

**Milano II Feasibility Trial
Early Experiences
Edwards MOBIUS Leaflet Repair
System**

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MOBIUS: Leaflet Repair System

Edwards LifeSciences

● Purpose

- ▶ Repair degenerative/Organic Mitral valve disease

● Basic Concept

- ▶ Perform an edge to edge (**Alfieri**) repair using **Percutaneous** approach

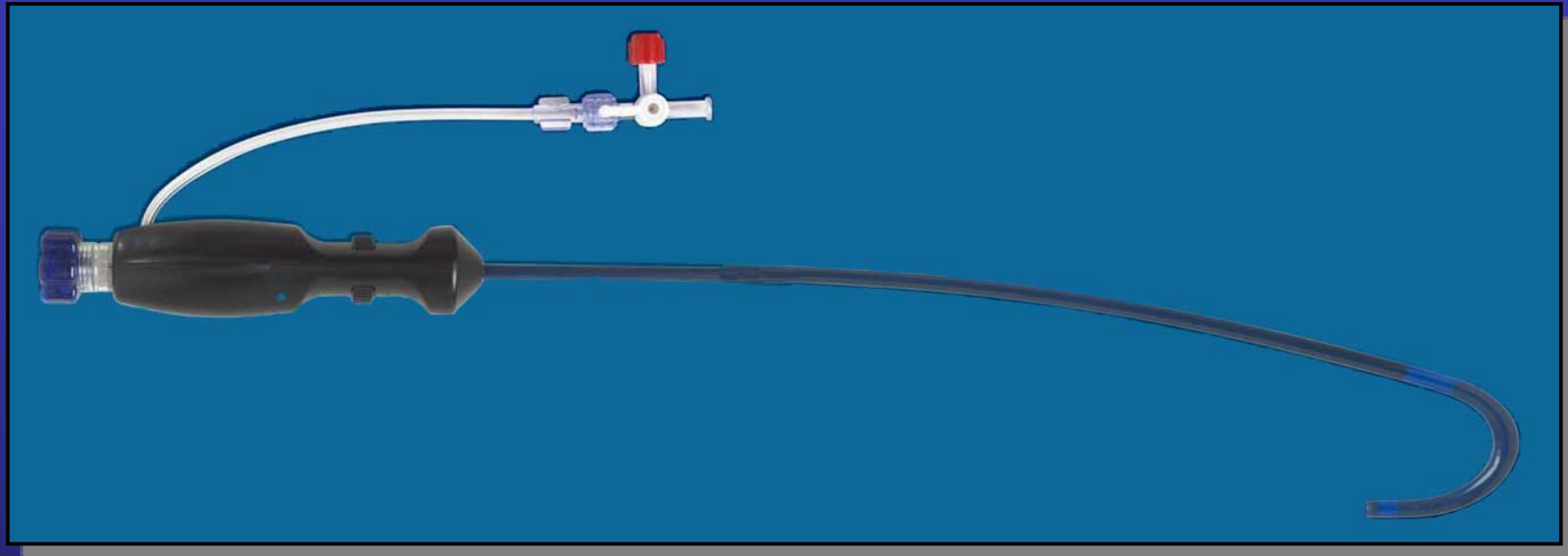
● Working Principle

- ▶ Deliver **suture(s)** across Mitral valve
- ▶ Secure suture with **Nitinol clip(s)**

