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Innovations in Transcatheter Tricuspid Valve Intervention: What is Coming?

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Disclosures

Physician name	Company	Relationship
Horst Sievert	4tech Cardio, Abbott, Ablative Solutions, Adona Medical, Akura Medical, Ancora Heart, Append Medical, Axon, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Cardiac Dimensions, Cardiac Success, Cardimed, Celonova, Contego, Coramaze, Croivalve, CSL Behring LLC, CVRx, Dinova, Edwards, Endobar, Endologix, Endomatic, Esperion Therapeutics, Inc., Hangzhou Nuomao Medtech, Holistick Medical, Intershunt, Intervene, K2, Laminar, Lifetech, Magenta, Maquet Getinge Group, Medtronic, Metavention, Mitralix, Mokita, Neurotronic, NXT Biomedical, Occlutech, Recor, Renal Guard, Terumo, Trisol, Vascular Dynamics, Vectorious Medtech, Venus, Venock, Vivasure Medical, Vvital Biomed, Whiteswell	Study honoraria to institution, travel expenses, consulting fees to institution ¹





What means "What is coming?"

- Devices on the drawing board?
- In pre-clinical?
- FIM?
- Approved? – CE mark, FDA,?
- Available in all specialized hospitals?
- Reimbursed?
- In one or the other way all tricuspid devices are "coming" – somewhere

Tricuspid Interventions

Leaflet and chordae interventions
Annuloplasty
Spacer
Heterotopic Implantation
Orthotopic Implantation

Tricuspid Interventions

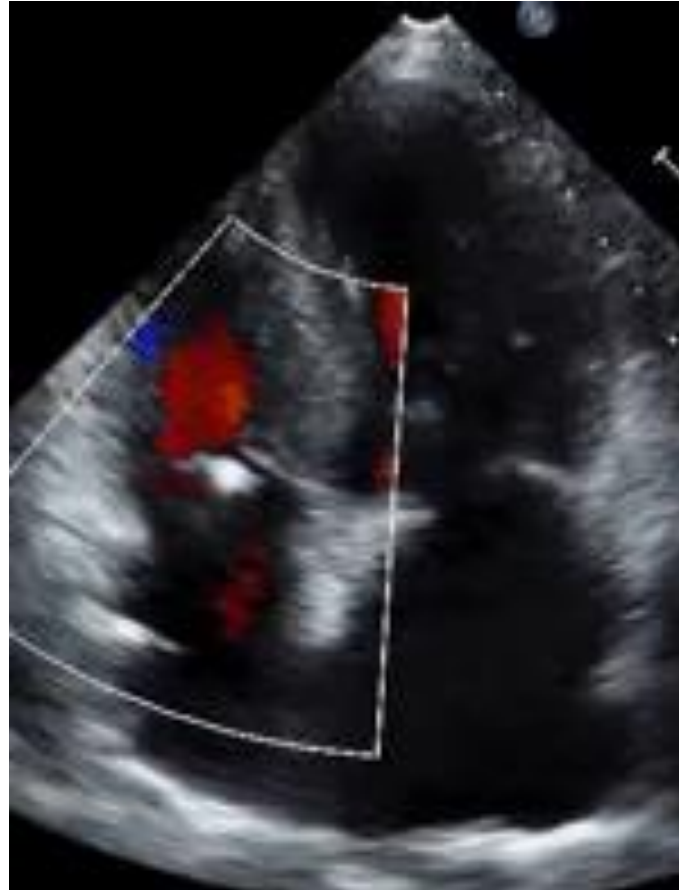
Leaflet and chordae interventions	 Triclip	 Pascal	 Dragonfly	 Mitratrix
Annuloplasty				
Spacer				
Heterotopic Implantation				
Orthotopic Implantation				

It all started with MitraClip in tricuspid position – off label



Before Clip

CVC Frankfurt

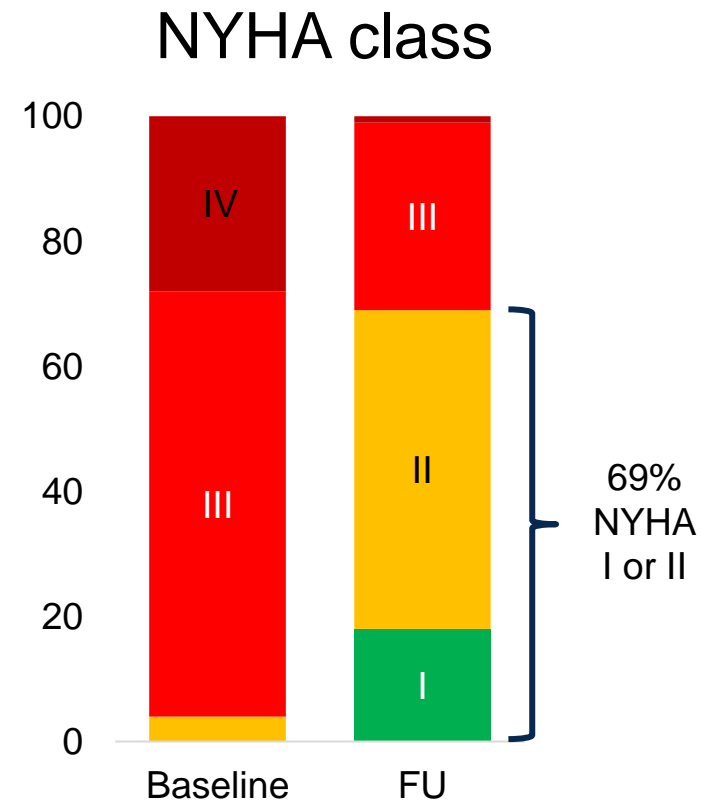
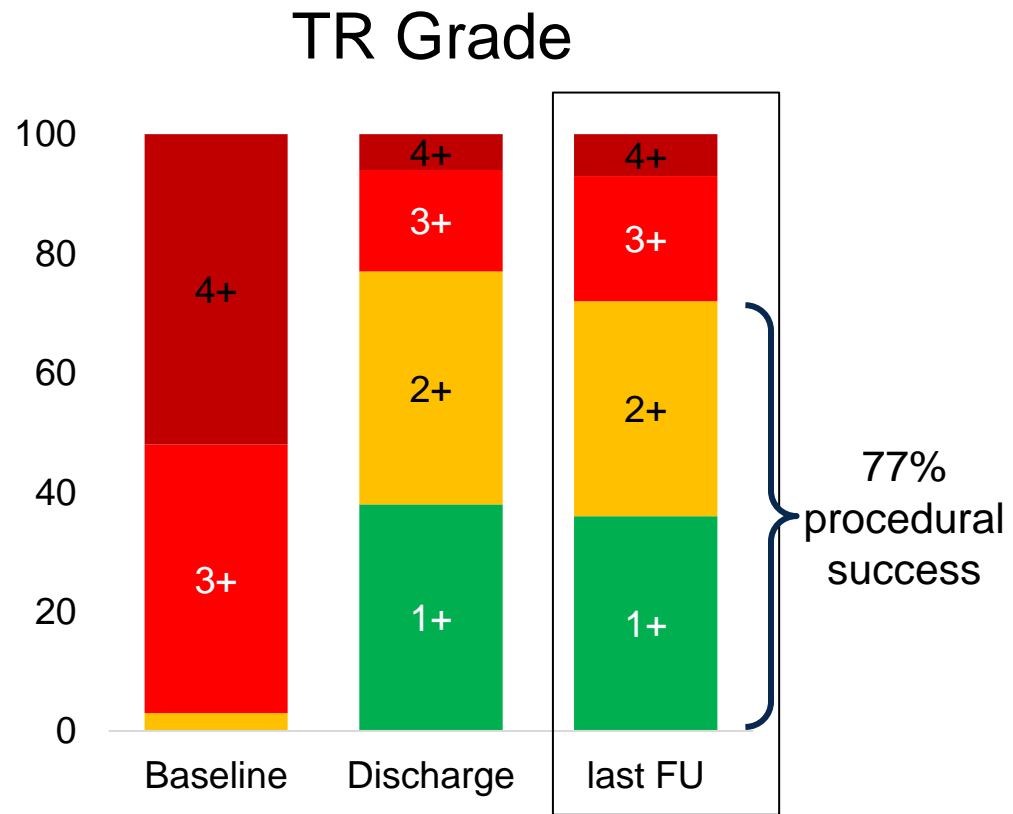


