

# Transcatheter interventions in the tricuspid valve

## Professor Darren Walters

University of Queensland

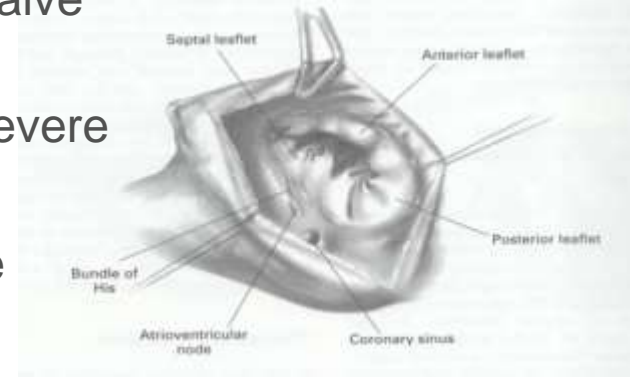
Heart Lung Institute

The Prince Charles Hospital



# Background

- Tricuspid valve disease has long been ignored
  - TR would improve after surgical correction of left valve disease
- Population studies 15-18% at least mild while 1.2% severe
- 1.6 M prevalence 5800 Surgical operations
- Isolated or in conjunction with left sided valve disease
- Congenital versus acquired, primary versus secondary

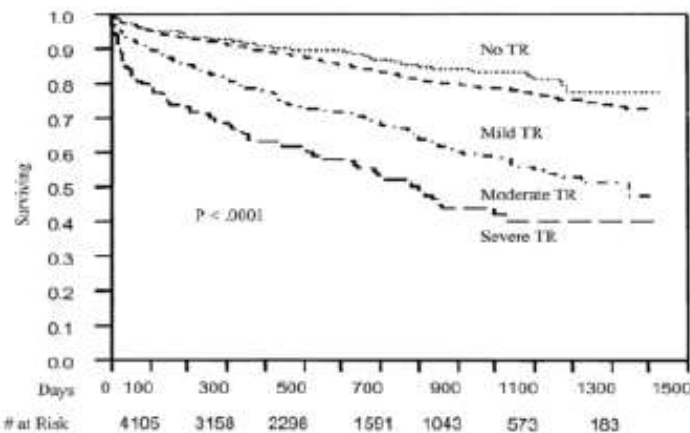


Primary Valvular pathology			Functional
<b>Type 1</b>	<b>Type 2</b>	<b>Type 3</b>	<b>Type 1</b>
Endocarditis (perforation) Congenital (cleft leaflet) (associated CHD TOF/TA) PM leads	Degenerative (prolapse) Endocarditis (ruptured chordae) Traumatic (ruptured chordae)	Rheumatic iatrogenic (radiation/drug) Carcinoid PM leads	Left heart disease (valvular, myocardial) Left-sided valve surgery Primitive RV dysfunction (cardiomyopathy, ischemic) Secondary RV dysfunction/dilation (PAH, pulmonary diseases)

Huttin et al (2016) Archives of Cardiovascular Disease 109, 67–80  
 Stuge and Liddicoat. J Thorac Cardiovasc Surg. 2006;132:1258-61  
 Nath et al. J Am Coll Cardiol. 2004;43:405–9

# Background

- There is an independent ( LVEF/PAP) effect on survival of significant TR
  - There is a 4X increased late mortality in patient with functional TR
  - 50% increase in mortality in first year post Mitraclip if severe TR
- Moderate to severe TR is an under-treated condition
- More frequent indications for combined tricuspid surgery
  - Inherent risk of subsequent dysfunction of tricuspid repair or replacement
- Redo tricuspid valve surgery is often associated with high morbidity-mortality rates (15-35%)
- Increased in patients with co morbidities



Stuge and Liddicoat. J Thorac Cardiovasc Surg. 2006;132:1258-61  
Nath et al. J Am Coll Cardiol. 2004;43:405-9  
Kim et al. Circulation. 2009;120:1672-78  
McCarthy PM, et al. J Thorac Cardiovasc Surg 2004;127:674-85.  
Pfanmuller B, et al J Thorac Cardiovasc Surg 2013;146:841-7

# Background

- Transcatheter Valve-in-Valve is new treatment option
- 85% tricuspid Valve in Valve procedure been for ACHD ( TA,TOF)
- 2/3 for stenosis
- A number of pipeline technologies for TV repair
  - Mitralign, Mitraclip, Tricinch, Millipede, Forma

Complete annuloplasty

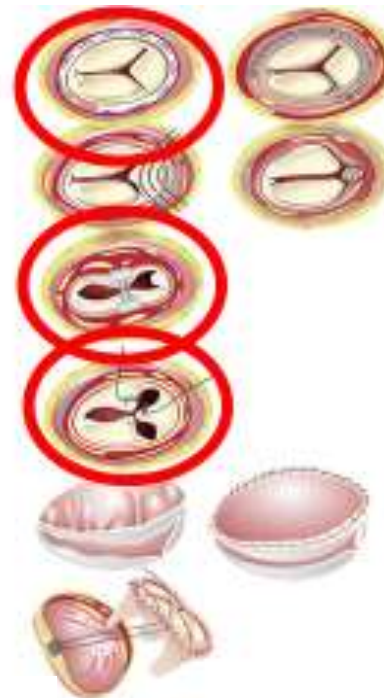
Partial annuloplasty

Cinching annuloplasty

Edge-to-edge

Leaflet augmentation

Replacement



From Maissanno 2017

# Tricuspid valve intervention

23 year old female

- Tetralogy of Fallot
- VSD patch closure + RVOT homograft + suture closure of PDA in 1990
- Reconstruction of pulmonary valve and tricuspid valve annuloplasty 1992
- TV repair with 27 mm ring and pulmonary valve repair 1997
- Tricuspid bioprosthesis (Mosaic 31 mm) and 25 mm pulmonary homograft in 2005
- Diastolic dysfunction: LVEDP 23, RVEDP 21, mean PA 37, RA 26
- Moderate pulmonary hypertension: Main PA pressures: = 56/25/37 mmHg
- Left SVC and dilated coronary sinus
- Atrial flutter
  - RFA ablation September 2012 and Dec 2014
  - DCCV in 2012 and 2014
- Asthma
- Iron deficiency
- Ex-smoker
- Morbid obesity BMI 42
- Chronic liver disease (liver 21mm, nodular surface, prominent portal vein).

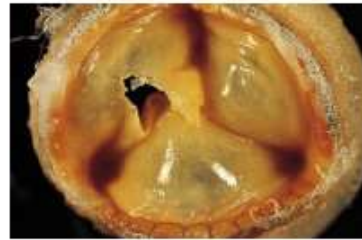
**Typical case**

# Reasons For Bioprosthetic valve failure

Longevity?

- Reoperation 20% at 10 years
- Severe TR 60% at 5 years

A



Wear and tear

B



Calcification

C



Pannus

D



Endocarditis

E



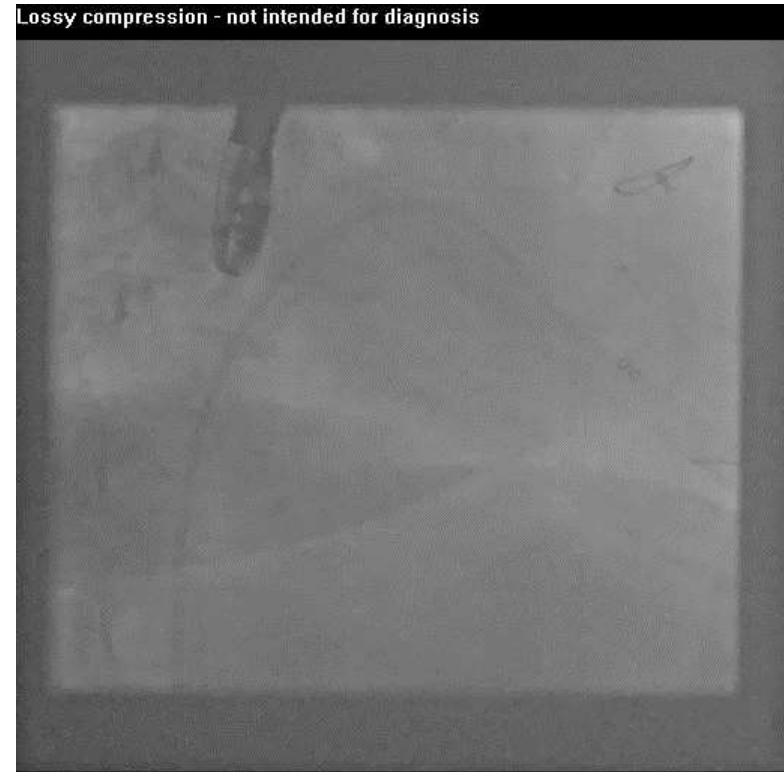
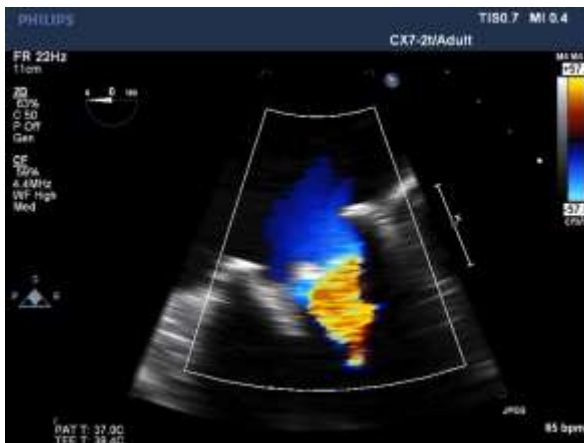
Thrombus

Piazza N, Bleiziffer S, Brockmann G, et al. *J Am Coll Cardiol Intv.* 2011;4(7):721-732.