● Guidance

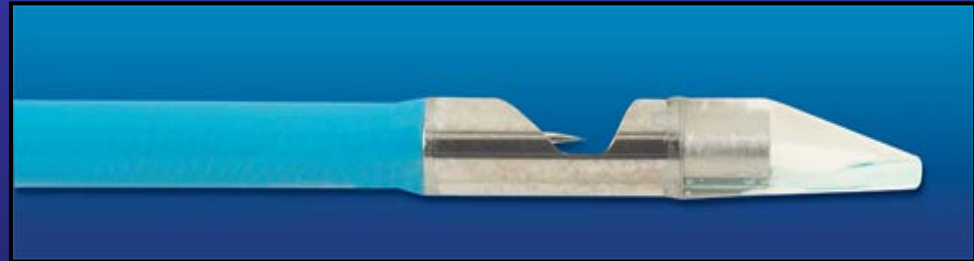
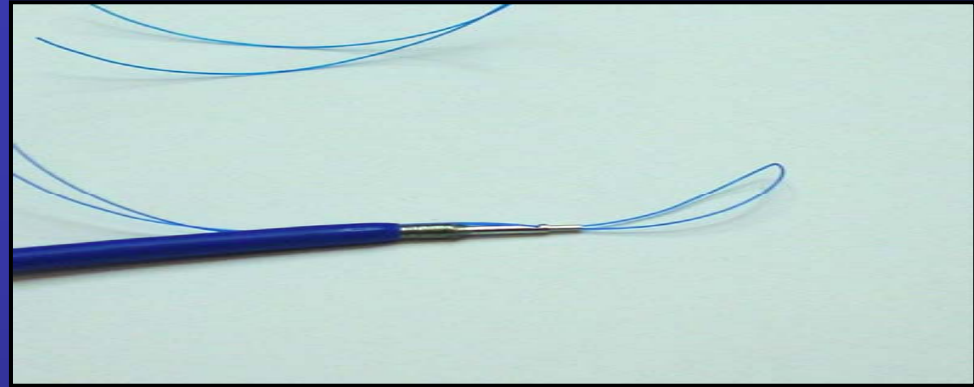
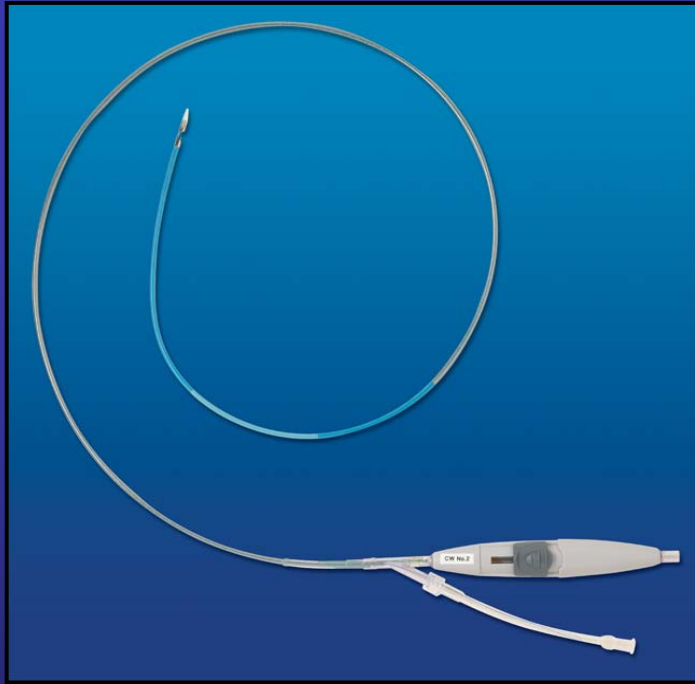
- ▶ **Angiography**
- ▶ **Echocardiography (ICE or TEE)**

MOBIUS system:



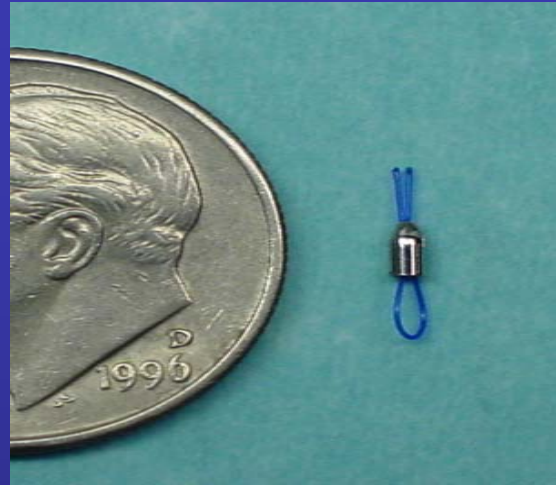
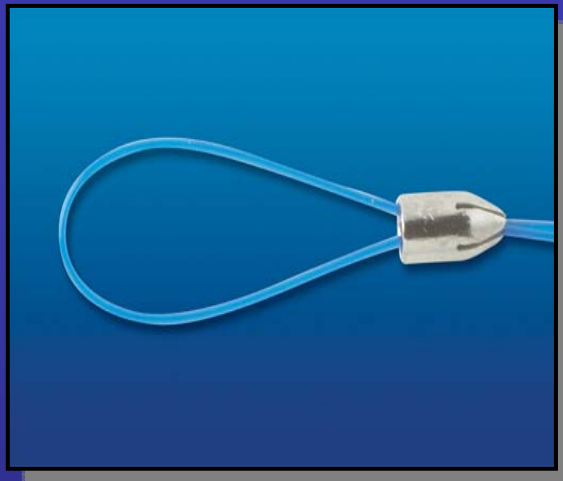
Guide catheter – 17F single plane deflecting tip device