2 months after Clip



TriValve Registry – Mitraclip

- N = 249
- Mean FU: 292 ±195 days



TriClip

New steerable sheath for the tricuspid valve



MitraClip NT



TVRS

CE Mark

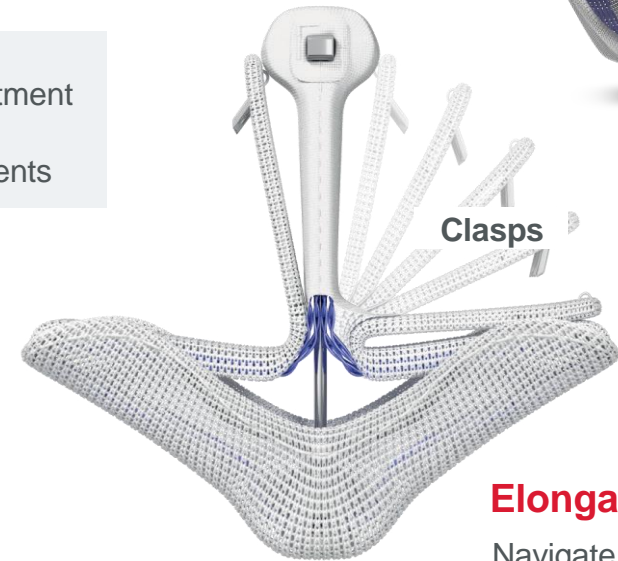
Tricuspid TEER

PASCAL Implant

PASCAL Ace Implant



Paddles



Clasps

Elongation

Navigate in dense chordae

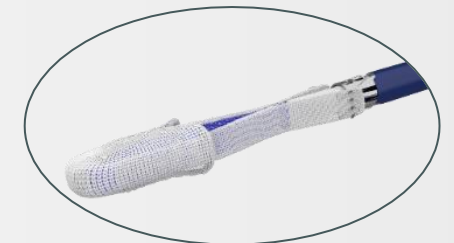
Independent grasping

- Staged leaflet capture and adjustment
- Clasp and reclamp capability with single row of retention elements



Nitinol construction

Passive clo
acute impla



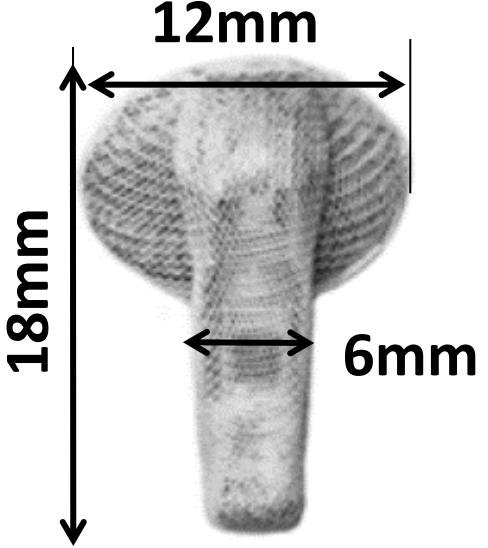
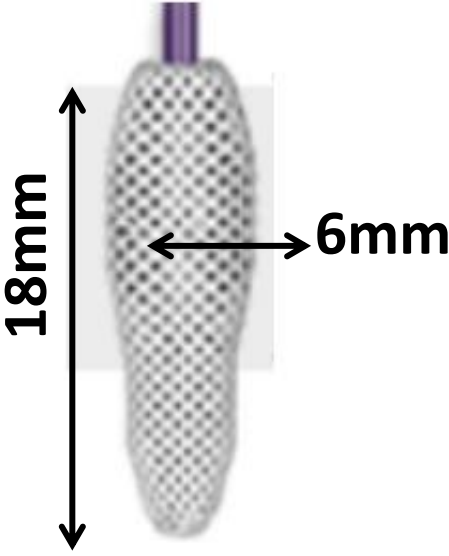
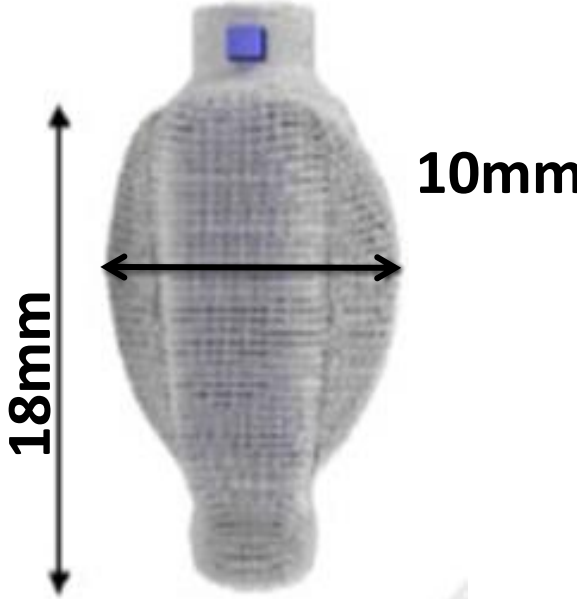
5.000+ Patients treated worldwide with all generations of PASCAL and Ace



TRICLIP™ G4

10.000+ Patients treated worldwide with all generations of TriClip

DragonFly Size Comparison

DragonFly-T	Mitra/TriClip	PASCAL
		
<p>The max width: 12mm</p>	<p>The max width of clip: 6 mm 2.2 clips implanted per patient¹</p>	<p>The max width of clip: 10 mm 1.4 clips implanted per patient²</p>

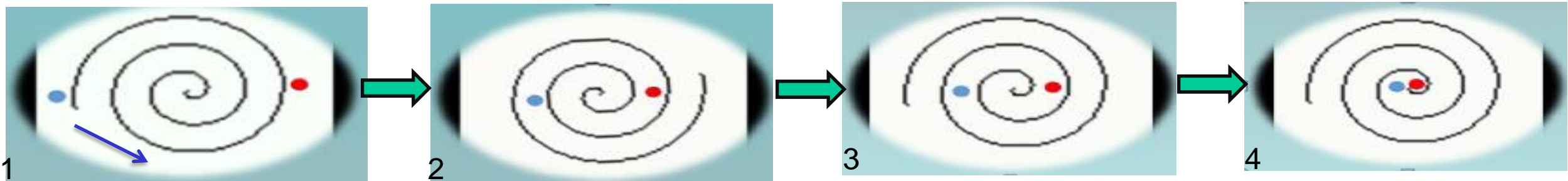
1. Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study
 2. 12-Month outcomes of transcatheter tricuspid valve repair with the PASCAL system for severe tricuspid regurgitation

Mistral Device



Improves leaflet coaptation by grasping chordae from adjacent leaflets

Mode of Action -



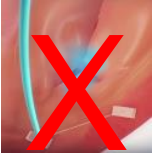

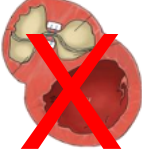
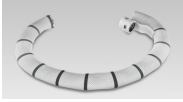





1 Start to turn

4 Grasped Chords!

● - Chords from **Posterior** Leaflet

● - Chords from **Anterior** Leaflet

Tricuspid Interventions

Leaflet and chordae interventions									
Annuloplasty	 Trialign	 MIA	 PASTA	 Cardioband	 Millipede	 DaVinci	 TriCinch	 TRAIPTA	 Trans annular bridge
Spacer									
Heterotopic Implantation									
Orthotopic Implantation									