# Tricuspid Valve Intervention

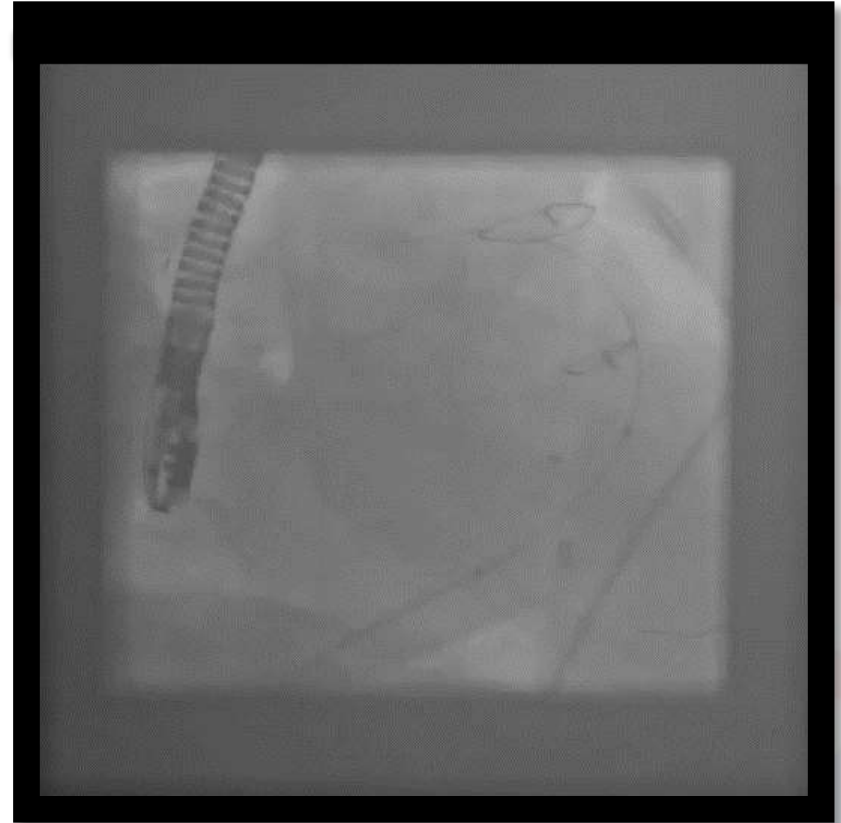
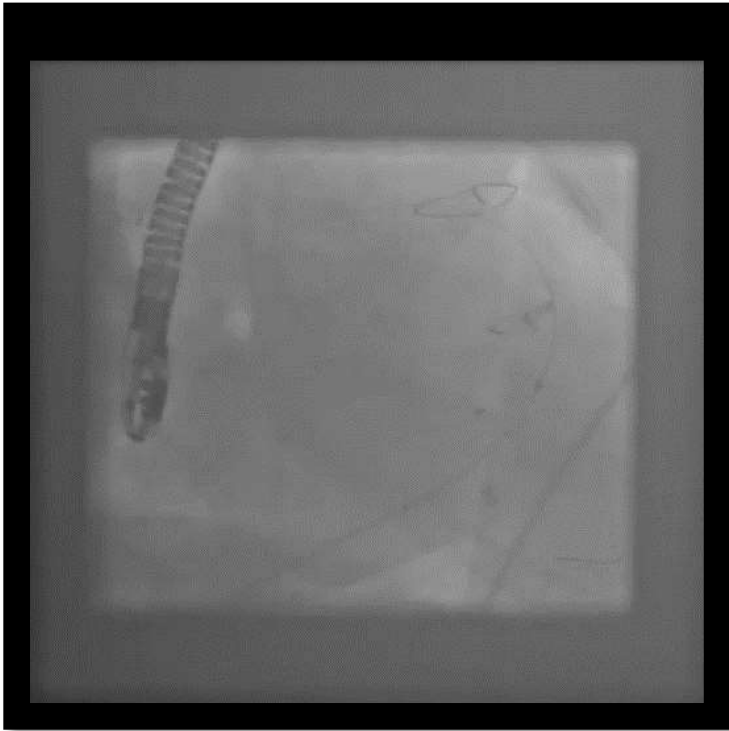
- Tricuspid valvuloplasty
- Useful palliate Bioprosthetic stenosis\*
- Acute TR tolerated
- Crossing with Cournand catheter



\*Burstow DJ, West ML, Walters DL. Intracardiac echo guided valvuloplasty of a stenotic tricuspid prosthetic valve in a patient with idiopathic hypereosinophilic syndrome. Echocardiography 2006;23:324-8.

