

The New 4-Tech Approach for Tricuspid Valve Repair

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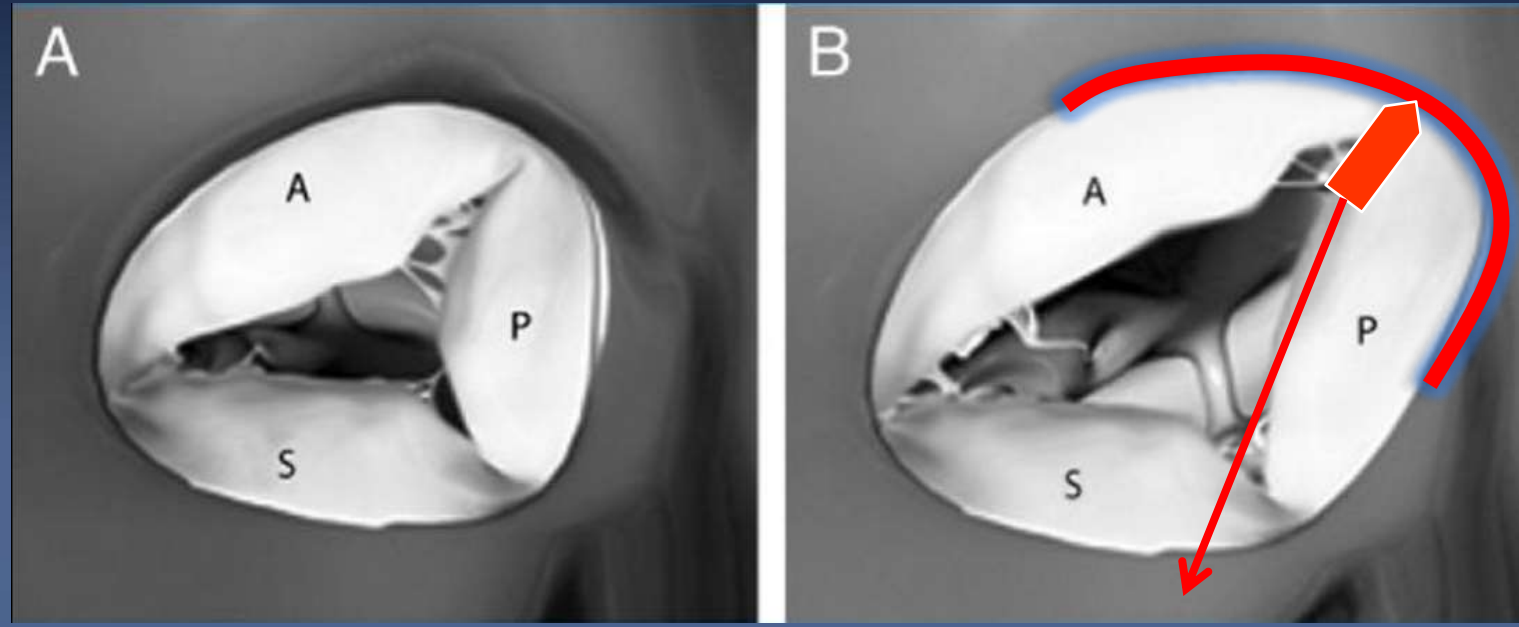
Functional TR

- High prevalence US (1.6m)
- Makes up ~75% -90% of all TR
- Often associated with Left sided disease (30-50% MR)
- Increase in late Mortality with FTR

