VENUS A PRO

DR MÁRCIO MONTENEGRO

COORDENADOR DO CENTRO DE TRATAMENTO DE VALVA

INSTITUTO ESTADUAL DE CARDIOLOGIA ALOYSIO DE CASTRO

CONFLITO DE INTERESSE

- PROCTOR VENUS MEDTECH

VenusA-Pro™ System

10 years

In China, with up to 10 years of follow-up data

400+

Lauch in more than 400 centers

10000+

Did more than 10,000 Cases

2012/9

The first China clinical trial case had been done

2017/04

Venus A-Valve

Venus Medtech is the first company to obtain NMPA in China

2020/11

Venus A-Plus

Obtain NMPA ,The first retrievable transcatheter aortic valve replacement product in China.

2022/05

Venus A-Pro

Obtain NMPA

BRAZILIAN EXPERIENCE – VENUS A

- CASES: 27
- MEAN AGE: 80yo
- MALE: 12
- FEMALE: 15

TYPE OF AORTIC VALVE

- TRICUSPID: 21
- BICUSPID: 06 (22%)

CALCIFICATION GRADE

- MILD: 08
- MODERATE: 07
- HEAVY:12

VALVE SIZE SELECTED

23mm: 03

26mm: 09

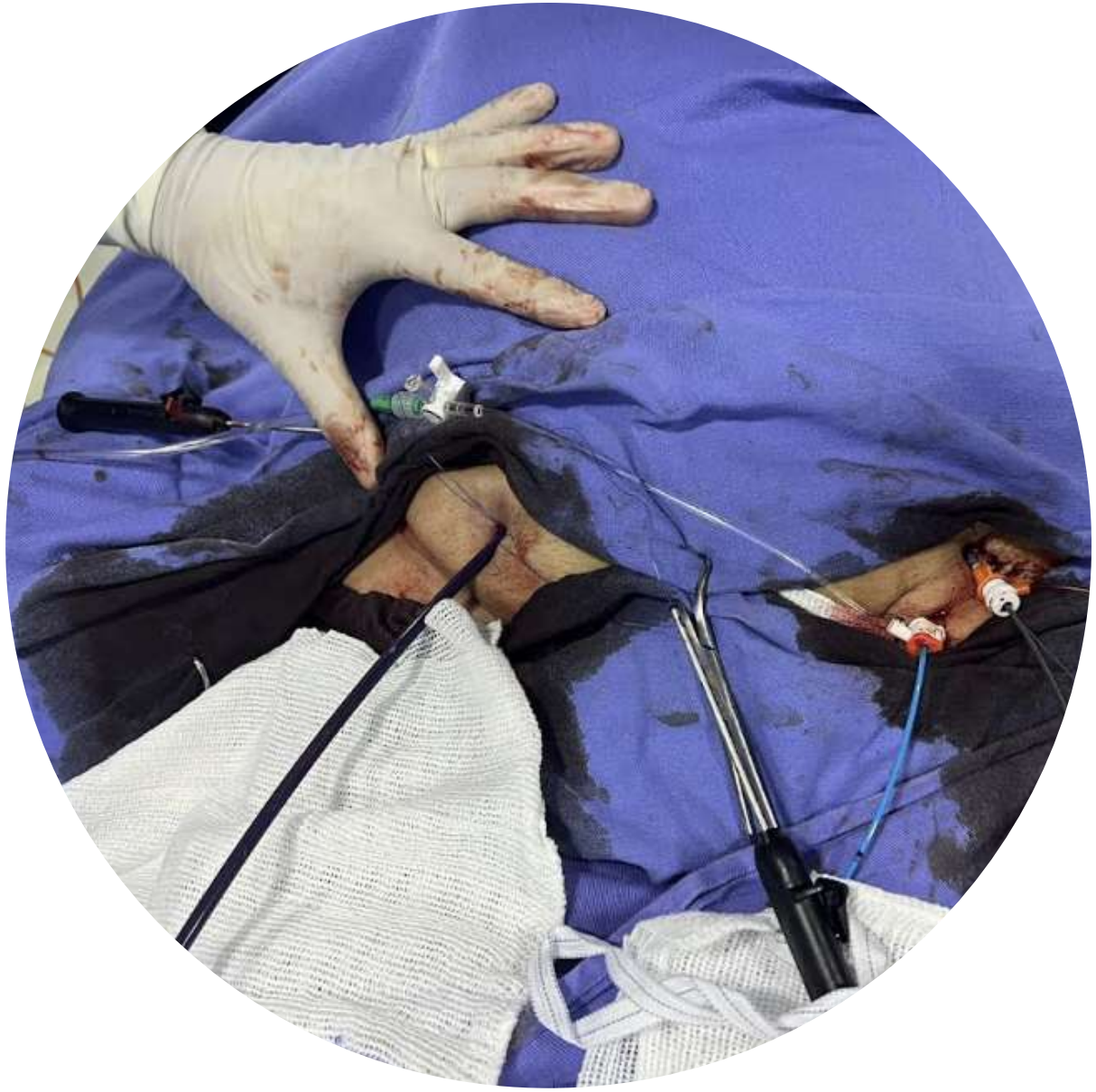
29mm: 12

32mm: 03

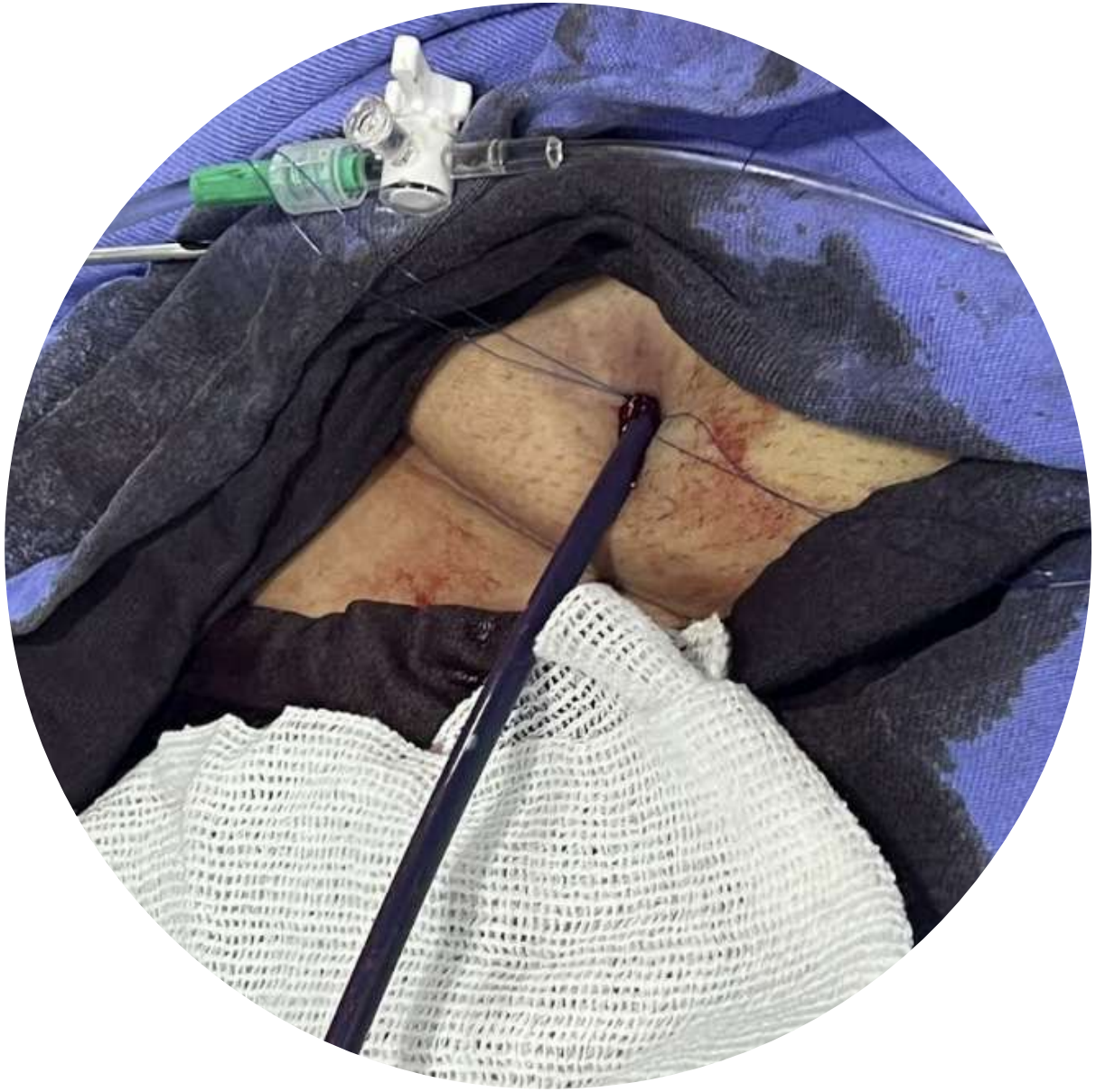
FEMORAL ACCESS

- INTRODUCER SHEATH: 06
- SHEATHLESS: 21

SHEATHLESS APPROACH

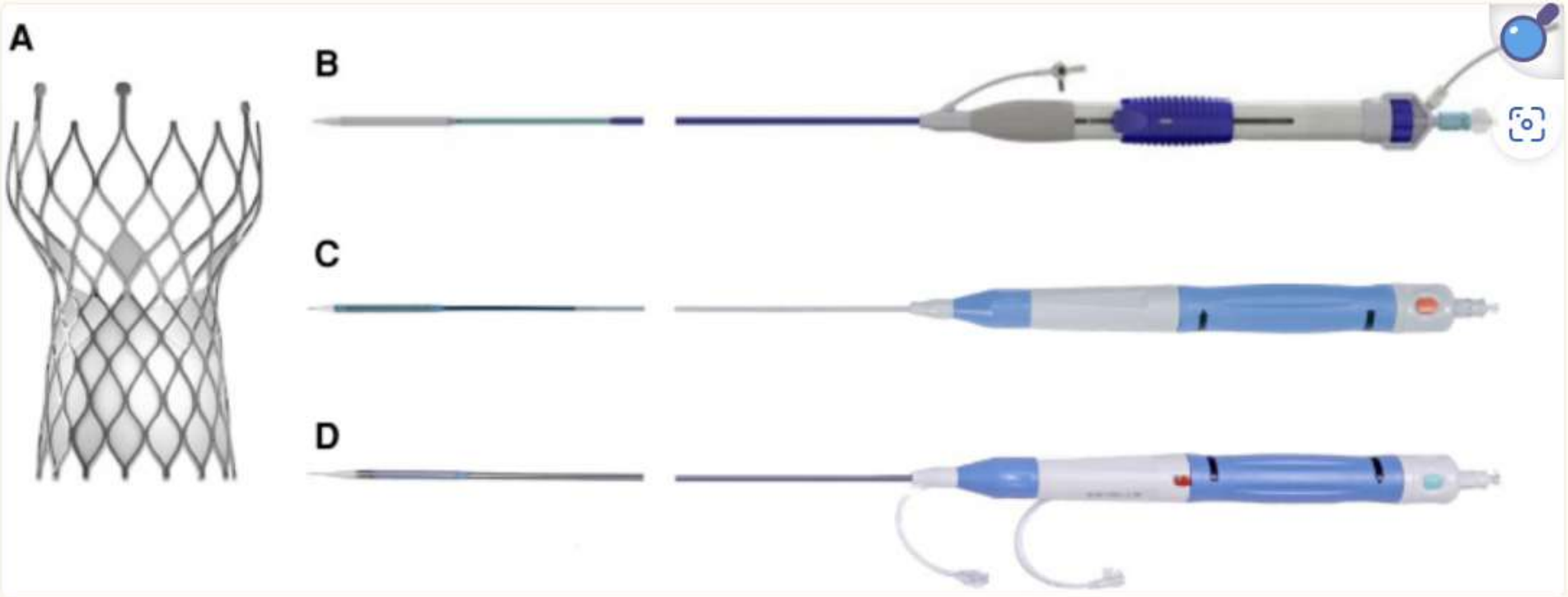


SHEATHLESS APPROACH



Transcatheter aortic valve replacement with the VenusA-Pro and VenusA-Plus systems: preliminary experience in China