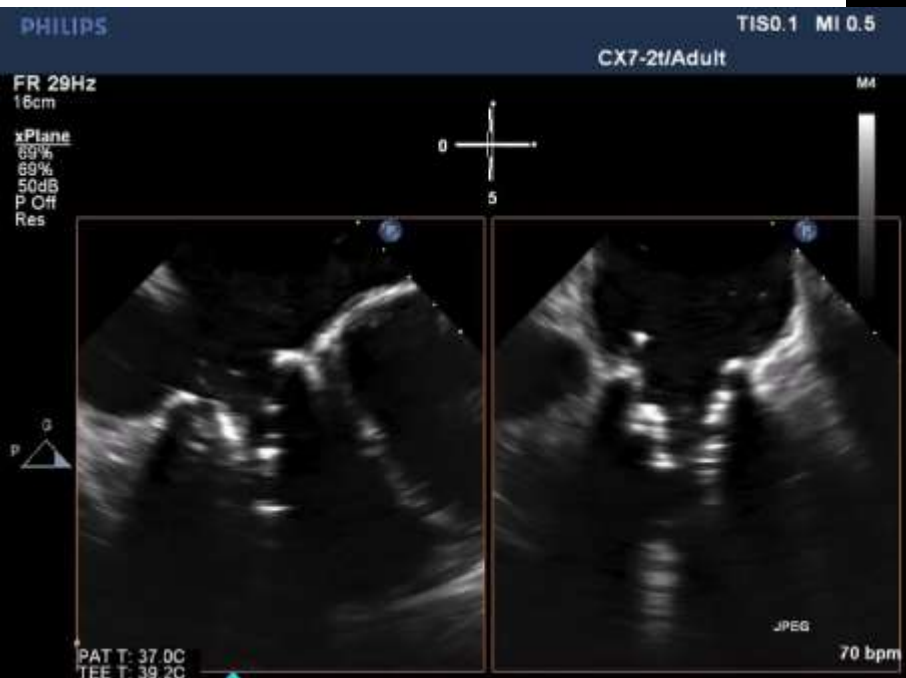
# Tricuspid Valvuloplasty

25mm x 50mm BALT Cristal balloon





# Tricuspid Valvuloplasty



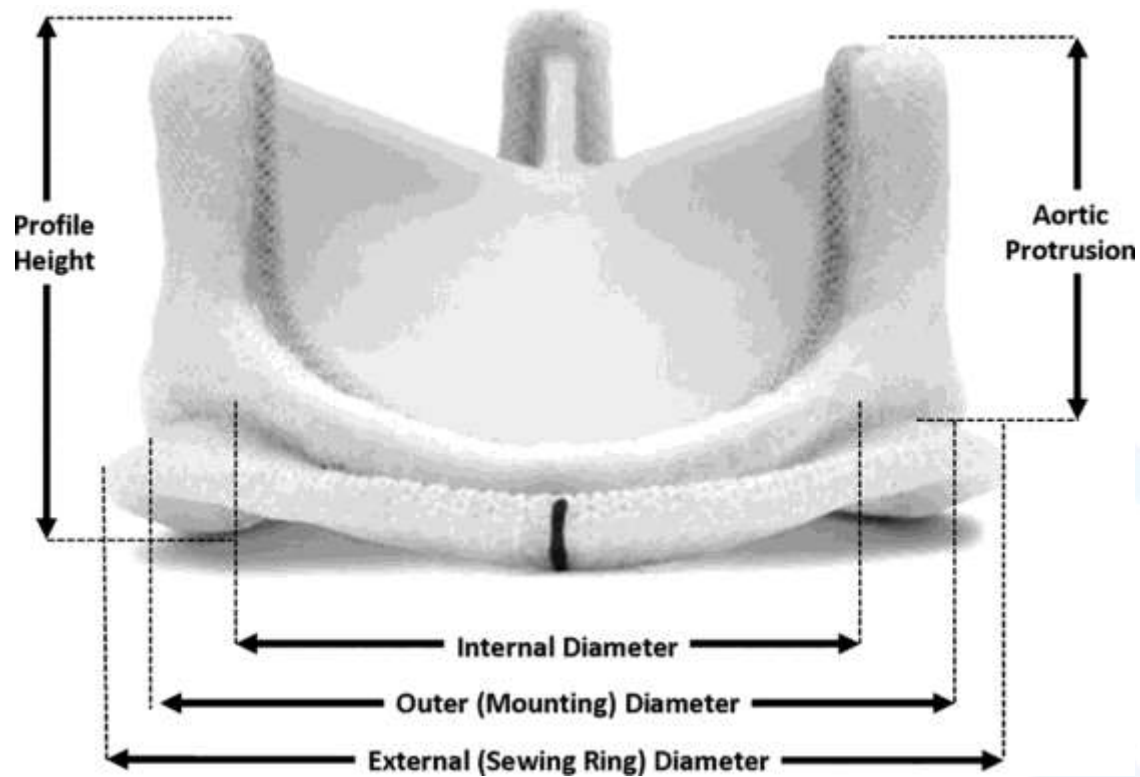
# Clinical Representation

- Severe Right heart failure 3 years later

## Transthoracic echo:

- Normal LV size and low normal systolic function, Visual EF = 55 %.
- Moderate RV dilatation with mild impaired RV systolic function.
- Severe RA dilatation.
- Mosaic 31mm TVR: Severe TS; MPG 16 mmHg; 1/4 TR.
- Allograft PVR (25 mm): Normal haemodynamics, no abnormal regurgitation

# Dimensions of stented bioprosthetic valves.



American  
Heart  
Association

John G. Webb, and Danny Dvir  
*Circulation*. 2013;127:2542-2550

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# The “App”



App Store > Medical > UBQO Limited



## Valve In Valve 12+

UBQO Limited >

[Details](#) [Ratings and Reviews](#) [Related](#)

Screenshots

iPhone

iPad

+ Downloaded

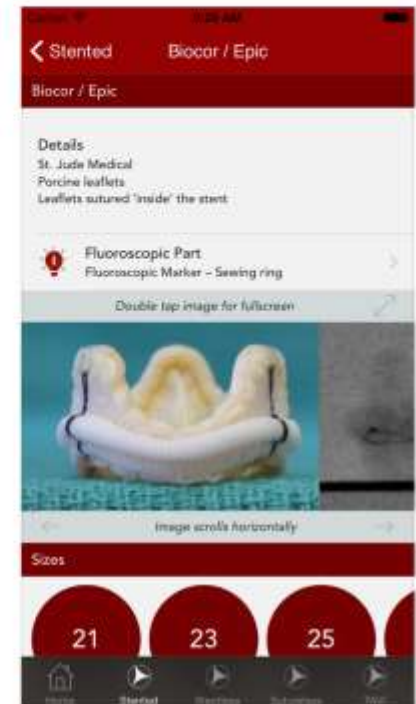
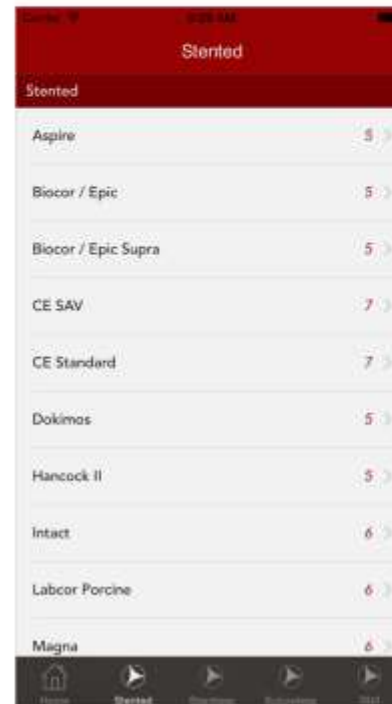
This app is designed for both iPhone and iPad

Rating: 12+

LINKS

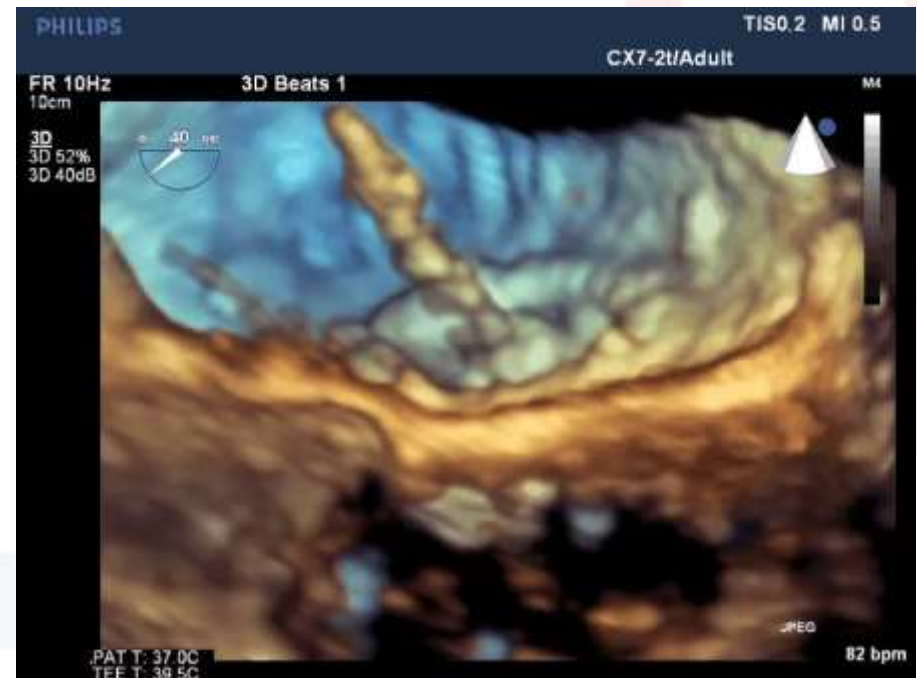
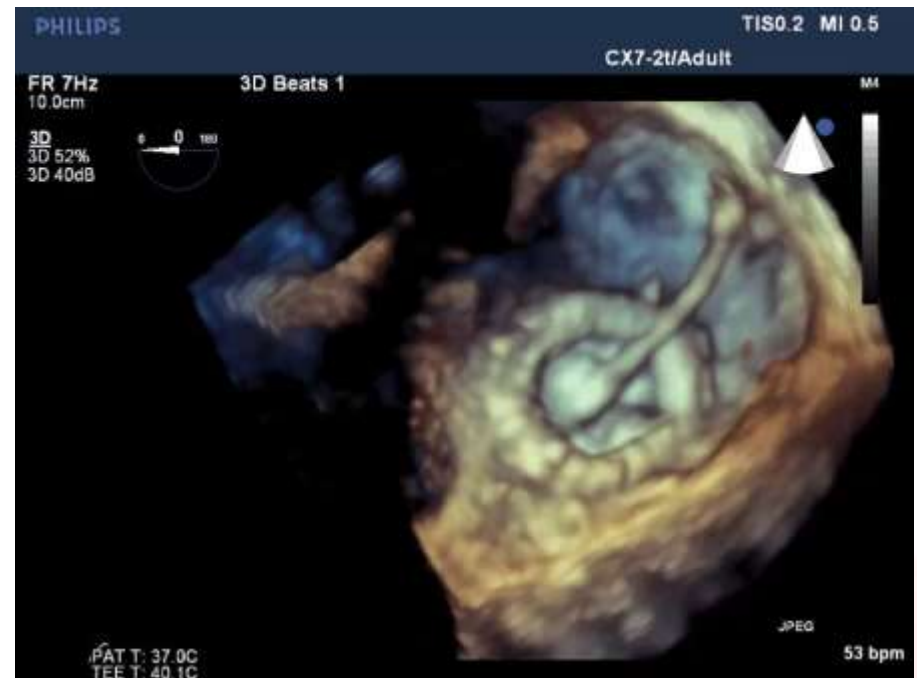
Developer Website

