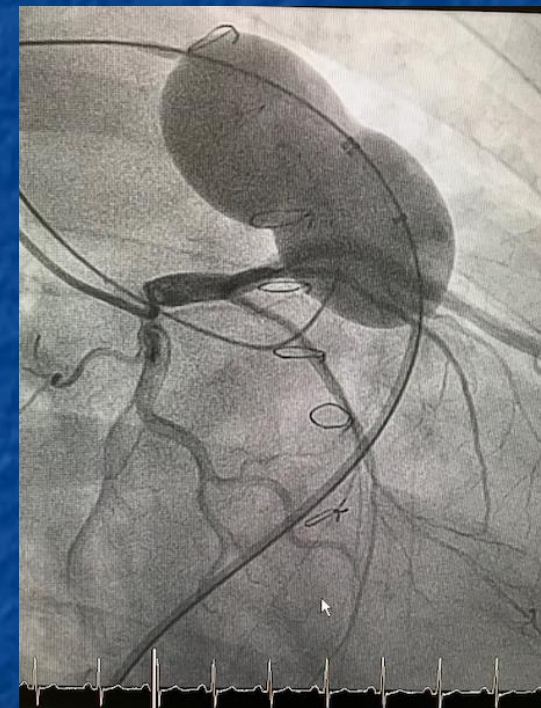
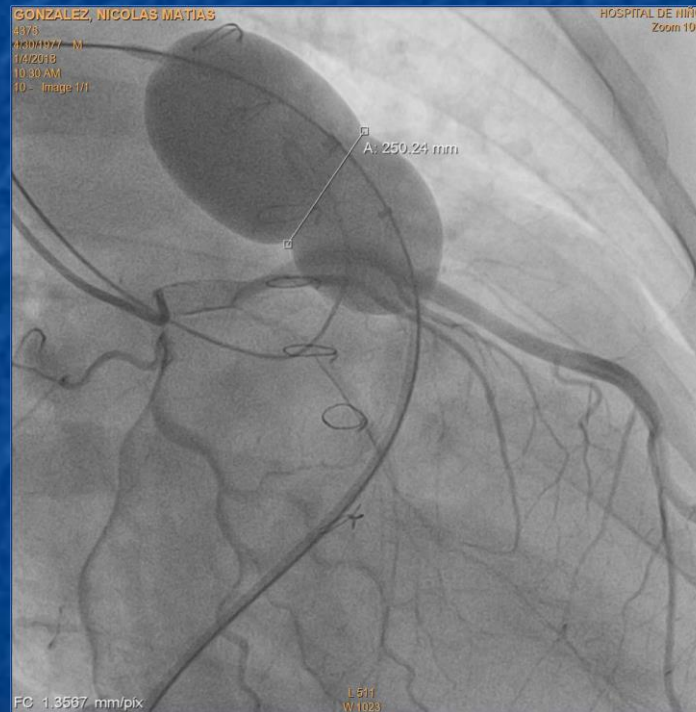
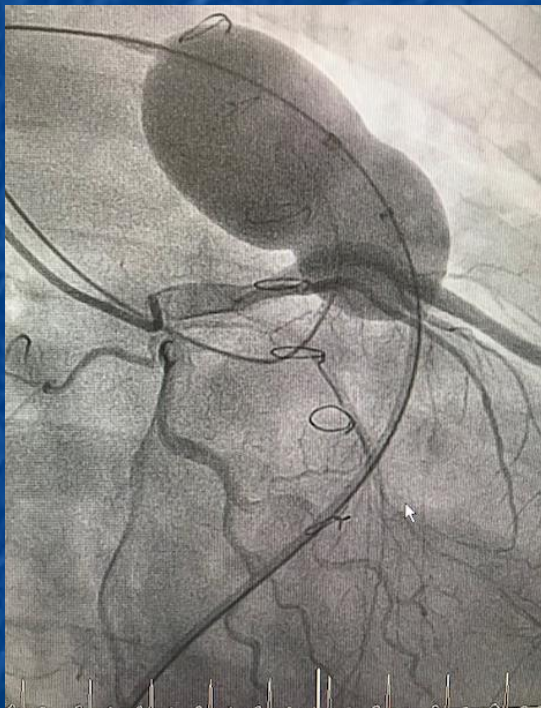
PULSTA VALVE SCREENING