Jie Li [1,†,‡], Yinghao Sun [1,‡], Songyuan Luo [1], Shengneng Zheng [1], Jiaohua Chen [1], Ming Fu [1], Zhenfei Fang [2], Yan Wang [3], Guang Li [1], Ruixin Fan [1], Jianfang Luo [1,*]



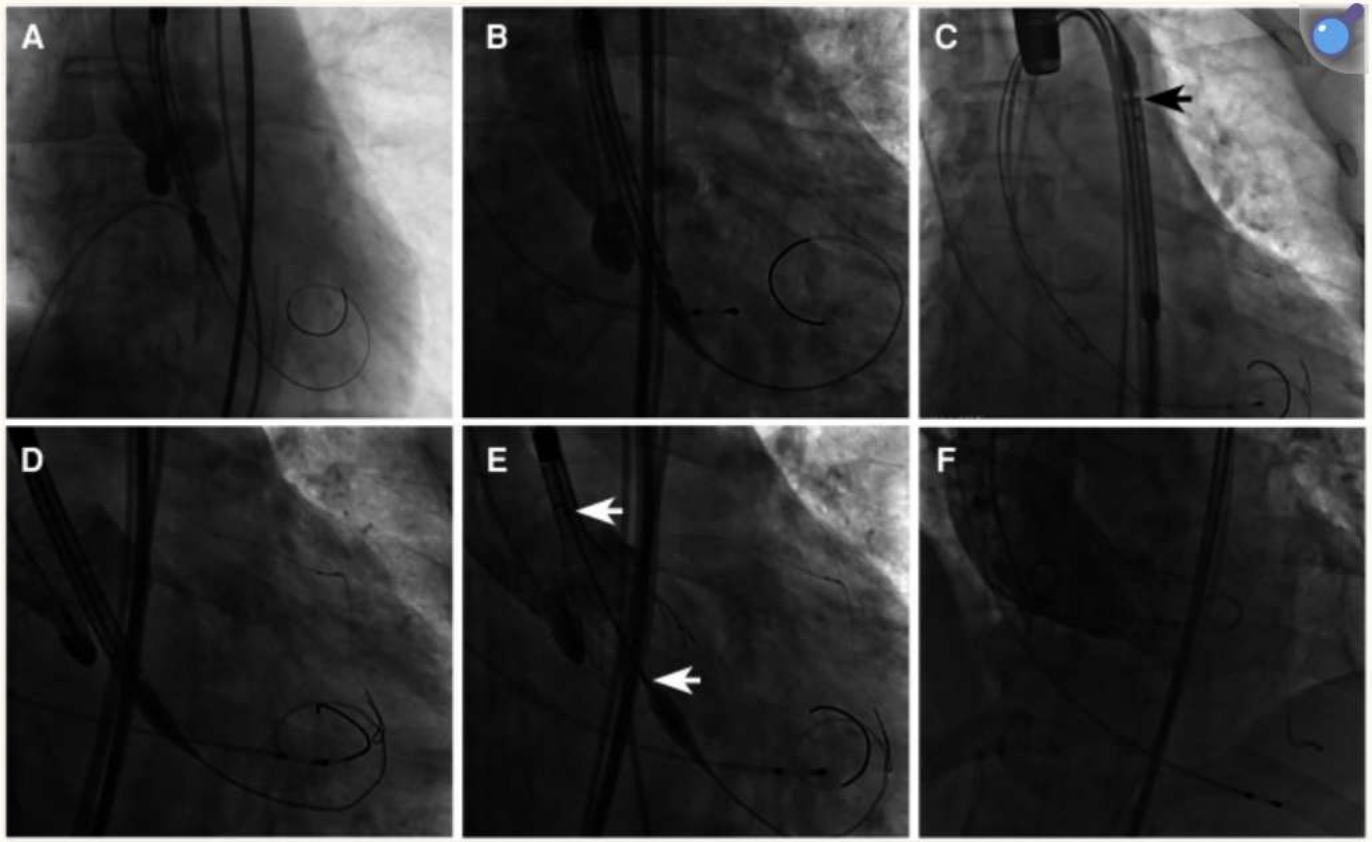
Open in a new tab

VenusA-Valve prosthesis and iteration of its delivery systems. (**A**) VenusA-Valve prosthesis, (**B**) first-generation non-retrievable delivery system, (**C**) second-generation retrievable VenusA-Plus delivery system, (**D**) second-generation retrievable VenusA-Pro delivery system. The red button in the middle of the handle is the safety lock.

