



ECOCARDIOCHIRURGIA®
ECO-RM-TC CHIRURGIA-INTERVENTISTICA

**IX CONGRESSO NAZIONALE
ECOCARDIOCHIRURGIA 2017**

Alternative percutanee nel trattamento dell'insufficienza tricuspidalica: stato dell'arte e prospettive future

Sergio Berti

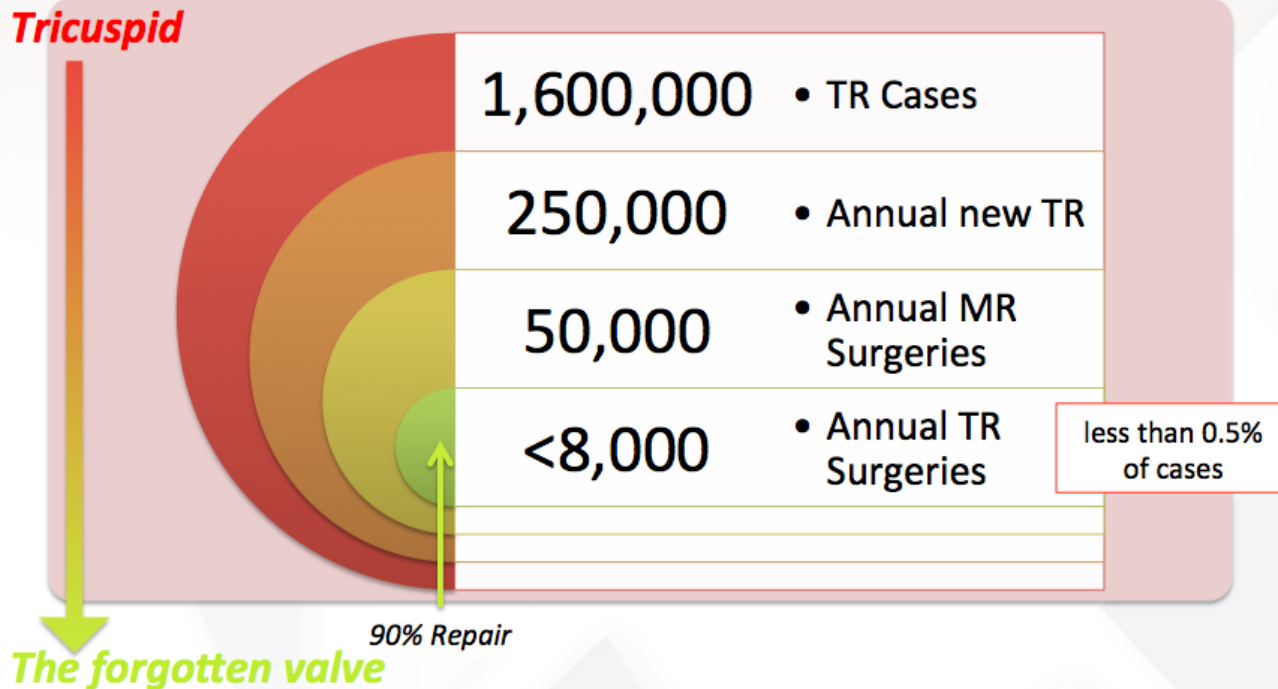
Ospedale del Cuore

Fondazione C.N.R. Reg Toscana Massa/Pisa

Clinical background

Tricuspid Regurgitation and Low penetration of cardiac surgery

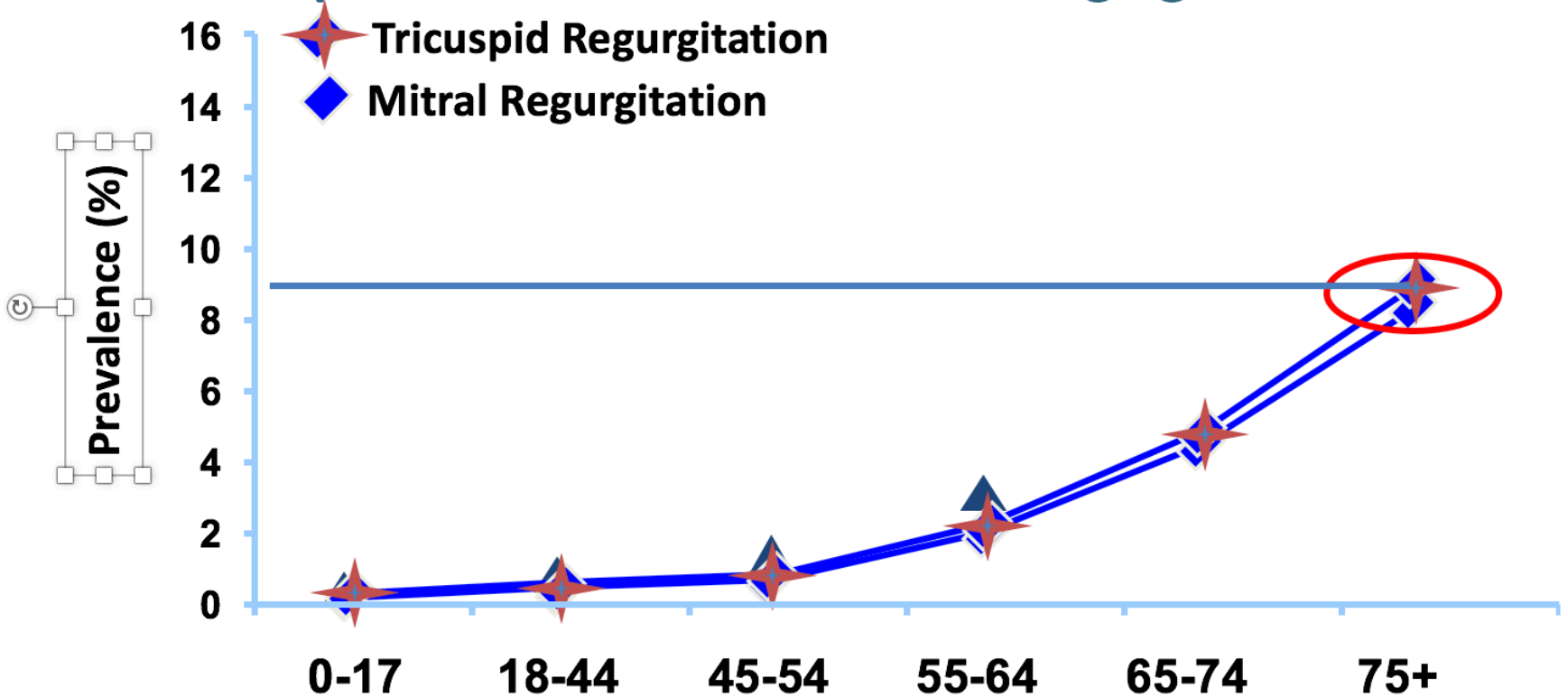
Estimated structural heart disease opportunity: US



Agarwal et al. *Circ Cardiovasc Interv* 2009;2:565-573

Stuge O, Liddicoat J. *J Thorac Cardiovasc Surg*. 2006 Dec;132(6):1258-61

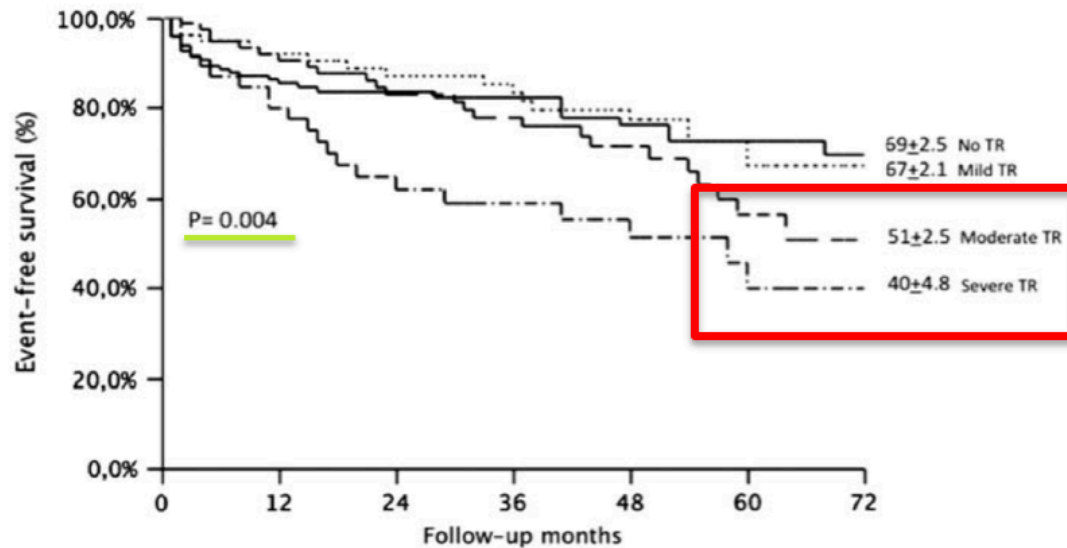
Functional Tricuspid and Mitral Regurgitation have the same incidence & prevalence and are related to aging*



* Diagnosed in Olmsted County, MN, USA Data presented by Prof. M. Enriquez-Sarano - Mayo Clinic

CONFIDENTIAL

TR highly impacts the rate of events



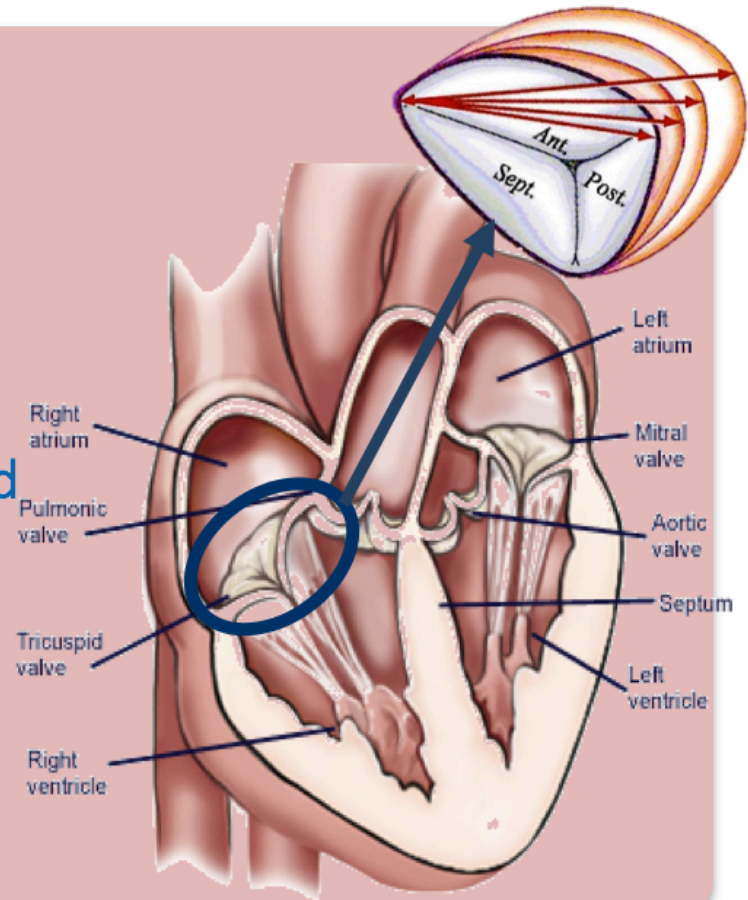
“Moderate to severe TR is independently associated with increased risk of events”*

