Catheter based Mitral Valve Therapy

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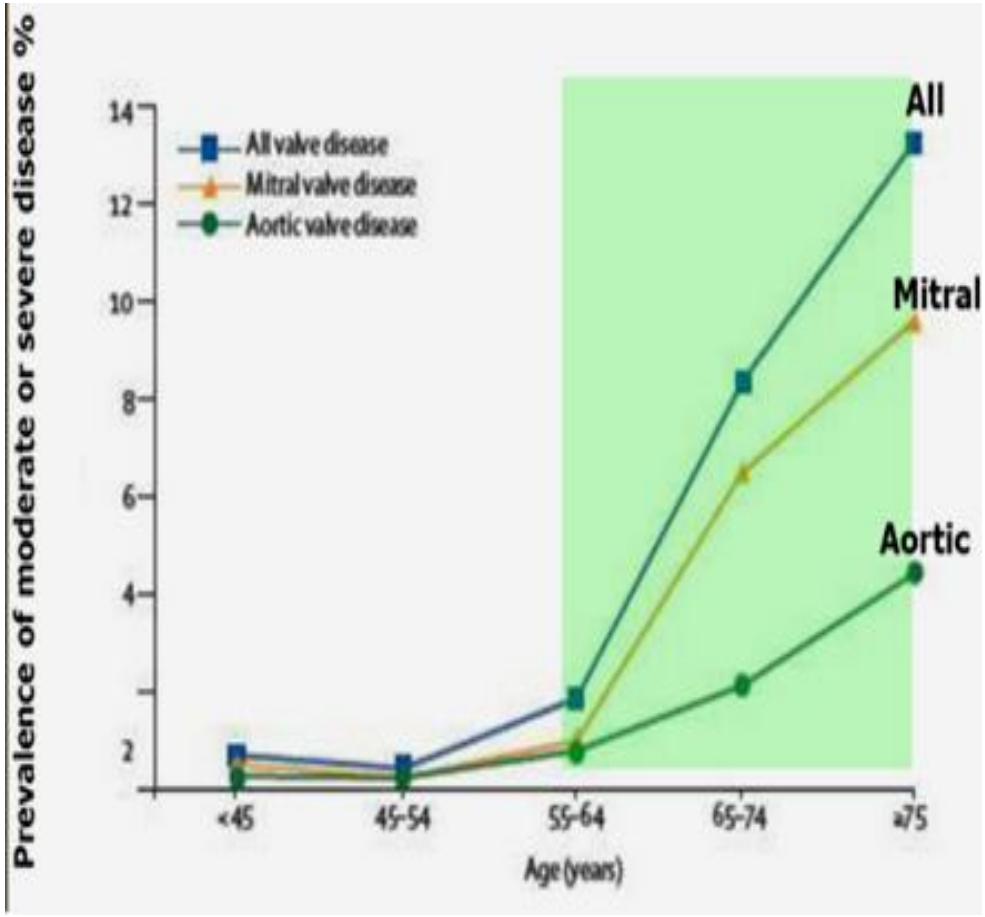
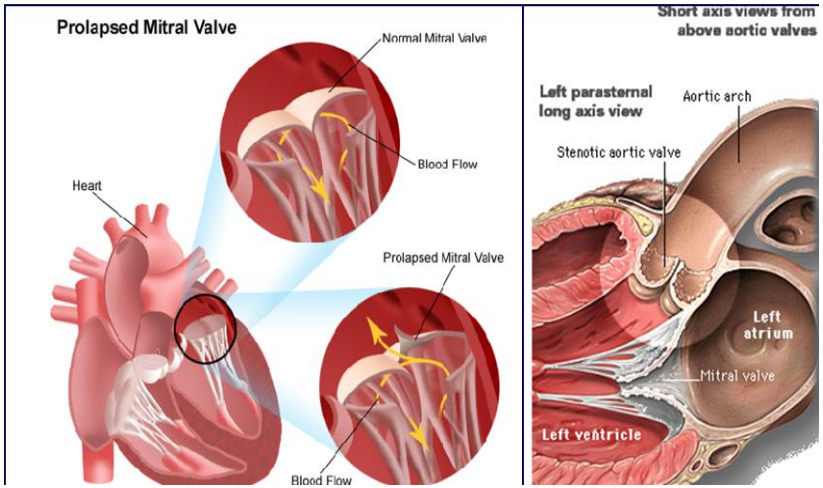
Valvular Heart Disease

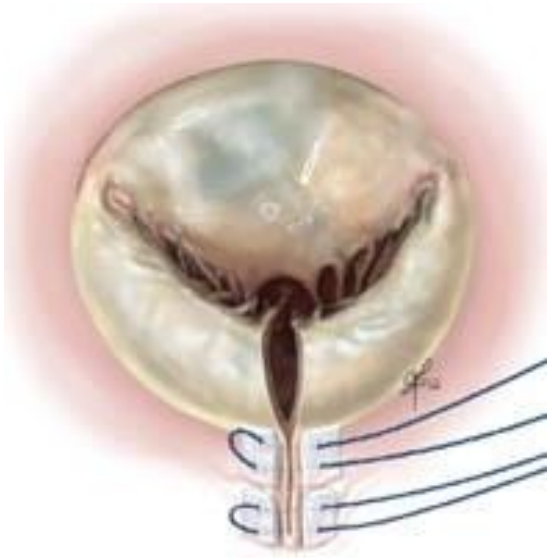
MR : 6% in population over than 55 years

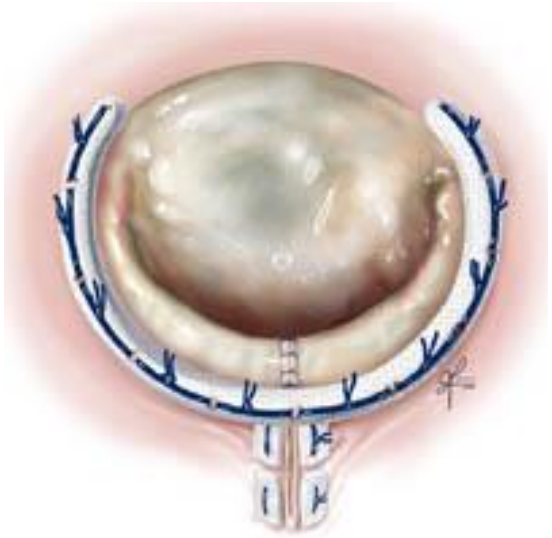


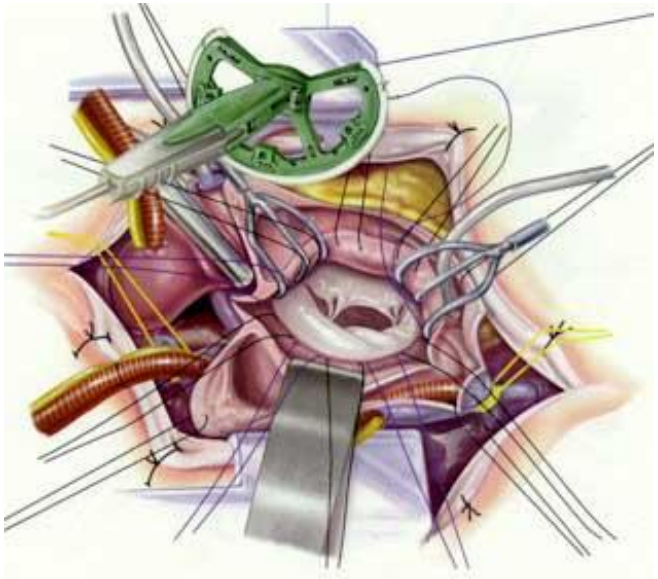


Lancet. 2006;368:1005-11

Standard Surgical Repair



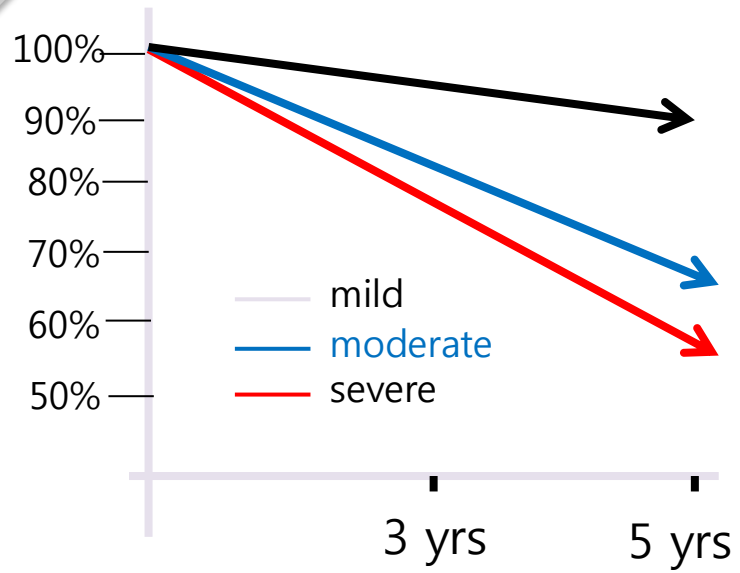




Minimal invasiveness makes patients happy

Conventional stenotomy → Catheter based approach

Survival according to MR severity



\+ **Functional** MR moderate or severe

	Surgical Probe		Lateral device	
	US	World	US	World
Procedure (annual)	50,000	150,000	250,000	750,000

Innovation is Alive in 2013

Leaflet Solutions

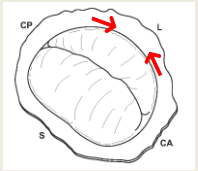
- **Evalve/Abbott MitraClip**
- **Neochord**
- **Cardiosolutions, Middle Peak Medical**

Leaflet Clip

Direct Annular Shape Change

- **Mitralign**
- **Valtech (Cardioband)**
- **Guided Delivery Systems**

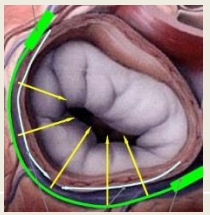
Annular Reshaping



Coronary Sinus Annuloplasty

- **Carillon**
- **Mitral Valve Cerclage**

Coronary Sinus Reshaping



Mitral Valve Replacement

- **Endovalve**
- **CardiAQ**
- Tiara
- **M-Valve**

MV Replacement

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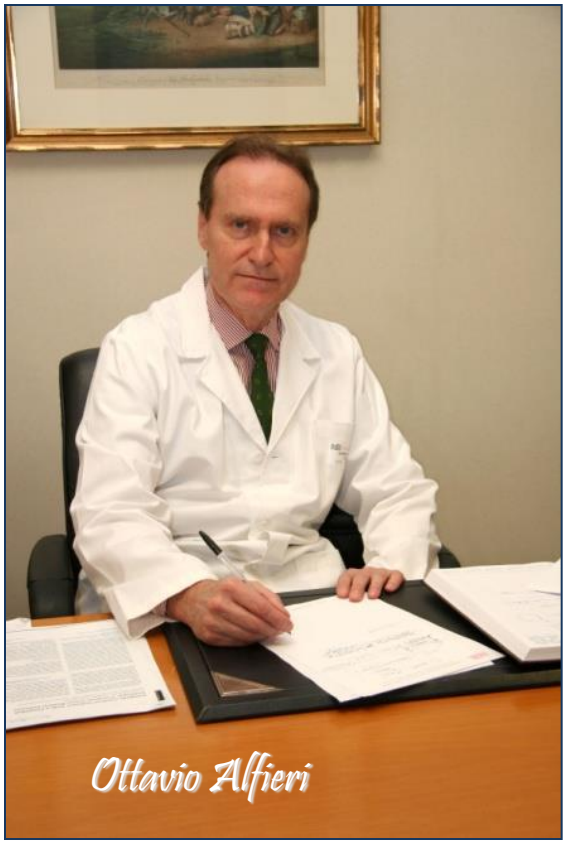
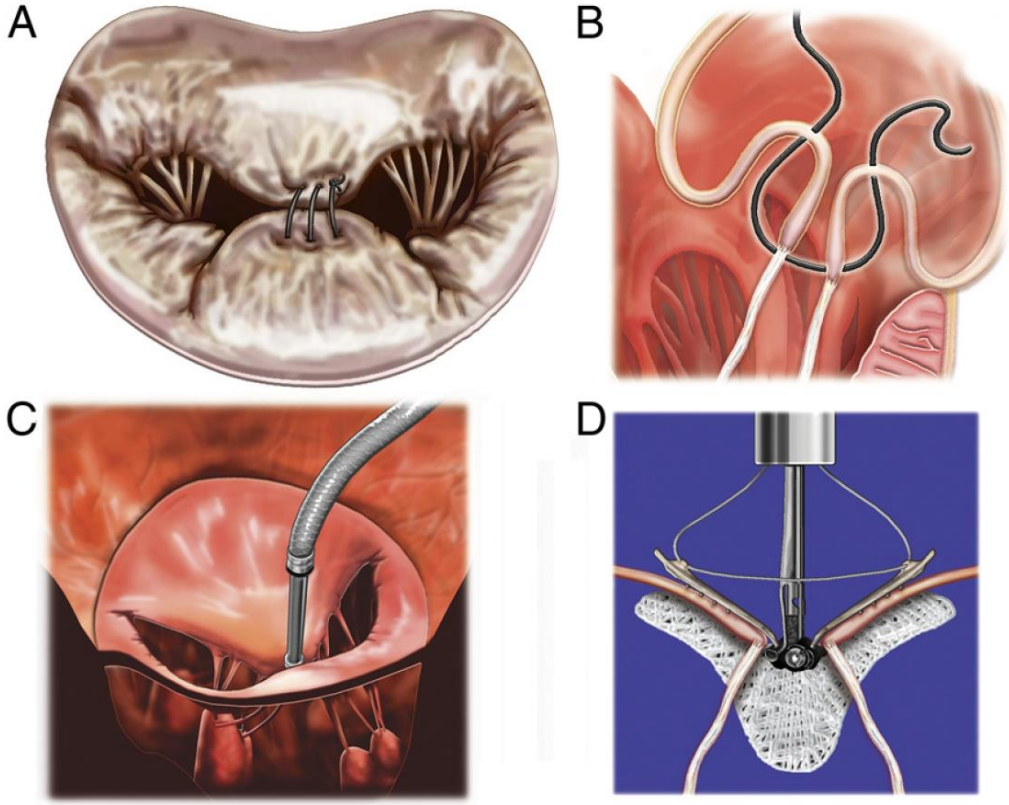
MitraClip™ Repair

Porcine model, 6 mos

TCT 2013 Jason Rodgers

Edge-to-Edge Technique





Maisano. JACC 2011;58:2174-82.

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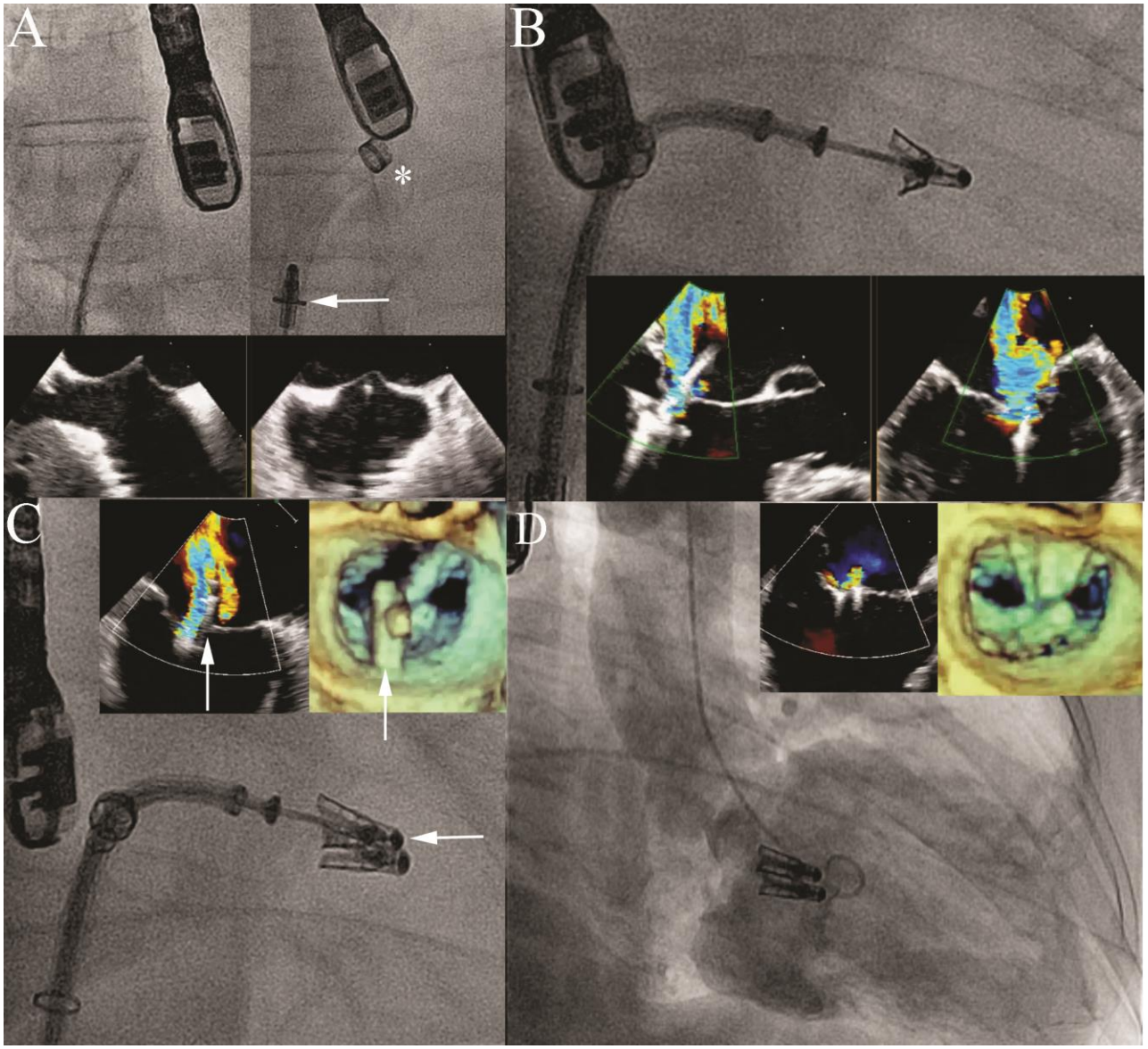
MitraClip Procedure



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MitraClip Timeline

1998
Fred St. Goar
Inception of
Catheter-based
Approach

EVEREST
Trial Completed
Published
JACC 2005

March 2008
CE-Mark
Approval

1992
OttavioAlfieri
Reports
Edge to Edge
Technique

June 2003
First Human
Implants
Caracas
Jose Condado,
Then Ted Feldman, Evanston IL

October 2008
EVEREST II
Trial Completed,
Published
NEJM 2011

FDA
Approval
Oct 25,
2013

Worldwide Experience > 10,000

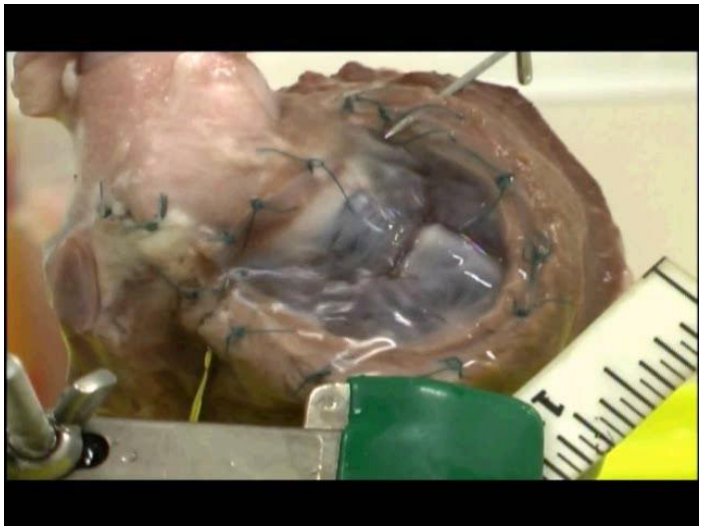
Study	Population	N*
EVEREST I (Feasibility)	Feasibility patients	55
EVEREST II (Pivotal)	Pre-randomized patients	60
EVEREST II (Pivotal)	Non-randomized patients (High Risk Study)	78
EVEREST II (Pivotal)	Randomized patients (2:1 Clip to Surgery)	279 184 Clip 95 Surgery
REALISM (Continued Access)	Non-randomized patients	881
Compassionate/Emergency Use	Non-randomized patients	66
ACCESS Europe Phase I	Non-randomized patients	567
ACCESS Europe Phase II	Non-randomized patients	286
Commercial Use	Commercial patients	8,556
Total		**10,733** **+95 surgery**

*Data as of 9/30/2013. Source: Abbott Vascular

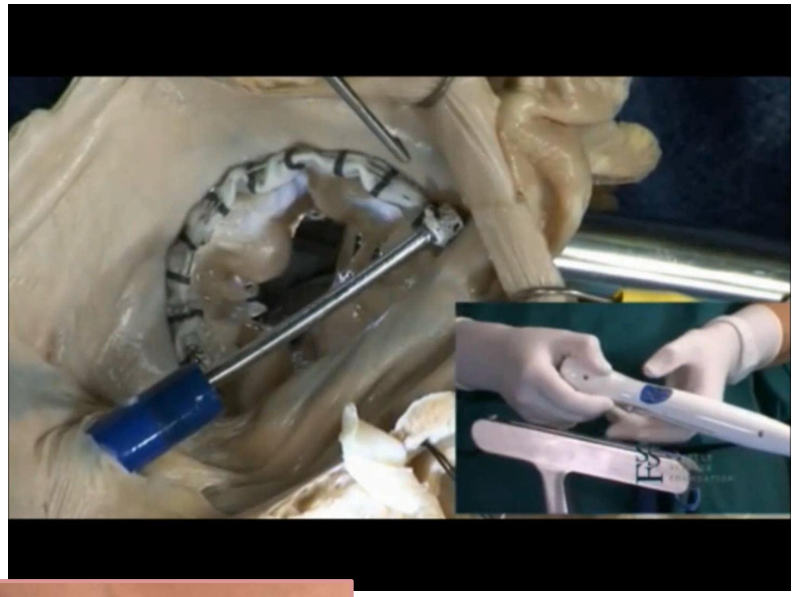
Direct Annular Shape Change Technologies

