



The Mistral Device (Mistralix): Device Features and FIH Data

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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

Consulting

Company

Mitralix, V Wave, Eximo, Sunatco, Abbott,
Innoventric, Endospan

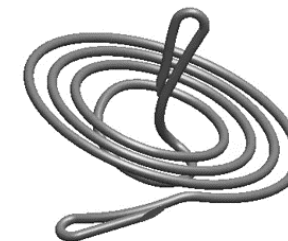
Background



- Mistral [Mitralix Ltd., Israel] is a catheter-based treatment 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
- Four compassionate cases were performed previously showing procedural safety and device stability
- This is a report of the ongoing tricuspid FIM trial



Mistral – Mitral and Tricuspid repair device



Large outer loop to grasp remote chords

Small inner loop to bring leaflets together

Chords Entrance

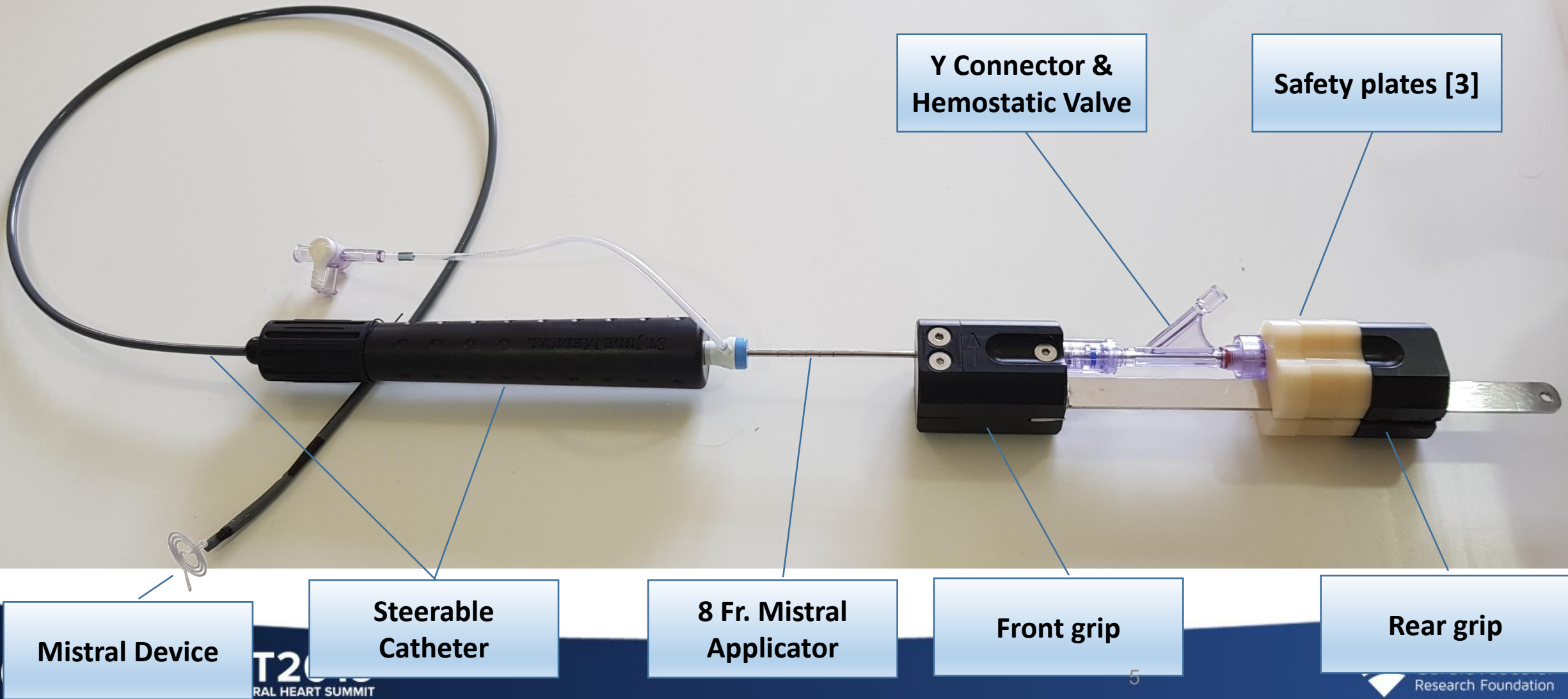
Mistral Connector

Made of single part, Biocompatible Nitinol, 0.4mm wire diameter

