Traitement percutané de la fuite tricuspide

Laborde Jean-Claude

GRCI 2018, PARIS , FRANCE

DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

Intervenant : Jean-Claude LABORDE, London

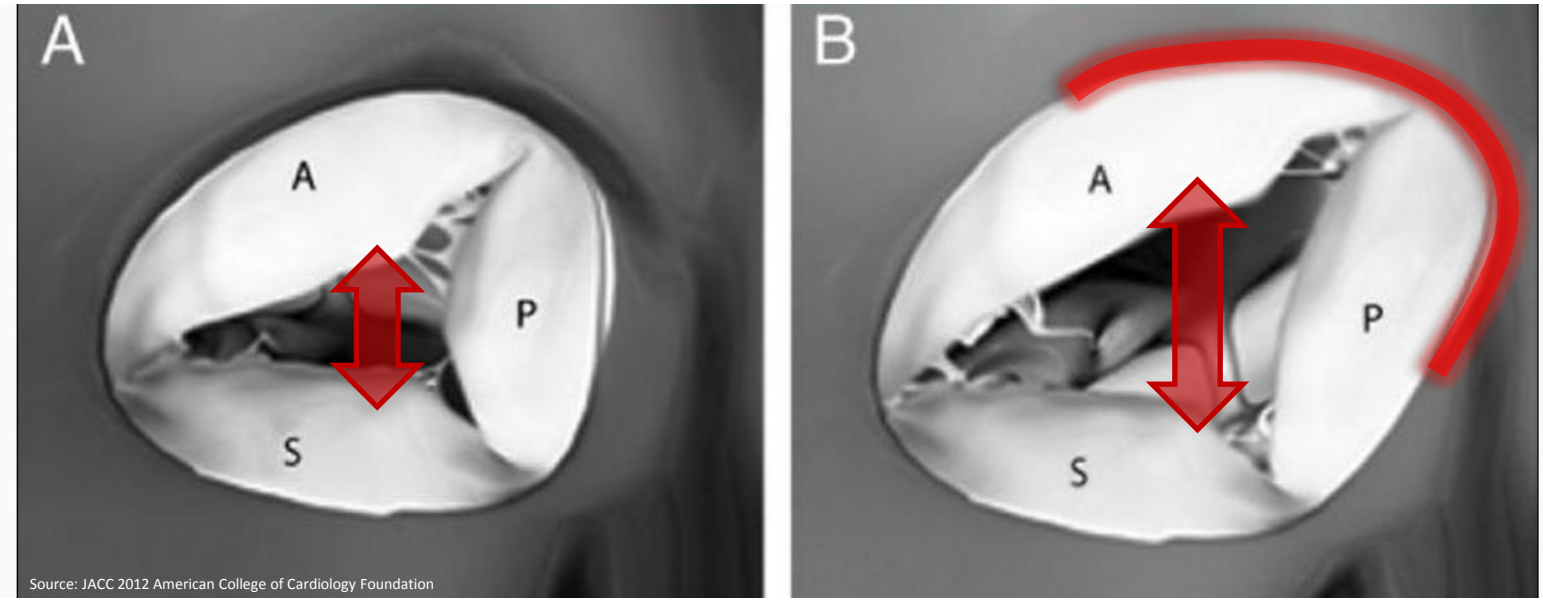
☑ Je déclare les liens d'intérêt suivants :

Conseil : 4 Tech

LA DILATATION ANNULAIRE EST LA COMPOSANTE PRINCIPALE DE LA RT

ValveTricuspid Normale

Dilatation Antero-Posterieur de l'Anneau Tricuspide



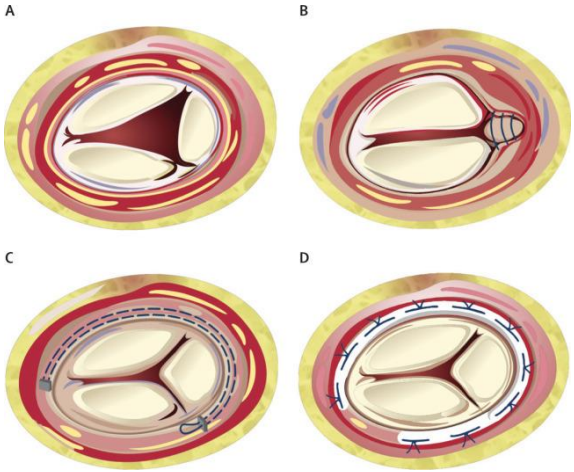
A = Anterior leaflet; P = Posterior leaflet; S = Septal leaflet

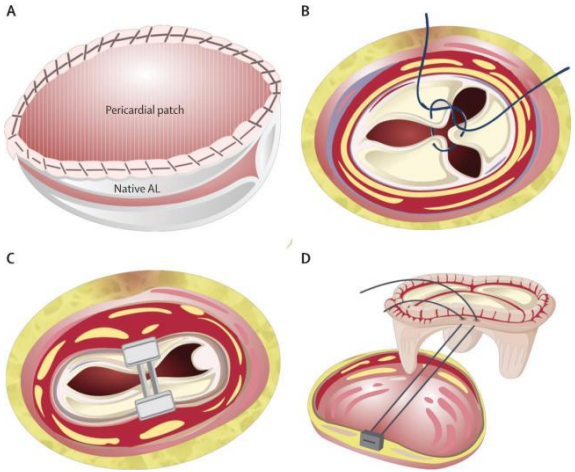
- FTR is primarily due to tricuspid antero-posterior dilatation[1]
- FTR is often secondary to left-sided heart disease[1]
- Approx. 30% - 50% of patients with MR have significant FTR[1]

1. Dreyfus, G. (2015). Functional Tricuspid Regurgitation. JACC Vol 65, Issue 21

RT Fonctionelle: traitement chirurgicale le “gold standard”

« The threshold for restrictive ring annuloplasty repair of secondary tricuspid regurgitation at the time of left-sided valve surgery has decreased over time with recognition of the risk of progressive tricuspid regurgitation and right heart failure in patients with moderate or lesser degrees of tricuspid regurgitation and tricuspid annular dilatation, as well as with appreciation of the high risks of reoperative surgery for severe tricuspid regurgitation late after left-sided valve surgery ».





Rodés-Cabau J, Taramasso M, O'Gara P. Lancet 2016

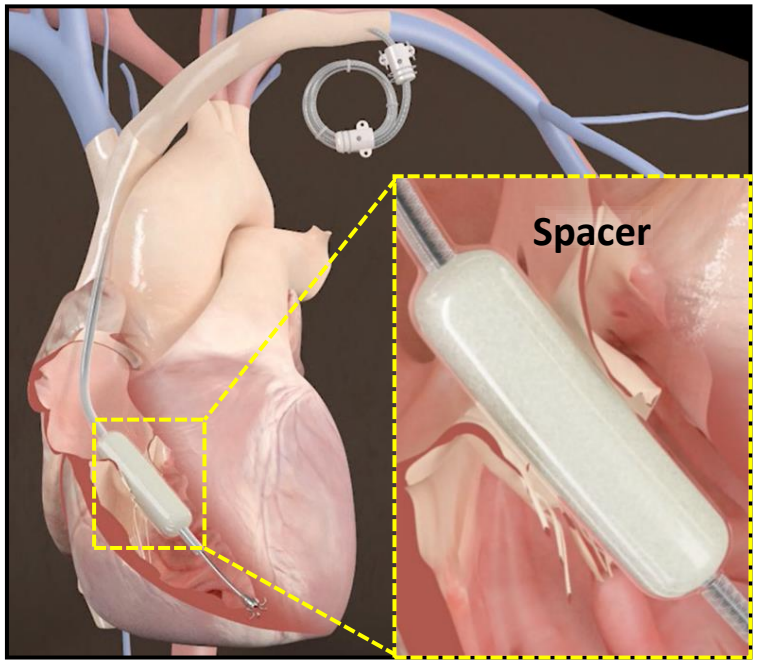
RT Fonctionelle : challenges techniques

- Diamètre de l ’anneau tricuspide important
- **Fragilité tissulaire (anneau et feuillets valvulaires)**
- Angulation en relation avec la veine cave inférieure et supérieure
- **Faible épaisseur du tissu myocardique**
- **Proximité de l’artère coronaire droite à l’anneau Tricuspide**
- Nombreux patients avec sondes de Pacemakers ou Défibrillateurs
- Importantes trabéculations ventriculaires
- …