DOI: 10.3389/fcvm.2023.1169590

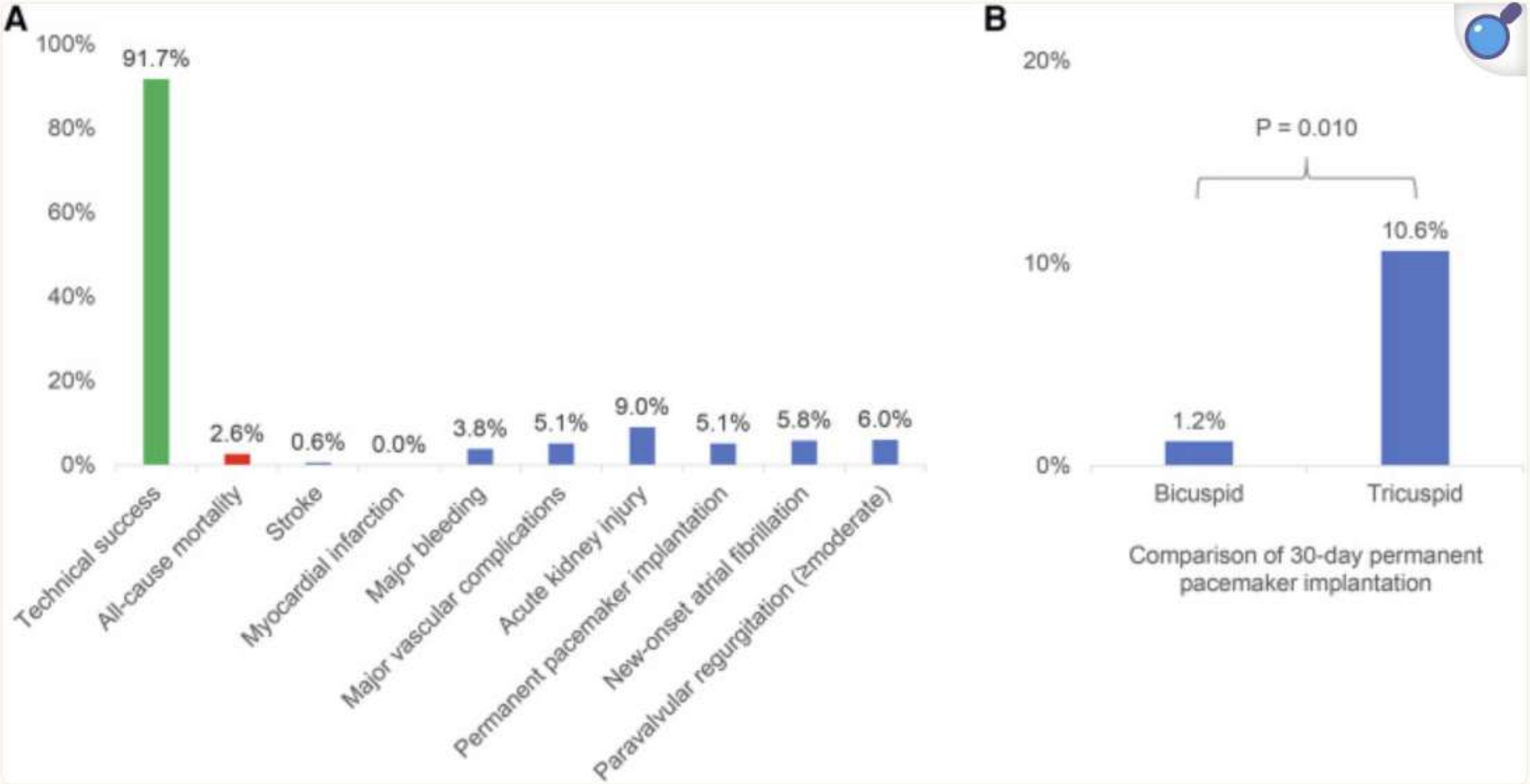
The VenusA-Valve features supra-annular design similar to the Medtronic CoreValve (Medtronic Inc., Minneapolis, MN, USA) but with stronger radial force at the inflow end, which may be advantageous in bicuspid anatomy and severe calcification (2). Both VenusA-Pro and VenusA-Plus are second-generation retrievable and repositionable delivery systems that use the same prothesis VenusA-Valve as in the first-generation non-retrievable delivery system. The prosthesis is available in four different sizes (23, 26, 29, and 32 mm). The VenusA-Pro has the same profile as the VenusA-Plus, with an outer diameter ranging from 18 to 19 Fr. Compared to the VenusA-Plus, the VenusA-Pro offers more major advantages. First, the VenusA-Pro features a safety lock to prevent accidental valve deployment. Second, there is an additional marker for delivery system orientation for a better commissural alignment and coronary protection, which should point to the greater curve of the aortic arch. Third, the front end of the sheath has better flexibility when confronted with the horizontal aorta. Lastly, two limiting markers were used as reference during release or retrieval (Figure 1, 2).

