Mitralix Transcatheter Mitral and Tricuspid Valve Repair: Report of the ongoing tricuspid FIM trial

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Disclosure Statement of Financial Interest

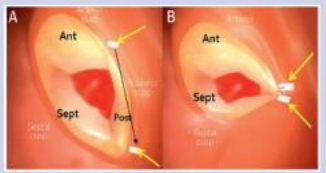
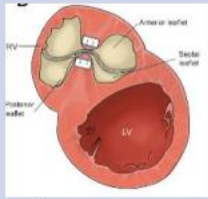
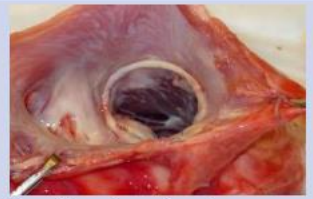
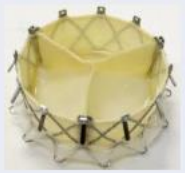
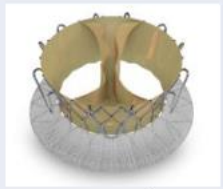
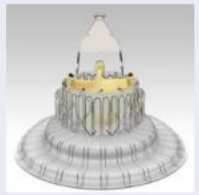
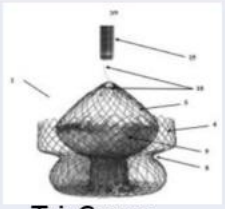
Within the past 12 months, I or my spouse/partner have had a financial interest, arrangement, or affiliation with the organization(s) listed below:

Affiliation/Financial Relationship	Company
Grant/Research Support	**Mitralix**
Consulting Fees/Honoraria	**Endospan, Mitralix, Innoventric, Eximo medical, Heartpoint Global, V Vital, Abbott**

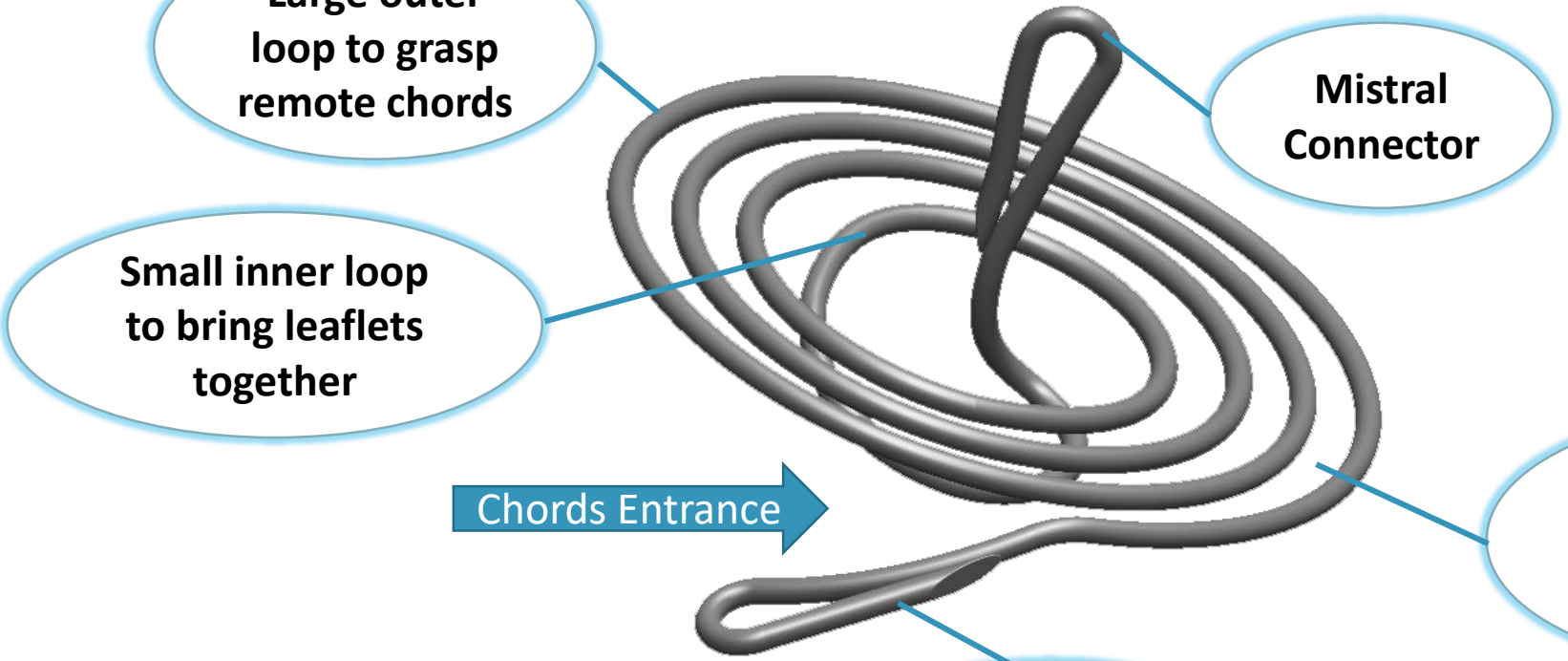
Background

- Mistral [Mitralix Ltd., Israel] is a catheter-based treatment for tricuspid (TR) and mitral (MR) regurgitation
- Spiral shaped implant and an 8.5F delivery system
- The device improves leaflets coaptation by gently grasping chords from two or three leaflets
- This is a report of the ongoing tricuspid FIM trial

New tricuspid therapies

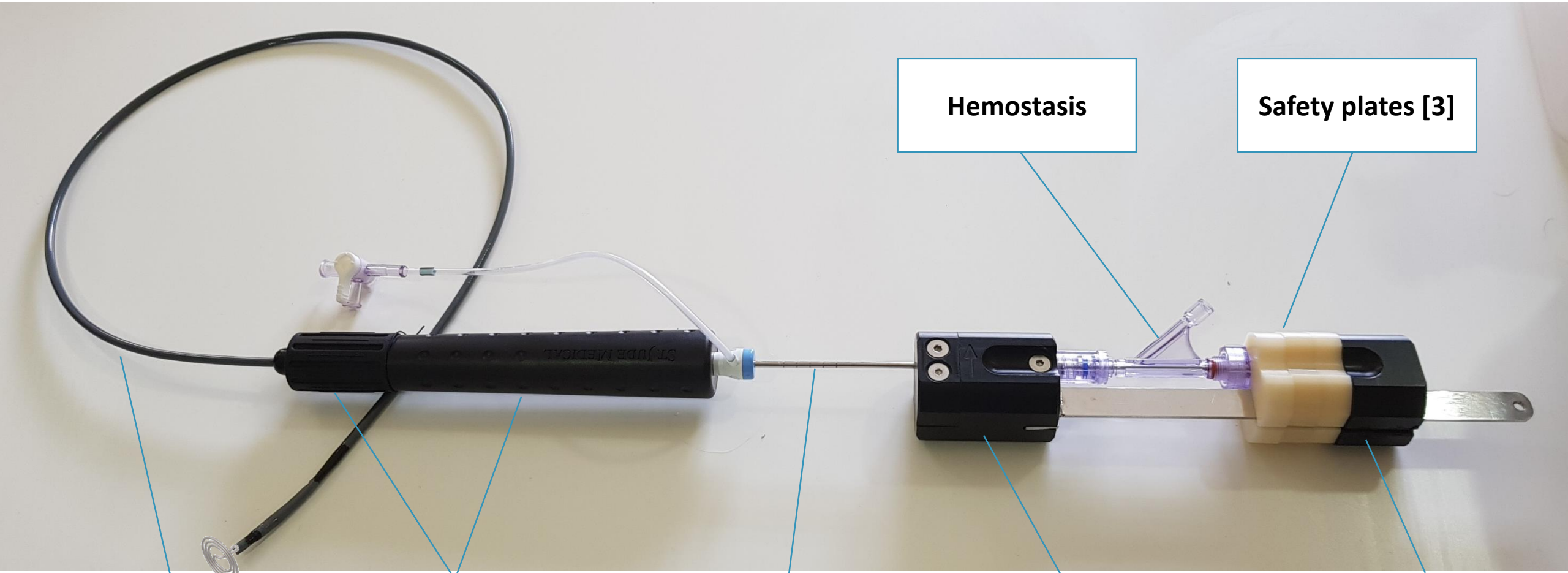
Mechanism	New Technologies
Annuloplasty (Direct and Indirect) Device	 TriAlign  Cardioband  4Tech  Millepede  Pasta  Cardiac Implants  MIA PolyCor Anchors
Leaflet Device	 Forma  MitraClip  PASCAL  Mistral
Heterotopic Valve (in IVC/SVC)	 Trinity /Sapien  TriCentro  SAPIEN in IVC
Orthotopic Valve Replacement	 Navigate  Trisol  LUX  Tri-Cares