Functional TR is a Result of Annular Dilatation

Normal Tricuspid Valve

Antero-Posterior Dilatation of Tricuspid Annulus



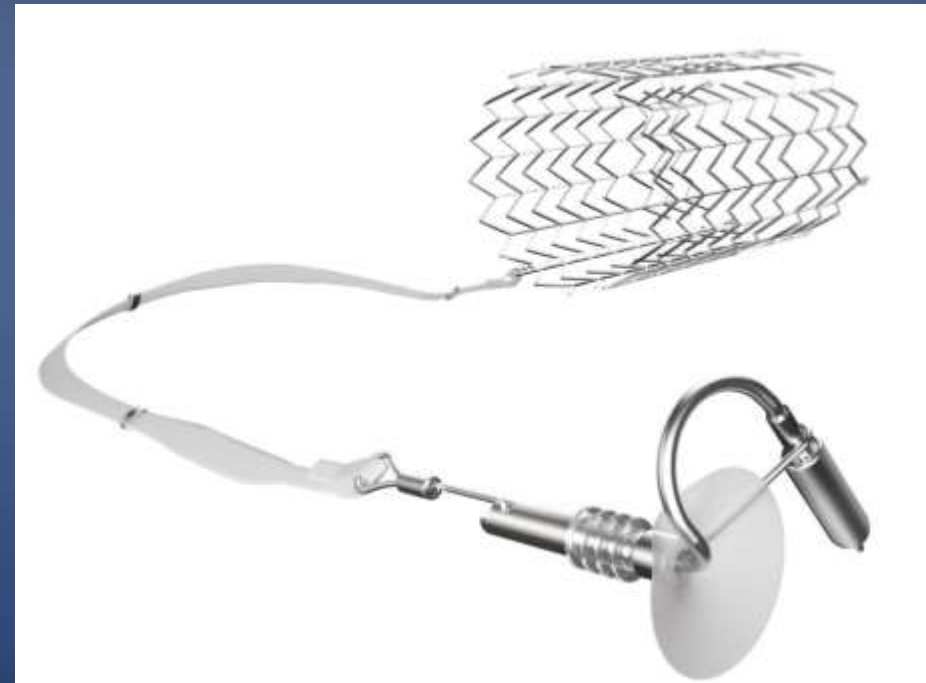
A = Anterior leaflet; P = Posterior leaflet; S = Septal leaflet

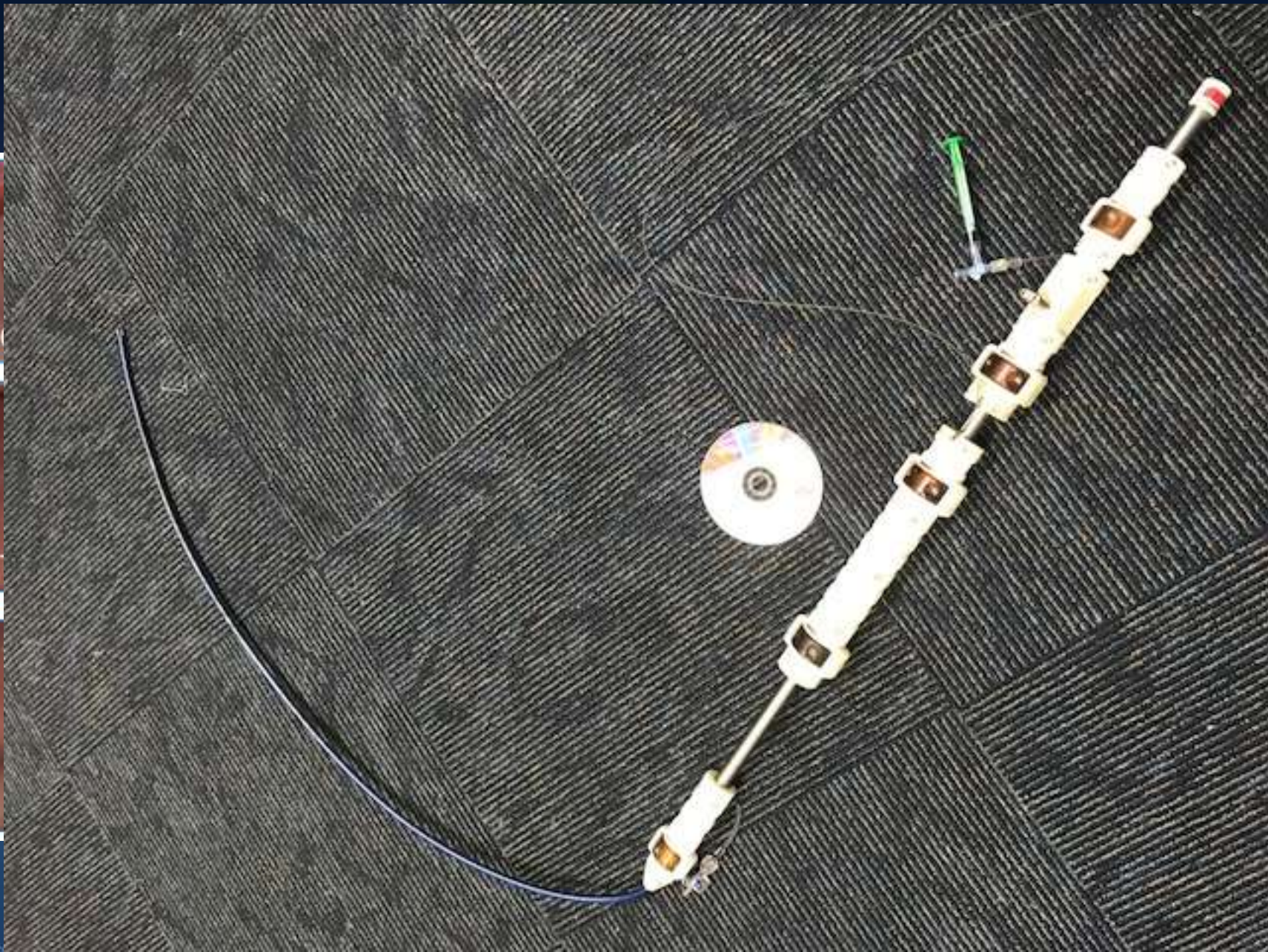
- FTR is primarily due to tricuspid antero-posterior dilatation¹