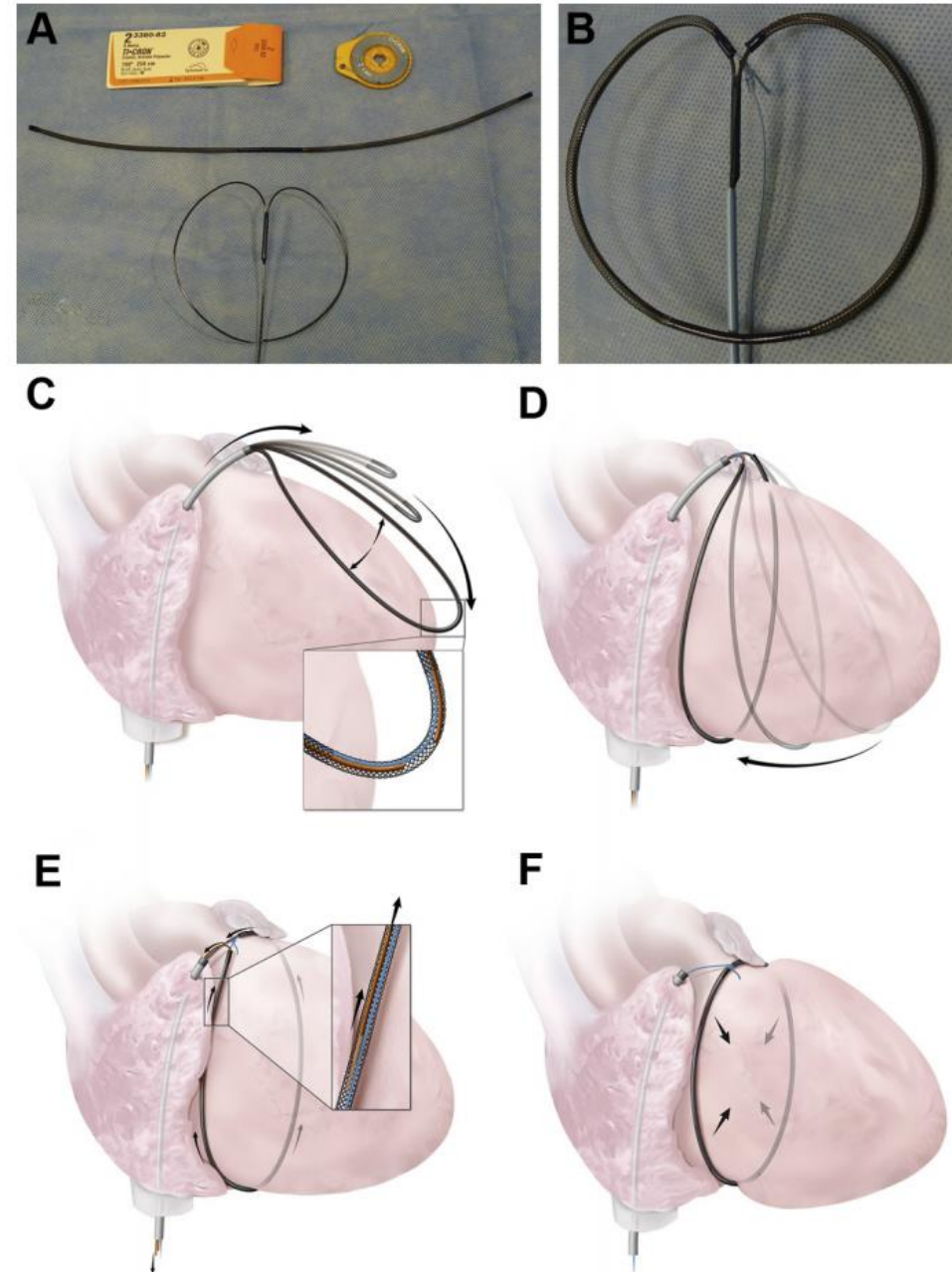
Cardioband TR



- Developed as an annuloplasty technique for mitral
- Same implant and delivery system
- CE marked for mitral and tricuspid
- Currently under re-design

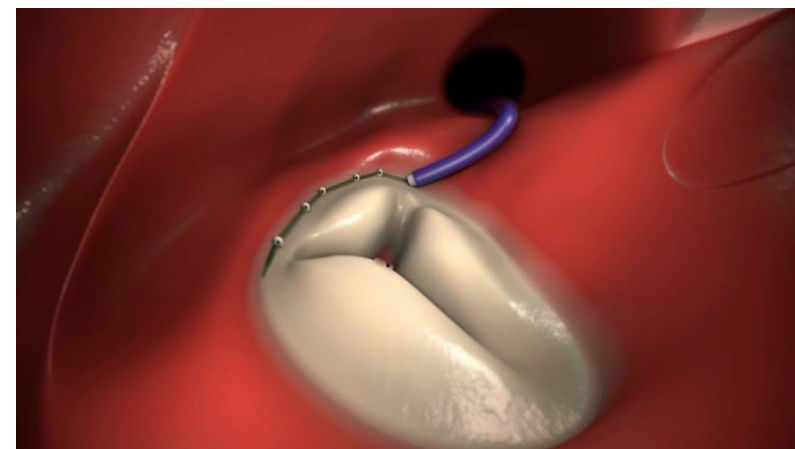
TRAIPTA

- RAA puncture → pericardial access
- Circumferential implant delivered along atrioventricular groove
- Tension adjusted
- RAA puncture hole closed with an umbrella closure device

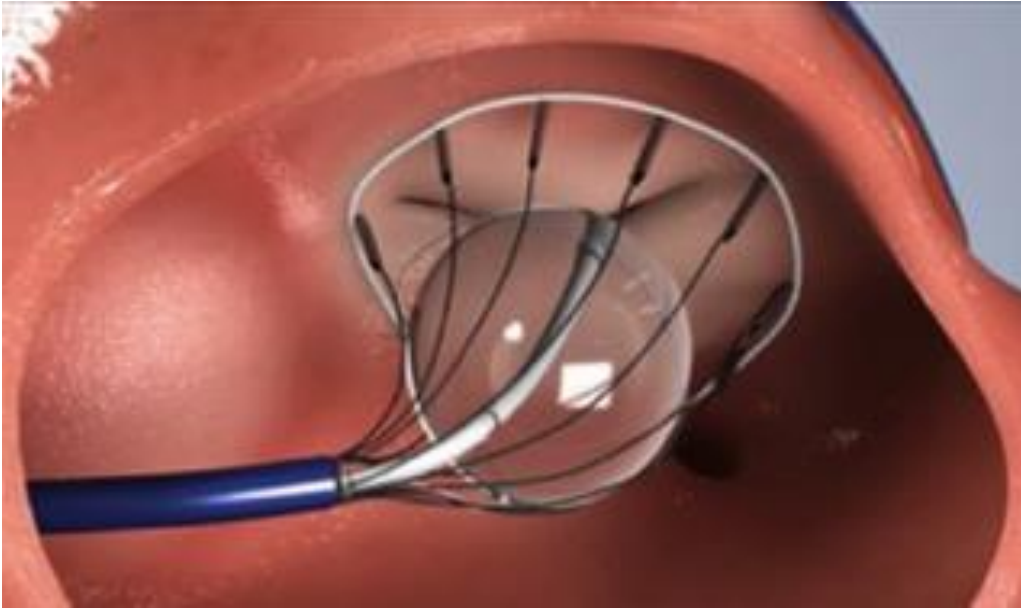


MIA Device

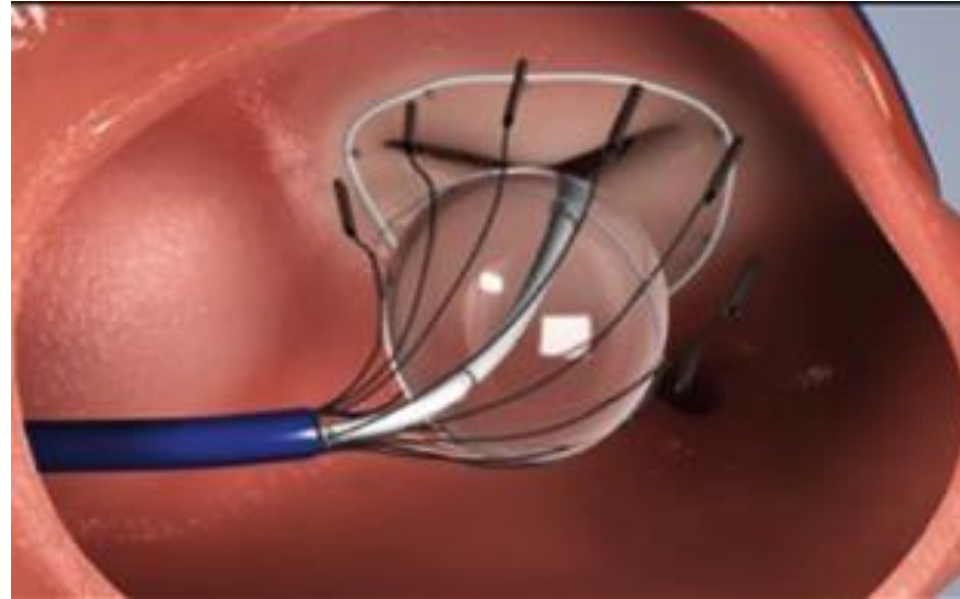
- PolyCor anchors and a thermoplastic elastomer
- Multiple anchors are placed into the annulus between the postero-septal and antero-posterior commissures which subsequently create tension between the commissures
- Preliminary experience in 31 patients
 - no adverse events related to the device
 - Significant reduction in annulus dimensions and TR
 - Improvement in quality of life