Mistral – Mitral and Tricuspid Repair Device

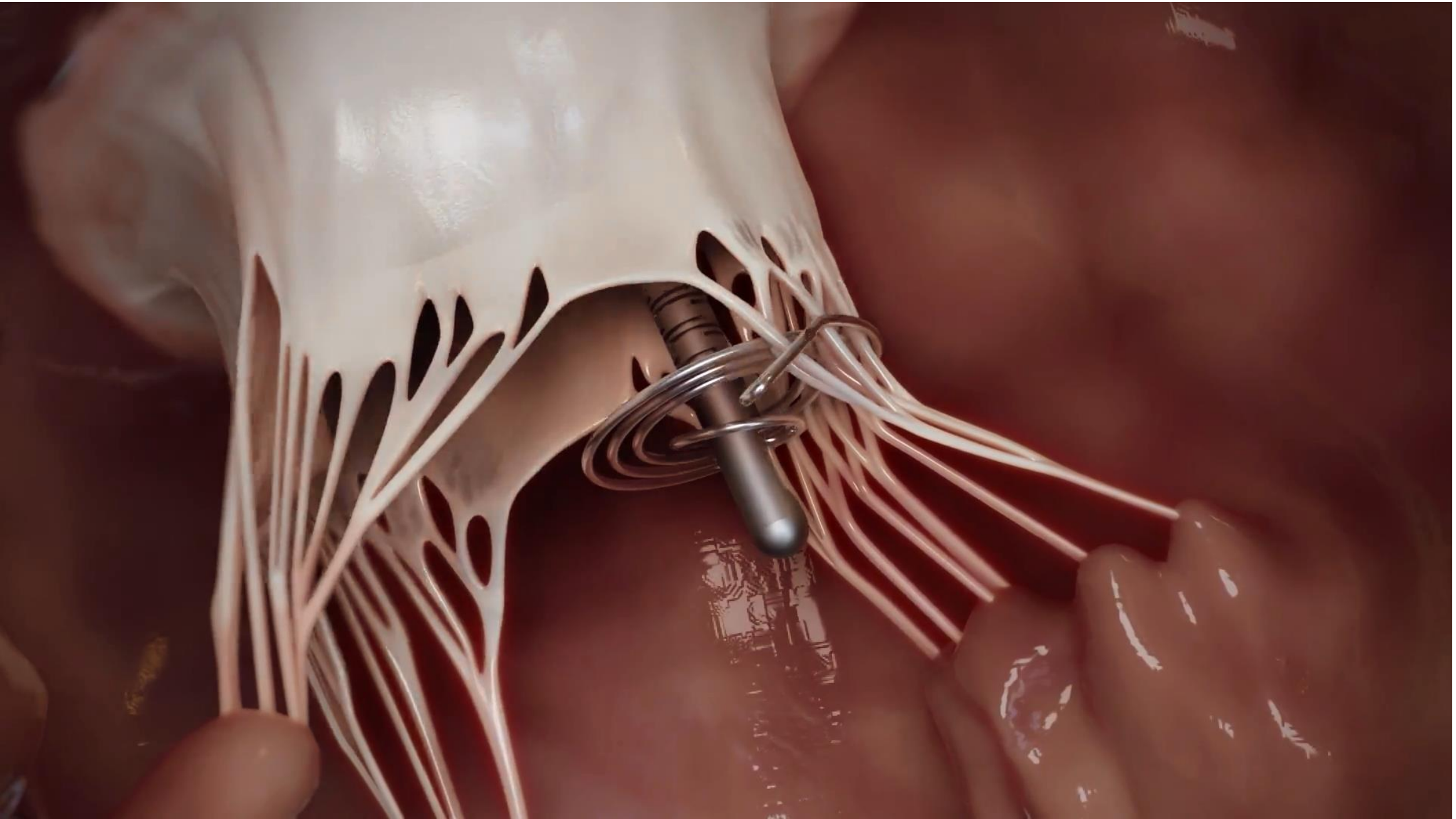


Made of single part, biocompatible Nitinol, 0.4mm wire diameter.

MDS - Mistral Delivery System



Mistral Transcatheter Tricuspid Valve Repair System



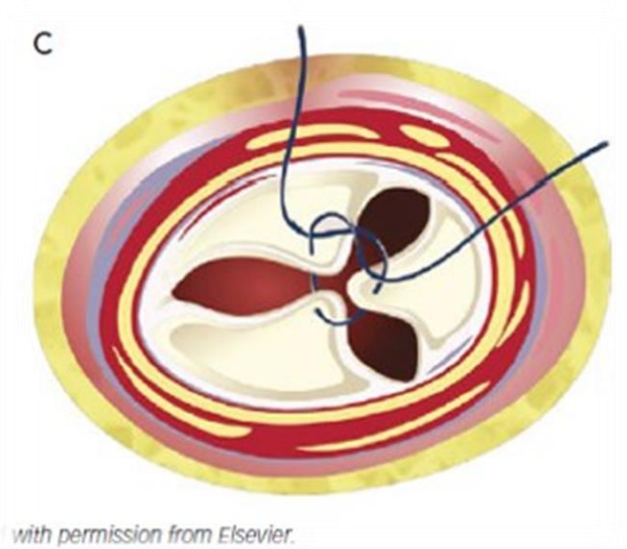
https://www.youtube.com/watch?v=b9FvRliOI1I

SAP Grasp Method

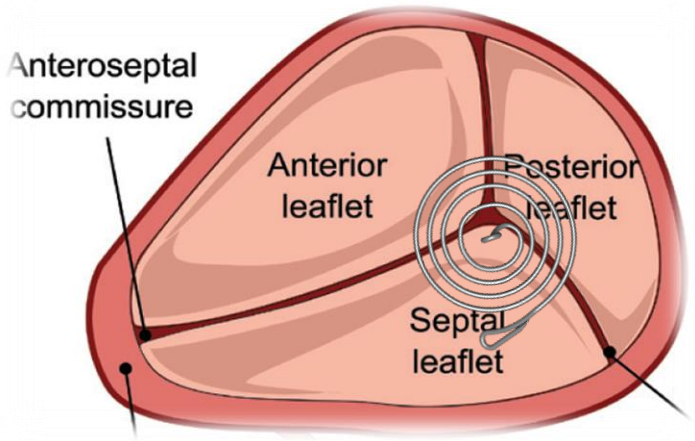
(**S**eptal-**A**nterior-**P**osterior)

Clover repair

Source: Rodes-Cabau, 2016 [2]