4Tech TriCinch Coil System

Antero-posterior annuloplasty solution for treating FTR

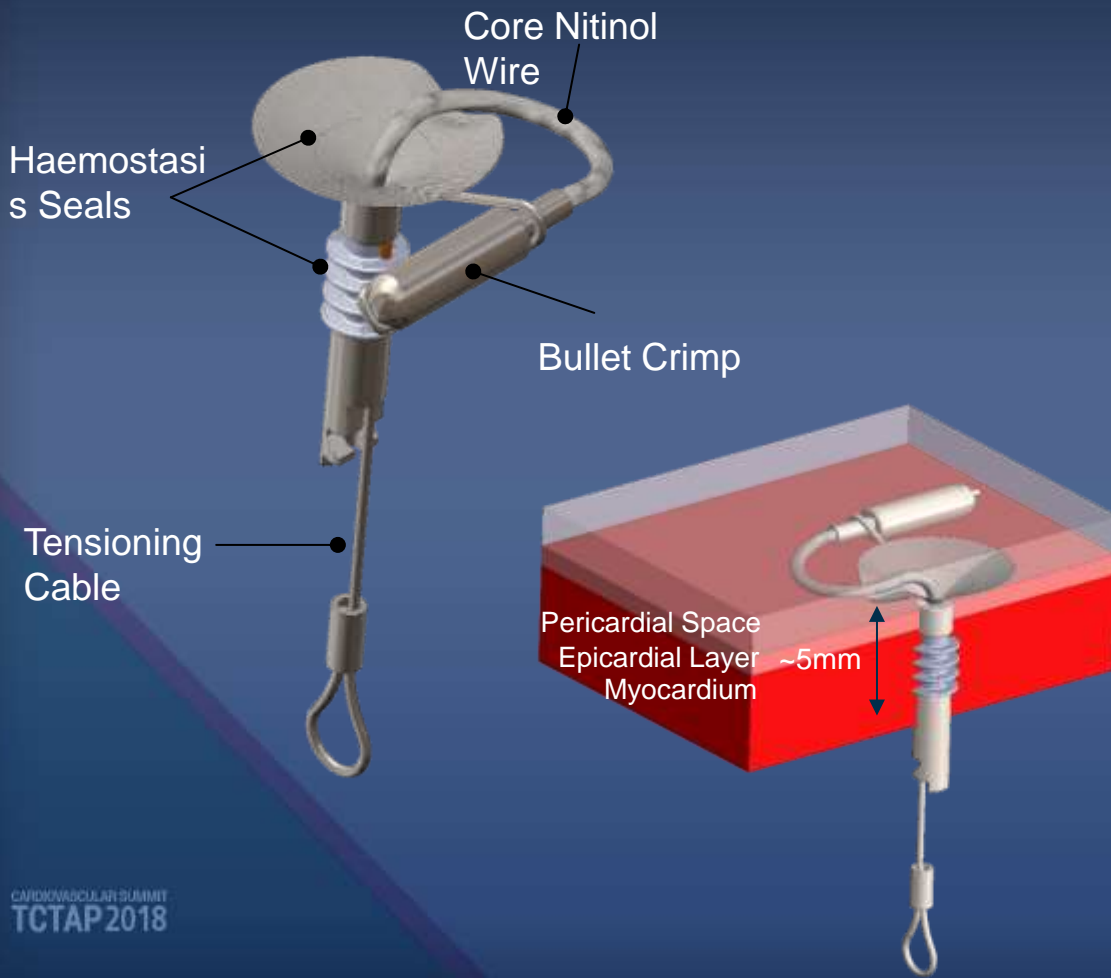
- Simple controlled venous based delivery. 22F
- Secure, small profile anchor covering large surface area
- Restores leaflet coaptation
- Respects native anatomy
- GA with TOE and ICE guidance





