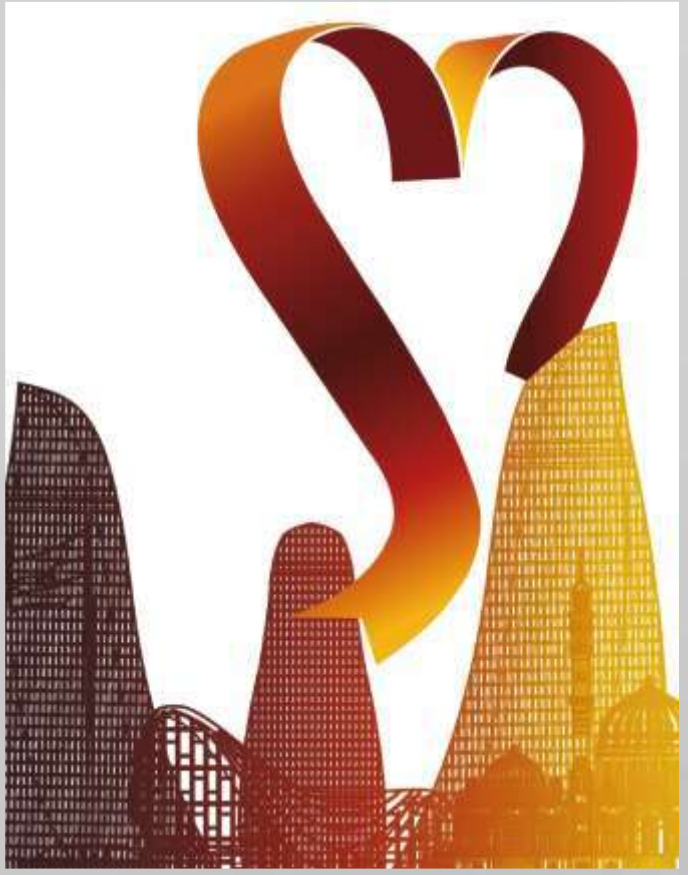
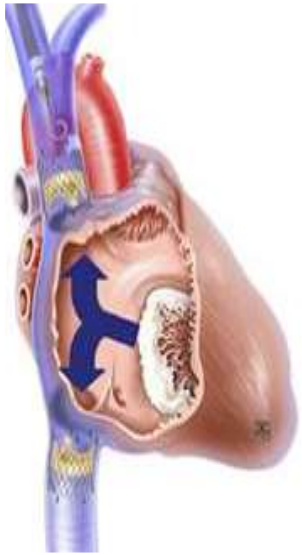
Tricvalve for the Treatment of severe Tricuspid Regurgitation and Right Heart Failure Patients

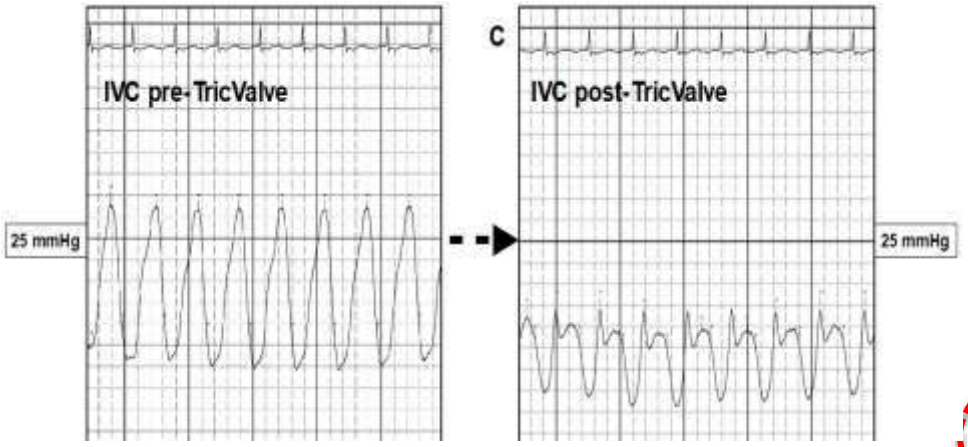


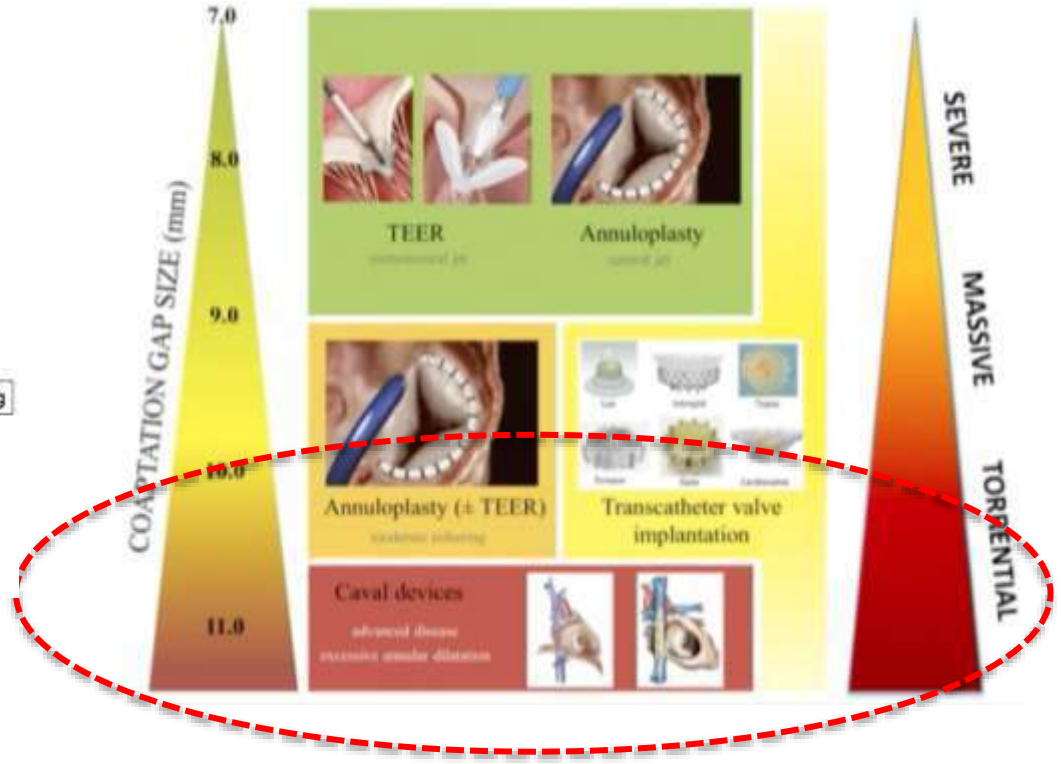
Katharina Kiss, MD
Vienna Austria

P&F PRODUCTS & FEATURES

Tricvalve for right heart failure patients





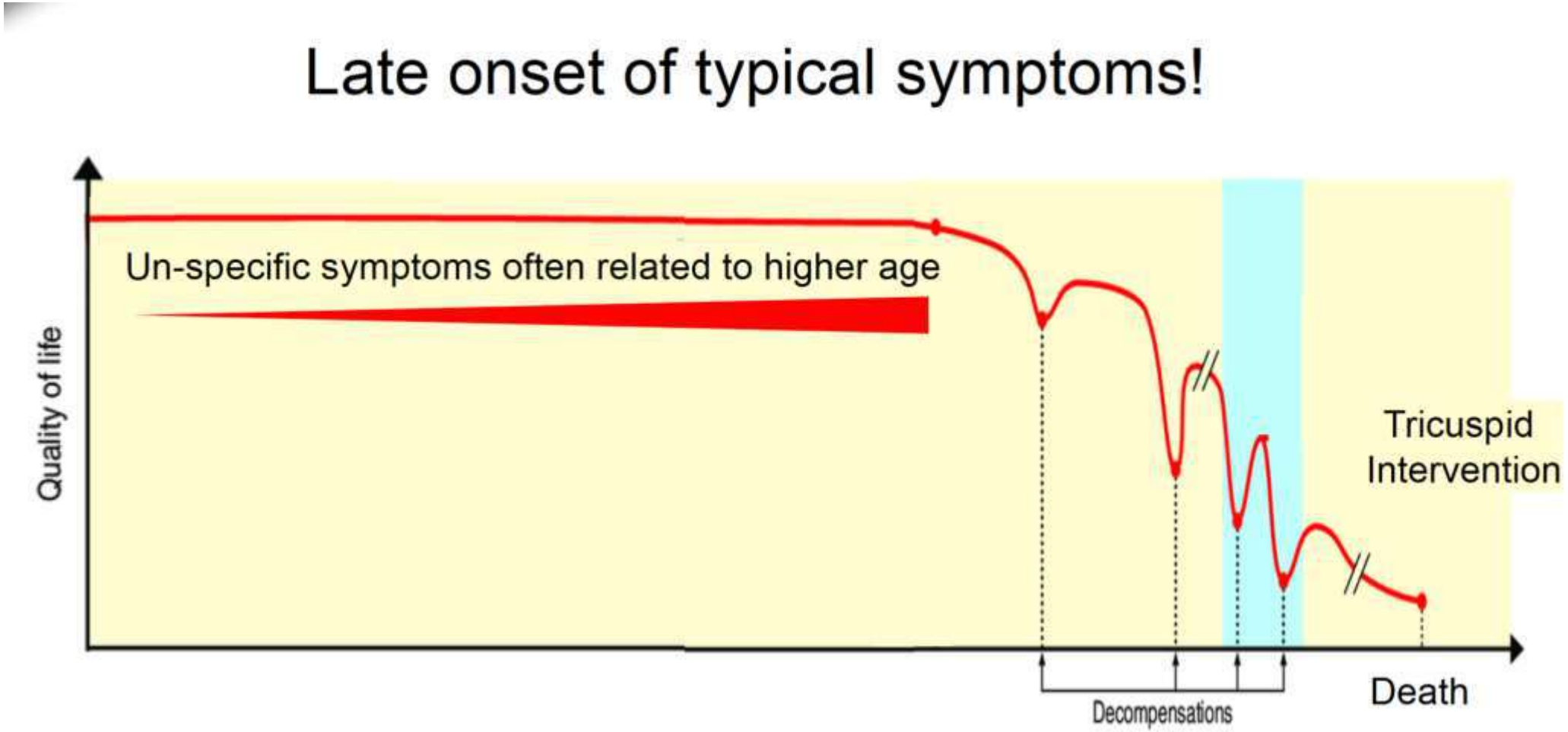


Heterotopic approach: to abolish TR backflow into venous system reducing peripheral venous congestion and over time increasing forward flow (CO)

RHF // Organ failure

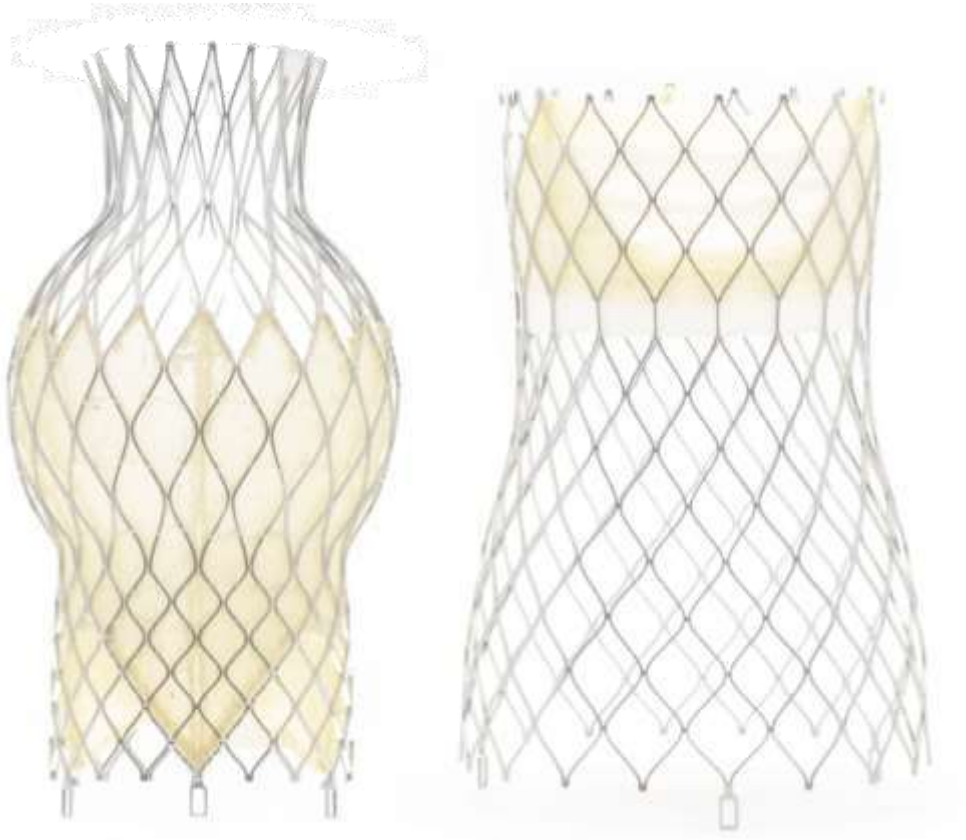
Will MG, Praz F. J Am Coll Cardiol Intv 2022;15:1378-81