Mistral SAP

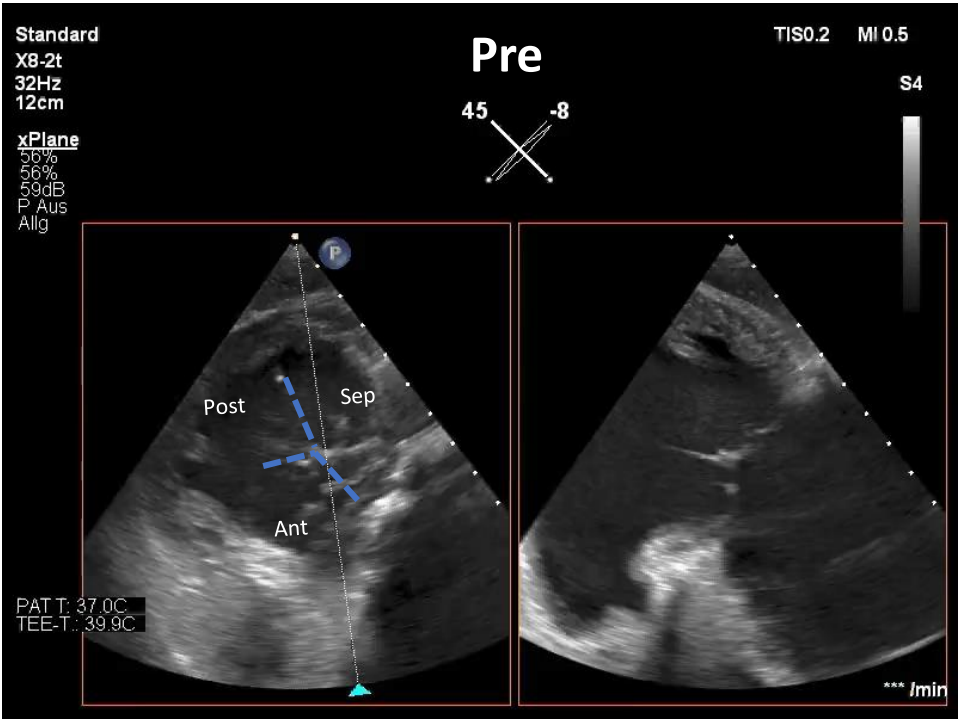


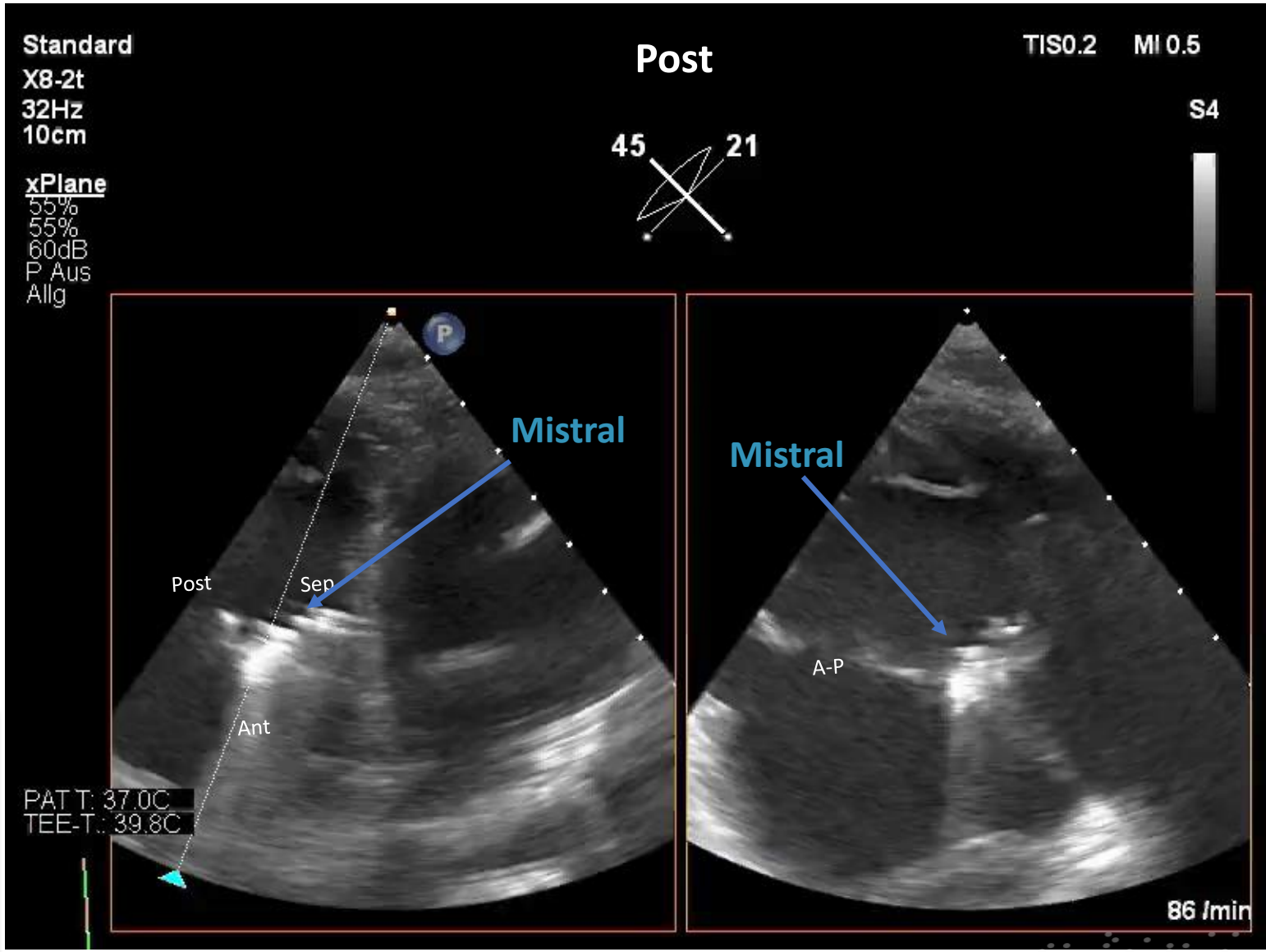
SAP Method – Single Implant

Run 33 Pre procedure SAX Baseline

MN901: **Pre Vs. Post Implantation**

Run 117 Post Procedure





(**S**eptal-**A**nterior-**P**osterior)

Central Septal chordae and A-P PM chordae (from both Posterior and Anterior leaflets)

were grasped – SAP (Single Implant)

Mistral Release in Fluoroscopy

https://youtu.be/y8iwOyTvNXQ

Mistral Advantages

MR and TR procedure: (1) SAME Device (2) SAME Delivery system and (3) Similar procedure steps.

Single implant that can grasp all 3 TR leaflets (SAP).

Device: Single component.

Delivery System: Simple and intuitive 8.5Fr.

Chords Grasping: gradualy and gently [Not 0 or 1].

Revesability: Mistral can easily be turned backwards along procedure.

Mitralix - Very Low Profile Delivery System – 8.5 Fr

MitraClip – 24 Fr | Cardioband – 25 Fr | FORMA – 24 Fr

→ Significantly less traumatic.

→ Easier Angulation with IVC [and SVC] (In Tricuspid).