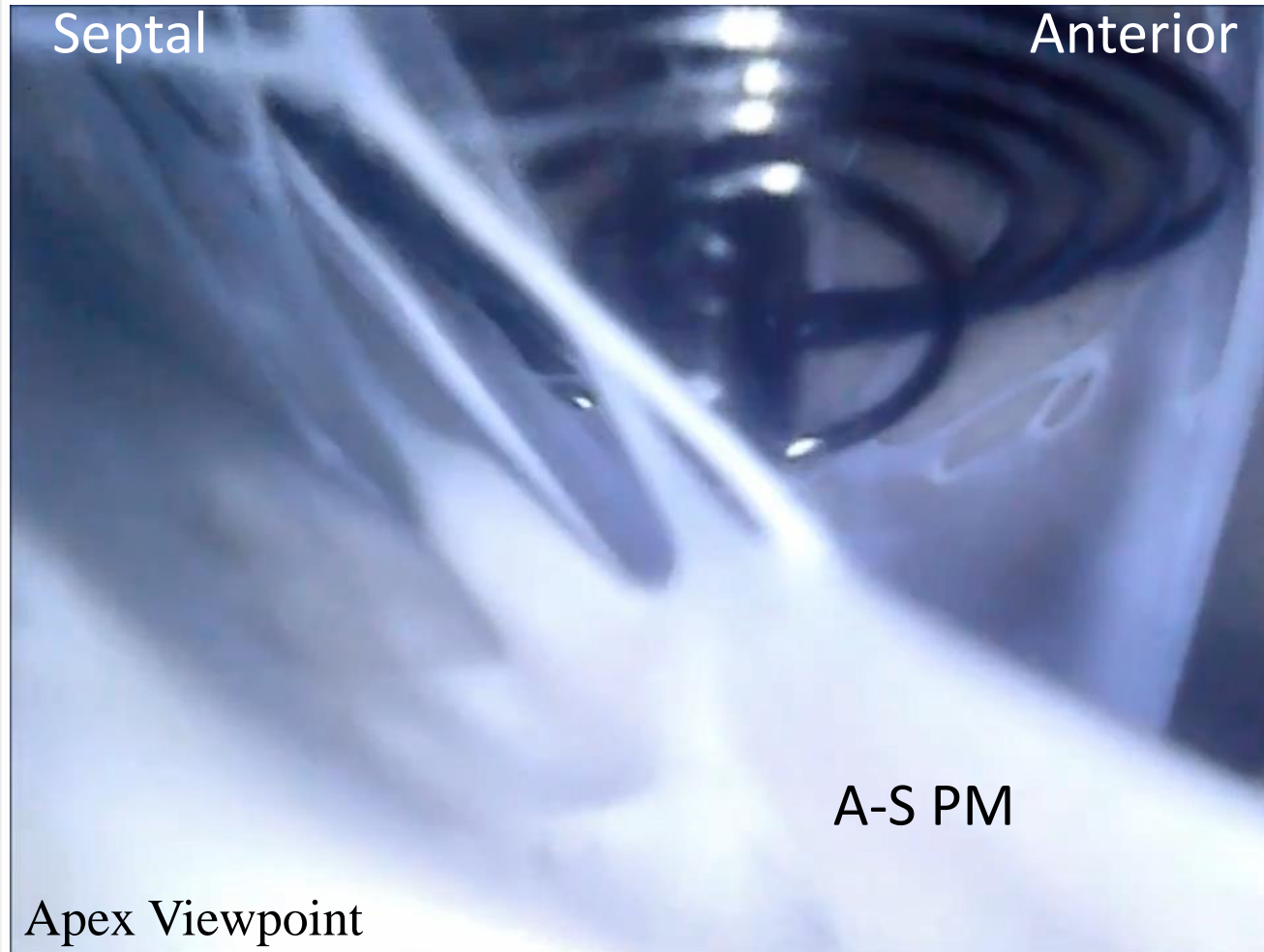
Spiral shape enables gradual grasping

A-traumatic Grasping tip

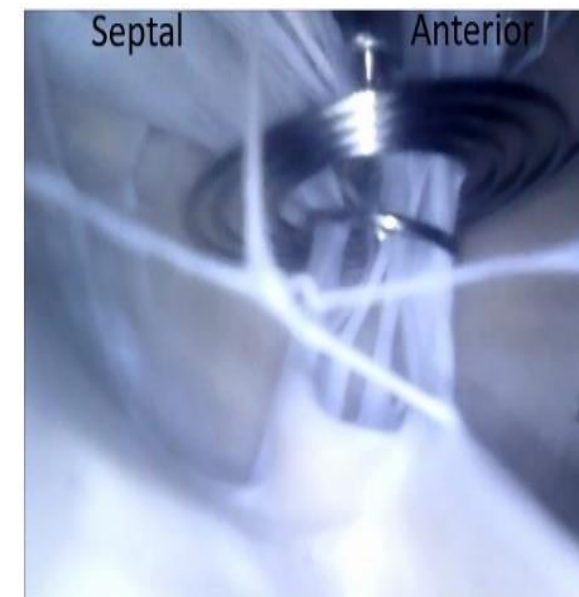
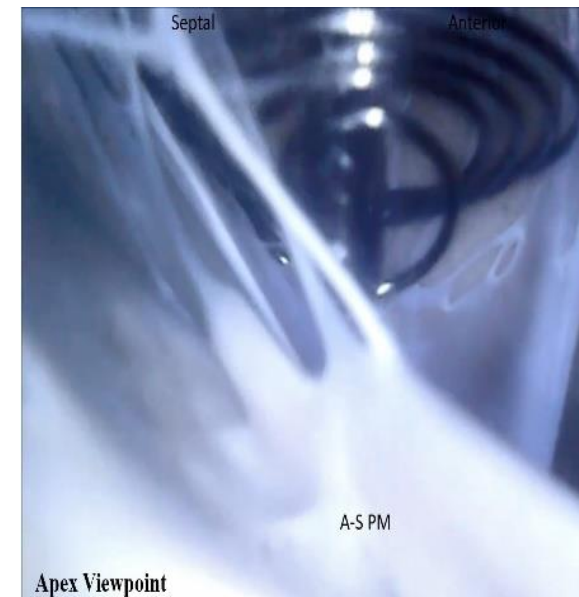
MDS - Mistral Delivery System



Mistral – Mode of Action 40sec



Cadaver Heart - Tricuspid Valve



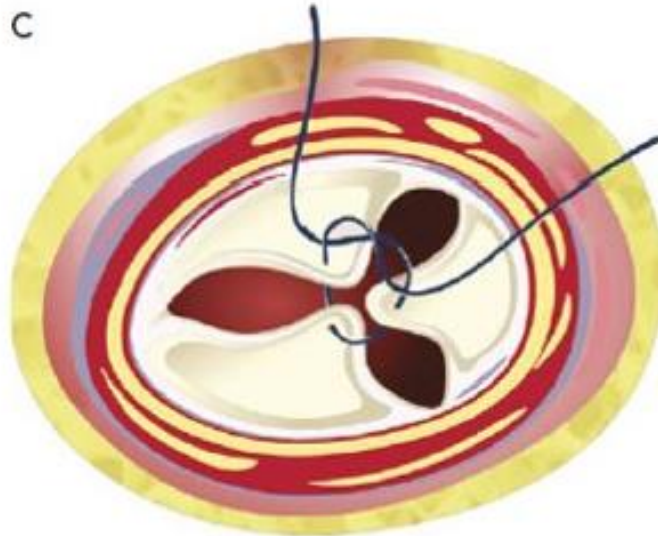
You can watch online: <https://youtu.be/qcQ8Wm8YiNQ>