Da Vinci System



A scaffold is positioned
on the annulus

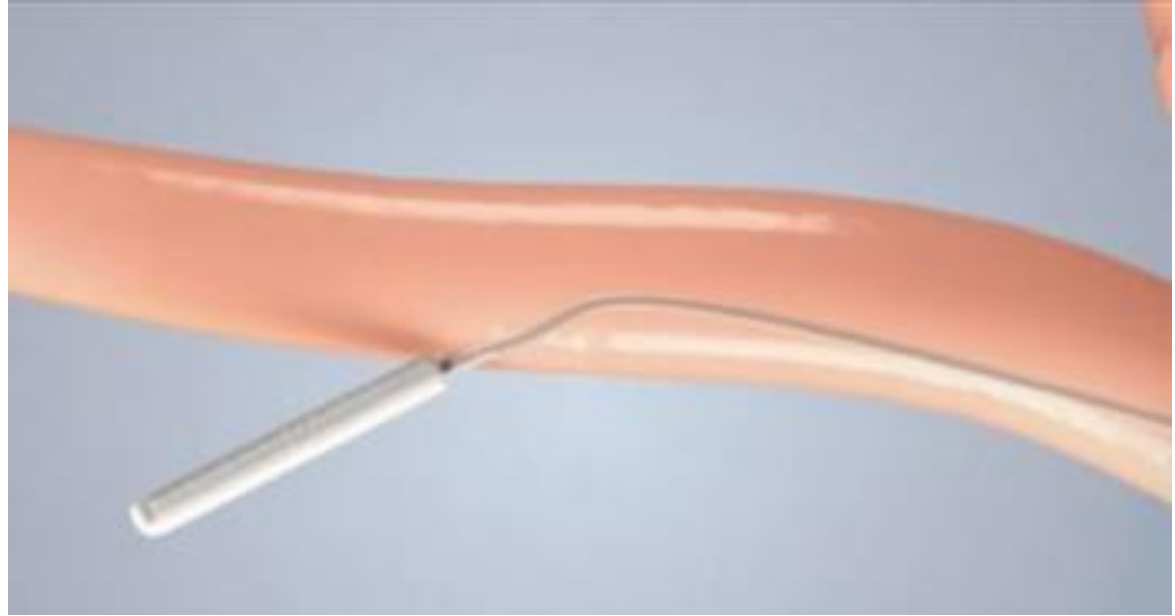


A ring and stakes are
attached to the annulus
in a single shot

Da Vinci System

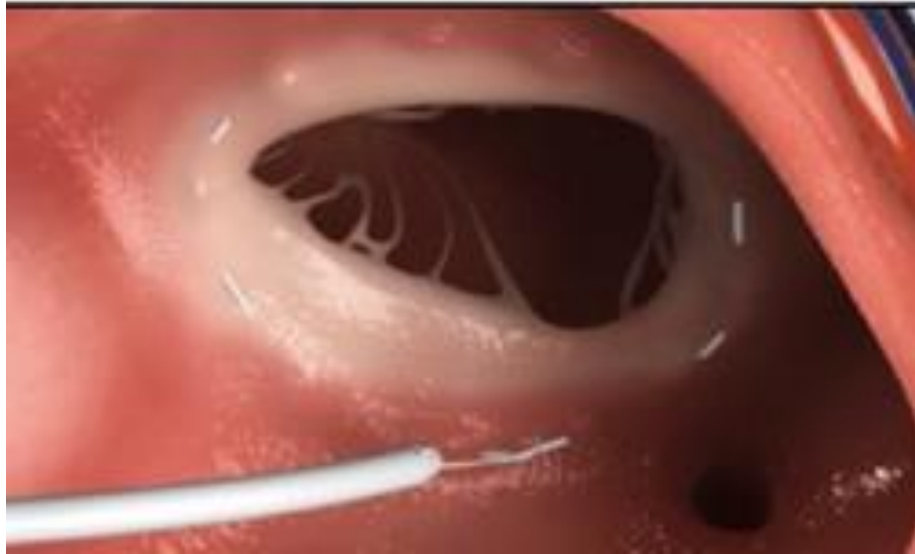


The ring and a tether cord remain in place



The tether cord remain is secured below the skin

Da Vinci: After 30-90 days - Adjustment Phase

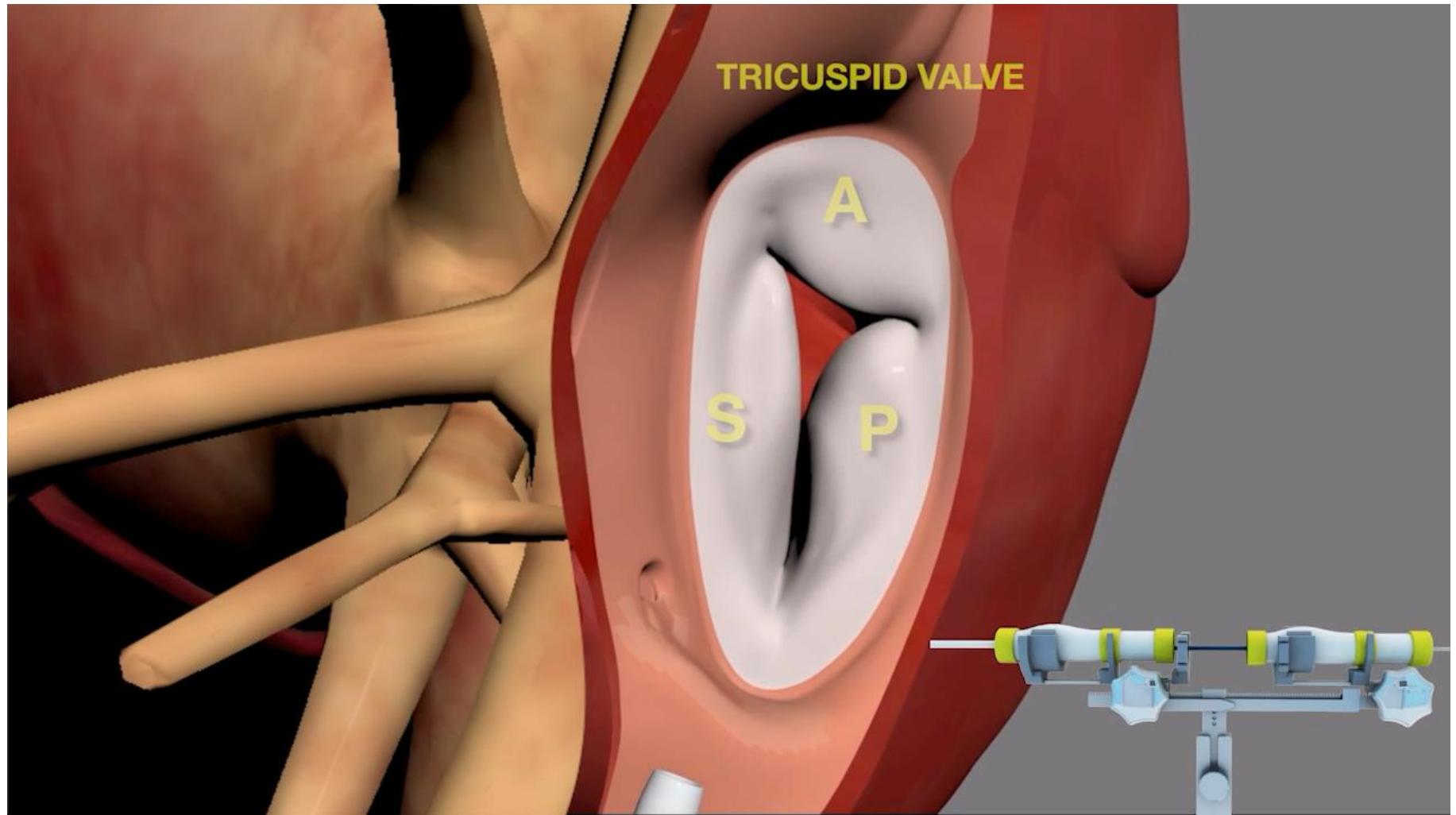


The adjustment tool is advanced over the cords, tension is applied

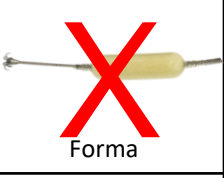
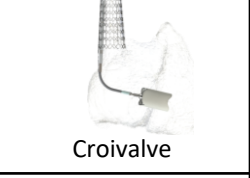
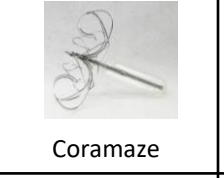
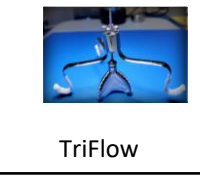