*Agricola E et al. Eur J Heart Fail. 2012 Aug;14(8):902-8

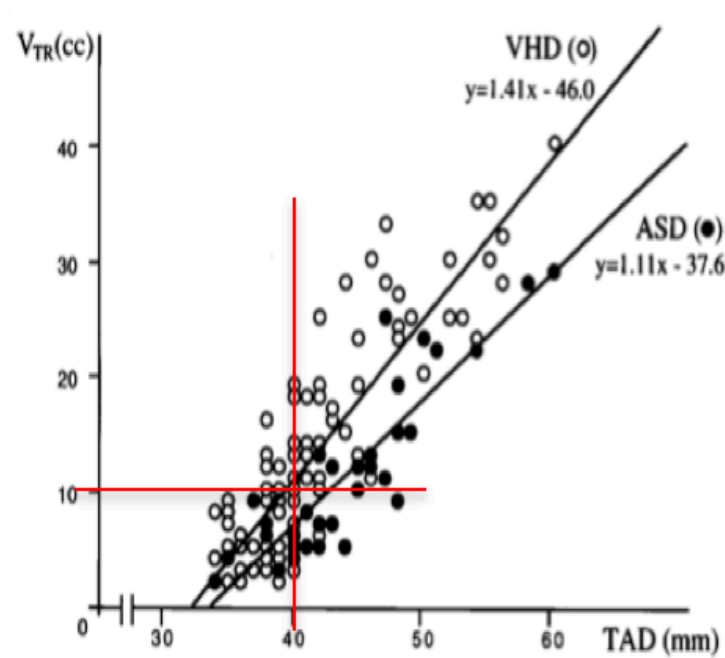
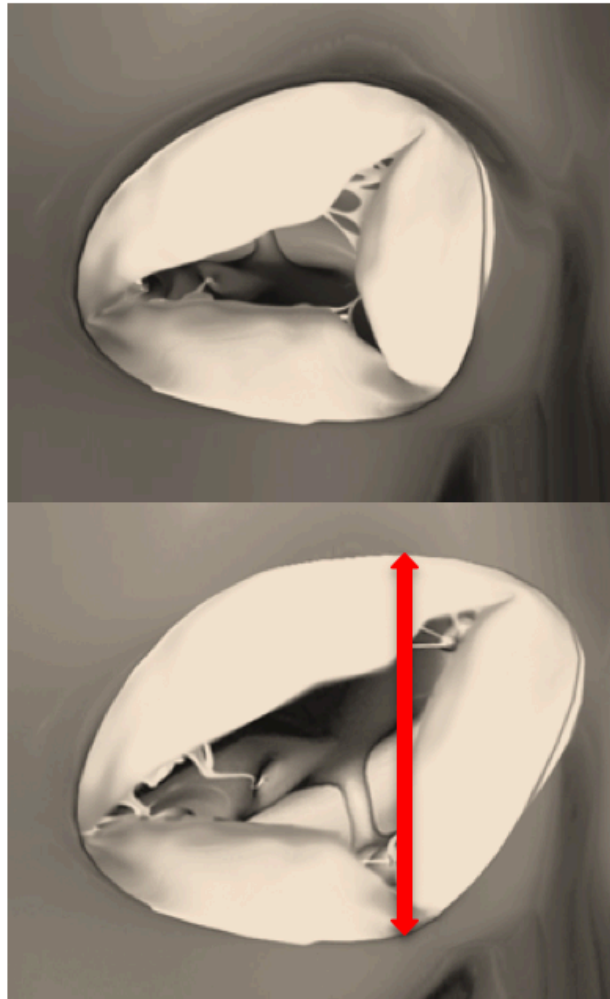
Tricuspid Regurgitation - Clinical Scenarios

TR Etiology

- Isolated primary (organic) TR
- Secondary (functional) TR in patients undergoing left-sided valve surgery
- Late TR following left-sided valve surgery

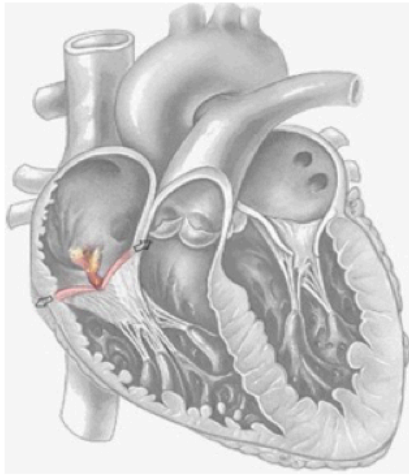


Functional tricuspid regurgitation disease mechanism



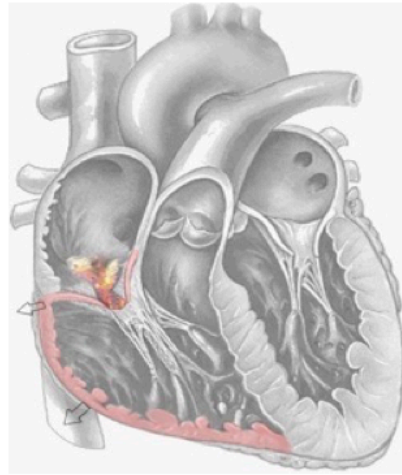
Correlation between Tricuspid Annular Diameter and Regurgitant Volume

When should we treat ?



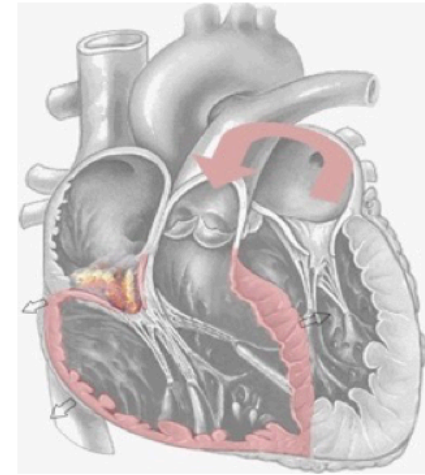
Phase I

Initial dilation of RV
results in TA dilation



Phase II

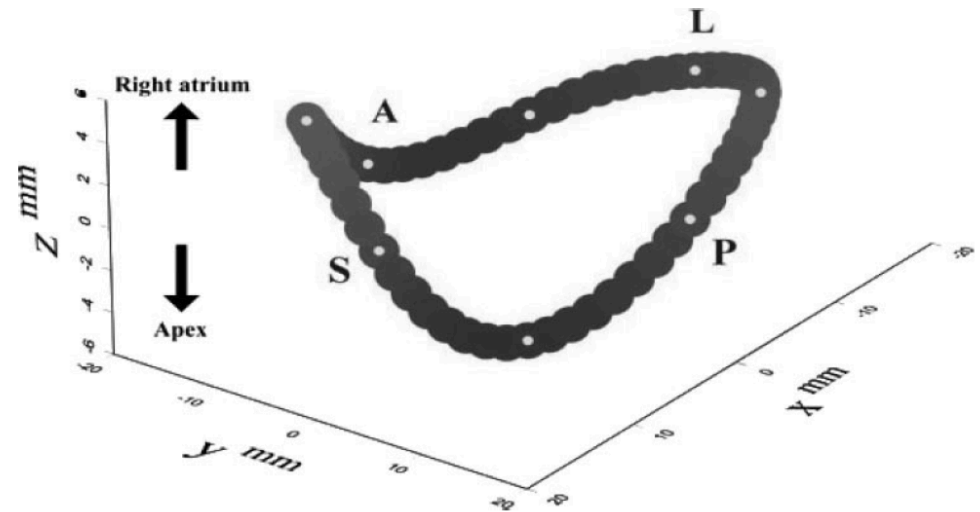
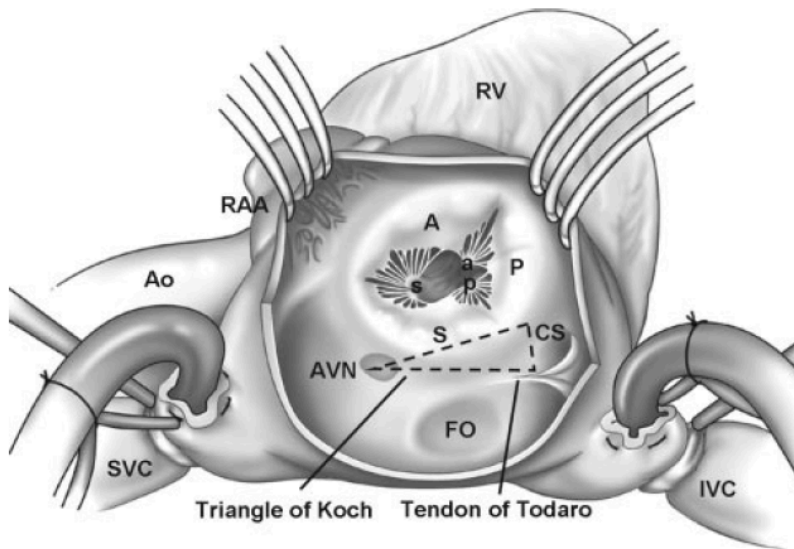
Progressive RV and TA dilation
results in lack of coaptation



Phase III

Progressive RV distortion
tethering of the leaflets,
TA dilation, pulm hypertension

Tricuspid valve: a complex 3-dimensional structure



Surgical techniques for functional Tricuspid Regurgitation

- **Annular plication by suture annuloplasty**

 - Localized

 - Kay repair (bicuspidalization)

 - Semicircular

 - De Vega repair

- **Reduction annuloplasty with flexible rings**

 - SJM Tailor Annuloplasty ring

 - Cosgrove-Edwards ring

 - Duran ring

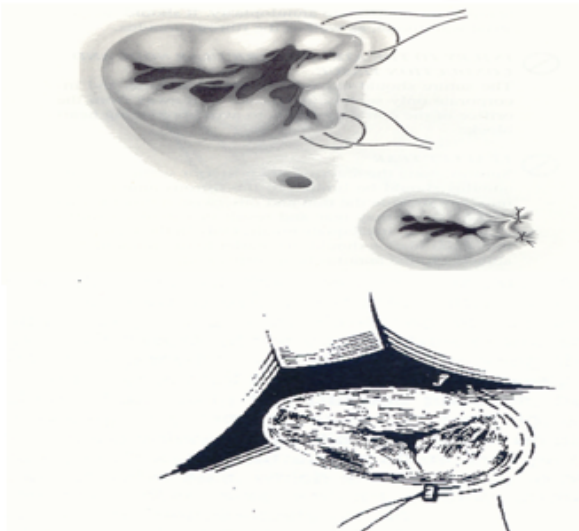
- **Remodeling annuloplasty with semi-rigid rings**

 - Carpentier-Edwards

 - Edwards MC3 system

Annular plication

Kay Repair (bicuspidalization)

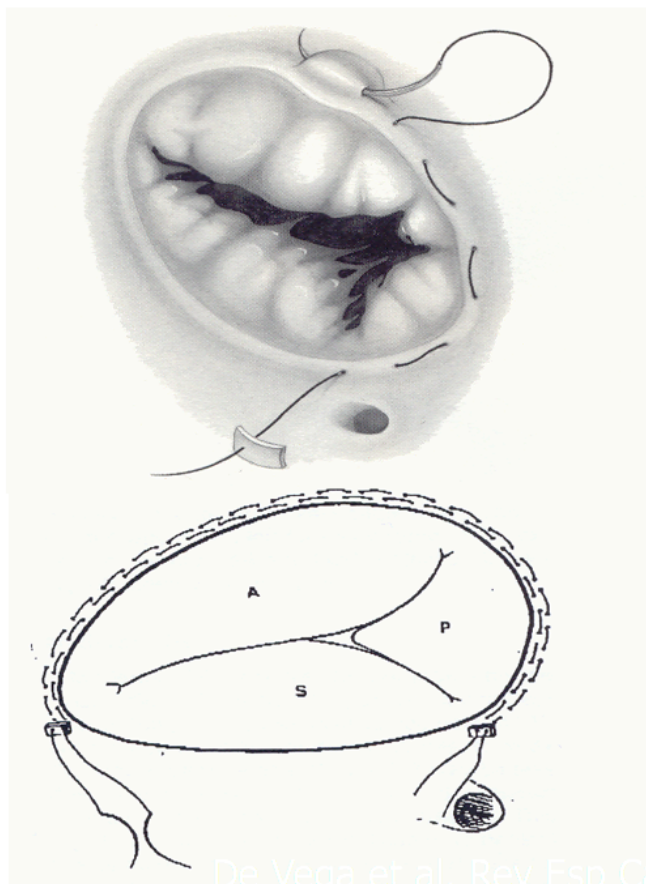


Kay et al. Ann Surg 1965, 53

- Bicuspidalization of the TV by exclusion of the posterior leaflet
- Simply, fast, unexpensive and safe (conduction system avoided)
- Late dilatation of the anterior annulus