MOBIUS system:



- **Therapy catheter – 11F**
- **“Housing” includes vacuum port, needles, suture**

MOBIUS system:



● **Fastener catheter – 7F**

- ▶ **Low profile**
- ▶ **Flexible**
- ▶ **Built-in nitinol clip**

Clinical Experience

- **Phase I Feasibility – Europe & Canada**
- **Non-randomized, multi-center study**
- **Purpose: To demonstrate the safety and feasibility of the Edwards MOBIUS Leaflet Repair System for the treatment of organic MR**
- **Current Status: Study is in re-activated phase of enrollment**

MILANO II Study

Inclusion criteria

- **MR grade 2 - 4**
- **Degenerative etiology with no significant annular enlargement**

MILANO II Study

Endpoints

	Safety	Efficacy
Primary	Death / pericardial effusion / embolisation / AMI at 30 days	Procedural success: MR reduction \geq 1 grade, w/o complication
Secondary	Death / AMI/ pulmonary edema/ Worsening MR / Persistent ASD /embolisation at 3-months	MR reduction \geq 1 grade @ 3-months

Milano II Study Team

Site	Interventional PI	Echo PI
Hospital Bichat	Alec Vahanian	Eric Brochet
Montreal Heart Institute	Raoul Bonan	Arsenè Basmadjian
St. Paul's Hospital	John Webb	Brad Munt
San Raffaele Hospital	Francesco Maisano	G. LaCanna

- **Study PI:**
 - ▶ Maurice Buchbinder, Scripps Memorial, La Jolla
- **Echo PI:**
 - ▶ Maurice Sarano, Mayo Clinic; Rochester
- **Echo Core Lab:**
 - ▶ Neil Weissman, Cardiovascular Research Institute; Washington, DC
- **Protocors:**
 - ▶ Maurice Buchbinder, Scripps Memorial, La Jolla
 - ▶ Francesco Maisano, San Raffaele; Milan
 - ▶ Tasneem Naqvi, Cedars-Sinai; Los Angeles