RT Fonctionelle : traitement percutané alternatives potentielles

- RT réducteur central pour amélioration de la coaptation des feuillets valvulaires — FORMA
- Le système « Edge-to-Edge » Mitraclip — TRI CLIP
- Réduction de l'anneau Tricuspide — CARDIOBAND
  TRIALIGN
  4Tech TRICINCH
- Implantation de valves — CAVAL VALVE

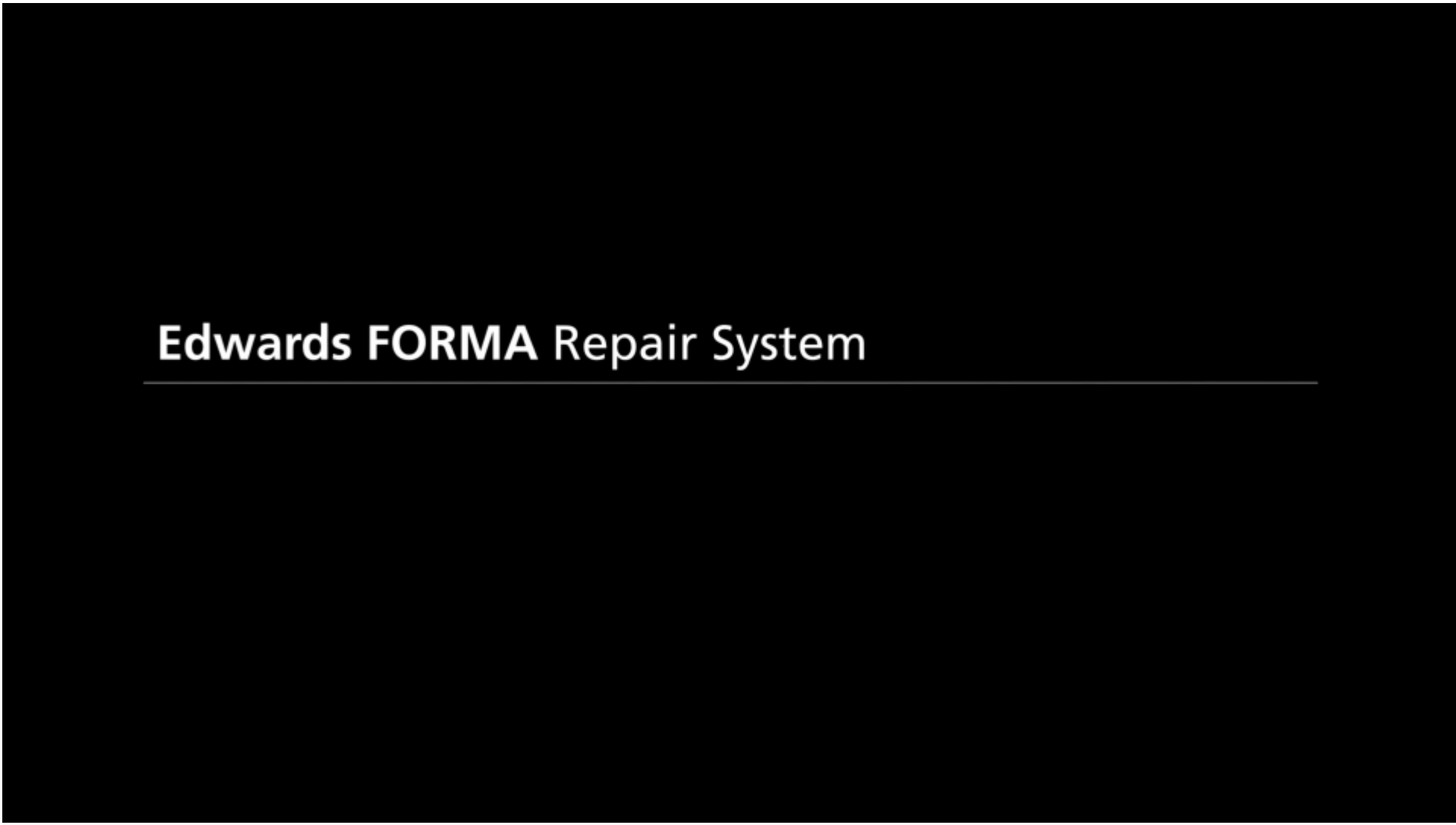
The FORMA concept



Review:
FORMA Repair System consists of:
1. Spacer
- Positioned into the tricuspid regurgitant orifice
- Creates a platform for native leaflet coaptation

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

FORMA System Animation



The FORMA study
(n=25)
At 30-days

ECHO	PISA EROA : 1.1 to 0.6 cm2 (p=0.001)	
	2D/3D quantitative analysis 2.1 to 1.1 cm2 (p=0.012)	
SAFETY	Deaths	6.9%*
	Major bleeding	13.8%*
	Acute kidney injury	10.3%
	Device-related surgeries	10.3%*

* Distal anchor detachments and VT perforations

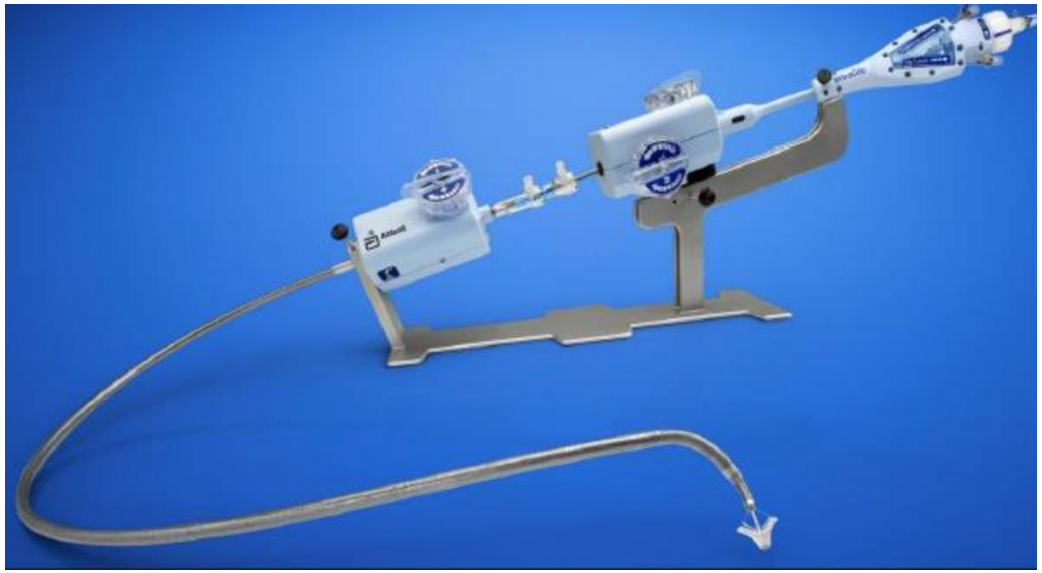
The SPACER study
(n=78)
On-going, not recruting

Etude prospective multicentrique

15 centres US et Europe / 78 patients

Device redesign in progress

The Edge-to-Edge Valve Repair



Technologie développée pour la valve Mitrale appliquée à la valve Tricuspide

Clips de 2 feuillets valvulaires

The Edge-to-Edge Valve Repair
TRIVALVE Registry (n=249)
Compassionate use in 14 centers

Procedural results

In-Hospital Events	249 patients
Mortality	7 (2.8%)
Blood transfusion / severe bleeding	15 (6.0%)
Infection	12 (4.8%)
Acute kidney injury	9 (3.6%)
Stroke	2 (0.8%)
Conversion to surgery	1 (0.4%)

Follow-up data:

Mean FU: 292 ±195 days

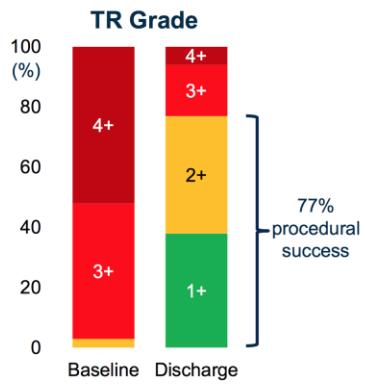
FU on mortality: 100%
Echocardiographic FU: 79%

Sécurité en terme de Mortalité/ Morbidité

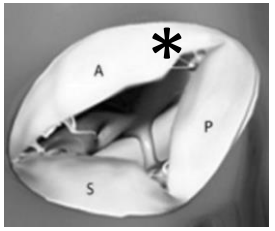
Procedural Results

(249 patients)

Number of clips	2 ± 1 (range: 0 - 5)
Clip location, n (%)	
Antero-septal	162 (65.1%)
Antero-septal + postero-septal	52 (20.9%)
Other	35 (14.0%)
Duration of TR procedure, min	136 ±62
Reduction of ≥1 TR grade, n (%)	222 (89.2%)
Concomitant MR treatment, n (%)	129 (51.8%)



Efficacité en terme de TR réduction



* Feuillet Antéro-Postérieur

Limitation technologique plaidant pour le développement d'une seconde génération

The Edge-to-Edge Tricuspid Valve Repair System (TVRS)
TRILUMINATE Study
On going study, currently enrolling

Etude prospective multicentrique

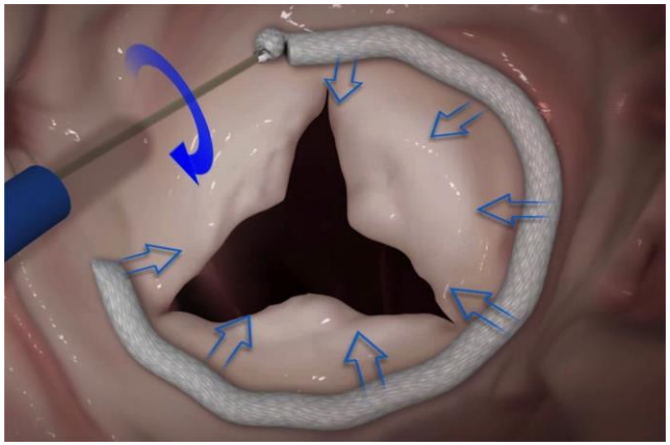
25 centres (US et Europe) / 85 patients

Objectifs

CE Mark approval

U.S. FDA regulated Device approval

The CARDIOBAND system



Review:

- Adapted from Mitral technology
- Surgical background
- Transfemoral access
- Anchoring system in supra-annular position
- Echocardiographic and Fluoroscopic guidance

First Percutaneous Tricuspid Valve Annuloplasty Repair

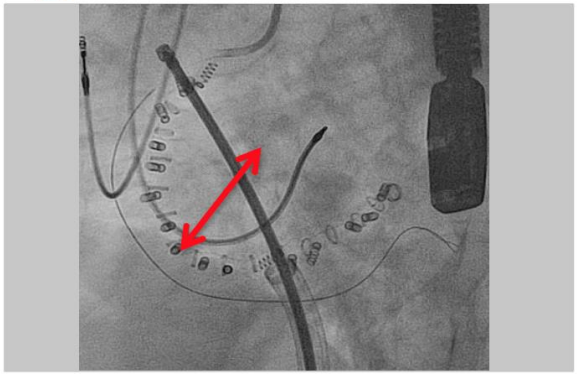
June 2016

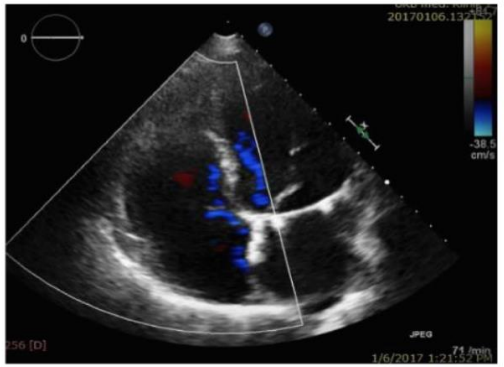
UniversitätsSpital
Zürich

The CARDIOBAND System
TRI REPAIR Study (n=30)
9 centers in Europe

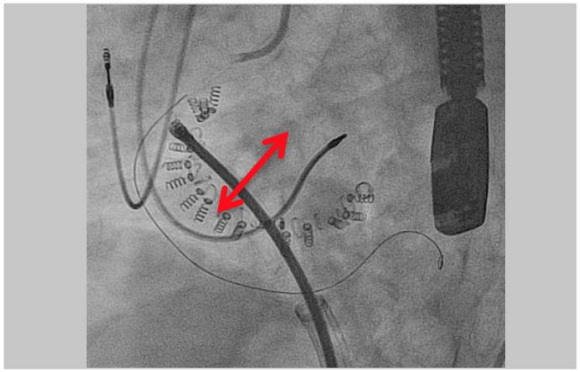
Delivers a significant and consistent reduction in tricuspid regurgitation (Technical success : 30/30 (100%)*

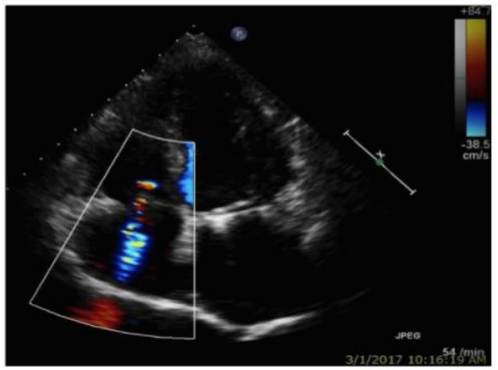
Baseline





Post-reduction





* Screws detachments reported

The CARDIOBAND System
TRI REPAIR Study (n=30)
9 centers in Europe

TRI-REPAIR Study

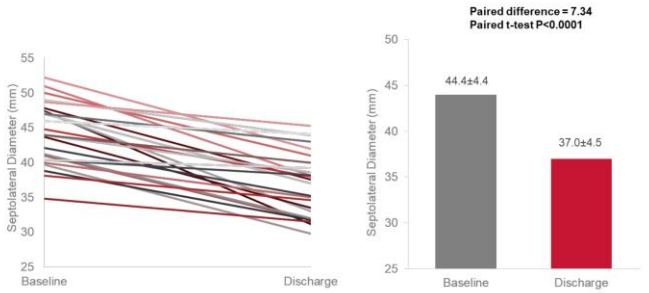
Favorable safety profile

Adjudicated 30 Day Events	n (%)
Death	2 (6.7)
Stroke	1 (3.3)
MI	0
Bleeding complications*	4 (13.3)
Fatal	1 (3.3)
Life-threatening	1 (3.3)
Extensive	2 (6.7)
Coronary complications	3 (10.0)
Device related cardiac surgery	0
Renal failure	1 (3.3)
Conduction System Disturbance	1 (3.3)
Ventricular Arrhythmia	2 (6.7)

23/30 patients (77%) had none of the above events

TRI-REPAIR Study

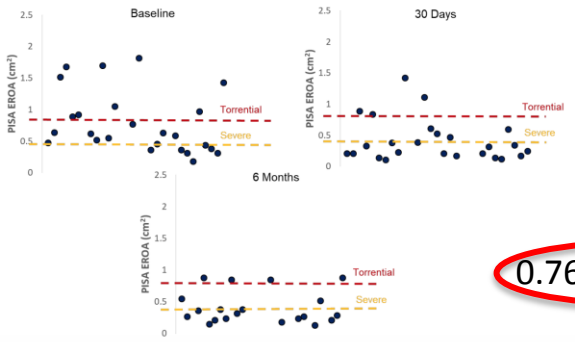
16% average annular reduction in septolateral diameter by Core Lab[1] (paired analysis)