Semicircular annuloplasty (De Vega)

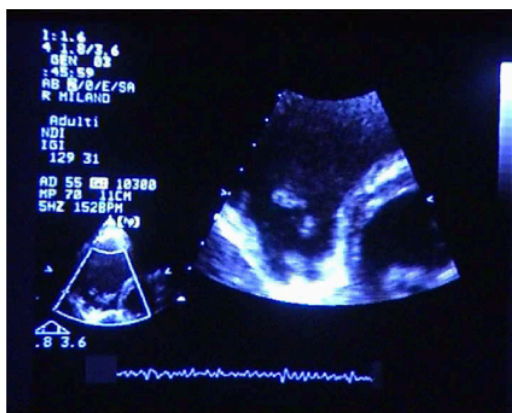
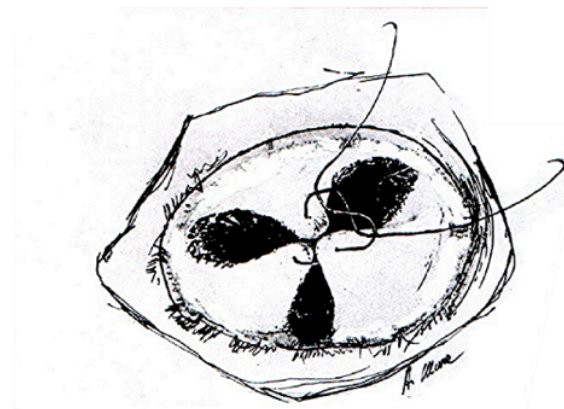


- Simple, fast, unexpensive
- No prosthetic material
- No AVN injury
- Significant late recurrence of
TR

De Vega et al. Rev Esp Cardiol. 1972; 23(1): 1-6

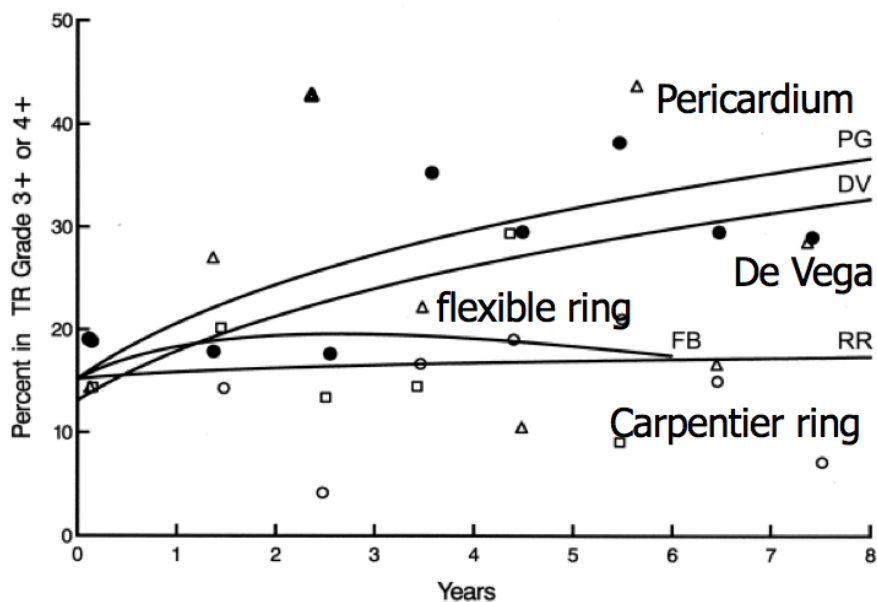


Clover technique

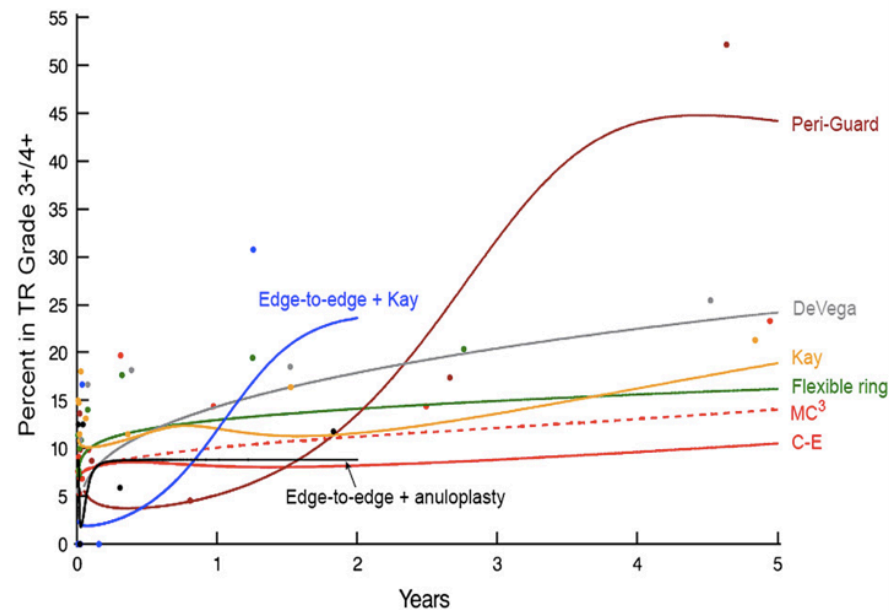




Current results of tricuspid plasty are suboptimal



McCarthy et al. JTCVS 2004;127:675



Navia et al. JTCVS 2010;139

Transcatheter solution for Tricuspid Valve Regurgitation

- Transform proven surgical techniques in percutaneous procedure to perform a remodeling of tricuspid valve annulus in a minimally invasive percutaneous approach.
- Answer an unmet clinical need with a simple, reproducible and cost-effective procedure that will relief non-surgical and high risk patients and decrease health-care spending.

What does the future hold?

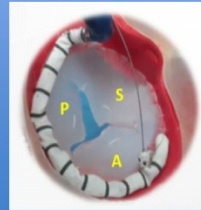
Annular modification



Tricinch



Trialign



Cardioband

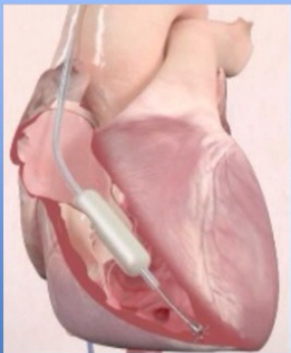


Millipede



TRAIPTA

Leaflet apposition



Forma Device

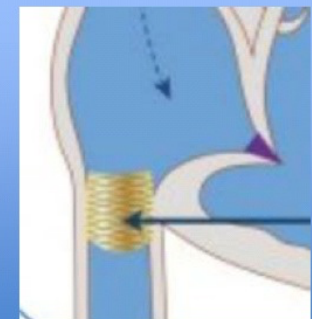


MitraClip

Caval Valve Implantation

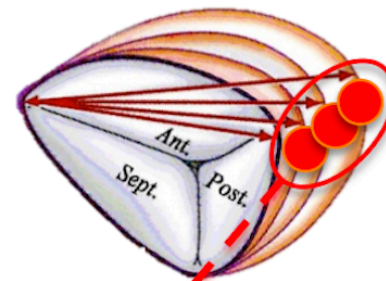
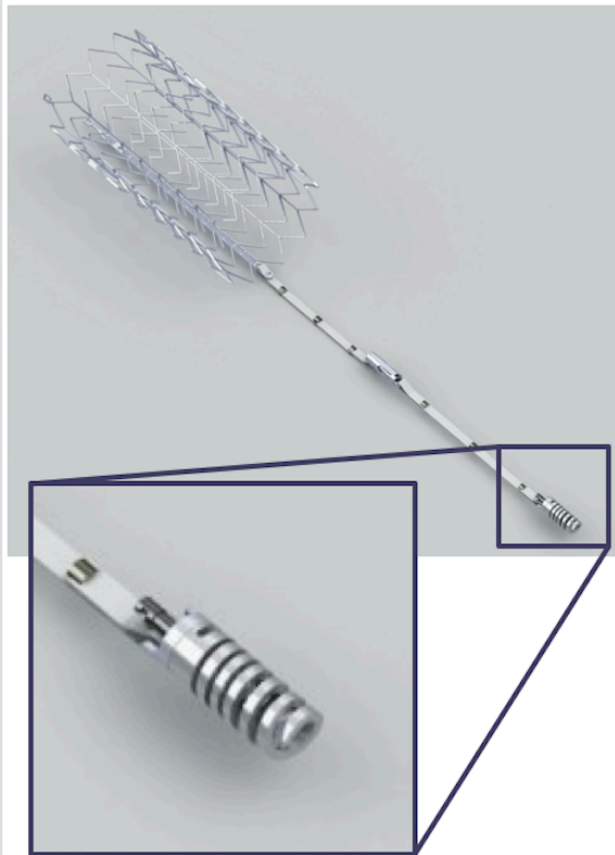


TricValve



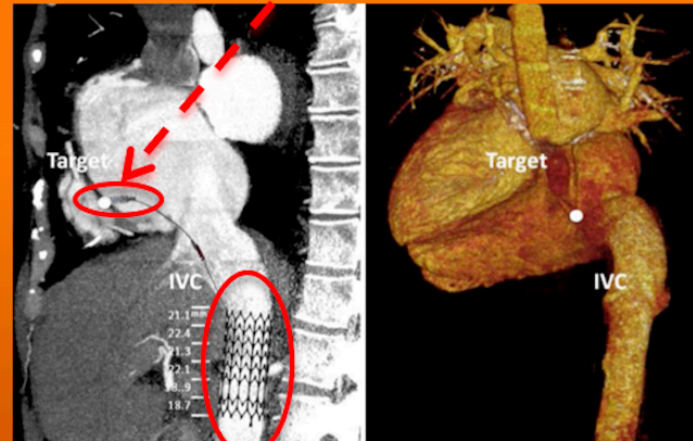
Sapien Valve implanted in the inferior cava vein

Target areas in the Anterior Posterior Commissure and stent landing zone in the Inferior Vena Cava



Target areas in the APC

CT Target zone analysis

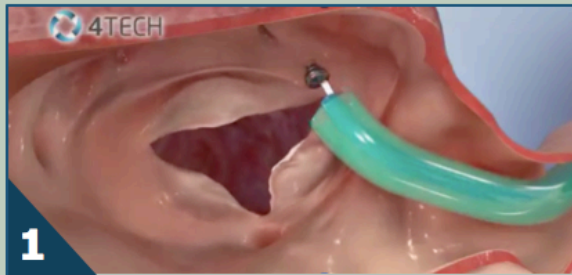


4Tech-TriCinch System™

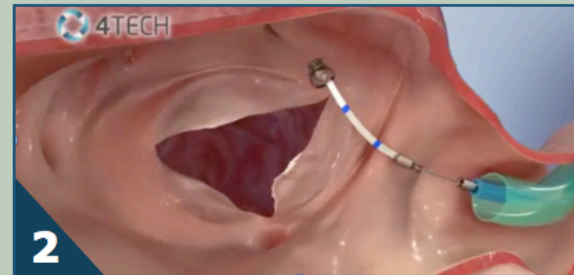
Innovative Percutaneous Solution to Treat
Tricuspid Valve Disease