Case Reviews of MOBIUS System Patients

- Case # 1: P2 prolapse

- Case # 2: P2 flail

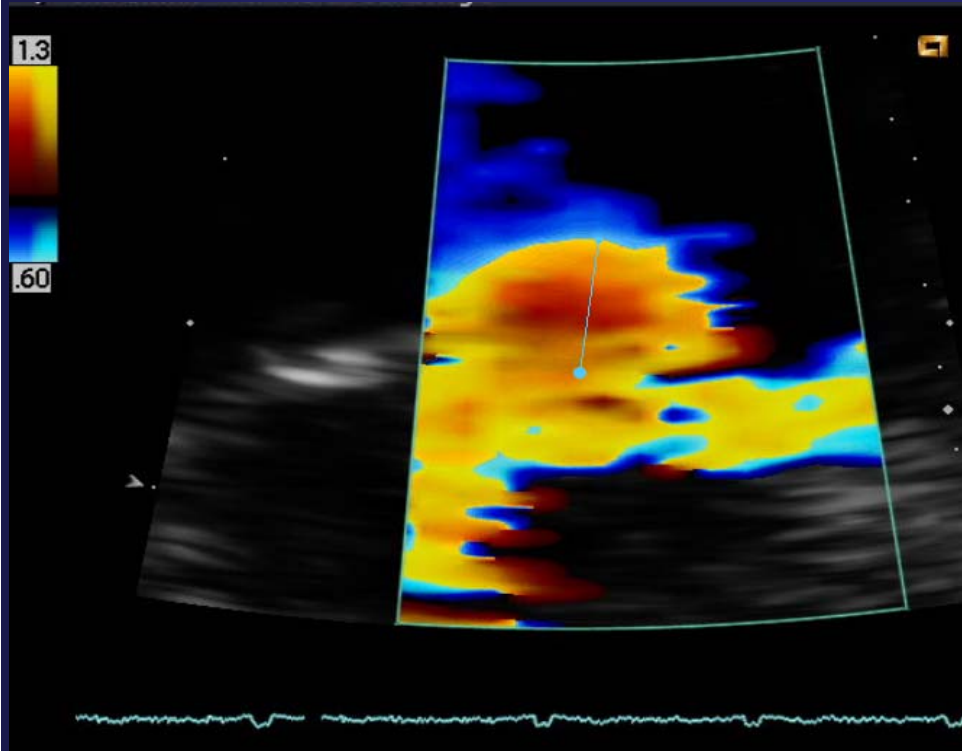
- Case # 3: P2 flail with ischemic MR

Clinical case

- **72 year male**
- **Active Smoldering Lymphoma (1995), chemotherapy, thrombopenia**
- **Pacemaker 2004**
- **History**
 - ▶ **MR dg. 1995. Pulmonary edema**
 - ▶ **Surgery was contraindicated**
 - ▶ **Currently: Dyspnea NYHA class III**
 - ▶ **Med Rx: ACE inhib, Furosemide**

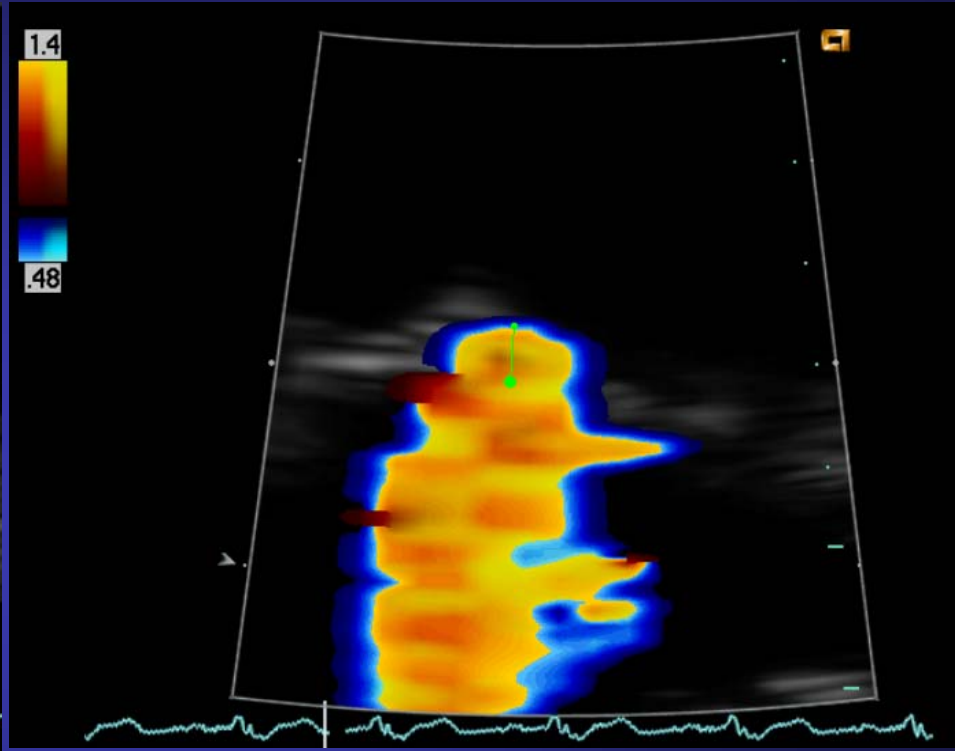
Echocardiography

- **LV ESD: 43 mm**
- **LVEF: 40 %**
- **Severe MR: ERO = 68mm²; R Vol = 57ml**
- **SPAPs: 45 mmhg**