SAP Grasp Method

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

Clover repair

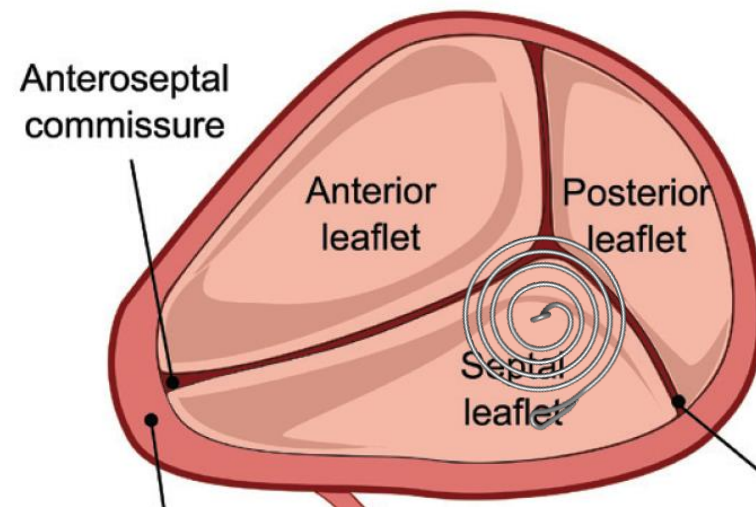
Source: Rodes-Cabau, 2016 ²



d with permission from Elsevier.