Objective: Reduce the septo-lateral distance and restore leaflets coaptation

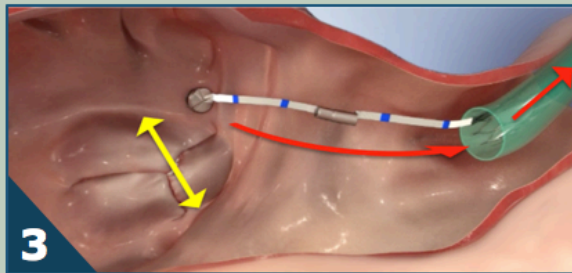
4 steps procedure



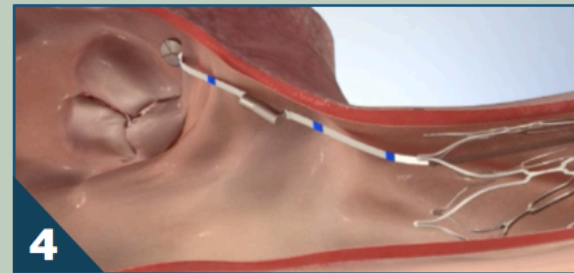
Corkscrew implant in APC



Coupling mechanism



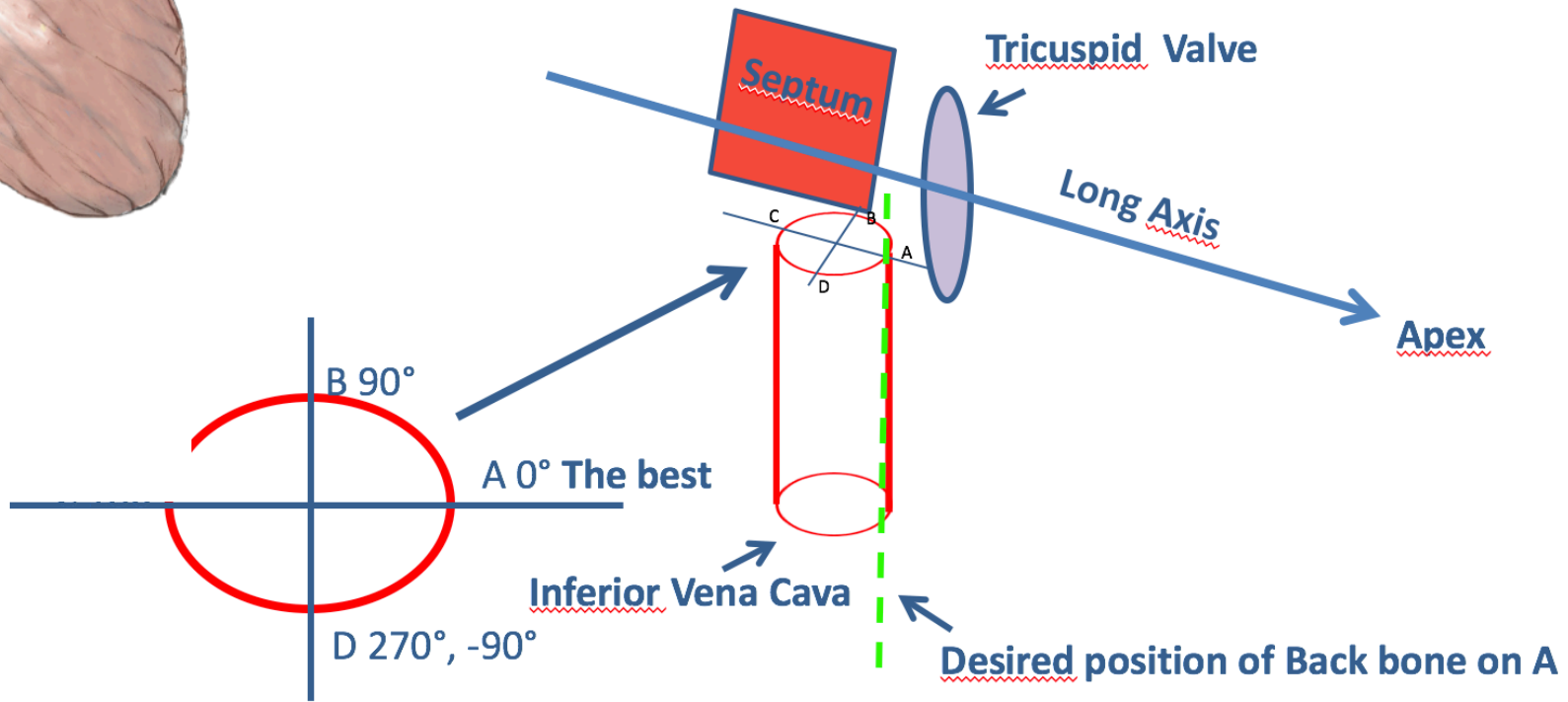
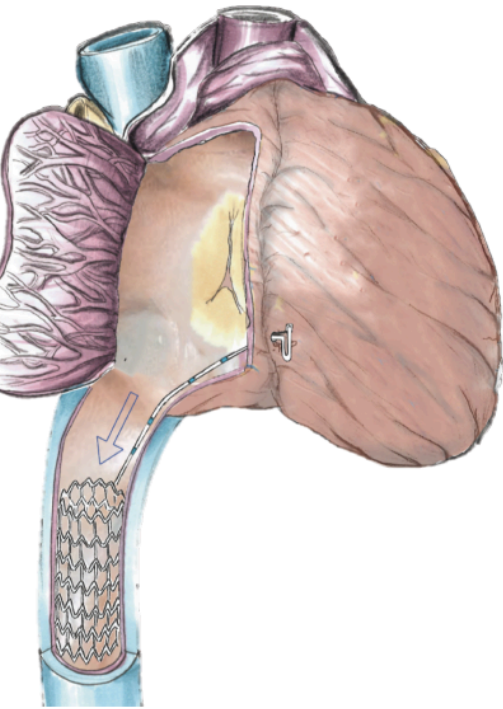
Tension applied



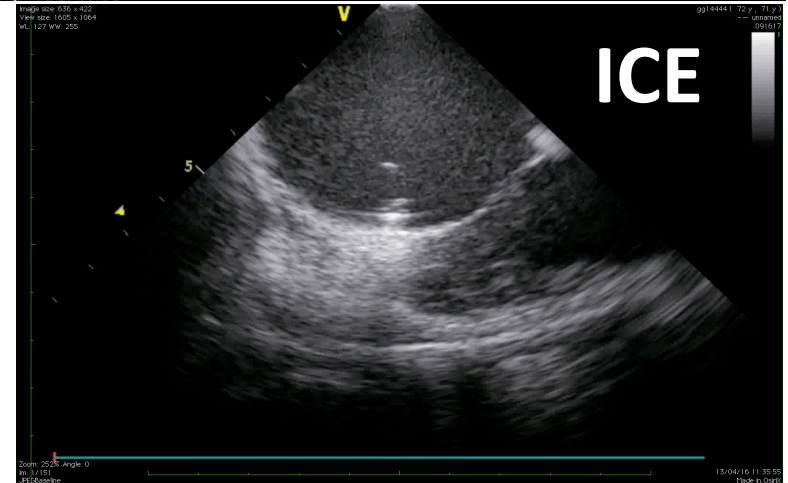
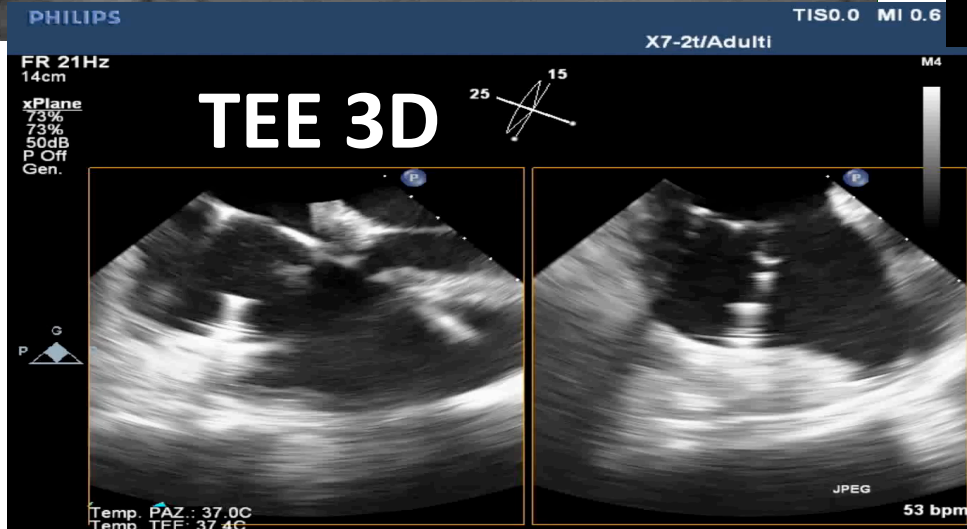
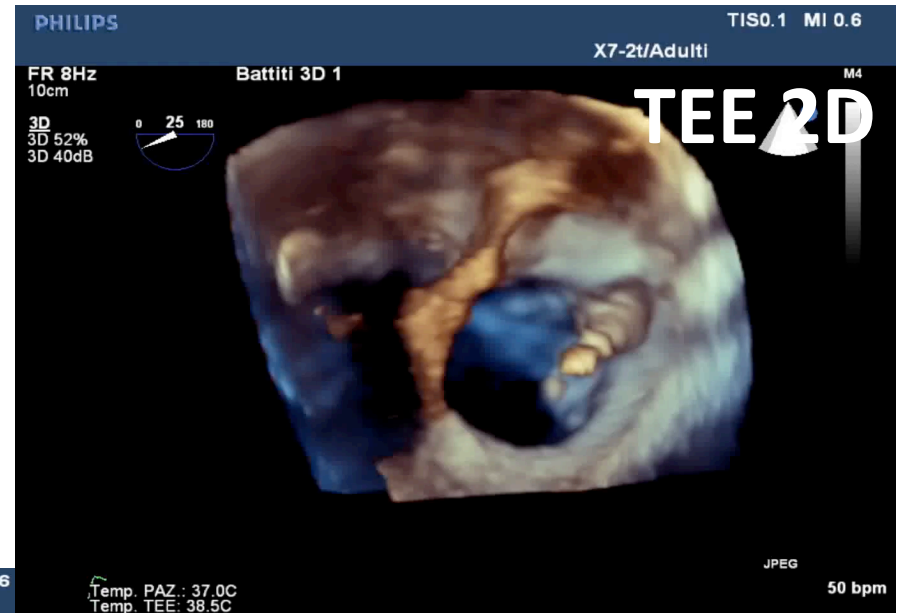
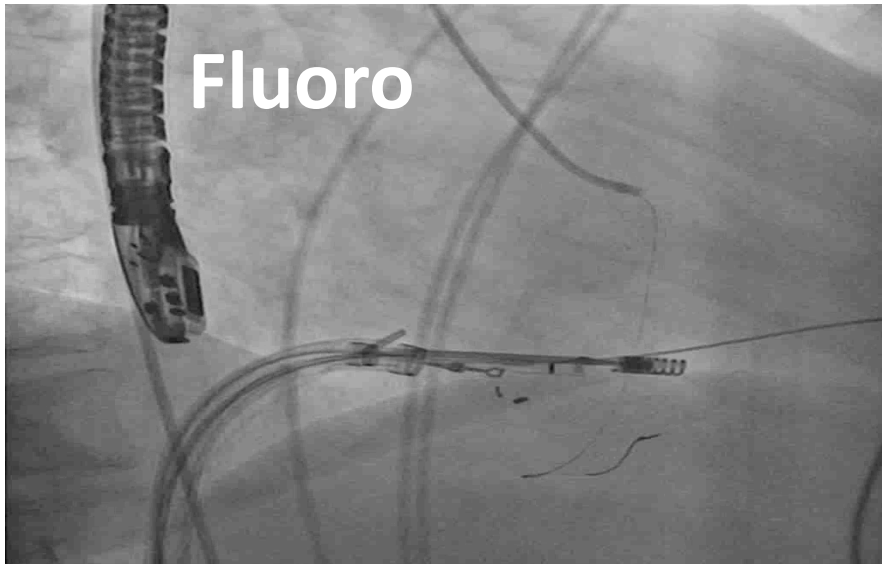
Stent deployment in IVC