PRE

ERO : 48 mm² RV : 57 ml



POST

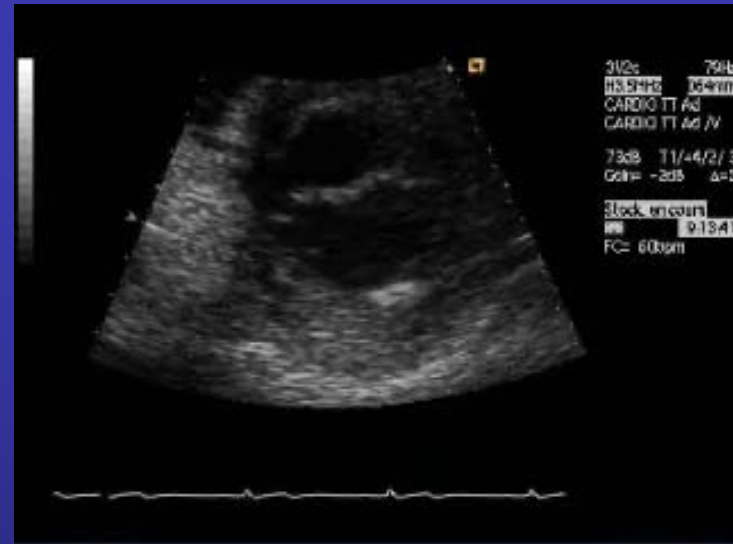
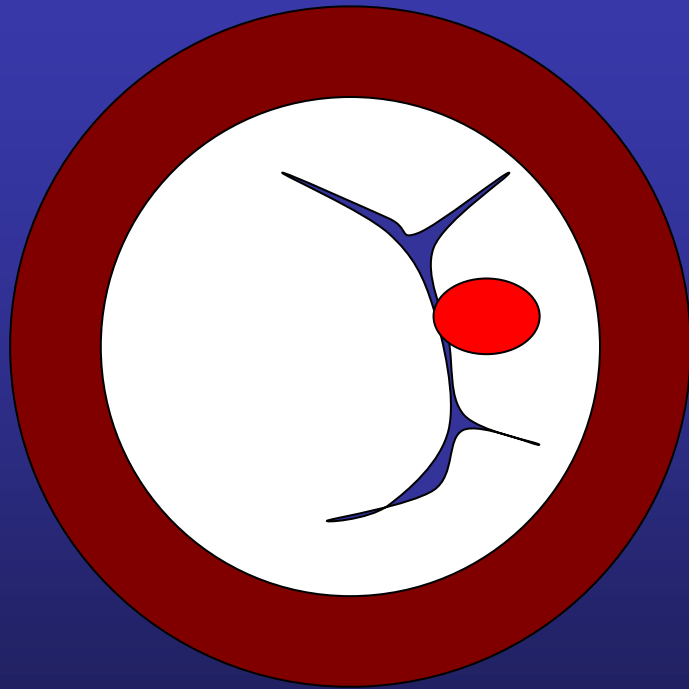
ERO : 8 mm² RV : 12 ml

Case # 2 – Flail P2 scallop with severe, anteriorly directed jet

- **Male, 61 years old**
- **Presented with 4+ MR, active tuberculosis**
- **Mild/Moderate annular dilatation**
- **Moderately thickened leaflets with flail P2**