Sizing balloon measurements – RAO view



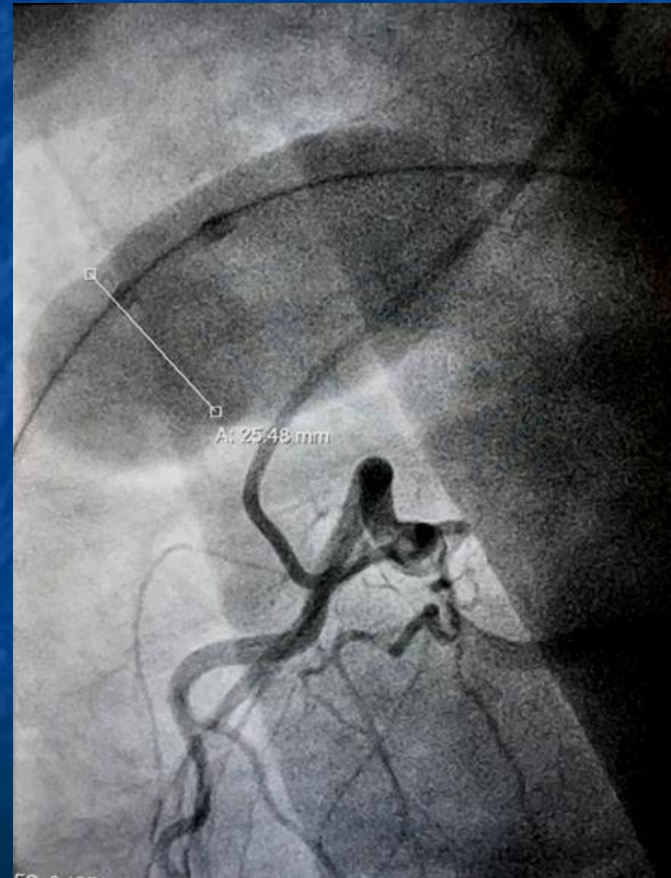
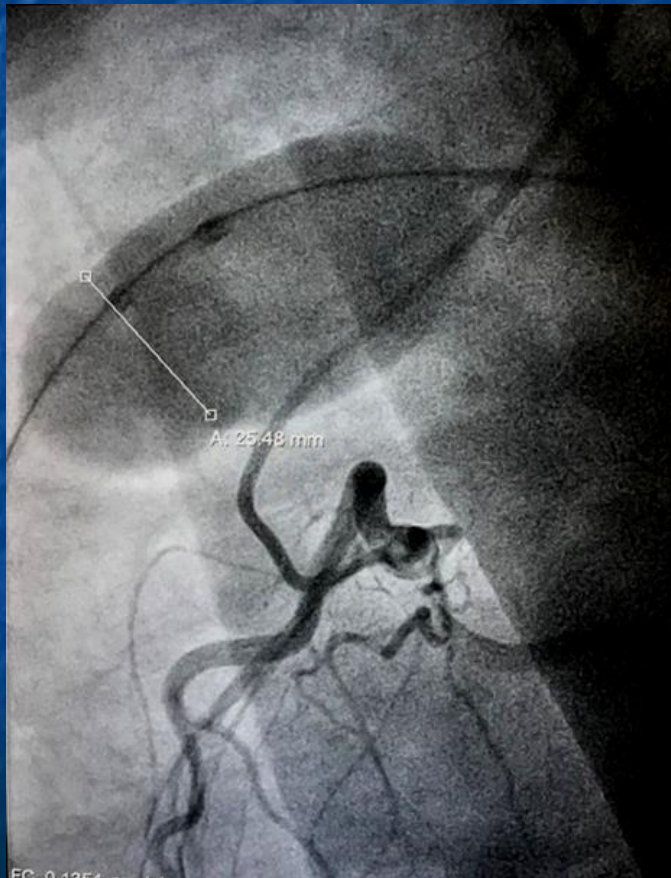
PULSTA VALVE SCREENNING