The cords are cut and the implant is locked

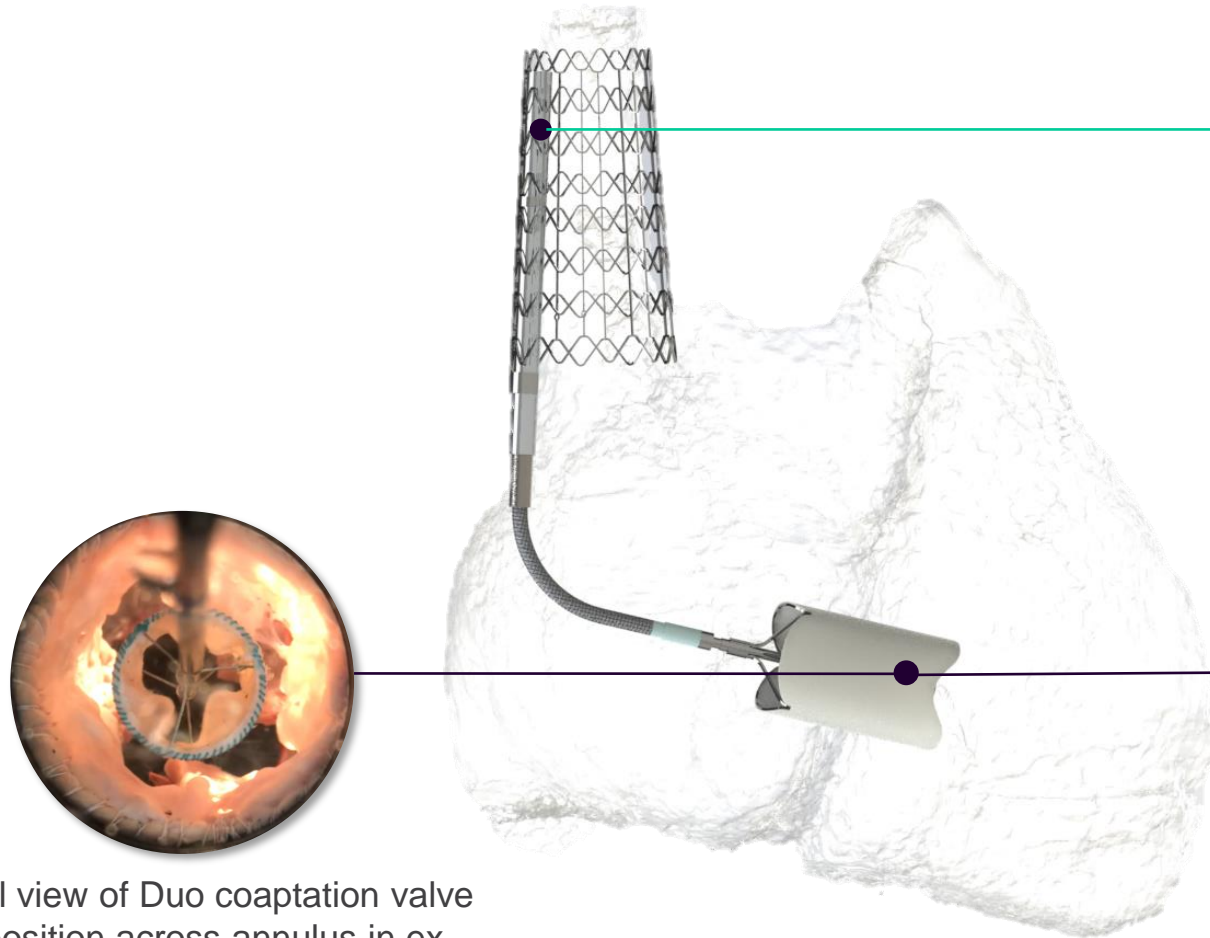
Tricuspid Bridge Implantation



Tricuspid Interventions

Leaflet and chordae interventions				
Annuloplasty				
Spacer	 Forma	 Croivalve	 Coramaze	 TriFlow
Heterotopic Implantation				
Orthotopic Implantation				

CroíValve



Anchor System

- Anchored in the SVC
- Adjustable, lockable, disconnectable system
- Allows for respiratory & cardiac motion

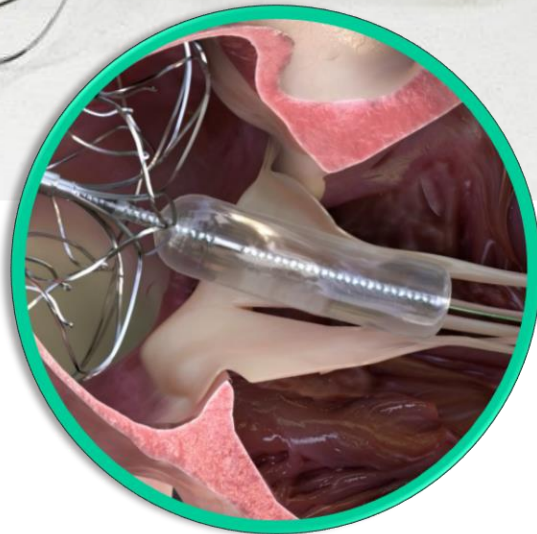
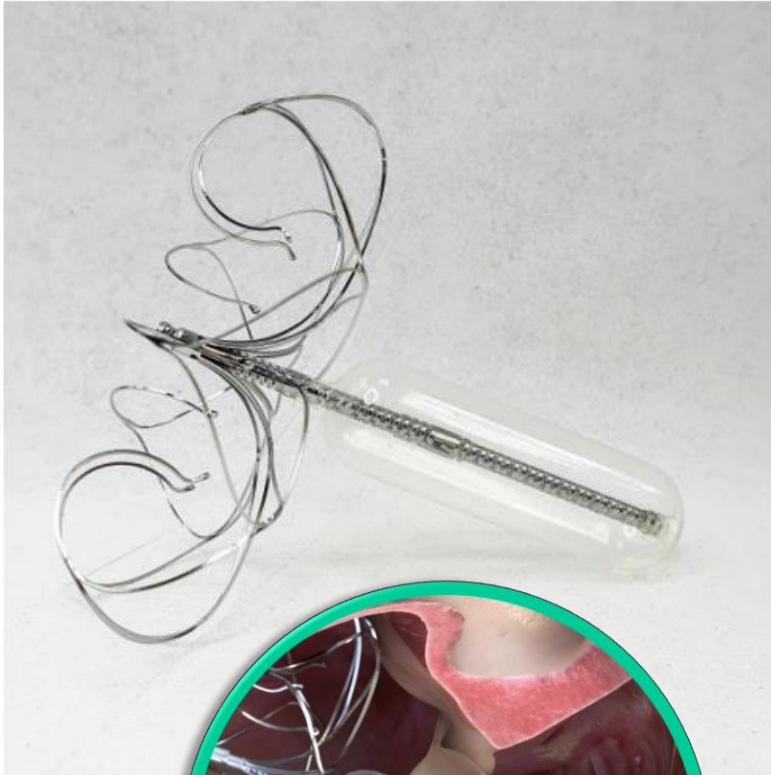
Coaptation Valve

- Fills the regurgitant orifice
- Native leaflets seal against atraumatic pericardium skirt
- Prosthetic valve to support diastolic flow
- One size fits all

Atrial view of Duo coaptation valve
in position across annulus in ex-
vivo model




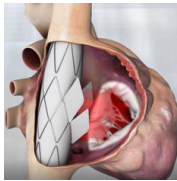
FIM done (temporary implant)

Coramaze

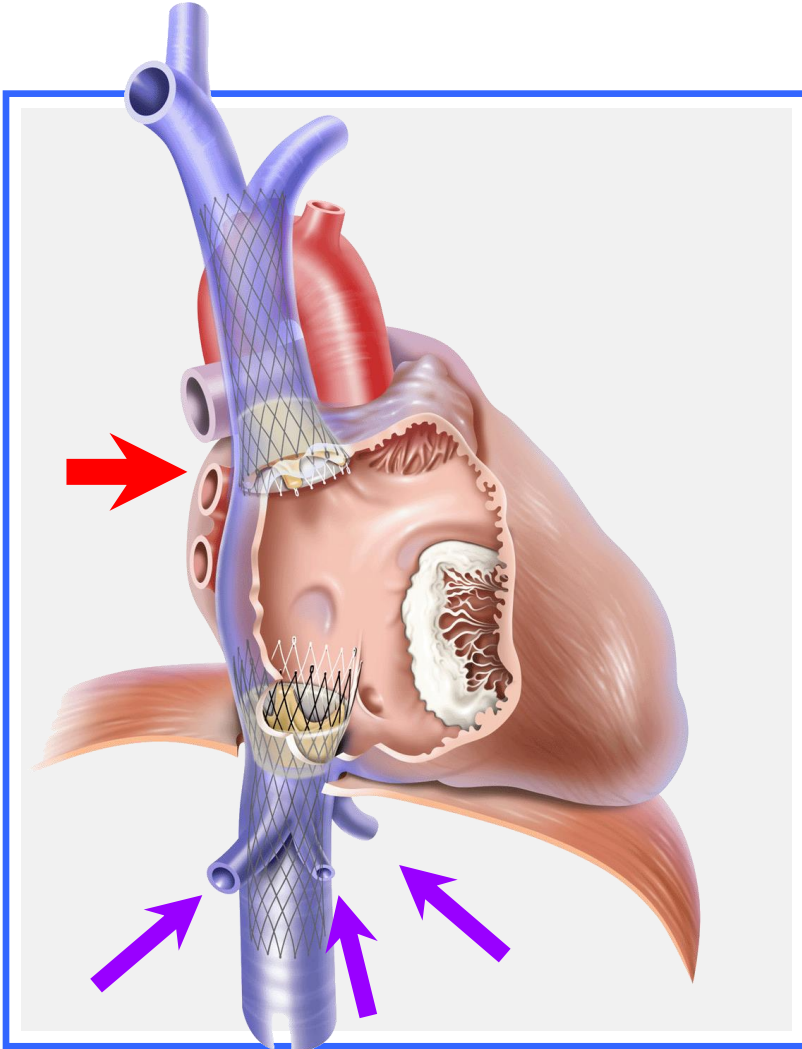


- Anchor in the right atrium
- Flexible joint between anchor and spacer
 - The spacer finds its space between the leaflets
- FIM ongoing