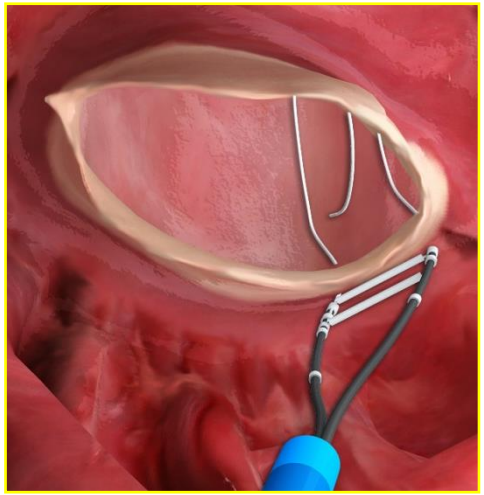
Direct Annuloplasty

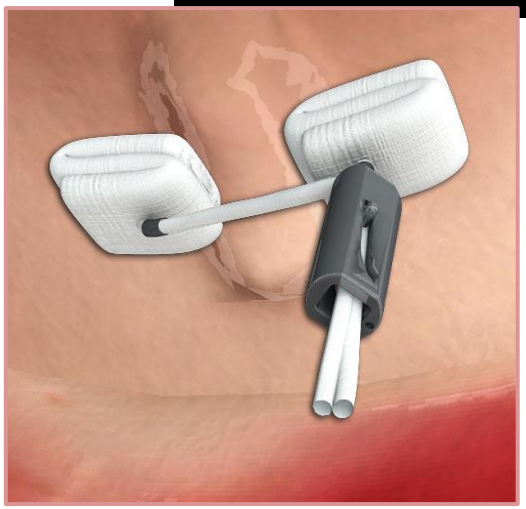
Guided Delivery System



Cardioband



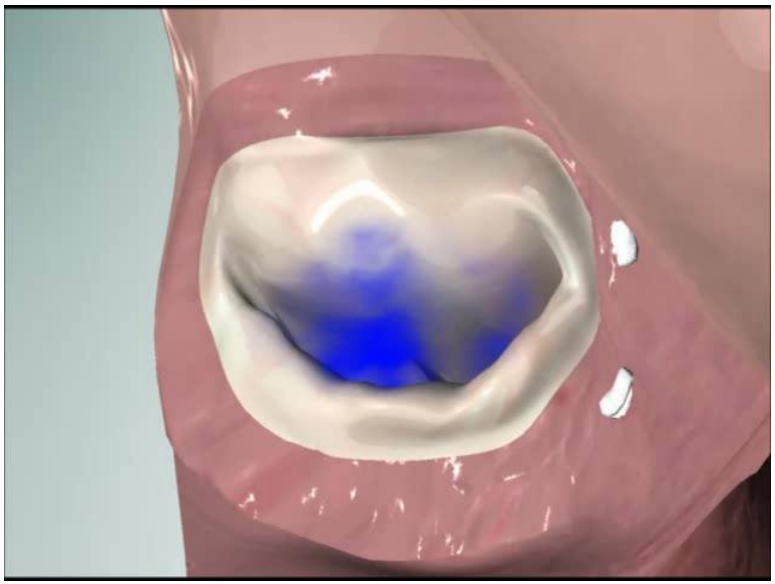




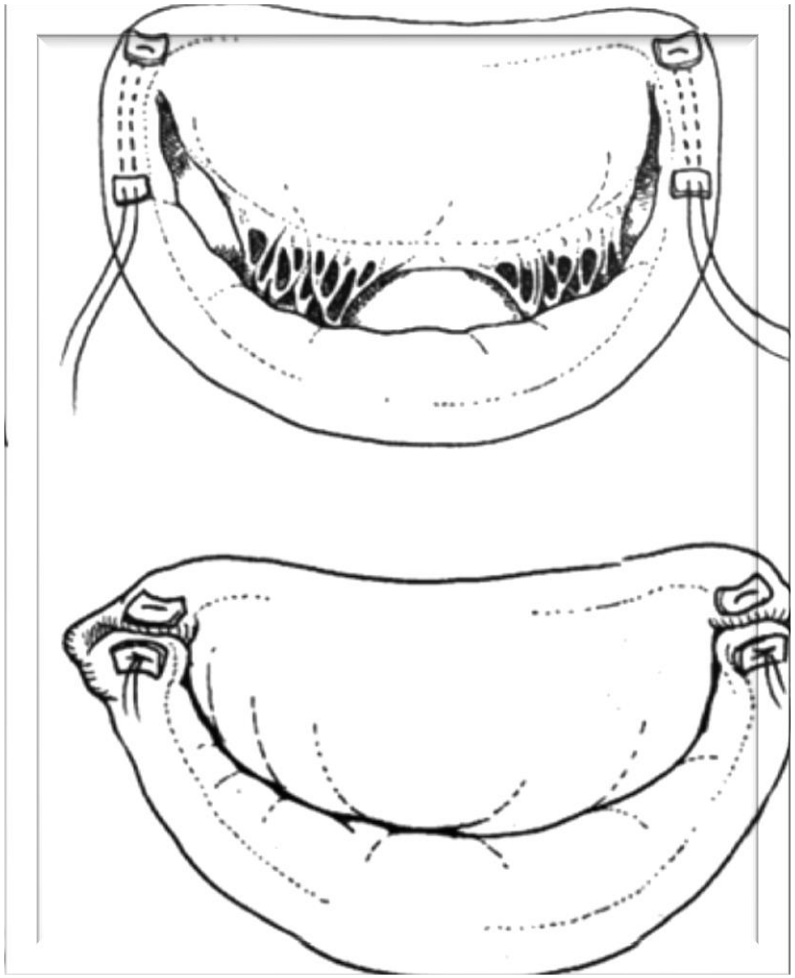
Mitralign

Mitralign

: procedure based on successful surgical procedure



Reduction of the posterior mitral annulus to coapt



Kay annuloplsty

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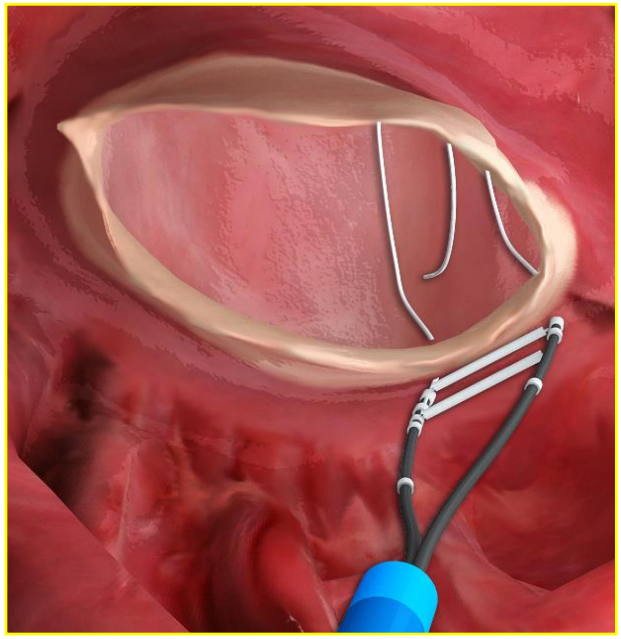
Mitralign Procedural Steps

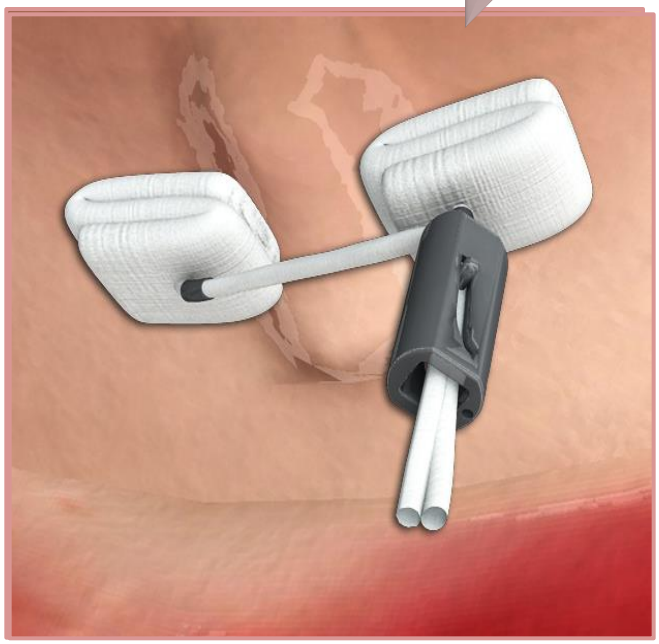
Three main components

Wire Placement

Pledget Delivery

Plication & Lock





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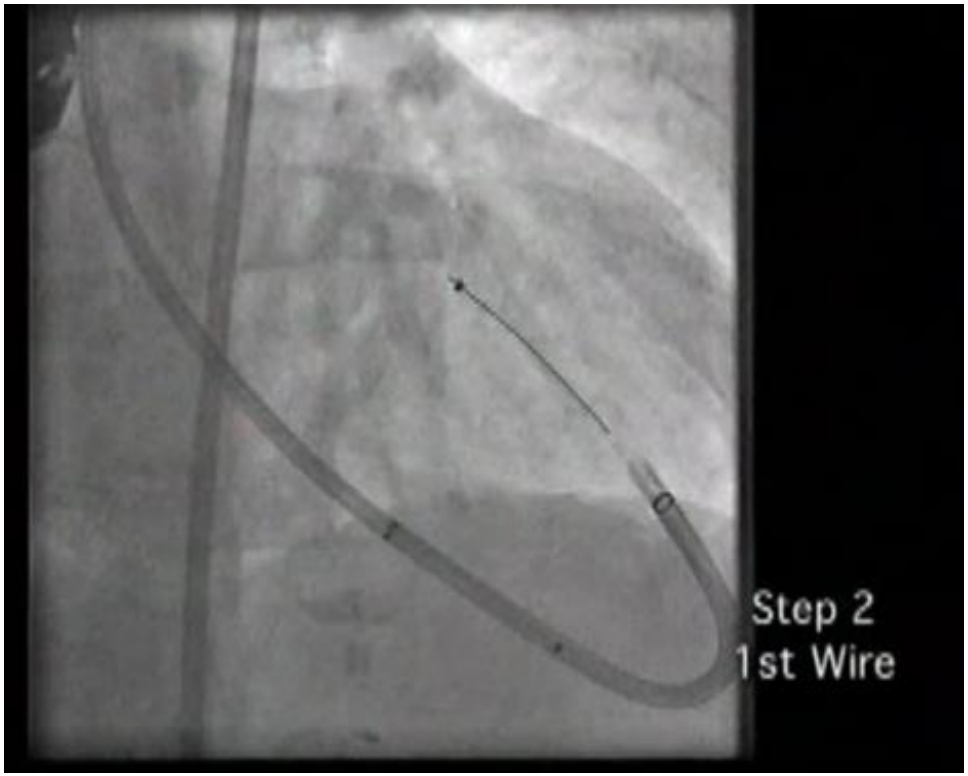
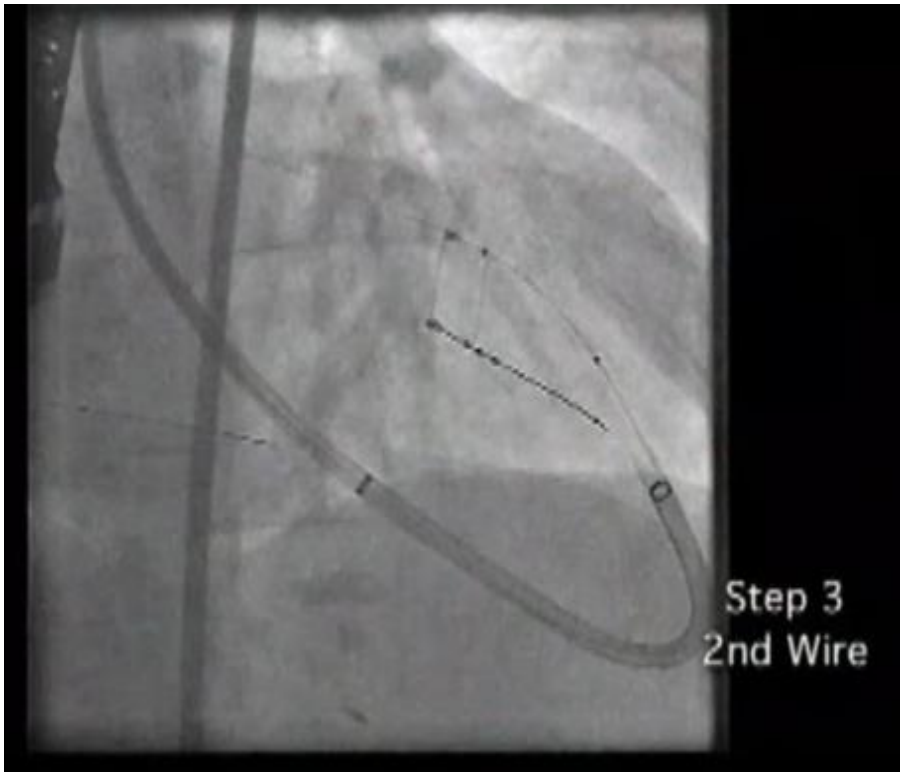
Wire Placement:

1st wire and 2nd wires delivered





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Mitralign Clinical Update

Treatment of FMR in symptomatic patients with MR ≥ 2+

CE Mark Study is on-going

- > 50 % complete (43/61)
- Expect enrollment to be complete in Q4 ‘13
- Expect CE Mark by Q2 ’14

2nd Generation

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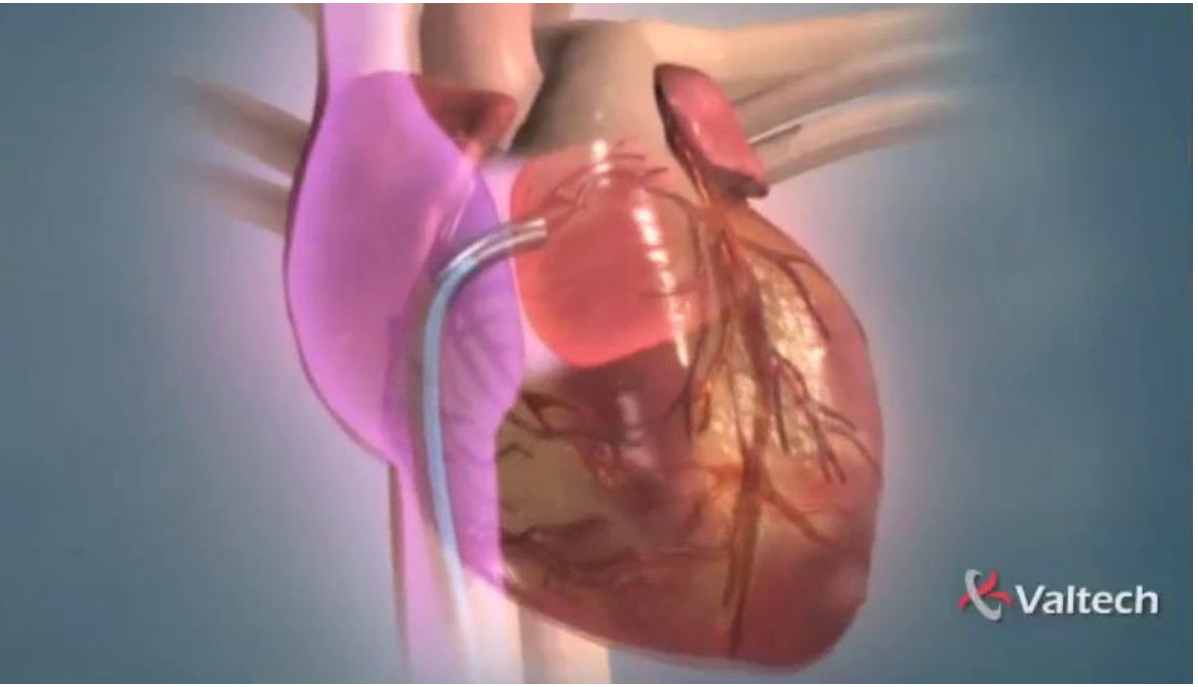
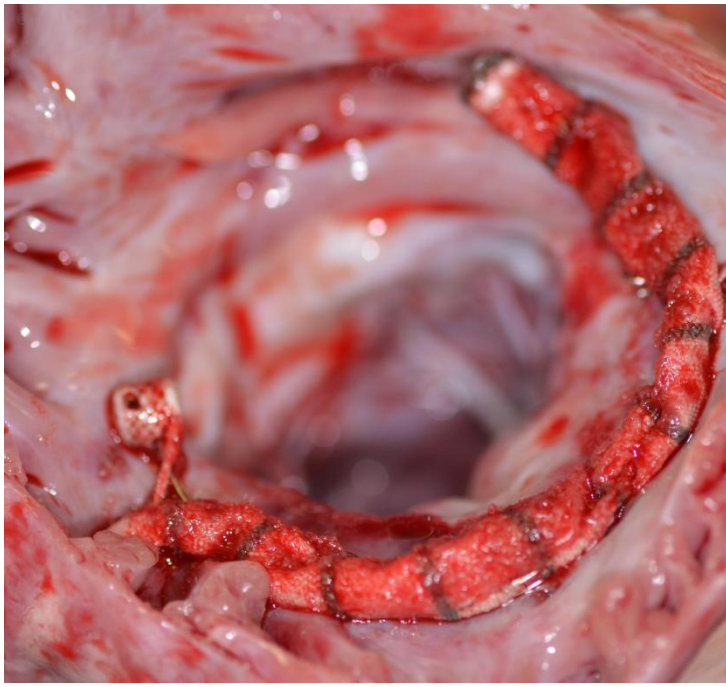
Valtech Cardioband

a surgical ring implanted percutaneously

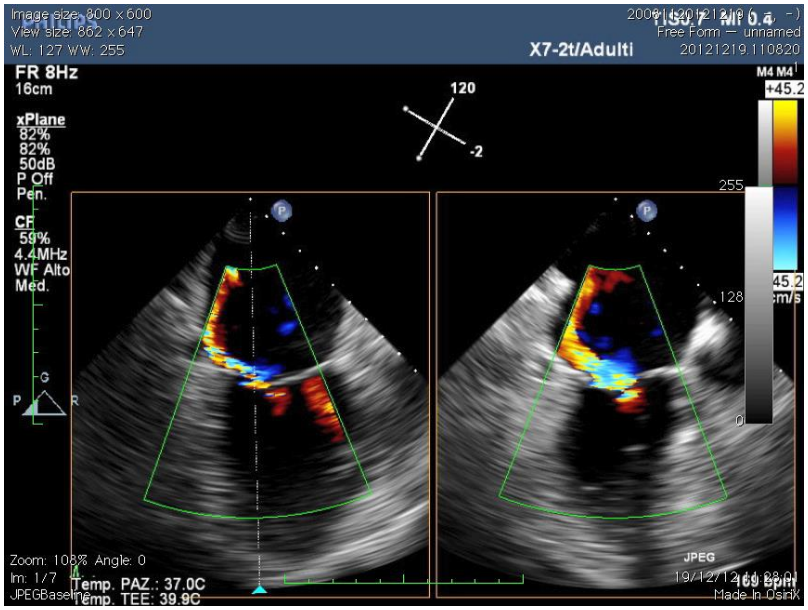


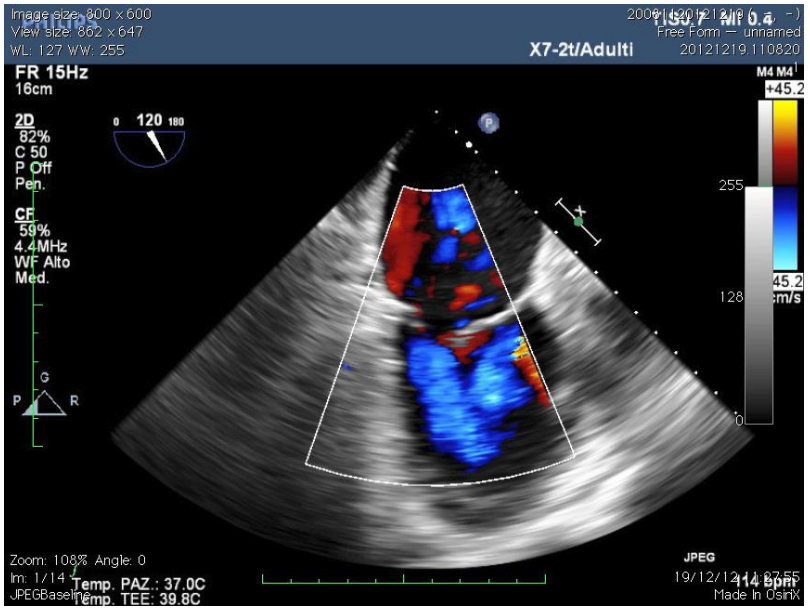


TCT 2013, Francesco Maisano

FIM, Feb 2013, San Raffaele Hospital, Milano, Italy

high risk IMR patient with previous CABG, Severe type IIIb MR





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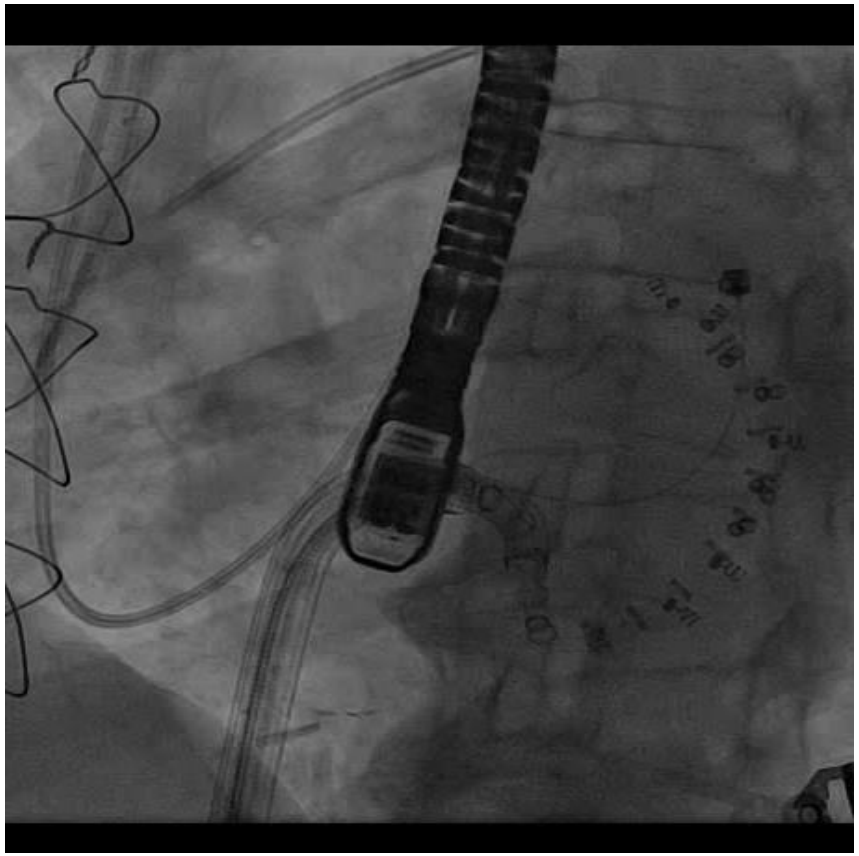
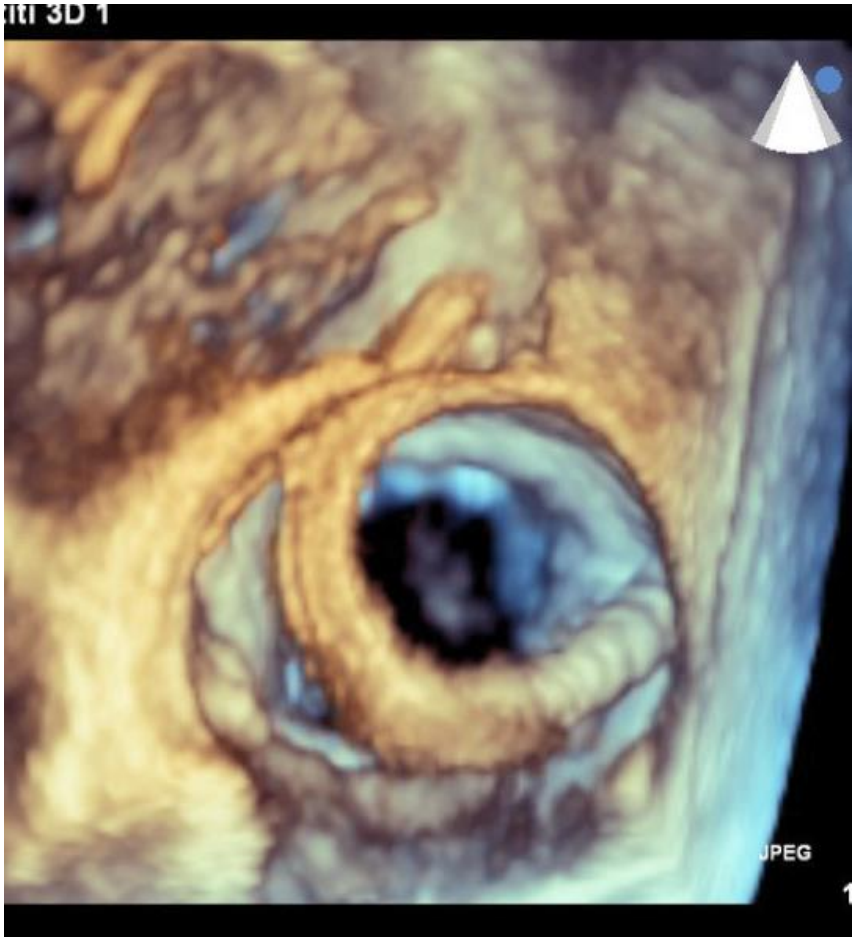
Fluoro and echo guidance





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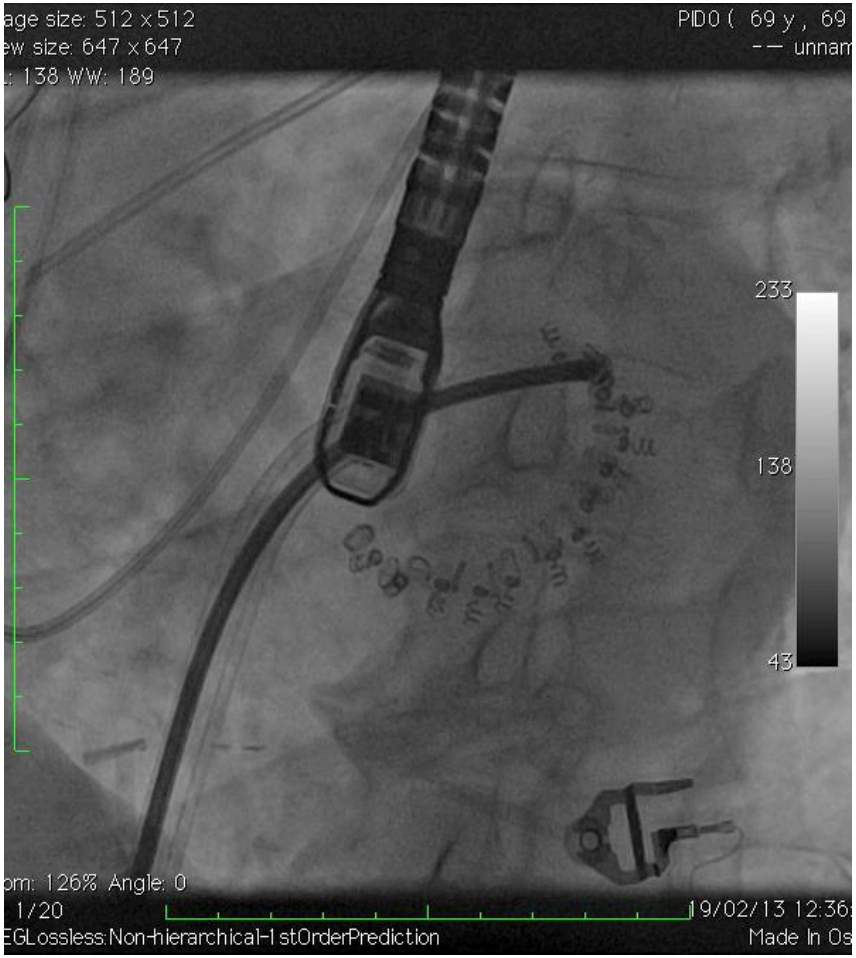
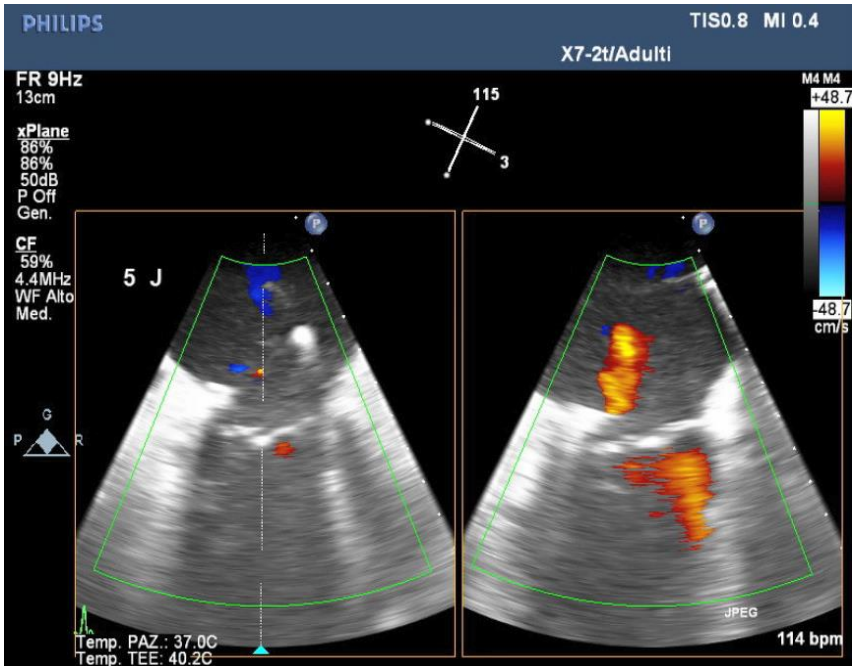
Cardioband contraction 40%