Sizing balloon + left main coronary artery + RAO view



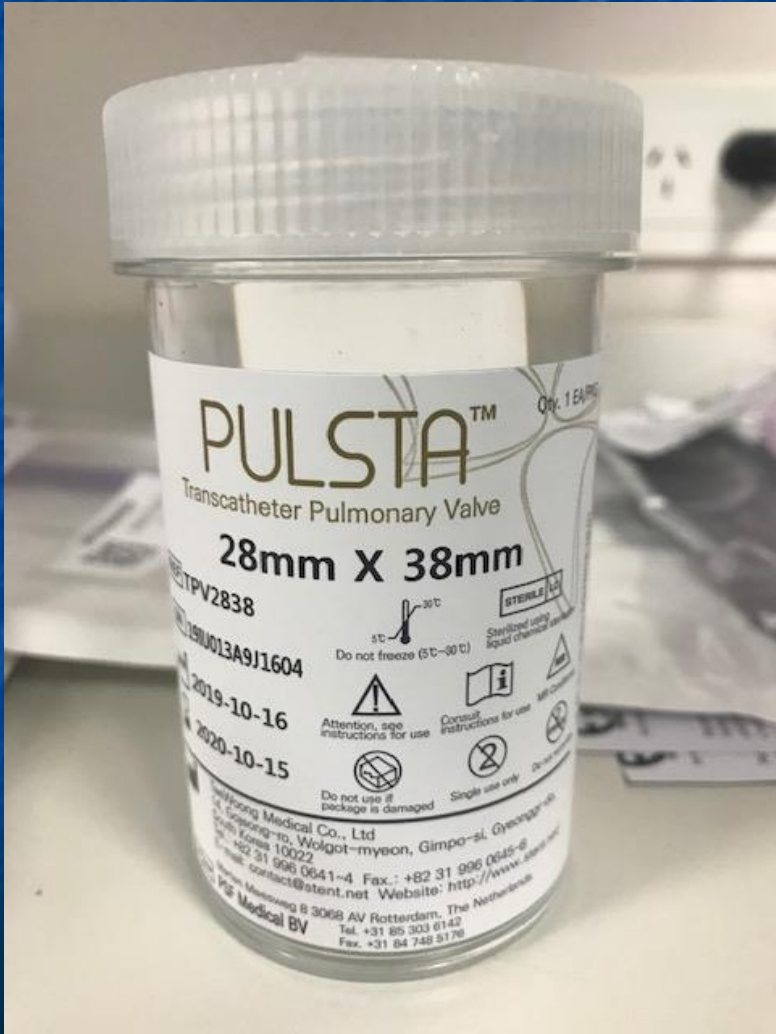
PULSTA VALVE SCREENNING

Sizing balloon + left main coronary artery + left lateral view



PV replacement

Pulsta Valve (TaeWoong Medical)



Initial angiography RAO 45

Im: 1/94
Se: 2

GONZALEZ NICOLAS MATIAS

217904

30/04/1977 M

HOSPITAL PRIVADO CORDOBA

1530293

CARD Ped<6kg

Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 08:50:54

Balloon sizing

Im: 1/32
Se: 3

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped <6kg
Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 08:56:26

System advanced in position

Im: 1/97
Se: 7

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped<6kg
Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 09:48:26

Distal flare initially opened

Im: 1/74
Se: 10

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped<6kg
Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 09:50:48

Distal flare partially opened

Im: 1/77
Se: 14

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped<6kg
Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 09:53:43