Tricuspid Interventions

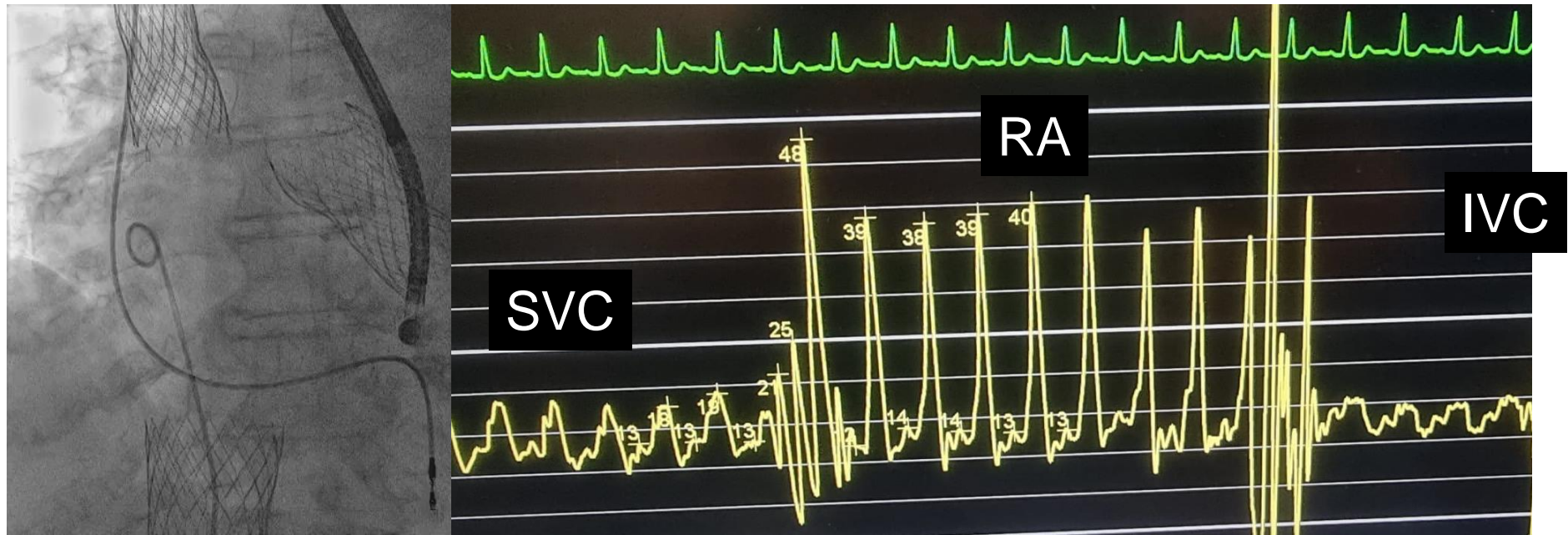
Leaflet and chordae interventions				
Annuloplasty				
Spacer				
Heterotopic Implantation	 Sapien in IVC	 TricValve	 TriCento	 Trilium
Orthotopic Implantation				

Transcatheter CAVI - Tricvalve



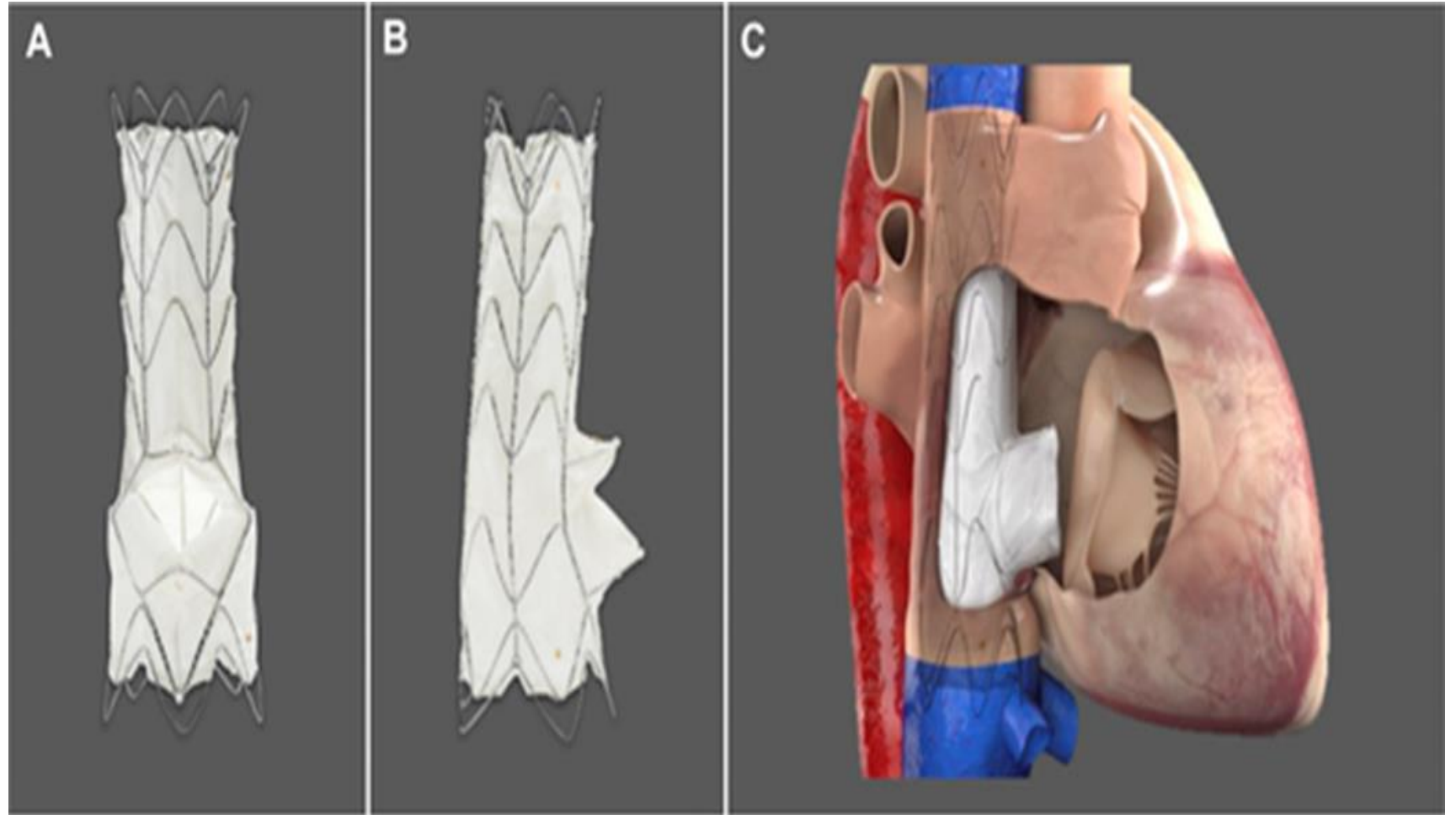
- Implantation of self-expandable valve in SVC
- Implantation of self-expandable valve in IVC above hepatic vein inflow