© UBQO Limited

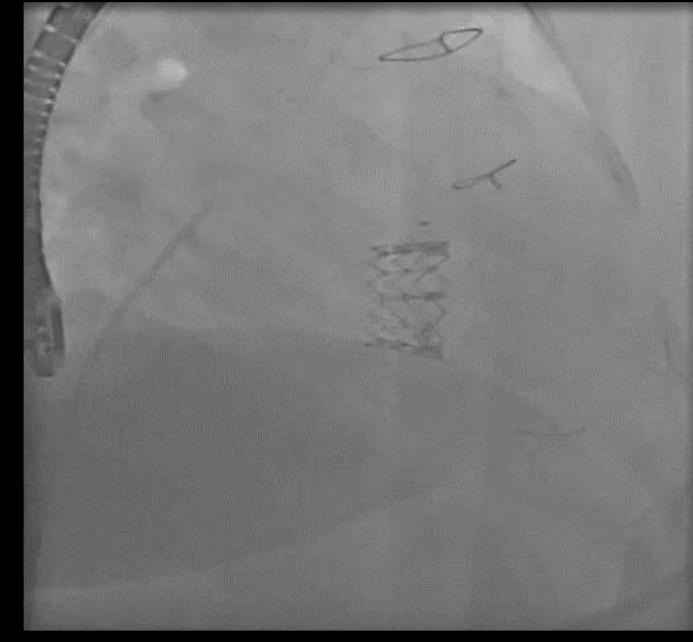
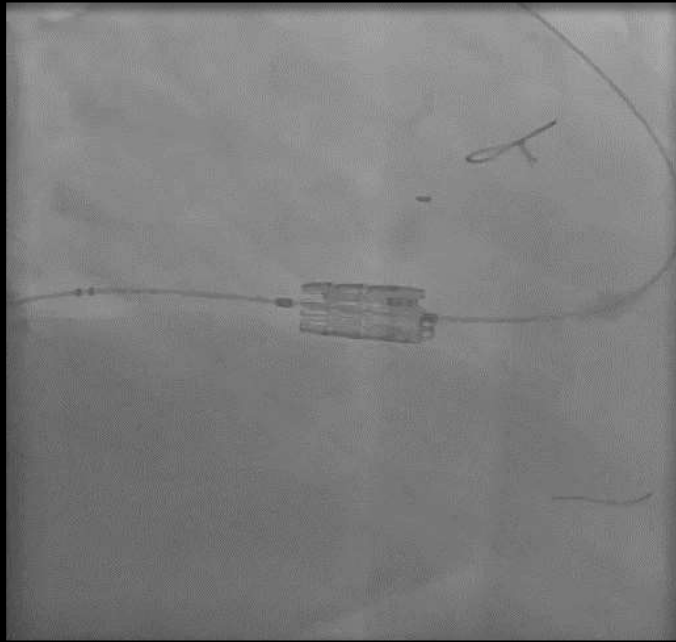
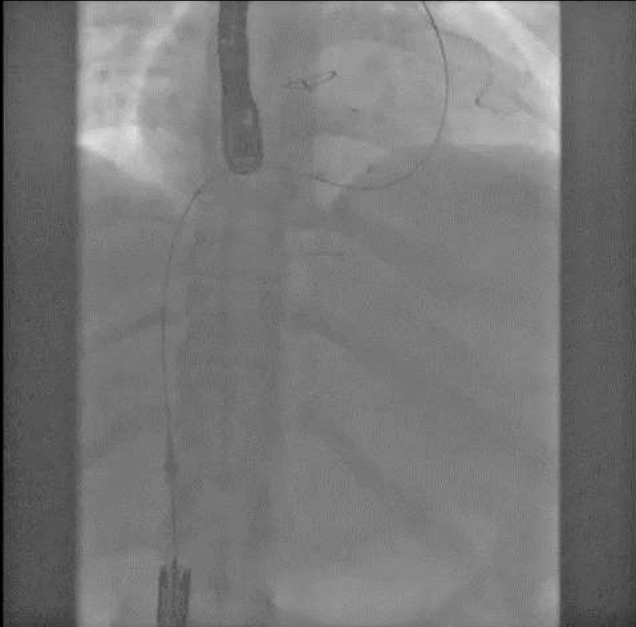


# Tricuspid Valve-in-Valve

## Role of 3 D TOE







# Post Tricuspid Valve in Valve





# Novel Interventions: Functional tricuspid regurgitation

- **The TriCinch System™**
- **Mitraclip**
- **Edwards FORMA Repair System**
- **Cardioband**
- **Millipede**
- **Trialign**
- **Triapta**
- **Caval Valve**

**Adapted from  
Mitral Intervention**





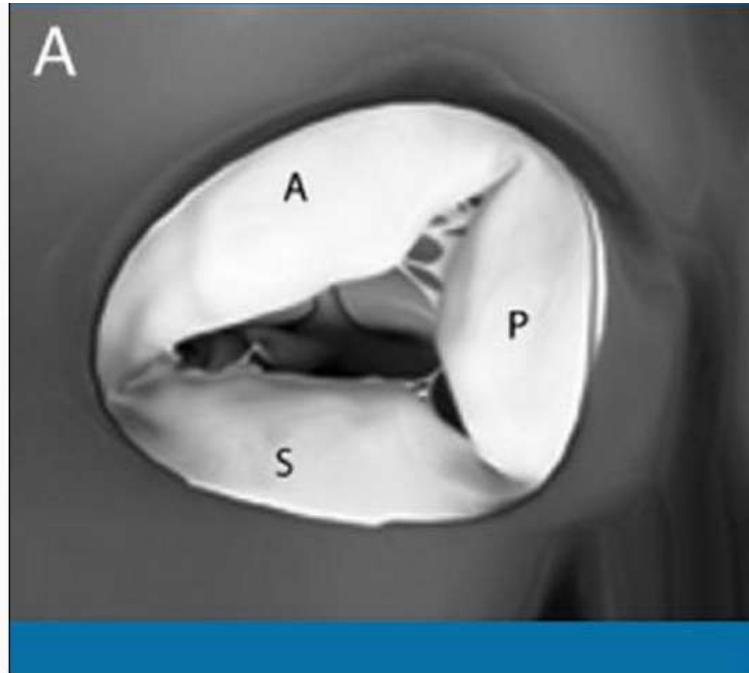
**4TECH**

**Feasibility Study of the  
Percutaneous 4Tech  
TriCinch Coil Tricuspid Repair  
System**

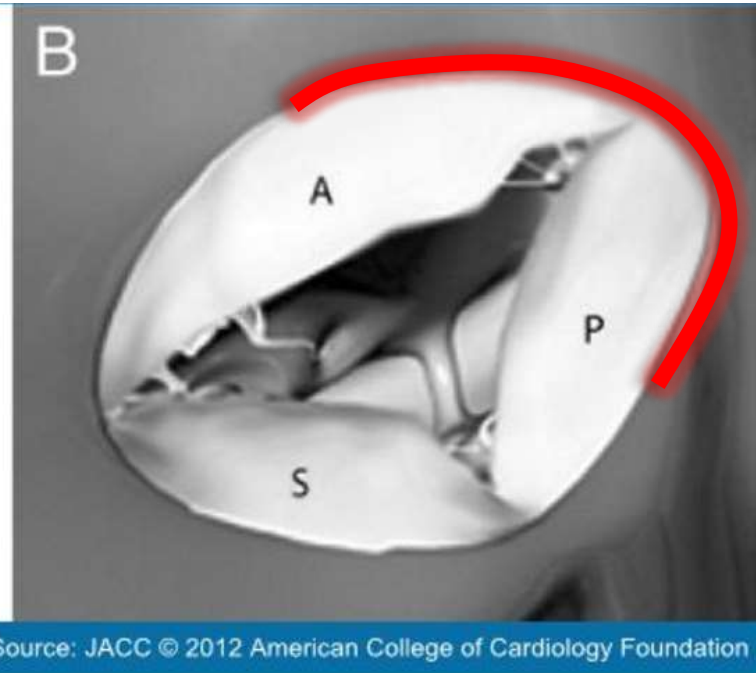
*17 April 2017*

# Functional TR is a Result of Annular Dilatation

Normal Tricuspid Valve



Antero-Posterior Dilatation of Tricuspid Annulus



Source: JACC © 2012 American College of Cardiology Foundation

A = Anterior leaflet; P = Posterior leaflet; S = Septal leaflet

- FTR is primarily due to tricuspid antero-posterior dilatation<sup>1</sup>
- FTR is often secondary to left-sided heart disease<sup>1</sup>
- Approx. 30% - 50% of patients with MR have significant FTR<sup>1</sup>