Positioning of back bone and SCREW

Put it on the right in a projection perpendicular to the long axis of the heart

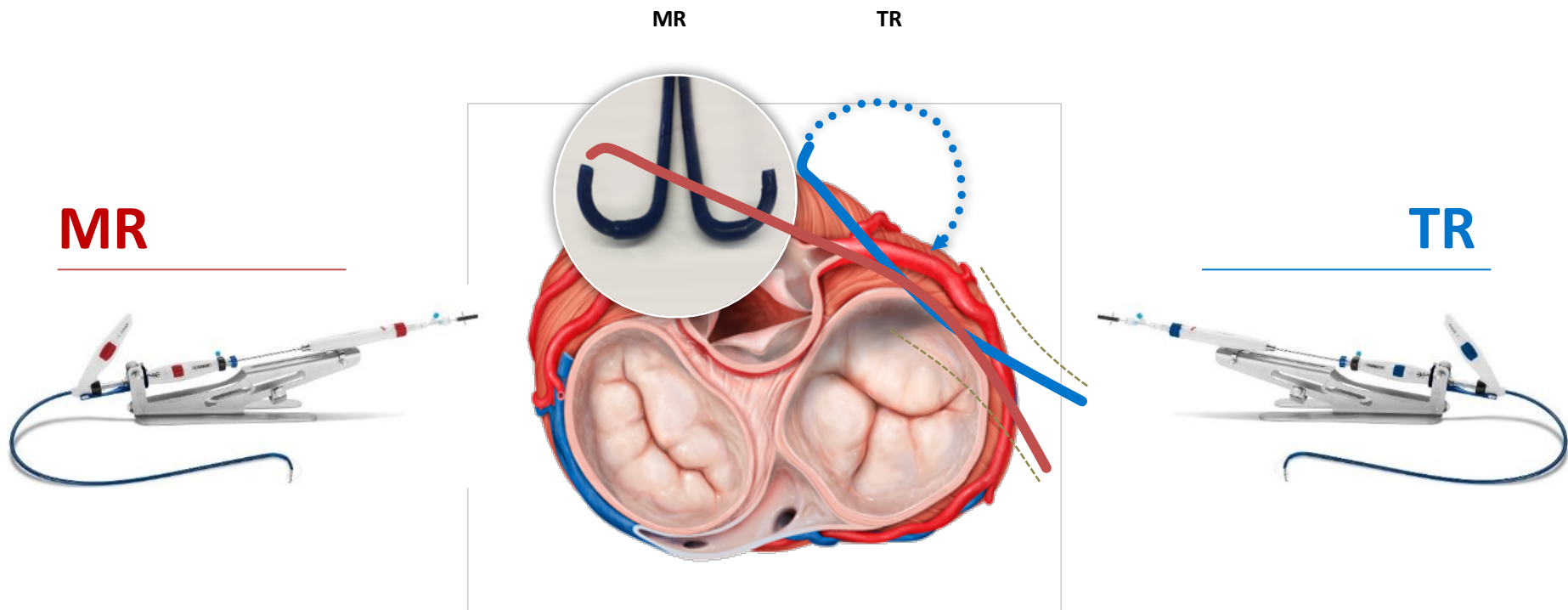


Multi Imaging Approach



Cardioband Mitral and Tricuspid

- Gold Standard Through a Catheter
- Cardioband TR is a mirrored version of Cardioband MR



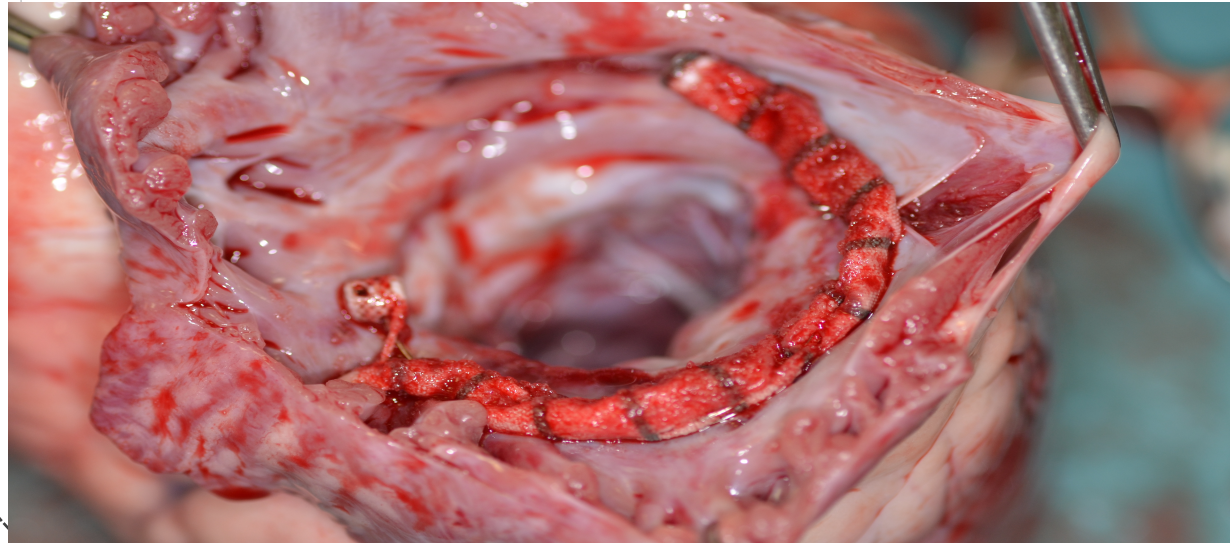
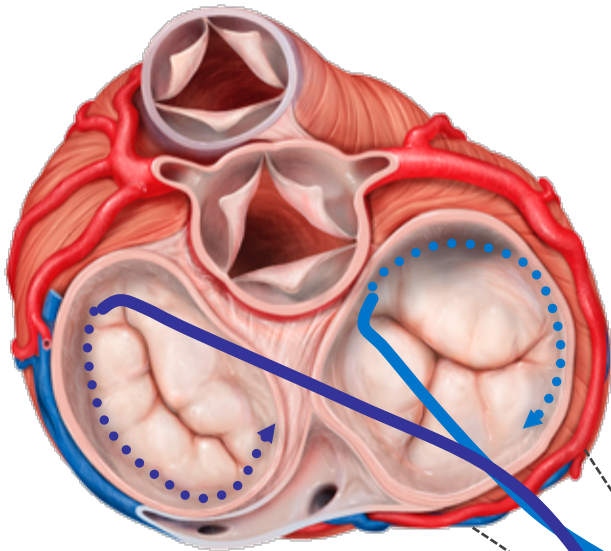
Introducing - Cardioband Tricuspid



Mitral



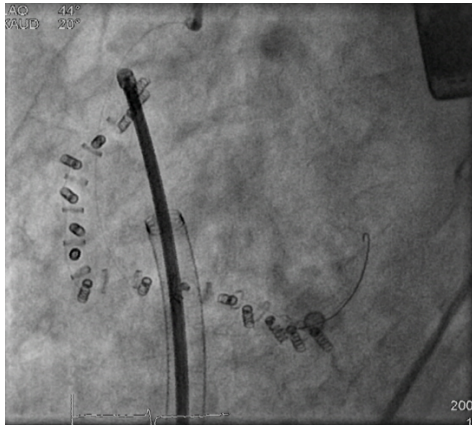
Tricuspid



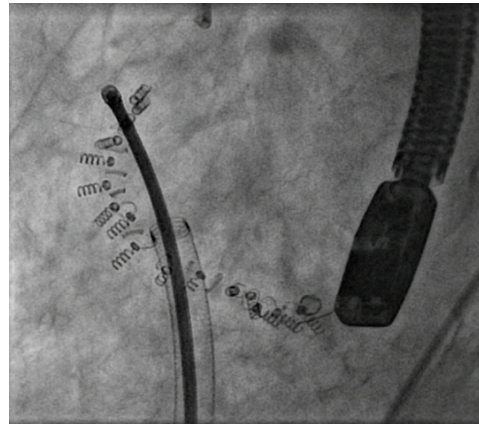
First in Human Experience

Fluoroscopy cinching up to 3.5 (out of 5.5)