Coil Anchor Overview

Coil anchor design provides significant surface area to distribute tensioning force

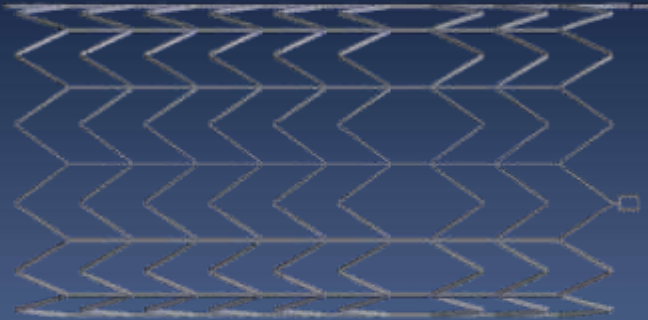


Coil Anchor Phases



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

Stent Sizes and IVC Diameter Guidelines



Stent Sizes for Varying Anatomies

Size	27 mm	32 mm	37 mm	43 mm
Diameter	18 – 22 mm s	22 – 26 mm s	25 – 30 mm s	29 – 35 mm s
Height	66 mm	66 mm	66 mm	66 mm

Vessel Diameter and Oversizing %

mm	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37
27			69%	59%	50%	42%	35%	29%	23%	17%	13%	8%	4%	0%	-4%	-7%	-10%							
32						68%	60%	52%	45%	39%	33%	28%	23%	19%	14%	10%	7%	3%	0%	3%	6%	-9%		
37								76%	68%	61%	54%	48%	42%	37%	32%	28%	23%	19%	16%	12%	9%	6%	3%	
43									95%	87%	79%	72%	65%	59%	54%	48%	43%	39%	34%	30%	26%	23%	19%	16%

Calculates the % growth in the initial vessel to allow the stent to return to its free diameter

Max oversizing justifiable by animal model in 120%, measurement error and prudence setting max at 60%

Min oversizing is based on stent plateau (13% of diameter plus measurement error of 7%) = 20%

Prevent TriCinch™ European FIH trial

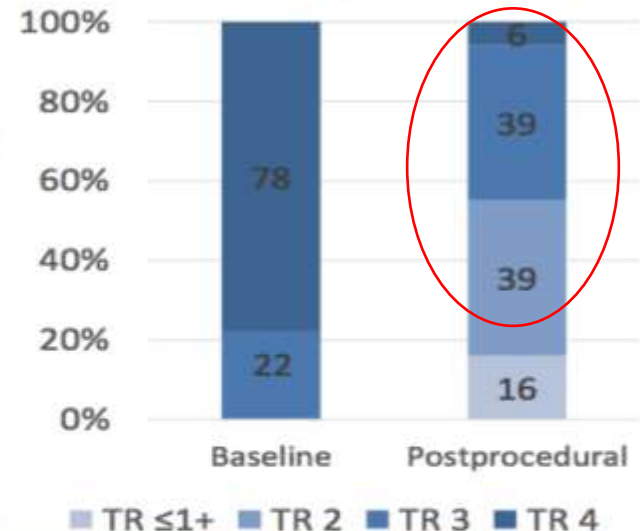
Baseline characteristics - Patients Enrolled: 24