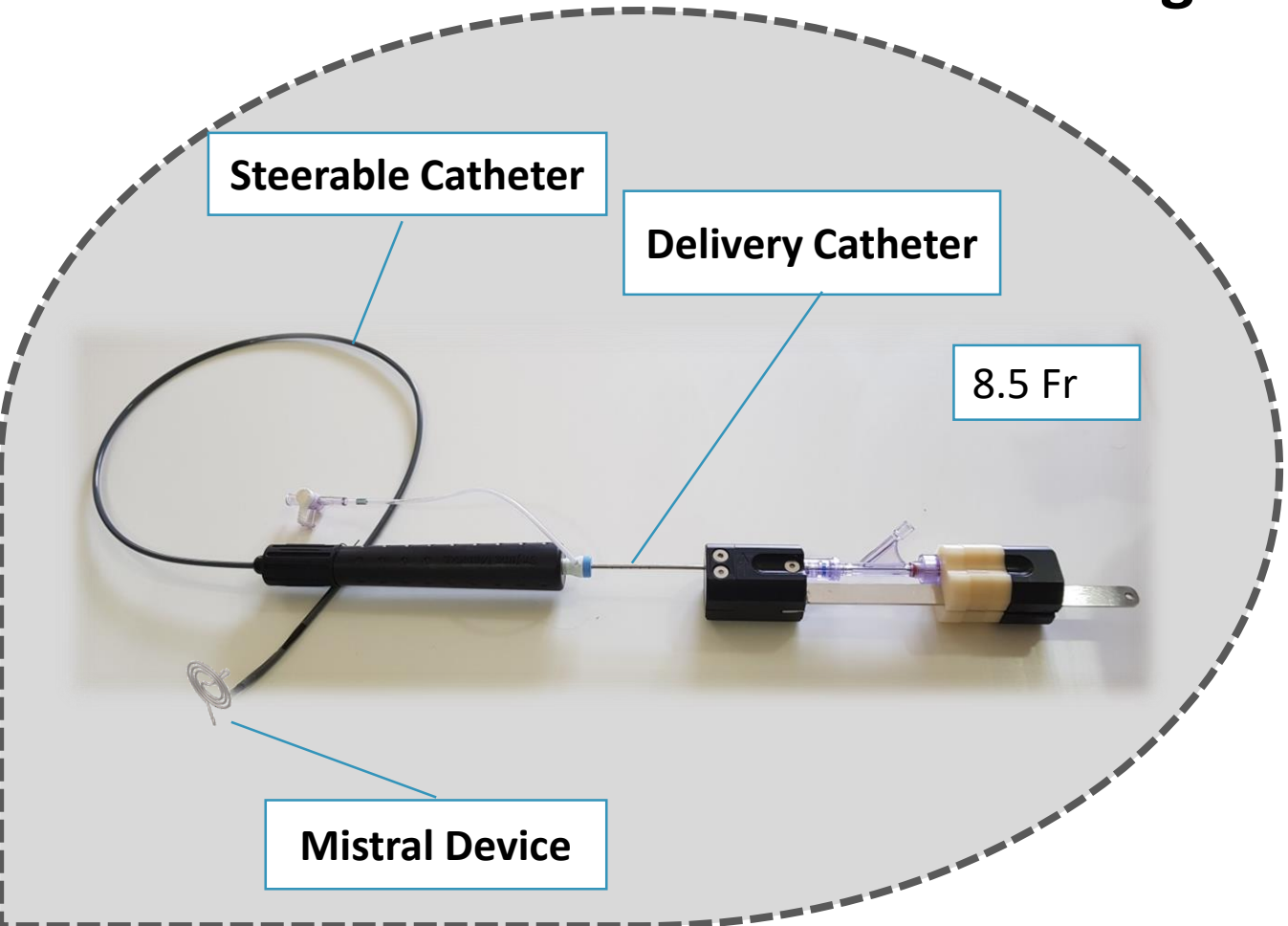
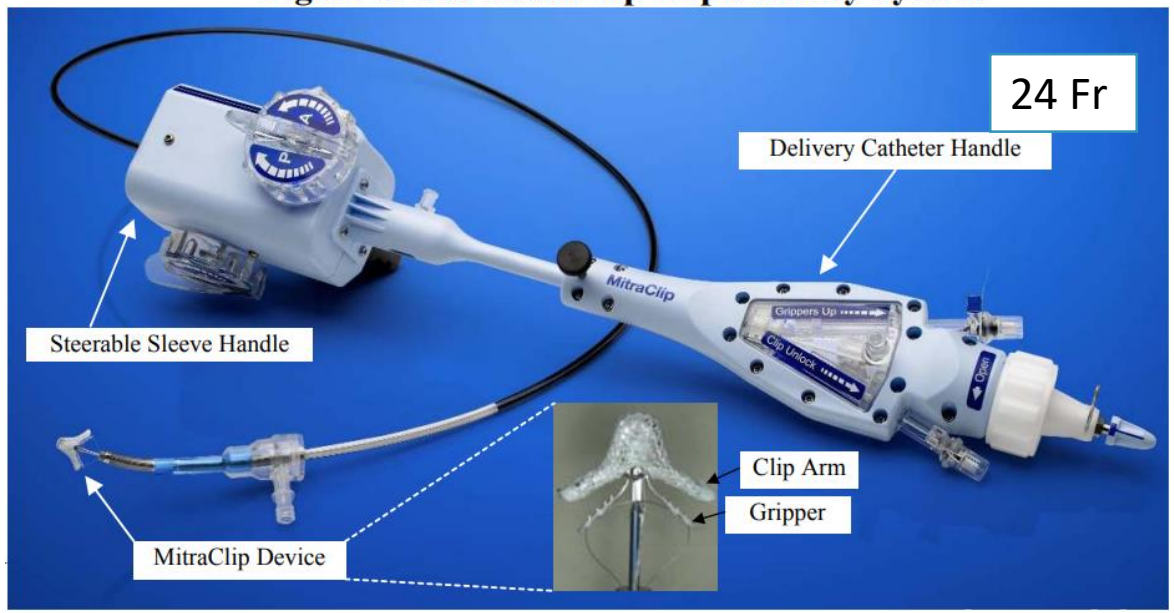


Figure 1: The MitraClip Clip Delivery System



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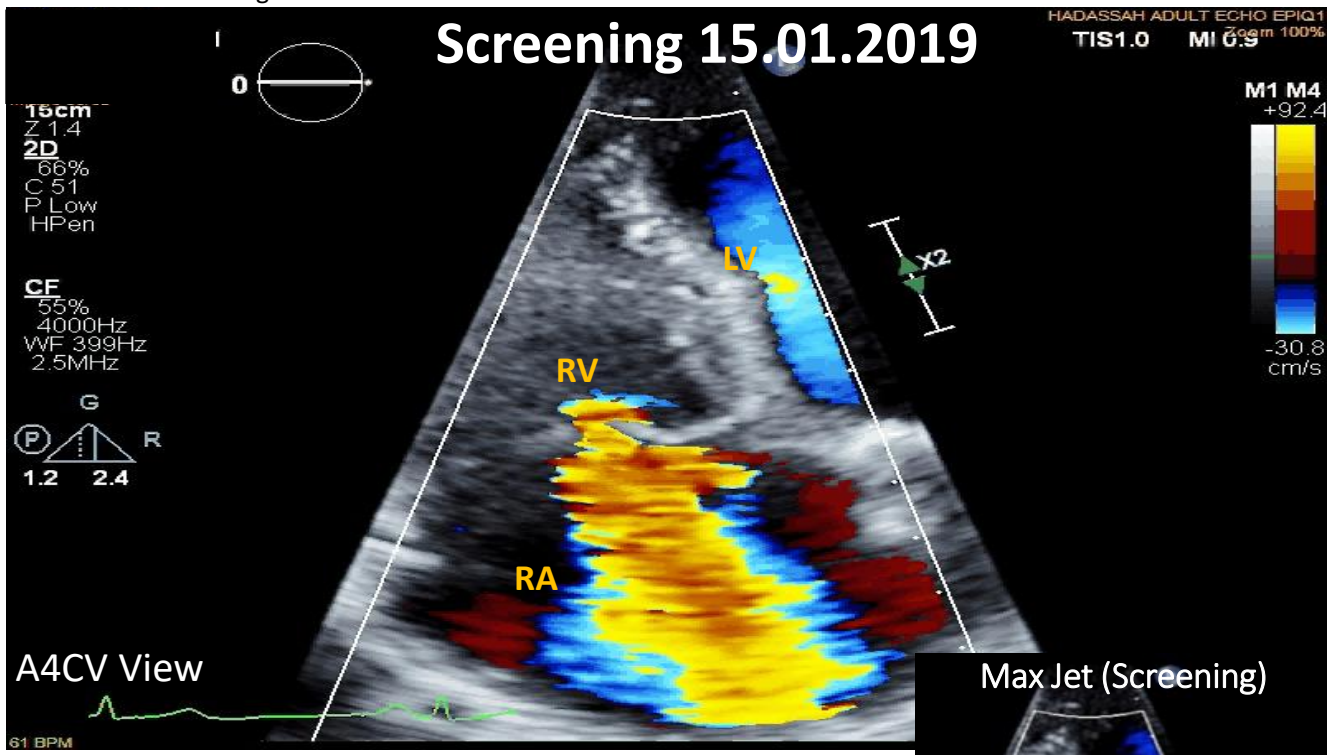
Clinical Data: TR Cases