Pre-procedure: Short Axis View

4+ MR

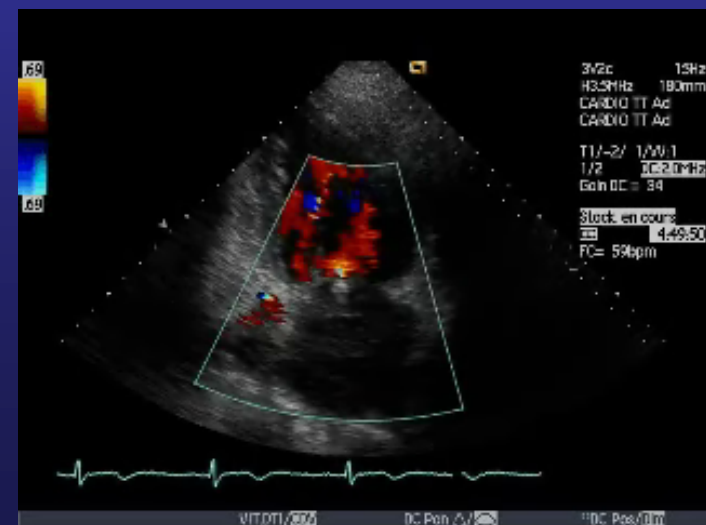
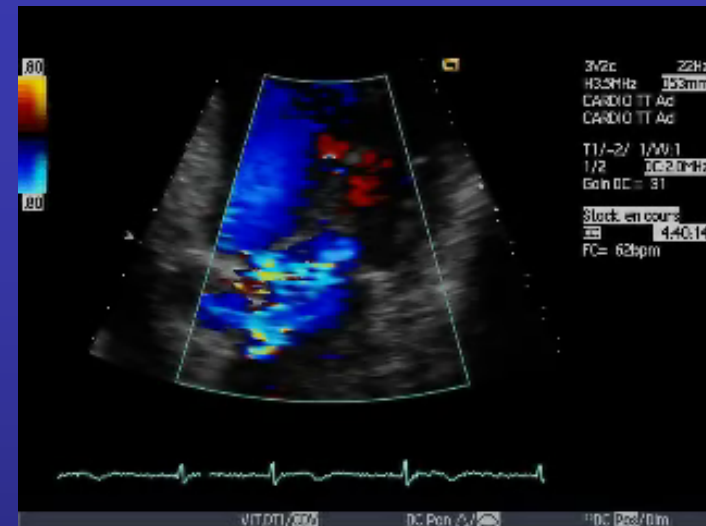
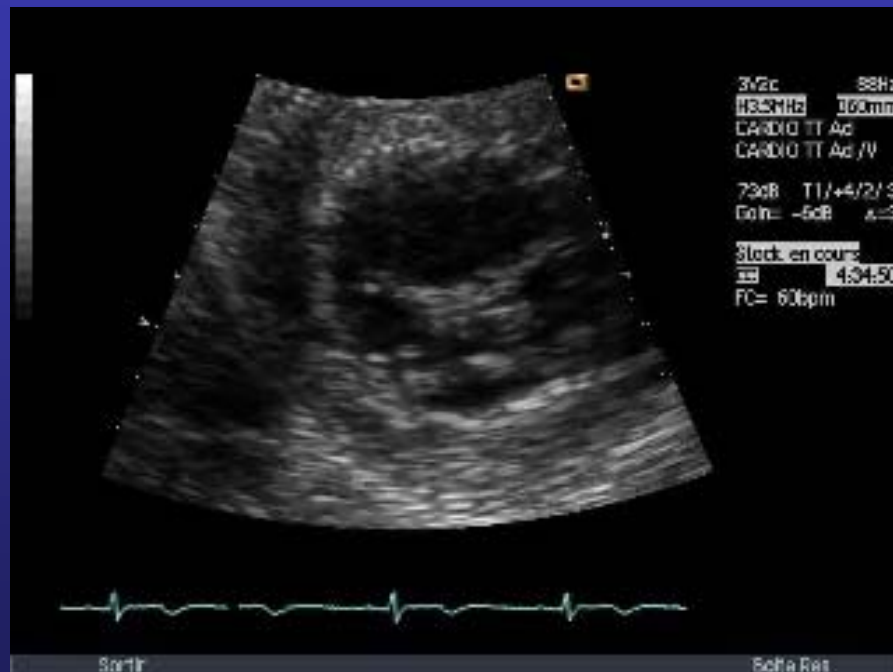