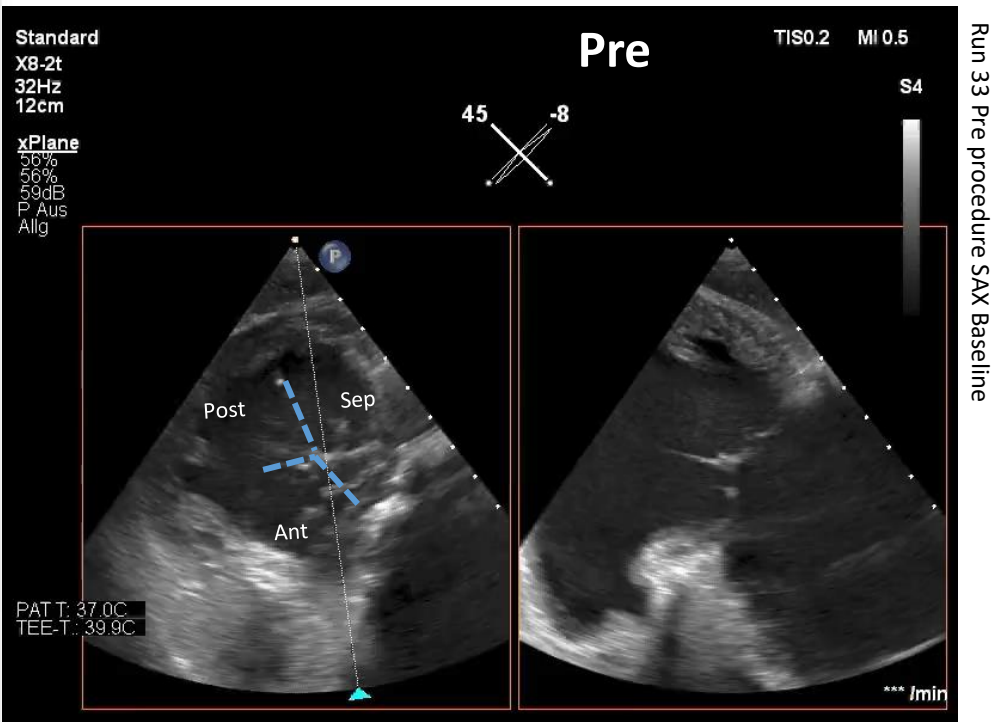


Mistral



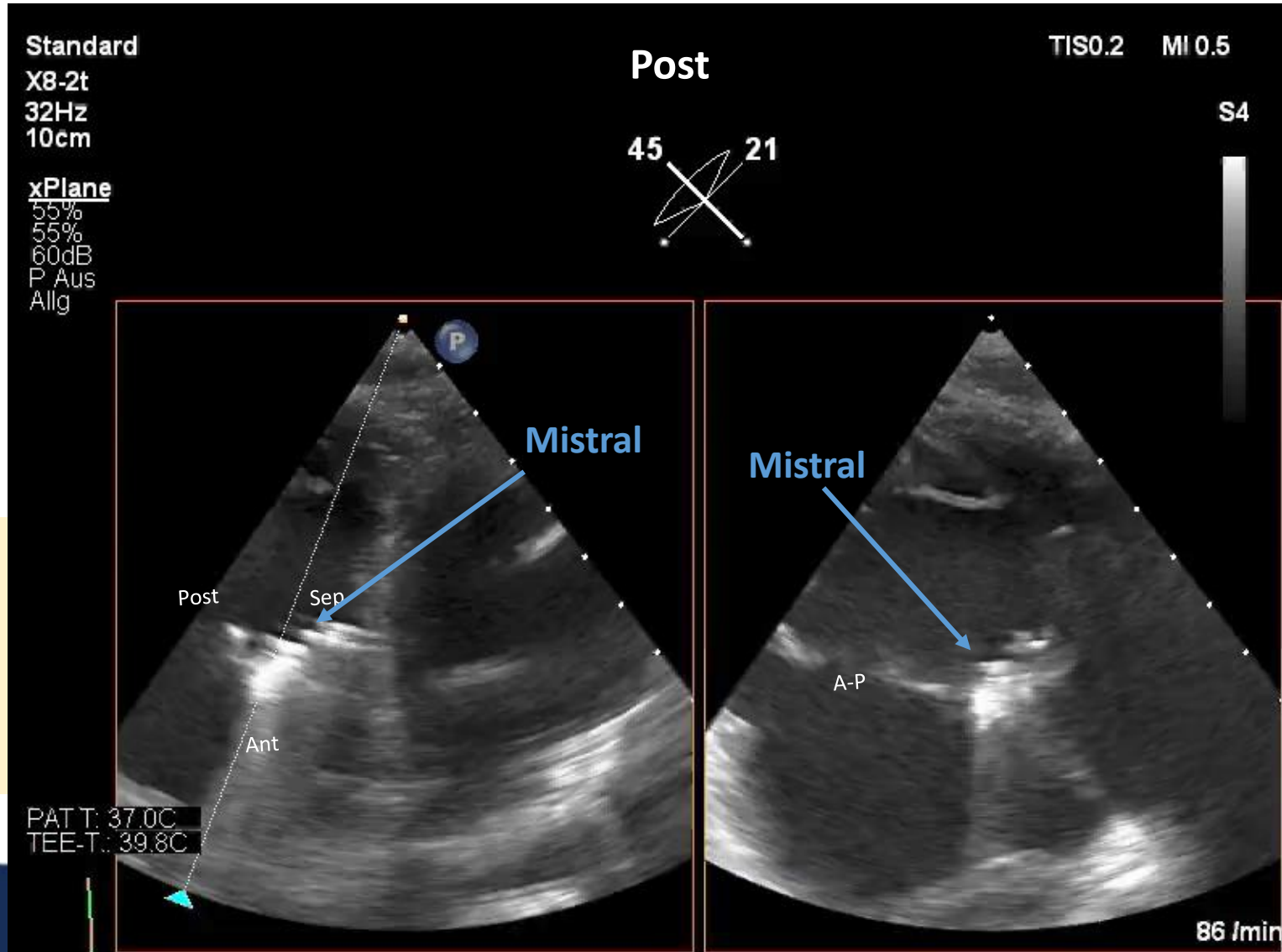
Alfieri et al. J Thorac Cardiovasc Surg. 2003 Jul;126(1):75-9