44 to 37 mm

TRI-REPAIR Study

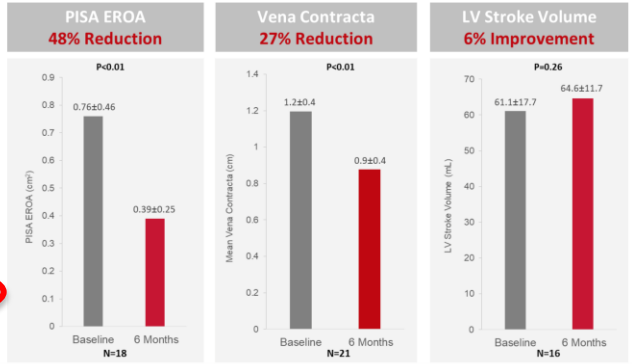
Significant reduction in TR severity at 30 days and sustained at 6 months[1]



0.76 to O.39 cm2

TRI-REPAIR Study

Sustained echo improvement at 6 months by Core Lab[1] (paired analysis)



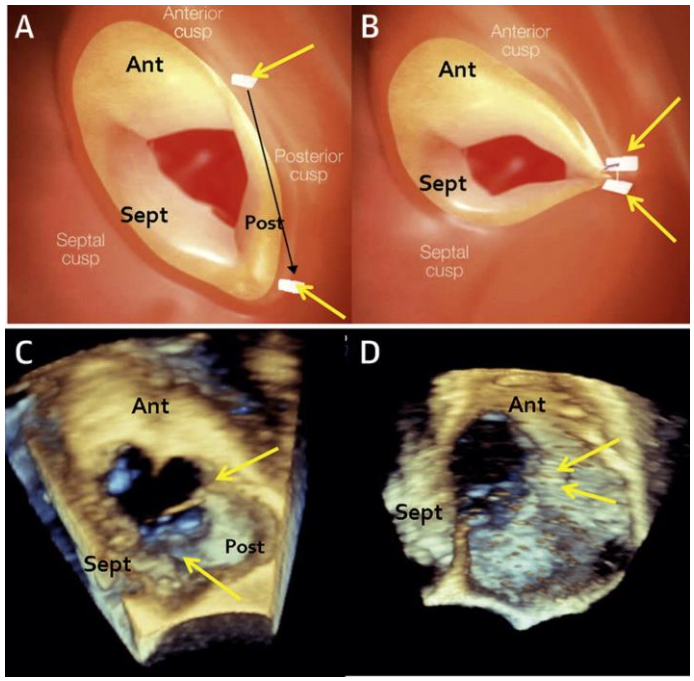
The CARDIOBAND System
Study to be planned
No on going study, not currently enrolling

Objectifs

CE Mark approval

U.S. FDA regulated Device approval

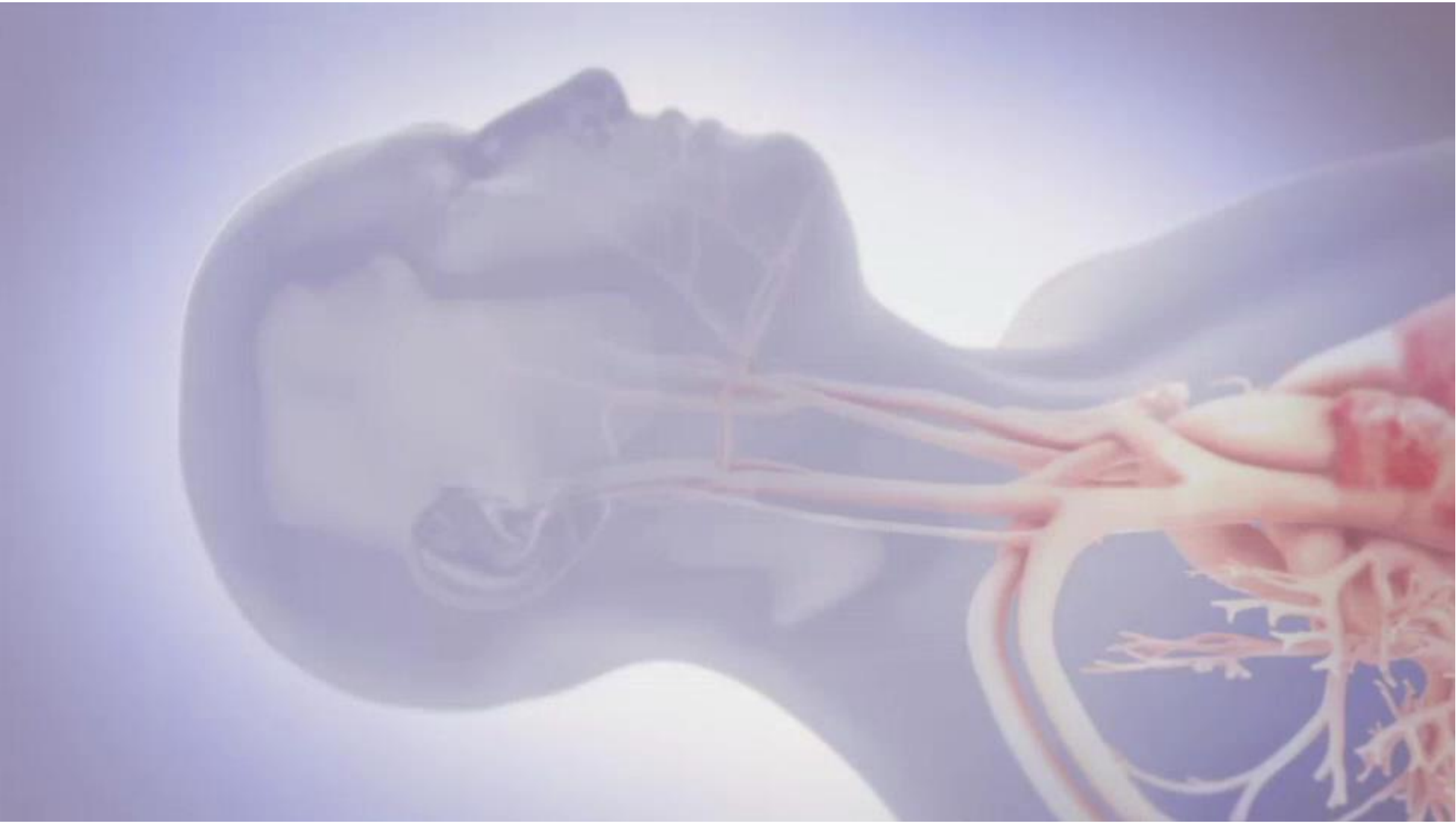
The Trialign concept



Review:

- Adapted from Mitral technology
- Implanted in sub-annular position
- Trans-jugular access
- Echocardiographic guidance
- Multiple pledgets possible

The Trialign concept

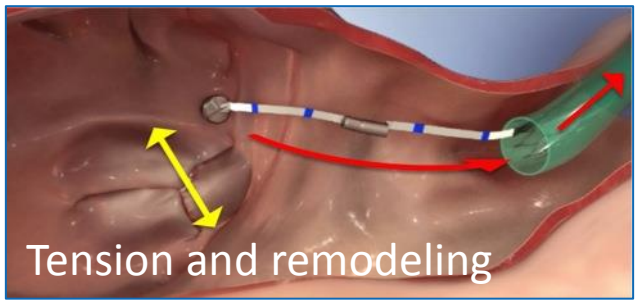


The Trialign concept
SCOUT Study (n=39)
Combined US and EU cohort (at 30-days)

PROCEDURE	Success 32/39	82%*
ECHO	TR EROA : 0.92 to 0.77 cm2 (p=0.013)	
	TR annulus diameter : 39.7 to 36.9mm (p=0.001)	
	2D/3D quantitative analysis 2.1 to 1.1 cm2	
SAFETY	Deaths	0%
	Major bleeding	0%
	Coronary complication	0%
	Device-related surgery	0%