Pulsta valve in final position. RAO projection

Im: 1/93
Se: 17

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped<6kg
Coro



WL: 127 WW: 153 [D]
RAO: 40 CAU: 2

26/11/2019 10:02:17

Pulsta valve in final position. LAO-cranial projection

Im: 1/110
Se: 18

GONZALEZ NICOLAS MATIAS
217904
30/04/1977 M
HOSPITAL PRIVADO CORDOBA
1530293
CARD Ped<6kg
Coro

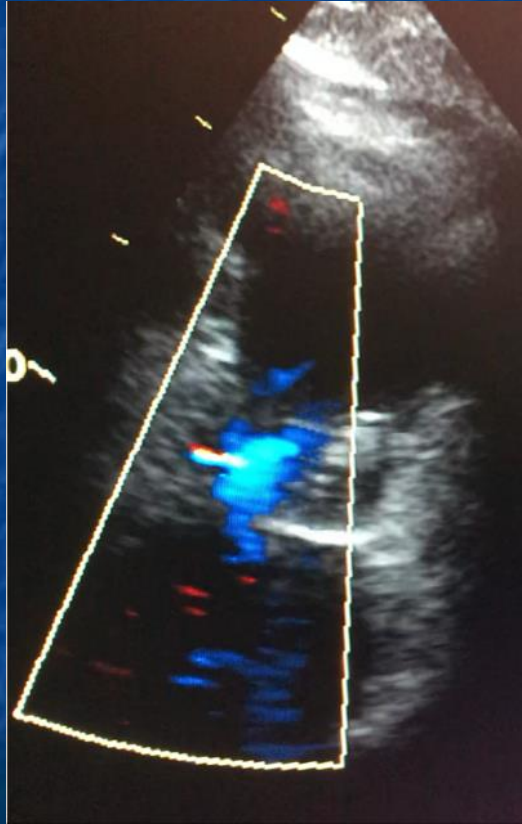
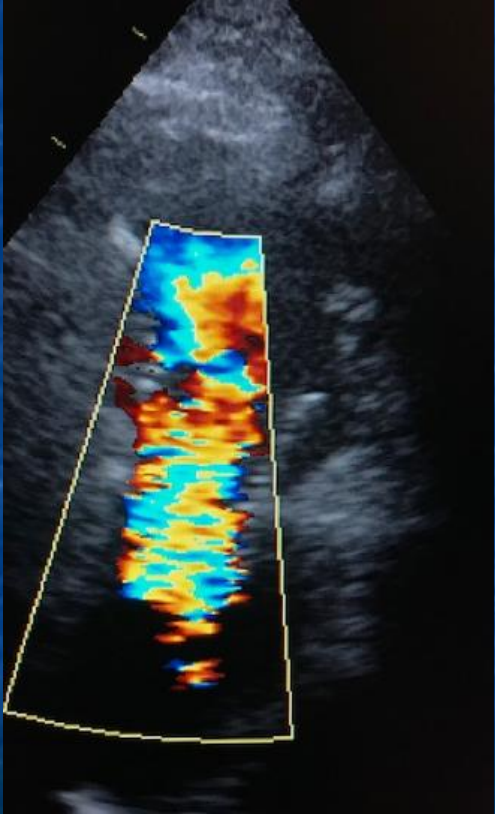