SAP Method – Single Implant



MN901: Pre Vs. Post Implantation

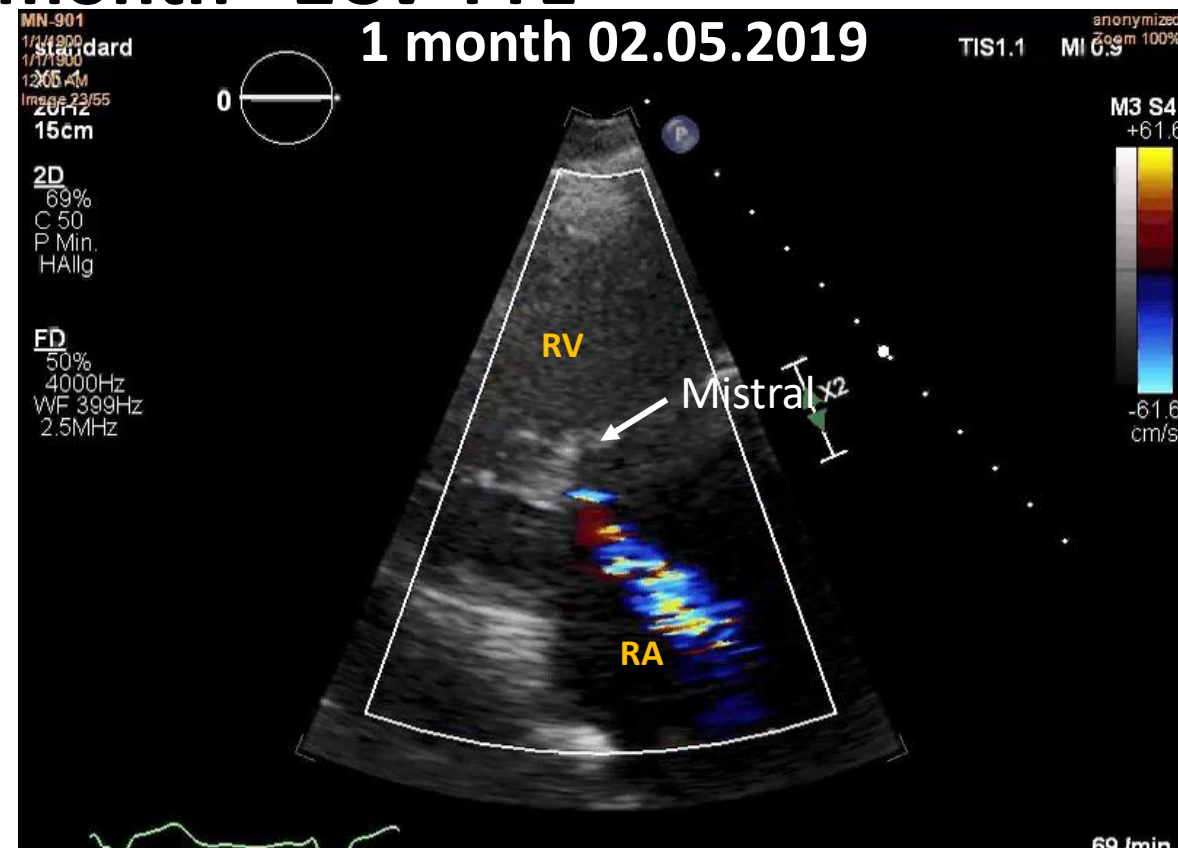
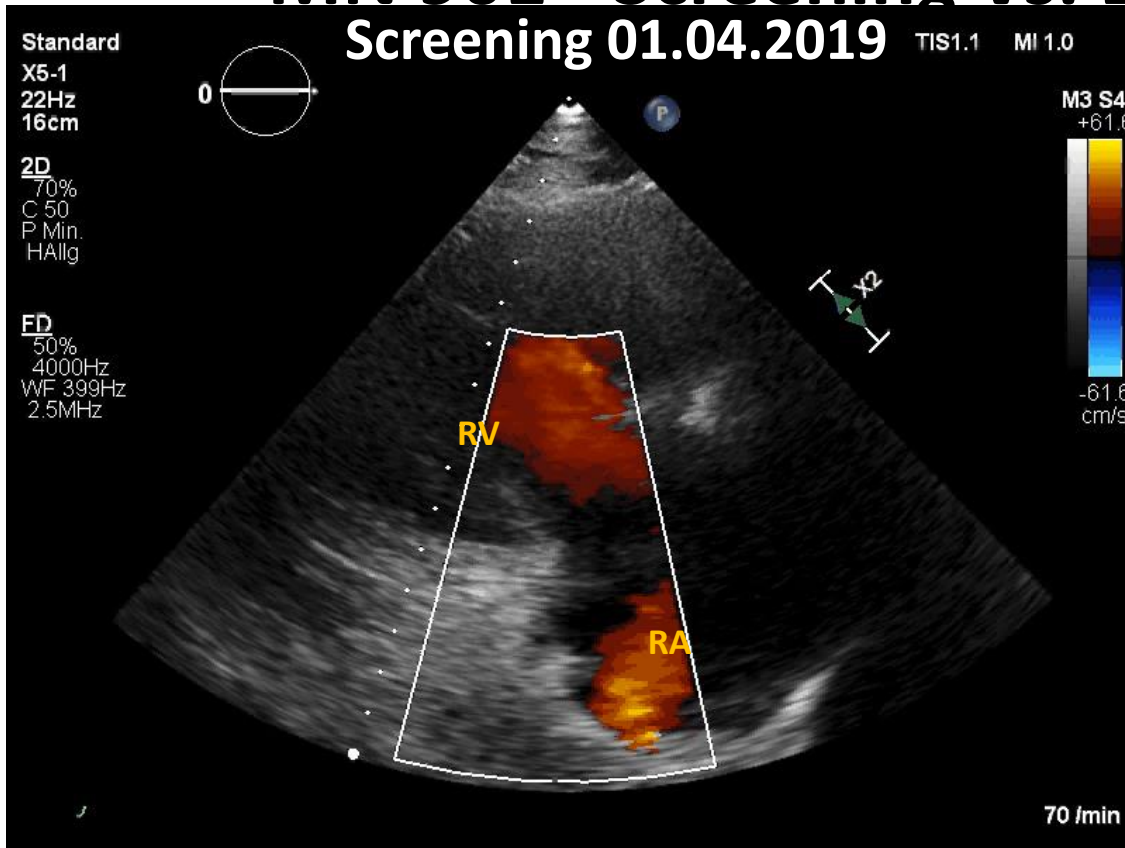
Run 117 Post Procedure