DOI: 10.3389/fcvm.2023.1169590



Fluoroscopic view of different delivery systems and their common VenusA-Valve prosthesis. (**A**) First-generation non-retrievable delivery system, (**B**) VenusA-Plus, and (**C**) VenusA-Pro. The black arrow shows the extra marker for orientation, which should point to the greater curve of the aortic arch. (**D**) VenusA-Pro locating the prosthesis, with left coronary artery under protection. (**E**) VenusA-Pro releasing the prosthesis after three times of retrieval and adjustment in a challenging case with a horizontal aorta with an aortic root angle of 73°. The white arrows show two limiting markers for reference during release or retrieval. (**F**) Final position of the VenusA-Valve prosthesis released by the VenusA-Pro delivery system, aortography showing trivial paravalvular aortic regurgitation.

DOI: 10.3389/fcvm.2023.1169590



DOI: 10.3389/fcvm.2023.1169590

55% DE BICÚSPIDE

Death	1 (1.2)	3 (4.5)	0.197
Stroke	1 (1.2)	0 (0)	0.379
Myocardial infarction	0 (0)	0 (0)	NA
Major bleeding (type 2–4)	1 (1.2)	5 (7.6)	0.086
Major vascular complications	6 (7.0)	2 (3.0)	0.280
Acute kidney injury (stage 2–4)	5 (5.8)	8 (12.1)	0.168
Permanent pacemaker implantation	1 (1.2)	7 (10.6)	**0.010**
New-onset atrial fibrillation	5 (5.8)	4 (6.1)	0.949
Post-procedural hemodynamic outcomes[b]			
Aortic valve area, cm^2	1.63 ± 0.53	1.82 ± 0.55	0.174
Mean transaortic gradient, mmHg	12.7 ± 5.5	10.5 ± 4.3	**0.031**
Peak aortic velocity, m/s	2.21 ± 0.63	2.02 ± 0.51	**0.049**
Left ventricular ejection fraction, %	57.5 ± 11.1	56.0 ± 13.6	0.440
Moderate-to-severe aortic regurgitation	5 (6.0)	4 (6.5)	0.901

DOI: 10.3389/fcvm.2023.1169590

CARACTERISTICA DO PROCEDIMENTO: BICUSPIDE X TRICUSPIDE

General anesthesia	83 (96.5)	59 (89.4)	0.079
Transfemoral access	81 (94.2)	63 (95.5)	0.728
Combined percutaneous coronary intervention	8 (9.3)	12 (18.2)	0.108
Pre-dilation	85 (98.8)	65 (98.5)	0.850
Post-dilation	48 (55.8)	26 (39.4)	**0.045**
Prostheses size[a]			**0.044**
23 mm	29 (34.1)	10 (15.2)	
26 mm	38 (44.7)	38 (57.6)	
29 mm	15 (17.6)	17 (25.8)	
32 mm	3 (3.5)	1 (1.5)	
Perimeter oversizing, %	2.8 ± 7.0	8.6 ± 6.9	**<0.001**
Second valve implantation	1 (1.2)	2 (3.0)	0.412
Coronary obstruction	0 (0)	0 (0)	NA
Conversion to open surgery	0 (0)	2 (3.0)	0.104
Technical success	79 (91.9)	60 (90.9)	0.835