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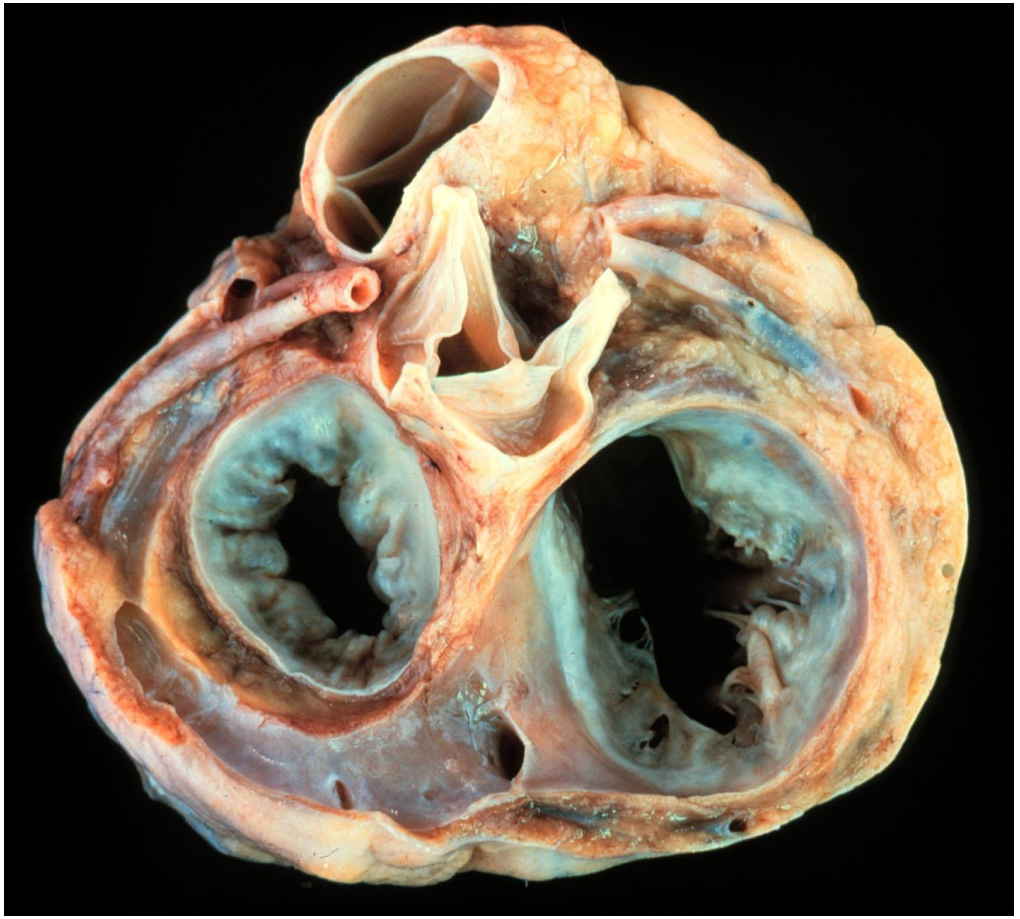
The Coronary Sinus Approach to Mitral Regurgitation : **Easy and Simple!!**

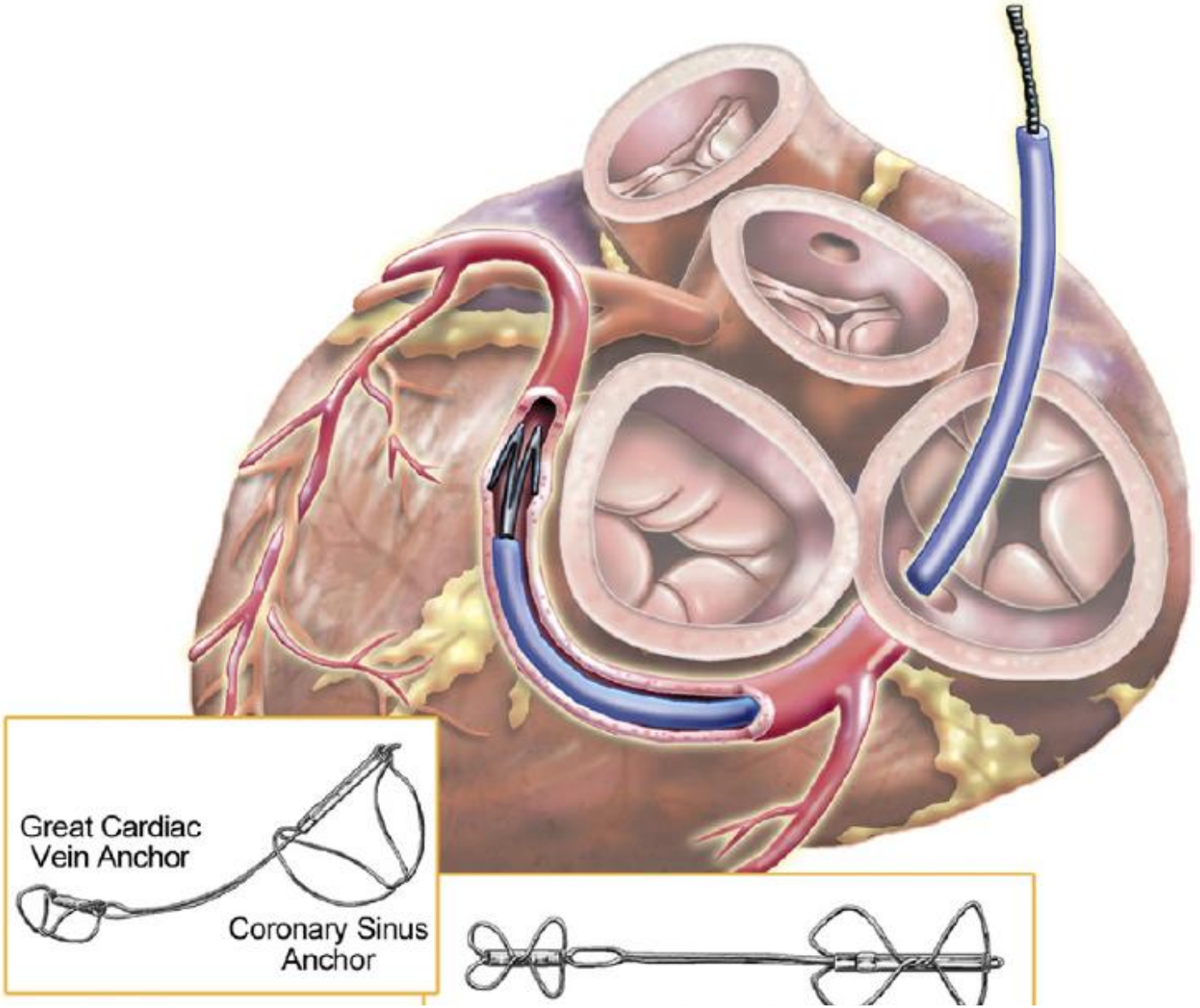
Takes advantage
of proximity of CS
to the mitral annulus

Easy access to CS

CS approach doesn't need **Sophisticated imaging guidance**

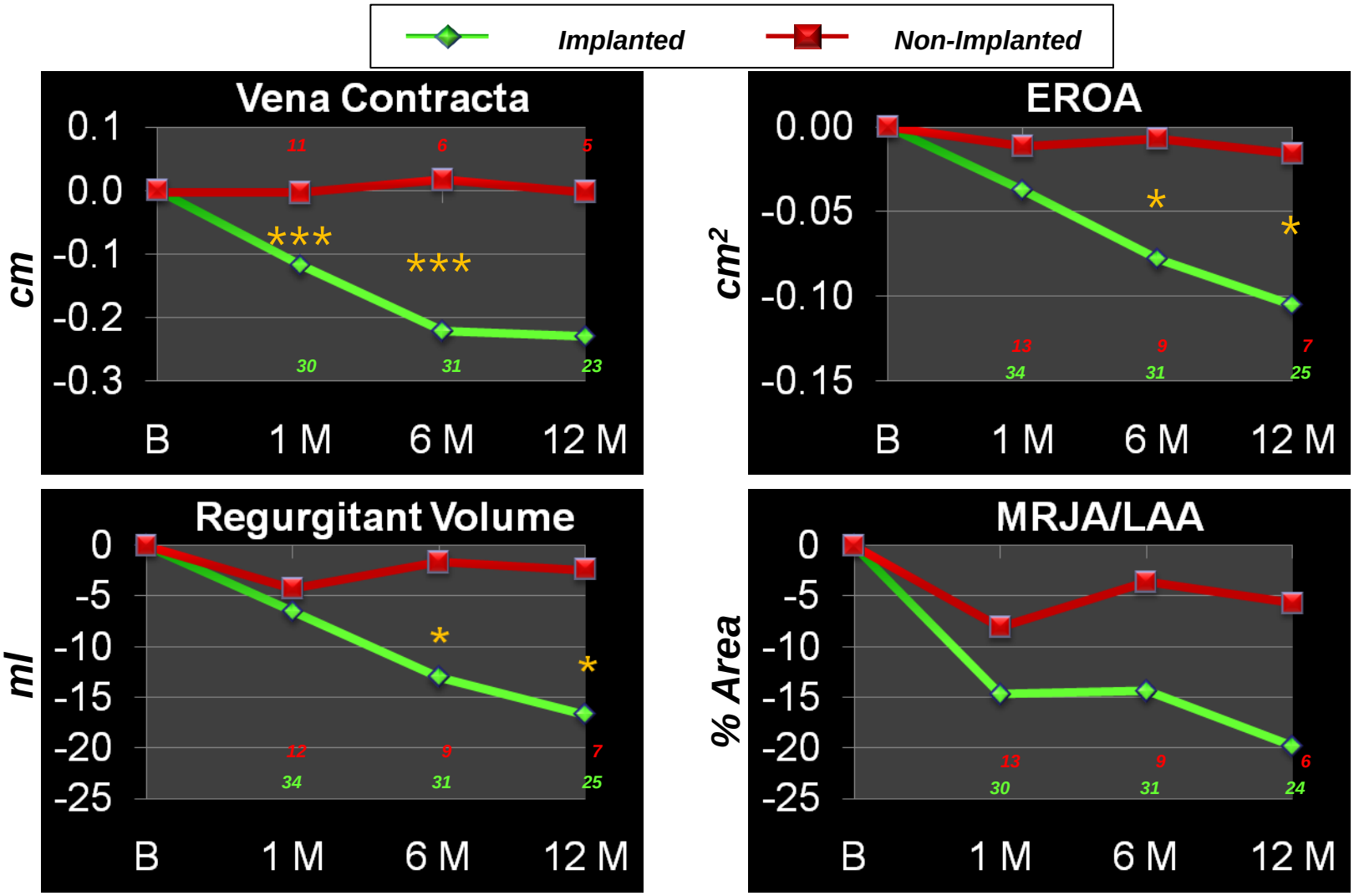


Carillon



TITAN – MR Results

Absolute differences from baseline

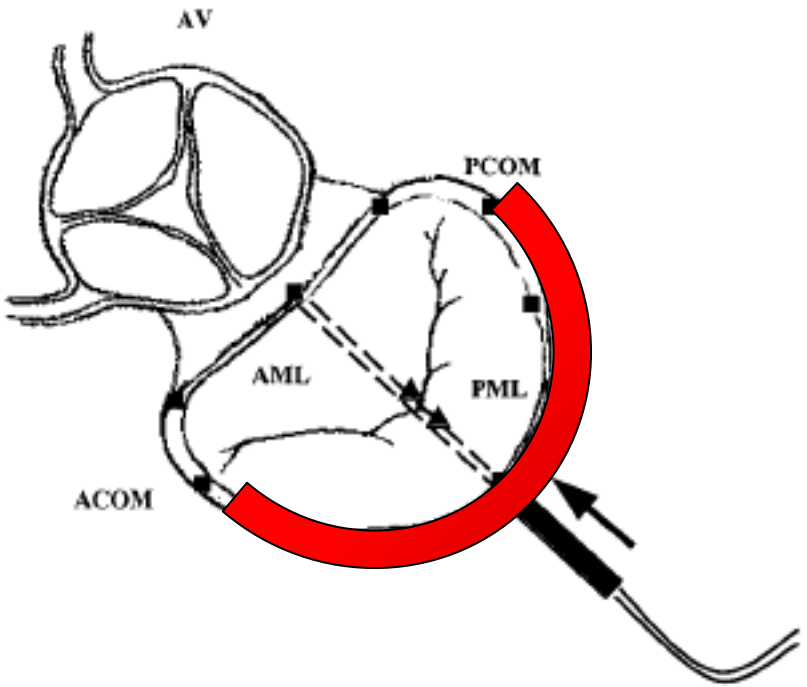


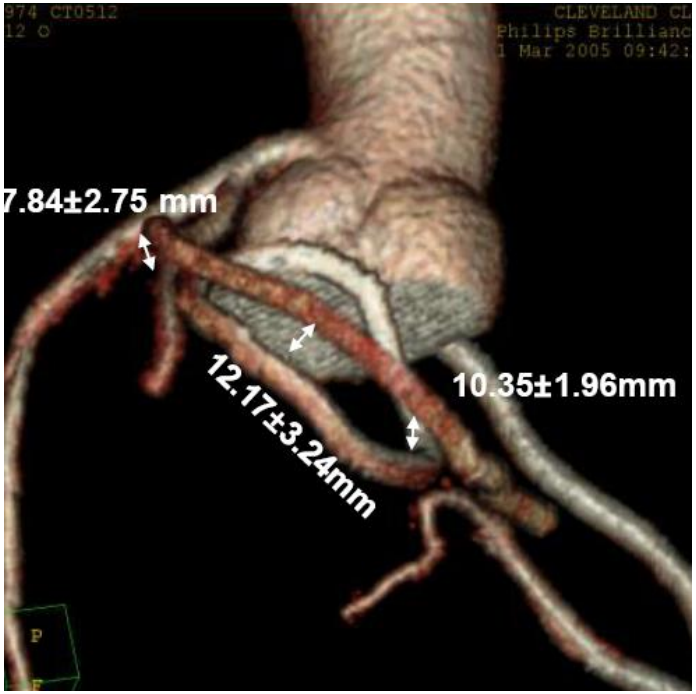
*p<0.05, **p<0.01, ***p<0.001

Paired between groups comparison of absolute differences from baseline

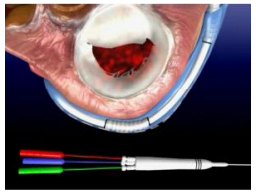
Siminiak et al, Eur J Heart Failure 2012

Sino-annular discordance+ partial ring tension ?

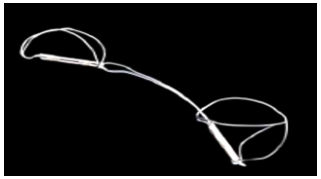




Monarc



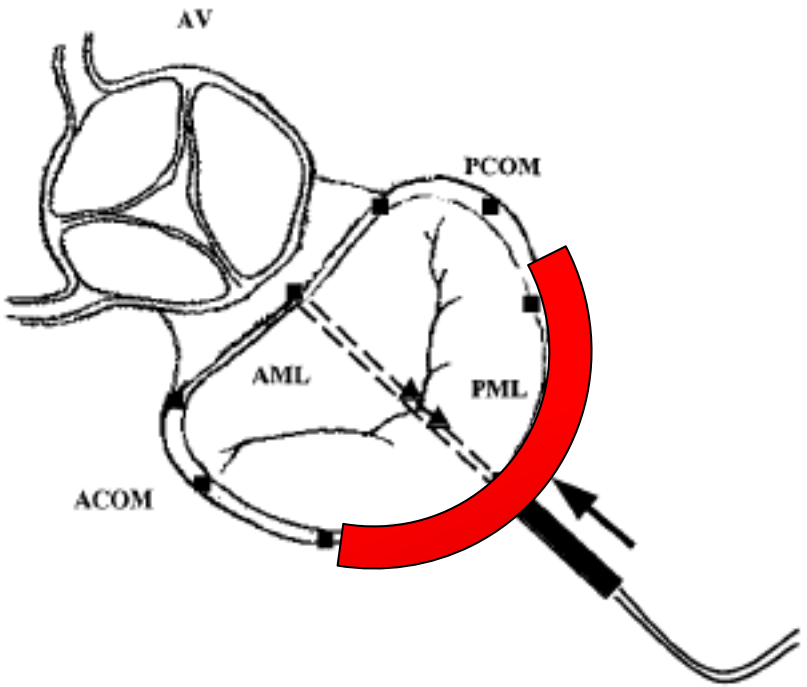
Viacor

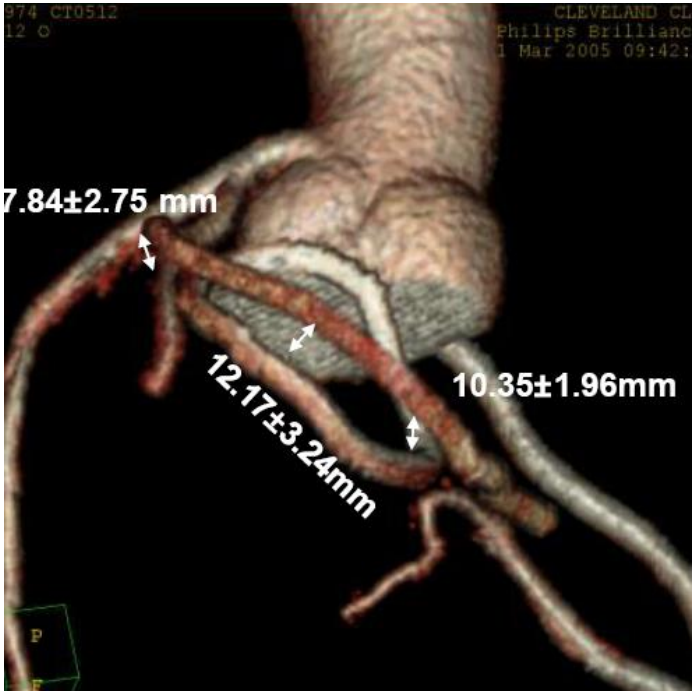


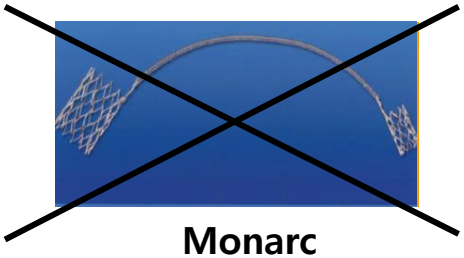
Carillon

Sino-annular discordance+ partial ring tension ?

Lesser efficacy ! Program shut down…







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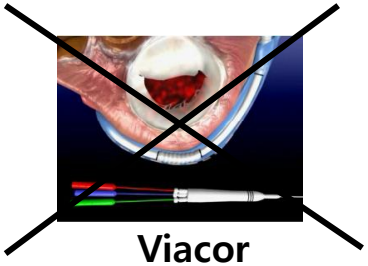

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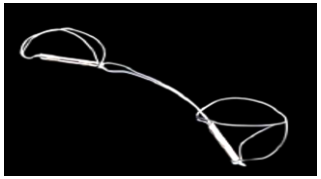

Carillon

MCA (Mitral Cerclage Annuloplsty)

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PRE-CLINICAL RESEARCH

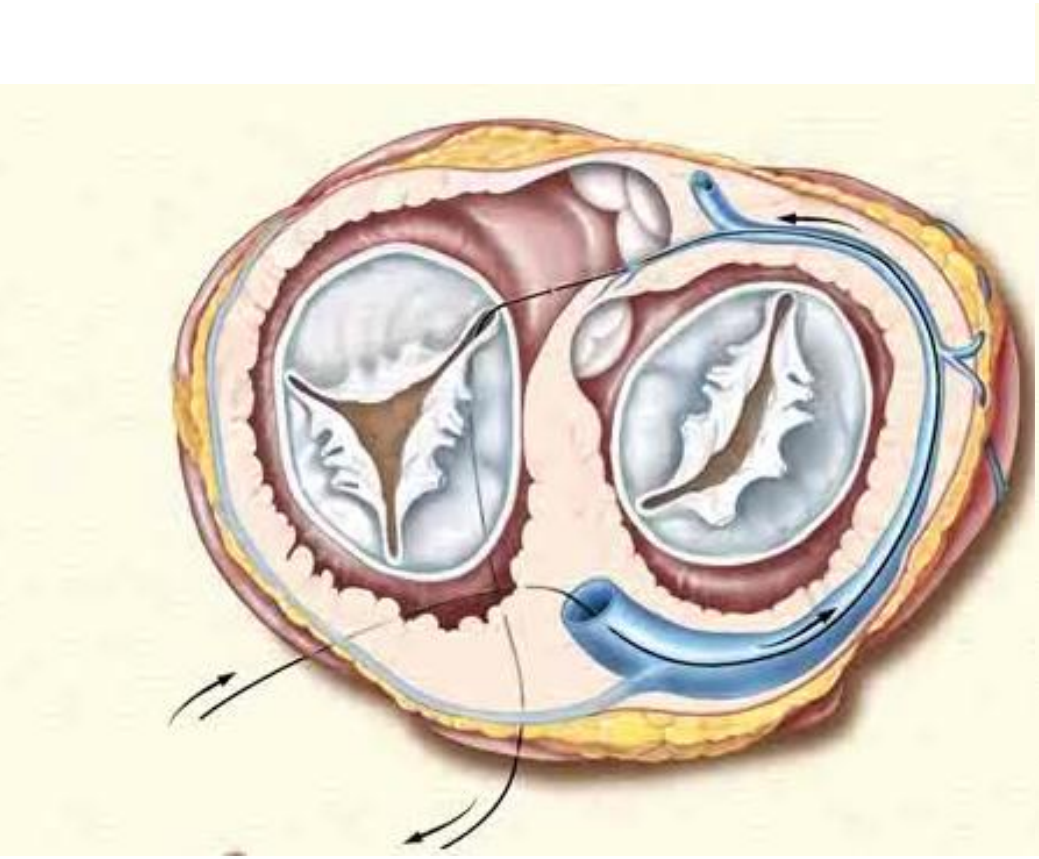
Mitral Cerclage Annuloplasty, A Novel Transcatheter Treatment for Secondary Mitral Valve Regurgitation

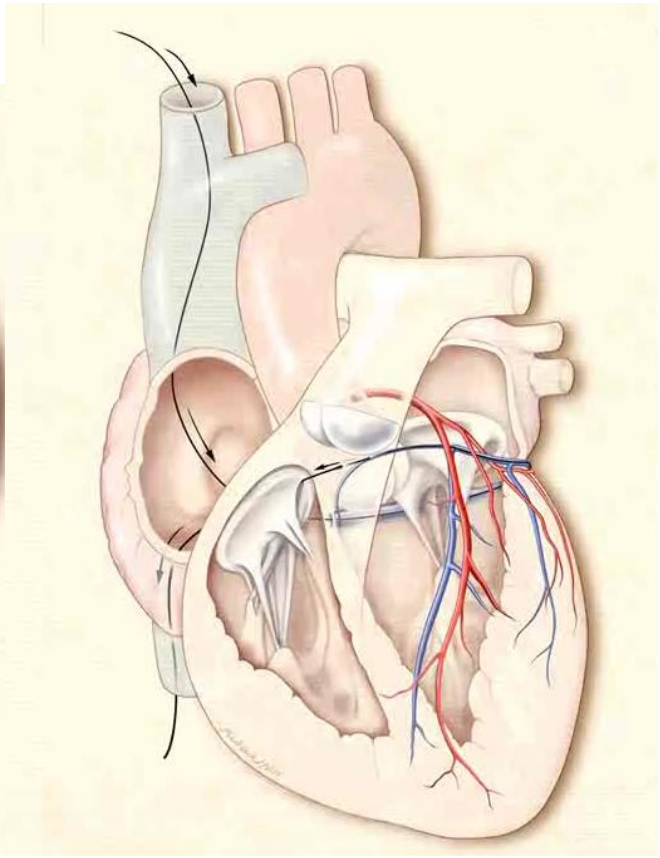
Initial Results in Swine

June-Hong Kim, MD,*† Ozgur Kocaturk, MSc,* Cengizhan Ozturk, PhD, MD,*‡
Anthony Z. Faranesh, PhD,* Merdim Sonmez, MSc,*‡ Smita Sampath, PhD,* Christina E. Saikus, BS,*
Ann H. Kim, BS,* Venkatesh K. Raman, MD,* J. Andrew Derbyshire, PhD,* William H. Schenke, BS,*
Victor J. Wright, BS,* Colin Berry, PhD, MD,* Elliot R. McVeigh, PhD,* Robert J. Lederman, MD*