WL: 128 WW: 153 [D]
LAO: 34 CRA: 21

26/11/2019 10:03:23

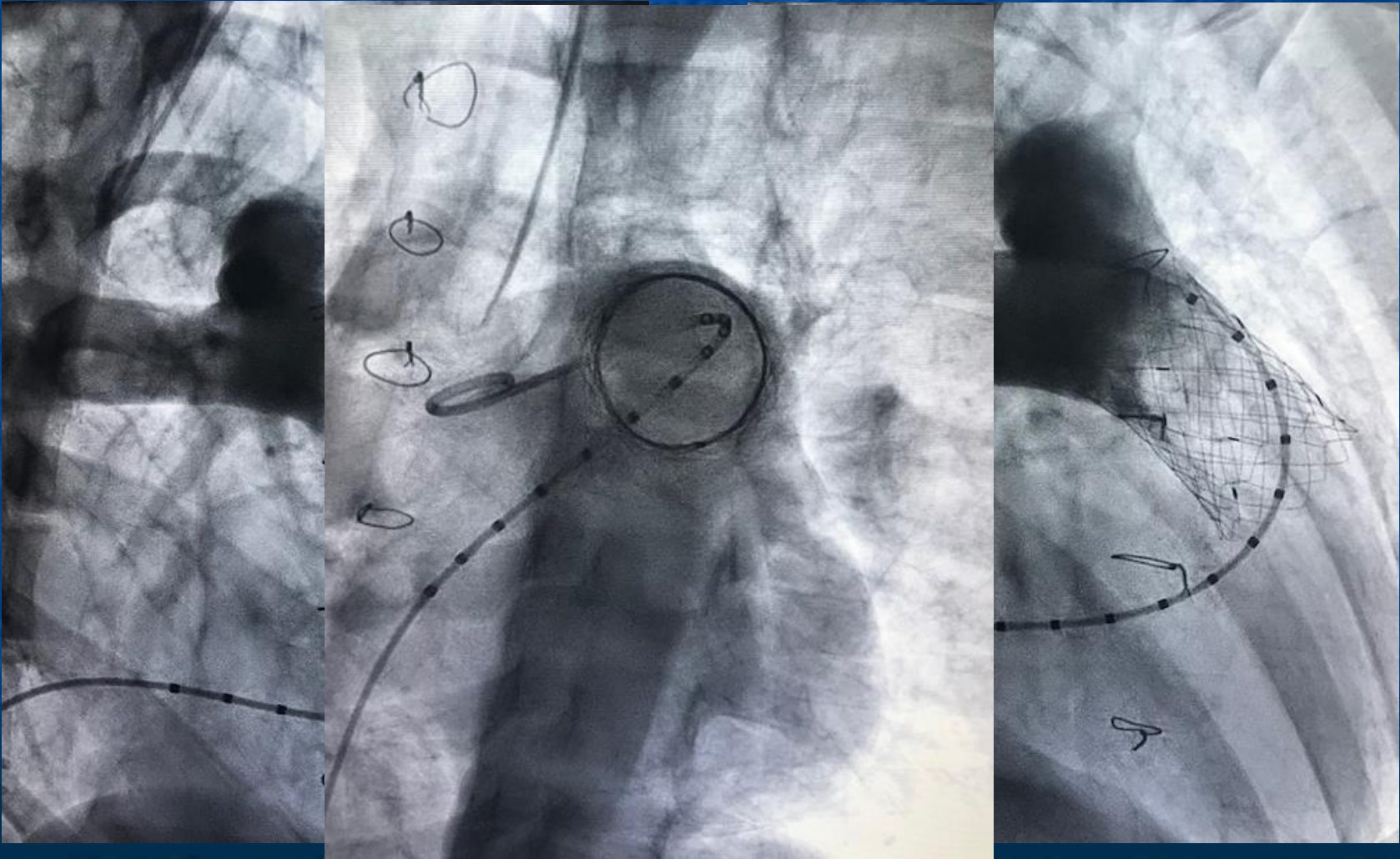
PV replacement

Pulsta Valve. TTE 48 hs post implantation



PV replacement

Pulsta Valve (TaeWoong Medical)