Baseline

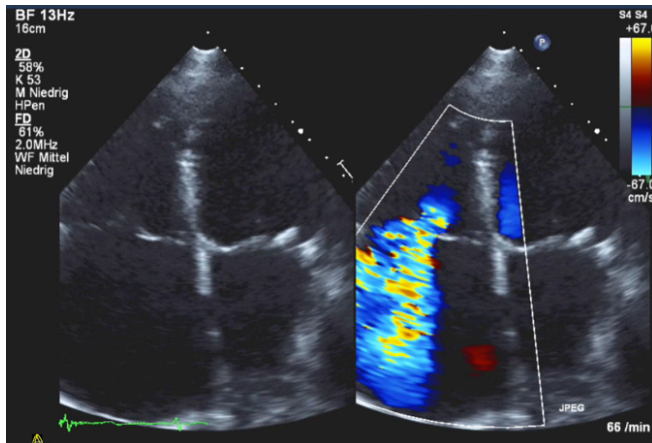


Post cinching

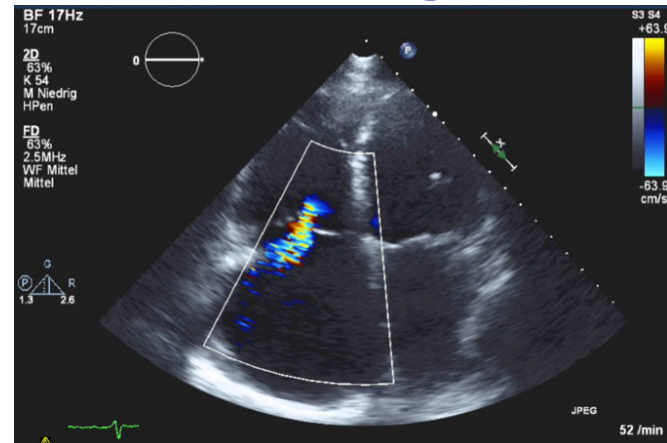


TEE

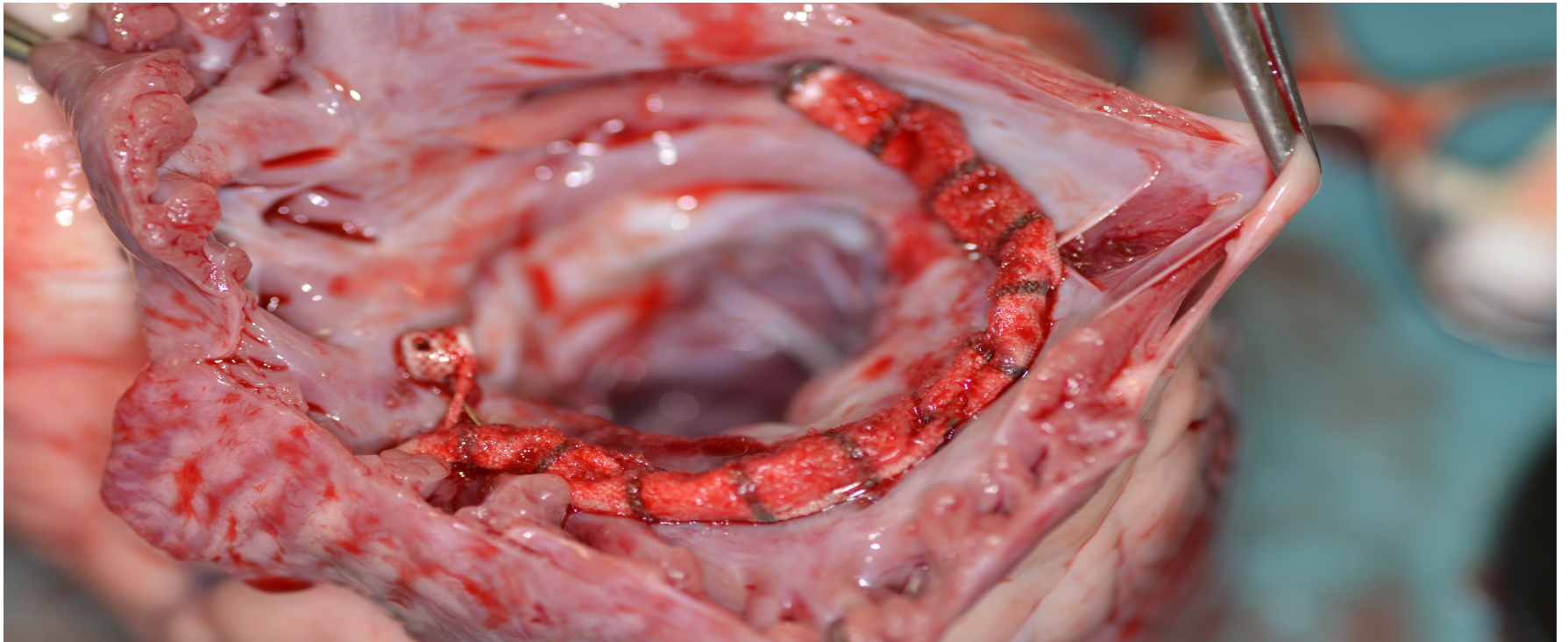
Baseline



Discharge

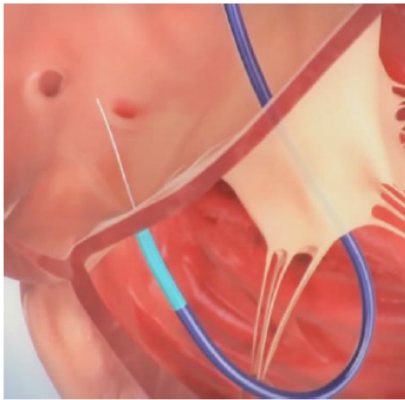


CARDIOBAND: surgical ring implanted percutaneously

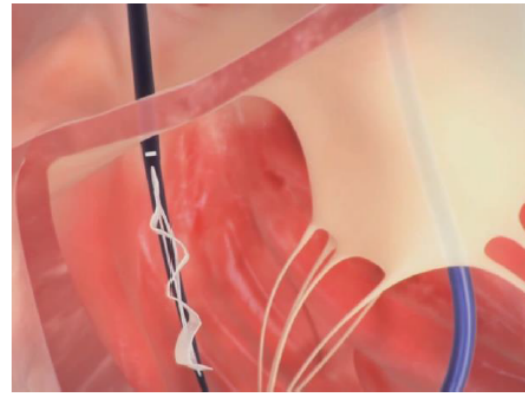


TRIALIGN: Transcatheter Kay Annuloplasty

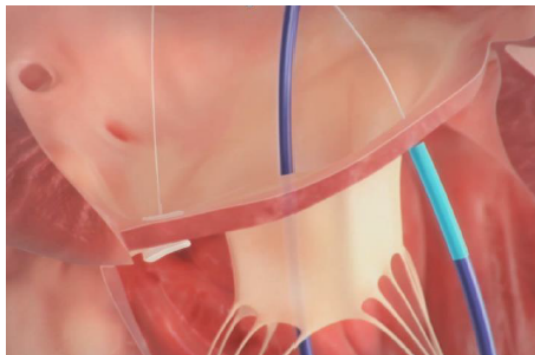
Step 1: Wire Delivery



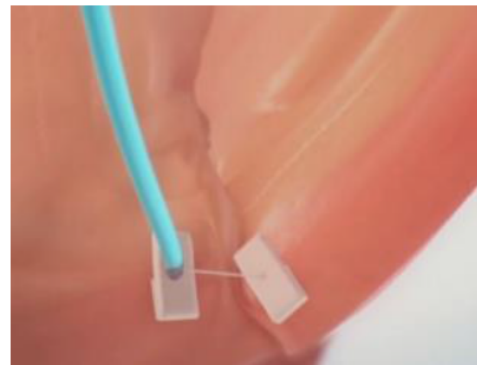
Step 2: Pledget Delivery



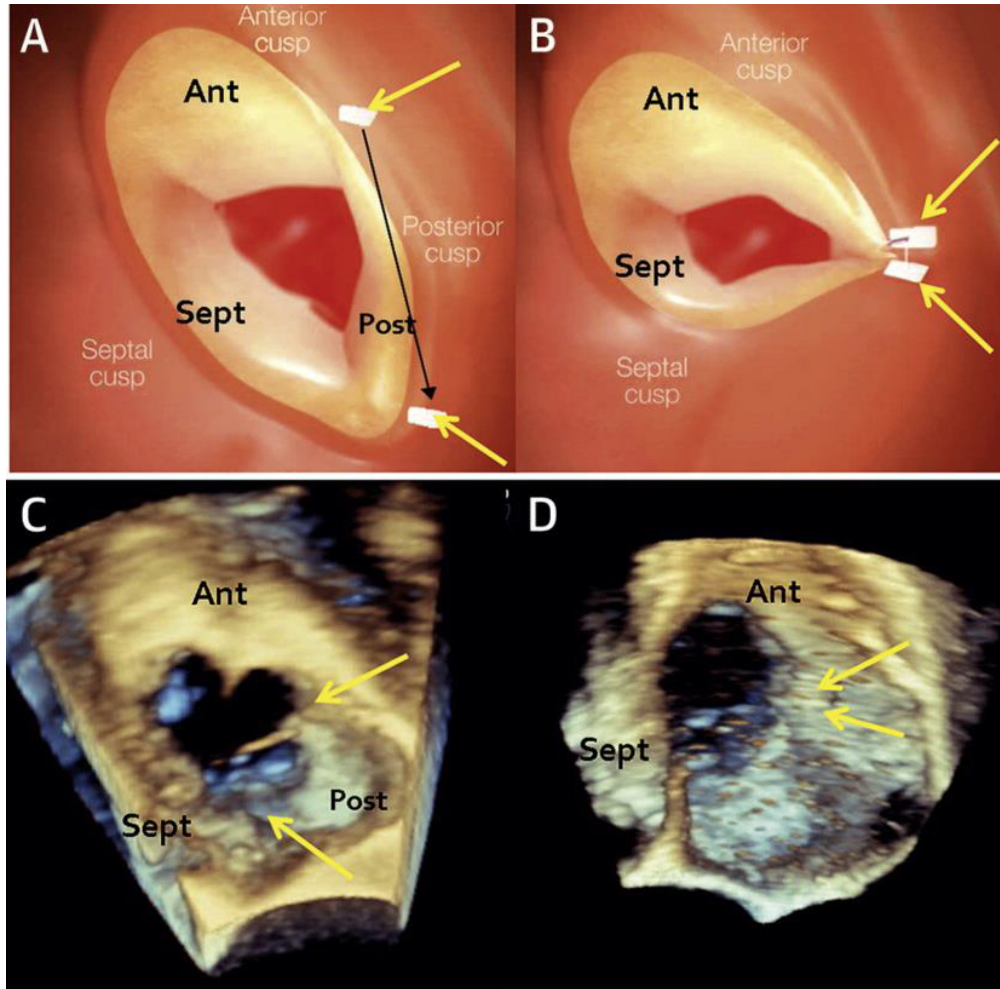
Step 3: Second Wire Delivery



Step 4: Plication and Lock

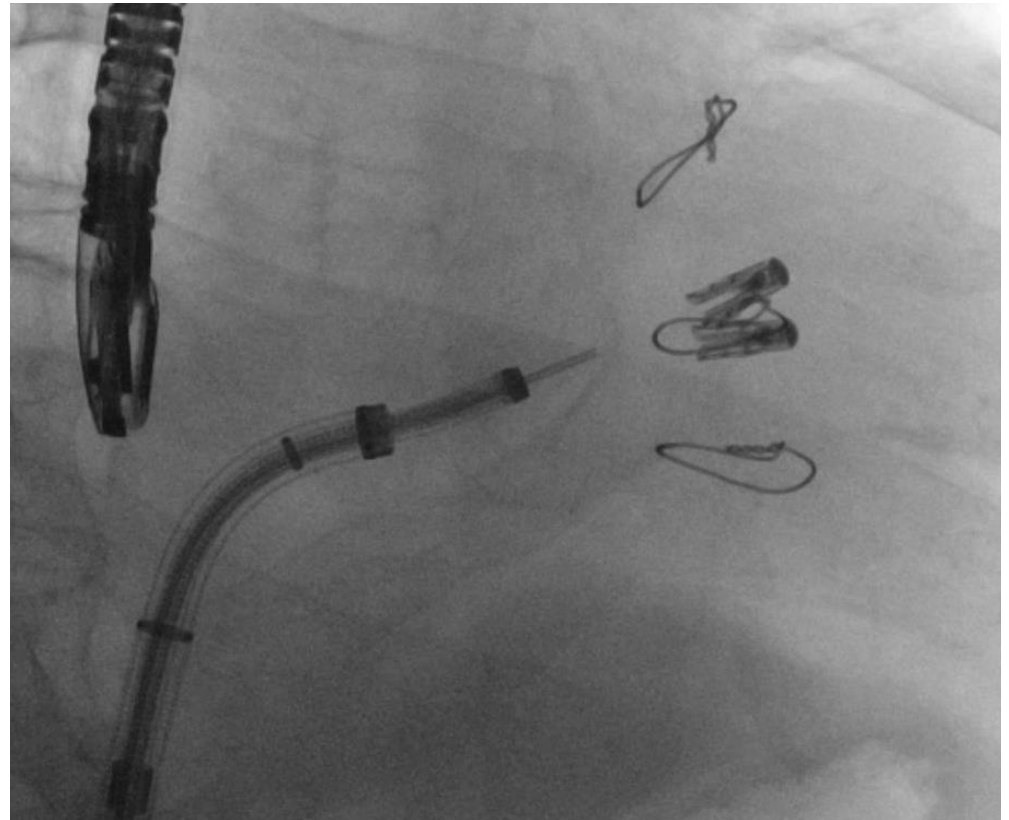


TRIALIGN concept



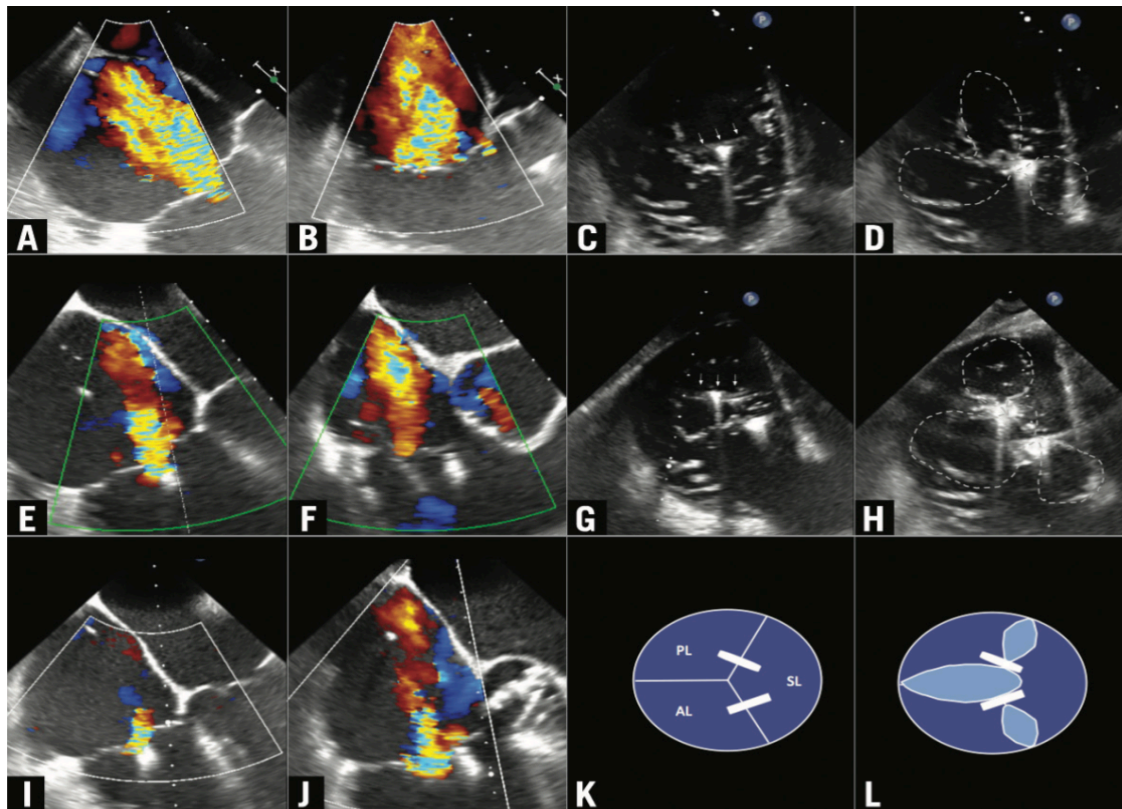
SCOUT Trial On going

Transcatheter Repair of the Tricuspid Valve Regurgitation using the MitraClip® system