Diuretics honeymoon
Decompensations permanently impair quality of life



Introducing the TricValve Transcatheter Self Expanding Bicaval Valve System

P&F PRODUCTS & FEATURES

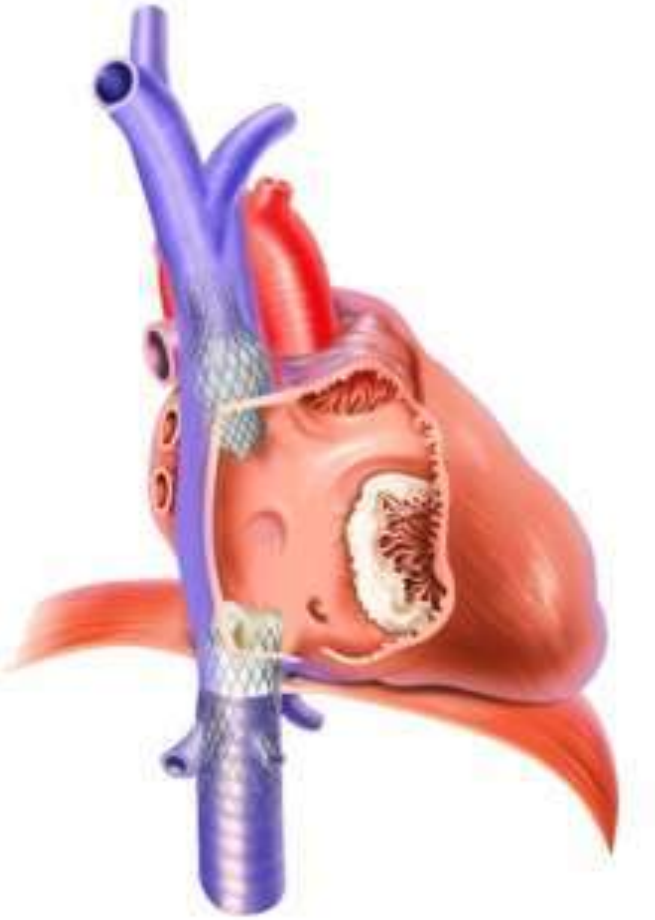


- **Dry bovine pericardium** technology
- **Pre-mounted on the delivery system**, ready to be used, eliminating the need for assembly and crimping of the device prior to valve implantation – “Off-the-shelf-use“
- **Repositionable and retrievable,** allowing for a more optimal prosthesis positioning to minimize residual paravalvular regurgitation

TricValve Insights

P&F PRODUCTS & FEATURES

- **Bio Designed Structure**
  - Assuring maximum stability and conformation with native cava anatomy
- **Self-expanding Nitinol Alloy**
  - Fatigue and Durability tested 600 million cycles (equivalent to 20 years) without structural degradation
- **Adjusted skirt length**
  - To maximize sealing and prevent obstruction of the Hepatic and Brachiocephalic Veins

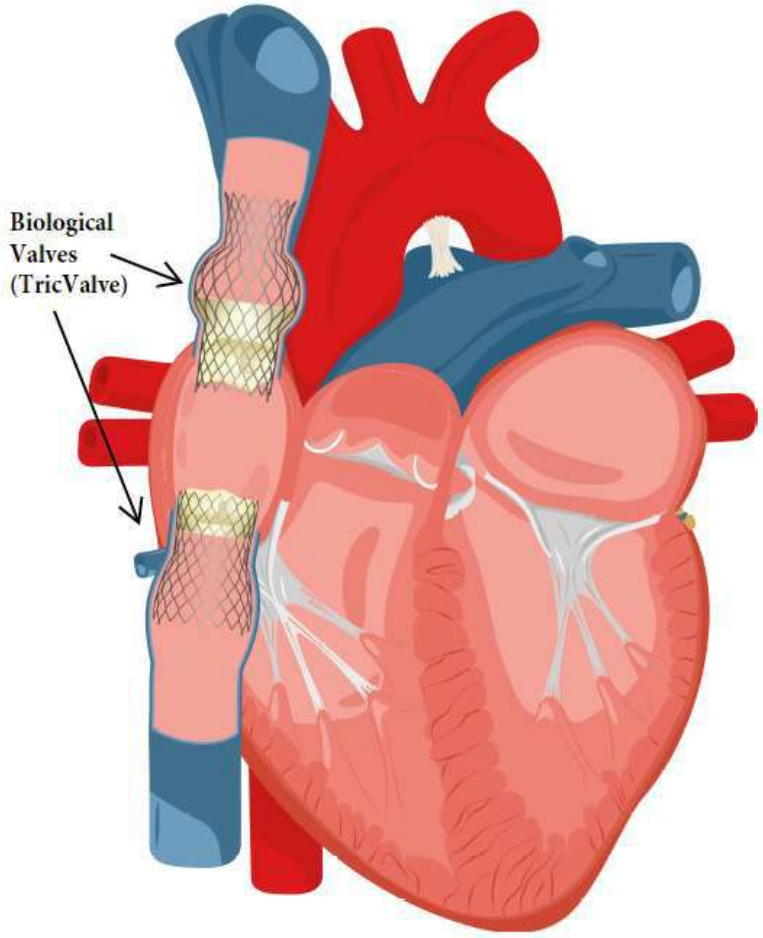


Population & Procedure Highlights

P&F PRODUCTS & FEATURES

Intended Use

The **TricValve Bicaval System** is intended for use in patients with **Severe Symptomatic Tricuspid Valve Regurgitation** with the required anatomical criteria who are at **high surgical risk** and accepted for transcatheter Bicaval valve implantation by the Heart Team.



Procedure Highlights

- Minimally invasive
- Reduced duration of the implantation (< 60 min)
- Procedure can be performed without general anesthesia
- Tricvalve does not interfere with the native Tricuspid valve anatomy
- Compatible with pre-existing pacemaker leads
- Allows for future treatment options

TricValve Valve Characteristics

- Specifically Designed for the SVC and IVC
- Versatile Available Sizes

TRICVALVE® MODEL	VALVE SIZE (mm)	PROXIMAL DIAMETER (mm)	DISTAL DIAMETER (mm)
SVC 25	25	25	20
SVC 29	29	29	20
IVC 31	31	34	38
IVC 35	35	38	47

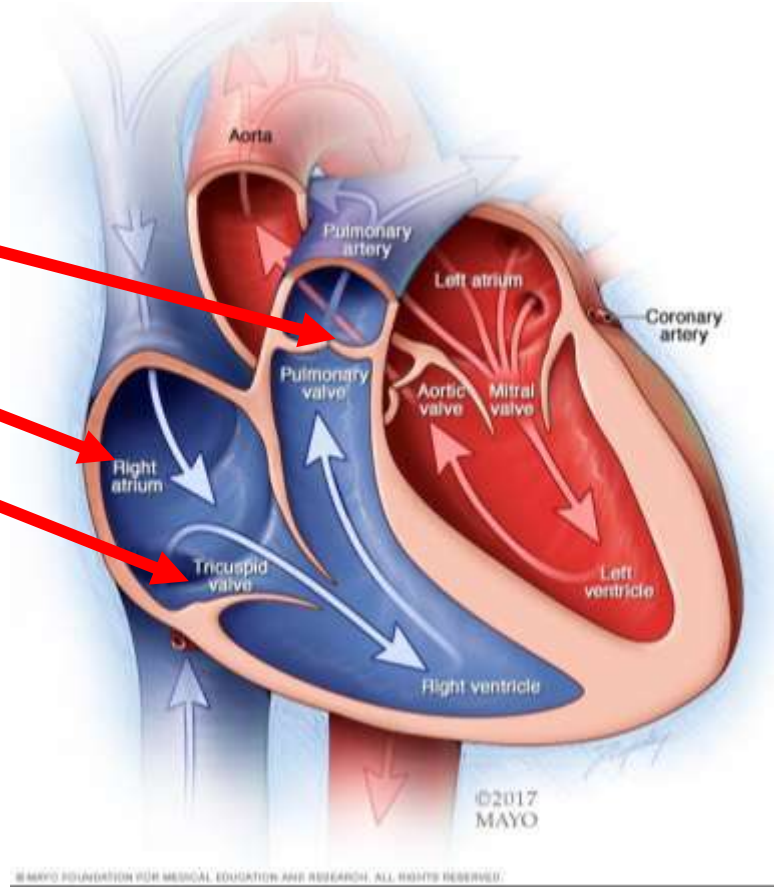
TricValve Transcatheter Self Expanding Bicaval Valve System

P&F PRODUCTS & FEATURES

- sPAP ≤ 65mmHg
- V-Wave in IVC and SVC ≥15mmHg
- TAPSE ≥ 13mm
- NYHA III-IV
- SEVERE TR & RHF

PATIENT SELECTION - SCREENING -

- CT with dedicated protocol
- Echo to ensure severity of TR and RV function (TAPSE/Strain)
- RHC to evaluate v-wave and sPAP
- Symptoms (leg edema/ascites/cardio-renal syndrom/liver congestion



Dry pericardium technology

❖ **P&F Proprietary Technology**

Biological material processed from bovine pericardium

❖ **Strong and Thin Leaflets with Cellular Preservation**

Decreased thickness, increased tensile strength and elongation at maximum stress

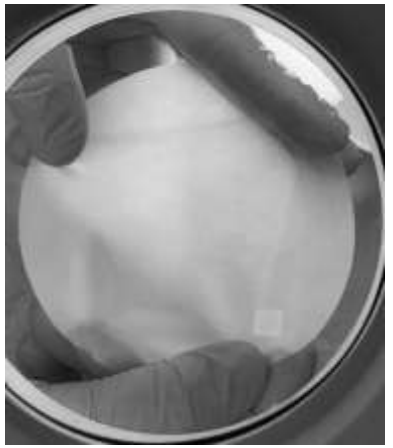
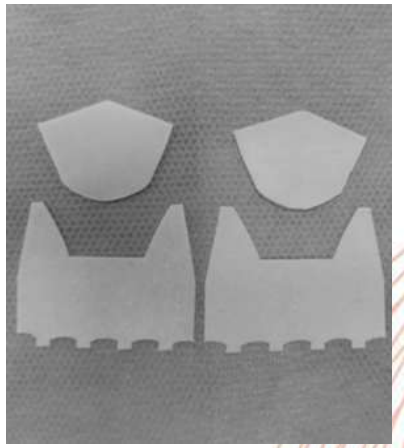
P&F PRODUCTS & FEATURES GmbH

Restoring Health & Extending Life

Dry Pericardium Technology

Acquisition, cleaning and selection → Chemical Treatment → Dimensional Evaluation → Mechanical and Biological Evaluation → Laser Cutting → Modelling and Sewing → Dry Process




P&F PRODUCTS & FEATURES

The TricValve System

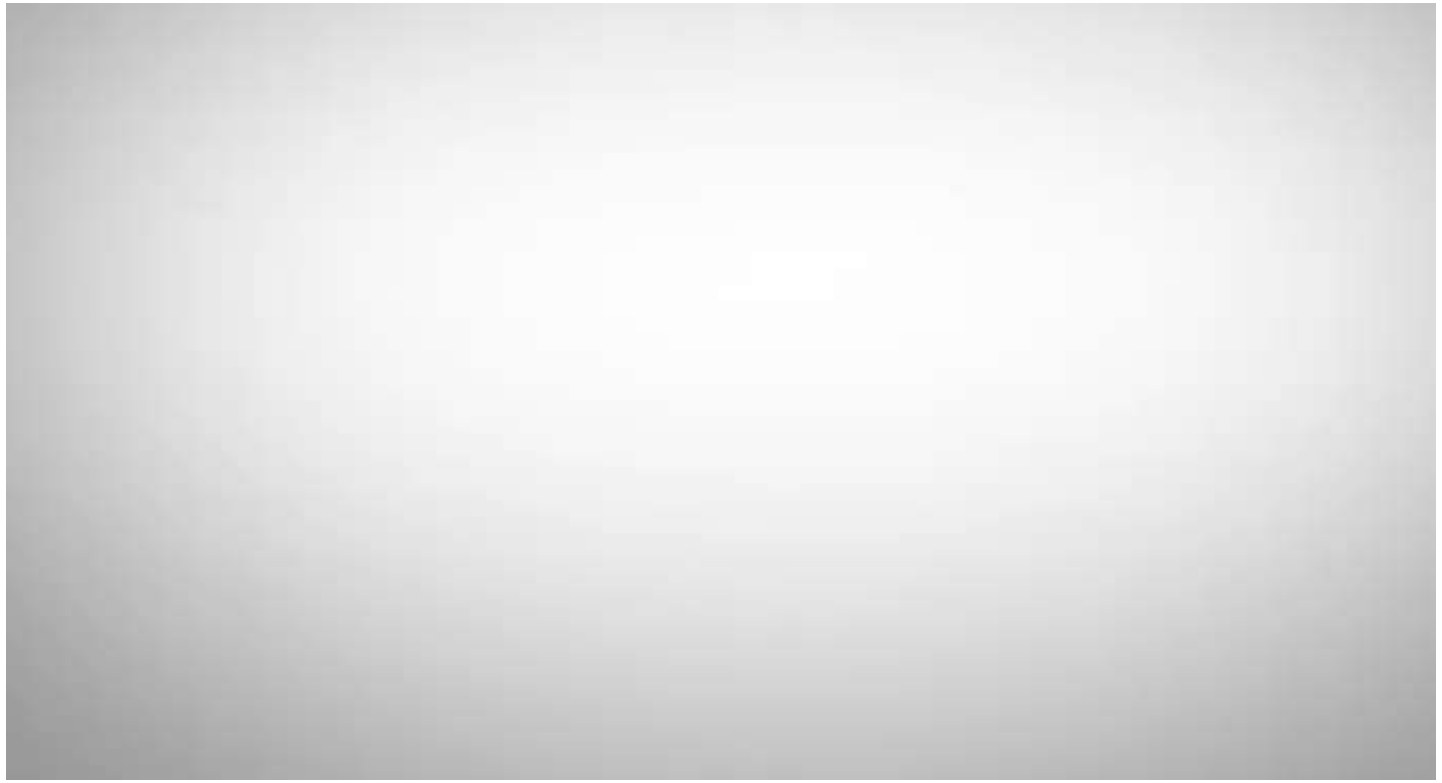
P&F PRODUCTS & FEATURES

- Pre-loaded Valve
- Simple Preparation
- Ready to Implant

TricValve Implantation Procedure (Valve Preparation)