Bethesda, Maryland; Busan, Korea; and Istanbul, Turkey

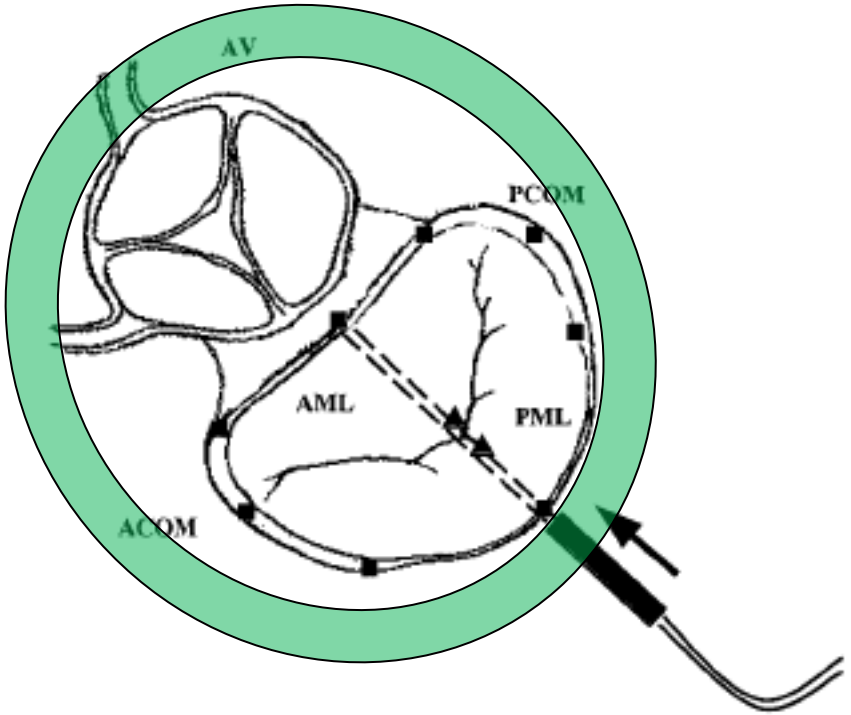
The unique design of MCA (mitral cerclage annuloplsty)

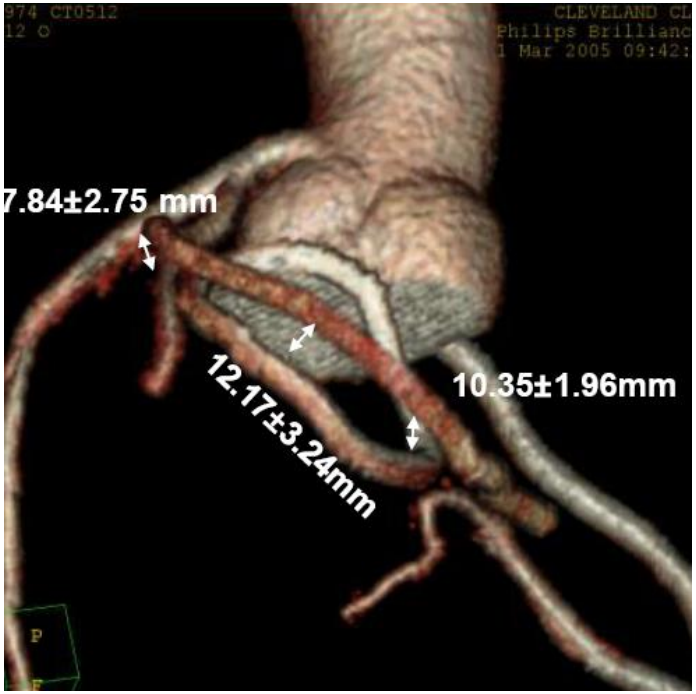




Specially designed in order to deliver circumferential tension around MV annulus

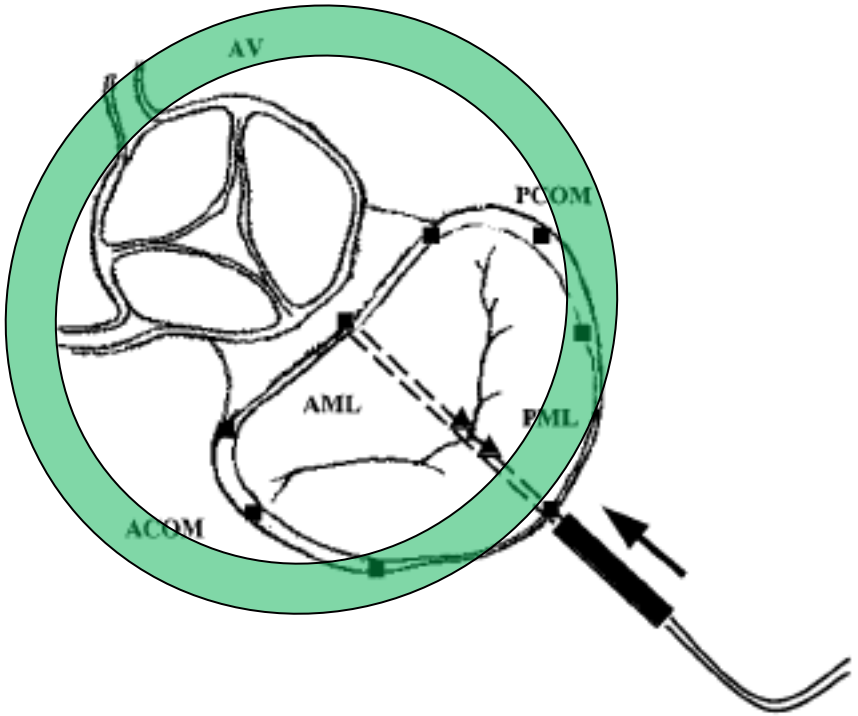
Sino-annular discordance + circumferrential tension….yes! It really works!

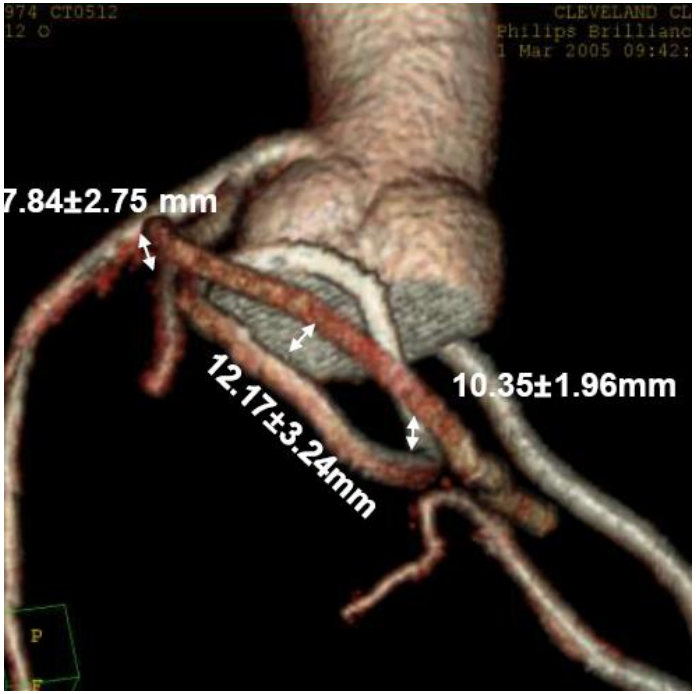




MVA deilivers circumferrential tension around MV annulus

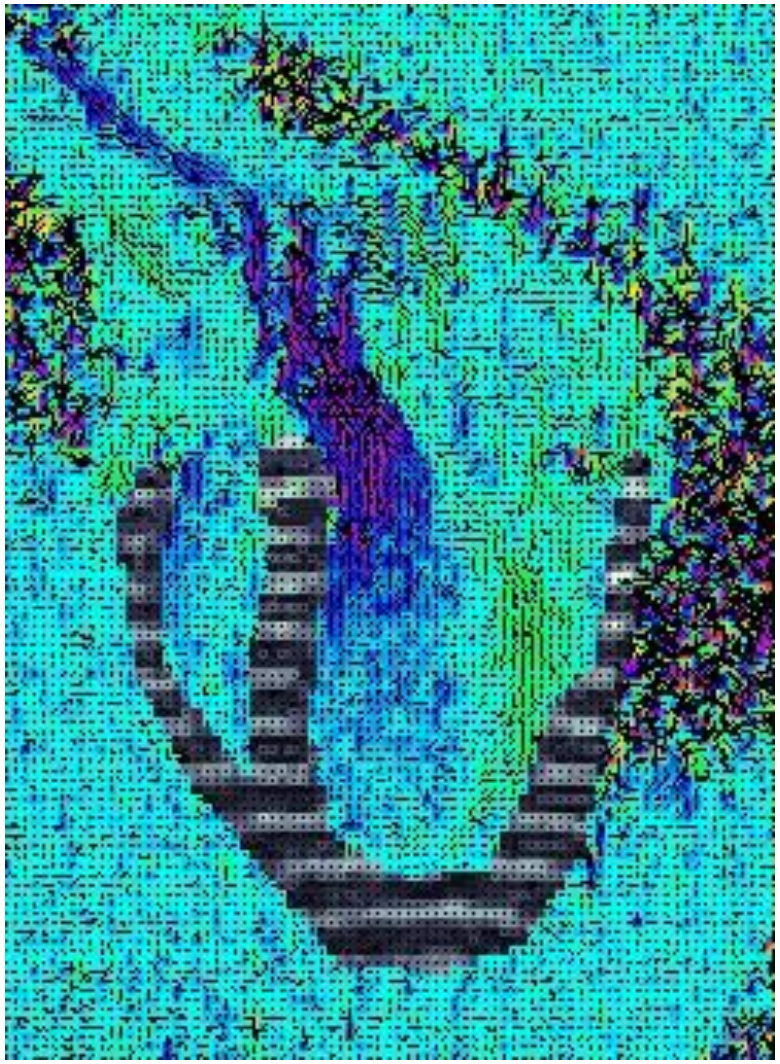
Sino-annular discordance + circumferrential tension….yes! It really works!



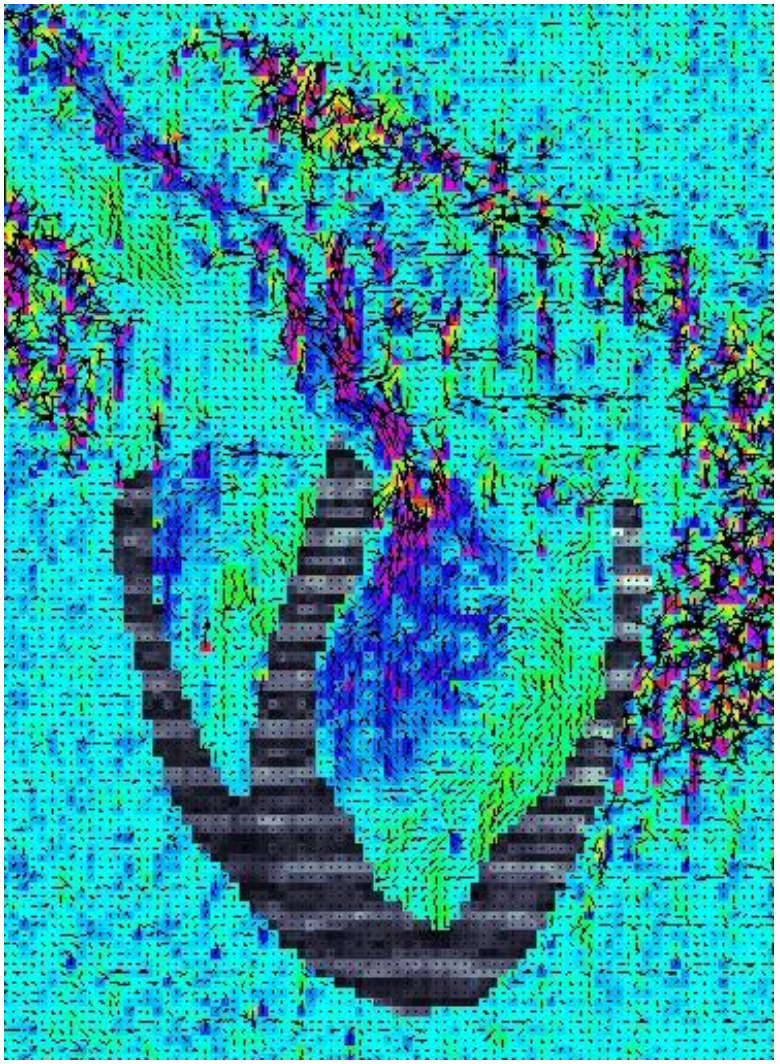


MVA deilivers circumferrential tension around MV annulus

MCA never fail to reduce functional MR!



No tension

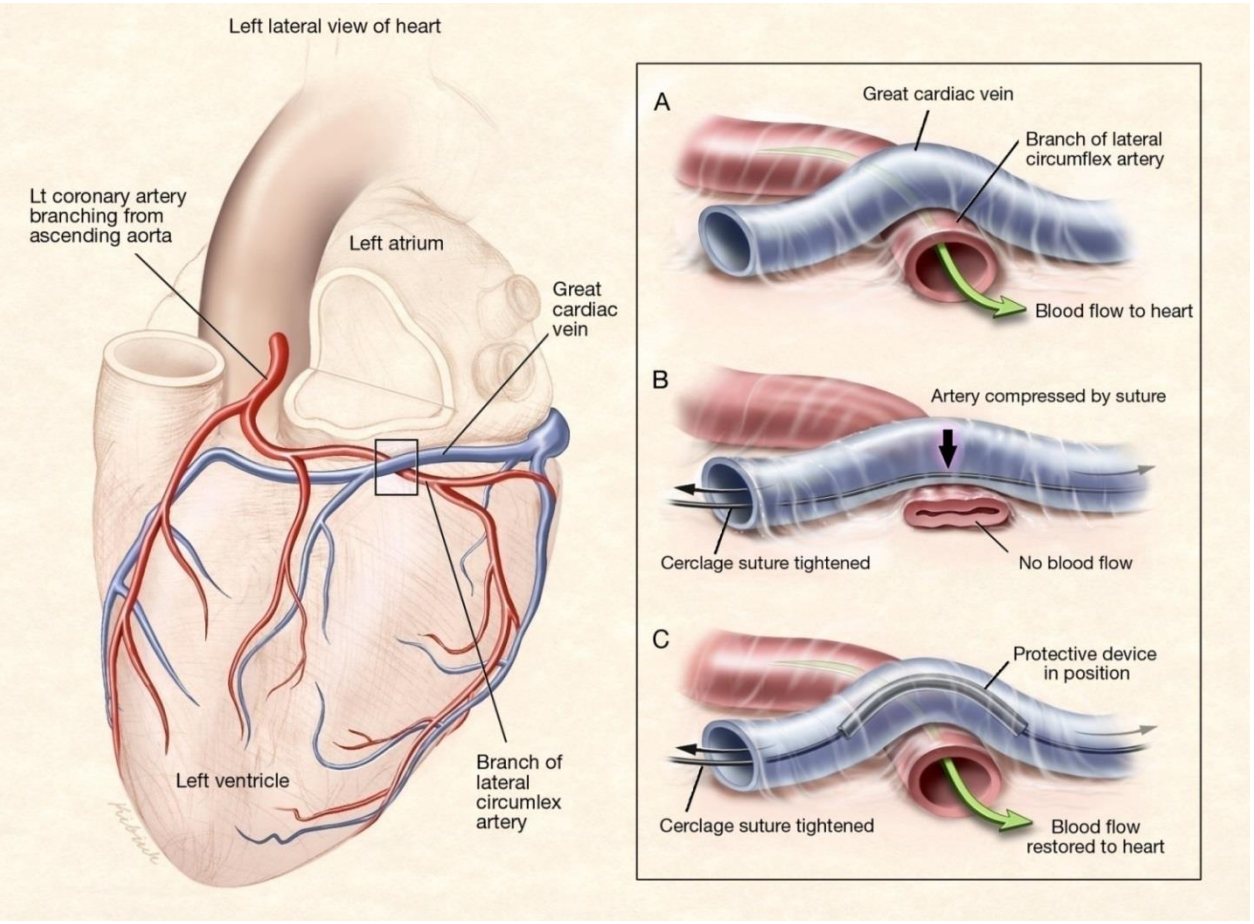


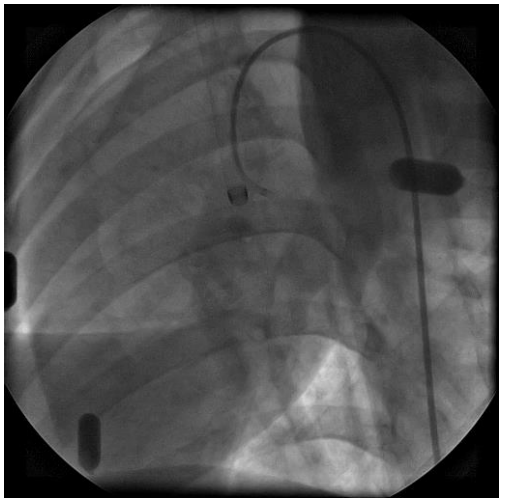
Tension

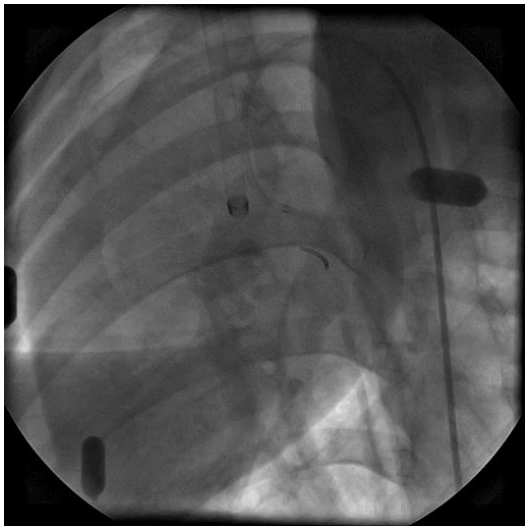
Kim JH et al. JACC 2009:54

What's more in MCA ?

MCA can avoid pinching of underlying LCx artery by simple Coronary Artery Protective Devide (CAPD)



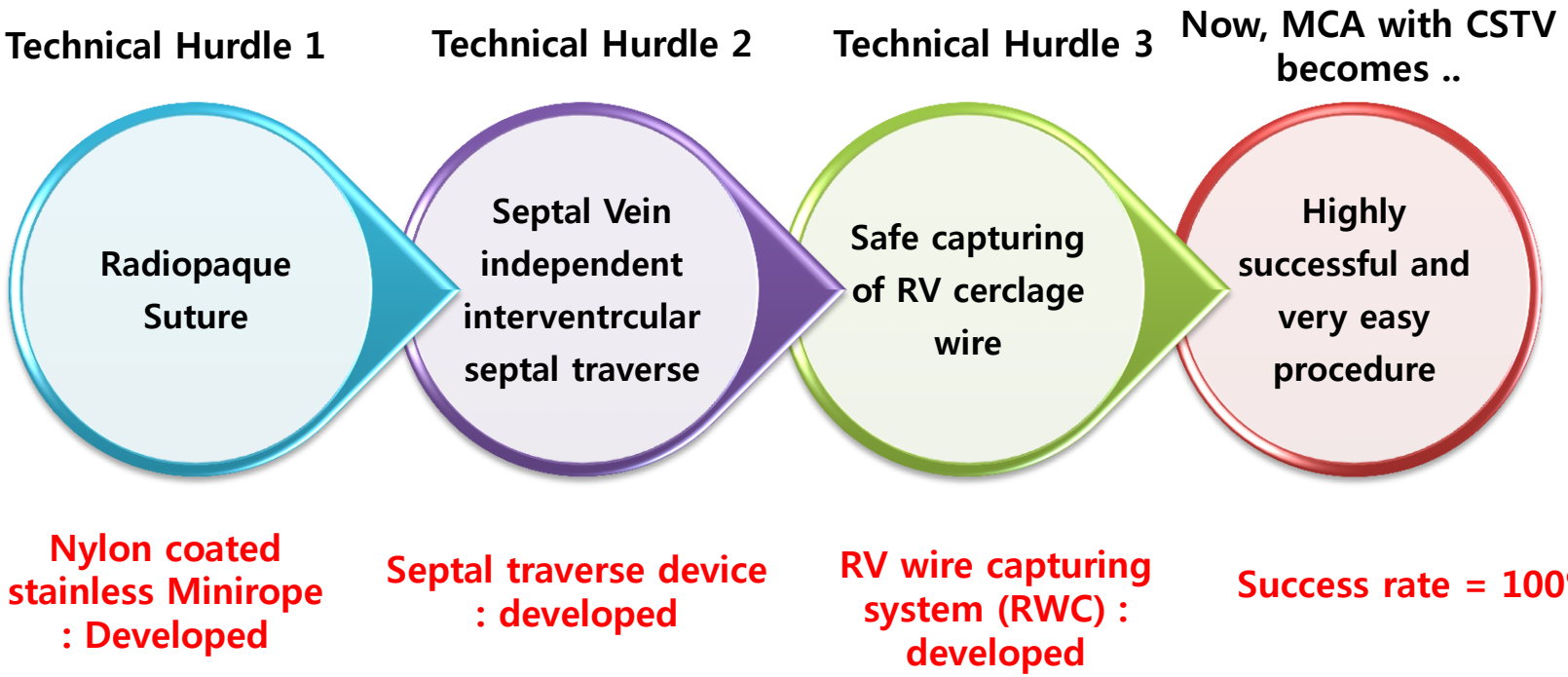




Kim JH et al. JACC 2009:54

The Recent progress for technical feasibility

Easy and Simple procedure !!

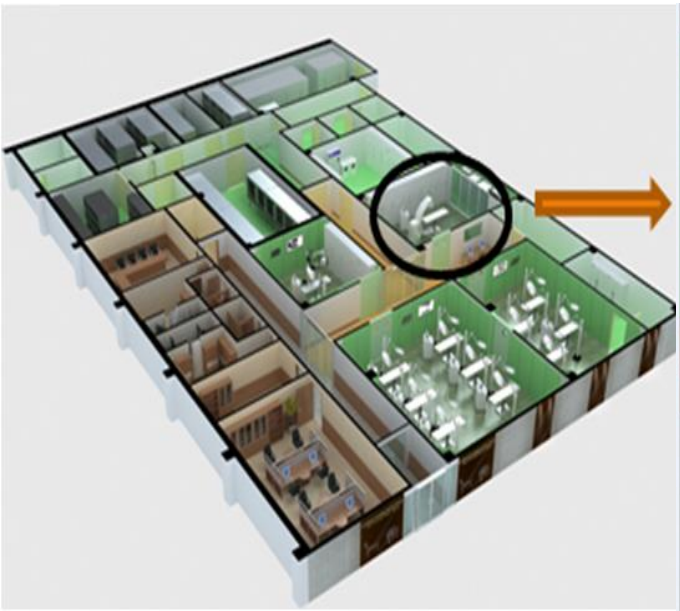


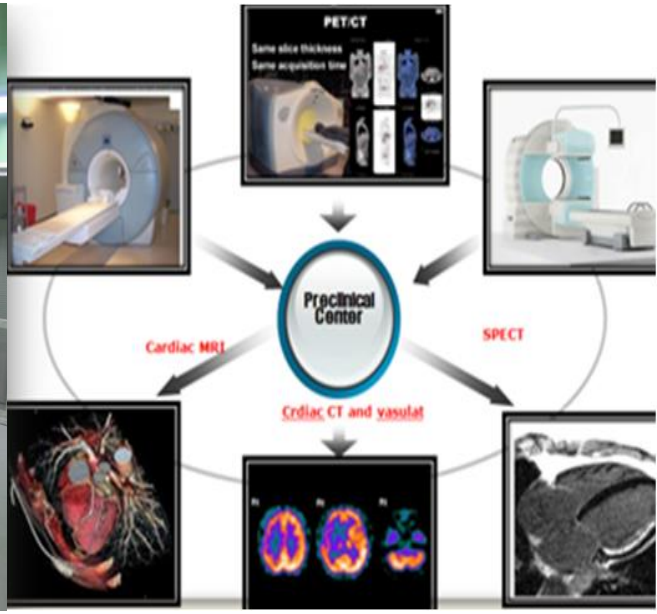
Whole Procedure time with current immature devices : 121 ± 20 Minutes

TCT 2013, June-Hong Kim et al.