- 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)

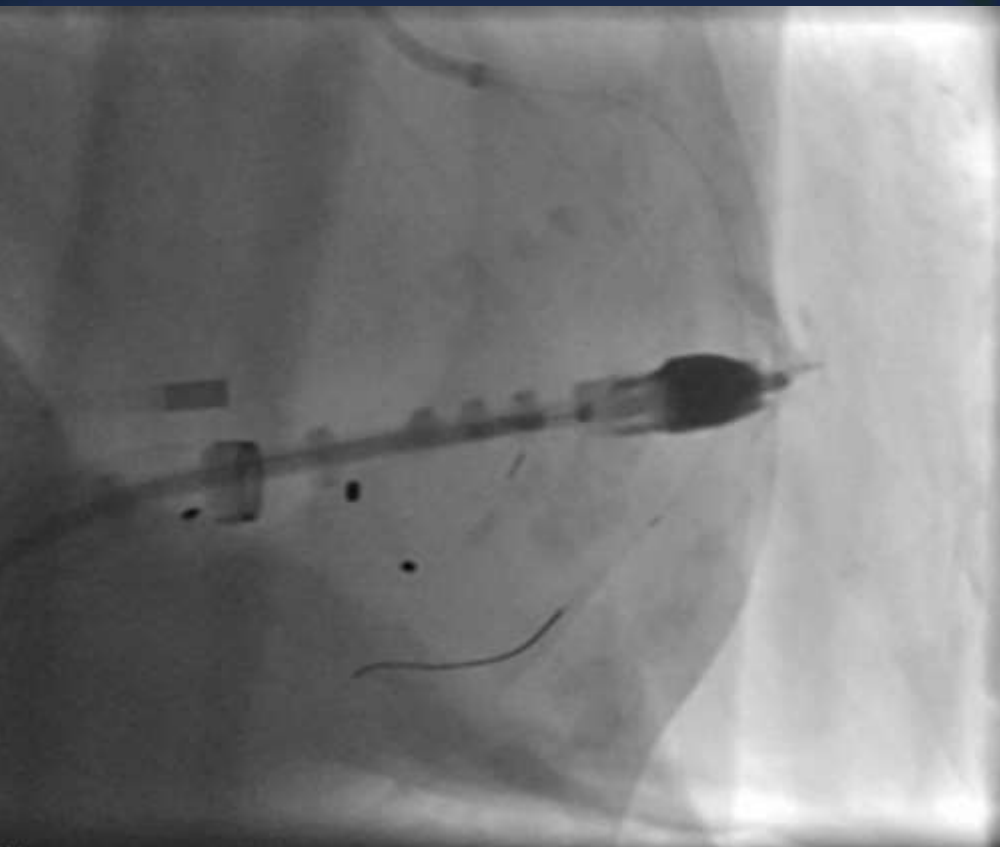
Accumulated implant time	43 months
Median follow-up time	1 month [1-6]
NYHA class	I - II 75% III 25% IV 0%
Quality of Life Improvement	6MWT (m) +53% - MLHFQ +38% - SF36-physical +42%
All-cause mortality	0 [0%]