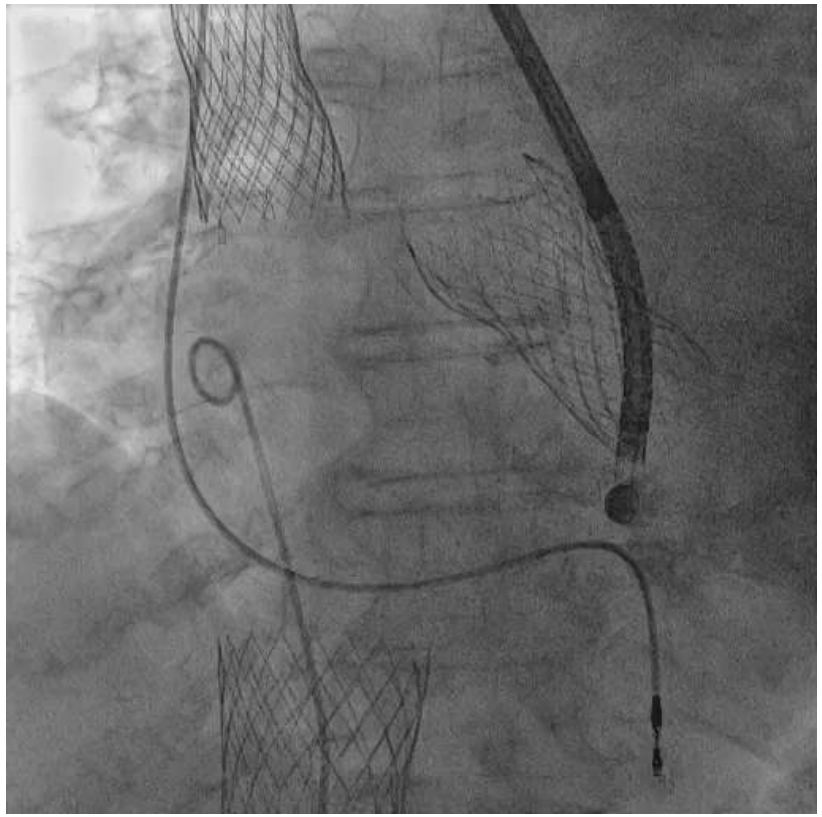
P&F PRODUCTS & FEATURES

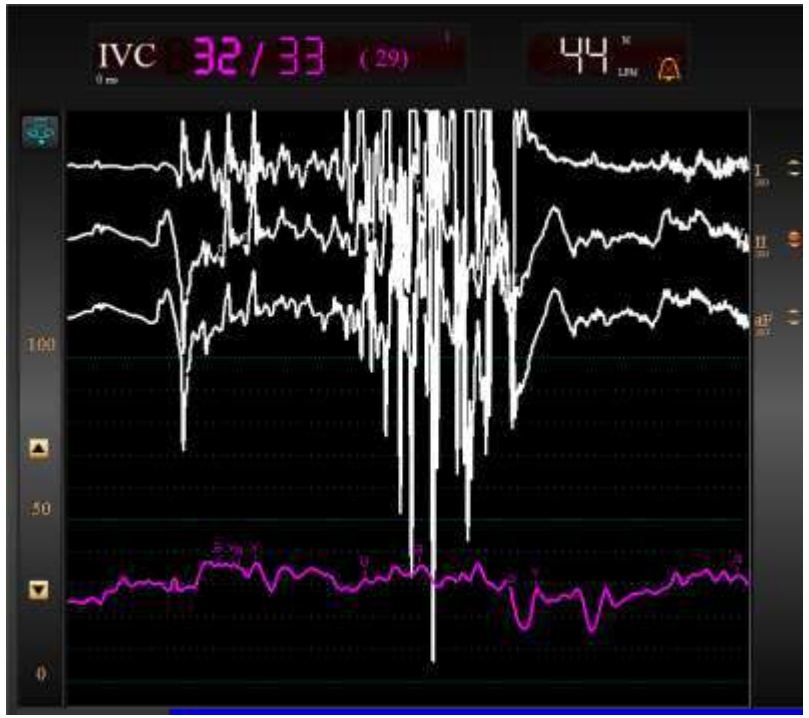
Mode of Action



- Reduces peripheral congestion by placing competent valves in the right atrium that are anchored into the SVC and IVC to reduce TR backflow
- Over time, the increased net forward flow may lead to improvement of QOL and TR symptom reduction
- Remodels Right Heart

TricValve®: Immediate hemodynamics

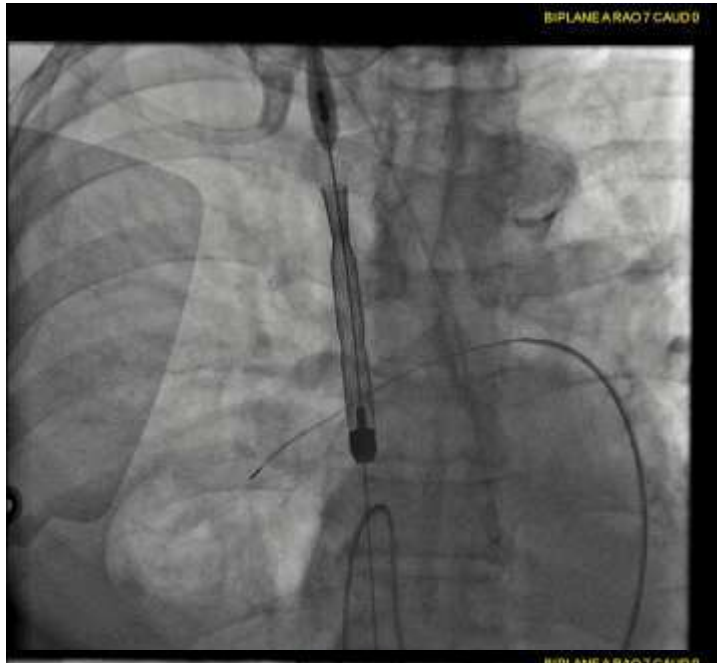


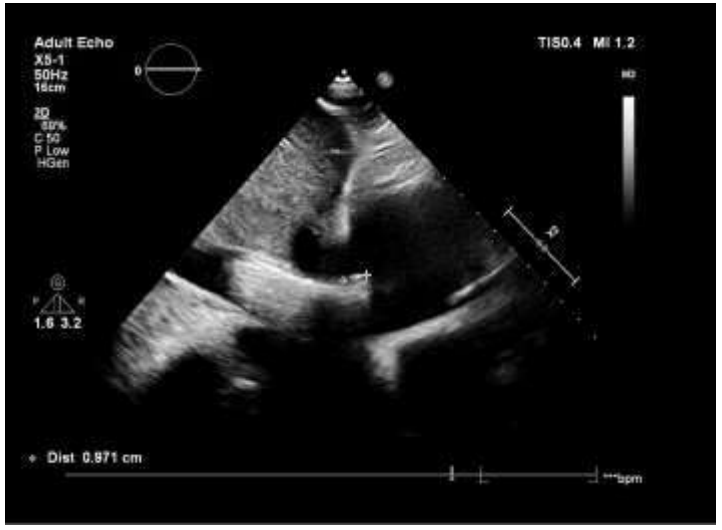


Significant decrease in IVC pressure

TricValve®: 1st Nth American Case @ CCF Feb 2022

P&F PRODUCTS & FEATURES



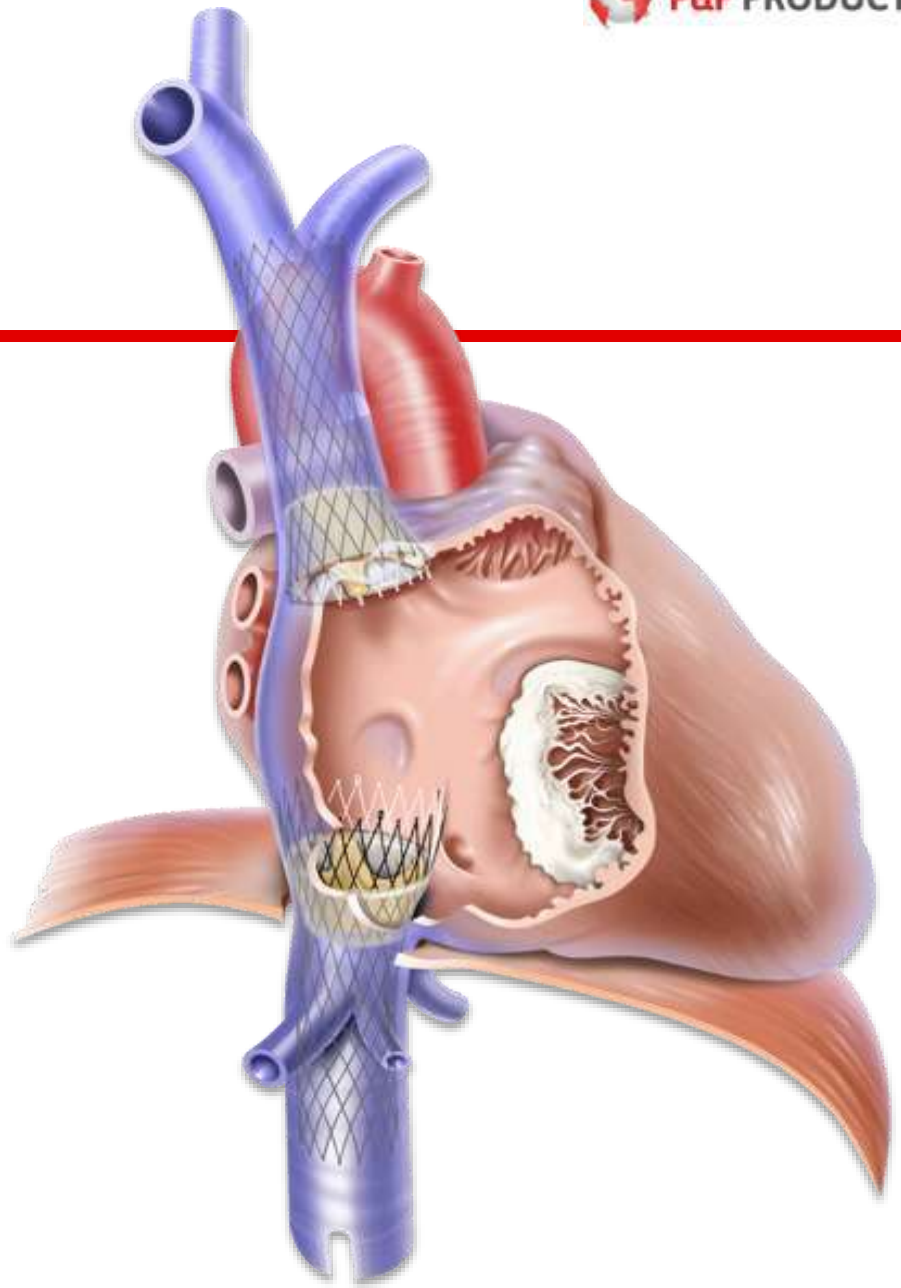


All Options Open

P&F PRODUCTS & FEATURES

TRICVALVE®

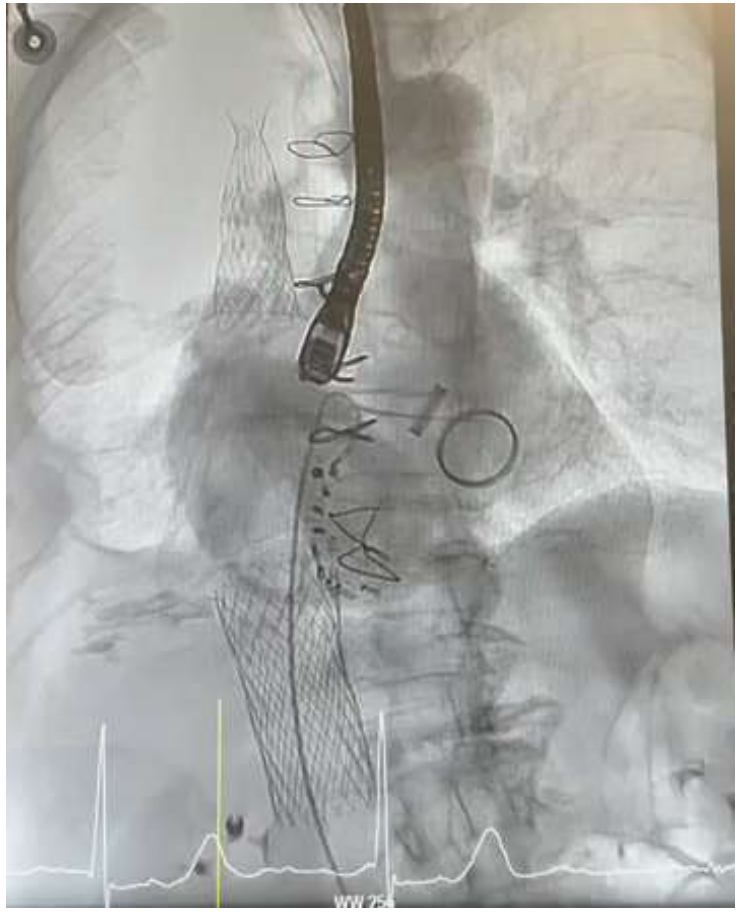
Conscious sedation
Local anesthesia
TTE guidance for IVC



TricValve® After……

P&F PRODUCTS & FEATURES

T-EER detachment



Cardioband failure

Pacing Lead

TricValve Implantation Post-Procedure

P&F PRODUCTS & FEATURES

- Anti-coagulation (DOAK or VIT K Antagonists)
- Pain medication (due to phrenic nerve compression) – administer Gabapentin
- Post Implantation echo for documentation
- Maintenance of diuretic dose for the first 4 weeks following Tricvalve implantation

JACC: CARDIOVASCULAR INTERVENTIONS

PUBLISHED BY ELSEVIER

NEW RESEARCH PAPER

Bicaval TricValve Implantation in Patients With Severe Symptomatic Tricuspid Regurgitation

One-Year Follow-Up Outcomes

PERSPECTIVES

WHAT IS KNOWN? Severe TR is a highly prevalent clinical entity associated with poor QOL and high mortality rate. Given the poor results of isolated TR surgery, several percutaneous therapies have been developed; however, many patients are deemed unsuitable. The TricValve bicaval valve system has shown positive clinical and structural short-term results, but long-term outcomes have not yet been established.

WHAT IS NEW? These are the first results at 1-year follow-up with the TricValve system and confirm a significant improvement in QOL, functional class, and congestive symptoms with a relatively low mortality rate despite the very advanced stage of the disease in the target population.

WHAT IS NEXT? Further prosthesis sizes along with structural improvements of the platform might help to provide better results and broaden the range of candidates for this therapy. In addition, the ongoing TricValve global registry along with a planned TRICAV pivotal randomized trial will yield further clinical and mechanistic insights into the longer term.