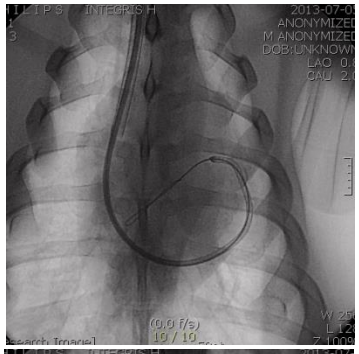
The high quality Preclinical (Animal) lab in PNUYH

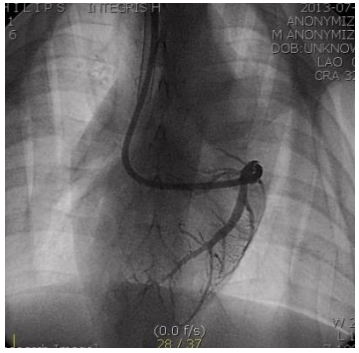
"This lab is one of the best labs that I have ever seen!" (R&D director of Boston Scientific)

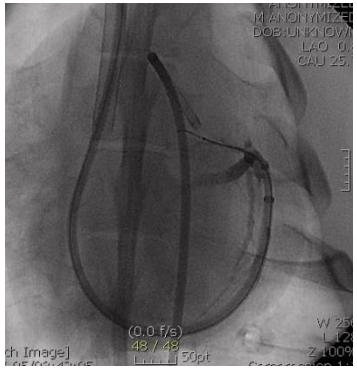


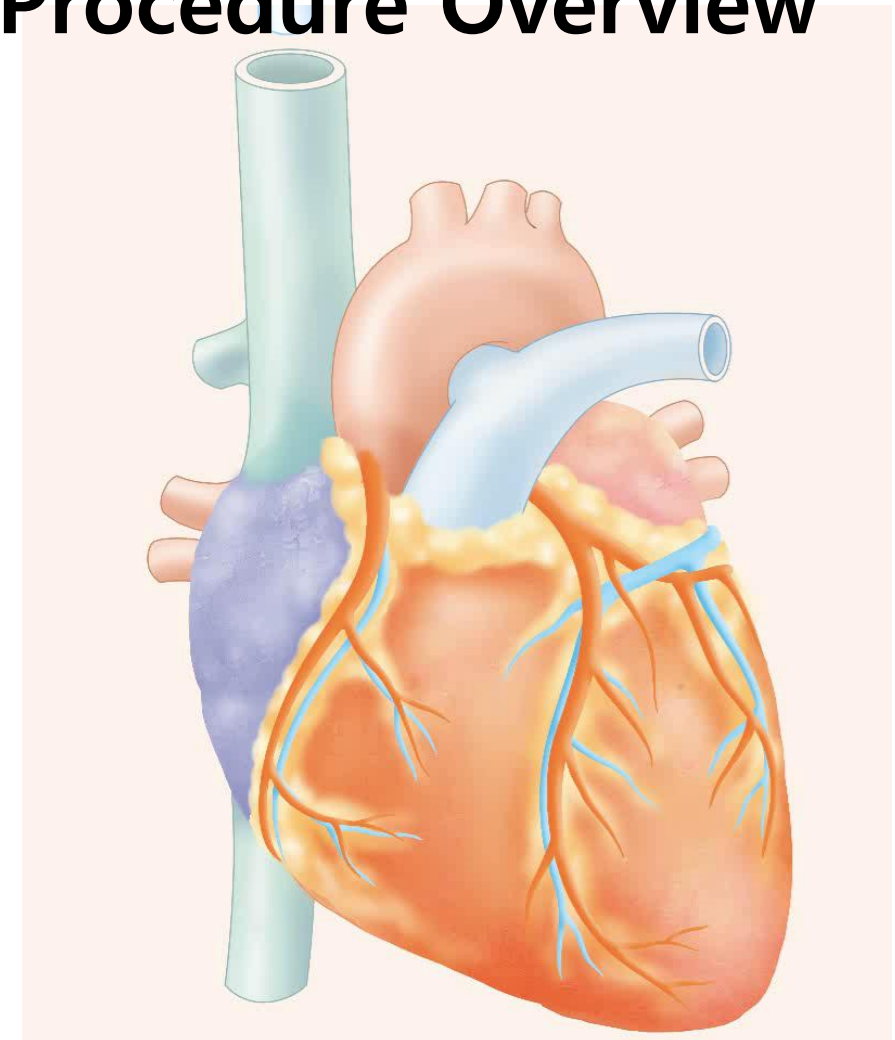


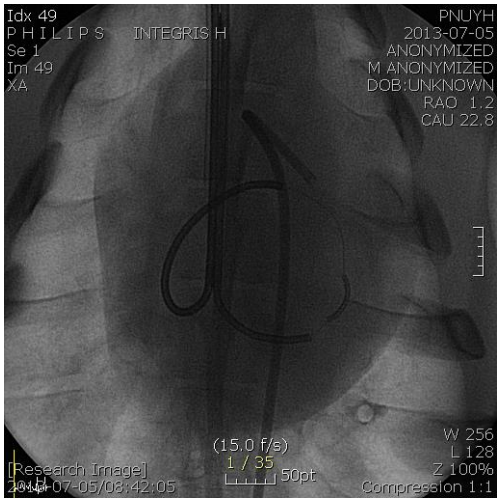
Procedure Overview

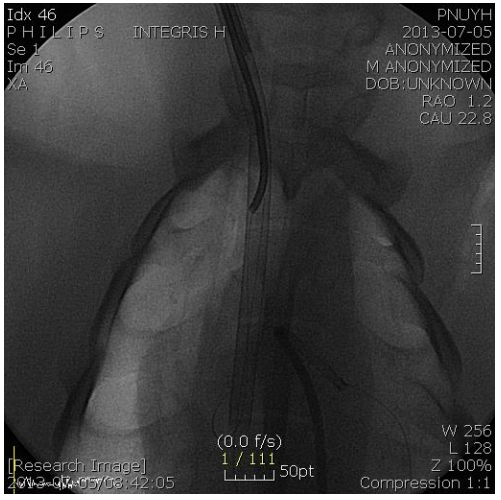


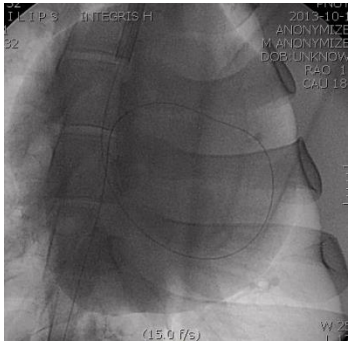


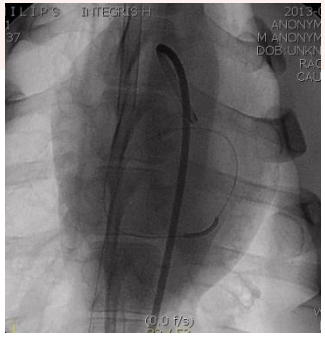


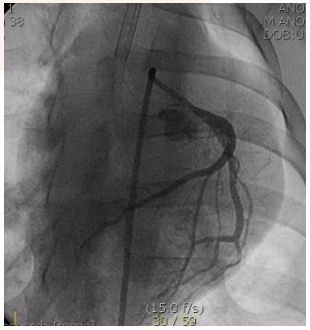


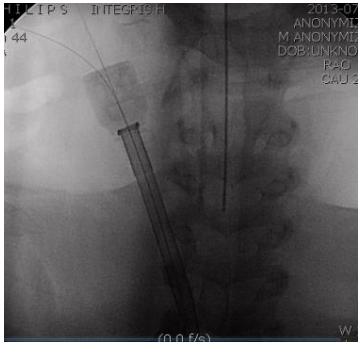






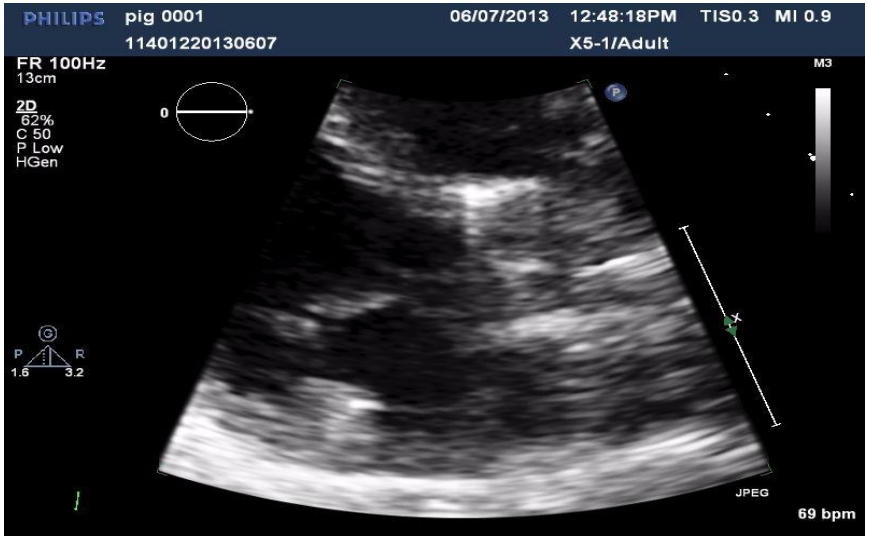






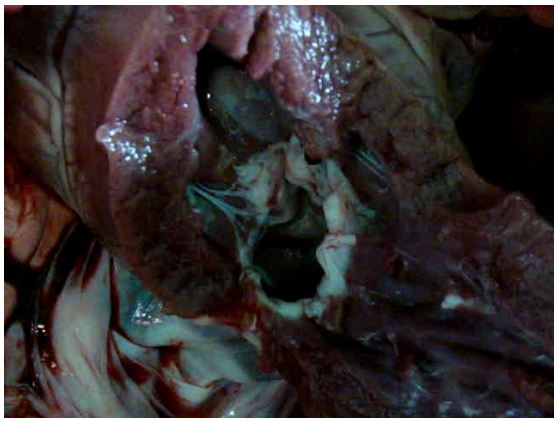
Efficacy of Mitral Cerclage

Effective reducing Septal Lateral distance of MV

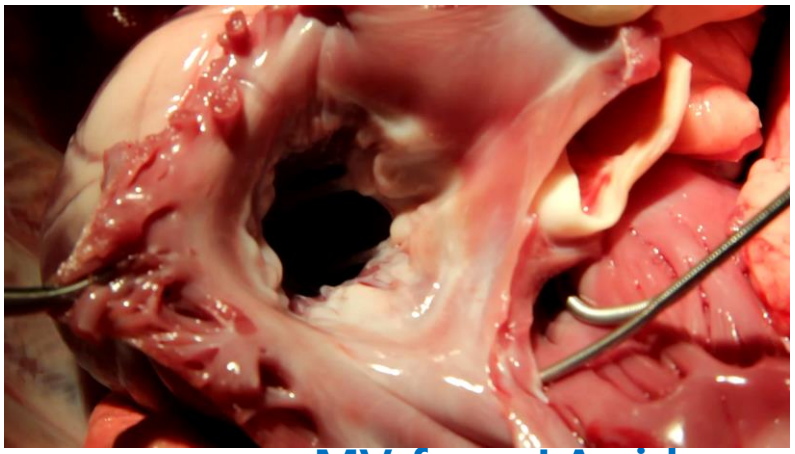


Interactive adjustment during procedure !

SL distance reduction
19.6 → 10.9 cm (by 44%)



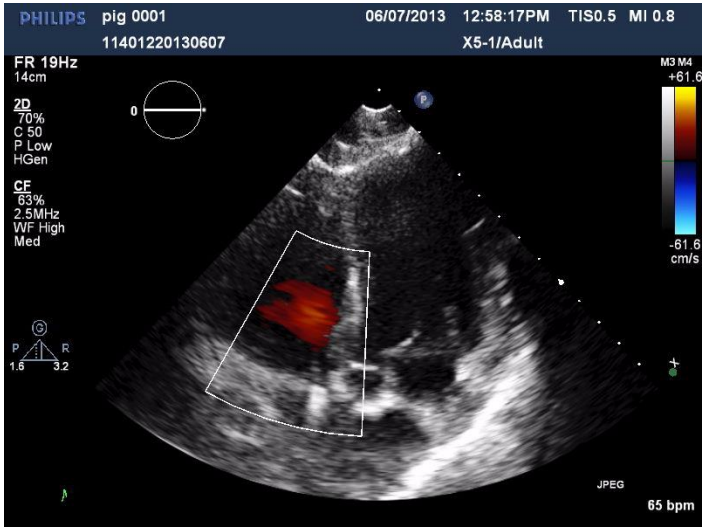
MV from LV side

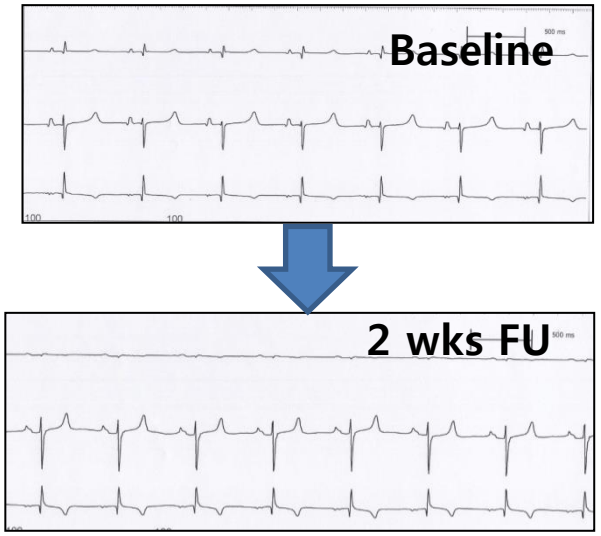


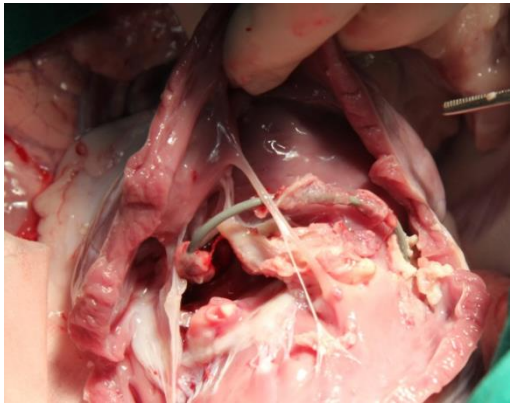
MV from LA side

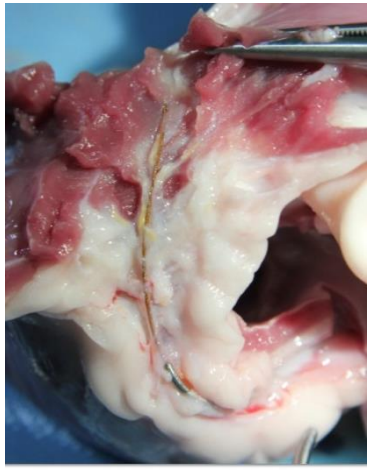
No evidence of Tissue erosion with CSTV (n=4, 2wks follow-up result)

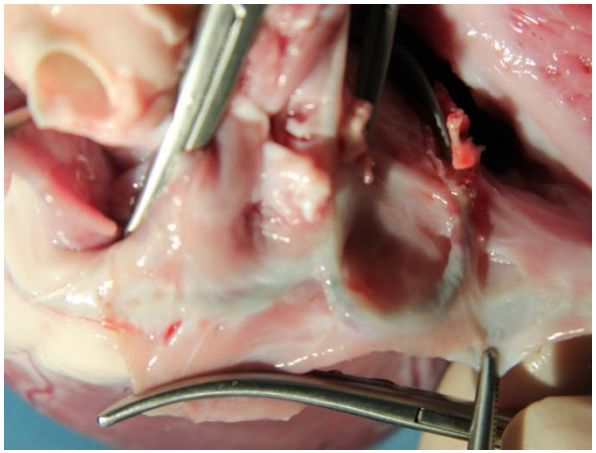
No Tricuspid Regurgitation, No conduction abnormality







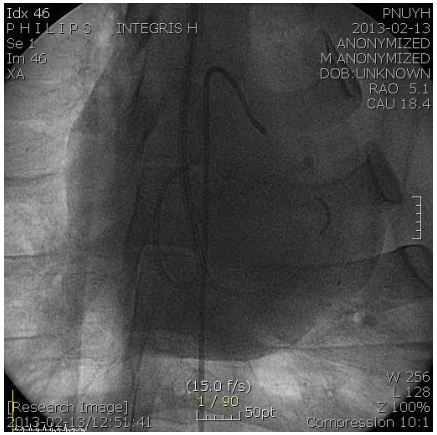


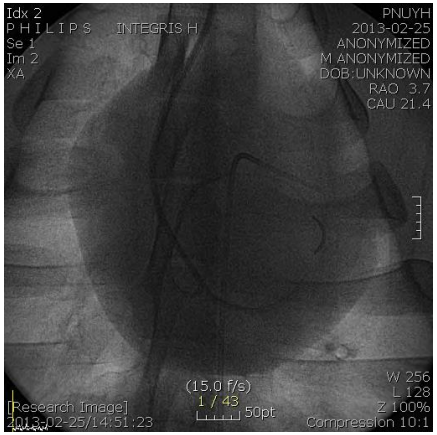


TCT 2013, June-Hong Kim et al.

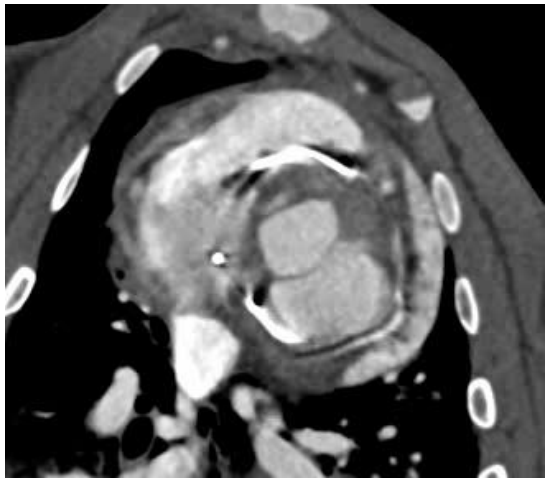
A representative case
2 wks FU Cardiac CT image

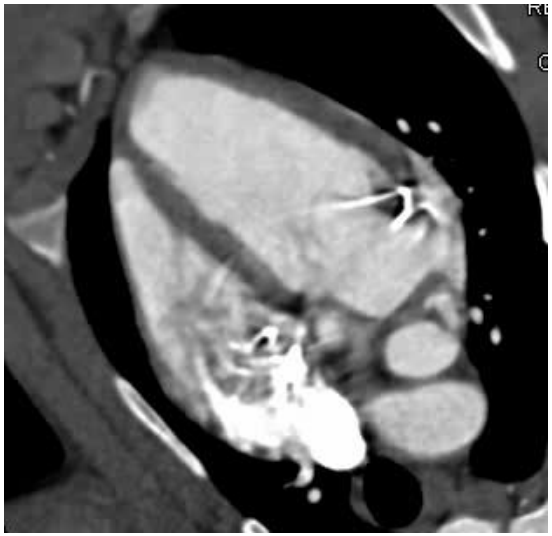
Post-procedure

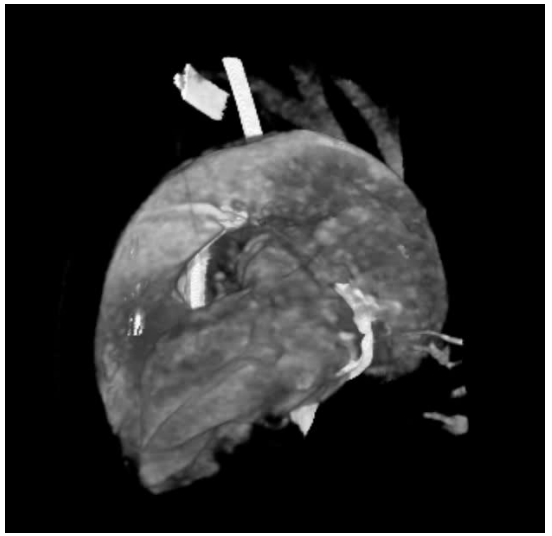




2 wks FU

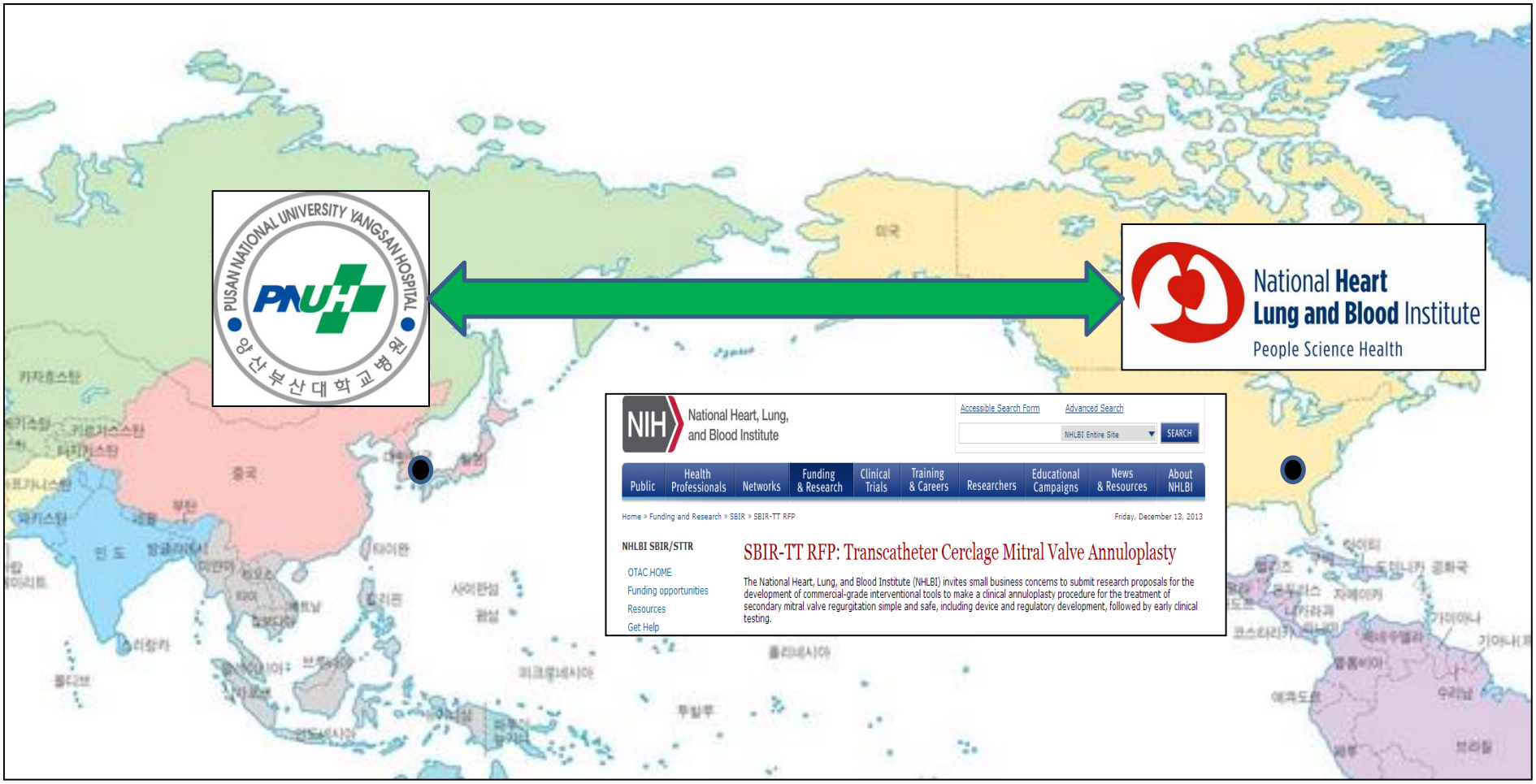






TCT 2013, June-Hong Kim et al.