RESULTADOS: BICUSPIDE X TRICUSPIDE

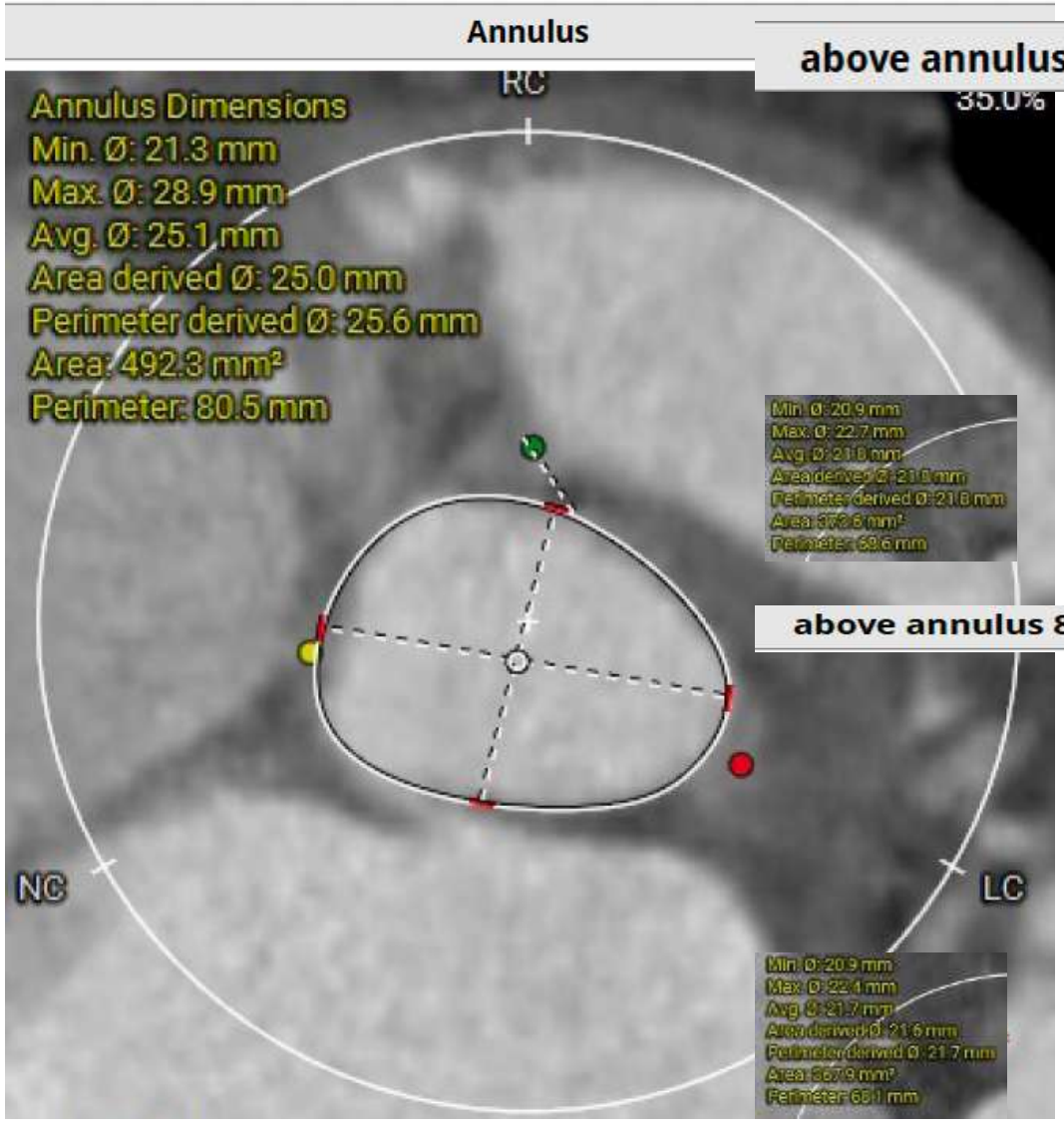
Death	1 (1.2)	3 (4.5)	0.197
Stroke	1 (1.2)	0 (0)	0.379
Myocardial infarction	0 (0)	0 (0)	NA
Major bleeding (type 2–4)	1 (1.2)	5 (7.6)	0.086
Major vascular complications	6 (7.0)	2 (3.0)	0.280
Acute kidney injury (stage 2–4)	5 (5.8)	8 (12.1)	0.168
Permanent pacemaker implantation	1 (1.2)	7 (10.6)	**0.010**
New-onset atrial fibrillation	5 (5.8)	4 (6.1)	0.949
Post-procedural hemodynamic outcomes[b]			
Aortic valve area, cm^2	1.63 ± 0.53	1.82 ± 0.55	0.174
Mean transaortic gradient, mmHg	12.7 ± 5.5	10.5 ± 4.3	**0.031**
Peak aortic velocity, m/s	2.21 ± 0.63	2.02 ± 0.51	**0.049**
Left ventricular ejection fraction, %	57.5 ± 11.1	56.0 ± 13.6	0.440
Moderate-to-severe aortic regurgitation	5 (6.0)	4 (6.5)	0.901

CASO CLINICO

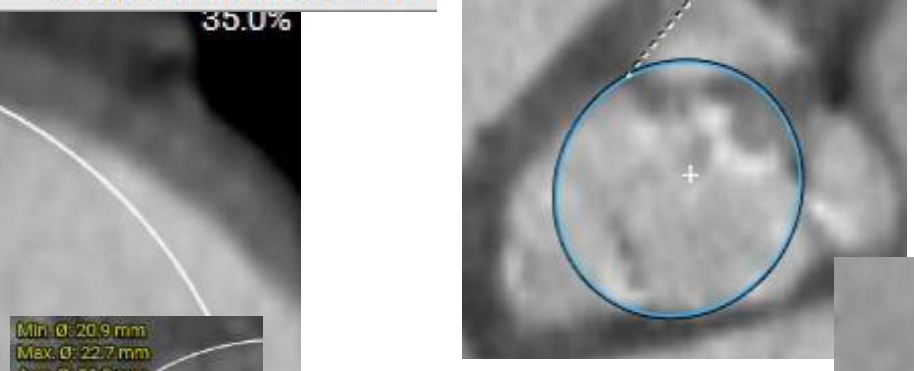
- ✓Male; 72 years-old
- ✓Hypertension, DM
- ✓Heavy Smoker
- ✓COPD/PAD
- ✓No CAD or rhythmic disturbances
- ✓Severe Ao Stenosis
- ✓Moderate AR & MR
- ✓Cr clearance < 50
- ✓CHF NYHA III/IV
- ✓ ⇩ LV function

- LV (increased and Hypertrofic (57x41 e 1,2x1,2) EF31%
- AoV thickened and Calcified – Aortica Val. Area 0,42 cm^2 (Index)
- Gd Max 75 e Med 48mmhg
- DVI 0,14 VMax4,3m/s
- Normal Aortic dimentions
- Tethering Mitral moderate Regurgitation - Vena Cont 0,6