TRIAL DESIGN

Prospective, nonblinded, nonrandomized, single-arm trials enrolling patients with symptomatic severe Tricuspid Regurgitation (grade ≥3 in a 5-grade classification) despite optimal medical treatment leading to NYHA functional class III or IV, ineligible for open heart surgery, with significant backflow in the IVC and/or SVC

NCT03723239

TRICUS Study

Early feasibility/first-in-human study, including patients from Lithuania

U.S. National Library of Medicine
ClinicalTrials.gov

NCT04141137

TRICUS EURO

CE mark trial testing the safety and efficacy of this CAVI system in patients with severe symptomatic TR with high surgical risk, enrolling patients from institutions in Spain and Austria

Endpoints

Primary endpoints

Clinical improvement evaluated by the composite of:

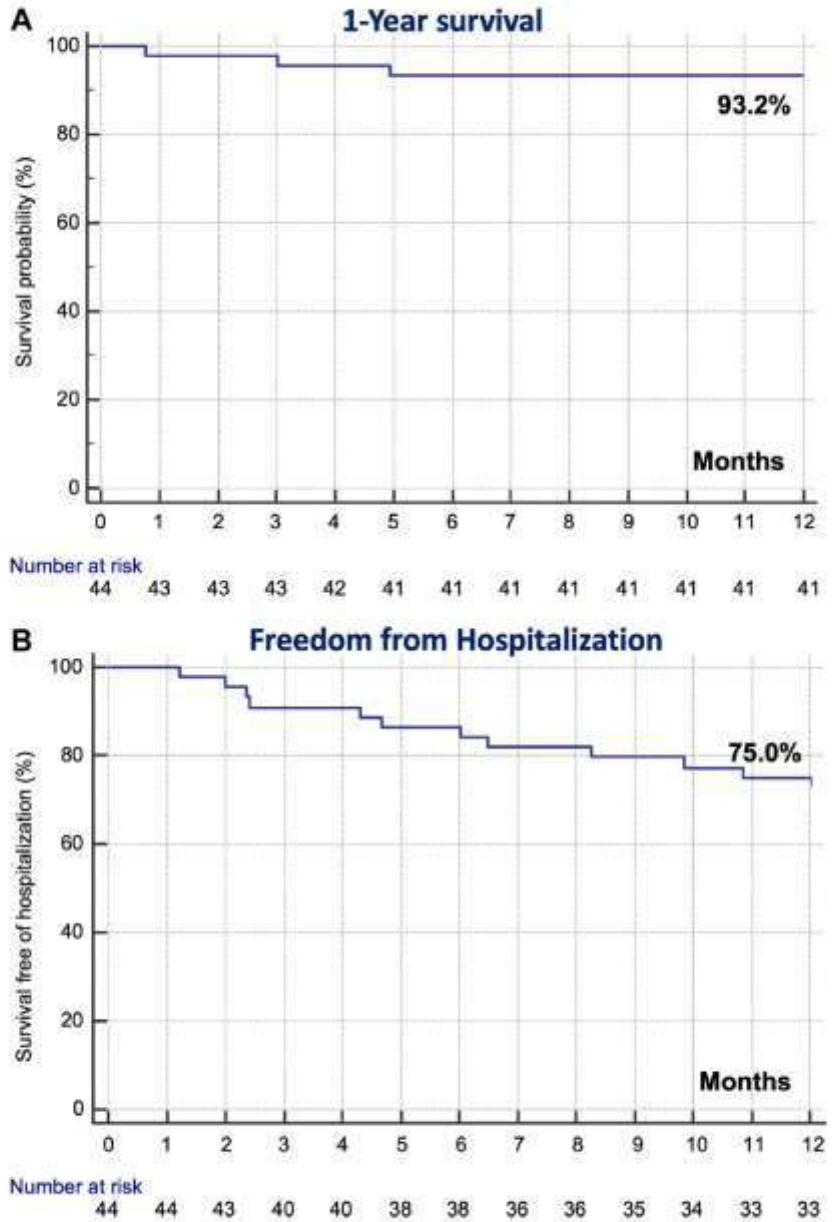
- Change in quality of life (QOL) measured with the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-12), with a large improvement defined as an increase of ≥15 points from baseline to 1-year follow-up;
- Improvement in NYHA functional class to I or II at 1-year follow-up;
- Or change in functional exercise capacity measured with the 6-minute walking test (6MWT) distance, considering a significant improvement an increase in at least 40 m from baseline based on previous heart failure trials aimed to assess the effect of different pharmacological and nonpharmacological therapies that suggest a 30- to 50-m increase as associated with a significant clinical improvement

Endpoints

Secondary endpoints

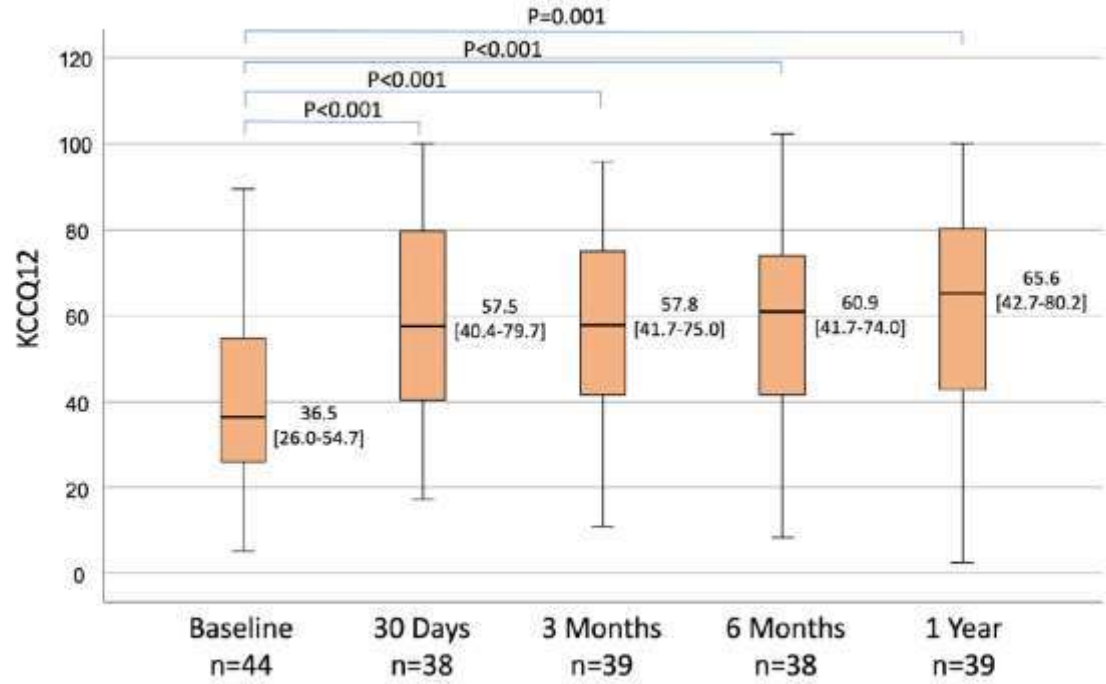
- Freedom from major adverse events including death, acute myocardial infarction, tricuspid valve surgery, cardiac tamponade, stroke, or major bleeding
- Freedom from heart failure rehospitalizations or serious adverse events related to the device at 1-year follow-up
- Changes in right heart dimensions as measured by assorted echocardiographic parameters at baseline and 3-month, 6-month, and 1-year follow-up
- Improvement in systemic venous congestion measured by echocardiographic and laboratory test parameters (hepatic vein backflow and N-terminal pro–B-type natriuretic peptide)
- Changes in renal and hepatic function measured by baseline and 1-year follow-up laboratory tests (creatinine, glomerular filtration rate, alanine aminotransferase, and aspartate aminotransferase)

FIGURE 4 Kaplan-Meier Curves



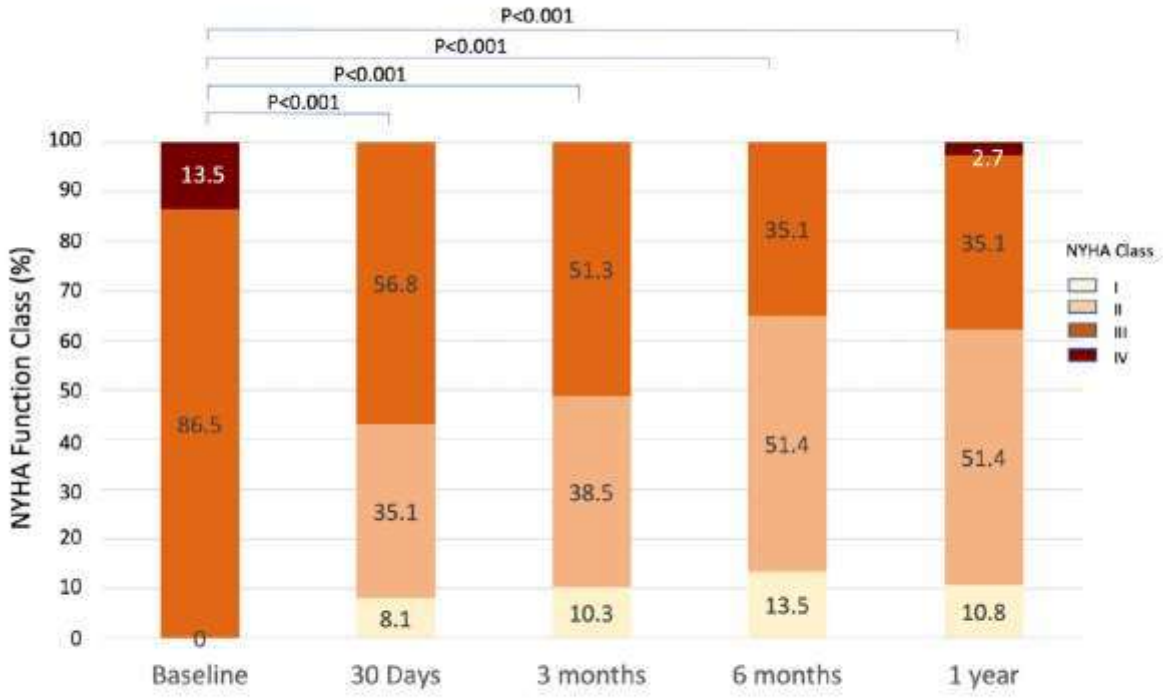
(A) Time-to-event curves for the incidence of all-cause death. (B) Time-to-event curve for the incidence of heart failure rehospitalization.

FIGURE 1 KCCQ-12 Score



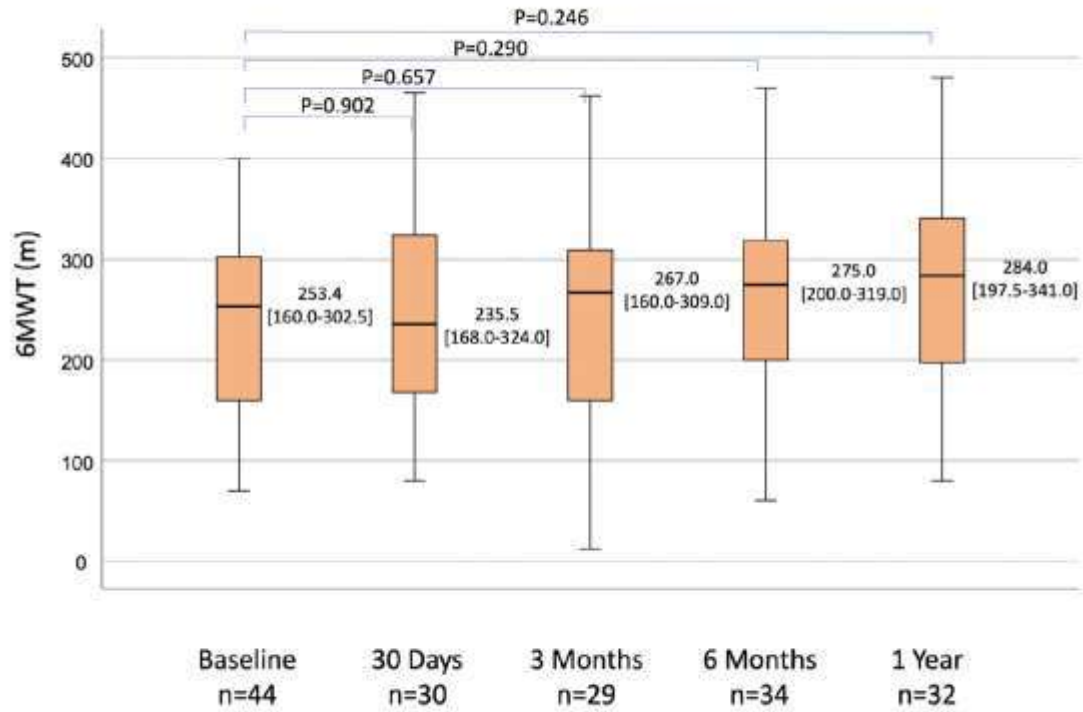
Baseline and 30-day, 3-month, 6-month, and 1-year follow-up in the 12-item Kansas City Cardiomyopathy Questionnaire (KCCQ-12) score. Values are median (Q1-Q3).

FIGURE 2 NYHA Functional Class



Baseline and 30-day, 3-month, 6-month, and 1-year follow-up in NYHA functional class. Data are presented as %.

FIGURE 3 6-Minute Walking Test



Baseline and 30-day, 3-month, 6-month, and 1-year follow-up in the 6-minute walking test (6MWT). Values are median (Q1-Q3).

TRICBICAVAL REGISTRY

- Investigator driven
- Commercial real-world data
- Up to 4 years FUP
- Aiming to include 250 pts.

TRICVALVE BICAVAL SYSTEM MULTICENTER REGISTRY (TRIC-BICAVAL)

Multicenter registry initiated by investigators and not supported by any external funding

27 hospitals
204 patients

RHF due to severe TR

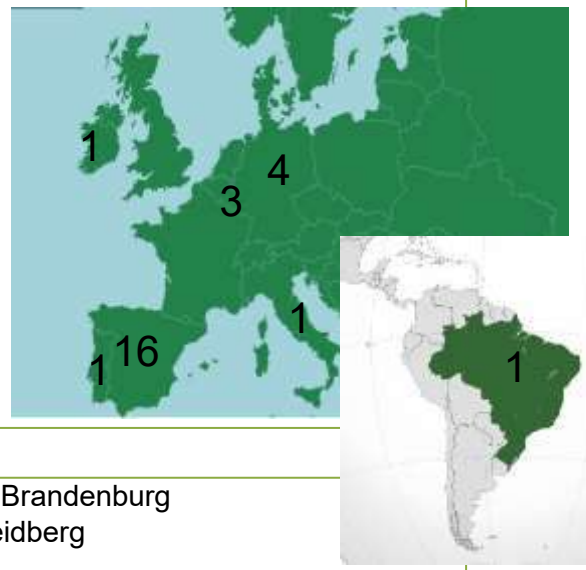
Inoperable and unsuitable for transcatheter orthotopic repair/replacement

Rejected for CAVI:
TAPSE < 13
LVEF < 40%
PSP > 65 mmHg
V-wave < 15 mmHg

Bicaval suitable Anatomy (CT-scan)

Participating Centers

SPAIN	• University Hospital Ramon y Cajal • University Hospital Clinico San Carlos • University Hospital Valladolid • University Hospital Salamanca • University Hospital Doce Octubre • University Hospital Clinic Barcelona • University Hospital Badajoz • University Hospital Reina Sofia Cordoba • University Hospital La Paz • University Hospital Alvaro Cunqueiro. Vigo • University Hospital Puerta de Hierro • University Hospital Valdecilla Santander • University Hospital Toledo • University Hospital Navarra • University Hospital Germans Trias i Pujol • University Hospital La Coruña
PORTUGAL	• University Hospital Santa Marta. Lisboa
GERMANY	• University Hospital Immanuel Heart Center Brandenburg • University Hospital Asklepios Klnik Nord Heidberg • University Hospital Heart Center Cologne • University Hospital Heart Center Munster
ITALY	• University Hospital Pierangeli Pescara
BELGIUM	• University Hospital ASZ Aalts • University Heart Center St. Antonius • University Hospital Maria Middelares
IRELAND	• University Hospital Galway
BRASIL	• Valve Center IECAC. Rio de Janeiro. Brasil.