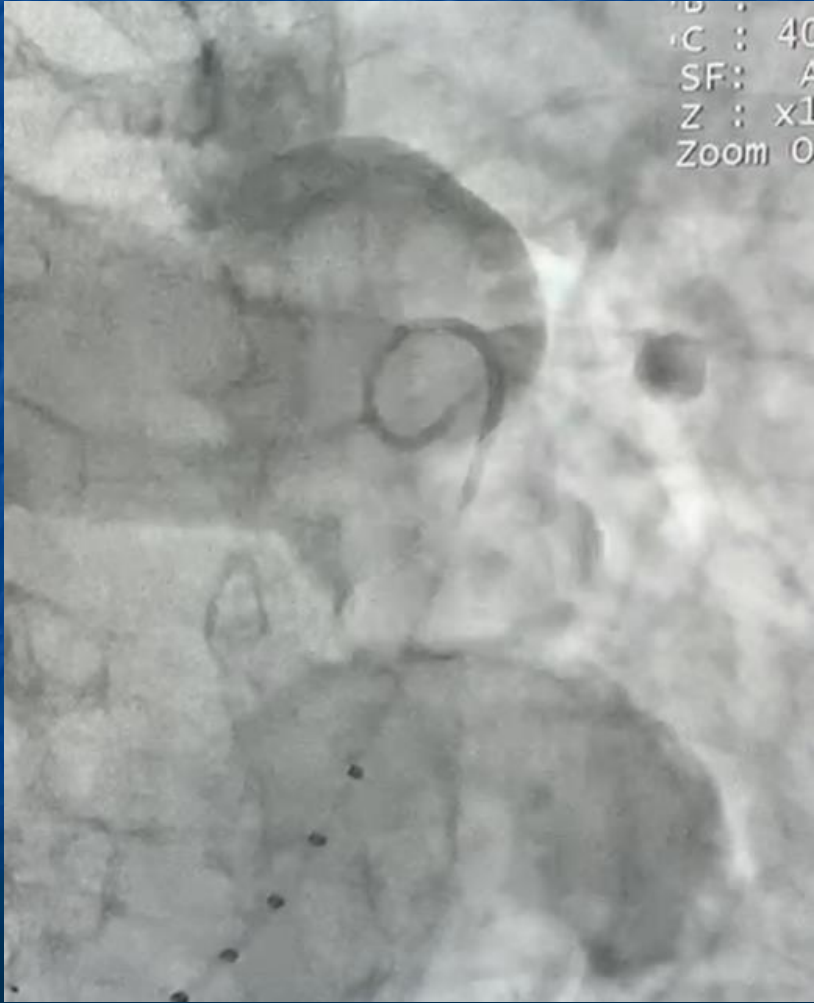
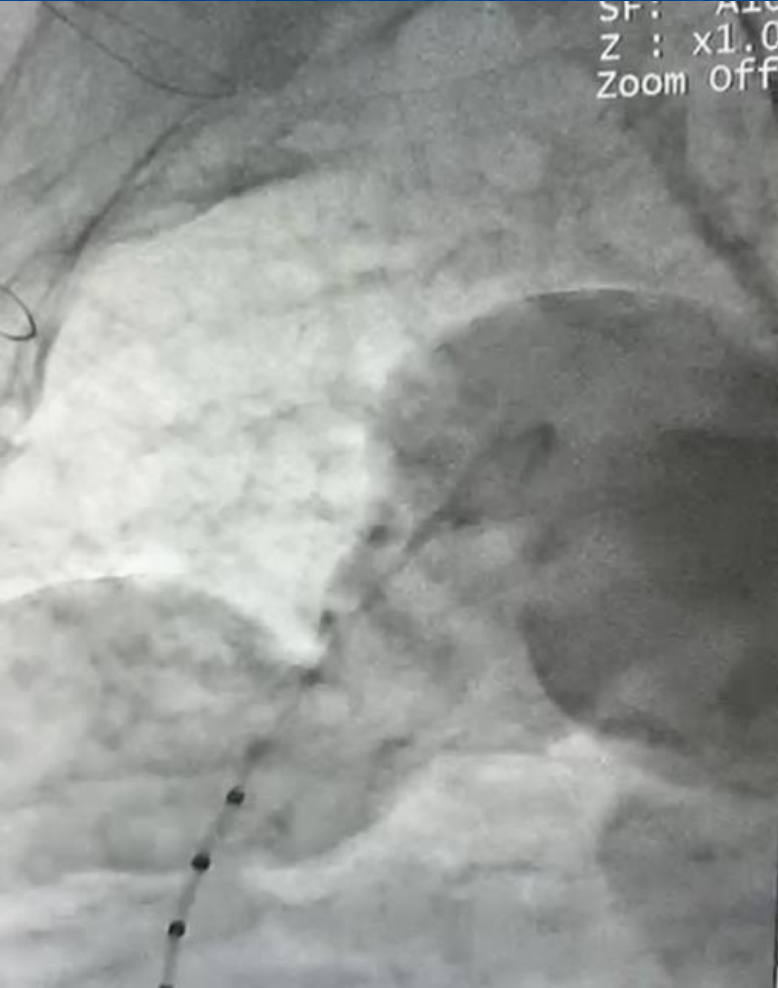
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