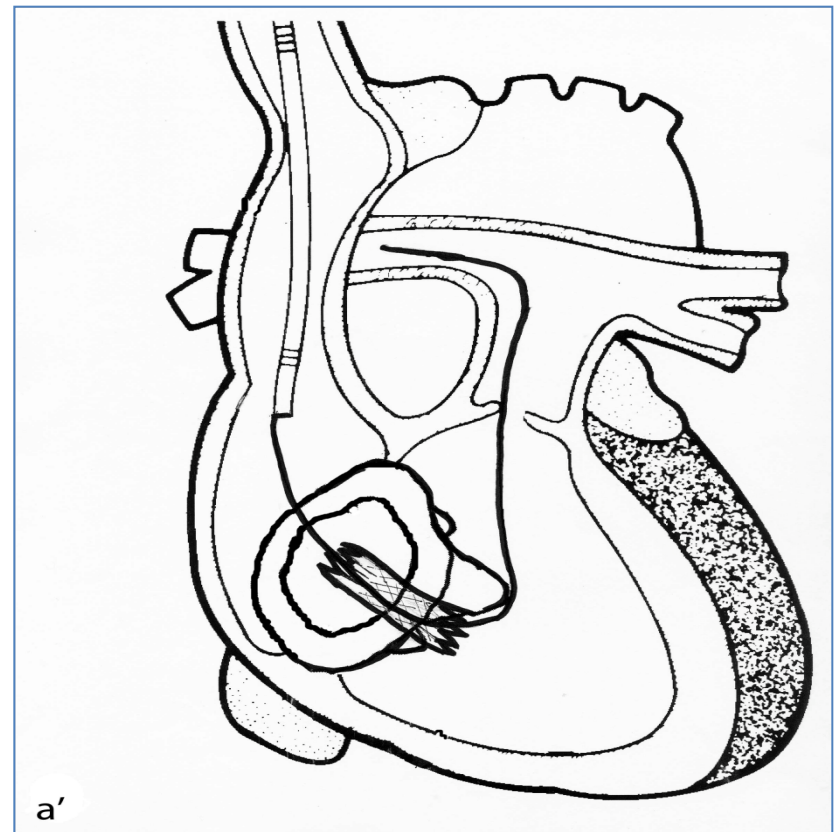
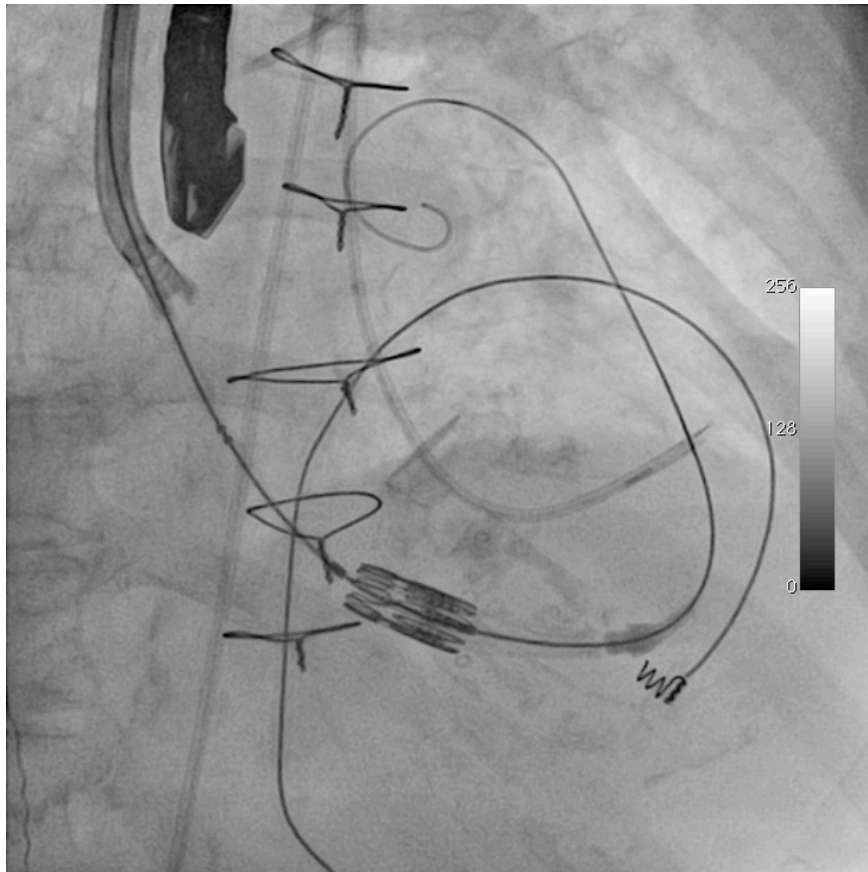


First transfemoral percutaneous edge-to-edge repair of the tricuspid valve using the MitraClip system

Tobias Wengenmayer^{1*}, MD; Manfred Zehender¹, MD; Wolfgang Bothe², MD; Christoph Bode¹, MD; Sebastian Grundmann¹, MD



Transjugular tricuspid valve-in-valve



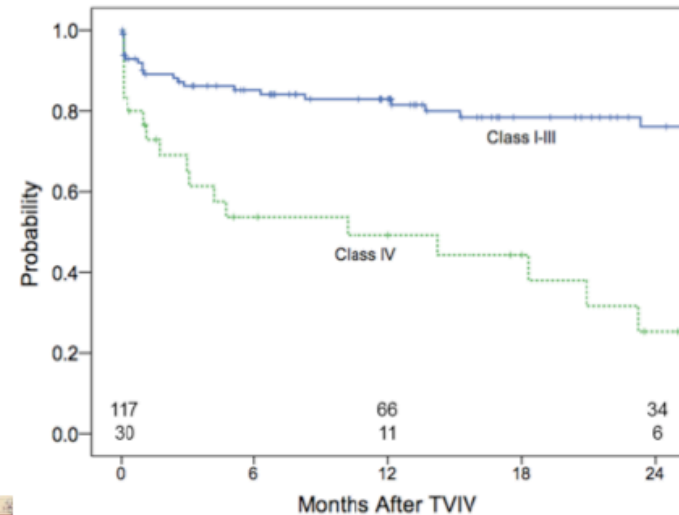
Interventional Cardiology

Transcatheter Tricuspid Valve-in-Valve Implantation for the Treatment of Dysfunctional Surgical Bioprosthetic Valves

An International, Multicenter Registry Study

Doff B. McElhinney, MD; Allison K. Cabalka, MD; Jamil A. Aboulhosn, MD;
Andreas Eicken, MD; Younes Boudjemline, MD; Stephan Schubert, MD;
Dominique Himbert, MD; Jeremey D. Asnes, MD; Stefano Salizzoni, MD; Martin L. Bocks, MD;
John P. Cheatham, MD; Tarek S. Momenah, MD; Dennis W. Kim, MD; Dietmar Schranz, MD;
Jeffery Meadows, MD; John D.R. Thomson, MD; Bryan H. Goldstein, MD;
Ivory Crittendon III, MD; Thomas E. Fagan, MD; John G. Webb, MD; Eric Horlick, MD;
Jeffrey W. Delaney, MD; Thomas K. Jones, MD; Shabana Shahanavaz, MD;
Carolina Moretti, MD; Michael R. Hainstock, MD; Damien P. Kenny, MD;
Felix Berger, MD; Charanjit S. Rihal, MD; Danny Dvir, MD;
for the Valve-in-Valve International Database (VIVID) Registry

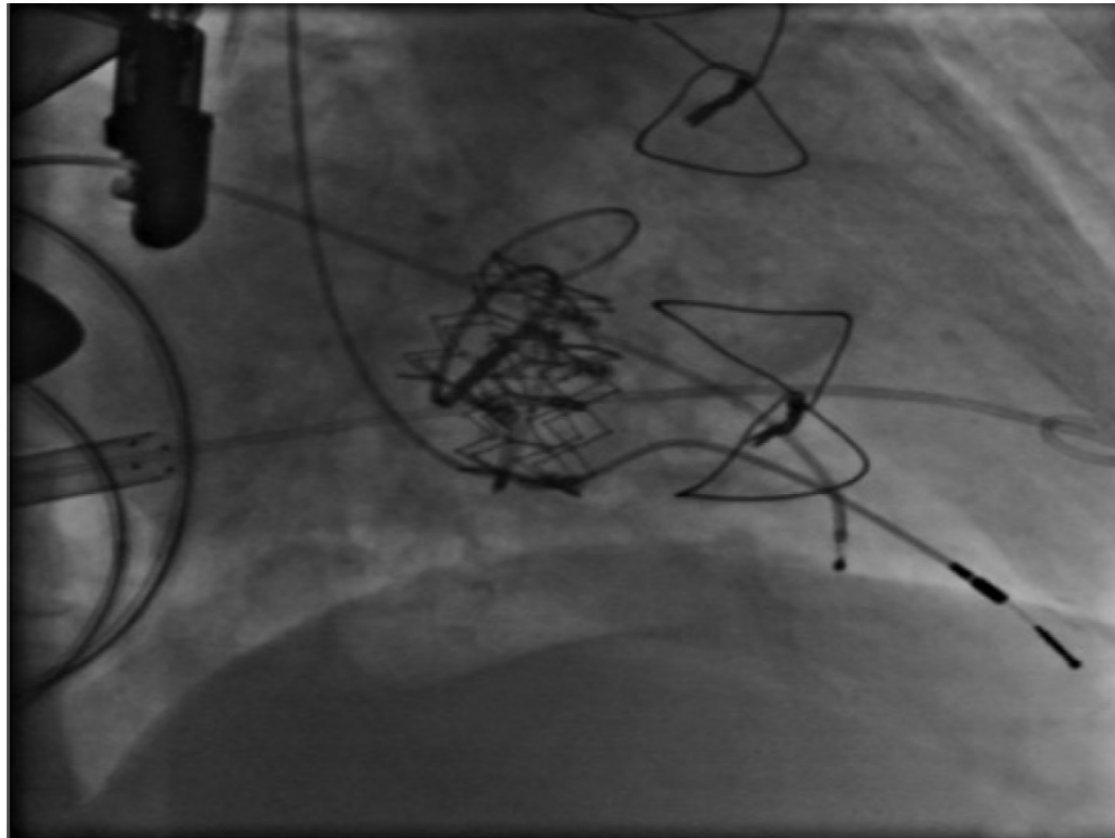
Survival free from TVIV reintervention or significant TS (mean gradient ≥ 10) or TR