Courtesy A.Recalde, Ramon y Cajal, Spain

TRIC-BICAVAL REGISTRY: Baseline Characteristics

Age, years: mean (SD)	77.8 ± 7.5
Female, n (%)	133 (65.2%)
BMI, mean (SD)	26.2 ± 4.8
Hypertension, n (%)	135 (66.2%)
Diabetes, n (%)	41 (20.1%)
Stroke/TIA, n (%)	29 (14.2%)
GFR <60 ml/min/m2, n (%)	143 (70.1%)
eGFR ml/min/m2, mean (SD)	48.5 (22.5)
Dialysis, n (%)	5 (2.5%)
COPD, n (%)	31 (15.2%)
CAD, n (%)	41 (20.1%)
PAD, n (%)	7 (3.4 %)
Cardiac valve surgery, n (%)	102 (50%)
Tricuspid, n (%)	20 (9.8%)
Transcatheter valve intervention, n (%)	39 (19.1%)
T-TEER	11 (28.2%)
T- Annuloplasty	7 (18.0%)
Left heart valve intervention	21 (53.8%)

Pacemaker/ICD/-CRT, n (%)	70 (34.3%)
EuroScore II, mean (SD)	6.9 ± 5.4
STS score, MVR, %, meand (SD)	9.5 ± 7.9
TriScore, mean (SD)	23.2 ± 19.1
Atrial fibrillation, n (%)	192 (94.6%)
Peripheral edema, n (%)	149 (73%)
Ascitis, n (%)	63 (31.2%)
NYHA class III-IV, (%)	158 (80%)
HF hospitalization in past 12 months, (%)	113 (60.8%)
TR etiology	
ASTR	68 (37.2%)
VSTR	76 (41.5 %)
LTR	23 (12.6%)
PTR	16 (8.7%)
TR Severity	
Severe	25 (12.7%)
Massive	76 (38.6%)
Torrential	92 (48.7%)

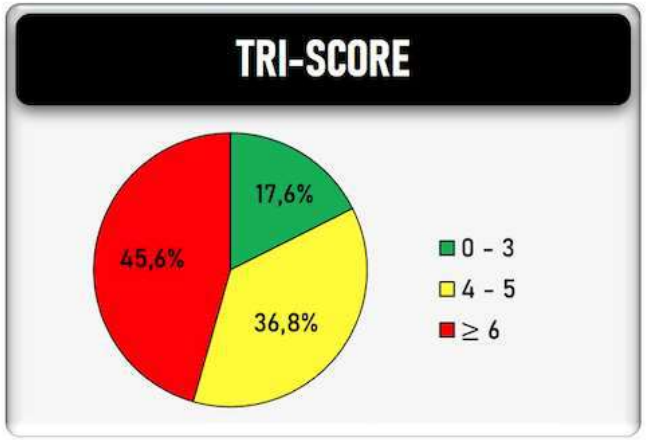
Courtesy A.Recalde, Ramon y Cajal, Spain

Most subjects had multiple comorbidities, were highly symptomatic, had high risk TRI-SCORE, and had massive/torrential TR

Fluoroscopic Time: **30 min** [20-41]

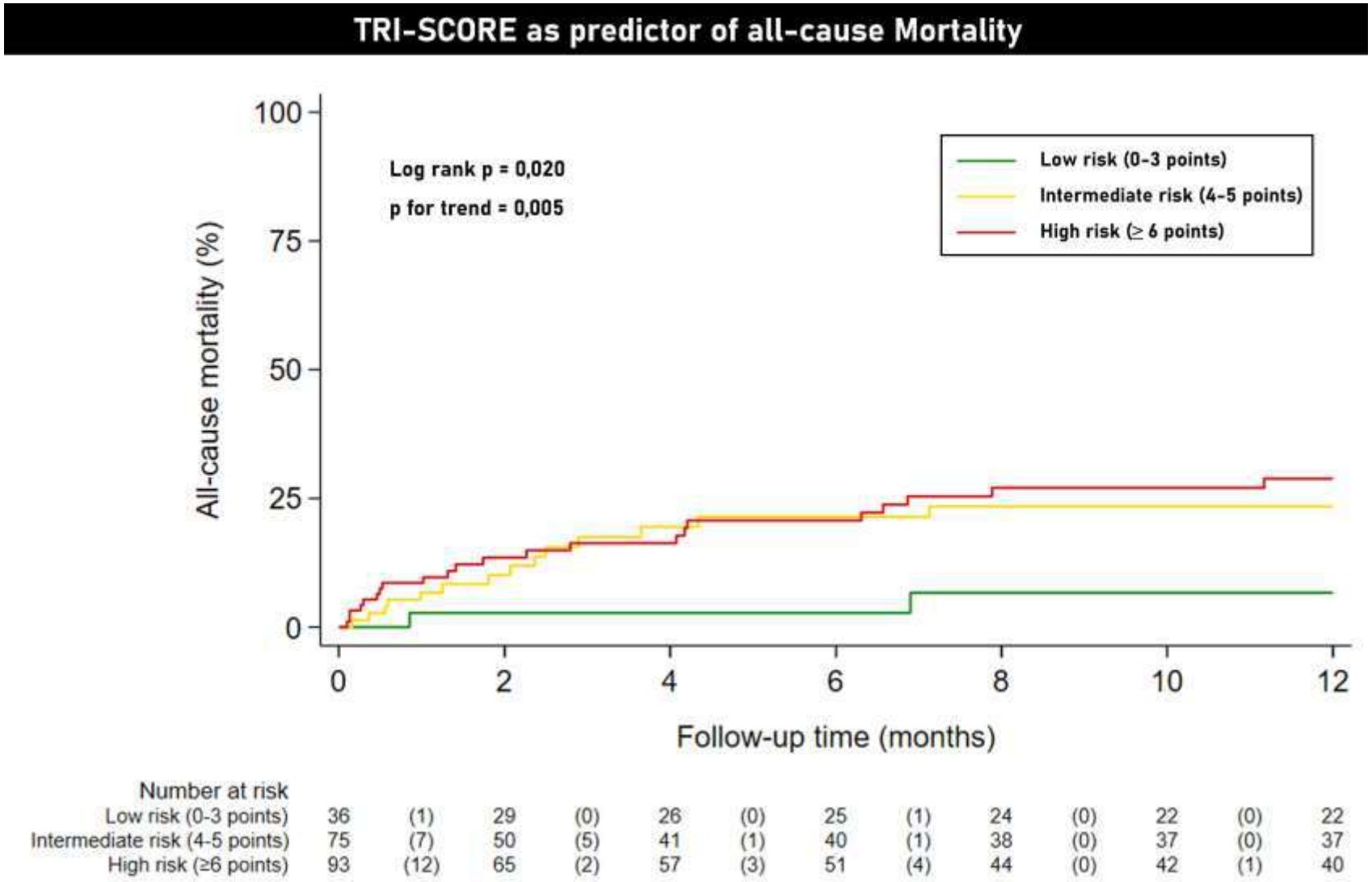
Intraprocedural success (TVARC)	**96.1 %**
SVC malposition – 2nd valve implantation	**1 (0.49%)**
IVC malposition – 2nd valve implantation	**6 (2.9%)**
In-hospital mortality	**17 (8.3%)**
TVARC bleeding ≥ 3	**20 (9.8%)**
TVARC major access complications	**11 (5.39)**
TVARC major cardiac complications	**8 (3.9%)**
Cardiac tamponade	***3 (1.47%)***
New pacemaker implantation (1 Lead dysfunction pacemaker)	***4 (1.96%)***
Shoulder pain	**96 (47.1%)**
AKI requiring dialysis	**5 (2.4 %)**
Length of hospital stay (days)	**8 (4 - 24)**

What are the essential results? Mortality & TriScore

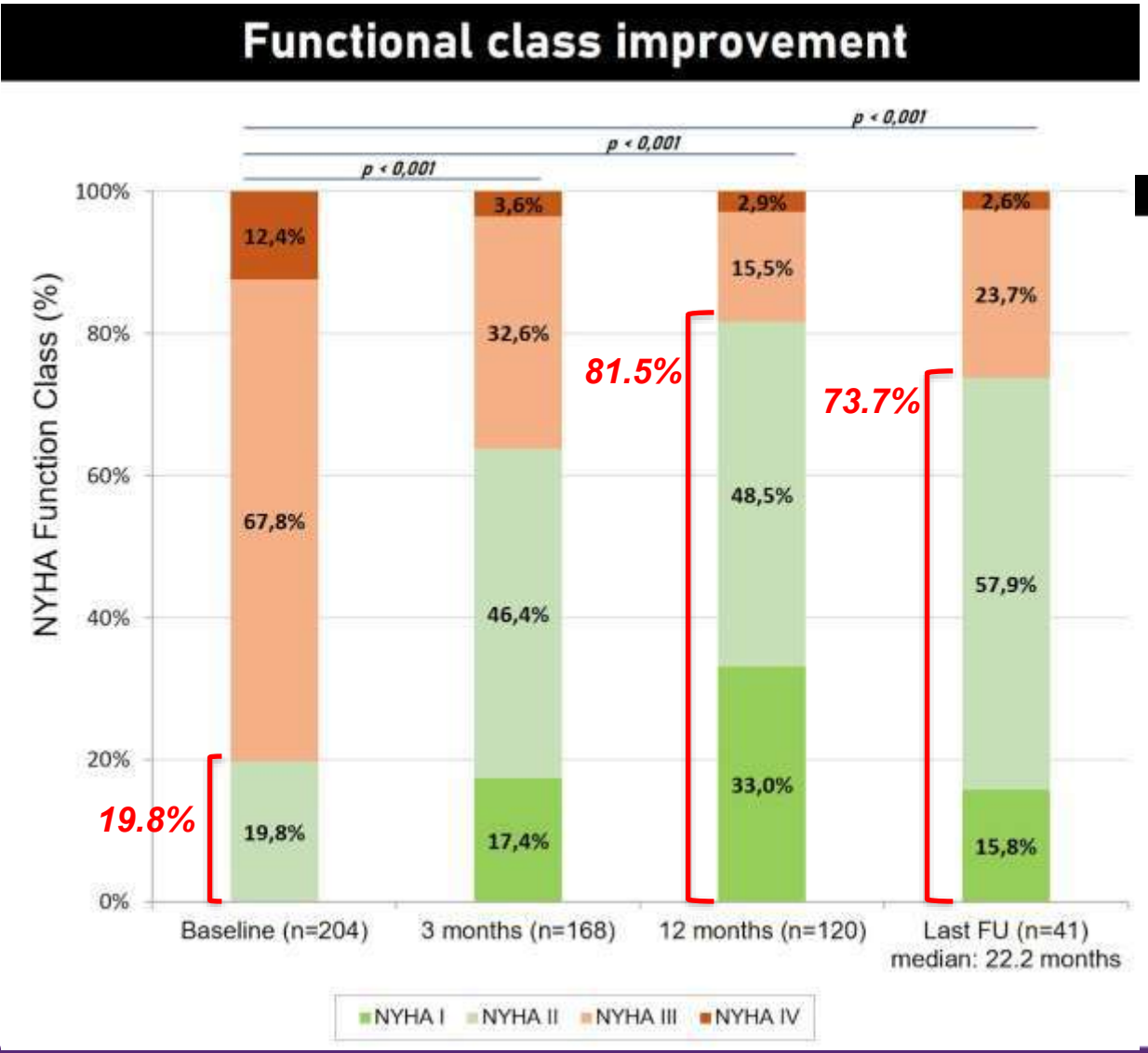


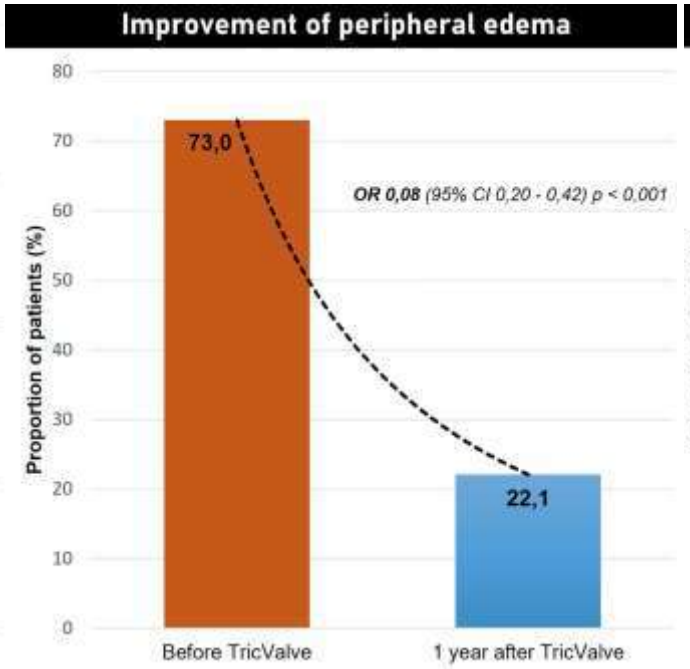
TRIscore:

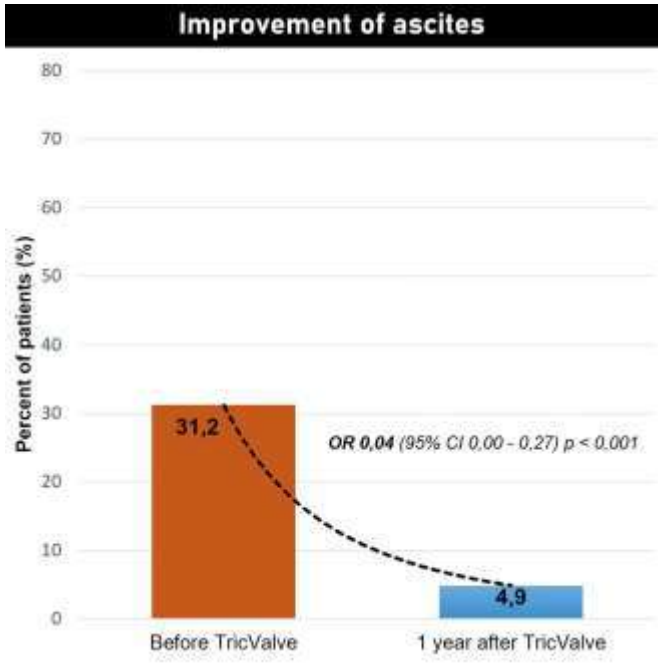
- Age >70
- Female Gender
- NYHA class III or IV
- Right-Heart Failure Signs
- Prior Left Sided Heart Valve Intervention
- Permanent PM/ICD
- AF
- Daily dose of diuretics
- GFR/renal impairment
- Elevated Bilirubin
- Moderate/severe ventricular Dysfunction and LVEF



TRIC-BICAVAL REGISTRY: Changes NYHA Class & peripheral congestion

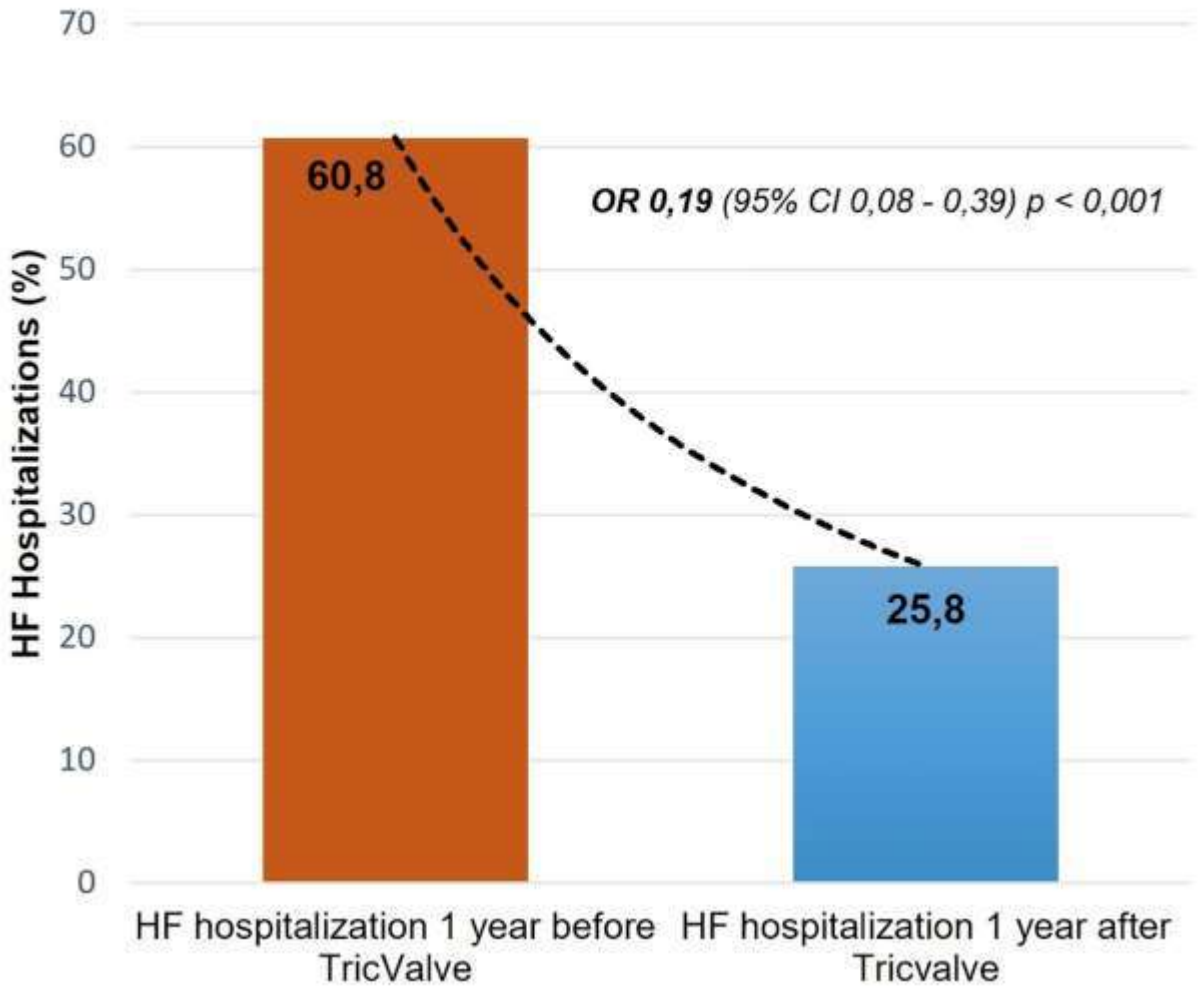




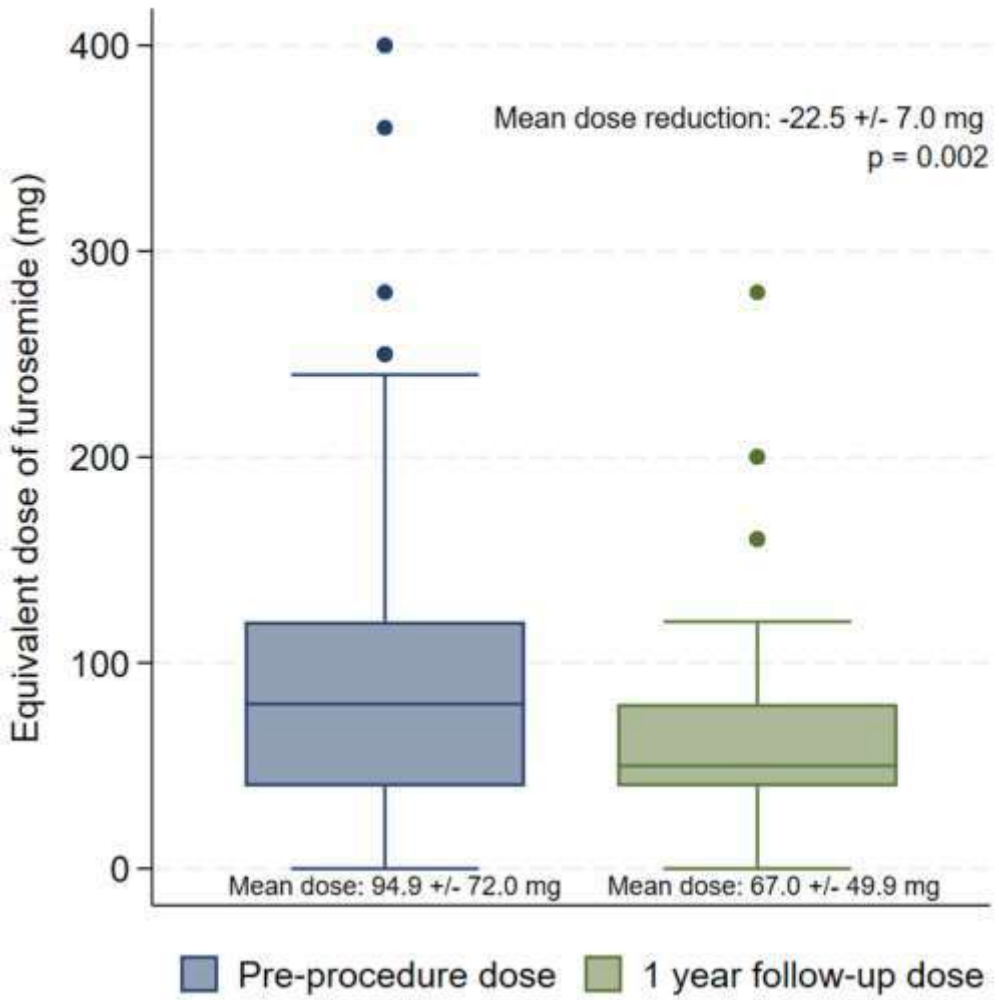


TRIC-BICAVAL REGISTRY: Re-hospitalizations & diuretic dose

Reduction in Heart Failure Hospitalizations



Change in diuretic dose at 1 year follow-up



Courtesy A.Recalde, Ramon y Cajal, Spain

Take Home Messages

P&F PRODUCTS & FEATURES

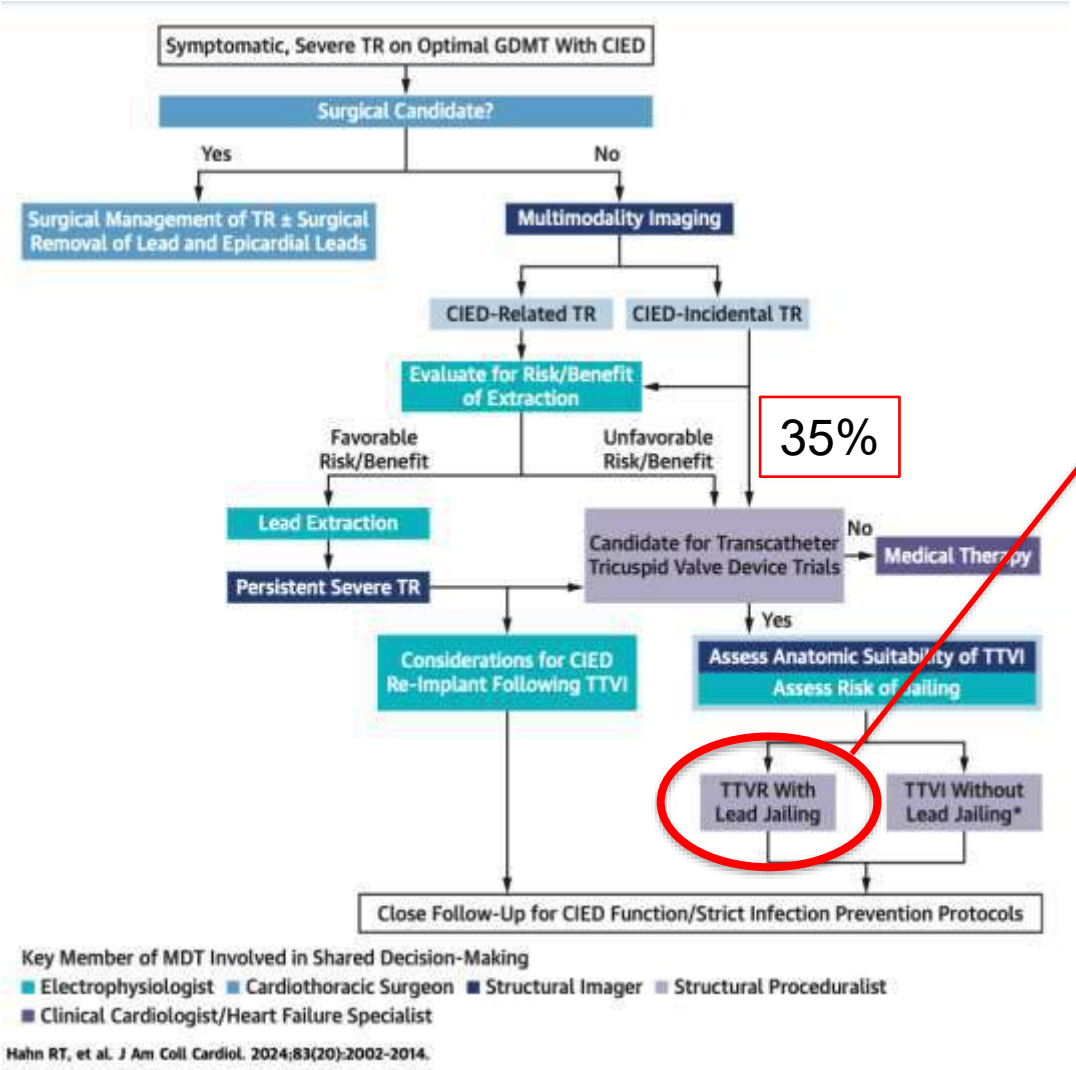
- Tricvalve offers a solution for a large range of anatomies
- Independent of prior valve interventions or Pace maker Leads
- Continous significant improvement in Quality of Life
- Easy procedure with low learning curve
- Significant reduced procedure time by premounted system using Dry Pericardium Technology

Considerations for Patients With Leads

P&F PRODUCTS & FEATURES

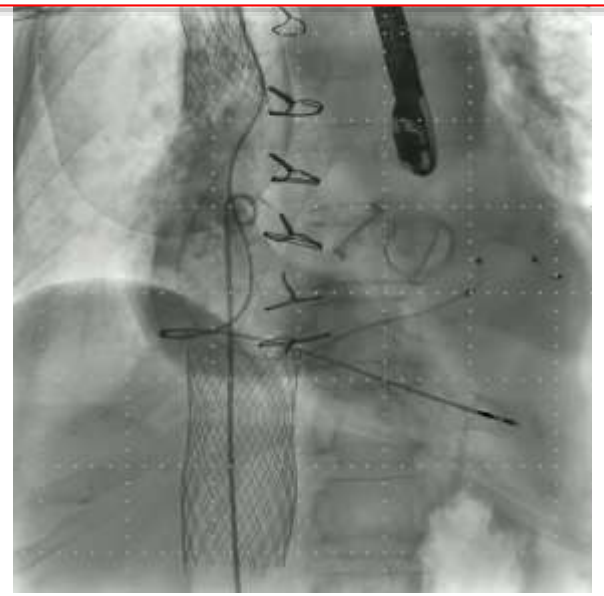
- Baseline device interrogation at screening and include in patient chart
- Device interrogation pre/post procedure, and monitored at discharge and scheduled visits
- If available, utilize remote monitoring to assess lead(s) integrity and notifications
- In collaboration with EP Attending, increase vigilance in monitoring of pacer dependent patients and ICD patients that have history of therapy being delivered
- During delivery of TricValve, observe for helixing of lead around device and/or increased tension on the lead
- Should this occur, consider recapture of valve before full deployment and reposition

MANAGEMENT OF PATIENTS WITH TR AND CIED



Hahn RT, et al. J Am Coll Cardiol. 2024;83(20):2002-2014.