* 5 pledgets detachments but no VT perforation or device-related surgery

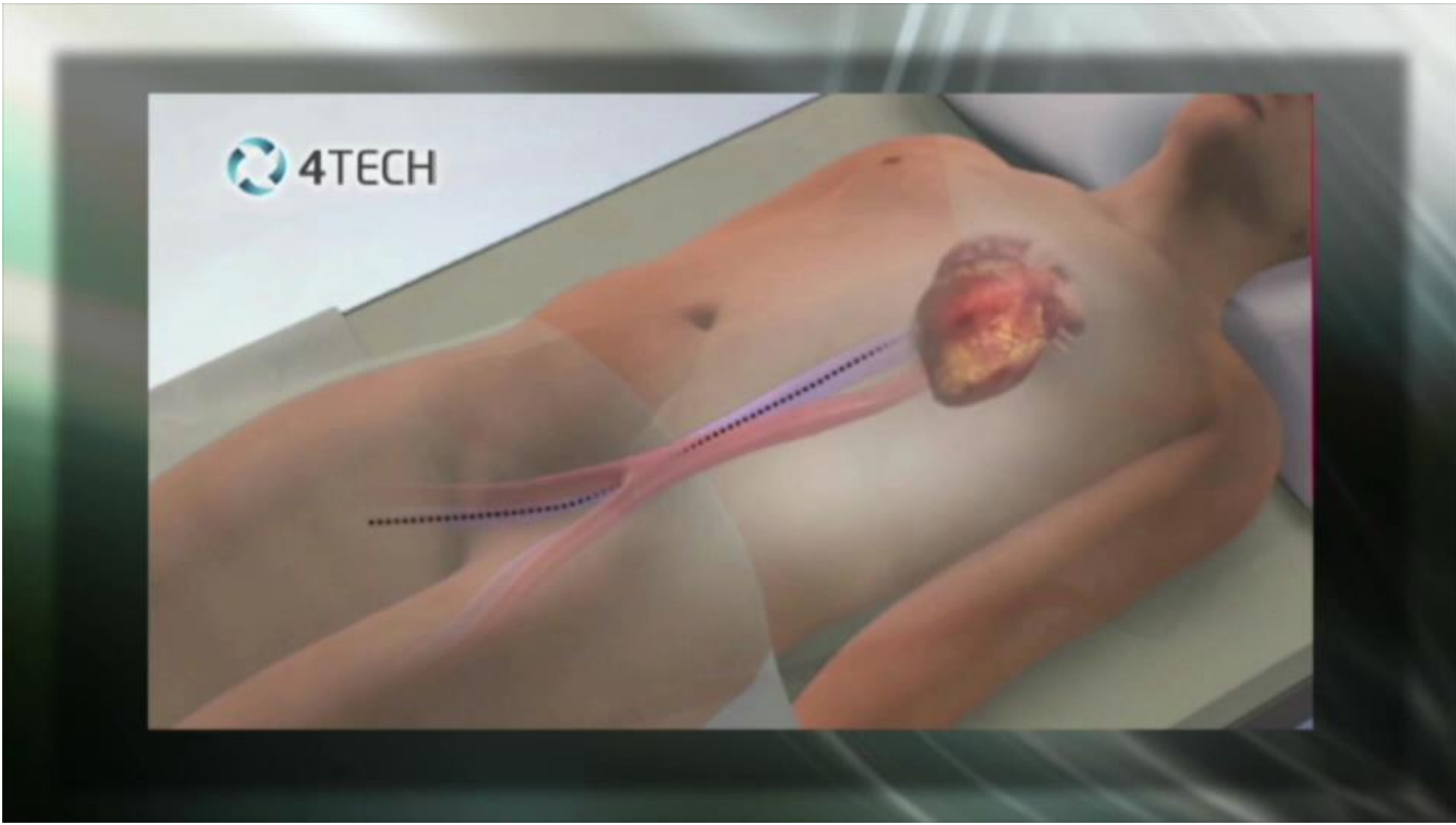
The 4TECH TriCinch concept



Review:

- Designed for the Tricuspid Valve
- Transfemoral access
- Simple anchoring system in supra-annular position
- Echocardiographic and Fluoroscopic guidance
- Under Clinical validation (European CE Mark Study)
- Learning curve completed

The 4TECH TriCinch concept



Early Clinical outcomes from TriCinch™ Gen 1

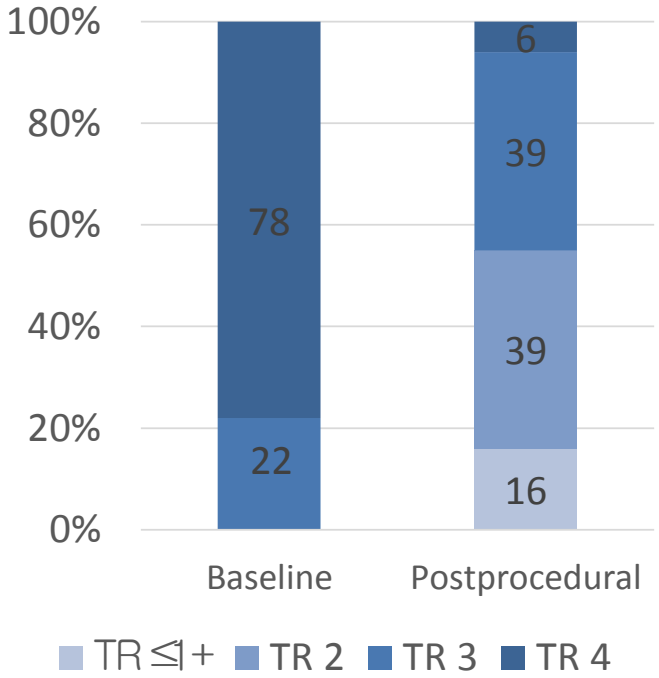
Baseline characteristics - Patients Enrolled: **24**

- Age	71±7yo
- NYHA class ≥III	17 [71%]
- LogES	median 12
- Signs of right HF	24 [100%]

Procedural and post-procedure

Patient Treated (successful implantation)	**18** [75%]
Perioperative complications	
hemopericardium	2 [8%]
Post-operative complications	
annulus anchor late detachment	4 [17%]
(no SAE/AE related to detachment)	
30-day all-cause mortality	**0 [0%]**

TR Reduction in 94% of the patients



6 Months Follow-up data (n=4)

Accumulated implant time	**43 months**
Median follow-up time	1 month [1-6]
NYHA class	**I** - **II** 75% **III** 25% **IV** 0%
Quality of Life Improvement	**6MWT** (m) **+53%** - **MLHFQ +38%** - **SF36-physical +42%**
All-cause mortality	0 [**0%**]

A Novel Cinching System (TriCinch)
Combined US and EU cohort (currently enrolling)

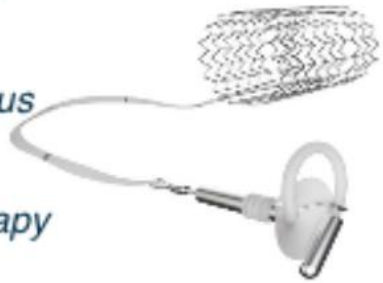
Correction of screw detachments and improve overall result

TriCinch™ Coil System

Simplicity Designed for Efficacy

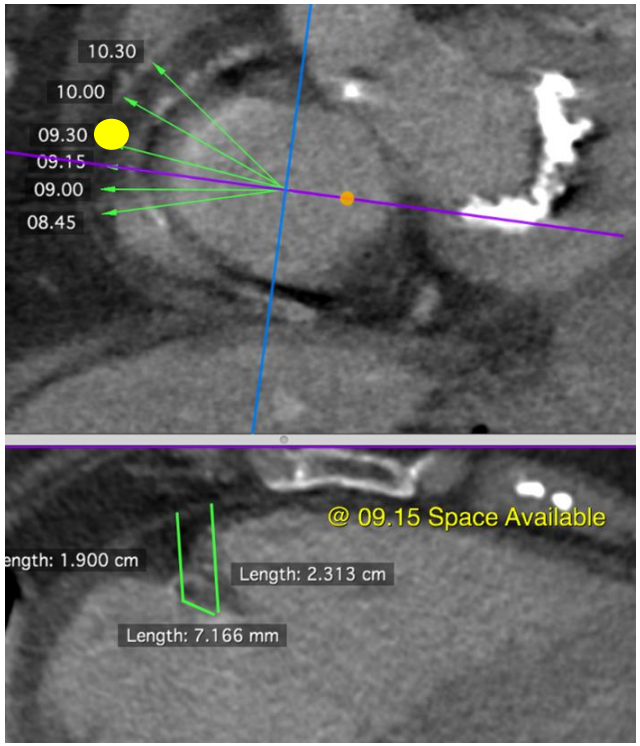
Direct annular remodelling solution for treating FTR