TricValve system

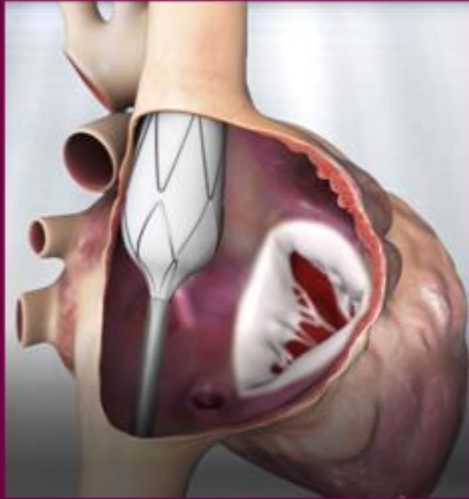


Massive decrease in SVC/IVC pressure

Tricento



Trillium




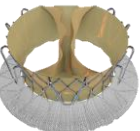

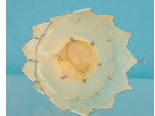




Transcatheter Insertion



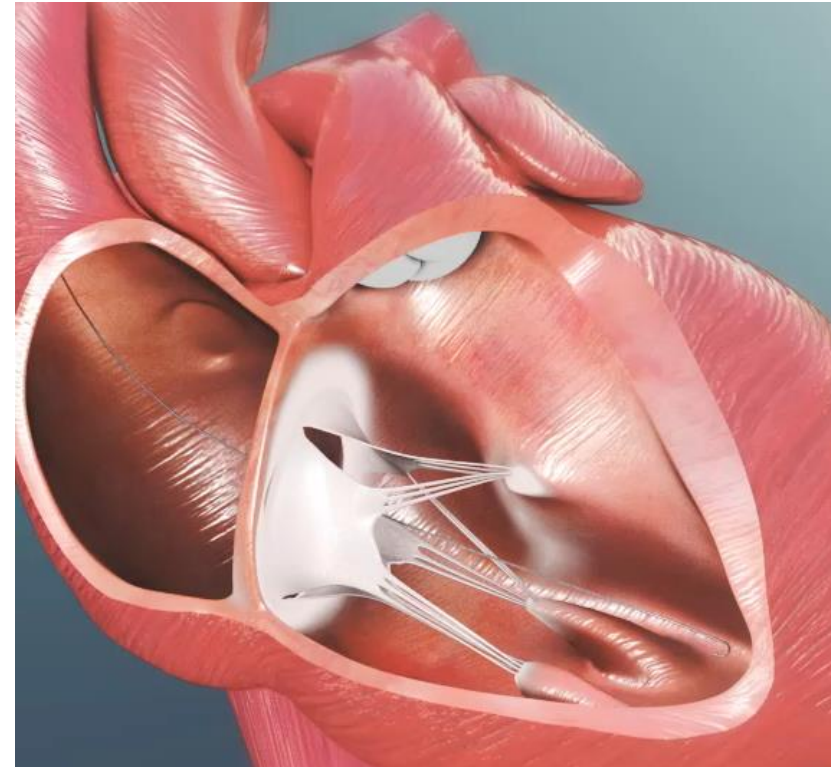
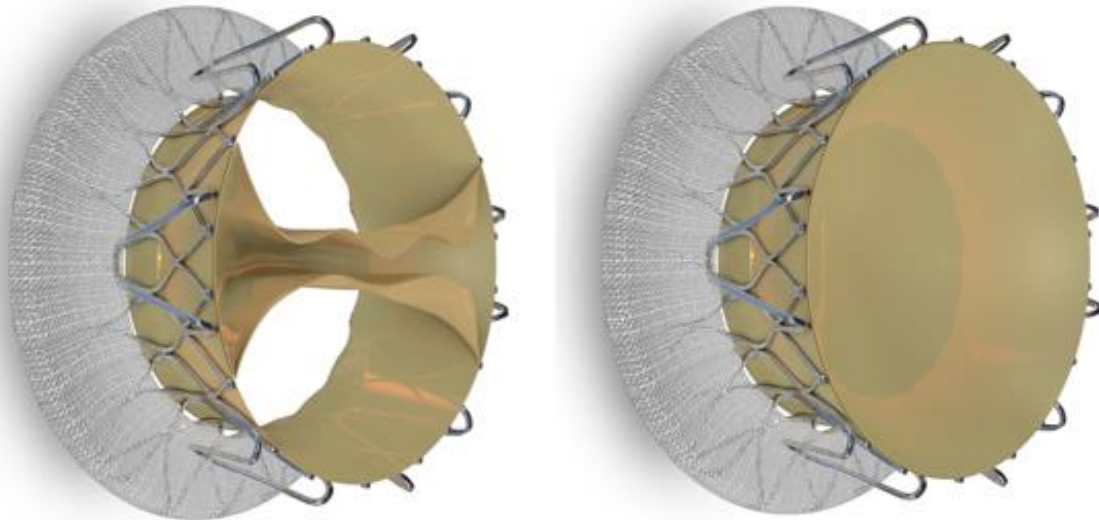
Cross-caval Anchoring

Tricuspid Interventions

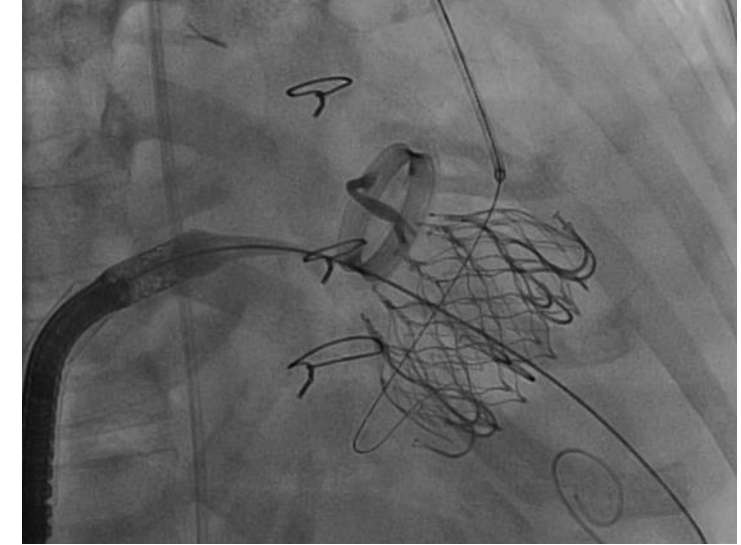
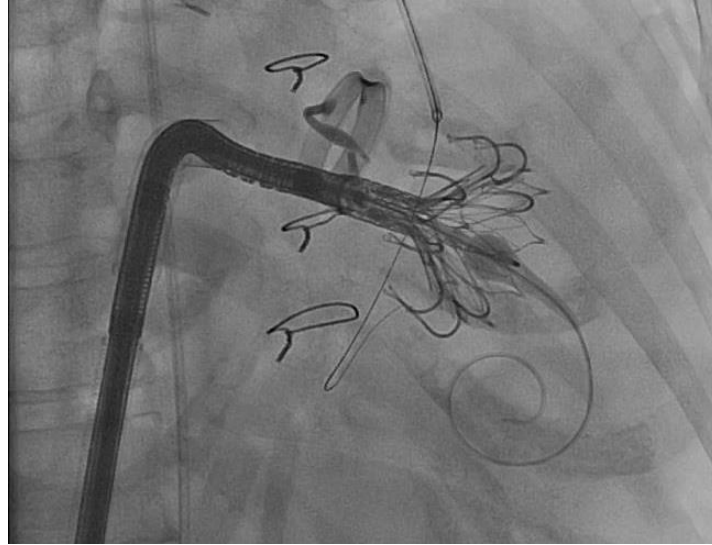
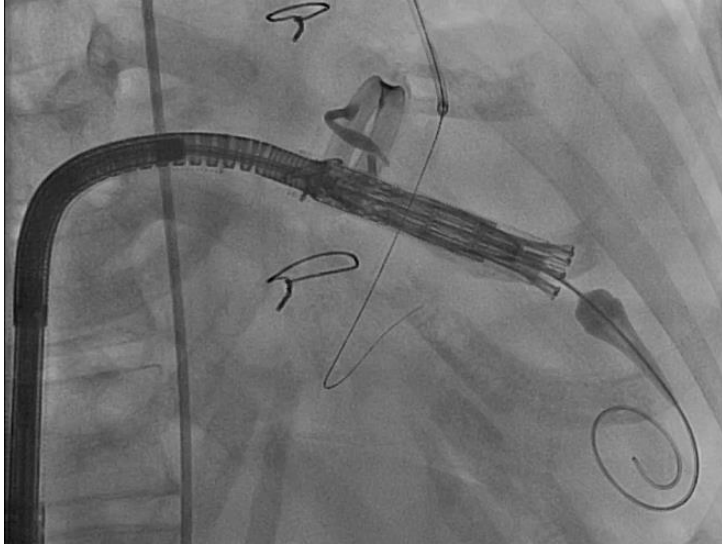
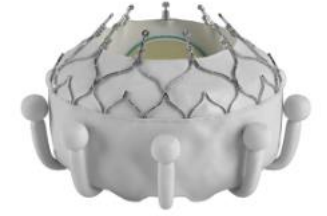
Leaflet and chordae interventions									
Annuloplasty									
Spacer									
Heterotopic Implantation									
Orthotopic Implantation	 Navigate	 Intrepid	 V-Dyne	 Trisol	 Lux	 Topaz/Tricare	 Evoque	 CardioValve	confidential Laplace

Trisol

- Single dome-shaped leaflet
- Transjugular approach
- 31F delivery system
- Anchors on the leaflets
- Can be repositioned and retrieved
- FIM 2021