Risks { device-related infection
lead fracture



- To determine outcomes of patients with jailed leads following CAVI

CONCLUSIONS

- **TricValve bicaval implantation in pacemaker patients is safe**, with high procedural success rate and a very **low risk of cardiac complications** or pacemaker lead damage
- Overall outcomes, including **improvement in NYHA functional class and right heart failure signs**, are **comparable to those observed in non-pacemaker patients**
- **No significant differences in mortality or HF hospitalization** at 30 days and 1-year follow-up

P&F Biological Valves Portfolio

P&F PRODUCTS & FEATURES

Developing new products and enhancing existing ones; our purpose is to leverage these capabilities to generate distinctive value and expand access to state-of-the-art technology for patients and healthcare providers worldwide

TricValve®
Transcatheter Bicaval Valves
CE / ANVISA

Vienna TAVR SE
Self-expandable

Vienna TAVR BE
Balloon-expandable

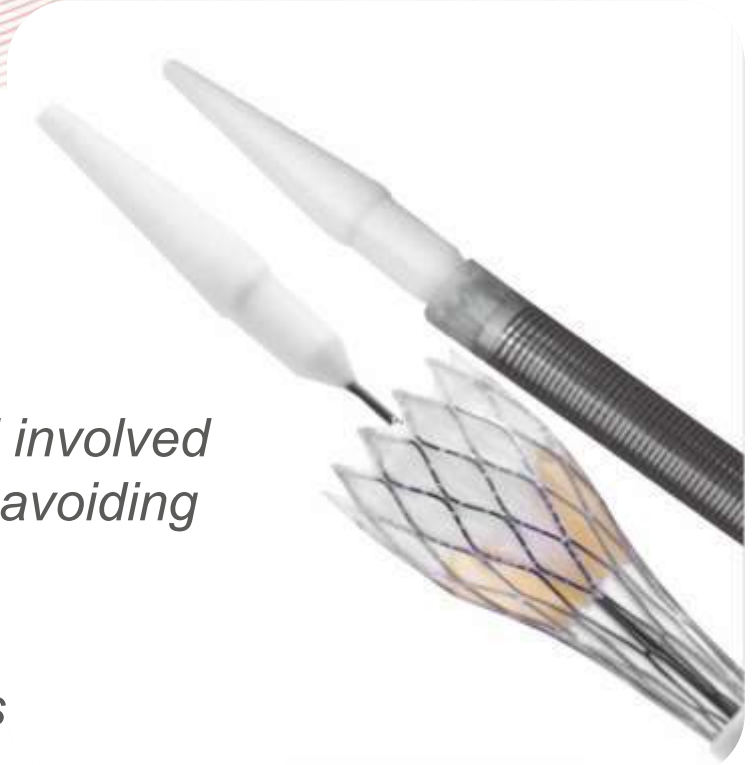
MUNICH TMVR
Self Expandable

AortoSave®
Ascending Aortic Reconstruction System

PERSPECTIVE
Transcatheter Pulmonary Valve Replacement
Self Expandable

ALL PRODUCTS EXCEPT THE TRICVALVE® ARE NOT CE MARK APPROVED YET. INVESTIGATION USE ONLY.

Vienna SE® TAVI Valve Design



- **Pre-mounted on delivery system**
  Simplifying surgical setup, reducing steps of procedure and involved team, enhancing safety by ensuring consistent positioning, avoiding contamination and risks of valve damage
- ***Commissural Alignment***
  Markers on Delivery System enabling control of comissures
- **Tantalum radiopaque markers**
  Avoiding improper valve positioning and reducing risks for coronary ostia obstruction or compression

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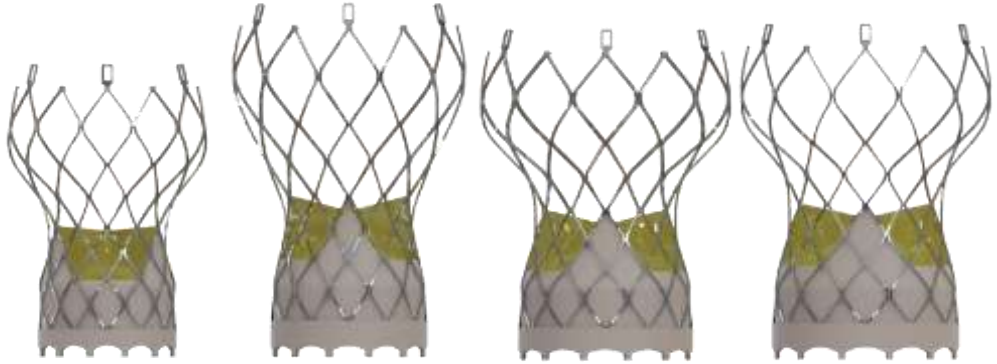
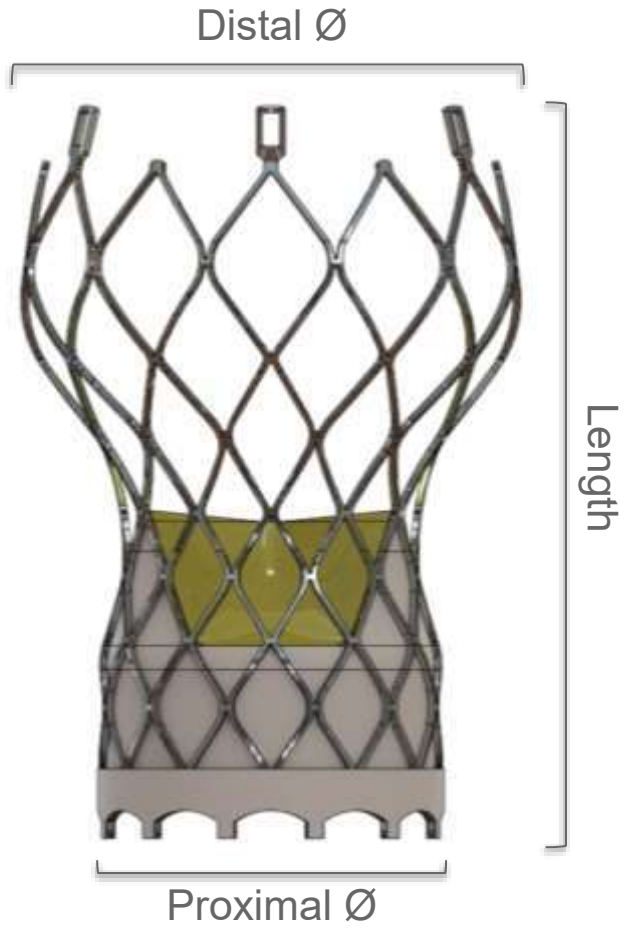
Vienna SE TAVI Valve Design

- **Supra Annular Valve Design**
  Maximizes EOA, reducing pressure gradients and turbulence for unsurpassed hemodynamics

- **Versatile Available Sizes**



Model (mm)	23	26	29	31
Proximal Ø	23	26	29	31
Distal Ø	34	40	42	43
Length	45	55	51	52



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INTRODUCING THE

VIVA

VIENNA VALVE PIVOTAL TRIAL

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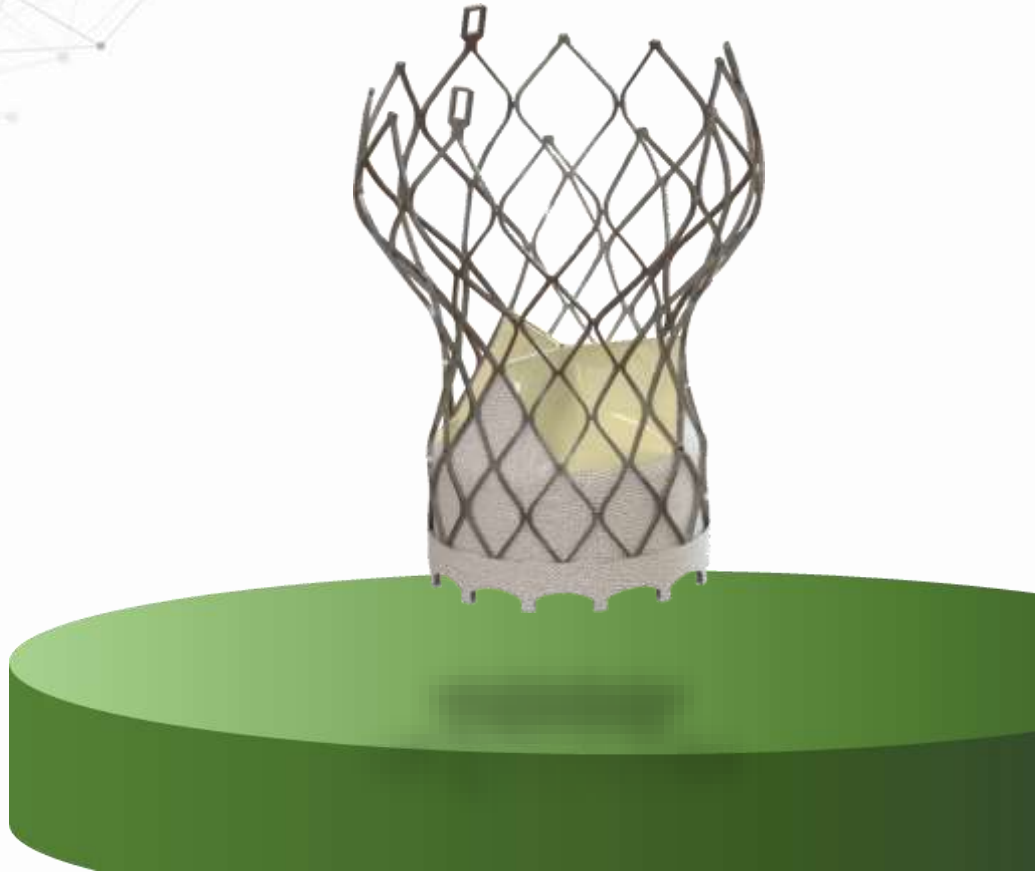
- Global Pivotal Trial for MDR Certification: Europe/LATAM/India



VIVA Study Phase I (FIH) 6 Month Results

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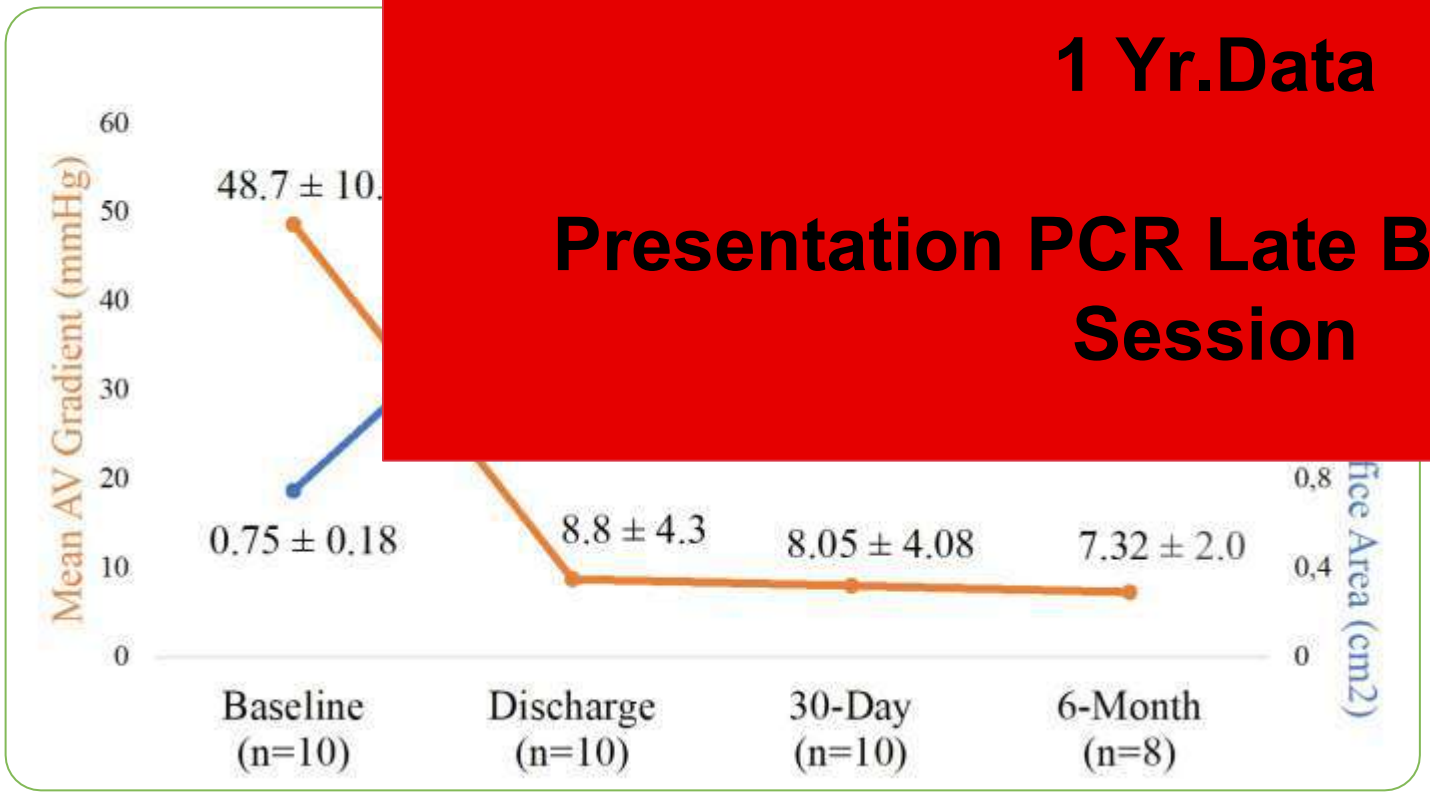
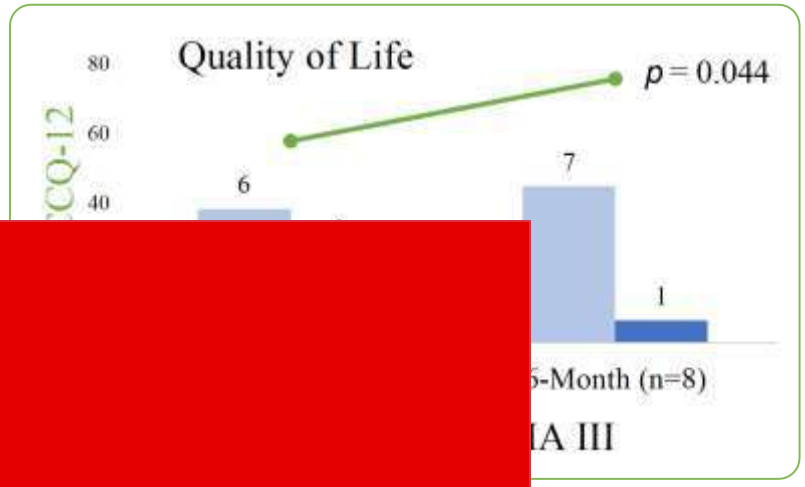
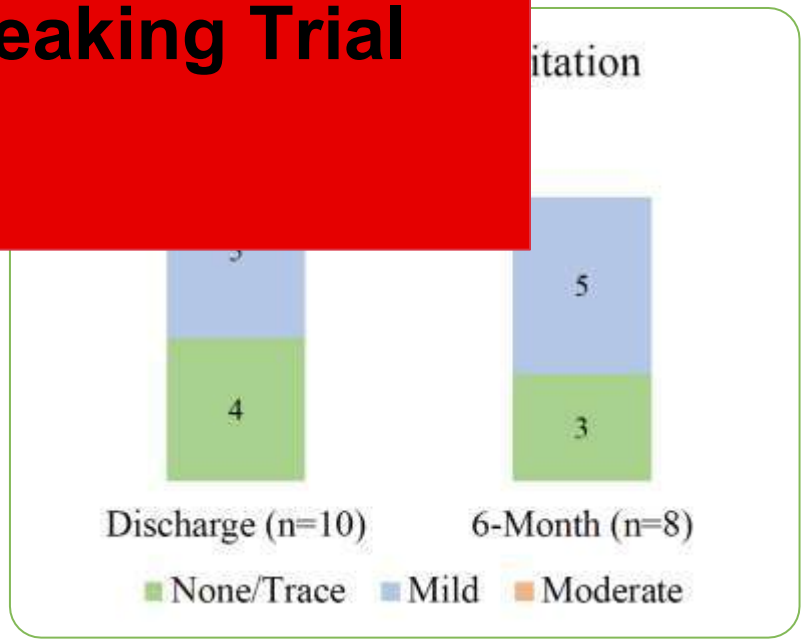
The VIVA first-in-human feasibility trial findings demonstrate that using Vienna TAVI system has a favourable and sustained 6-month safety and performance outcomes in patients with symptomatic seve