- *Single anchor implant allows for a simple and predictable procedure*
- *Epicardial placement provides robust anchor support*
- *Device directly targets annular dilatation while restoring ventricular geometry*
- *Simplified imaging guidance will facilitate treatment under conscious sedation*
- *Designed to respect native anatomy enabling potential future therapy*

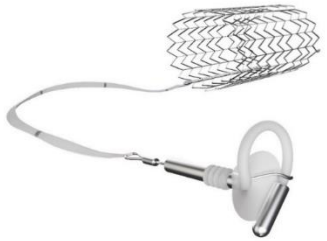


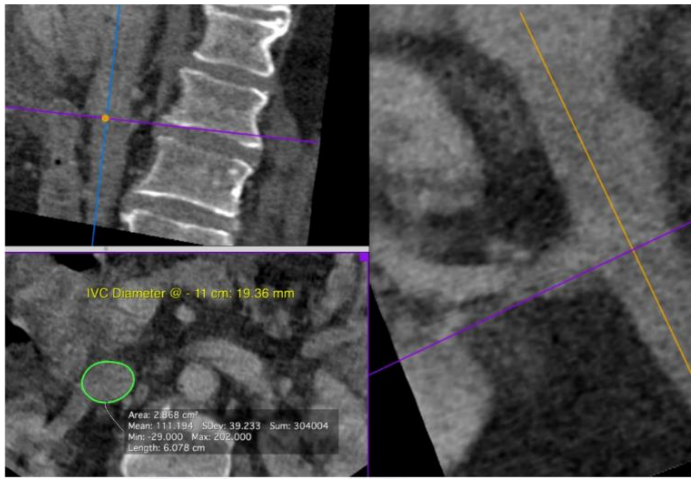
Pre-Procedural CT Scan Analysis

Annular target selection at **9:15**



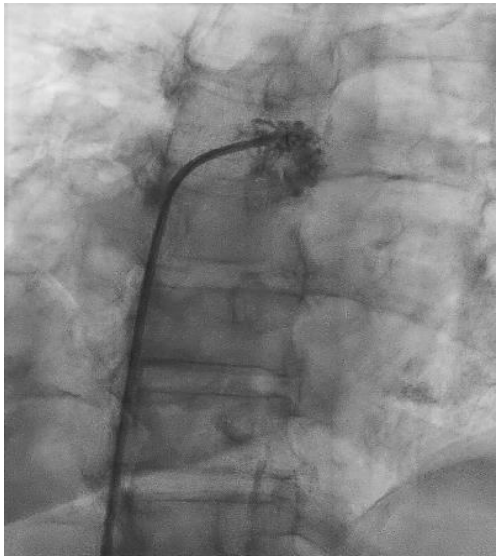
27 mm stent is suggested



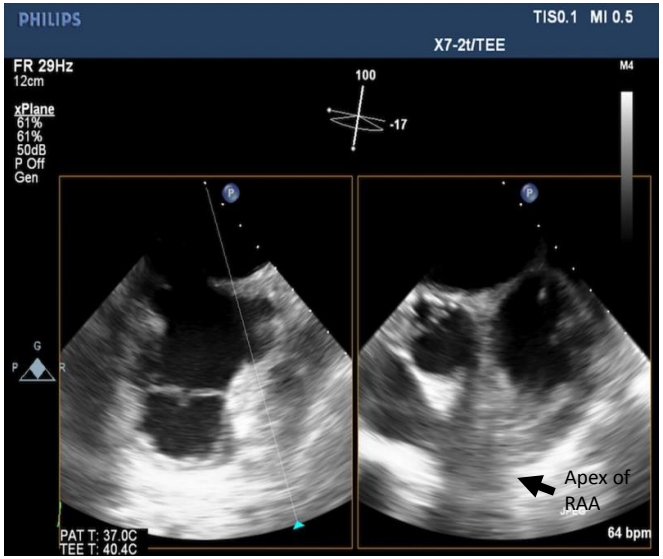


Case performed at St. Antonius Ziekenhuis by Dr. Jan Van der Heyden & Dr. Martin Swaans