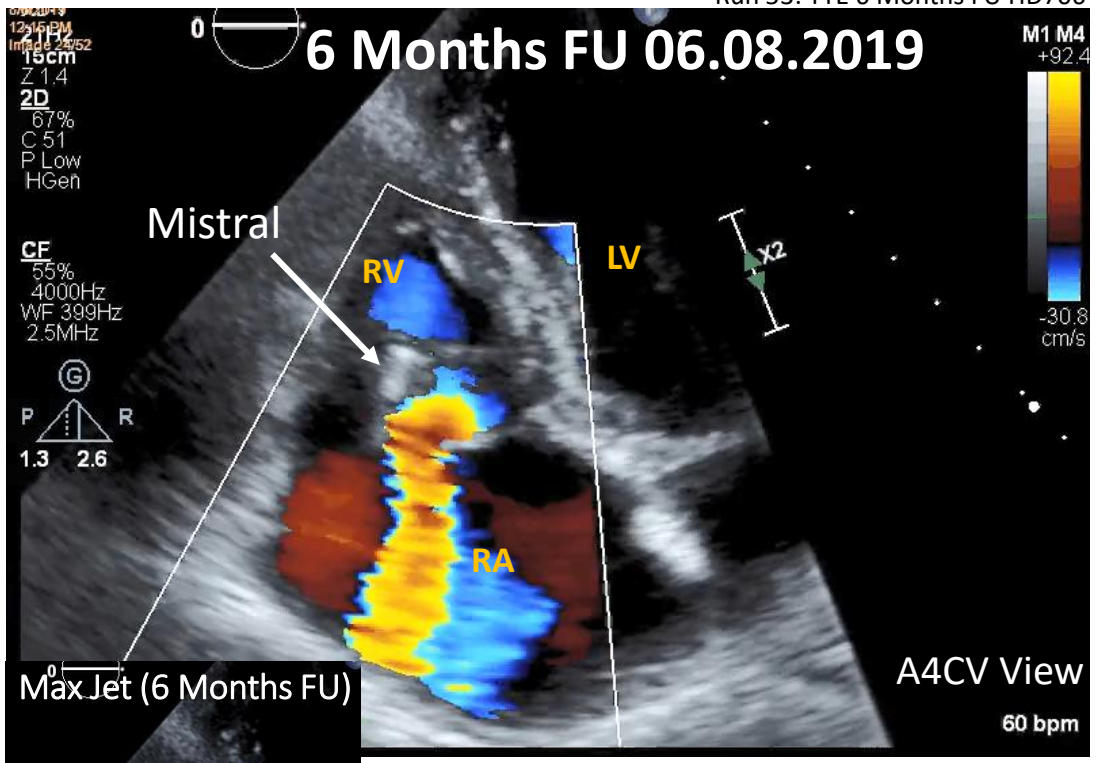
#	Patient (Age)	Follow up month	Case Type	Location	Cardiologist	Device Generation / Position	# Devices	Performance	Safety	Efficacy
1	AL301 (89)	12	Compassionate	Hamburg	Schofer	V1 / A-S, A-P	2	Success	✔	Unchanged
2	CV302 (76)	12	Compassionate	Frankfurt	Sievert	V1 / A-P	1	Success	✔	Unchanged
3	CV303 (85)	12	Compassionate	Frankfurt	Sievert	V4 / A-P	1	Success	✔	Unchanged
4	CV304 (78)	12	Compassionate	Frankfurt	Sievert	V4 / A-P	1	Success	✔	Significant improvement
5	HD701 (71)	-	FIM Study	Jerusalem	Planer	V4 / A-S	1	Removed	✔	N/A
6	HD702 (59)	12	FIM Study	Jerusalem	Planer	V4 / A-S	1	Success	✔	Excellent
7	HD703 (80)	12	FIM Study	Jerusalem	Planer	V4 / A-S	1	Success	✔	Improved
8	HD704 (73)	6	FIM Study	Jerusalem	Planer	V4 / S-A-P	1	Success	✔	Excellent
9	HD705 (78)	6	FIM Study	Jerusalem	Planer	V4 / A-P	1	Removed	✔	N/A
10	HD706 (78)	6	FIM Study	Jerusalem	Planer	V4 / S-A-P	1	Success	✔	Excellent
11	MN901 (73)	6	FIM Study	Munich	Hausleiter	V4 / S-A-P	1	Success	✔	Excellent
12	MN902 (84)	-	FIM Study	Munich	Hausleiter	V4 / S-A-P	0	Not Implanted	✔	N/A
13	SH707 (83)	3	FIM Study	Sheba	Guetta	V3 / A-S	1	Success	✔	Improved
14	SH708 (82)	1	FIM Study	Sheba	Guetta	V4 / A-P, A-S	2	Success	✔	Excellent
15	SH709 (65)	1	FIM Study	Sheba	Guetta	V4 / A-S	1	Success	✔	Unchanged
16	CV905 (76)	1	FIM Study	Frankfurt	Sievert	V4 / S-A-P	1	Success	✔	Excellent

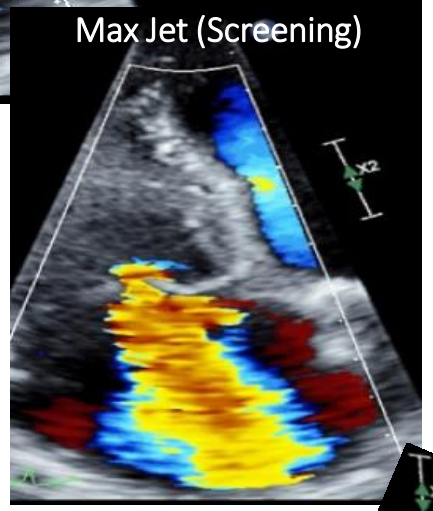
(HD706) Baseline Vs. 6M FU Mistral Device in Tricuspid

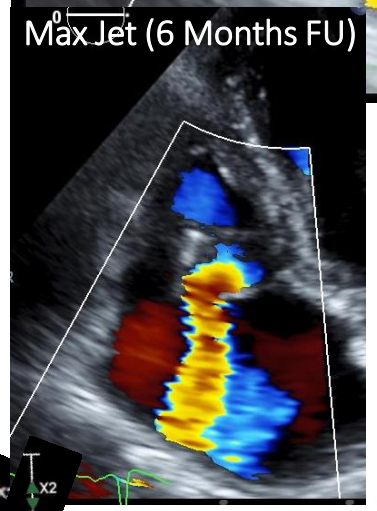
Run 58: TTE Screening HD706



Run 53: TTE 6 Months FU HD706







TR
- **VC Width** [cm]: **0.95** [Severe]
- **EROA** (by PISA) [cm²]: **0.52** [Severe]
- **Rvol** (by PISA) [ml/beat]: **45** [Severe]

RV
- **RV FAC** [%]: **36.7** [Normal]

QOL
- **6MWT** [m]: **400**
- **KCCQ**: **54.69**
- **NYHA class: III**

% Improvement:

- **VC Width** [cm]: **0.47** [Moderate] — **102%**
- **EROA** (by PISA) [cm²]: **0.17** [Mild] — **67%**
- **Rvol** (by PISA) [ml/beat]: **13** [Mild] — **71%**
- **RV FAC** [%]: **41** [Normal] — **12%**
- **6MWT** [m]: **458** — **14.5%**
- **KCCQ**: **94.44** — **73%**
- **NYHA class: I**