1 Yr.Data

Presentation PCR Late Breaking Trial Session





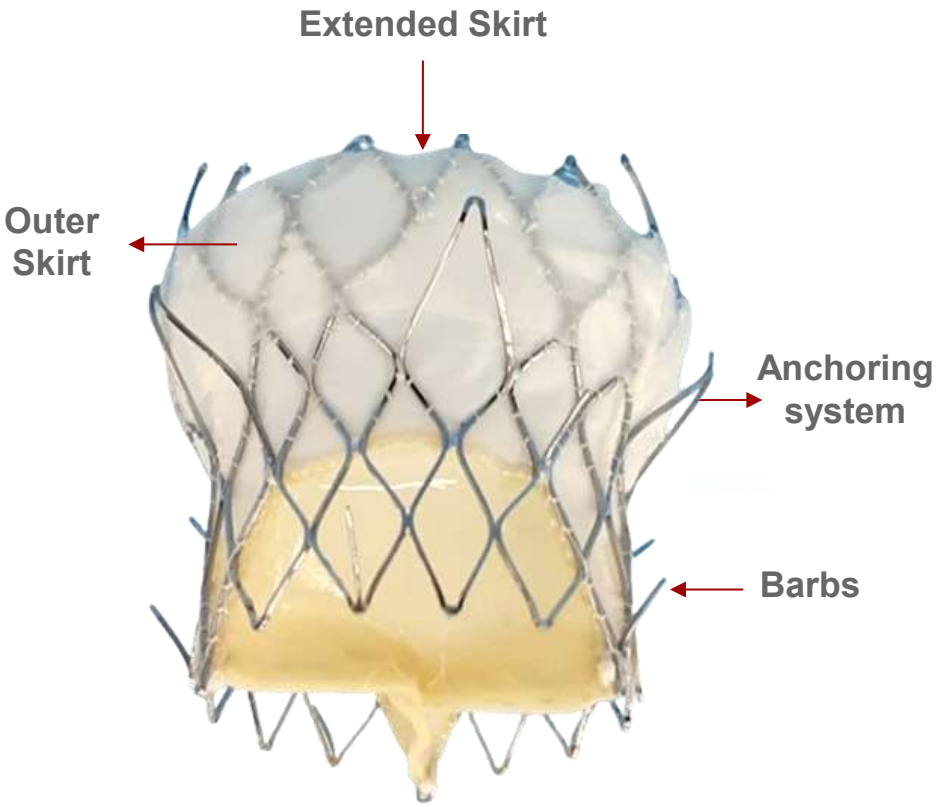


Munich Valve Design

- **Bio designed structure**
  Assuring passive and active fixation, through struts geometry, anchoring system and barbs

- **Advanced Sealing**
  In combination with an inflow and external polyester skirt reducing PVL

- **Pre-mounted on delivery system**
  Simplifying surgical setup, reducing steps of procedure and involved team, enhancing safety by ensuring consistent positioning, avoiding contamination and risks of valve damage



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Munich Valve Design

❑ Available Sizes

Model	Proximal diameter [mm]	Distal diameter [mm]	Length after deployment [mm]
29-40	29	40	30
29-48		48	30
29-55		55	30

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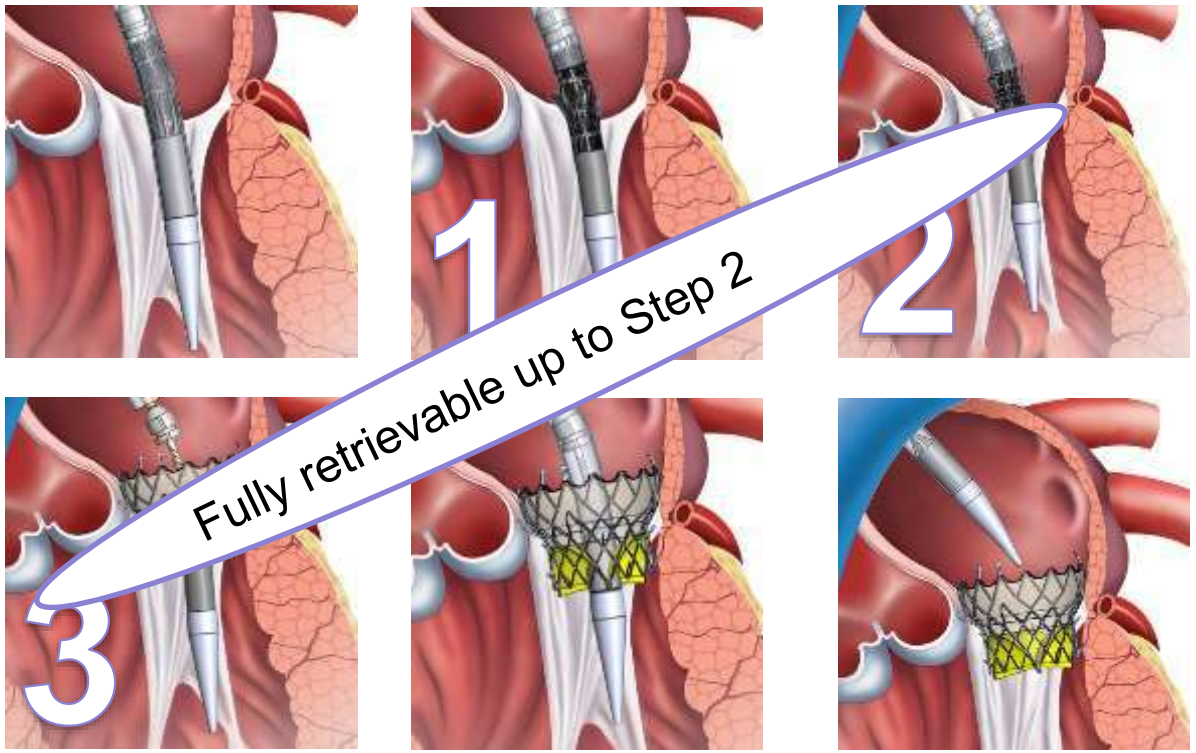
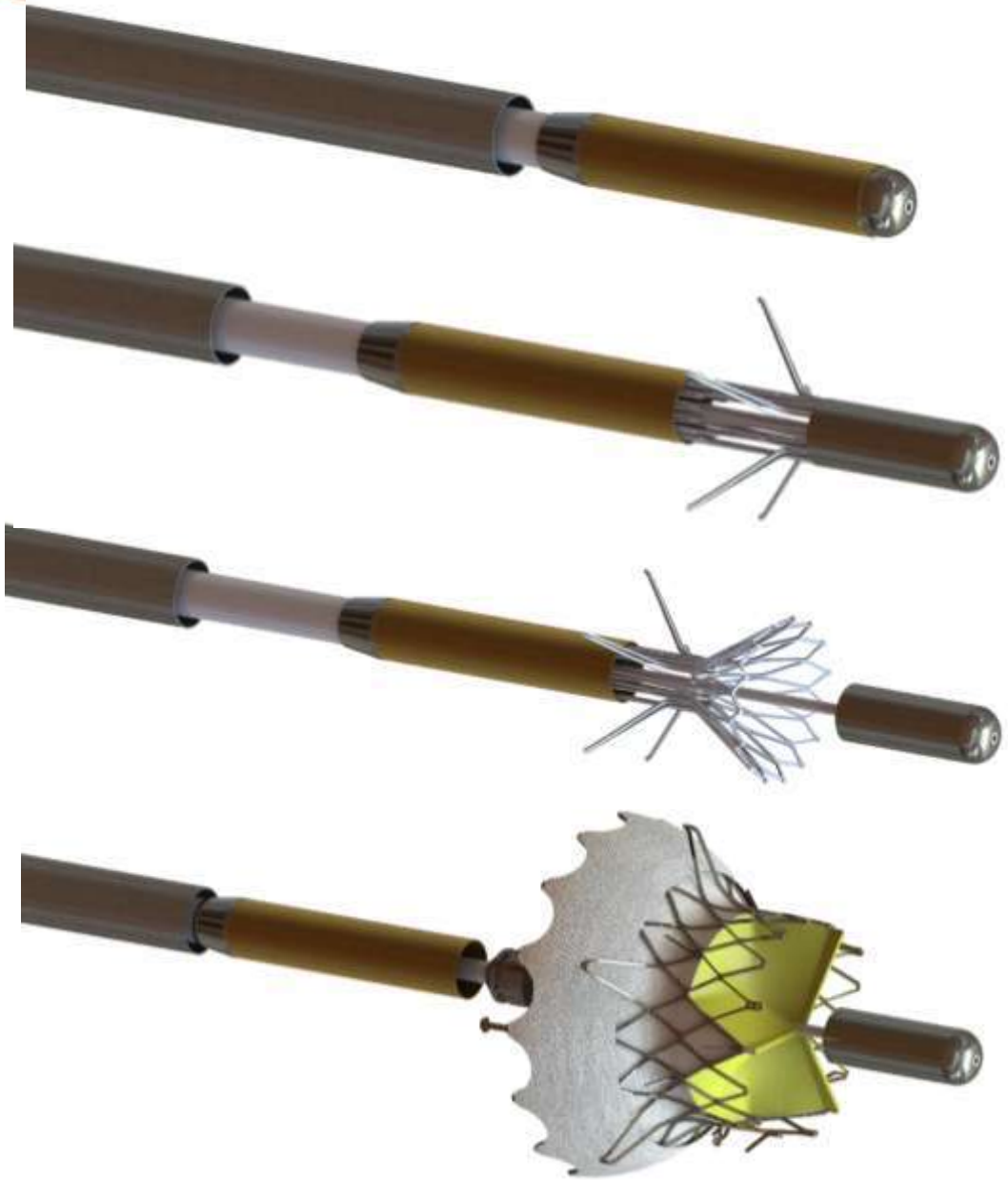
3-step deployment





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Munich Delivery System

- ***Allows repositioning of the valve***
  Minimizing risk of valve misplacement and invasive adjustments, improving procedure safety and success

- **Flexible Shaft with Inline Introducer, radiopaque capsule and atraumatic cone nose**
  Enhancing maneuverability, visualization and device placement

- ***3-step Valve Deployment***

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Perspective Pulmonary Valve SE – Self-Expandable Transcatheter Valve System

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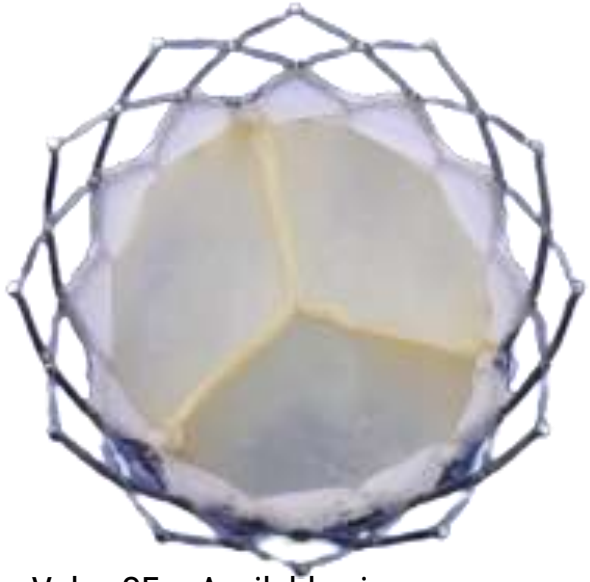
Device designed for the treatment of pulmonary valve diseases



Pulmonary Valve SE – Available sizes

Pulmonary Valve-SE Model	Valve Size (mm)	Proximal Diamenter (mm)	Distal Diameter (mm)	Length after Deployment (mm)
21	21	23	27	36
23	23	25	30	39
25	25	27	32	41
27	27	29	34	44
31	31	33	38	48
35	35	37	42	53

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Thank you!