Central **S**eptal chordae and chordae from A-P PM (from both **P**osterior and **A**nterior leaflets) were grasped – **SAP** (Single Implant)

MN 901 - Screening Vs. 1 month -2CV TTE

Run 57: TTE Screening MN901 2CV Doppler



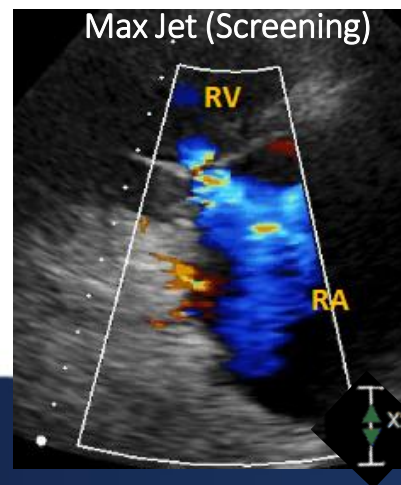
Run 4: TTE 1 month follow up MN901 2CV Doppler

TR

- VC Width [cm]: **0.82** [Severe]
- PISA Radius [cm]: **0.68** [Moderate]
- EROA (by PISA) [cm²]: **0.32** [Moderate]
- Rvol (by PISA) [ml/beat]: **28** [Mild]

QOL

- 6MWT [m]: **75**
- KCCQ: **36.46**
- NYHA class: **III**



% Improvement:

- VC Width [cm]: **0.55** [Moderate] **47%**
- PISA Radius [cm]: **0.5** [Mild] **26%**
- EROA (by PISA) [cm²]: **0.16** [Mild] **50%**
- Rvol (by PISA) [ml/beat]: **15** [Mild] **46%**
- 6MWT [m]: **277** **269%**
- KCCQ: **89.58** **145%**
- NYHA class: **II**

HD706: Screening vs. 1 Month FU - A4CV TTE

Run 52: TTE 1 Month FU HD706

Run 58: TTE Screening HD706

Screening 15.01.2019

HADASSAH ADULT ECHO EPIQ1
TIS1.0 MI 0.3
M1 M4
+92.4
-30.8
cm/s

15cm
Z 1.4
2D
66%
C 51
P Low
HPen
CF
55%
4000Hz
WF 399Hz
2.5MHz
G
P R
1.2 2.4

61 BPM

Max Jet (Screening)