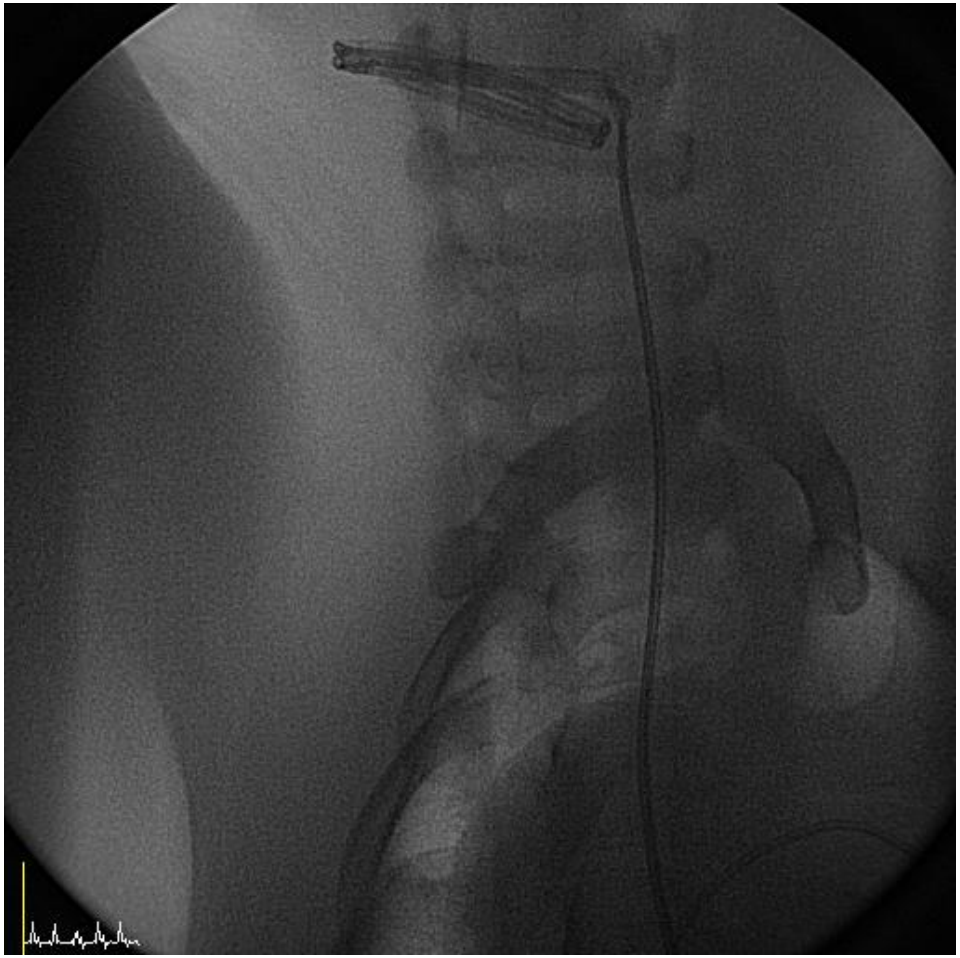
First-In-Man Trial (FIM) within 2 years through International collaboration



Summary

1. Transcatheter MV repair is the definite way to go
2. Currently, Mitraclip is the leading modality apporved by CE and US-FDA
3. Other promising technology such as “Valtech Cardioband” appears to be fantastic technology to perform transcatheter annular ring implantation which is comparable to surgery
4. CS approach is still very attractive because it gives a solution of easy and simple procedure
5. Mitral cerclage has now been matured to set out First In Man trial

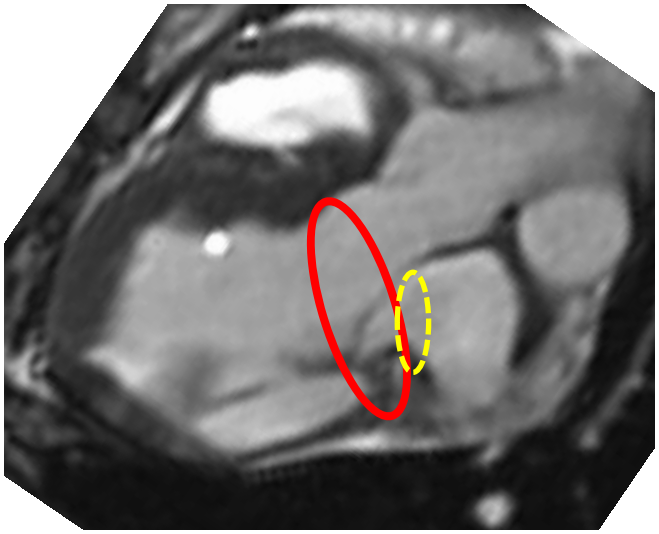
Thank you for your attention



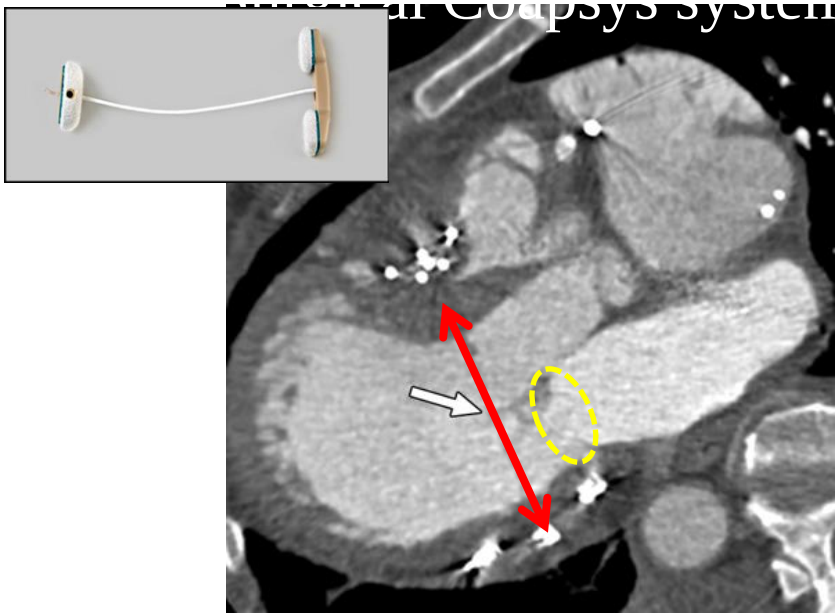
"LV basal squeezing" in Functional MR with Heart failure : more beneficial?

Surgical Coapsys : Survival Benefit & MACE reduction by 67% at 2yr compared with standard MV repair (p=0.019)

Mitral cerclage



'Surgical Coapsis'



RCT : Coapsys MV repair in *"Functional"* MR RESTORE-MV study (n=165)

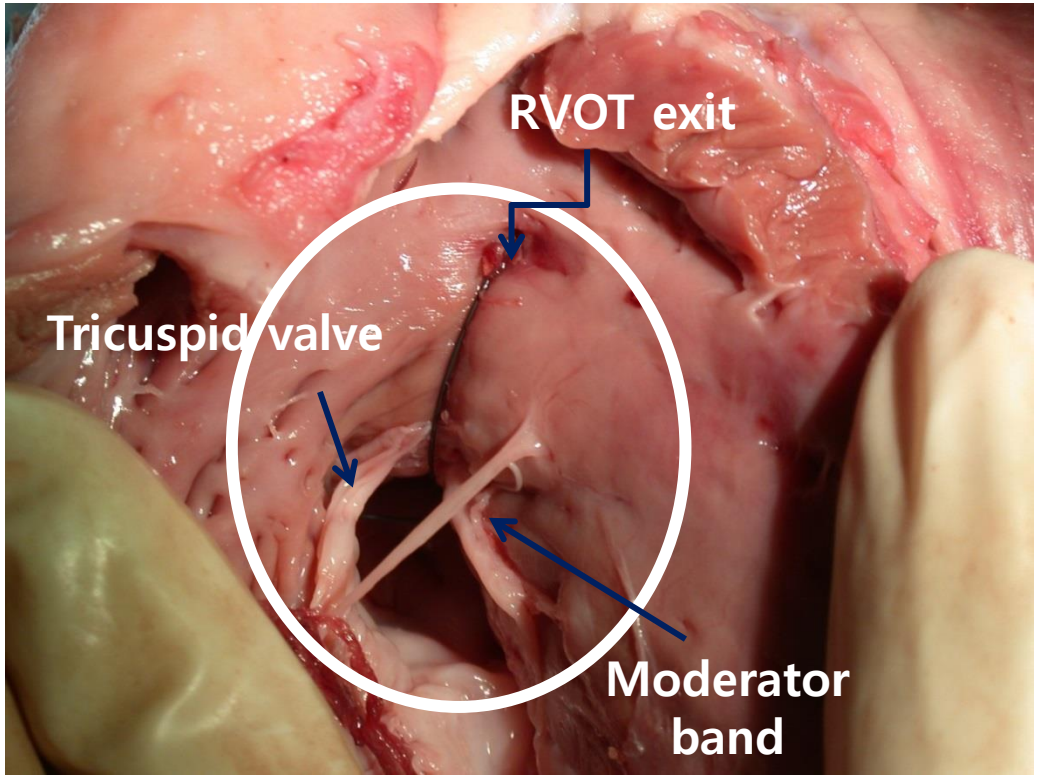
Grossi et al. JACC 2010. 56;1984-93

Then, MCA can stand alone for human translation?

No it needs more evolution?

Then, what are remained of MCA for human translation?

Safety issues #1 : Erosion and its consequent TV damage

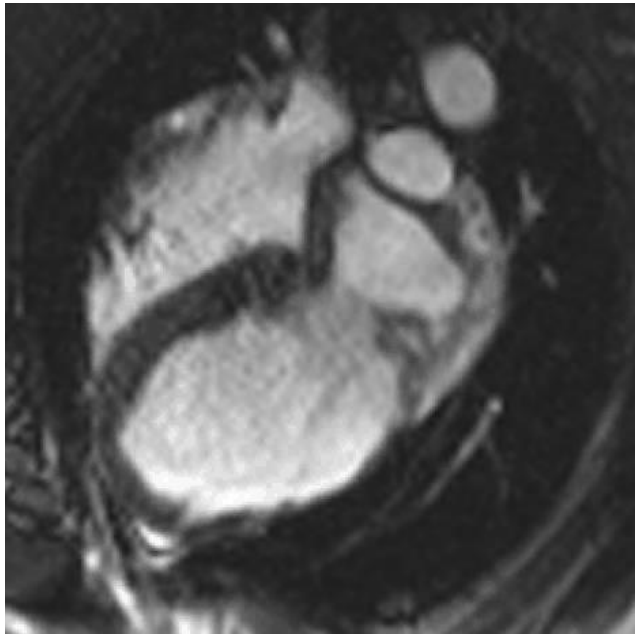


Subvalvular structure : vulnerable to erosive destruction by cerclage suture (nylon)

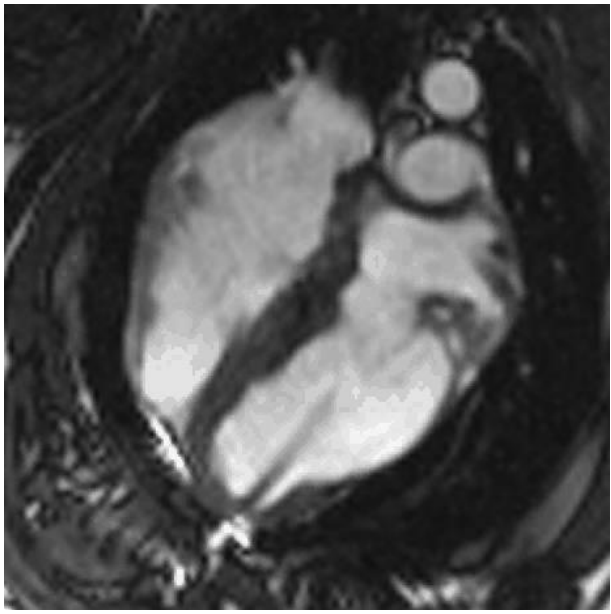
Then, what are remained of MCA for human translation?

Safety issues #1 : Erosion and its consequent TV damage

MR regurgitant fraction 43% in a pig



Cerclage abolish MR
Immediate post-procedure

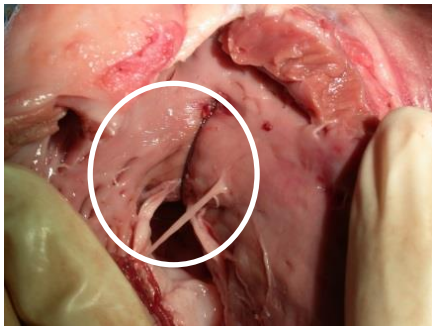


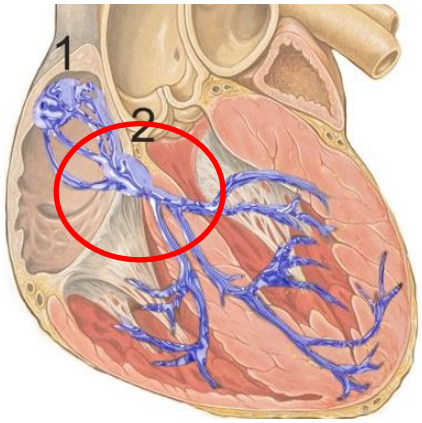
3wk FU. Persistent no MR
But severe TR due to valve destruction

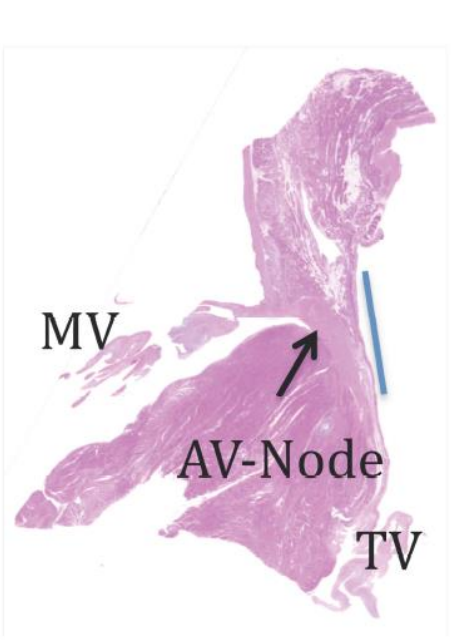
Unpublished data

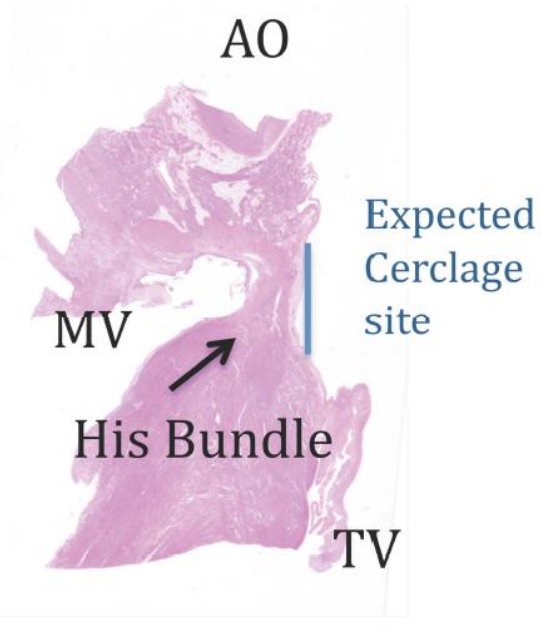
Then, what are remained of MCA for human translation?

Safety issues #2 : Potential risk of Conduction Block
: RV and RA part of cerclage path is too close to conduction system





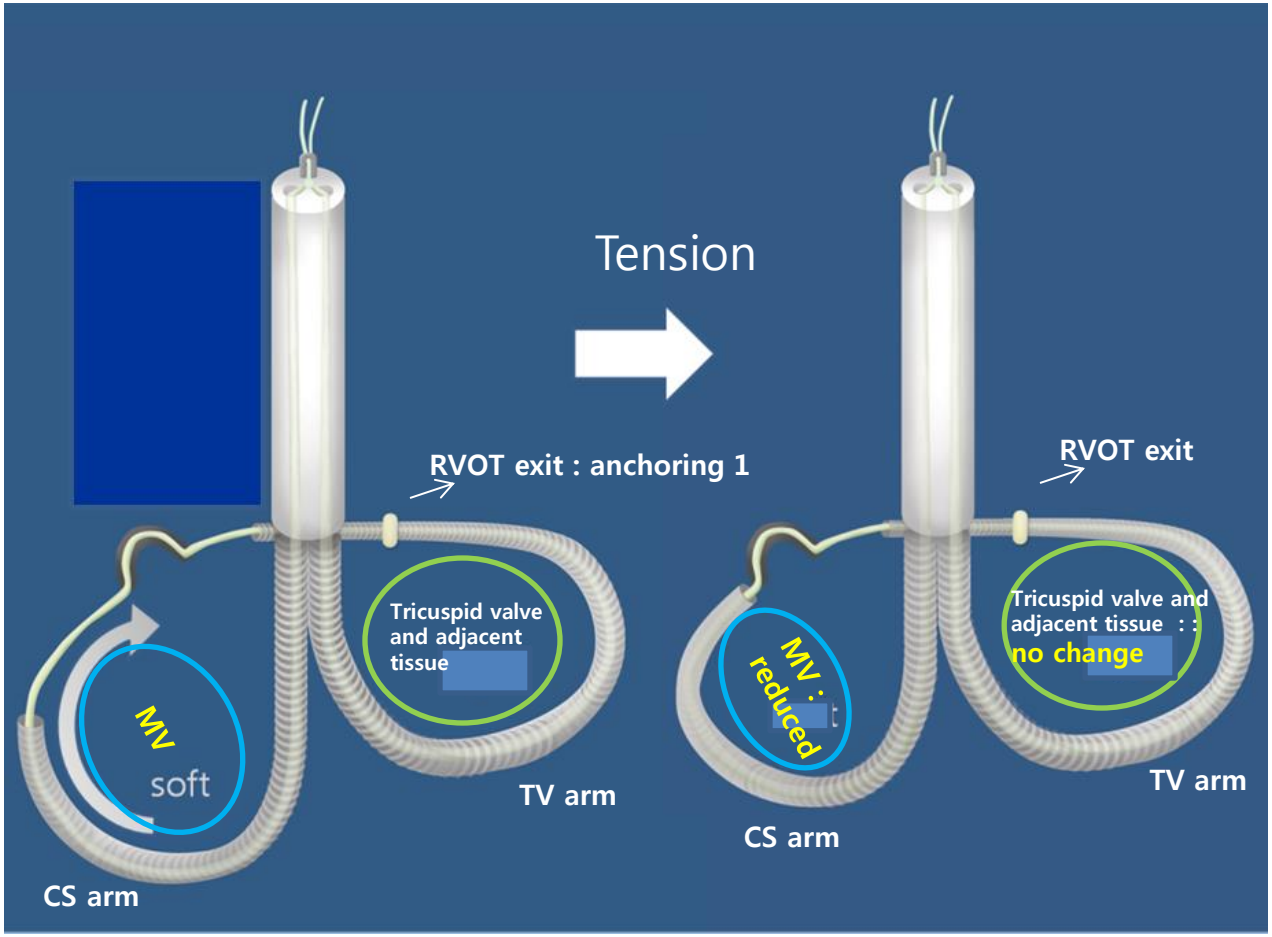




Human Cadaver Cercalge Pathologic Report
By Dr. Renu Virmani

Unpublished data

The design of CSTV

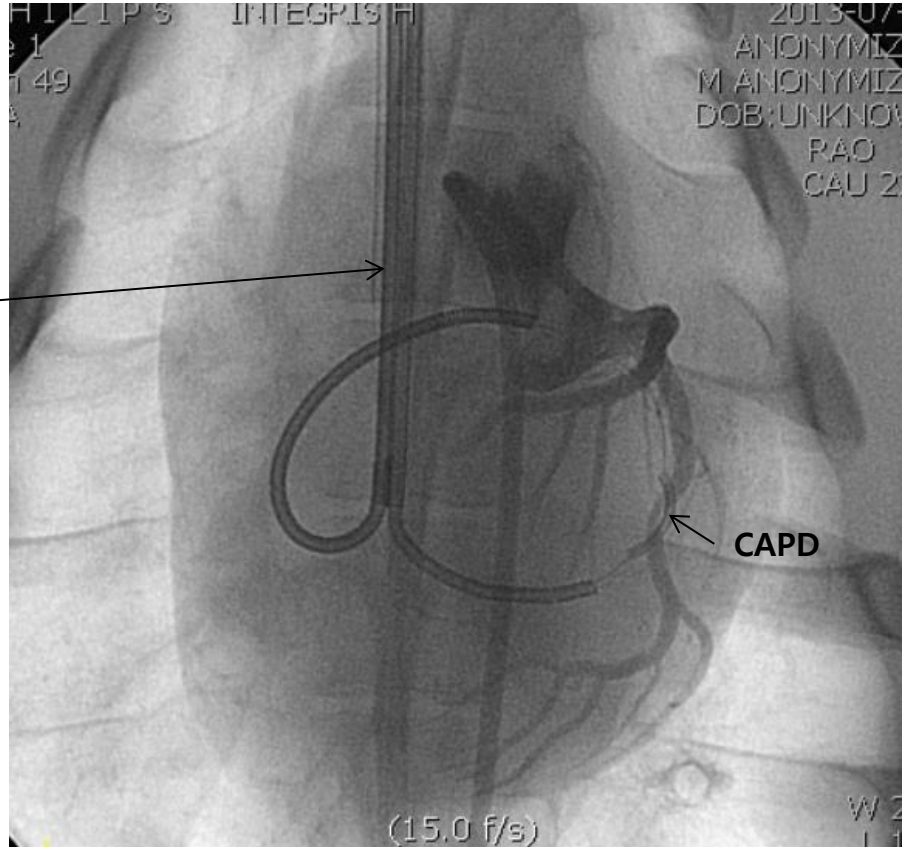


TV limb offers an arch so that right side of cerclage path can be averted from direct contact with undelying struture

What evolutions have been made?

Safety ⟷ Procedural Technique

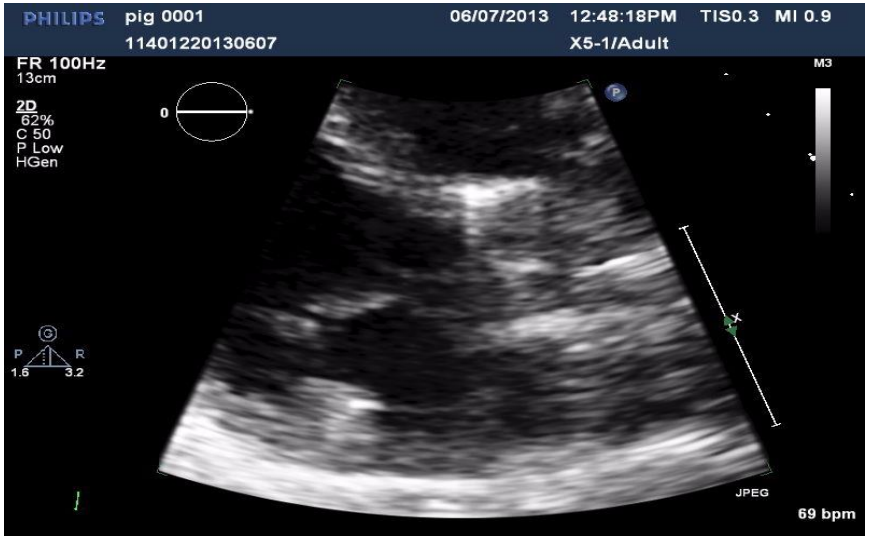
A Novel appliances : CSTV



Technical development in procedures

CS arm of CSTV (in healthy pigs)

Effective reducing Septal Lateral distance of MV



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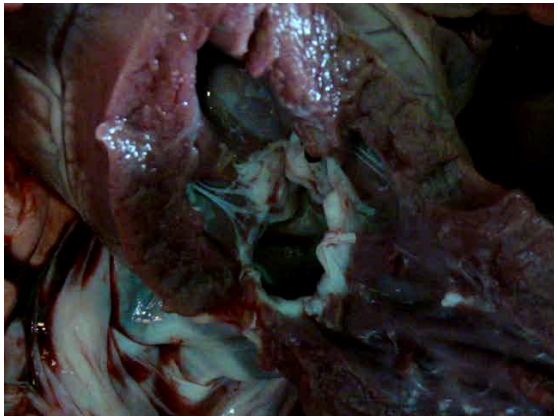
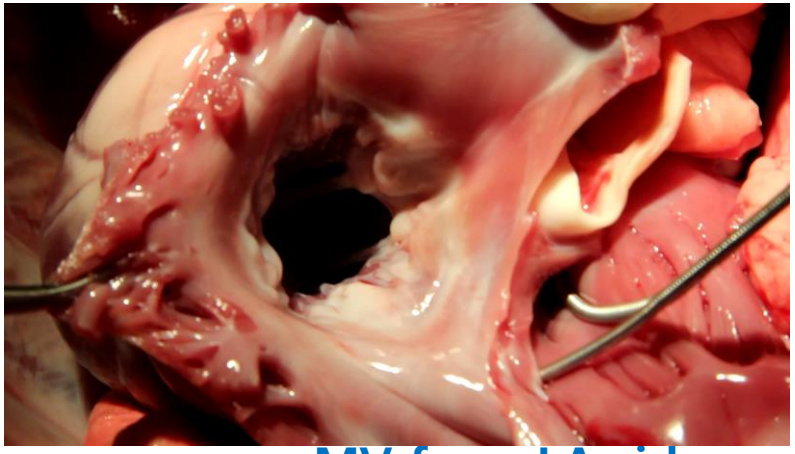
19.6 → 10.9 cm (by 44%)



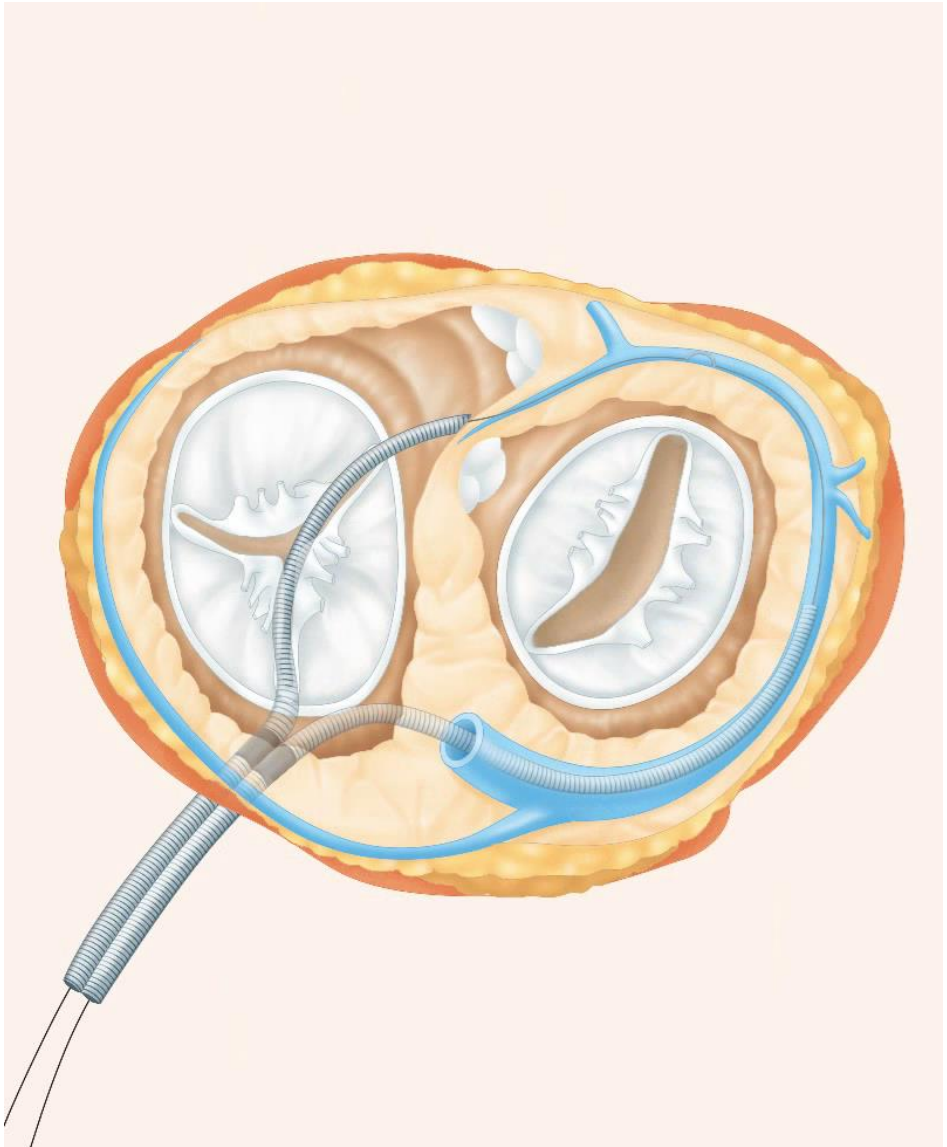
MV from LV side

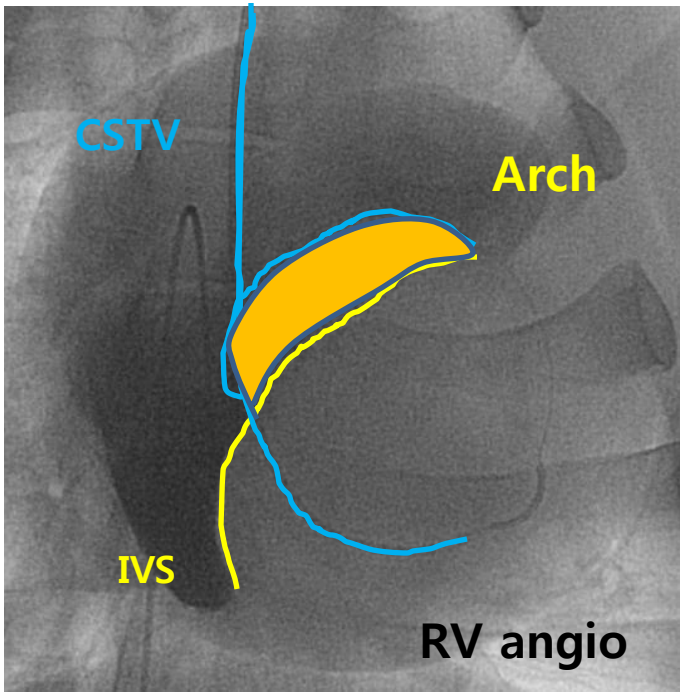


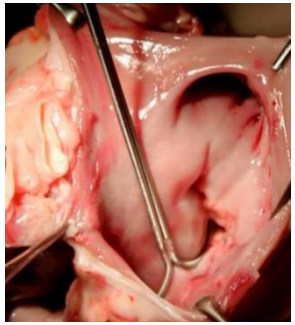
MV from LA side

TV arm of CSTV : Arch in right side

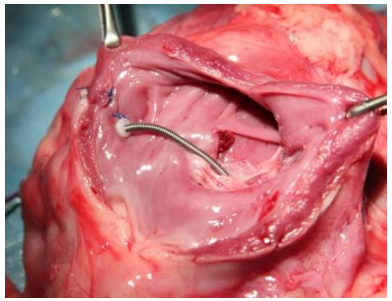
Arch formation during tension : TV & conduction system protection