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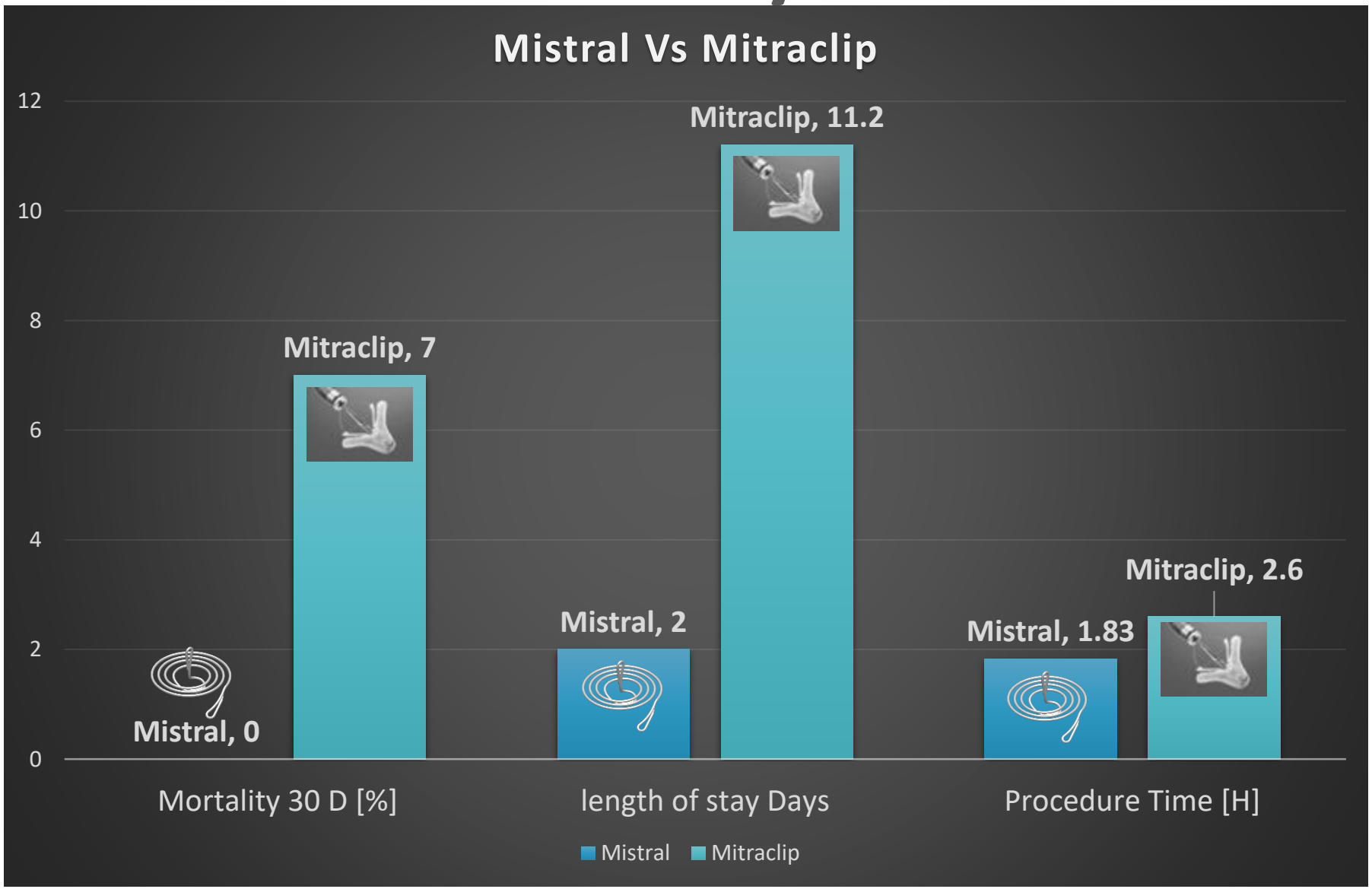
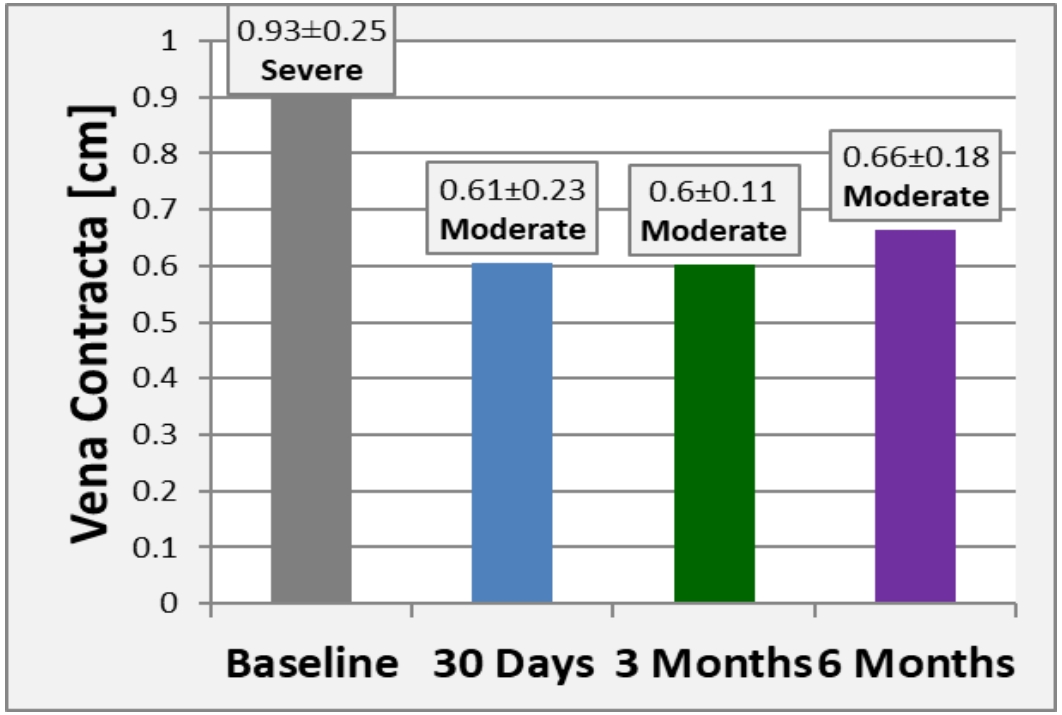
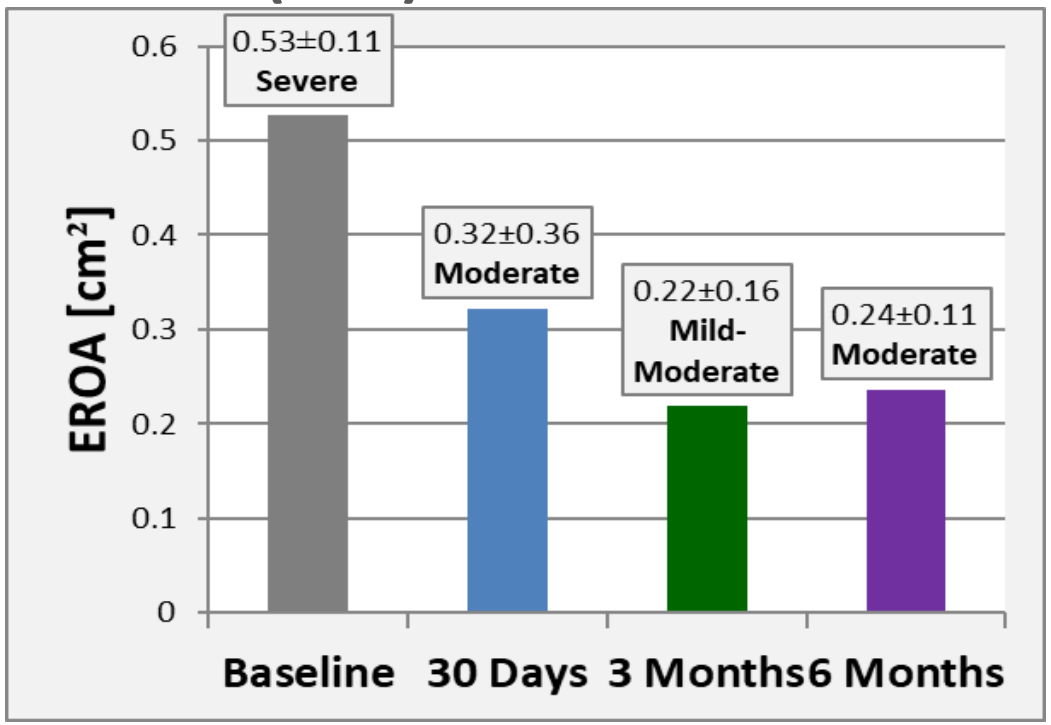
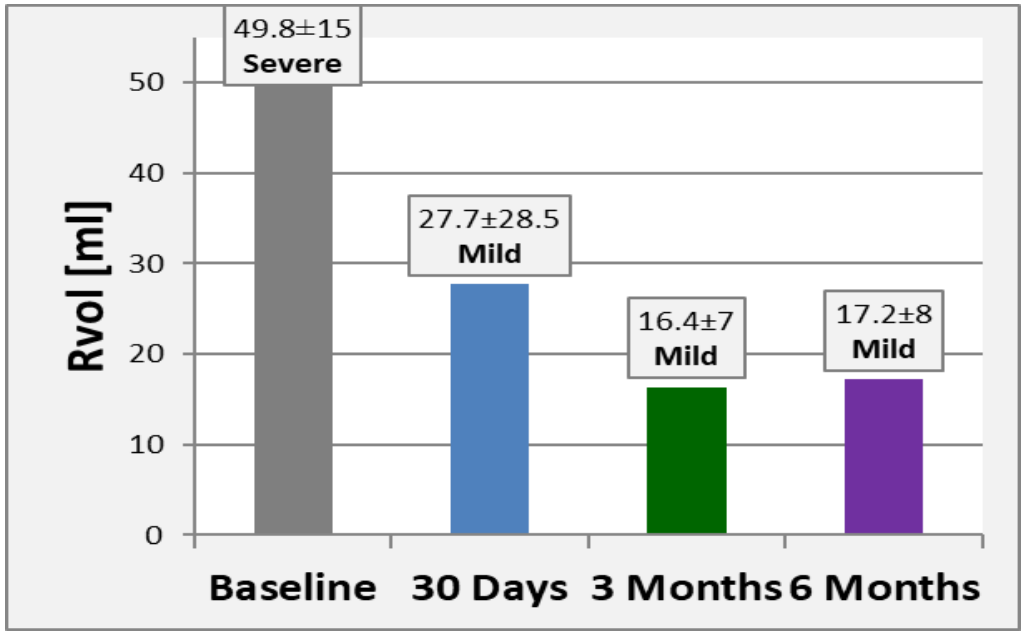
Safety