# The Tricinch system

## *Antero-posterior annuloplasty solution for treating FTR*

TriCinch Coil Implant

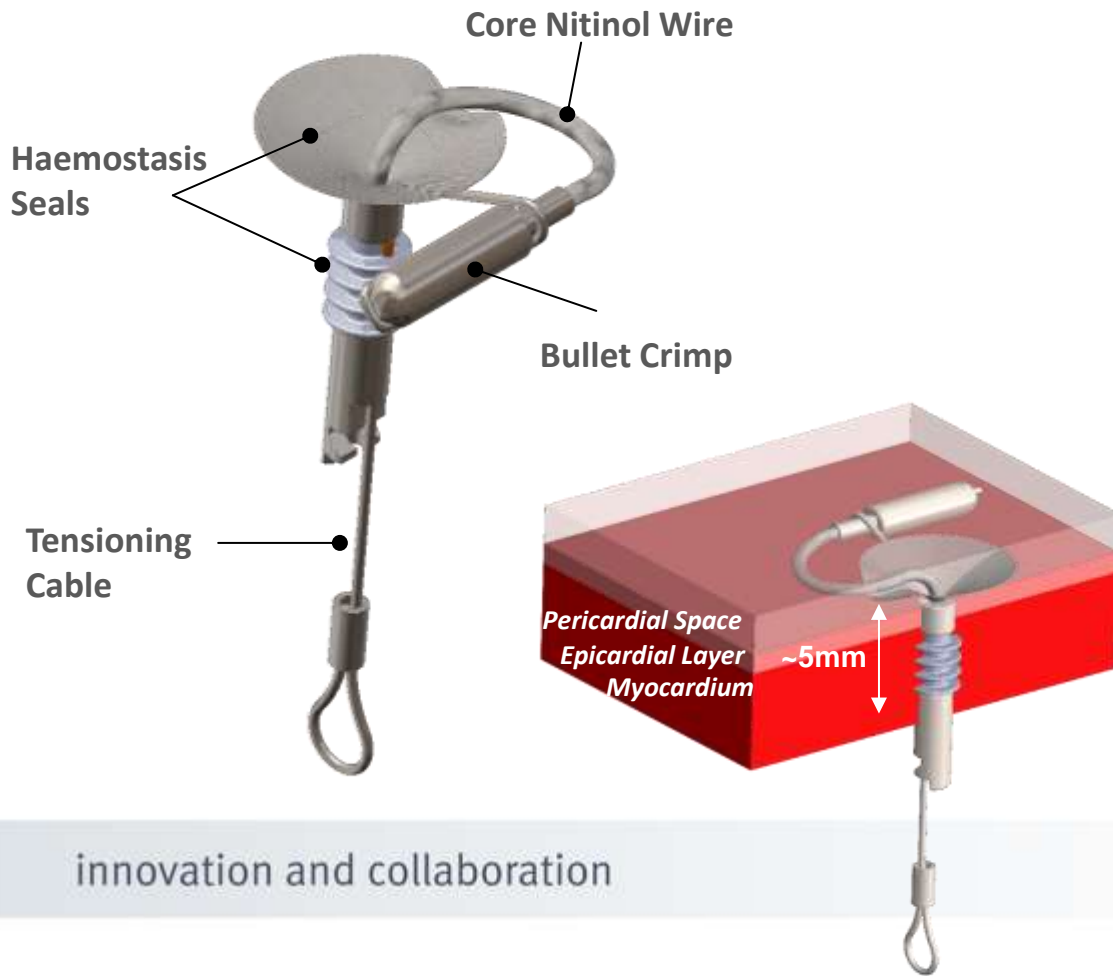
Single Delivery System



- *Simple controlled venous based delivery*
- *Secure, small profile anchor covering large surface area*
- *Restores leaflet coaptation*

# Coil Anchor Overview

*Coil anchor design provides significant surface area to distribute tensioning force*



## Coil Anchor Phases



Wire Exposed → Wire begins to coil → Hemi-spiral shaped anchor

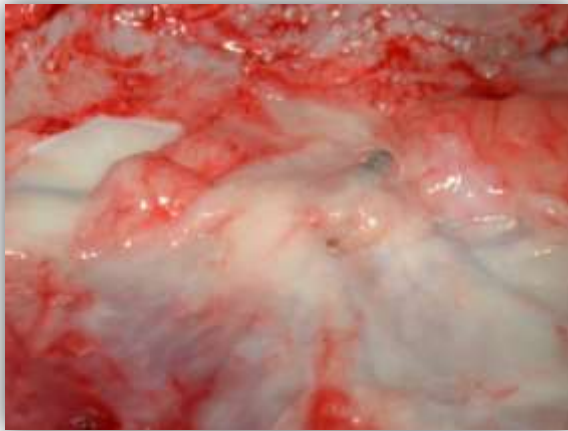
# PreClinical Test: Hemostatic Sealing

## 20+ Chronic Pigs

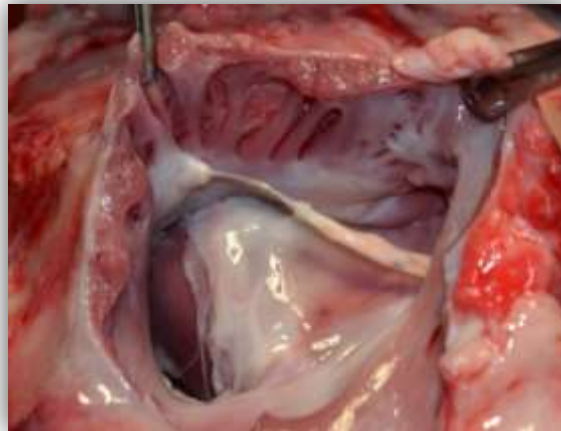
- ✓ Observed at 30, 60 and 90 days
- ✓ All animals survived
- ✓ No bleeding was found
- ✓ No severe complications were found
- ✓ At explant, the tissue healed

## 30+ Acute Pigs

- ✓ “In Wall” stacked ePTFE disk self-retained & sealed without tether tension
- ✓ No bleeding immediately after coil anchor delivery
- ✓ Pigs kept under observation for  $\geq 30$  mins and no bleeding was observed



innovative and collaboration  
**Coil Endothelialized**



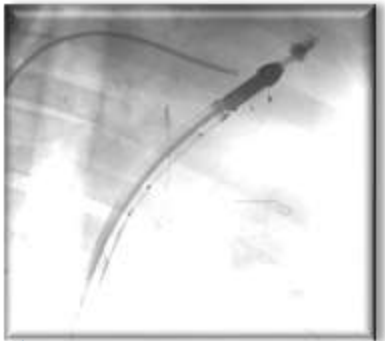
**Tensioning Band Endothelialized**



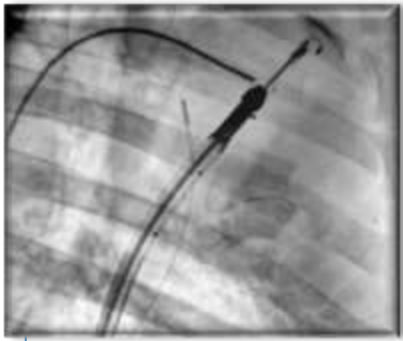
**Stable stent position at 90 days**

# TriCinch Coil System - Procedural Steps

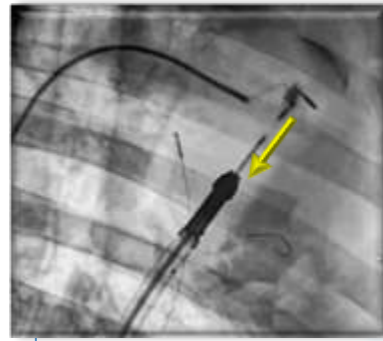
4 procedural steps to deploy the TriCinch Coil System



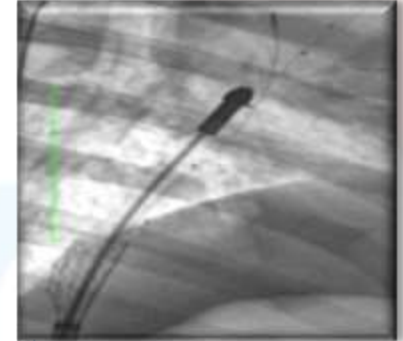
1 Position & puncture APC region



2 Deploy Coil anchor in pericardial space



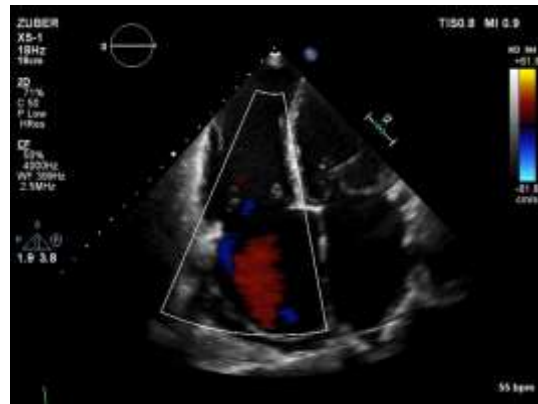
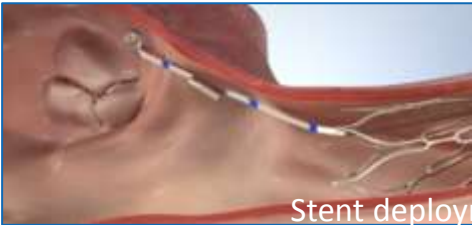
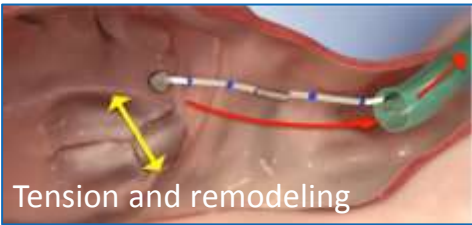
3 Tension applied