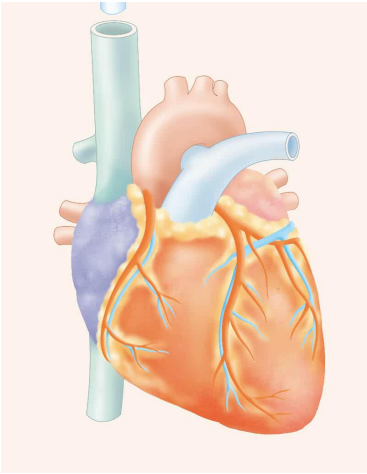




CSTV hinge around CS os

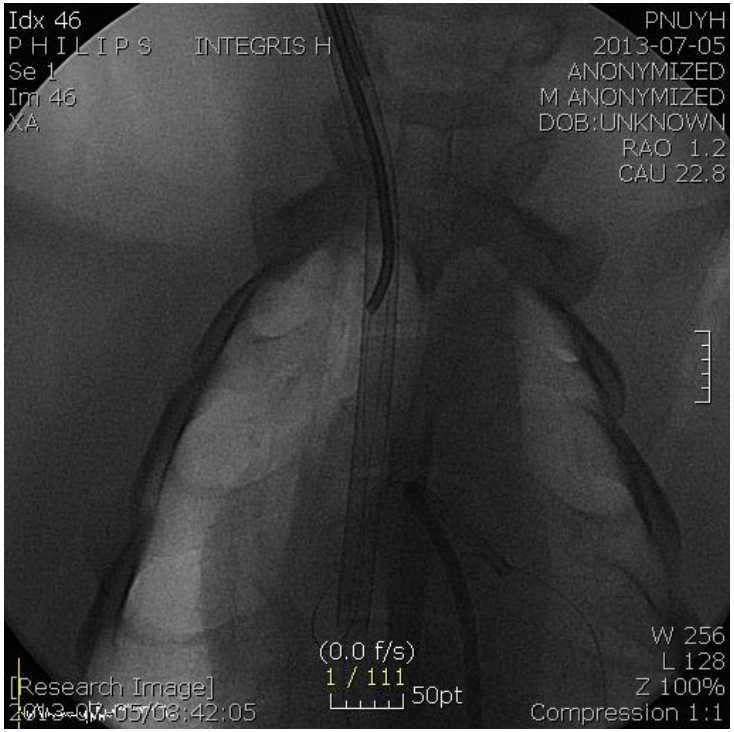


TV arm of CSTV

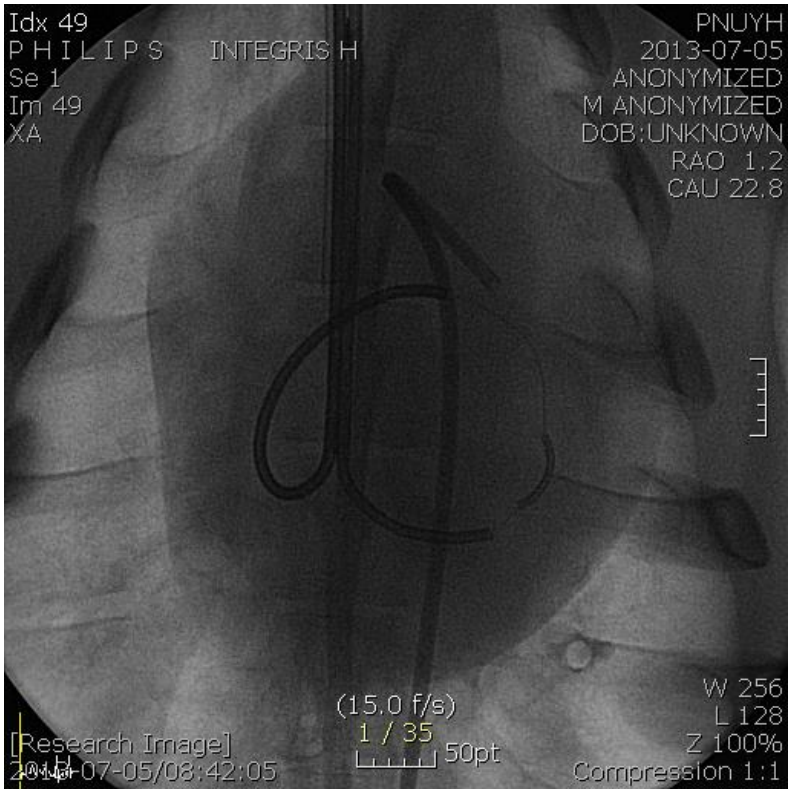


Delivery of CSTV

Easy and Simple procedure !!



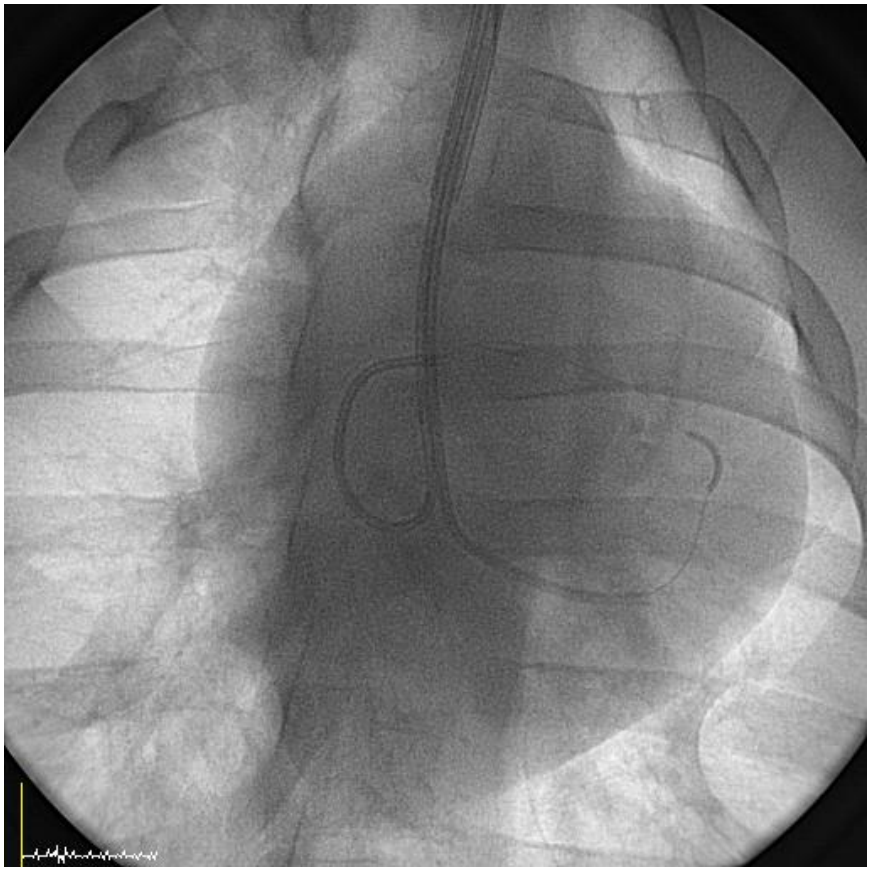
CSTV delivery though cerclage suture

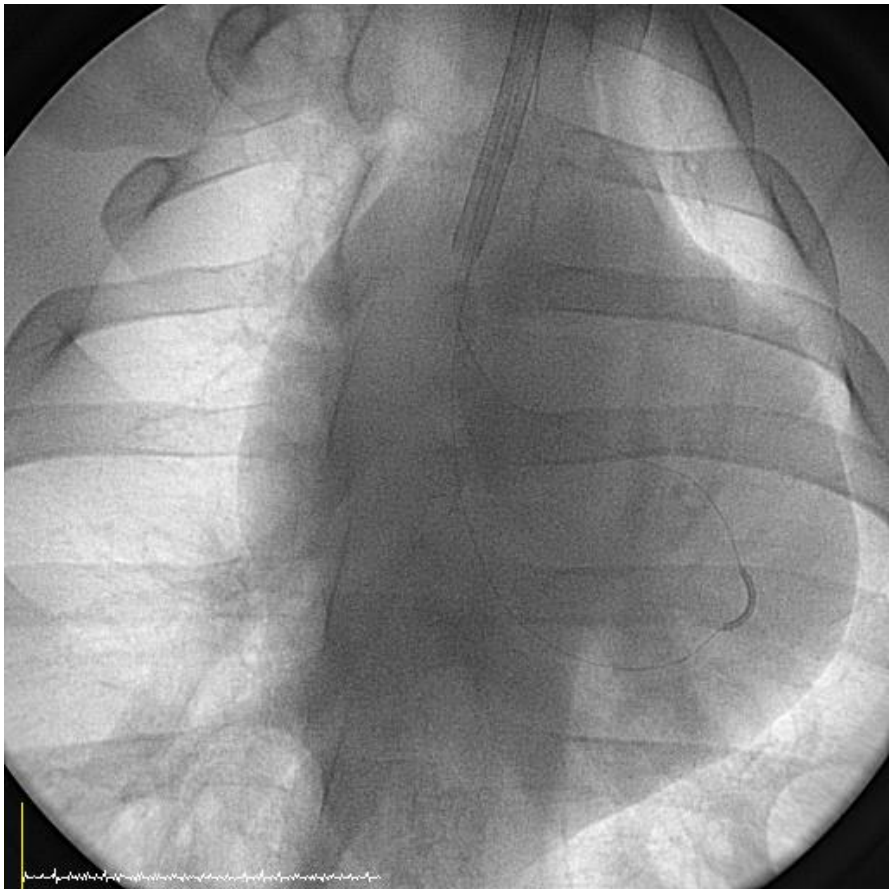


Tensioning though MC with CSTV

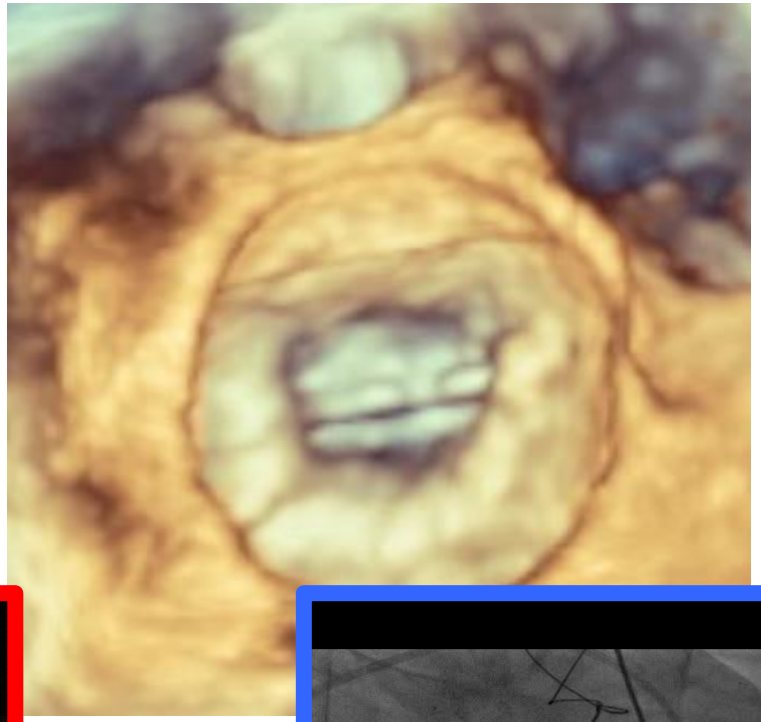
Retrieval of devices

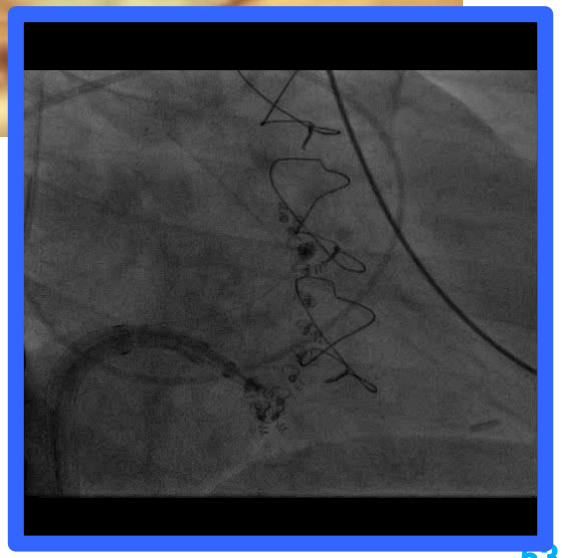
Easy and Simple !!



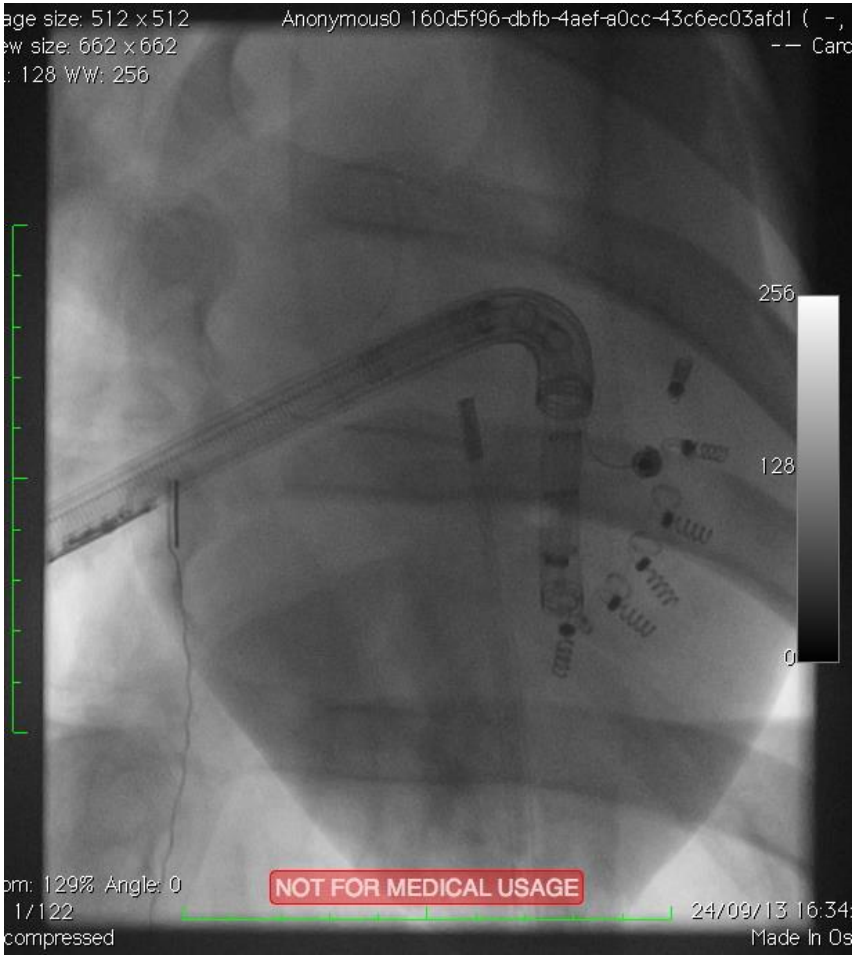


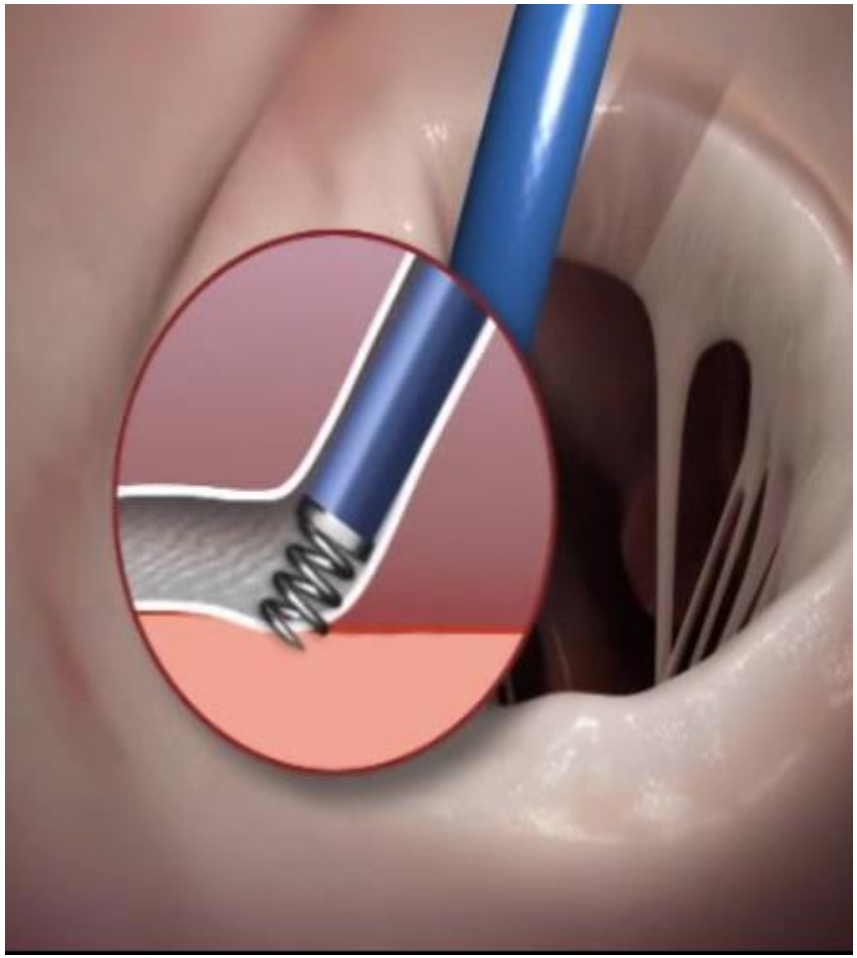
Find the difference....