Mistral Vs Mitraclip
12
10
8
6
4
2
0
Mitraclip, 7
Mitraclip, 11.2
Mitraclip, 2.6
Mistral, 0
Mistral, 2
Mistral, 1.83
Mortality 30 D [%]
length of stay Days
Procedure Time [H]
Mistral
Mitraclip

TR Grade Parameters (n=8)

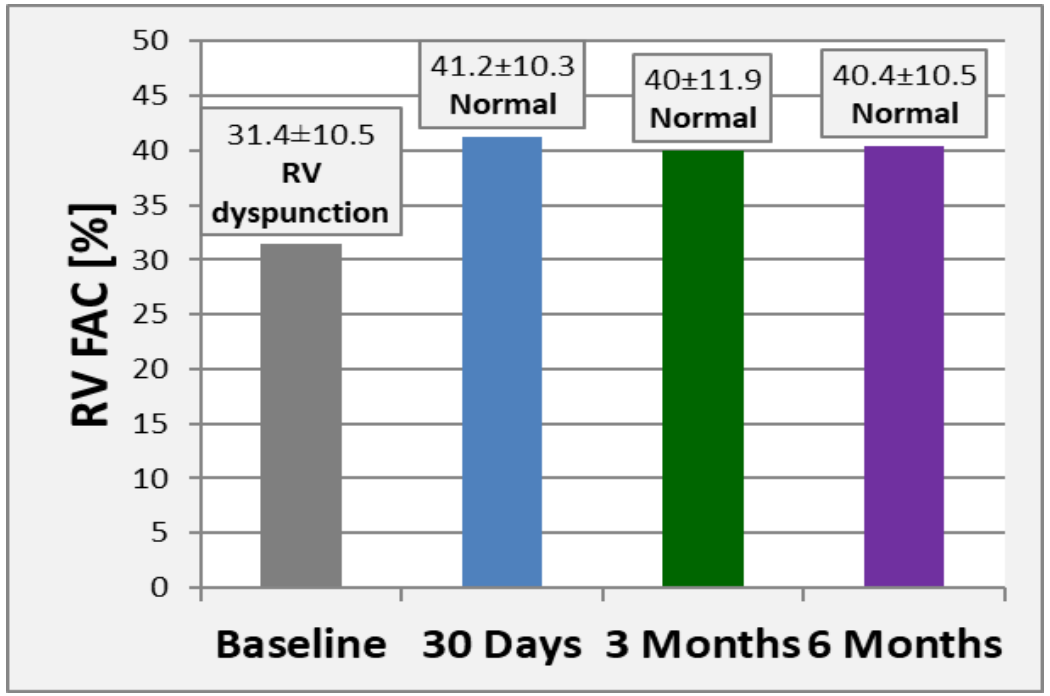




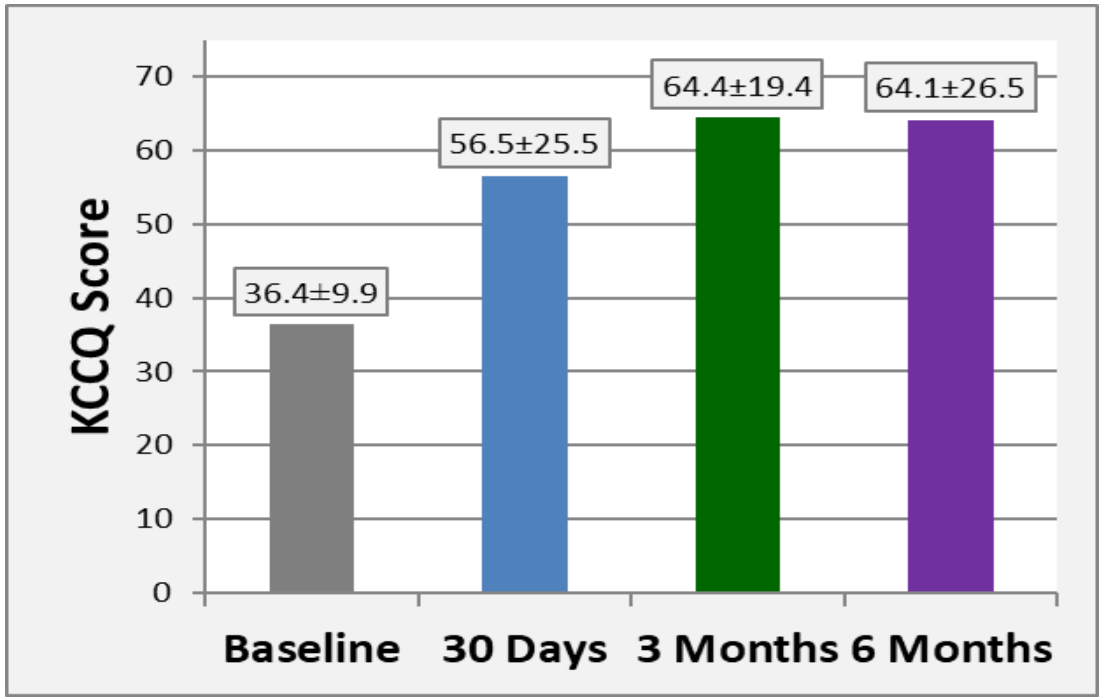


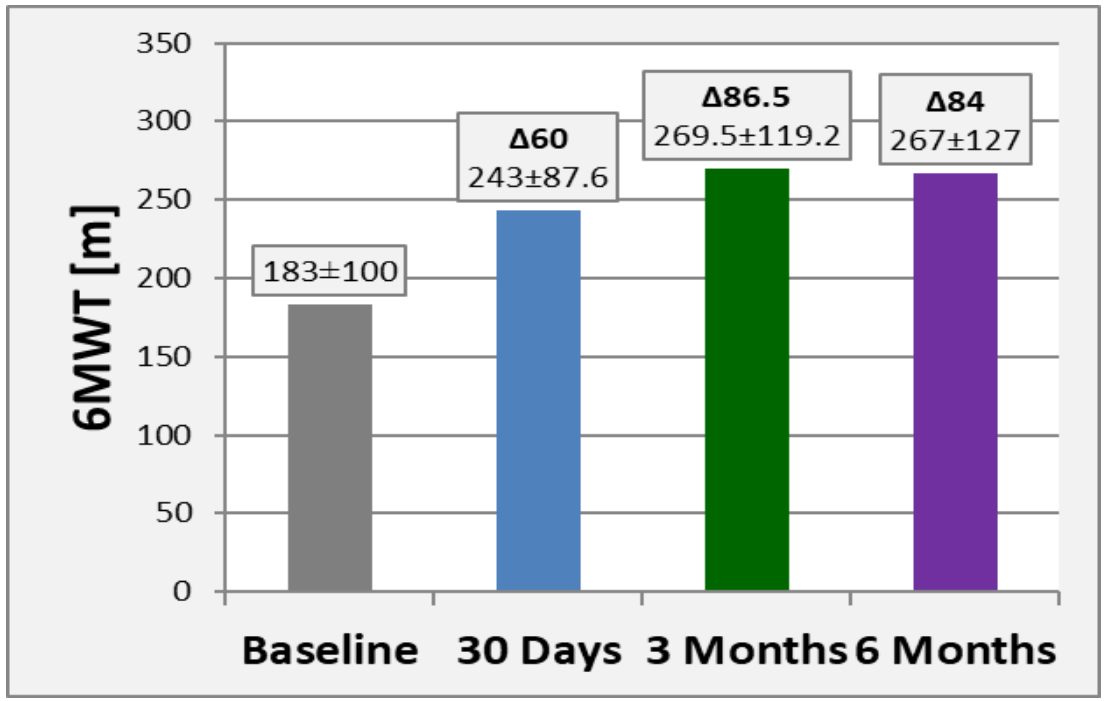
Note: 3 months n=6, 6 months n=5

RV function (n=8)