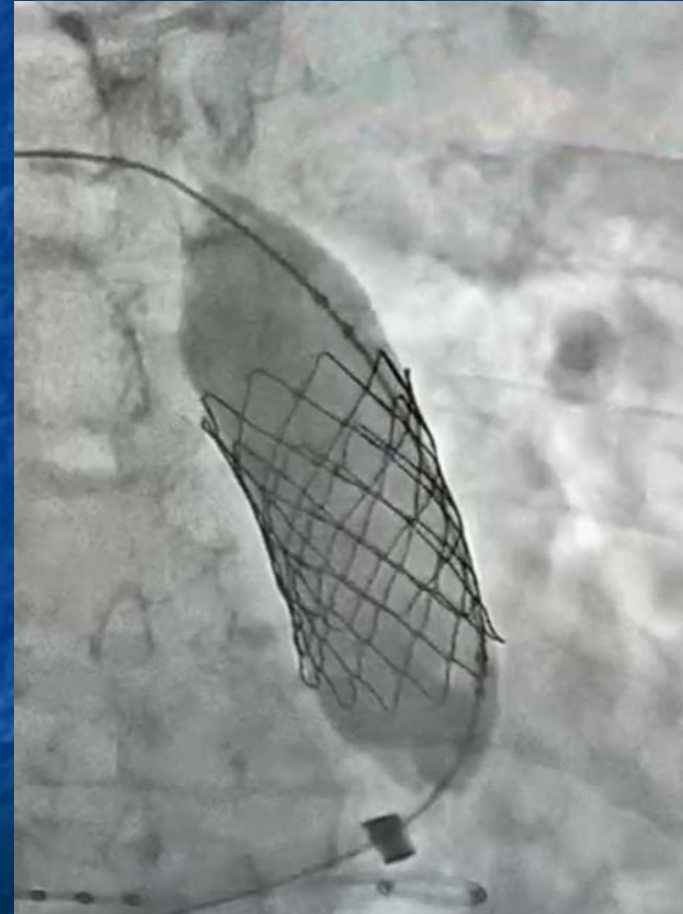
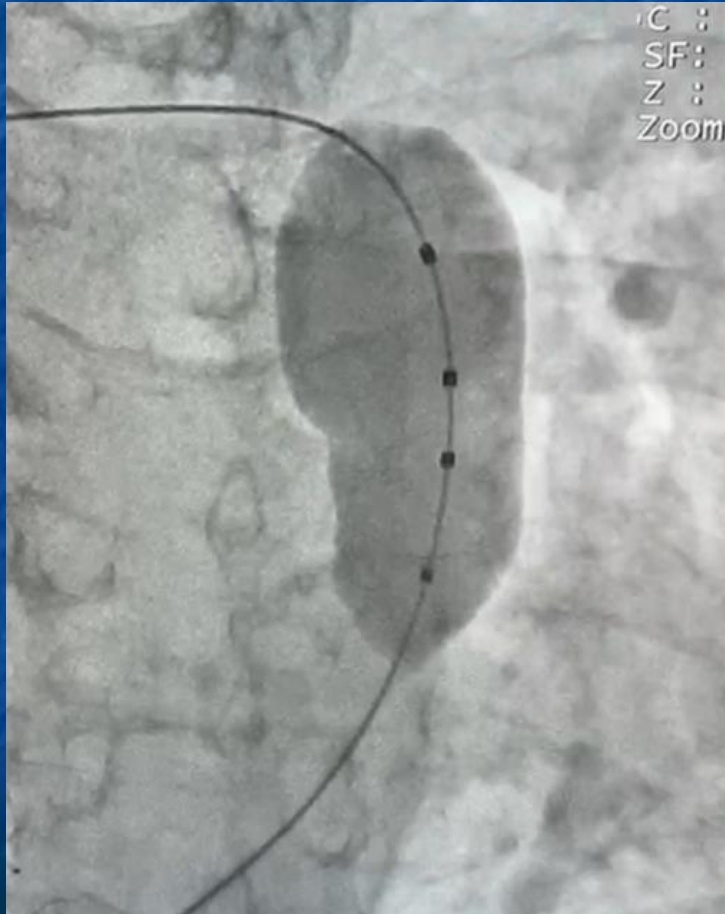
PV replacement