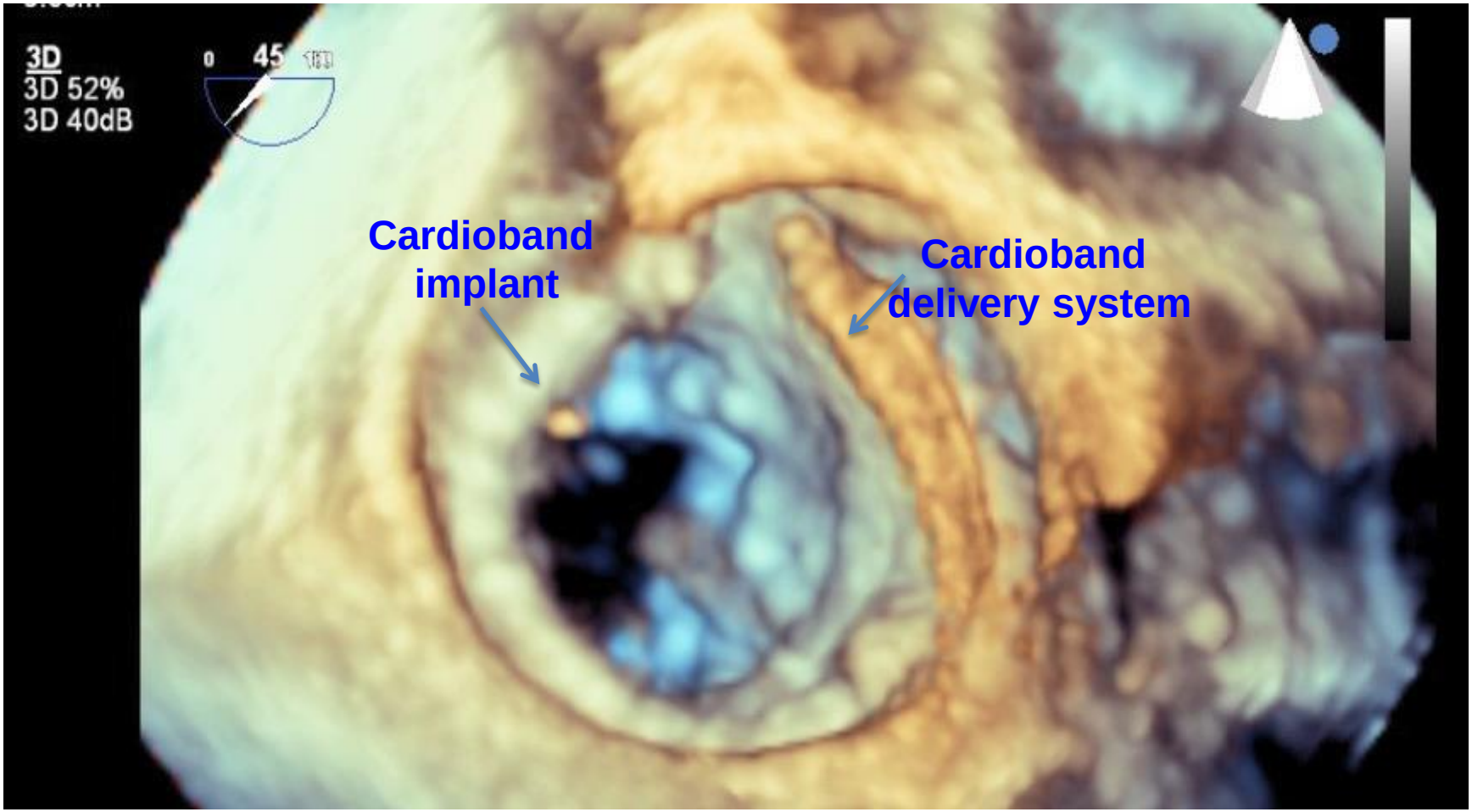


Deployment and implant

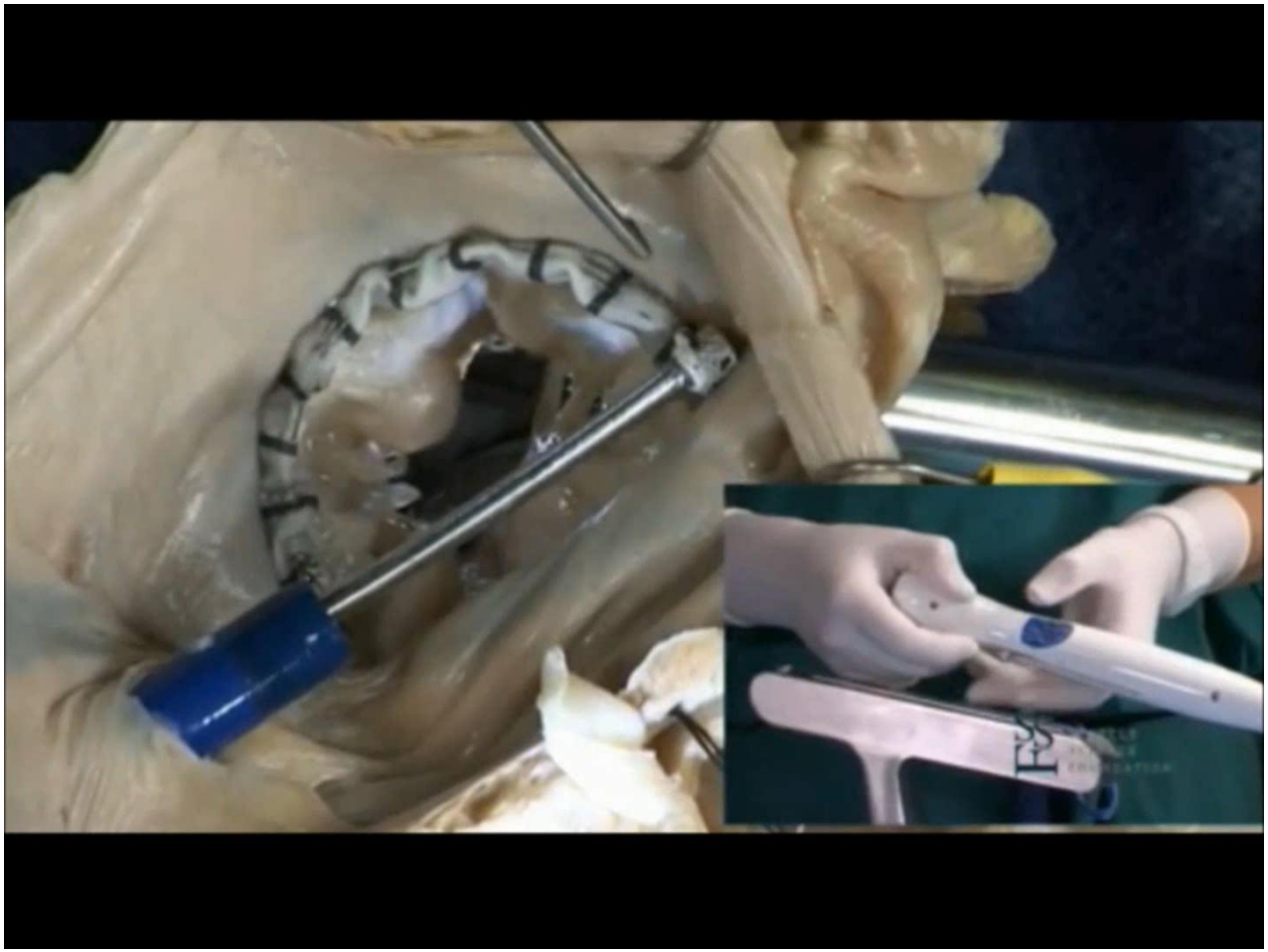




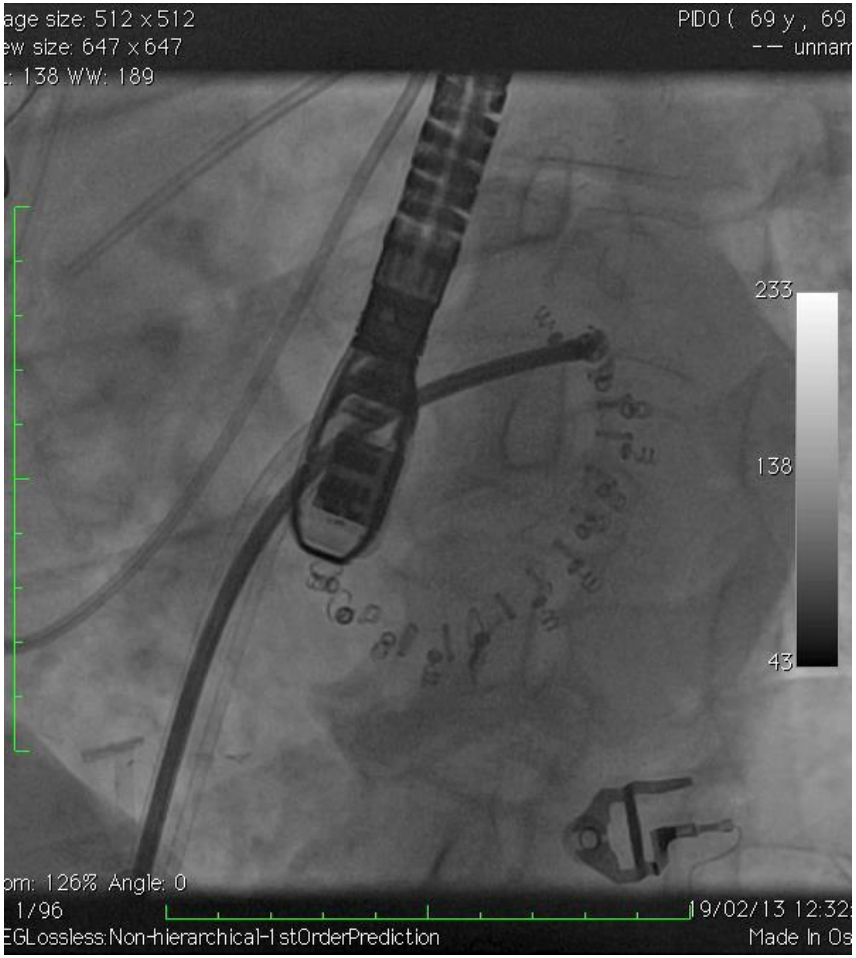
A surgical–grade ring implanted tr igone to trigone

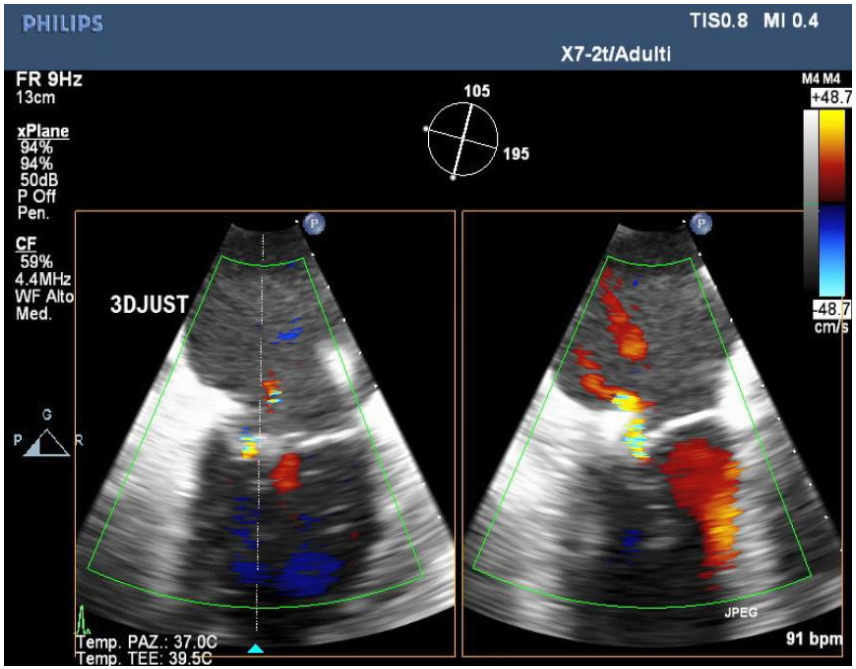


Annular cinching by Cardioband contraction



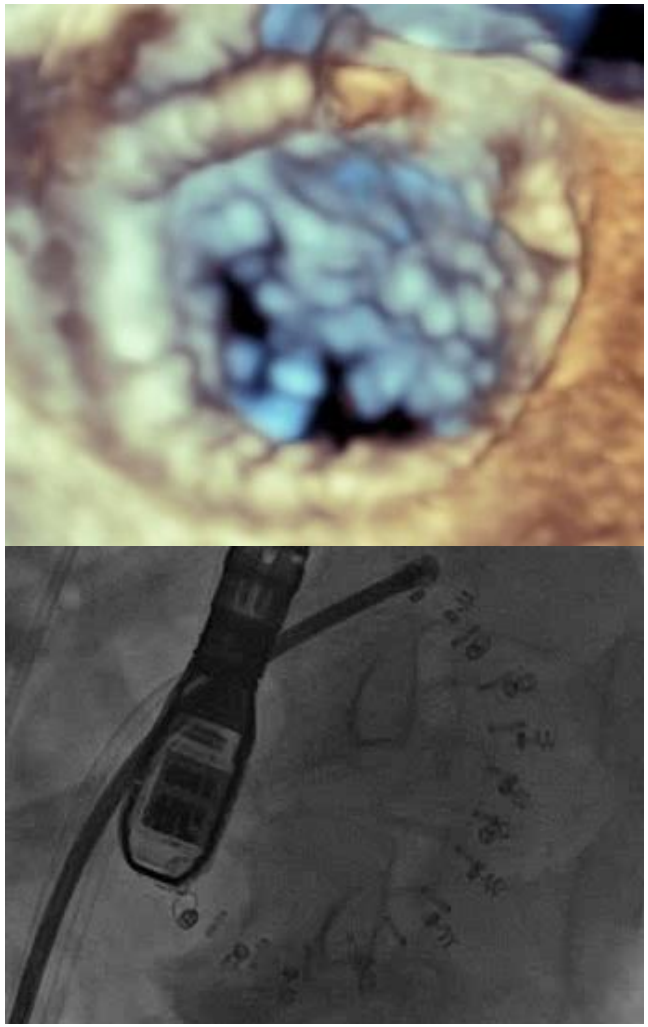
Cardioband contraction 20%



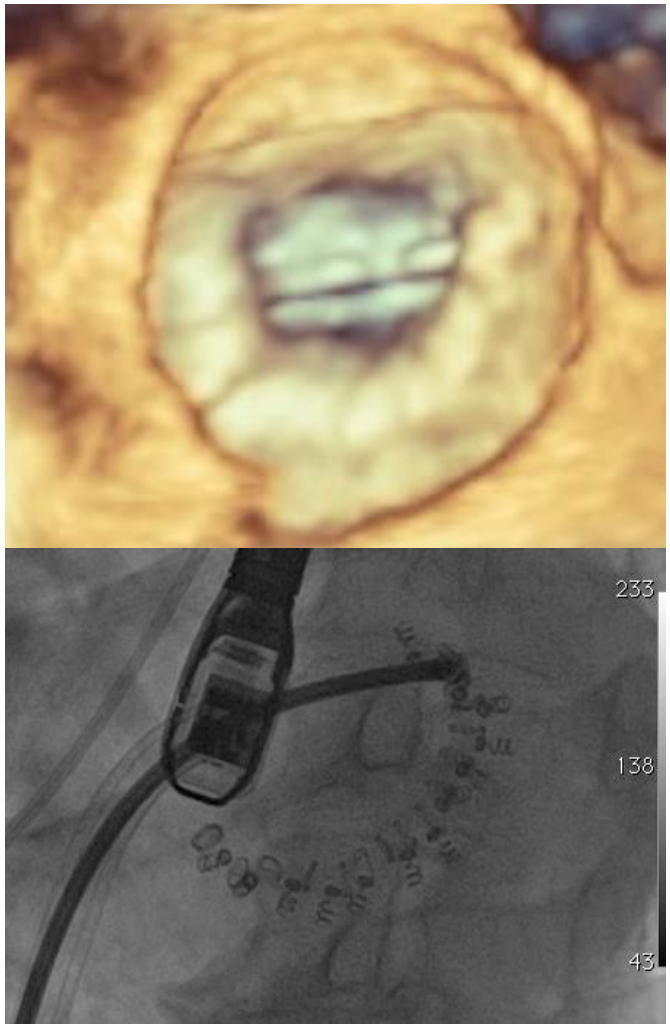


Annular size reduction

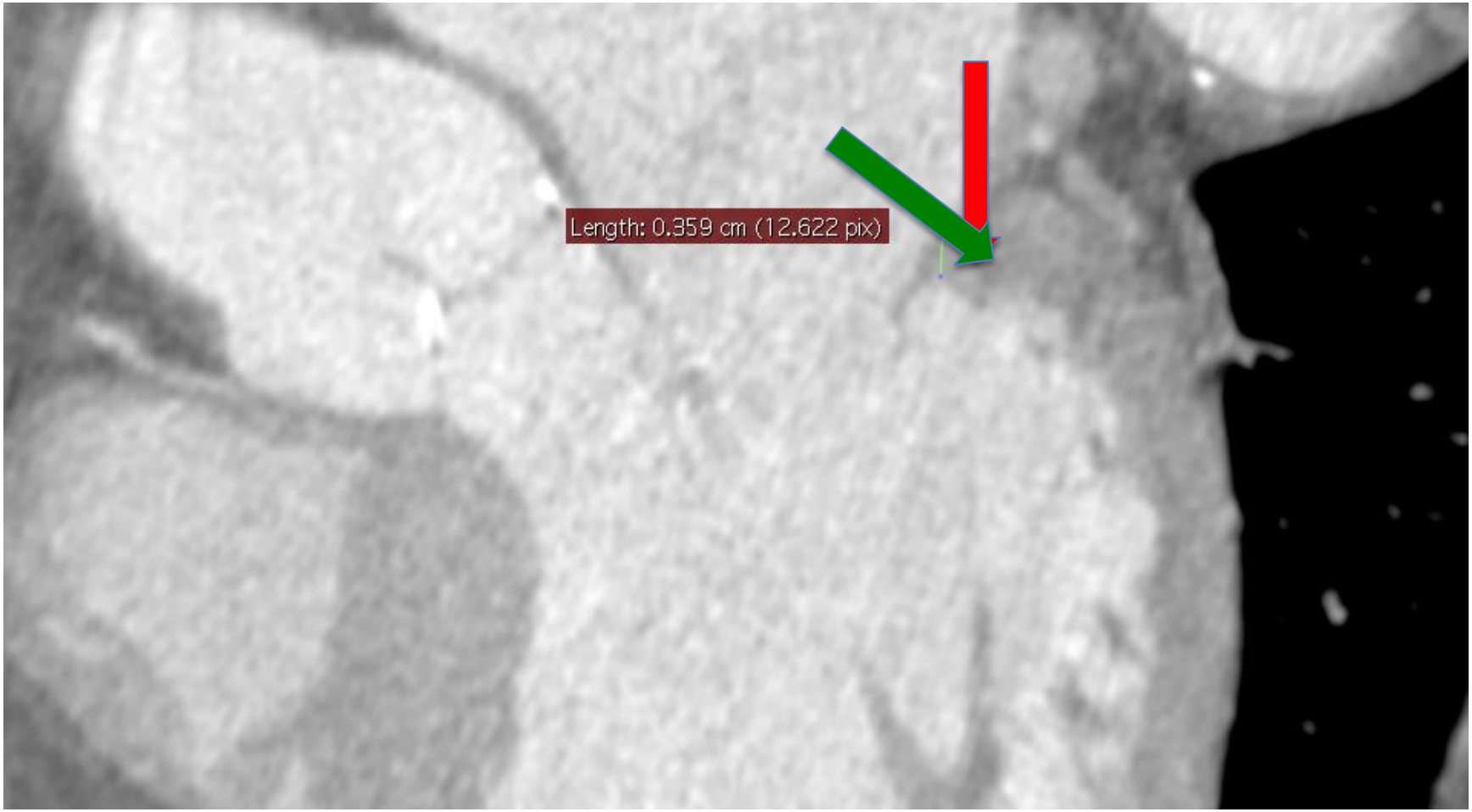
Before cinching



After cinching (40%)



P2 region



Patient #	Site	Age	FMR Etiology	NYHA Class Baseline	MR SEVERITY TTE BASELINE	MR SEVERITY TTE DISCHARGE	MR SEVERITY TTE 1MONTH	MR SEVERITY TTE 6 MONTH
C105	OSR, Italy	69	Ischemic	II	Moderate	Mild	Mild	Mild
C106	OSR, Italy	70	Ischemic	III	Severe	Mild	Mild	Mild
F101	Bichat, France	56	Non-Ischemic	III	Severe	Mild	Mild	NA
F102	Bichat, France	67	Ischemic	III	Severe	Mild	Mild	NA
F103	Bichat, France	77	Ischemic	IV	Moderate	Mild	Mild	NA
C107*	OSR, Italy	81	Ischemic	III	Severe	Severe	Severe	NA
F104	Bichat, France	62	Ischemic	III	Moderate	None	Mild	NA
F201	Hamburg	76	Ischemic	III	Moderate	Mild	Mild	NA
F202	Hamburg	76	Non-Ischemic	IV	Moderate	Mild	NA	NA
F105	Bichat, France	79	Ischemic	IV	Severe	Mild	NA	NA
C108	OSR, Italy	67	Ischemic	II	Severe		NA	NA

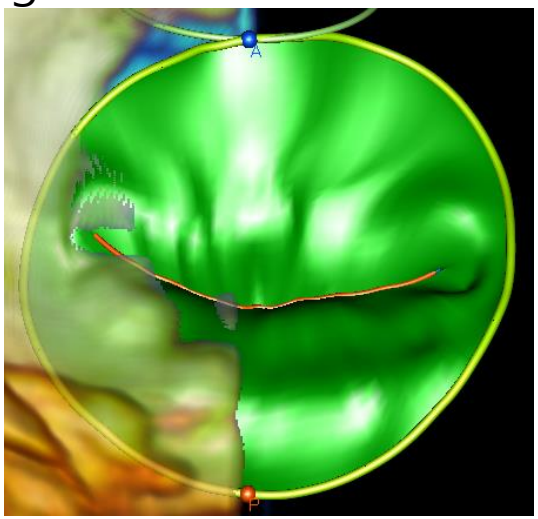
60

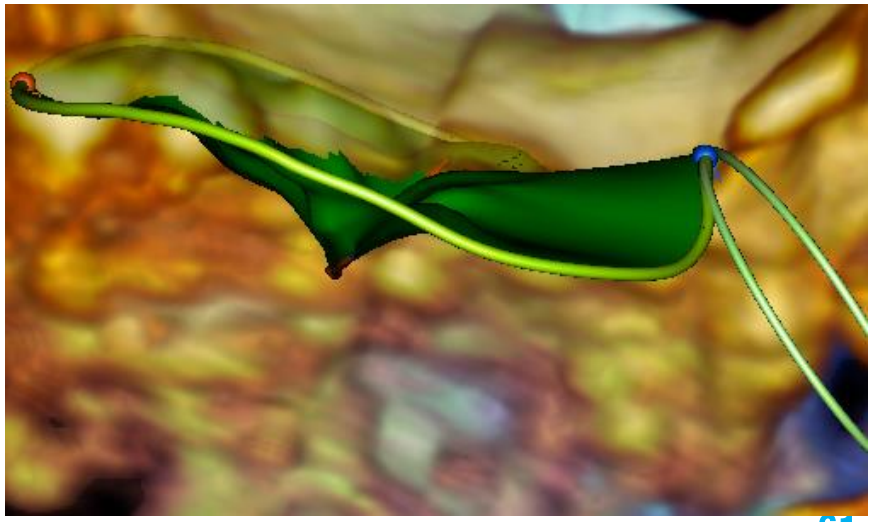
Echo Analysis

Summary analysis of 7 Bonn patients

	Percent Change			Difference		
AP Diameter	10	±	4%	0.39	±	0.15
Lateral Medial PM Diameter	13	±	7%	0.62	±	0.32
Annulus Circumference	11	±	4%	1.59	±	0.54
Annulus Area	22	±	7%	3.38	±	1.15

* One Patient Staged



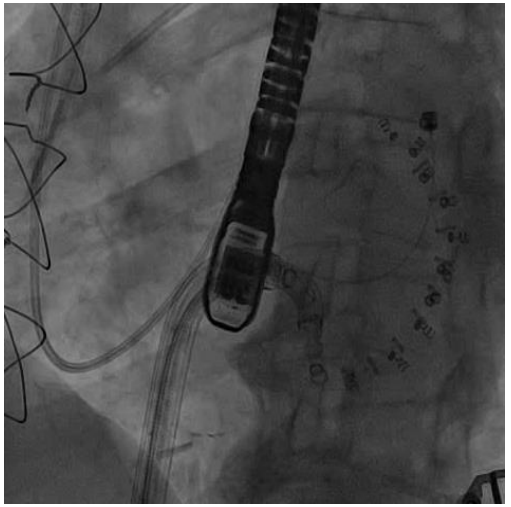


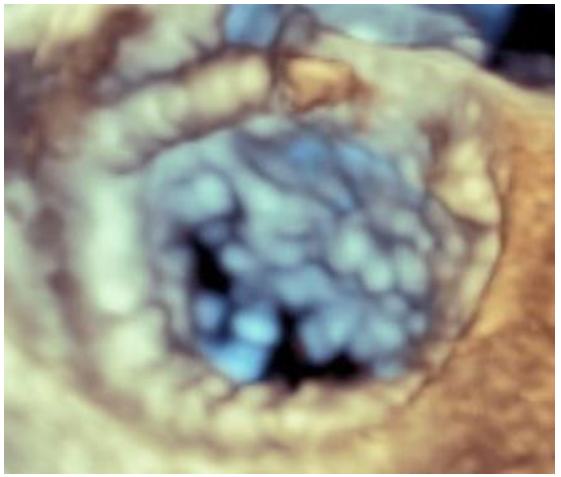
Preliminary data of Cardioband

- 11 patients enrolled
- CT properly assessed correct size of the device
- Implant was anatomically successfull in all patients with intraprocedural improvement of MR in all patients
- No Hospital mortality, all patients are alive at follow-up
- One procedural adverse event (groin hematoma)

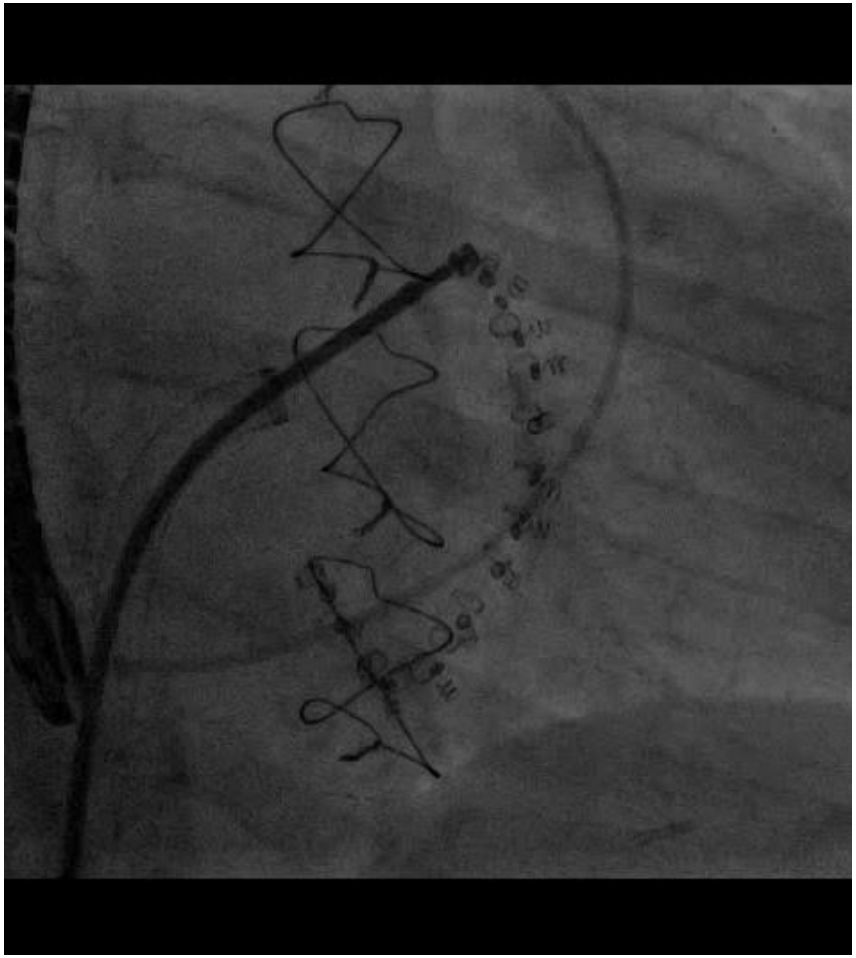
conclusions

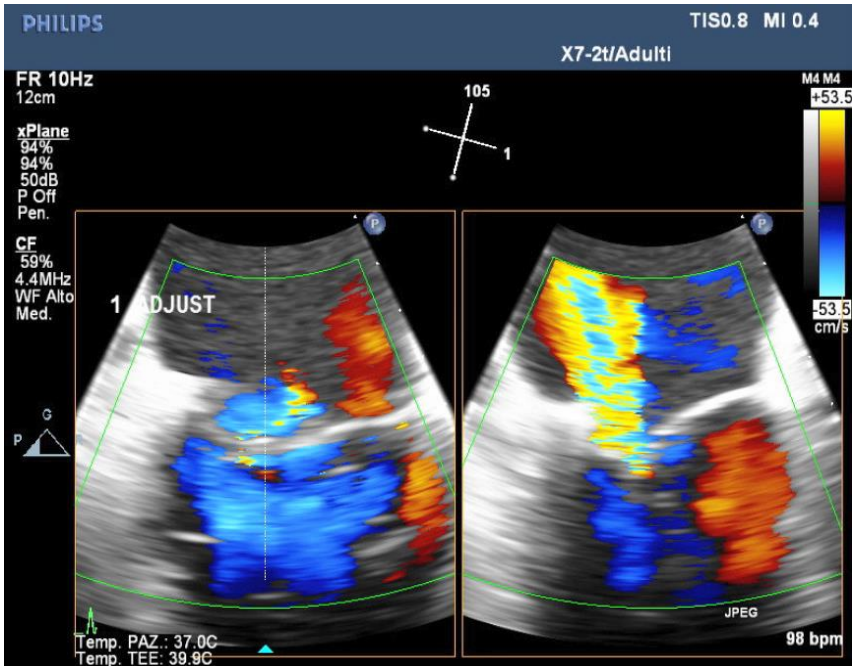
- Fully percutaneous implantation of a surgical grade mitral valve annuloplasty ring is feasible in man
- Safety and efficacy FIM trial is ongoing (11 pts enrolled).
- All patients had an anatomically successfull implantation, with efficacy (MR≤ 3+) obtained in 9 (81%) patients
- 8/11 patients have no or mild MR at discharge (73%) and stable at follow-up
- Imaging is key to perform the procedure safely and effectively





Cardioband contraction 10%





Mild residual MR