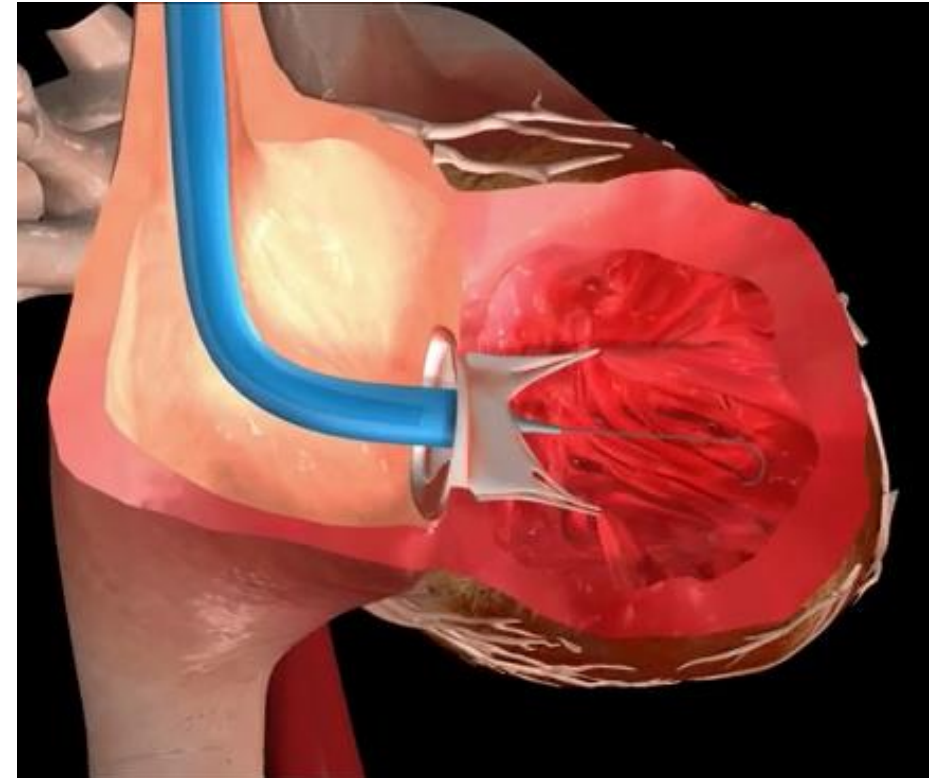
EVOQUE Tricuspid Valve



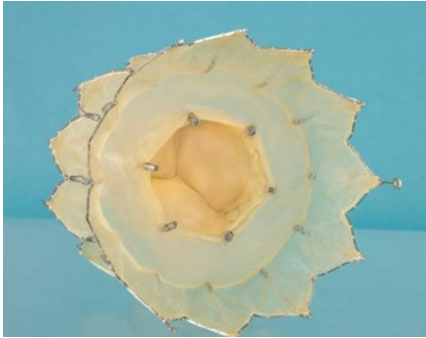
- Access transfemoral
- Sheath 28 F
- Anchors on anulus, leaflets and chords
- Valve sizes 44, 48, 52 mm

Jenscare LuX-Valve

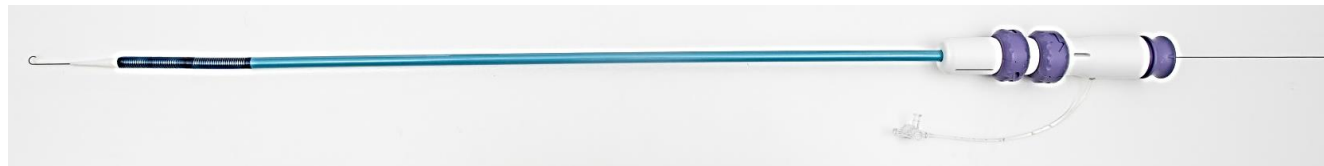
- Access trans-jugular
- Anchors on leaflets and interventricular septum
- Valve sizes 50, 60 and 70mm



TRiCares Topaz TTVR Prosthesis

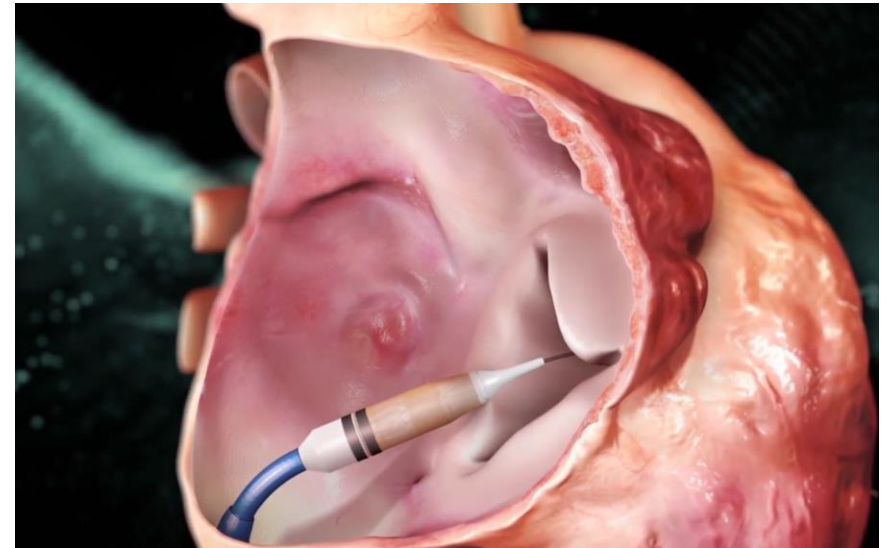


- Access transfemoral
- 29 F sheath
- Currently for tricuspid annuli up to 45mm
- Porcine pericardium – three leaflet valve
- Two stent design
- Conforms to patients' native tricuspid anatomy



CardioValve

- Access transfemoral
- Anchors on the leaflets
- Cuff to prevent paravalvular leak



Fits Annular Diameter up to:

45mm

Prosthetic Valve Diameter:

27mm

Fits Annular Diameter up to:

50mm

Prosthetic Valve Diameter:

29mm

Fits Annular Diameter up to:

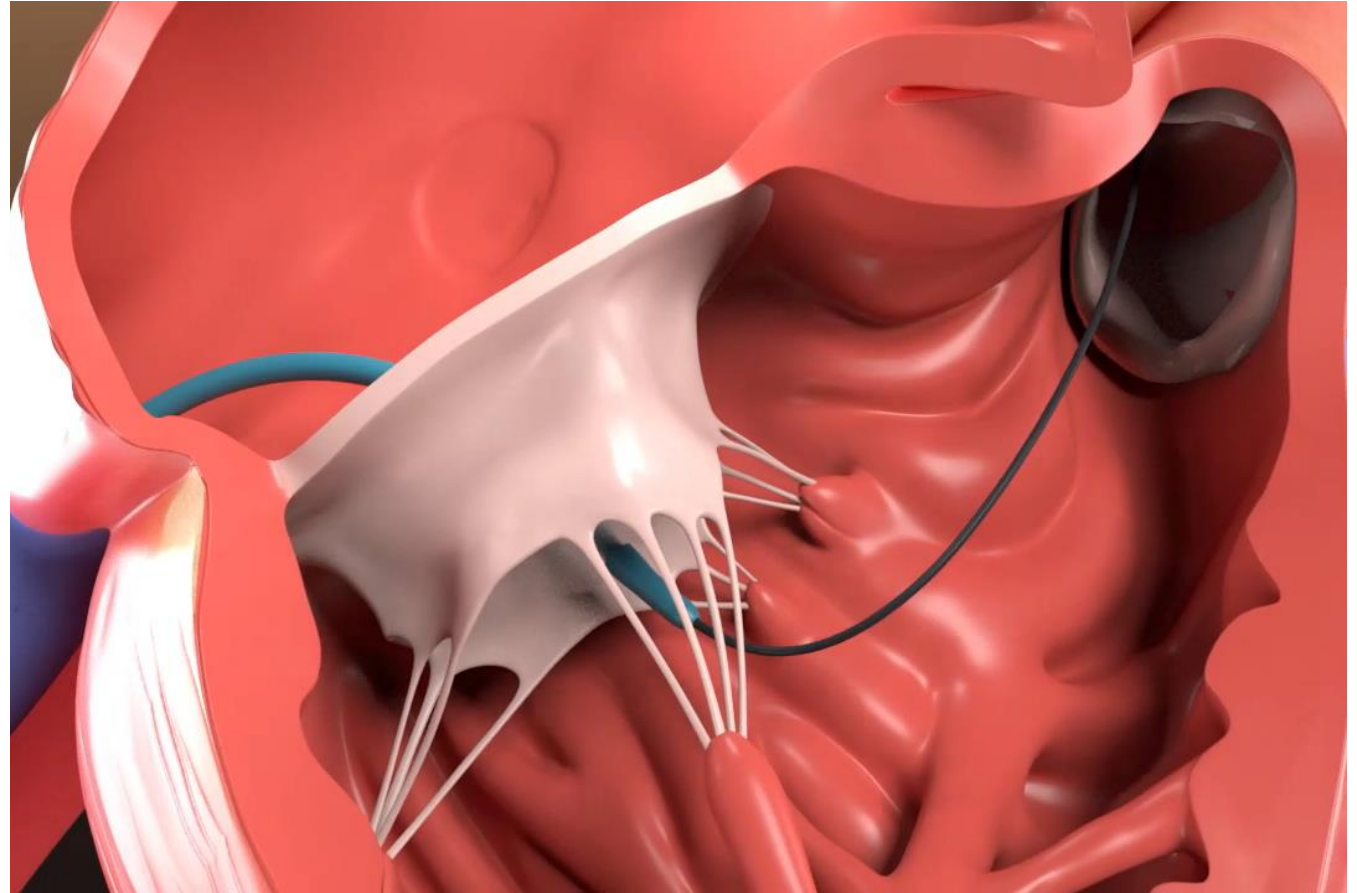
55mm

Prosthetic Valve Diameter:

29mm

VDyne

- Access transfemoral
- 28 F sheath
- "Side delivery", delivery system does not enter the right ventricle
- Repositionable and retrievable
- Valve sizes 50, 60 and 70mm



Tricuspid interventions ...

- ... have evolved to a routine procedure
- Currently the vast majority of patients are treated with TriClip
- Other edge-to-edge techniques (PASCAL, DragonFly-T, ...) will catch up
- Several other (non edge-to-edge) techniques for transcatheter tricuspid valve repair are in an early stage
- Several percutaneous tricuspid valves are in pre-clinical and clinical trials
- Extracardiac valve implantation is an option for patients with anatomy not suitable for direct repair or valve implantation