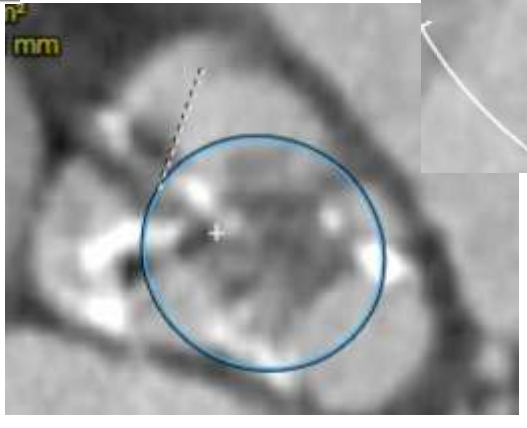
ANGIO CT



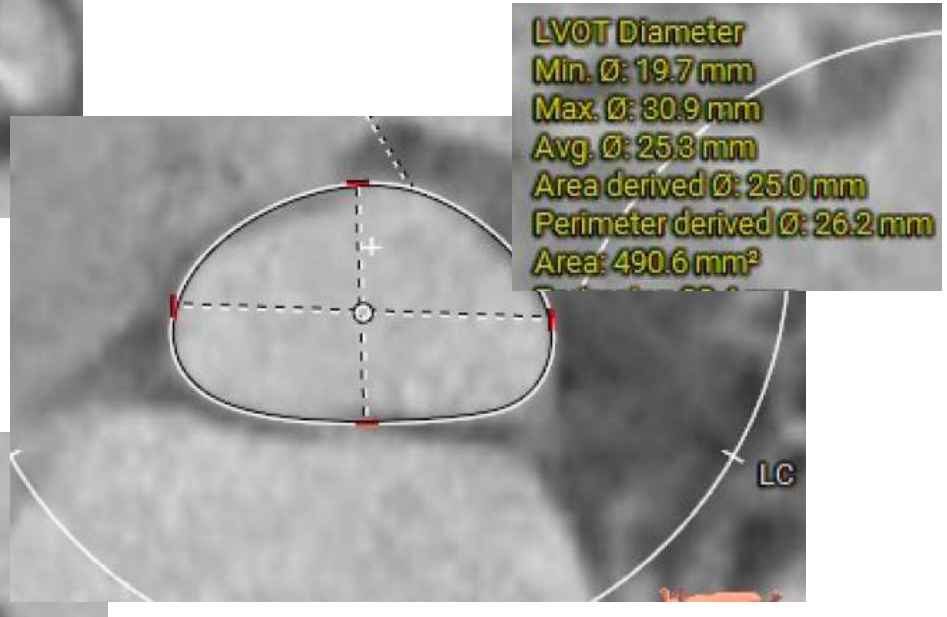
above annulus 4mm



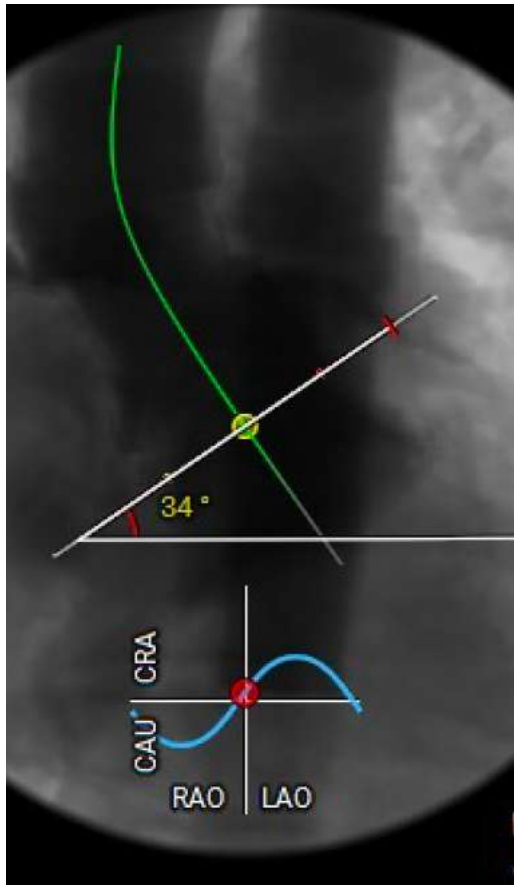
above annulus 8mm

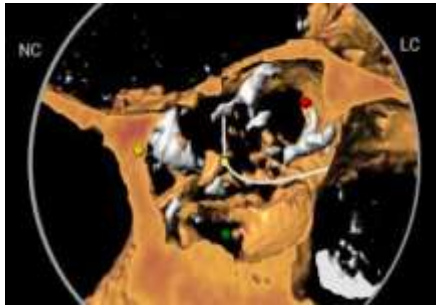


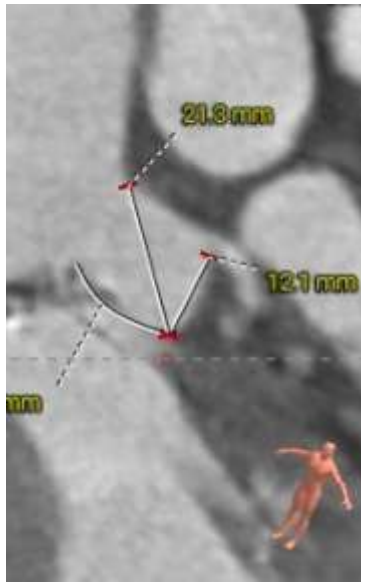
LVOT

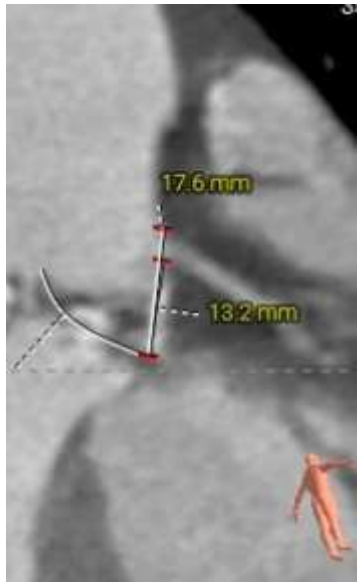


VENUS A PRO 29










First case in South America of VENUS-A PRO

New TAVI Devices Parade
Edited Cases

VENUS A-PRO

Next-Generation Aortic Valve Replacement System– Self-Expanding

Venus-PowerX

Venus-PowerX is Venus Medtech's next-generation self-expanding dry-tissue TAVR system for the treatment of patients with aortic valve stenosis. Venus-PowerX utilizes the innovative Venus-Endura technology, which integrates multiple anti-calcification techniques, immunogenicity removal technology and 3D force-controlled dehydration technology, providing exceptional durability, biocompatibility, and excellent anti-calcification performance. In addition, this design allows room temperature storage of the valve in a dry-tissue condition.