Francesco Maisano

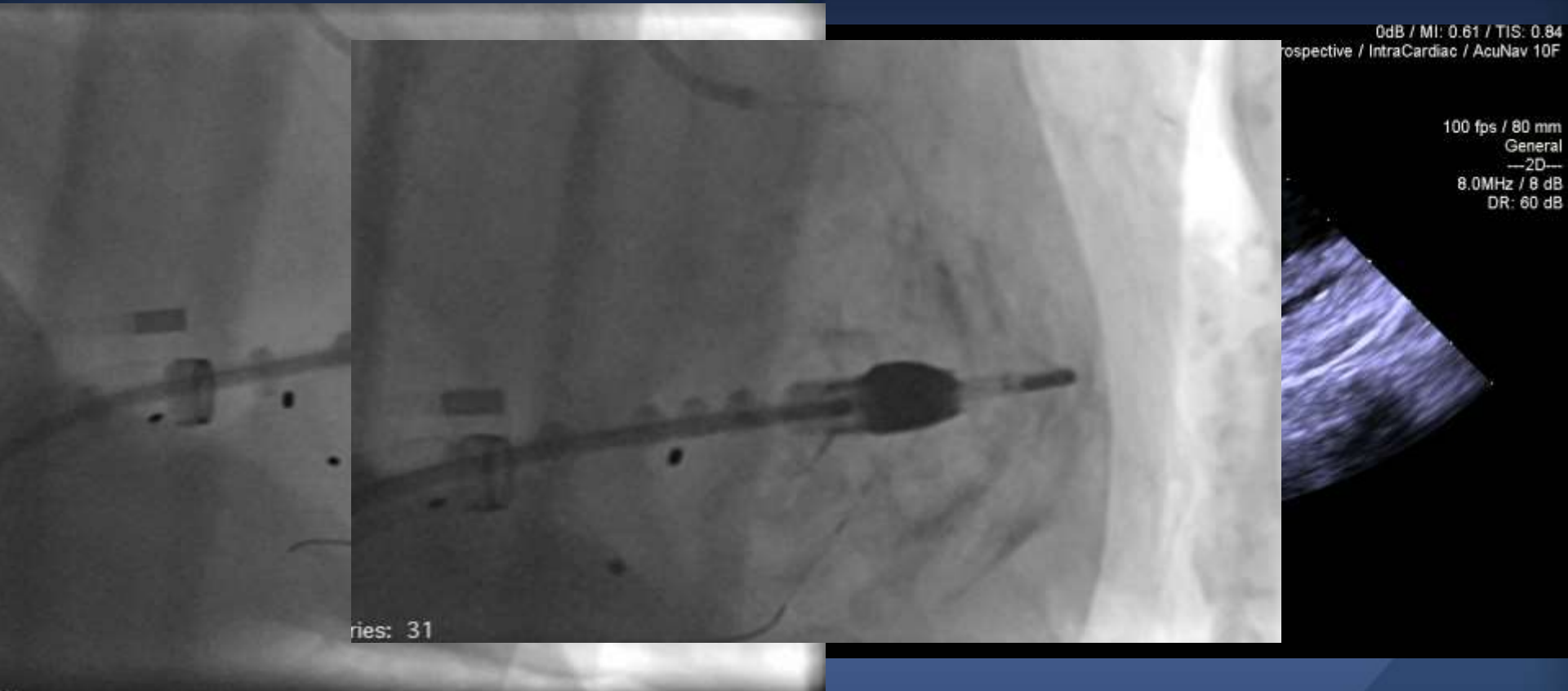
Finding Spot



Entering Pericardial Space

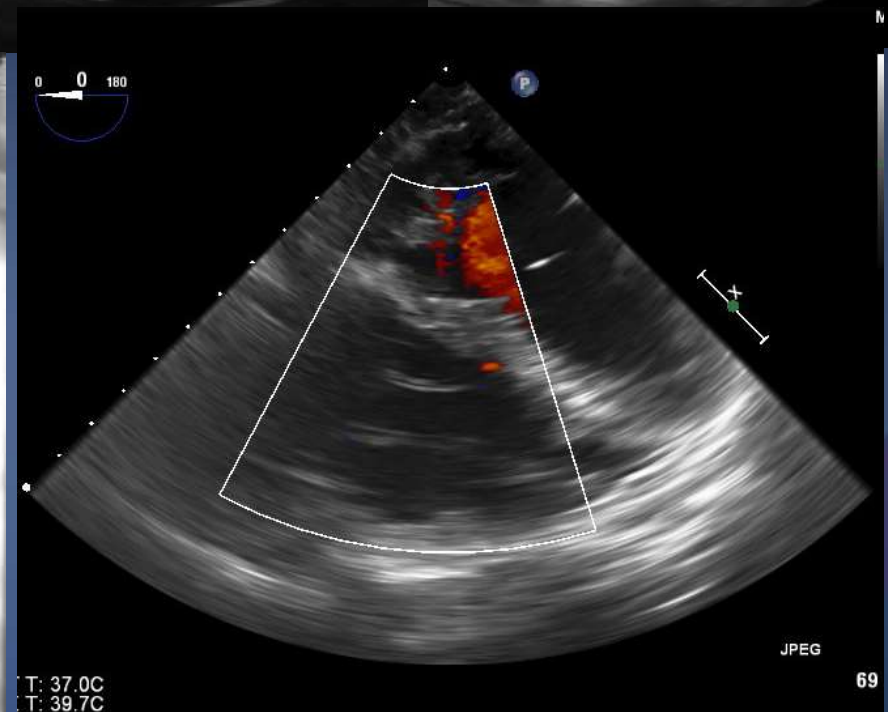
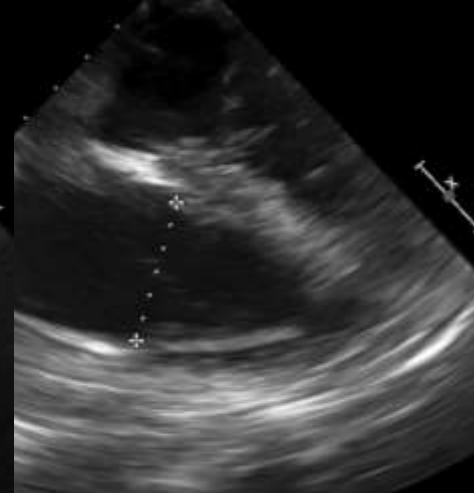
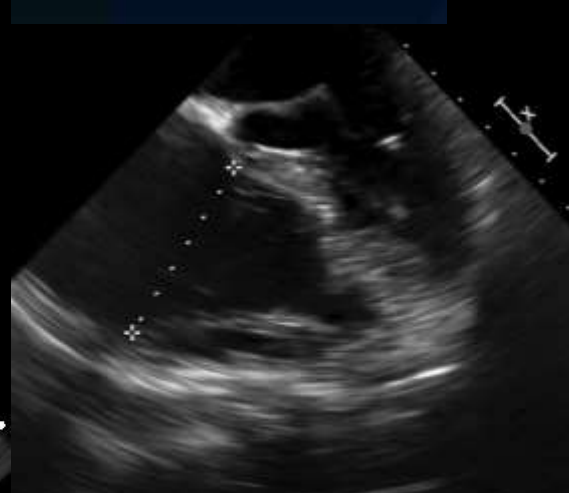
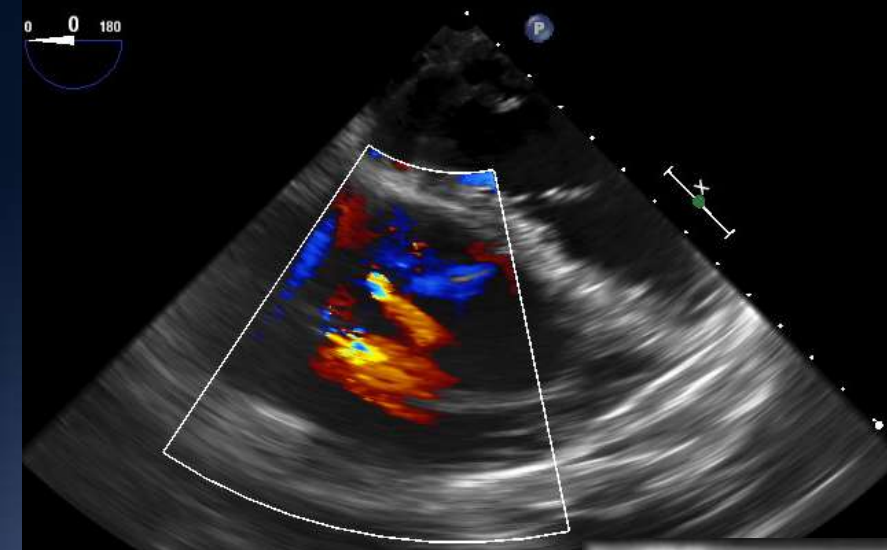


Deploying Coil in Pericardial Space



Deploying Tensioning Band





4-Tech TriCinch TVRepair

- Still early days,
- Ongoing 90 patient safety & feasibility study with current system – [ClinicalTrials.gov NCT03294200](https://clinicaltrials.gov/ct2/show/study/NCT03294200)
- Probably be fairly steep learning curve to get good reduction in TR
- Suitability for all FTR (?)
- Durability (?) – stability of anchoring system.



Not every Australian animal wants to kill you.



Thank You