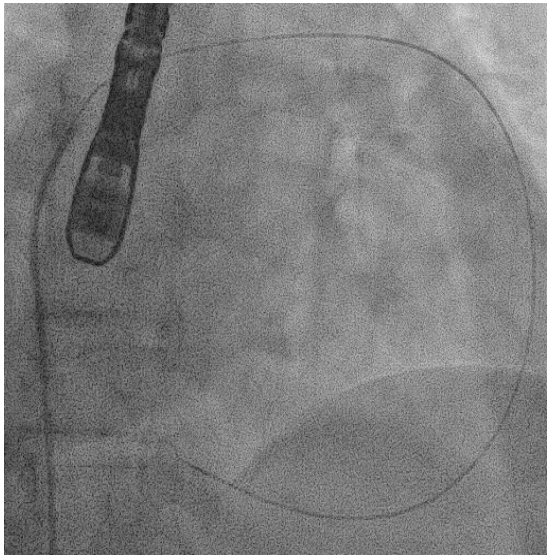
Right Atrial Appendage Access



Fluoroscopic guided

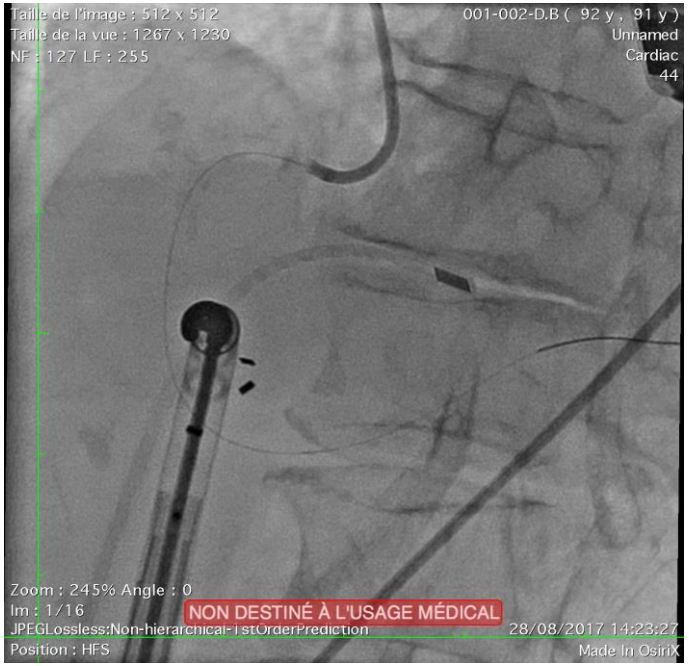


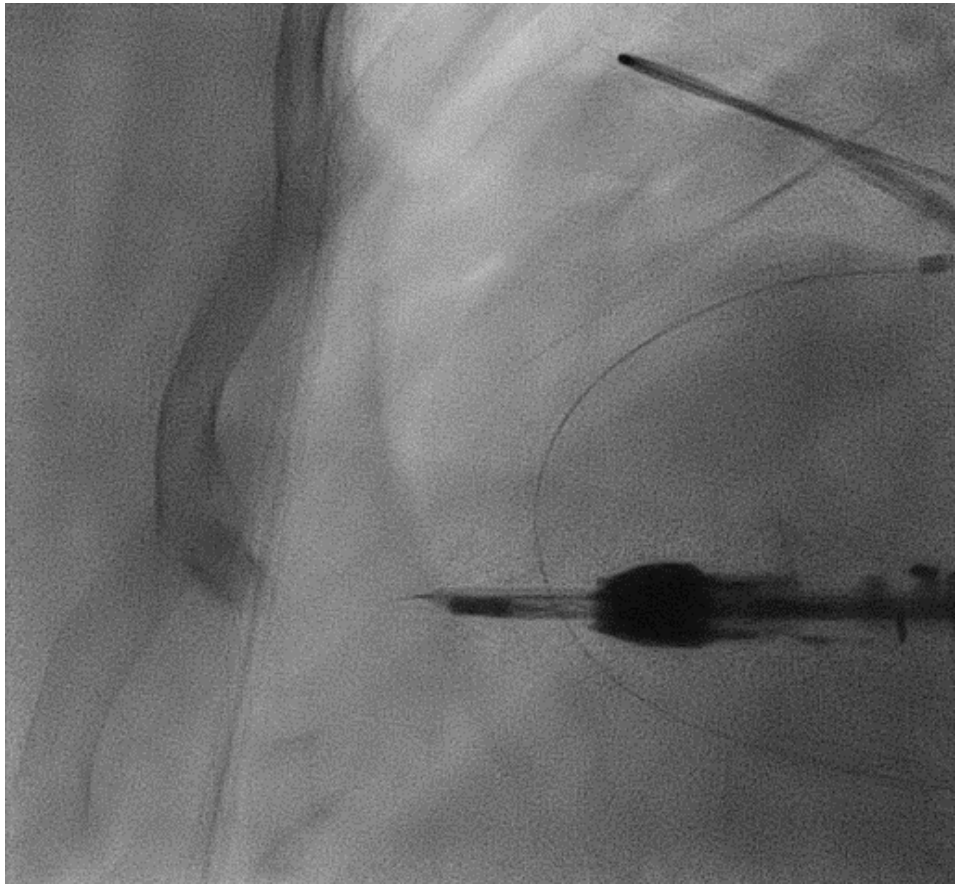
Echo (TOE/ICE) guided



Small injections of CO_2 through the microcatheter to confirm pericardial space access

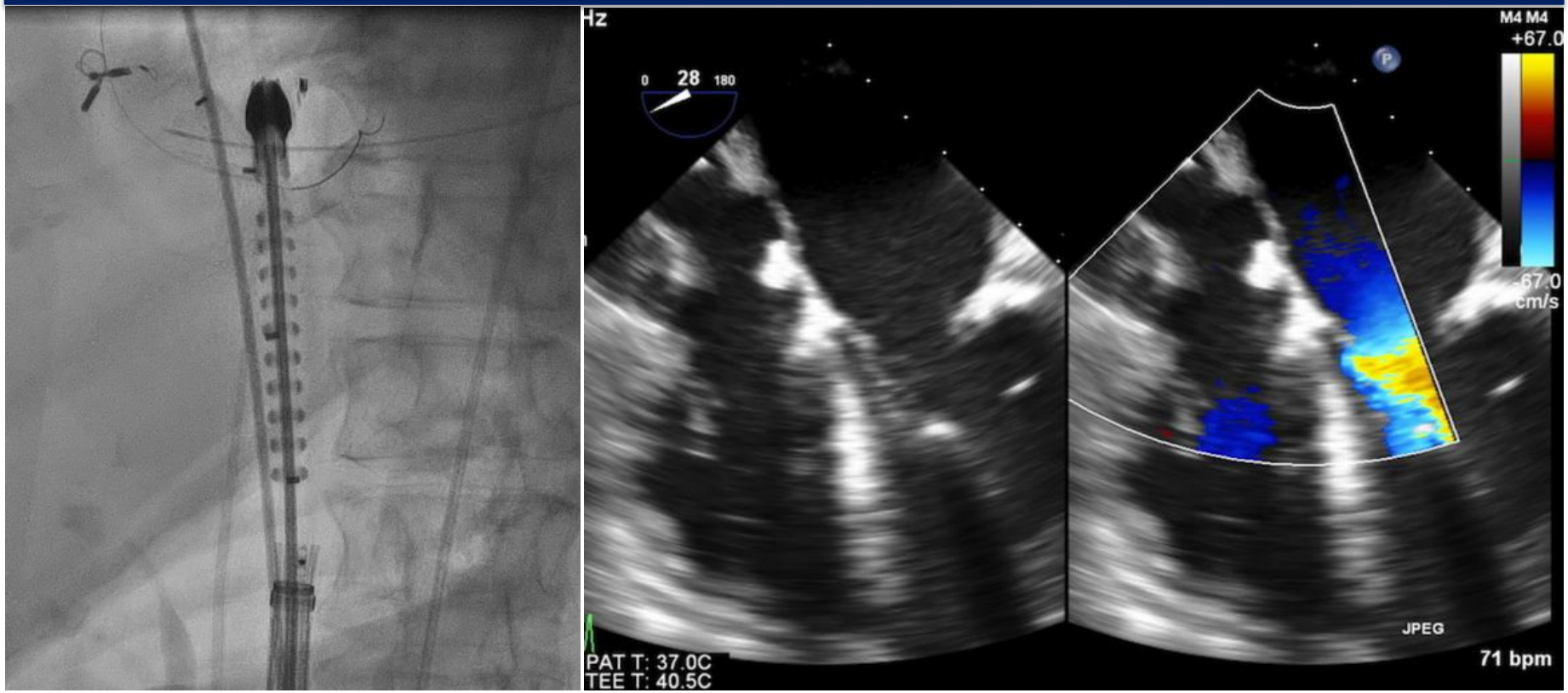
Transmural Puncture and Coil Deployment in the Pericardial Space