Venus-PowerX

Venus-Vitae

Next-Generation Aortic Valve Replacement System– Balloon-Expandable

Venus-Vitae

Venus-Vitae is the next-generation balloon-expandable transcatheter heart valve system developed by Venus Medtech, with global patent protection. Venus-Vitae utilizes the innovative Venus-Endura technology, which integrates multiple anti-calcification techniques, immunogenicity removal technology and 3D force-controlled dehydration technology, providing exceptional durability, biocompatibility, and excellent anti-calcification performance. In addition, this design allows for room temperature storage of the valve in a dry-tissue condition.

Cardiovalve

products of the same kind, its transfemoral approach improves the safety of treatment in significant ways.

Cardiovalve's treatment of mitral regurgitation has entered clinical trials in Europe and is currently in an early feasibility study in the U.S.. Furthermore, its device for the treatment of tricuspid regurgitation received 'Breakthrough Device Designation' by the FDA in January 2020 and entered an early feasibility study. It is worth mentioning that Cardiovalve is also the first privately held company to receive FDA's early feasibility study (EFS) approval for both TR and MR indications.

For more information, please click:: http://www.cardiovalve.com/

DragonFly™

DragonFly™ Transcatheter Mitral Valve Repair System (“DF”), independently developed by Valgen Medtech, is the first domestically engineered transfemoral mitral valve clip system approved in China. DragonFly™ entered the NMPA's Special Review and Approval Procedures for Innovative Medical Devices in March 2021 and received marketing approval on November 29, 2023.

Venus Medtech and Valgen Medtech jointly announced that both parties reached an exclusive strategic marketing cooperation intention in relation to the DragonFly™ Transcatheter Mitral Valve Repair System of Valgen Medtech on November 22nd, 2023. Both parties will carry out in-depth commercialization cooperation after the approval for listing of

VenusP-Valve™ System

The VenusP-Valve System is the first self-expanding nitinol stent for pulmonary valve in Europe known to Venus Medtech. The VenusP-Valve System was designed at 28-36 mm for valve diameter specifically for large RVOTs. The intended purpose of VenusP-Valve is to replace the pulmonary heart valve with an artificial valve using a minimally invasive percutaneous approach, to treat right ventricular outflow tract (RVOT) dysfunction and specifically for the dilated outflow tracts to restore pulmonary valve function.

View Demo

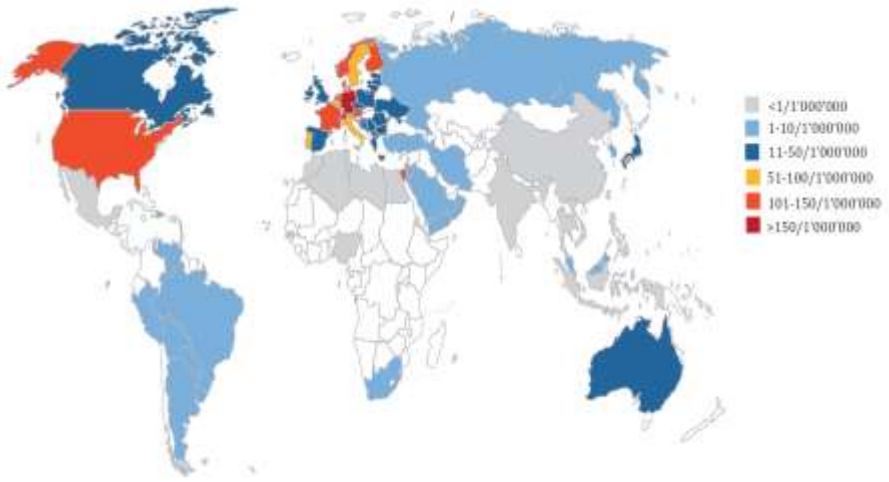
RDN Therapy

The principle of renal denervation (RDN) for the treatment of hypertension is to ablate sympathetic nerves in the walls of renal arteries and disrupt nerve signaling to lower blood pressure. Clinical studies have demonstrated the significant safety and efficacy of RDN therapy in the treatment of uncontrolled or resistant hypertension. Patients with resistant hypertension tend to benefit the most from RDN. At the same time, RDN provides an alternative for hypertensive patients with a poor compliance with oral drugs.

In June 2021, Venus Medtech announced Renaly Ltd., a joint venture with Healium Medical Ltd., to introduce next-generation innovative RDN devices and expand the R&D, manufacturing, and marketing of RDN

Take Home Message: ***So many valves choices !!!!***

Geographic Imbalance/Costs/Regulatory/Training/Clinical Data/Niche Indications



Distill the Essentials

THANK YOU FOR YOUR ATTENTION!