QOL (n=8)



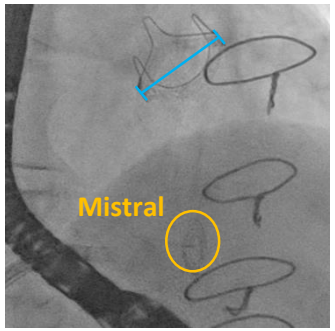


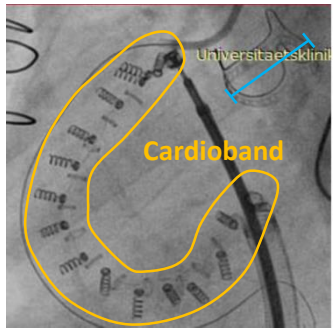
Note: 3 months n=6, 6 months n=5

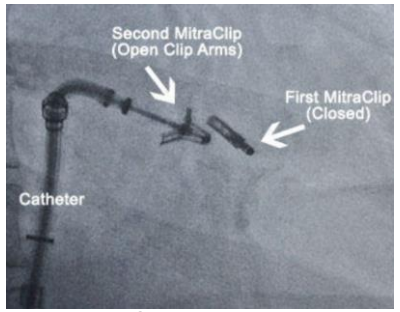
Safety: Mistral vs. Other devices

Product	N	Major Safety Issues in 30 Days	Published
Mistral, Mitralix (TR and MR) 	18	0 (0%) - Death 0 (0%) - RV Perforation 2 (11%) - Device migration 0 (0%) - Device related cardiac surgery Through latest followup in <u>all</u> patients	TVT June, 2019
CardioBand – CE mark approval, Edwards (TR) 	30	2 (7%) – Death	PCR London Valves 2018.
PASCAL, Edwards (TR) 	28	2 (7%) - Death 1 (3%) - Hospitalization, heart failure	TVT June, 2019
MitraClip, Abbott (TR) 	42	3 (7%) - Death	1802 May 9, 2017 Circulation. 2017;135:1802–1814. DOI: 10.1161/CIRCULATIONAHA.116.024848
		37% Death rate during 1 year F-U	Braun et al: one year result of Mitraclip for severe TR- report of 37% death rate during 1 year F-U
FORMA, Edwards (TR) 	29	2 (7%) - Death 2 (7%) - RV Perforation 2 (7%) - Device migration/explant 2 (7%) - Anchor dislodgement 3 (10%) - Device related cardiac surgery	Treatment of Tricuspid Regurgitation With the FORMA Repair System <u>Gidon Y. Perlman</u> and Danny Dvir Front. Cardiovasc. Med., 15 October 2018
Trialign, Mitralign (TR) 	15	13% Death at 6 months	

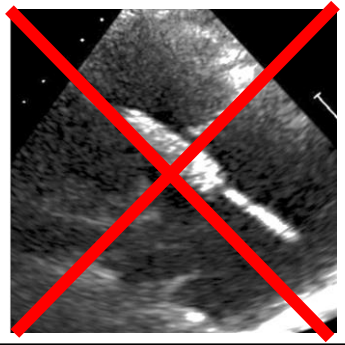
Mistral vs. Competitors:
6 Months follow up Results







2 MitraClip or More: 80%



TTE / Physical Measurement	Mistral (n=5)	Cardioband	TR MitraClip	FORMA*	Trialign
	6 Months % Improvement or mean	**TRI-REPAIR* CE** (n=30) **6 Months** % Improvement or mean	**TRILUMINATE**** (n=85) **6 Months** % Improvement or mean	**Feasibility Study, 30 days** % Improvement or mean	**Feasibility Study, 30 days** % Improvement or mean
Death in 6M	**0%**	11%	7%	7% **	None (13% at 1 year)
Age [years]	**76±7.6**	75±7	77.8±7.9	76±8	73.1
VC Width [cm]	**29%**	27%	50%	31%	25%
EROA (by PISA) [cm²]	**55%**	48%	46%	45%	37%
Rvol (by PISA) [ml]	**67%**	Not Published	44%	NA	28%
RV FAC [%]	**42%**	Not Published	5% (Negligible)	NA (Negligible in TAPSE)	NA (Negligible in TAPSE)
6MWT [m]	**46%** (84m)	23% (60 m)	22% (54.6 m)	21% (38 m)	29% (68m)
KCCQ Score	**76%**	52%	39%	73%	NA

Single Mistral Implanted (n=7),
2 Mistral Implanted (n=1)

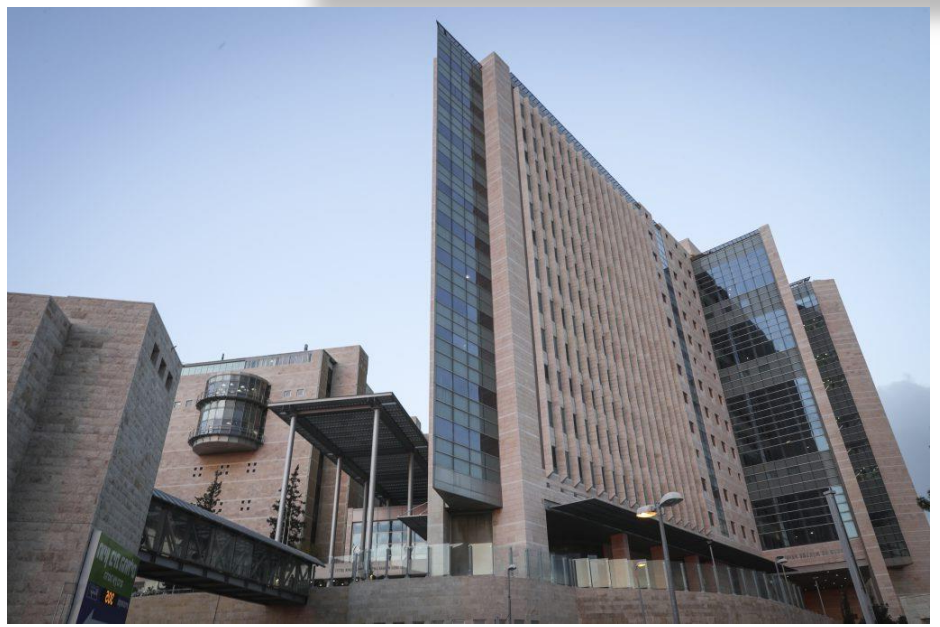
** "Edwards Cardioband Tricuspid Valve Reconstruction System" TRI- REPAIR Study.*
*** "Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation: 6 Month Outcomes from the TRILUMINATE clinical trial". Nickenig G, Lurz P, Hausleiter J et al.*

Conclusions

- Mistral is a novel trans-catheter spiral shape device aimed at grasping the chordae tendinae and thus improving leaflet coaptation.

- FIM cases (Israel, Germany) show that Mistral deployment is safe, effective in reducing tricuspid insufficiency, improving of RV function and associated with encouraging 6 months clinical benefits.

Thank You!



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