Pulsta Valve: caso desafiante....



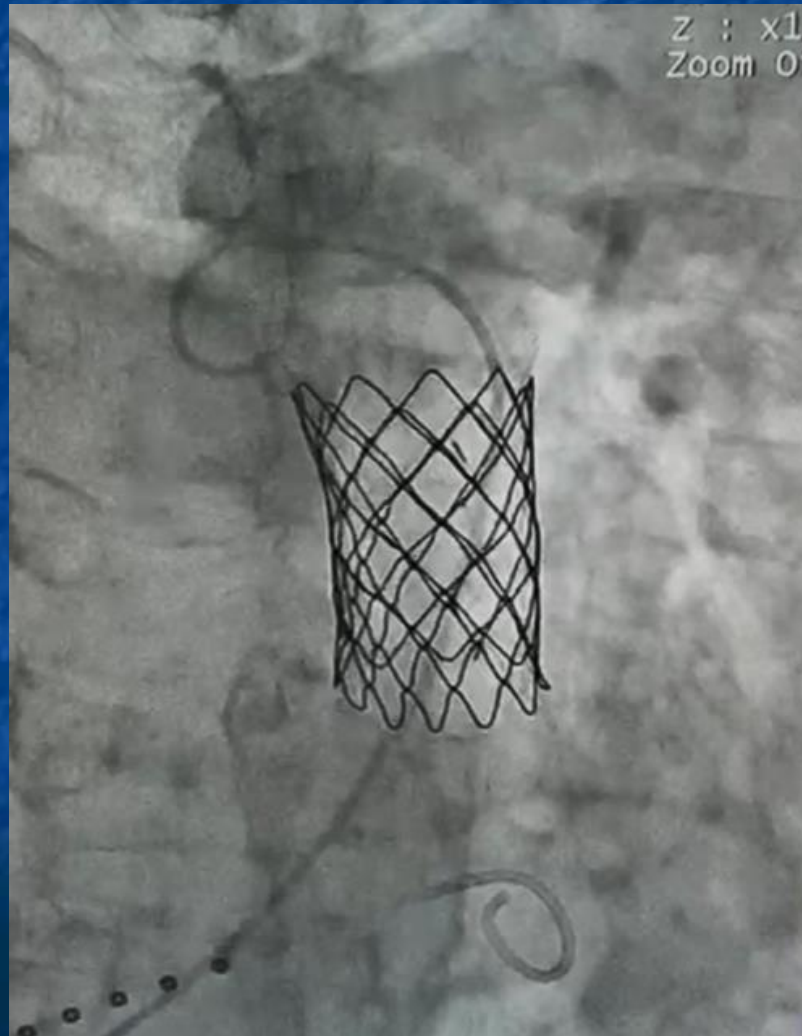
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Pulsta Valve: caso desafiante....



PV replacement

Pulsta Valve: caso desafiante....



Potential advantages....

- *User-friendly valve.*
- *Not bulky, not long.*
- *Easy valve loading.*
- *Good trackability into the target main PA.*
- *Can be implanted in the pts with branch PA stenosis, short main PA, even in the triangular shape main PA.*
- *Lower risk of stent fracture due to knitted (woven) stent nature.*

Conclusions

- *Transcatheter PV replacement is a safe and effective procedure. The valve restores early, sustained pulmonary competence with RV remodeling and improvement in clinical symptoms.*
- *Selection of pts and valve types are crucial to the outcomes of the procedure.*
 - *Pulsta valve seems to be a user-friendly, safe, versatile and attractive device.*
- *Further studies are evolving to evaluate an increased number of pts in more challenging anatomical scenarios.*

PV replacement

Reconocimientos



Gracias!