4 Stent deployment in IVC



# 4TECH TriCinch: septo-anterior cinching

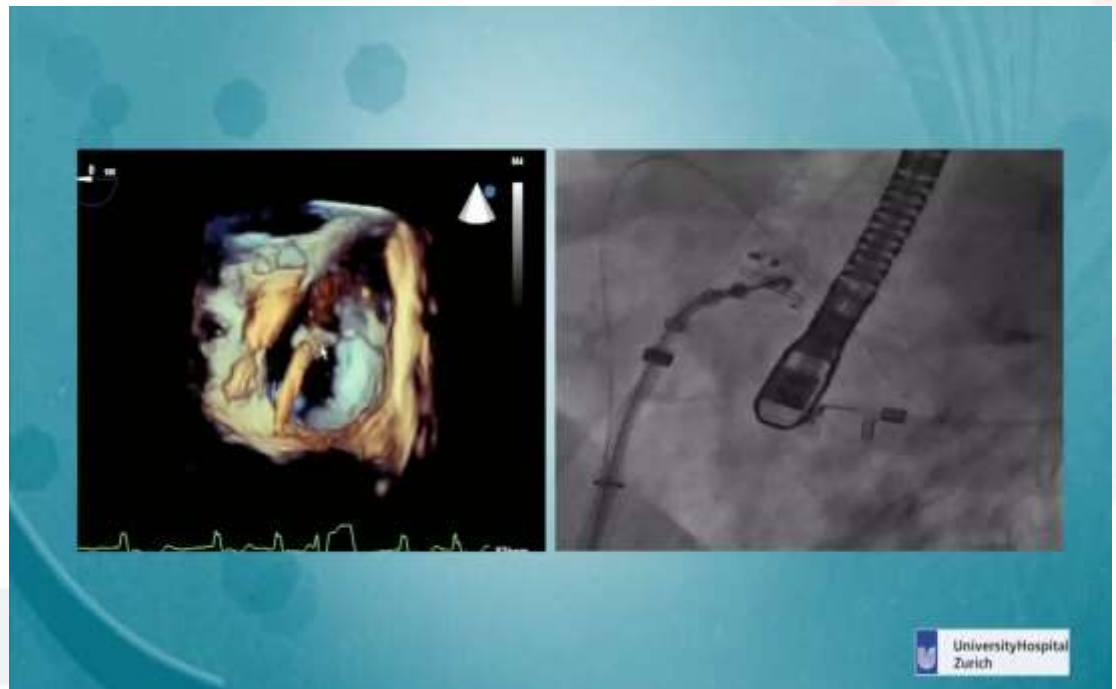
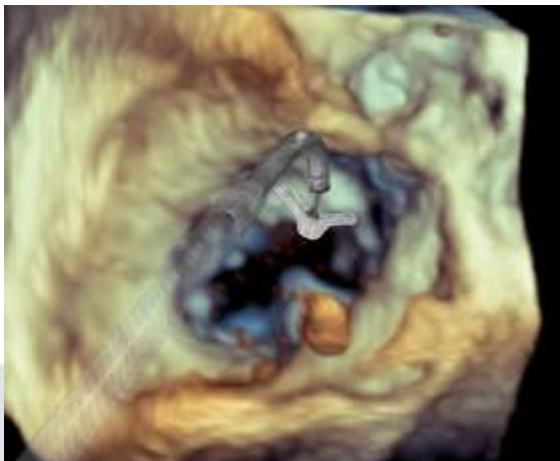


# 4TECH TriCinch: septo-anterior cinching



# Mitra Clip in the tricuspid position

- Adapted from Mitral technology
- Trans-jugular and more popular transfemoral access
- Tricuspid leaflets have different tissue properties than the mitral (durability) and no double orifice outcome
- Challenging intraprocedural echo guidance



# Mitra clip in tricuspid position

- >400 cases worldwide
- 1-2 clips for septal leaflet
- Imaging challenging TOE vs ICE
- Friable leaflets
- No double orifice result
- Not designed for the tricuspid

**Circulation**



ORIGINAL RESEARCH ARTICLE

## Transcatheter Treatment of Severe Tricuspid Regurgitation With the Edge-to-Edge MitraClip Technique

Georg Nickenig, Marek Kowalski, Jörg Hausleiter, Daniel Braun, Joachim Schofer, Ermela Yzeiraj, Volker Rudolph, Kai Friedrichs, Francesco Maisano, Maurizio Taramasso, Neil Fam, Giovanni Bianchi, Francesco Bedogni, Paolo Dentl, Ottavio Alfieri, Azeem Latib, Antonio Colombo, Christoph Hammerstingl, Robert Schueler

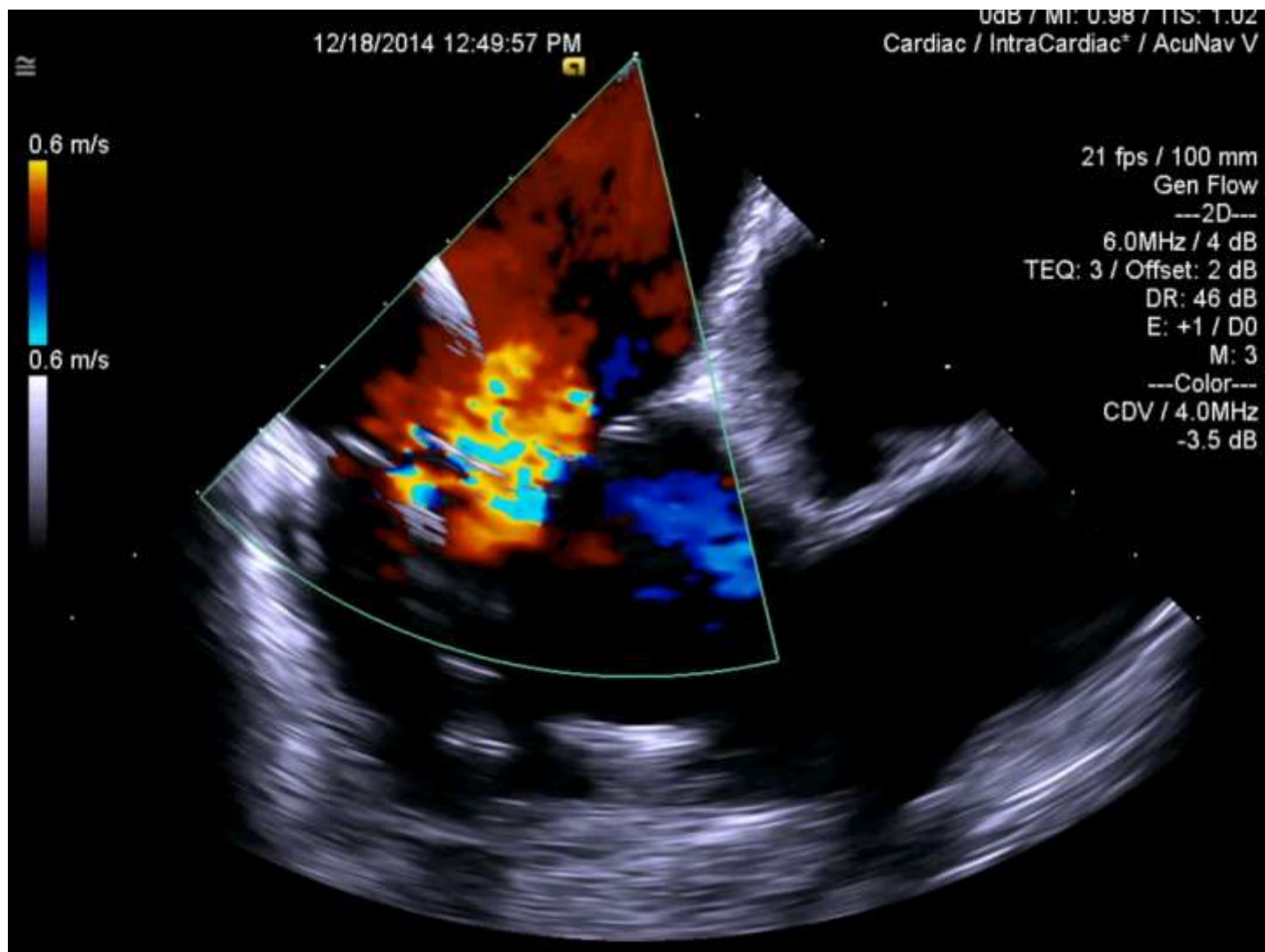
<https://doi.org/10.1161/CIRCULATIONAHA.116.024848>

Circulation. 2017;135:1802-1814

Originally published March 23, 2017







# Edwards FORMA Repair System

*Designed to restore leaflet coaptation*

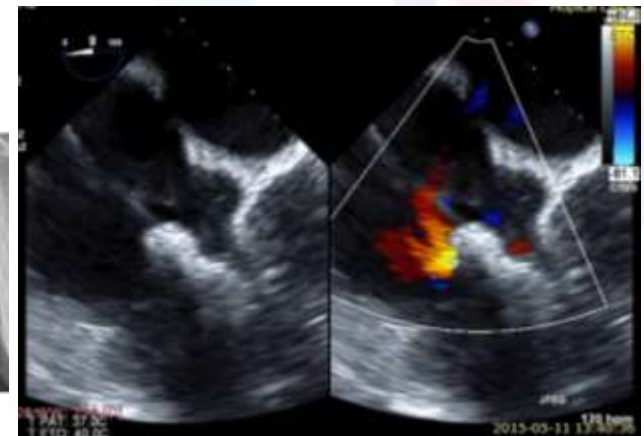
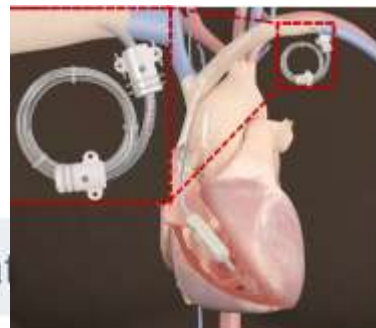
FORMA Repair System consists of:

## 1. Spacer

- Positioned into the regurgitant orifice
- **Creates a platform for native leaflet coaptation**

## 2. Rail

- Tracks Spacer into position
- Distally and proximally anchored

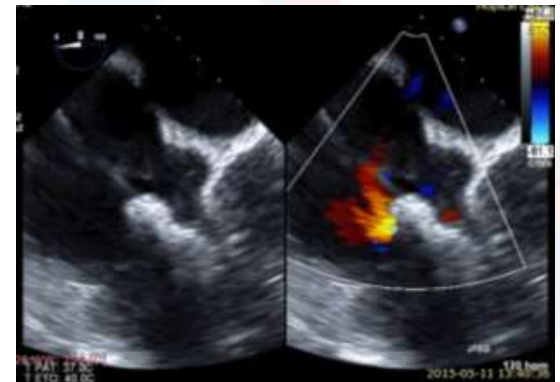
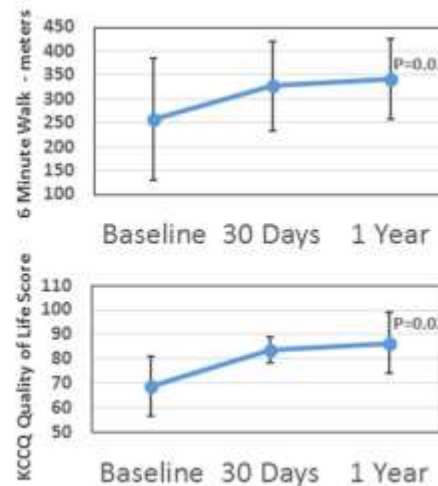
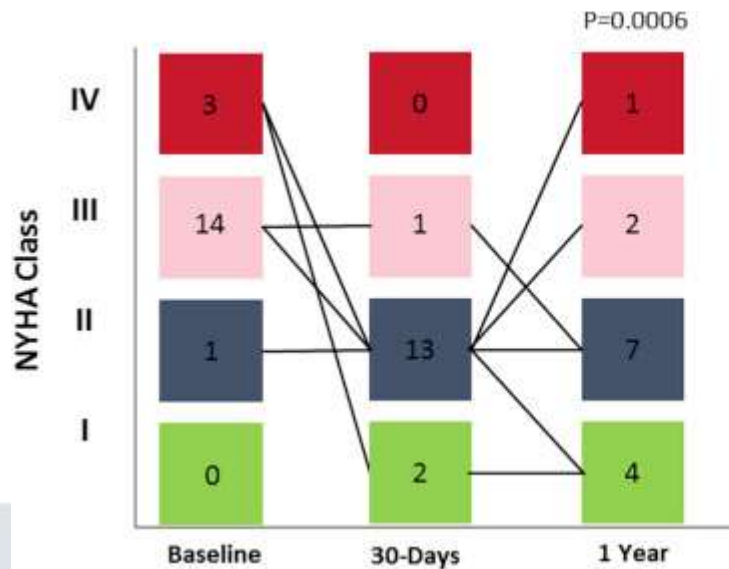




# Transcatheter Tricuspid Valve Repair With a New Transcatheter Coaptation System for the Treatment of Severe Tricuspid Regurgitation

## 1-Year Clinical and Echocardiographic Results

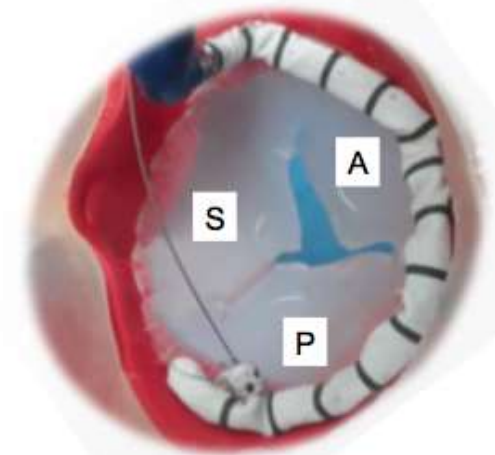
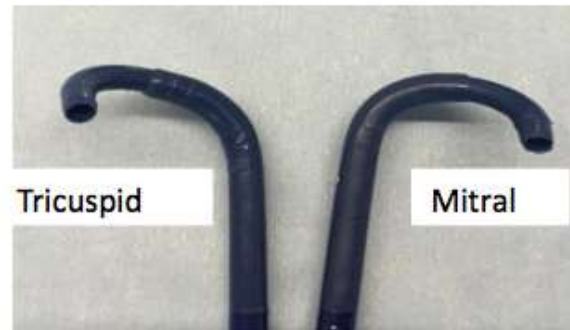
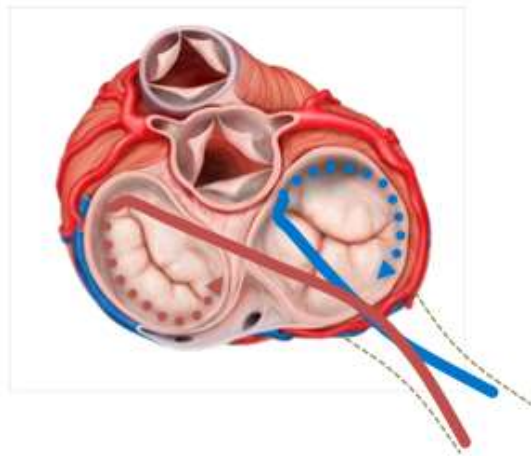
Gidon Perlman, MD,<sup>a,b</sup> Fabien Praz, MD,<sup>c</sup> Rishi Puri, MBBS, PhD,<sup>d,e,f</sup> Hadass Ofek, MD,<sup>a</sup> Jian Ye, MD,<sup>a</sup> Francois Philippon, MD,<sup>d</sup> Thierry Carrel, MD,<sup>c</sup> Philippe Pibarot, DVM, PhD,<sup>d</sup> Adrian Attinger, MD,<sup>a</sup> Nay Min Htun, MBBS, PhD,<sup>a</sup> Danny Dvir, MD,<sup>a</sup> Robert Moss, MD,<sup>a</sup> Francisco Campelo-Parada, MD,<sup>d</sup> Elisabeth Bédard, MD,<sup>d</sup> David Reineke, MD,<sup>c</sup> Aris Moschovitis, MD,<sup>c</sup> Sandra Lauck, PhD,<sup>a</sup> Philipp Blanke, MD,<sup>a</sup> Jonathon Leipsic, MD,<sup>a</sup> Stephan Windecker, MD,<sup>c</sup> Josep Rodés-Cabau, MD,<sup>d</sup> John Webb, MD<sup>a</sup>



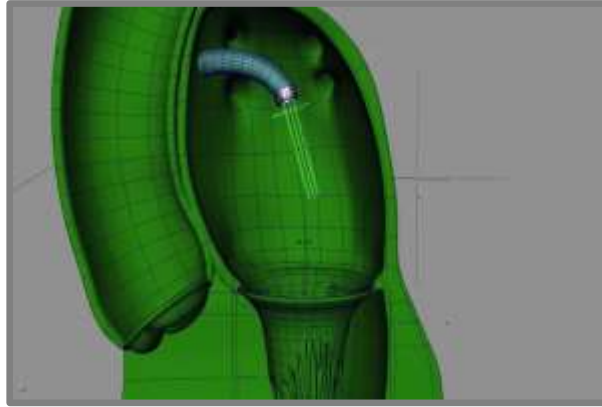
Available online 2 August 2017

# Cardioband Tricuspid

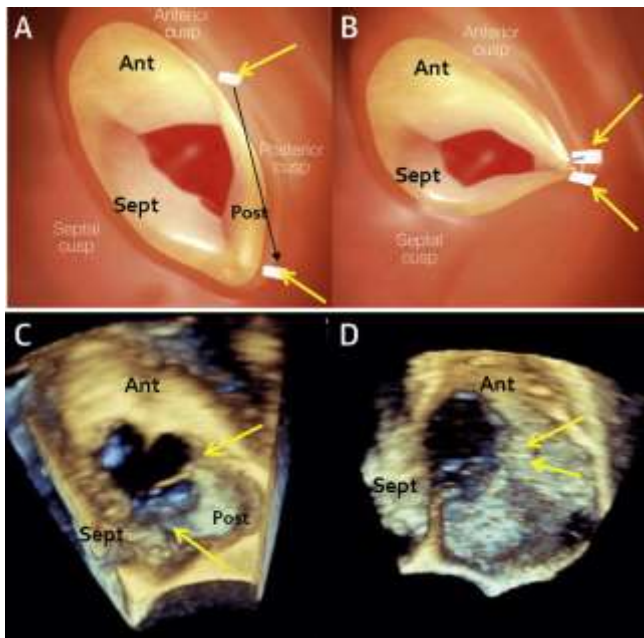
- Cardioband Tricuspid is an adjusted Cardioband Trans Femoral (CBTF – CE approved for mitral regurgitation treatment).
- Proven safety and performance with over 90 mitral patients.
- Quick learning curve to CBTF users.
- Applying the surgical gold standard with a trans femoral approach.