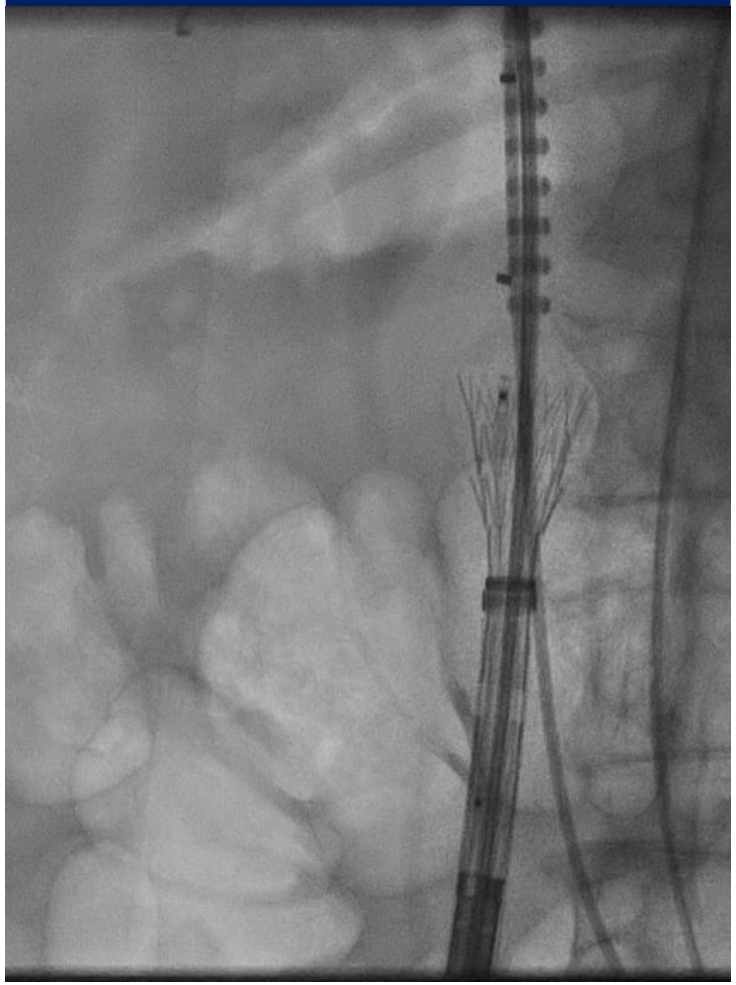
TR Reduction during System Tensioning

TR reduction monitored on fluoro and echo

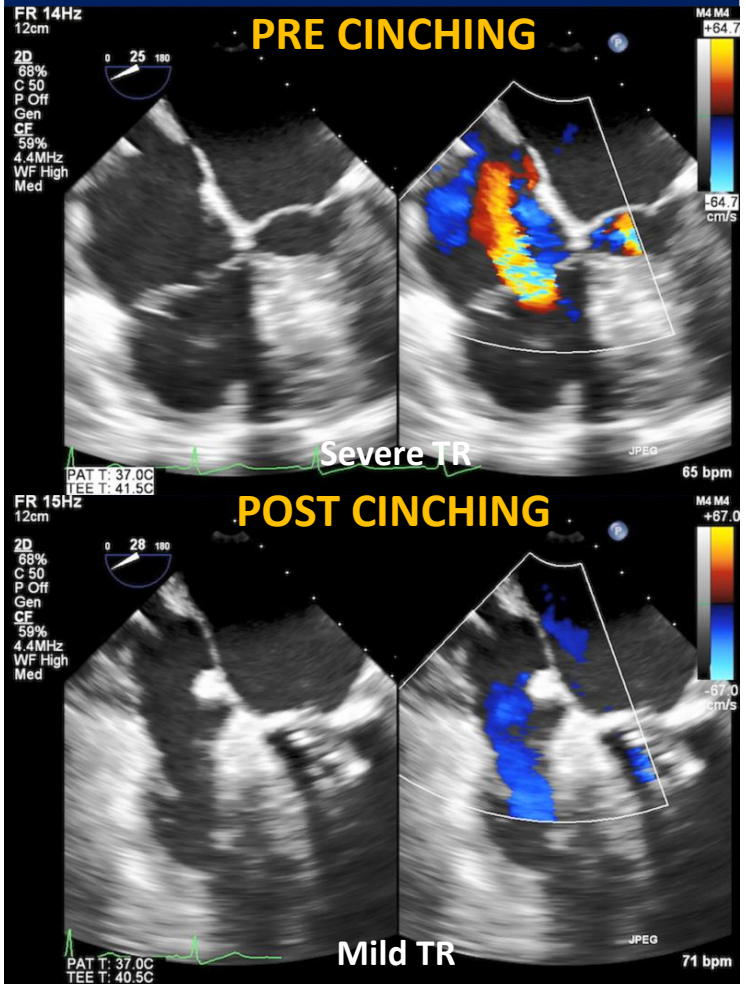


Stent Deployment and Final Result

Implantation time ≤ 60 min



Acute TR Reduction from 4+ to 1+



The TriCinch Coil TVRS System
Multicentrique, prospective Study
On going study, currently enrolling

15 centres (US* , Australie* et Europe*) / 85 patients

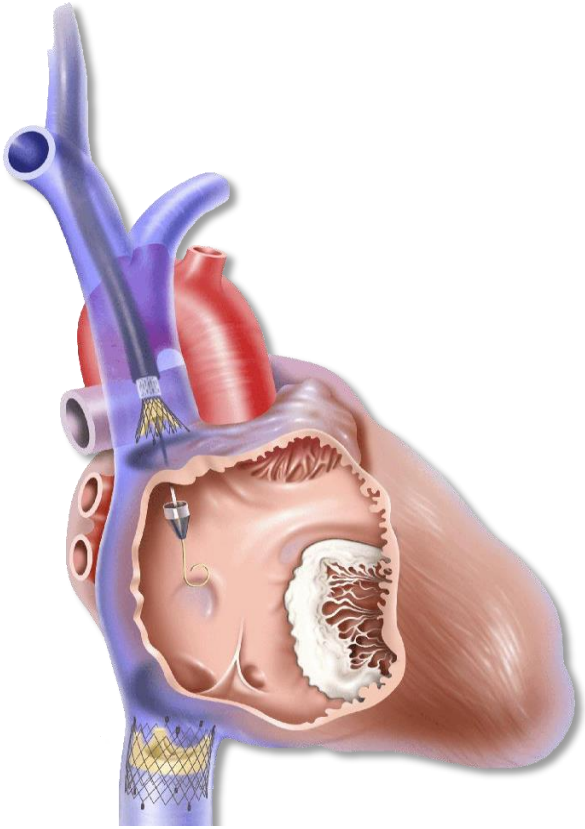
Objectifs

CE Mark approval

U.S. FDA regulated Device approval

* : actives centers enrolling patients (including Toulouse)

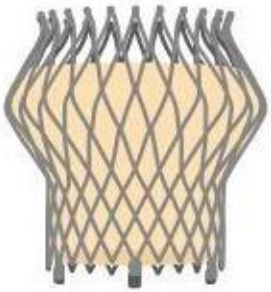
The CAVI concept



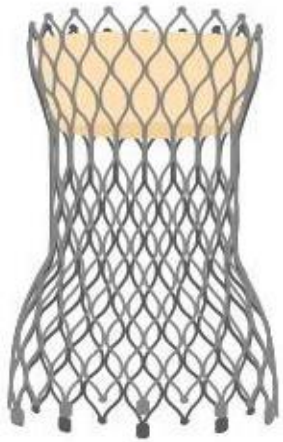
Review:

- Caval Valve Implantation
- Technology ad-hoc designed or Stent as support for TAVI implant
- Transfemoral-tranjugular access
- Risk of ventricularization of the right atrium
- About 50 cases performed
- Ongoing trials in EU and US

Devices: Self–Expanding Bioprosthetic Valves – (1st + 2nd Generation Devices)



SVC - Valve

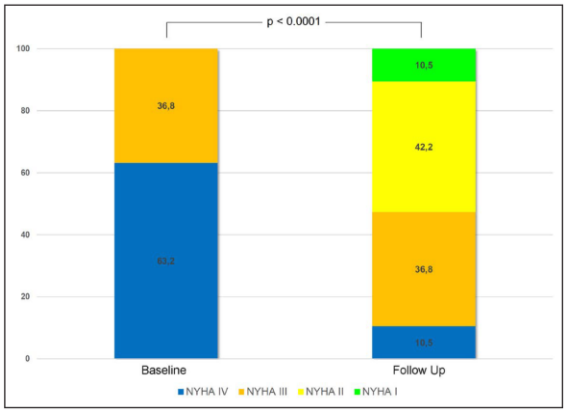


IVC - Valve

- Self-expandable pericardial tissue valve on nitinol stent frame
  - *IVC: up to 43mm*
  - *SVC: up to 38mm*
- 27F flexible catheter for trans-venous implantation

The CAVI concept
Compassionate Multicenter Study (n=25)
Combined Canada and EU cohort (6 centers)

PROCEDURE	Success	23/25	92%*
ECHO			
NYHA stage			



SAFETY	Deaths		12%
	(*In-Hospital mortality*		*24%)*
	Bleeding complication		12%
	Device-related surgery		8%**

*6 patients (24%) actually treated with BiCAVI
** 2 valves migrations

SURE	FIABLE	EFFICACE	SIMPLE	
6.9%	88%			FORMA
2.8%	100%	?		TRI CLIP
6.7%	100%			CARDIOBAND
0%	82%			TRIALIGN
0%	75%			4TECH TRICINCH*
12%	92%	?		CAVI

* La nouvelle génération est susceptible d'améliorer fiabilité et efficacité de la procédure

SURE	FIABLE	EFFICACE	SIMPLE	
				FORMA
		?		**TRI CLIP**
				CARDIOBAND
				TRIALIGN
?				**4TECH TRICINCH***
		?		CAVI

* La nouvelle génération

Conclusions

- La valve tricuspide n'est plus l'oubliée de la recherche cardiologique.
- Des technologies percutanées apparaissent dans le traitement de l' IT fonctionelle chez les patients où un traitement médical ou l'option chirurgicale n'est pas une option viable.
- Les premiers résultats avec ces systèmes de réparation percutanée de l'IT sont très encourageants en montrant la faisabilité, l'efficacité et souvent la sûreté de ces nouvelles technologies.

Conclusions

L’expérience avec ces nouvelles technologies reste préliminaire et de prochaines études sont nécessaires pour déterminer leur role dans la prise en charge de l’IT fonctionnelle.