VC Width [cm]: **0.95** [Severe]
EROA (by PISA) [cm²]: **0.52** [Severe]
Rvol (by PISA) [ml/beat]: **45.21** [Severe]
RV FAC [%]: **36.7** [Normal]
6MWT [m]: **400**
KCCQ: **54.69**
NYHA class: **III**

1 Month FU 12.02.2019

HGen
CF
53%
4000Hz
WF 399Hz
2.5MHz
G
P R
1.3 2.6

Max Jet (1 Month FU)

% Improvement:
VC Width [cm]: **0.67** [Mode-Severe] **29%**
EROA (by PISA) [cm²]: **0.09** [Mild] **82%**
Rvol (by PISA) [ml/beat]: **7.04** [Mild] **84%**
RV FAC [%]: **47.3** [Normal] **28%**
6MWT [m]: **352**, *in 3M – 428. **-12%**
KCCQ: **84.9** **55%**
NYHA class: **I**

Mistral unique features

- MR and TR procedure: (1) SAME Device (2) SAME Delivery system and (3) Similar procedure steps.
- Mistral is the only single implant that can grasp all 3 TR leaflets (SAP).
- **Device:** Single component.
- **Delivery System:** Simple and intuitive.
- Chords Grasping: gradually and gently [Not 0 or 1].
- Reversible: Mistral can easily turned backwards along procedure.

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	0	Failed	✓	N/A
6	HD702 (59)	12	FIM Study	Jerusalem	Planer	V4 / A-S	1	Success	✓	Significant improvement
7	HD703 (80)	6	FIM Study	Jerusalem	Planer	V4 / A-S	1	Success	✓	Improved
8	HD704 (73)	6	FIM Study	Jerusalem	Planer	V4 / S-A-P	1	Success	✓	Significant improvement
9	HD705 (78)	6	FIM Study	Jerusalem	Planer	V4 / A-P	1	Success	✓	Unchanged
10	HD706 (78)	3	FIM Study	Jerusalem	Planer	V4 / S-A-P	1	Success	✓	Significant improvement
11	MN901 (73)	1	FIM Study	Munich	Hausleiter	V4 / S-A-P	1	Success	✓	Significant improvement
12	MN902 (84)	-	FIM Study	Munich	Hausleiter	V4 / S-A-P	0	Not Implanted	✓	N/A

V1 is the old device, an improved version V4 is in use thereafter.

Clinical and Echo 30d., 3m. FU

n=5		Baseline	30 days	3 months
TR Grade	VC Width [cm] (biplane)	1.04 ^{+0.29} _{−0.24} Severe	0.629 ^{+0.28} _{−0.21} Moderate-Severe	0.589 ^{+0.19} _{−0.16} Moderate
	EROA [cm ²] (by PISA)	0.522 ^{+0.09} _{−0.1} Severe	0.212 ^{+0.31} _{−0.12} Moderate	0.22 ^{+0.32} _{−0.17} Moderate
	Rvol [ml] (by PISA)	50.2 ^{+15.3} _{−9.2} Severe	17.5 ^{+12.5} _{−10.4} Mild	14.75 ^{+12.5} _{−8.25} Mild
RV Function	RV FAC [%]	27.9 ^{+8.8} _{−7.9}	42.7 ^{+12.5} _{−17.1}	42.7 ⁺¹⁰ _{−14}
	TAPSE [cm]	1.5 ^{+0.49} _{−0.31}	2.05 ^{+0.34} _{−0.5}	2.03 ^{+0.8} _{−0.48}
QOL	KCCQ Score	40.35 ^{+14.3} _{−11.9}	56.3 ^{+35.5} _{−28.5}	64.75 ^{+29.7} _{−21.9}
	6MWT [m]	224.4 ^{+175.6} _{−76.4}	253.6 ^{+98.4} _{−113.6}	282.4 ^{+145.6} _{−154.4}

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 short term clinical benefit

Thank you!