# Millipede



# Trialign



## SCOUT I

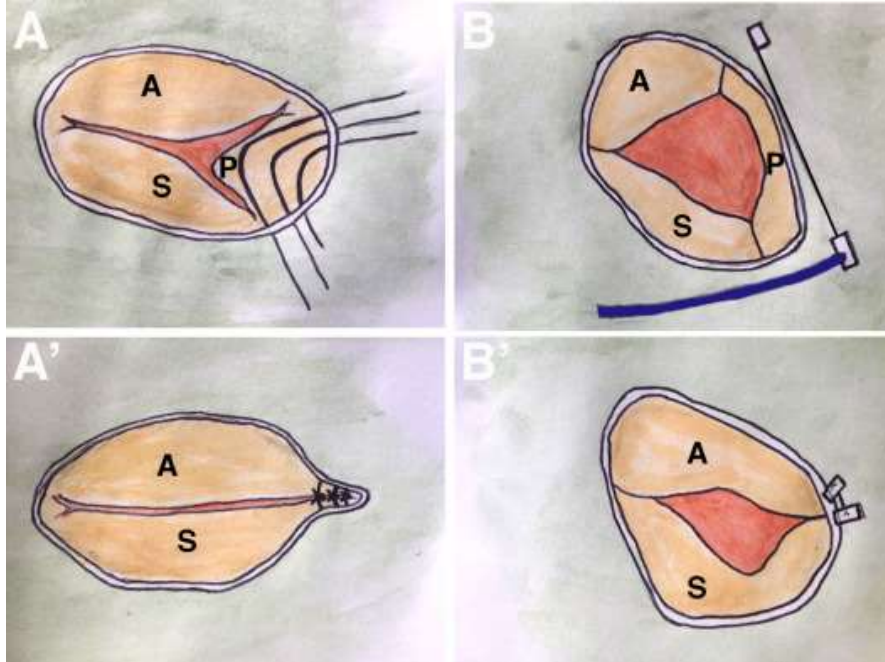
	n/N	(%)
<b>Acute Procedure</b>		
Implant Success	15/15	100%
Unplanned intervention	1/15	7%
Intraprocedural stenting of RCA		
<b>30 Day Follow Up</b>		
Freedom from death	15/15	100%
Technical Success	12/15	80%
3 single pledget dehiscence		
Major Adverse Events	0/15	0%

Trialign by MitraLign

courtesy of R. Hahn



# Kay repair



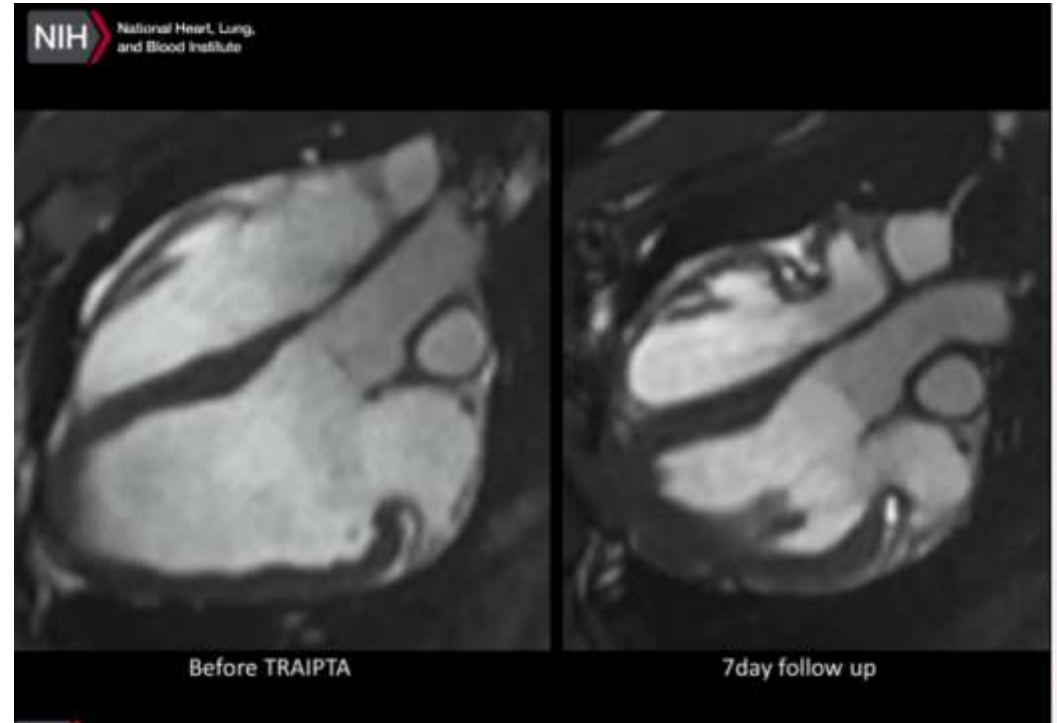
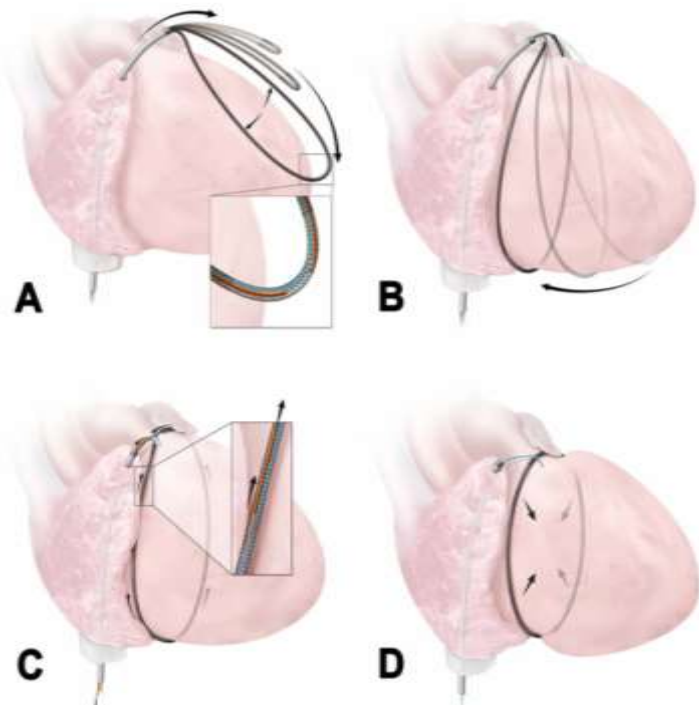
Kay Repair Technique (A and A') and corresponding percutaneous approach using the Mitralign system™ (Mitralign Inc., Tewksbury, MA, USA) (B and B'). A. Tricuspid valve bicuspidization is accomplished by plicating the annulus along the posterior leaflet

Claire Bouleti, Jean-Michel Juliard, Dominique Himbert, Bernard Lung, Eric Brochet, Marina Urena, Marie-Pierre Dilly, Phalla Ou, Patrick Nataf, Alec Vahanian

**Tricuspid valve and percutaneous approach: No longer the forgotten valve!**

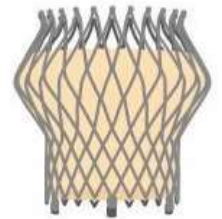
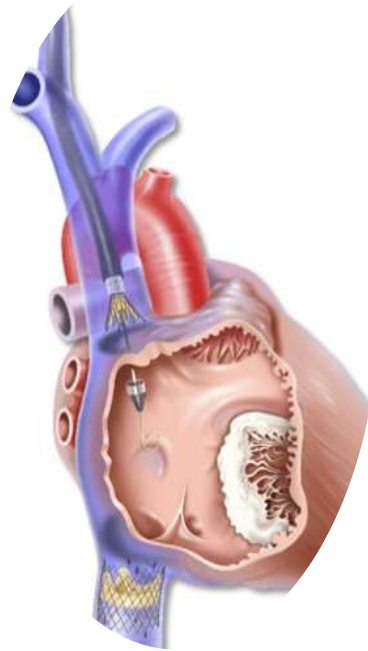
Archives of Cardiovascular Diseases, Volume 109, Issue 1, 2016, 55–66

# The TRAIPTA concept

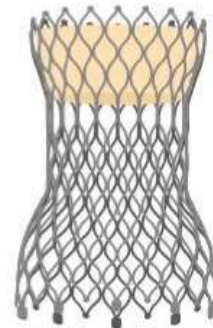


Rogers et al, JACC Cardiovasc Interv. 2015 Mar; 8(3): 483–491.

# Eterotopic implantation: the CAVI concept



SVC - Valve



IVC - Valve



# Conclusion

- Increasing recognition of the importance of tricuspid valve pathology
- Percutaneous interventions have an increasing place in the treatment of :
  - bioprosthetic tricuspid valve dysfunction
  - Functional tricuspid regurgitation
- Multiple new devices being trialled
  - Some are purposefully designed
  - Other adapted from the mitral valve intervention