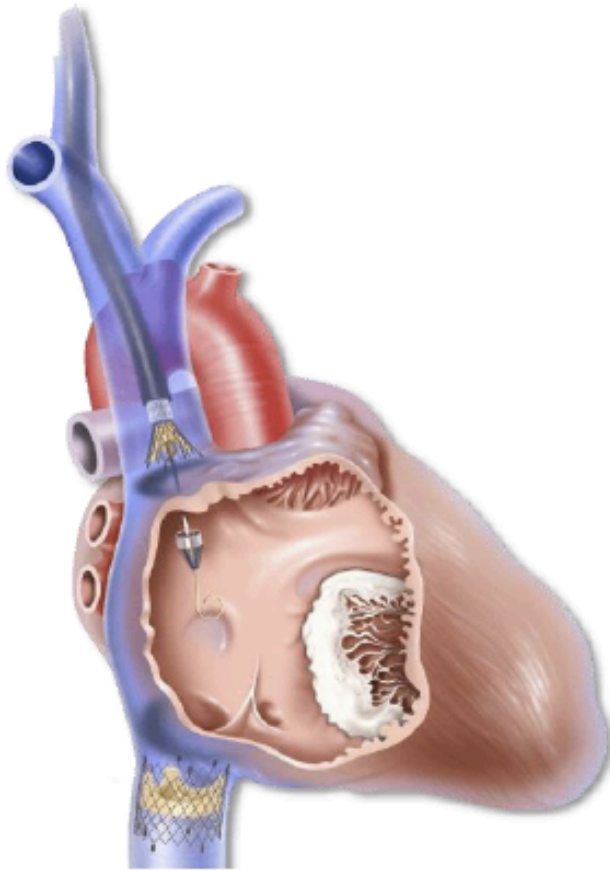
McElhinney D, Dvir, D. *Circulation*. 2016;133:1582-1593.

Transatrial Antegrade Approach for Double Mitral and Tricuspid “Valve-in-Ring” Implantation

Domenico Mazzitelli, MD, Sabine Bleiziffer, MD, Christian Noebauer, MD, Hendrik Ruge, MD, Patrick Mayr, MD, Anke Opitz, MD, Peter Tassani-Prell, MD, Christian Schreiber, MD, Nicolo Piazza, MD, and Ruediger Lange, MD



The CAVI concept



Review:

- Caval Valve Implantation
- Technology ad-hoc designed or Stent as support for TAVI implant
- Transfemoral-tranjugular access
- Risk of ventricularization of the right atrium
- Few clinical cases performed
- Few clinical data available

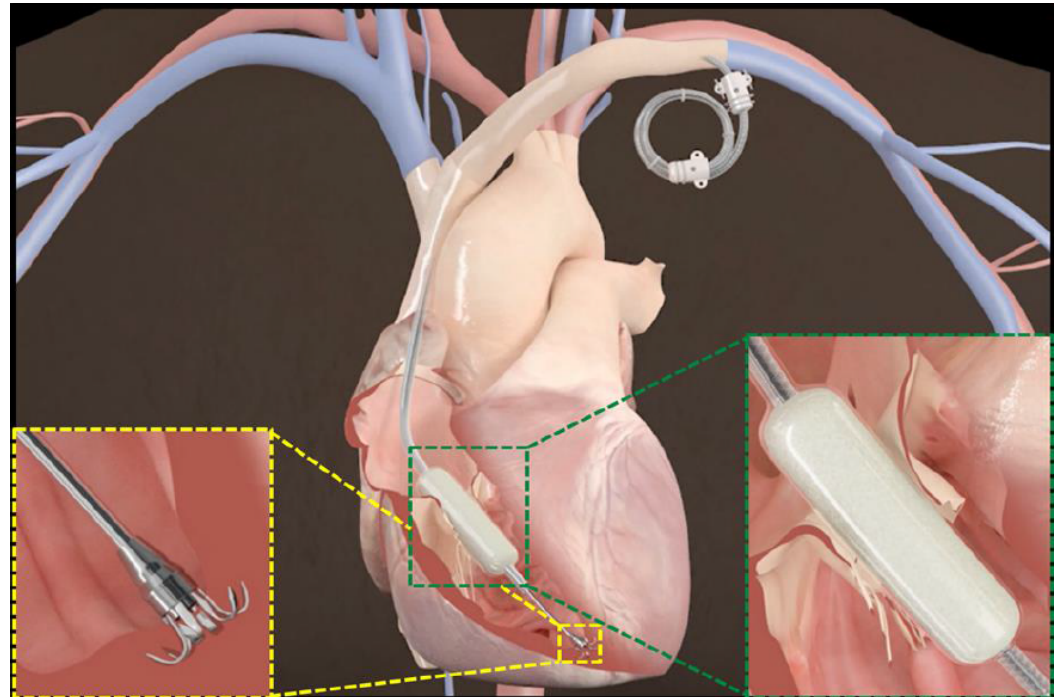
FORMA Repair System Overview

Spacer

- Positioned into the regurgitant orifice.
- Creates a platform for native leaflet coaptation.
- Preserves underlying structure.
- Limited contact with annulus.
- Works with the leaflet, no capture.
- Navigate through chords and papillary muscle.
- Limited contact with conductive system.
- Similar to a pacemaker lead implant.

Rail

- Tracks Spacer into position.
- Distally and proximally anchored.



Millipede System

(Millipede, LLC, Ann Arbor, MI)

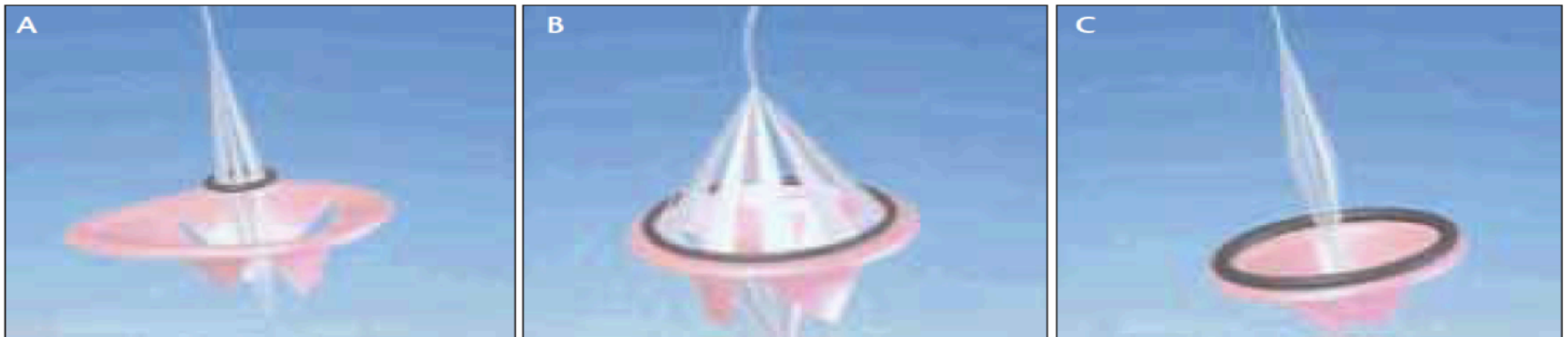
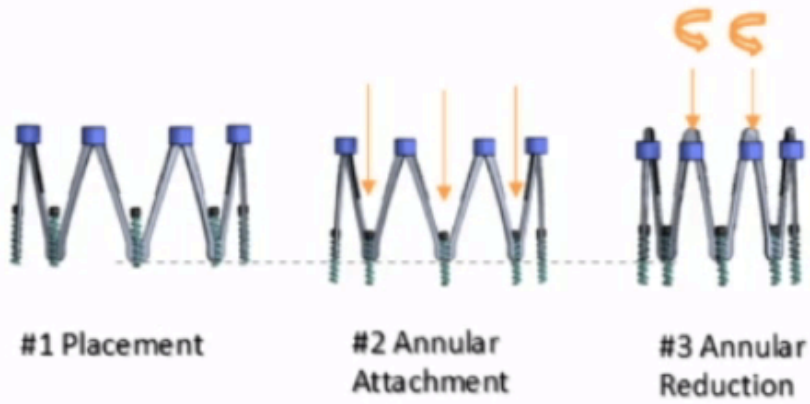


Figure 5. The Millipede system. Delivery of ring assembly to the tricuspid valve (A). Expansion of the annulus and attachment of the annular ring (B). Detachment and release of the ring, reducing annular dimensions and TR (C).

A novel tricuspid annular ring with an unique attachment system via either minimally invasive surgical or percutaneous methods, repositionable and retrievable.

Millipede System

(Millipede, LLC, Ann Arbor, MI)

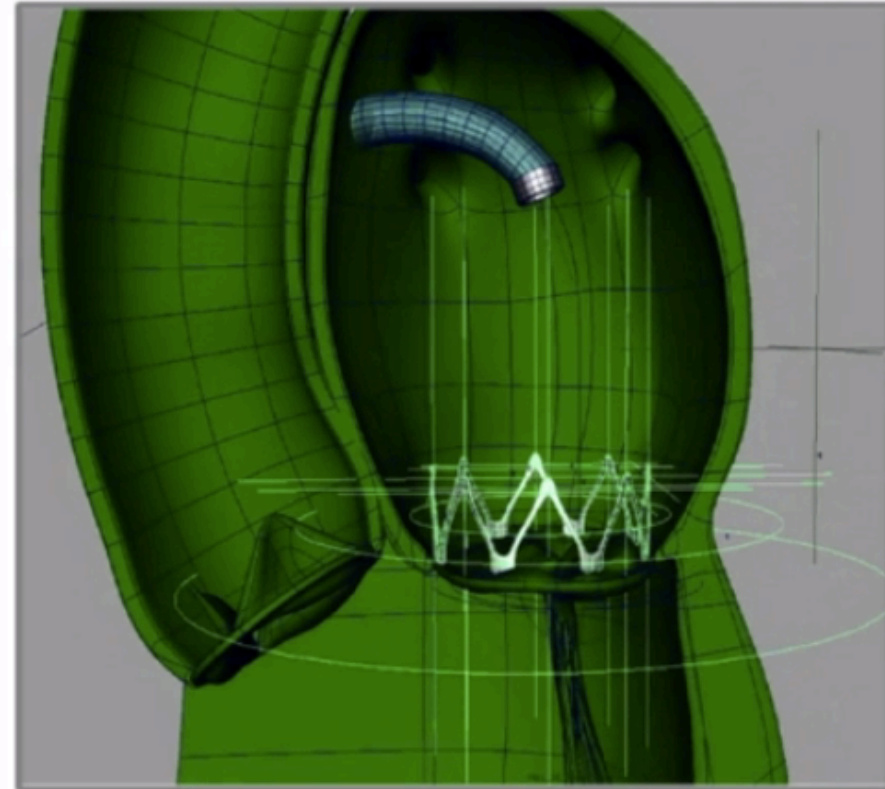


#1 Placement

#2 Annular Attachment

#3 Annular Reduction

Direct Vision



Catheter Delivery

Take-Home Messages

- The treatment of TR is now an emerging hot topic in the field of valve heart diseases therapies:
Large unmet clinical need
- Percutaneous TV technologies may be useful for a large amount of patients with TR who are at high risk for open-heart surgery.
- Ideas inspired from percutaneous MV repair/replacement.
- Waiting for routinely use of new imaging modalities.

Joint Symposium GISE-SIC

**Reparative system for tricuspid
regurgitation**

Sergio Berti

Ospedale del Cuore

Fondazione C.N.R. Reg Toscana Massa/Pisa