Pre-procedure: Long Axis View



Discharge: Echo Views

2+ MR (2 grade reduction)
Double suture repair



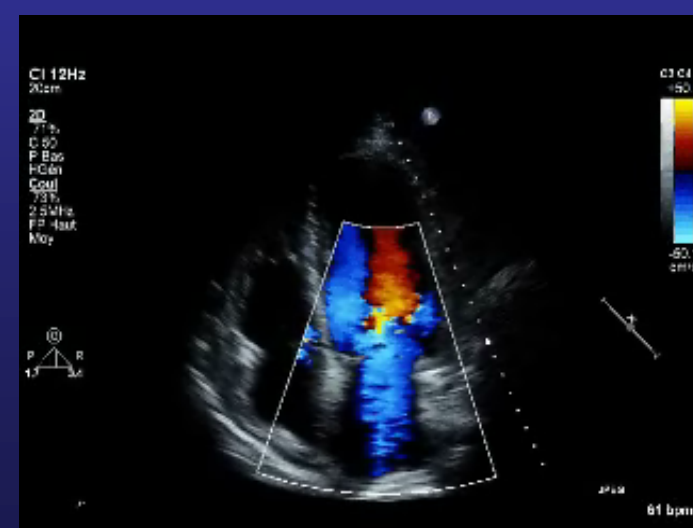
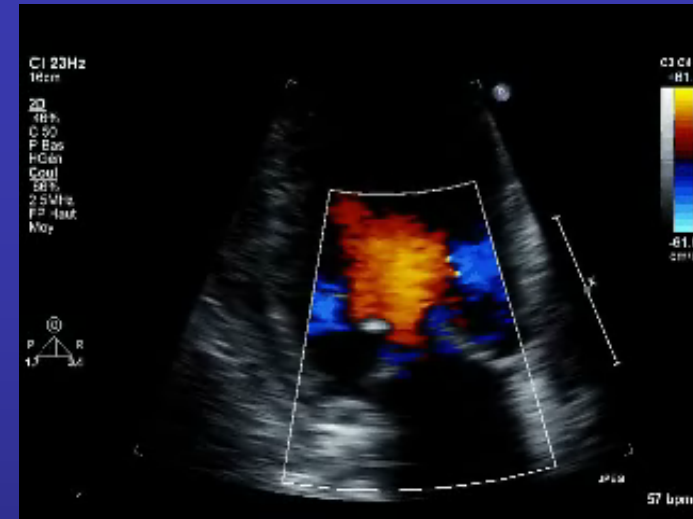
Case # 2: Summary

- **Anatomy: Flail P2 scallop with severe, anteriorly directed jet**
- **Repair: Double suture**
- **MR Reduction: 2 grades at discharge**

Case # 3 – Flail P2 with dilated left atrium, ventricle, and annulus

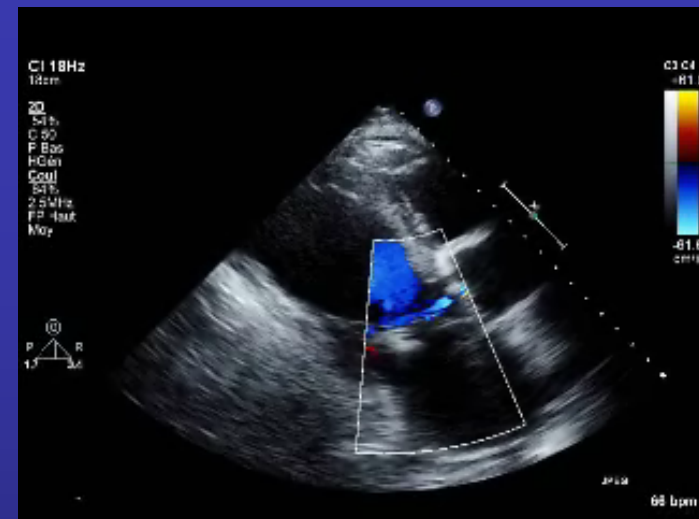
- **Male, 77 years old**
- **Presented with 4+ MR, CAD, old inferior infarct, CABG x3 (1991), PAD**
- **High risk surgical patient**
- **Central jet**
- **Thick leaflets**
- **Globally hypokinetic, inferior akinesia, dystrophic valves**

Pre-Procedure: Long Axis Views



Discharge: Echo Views

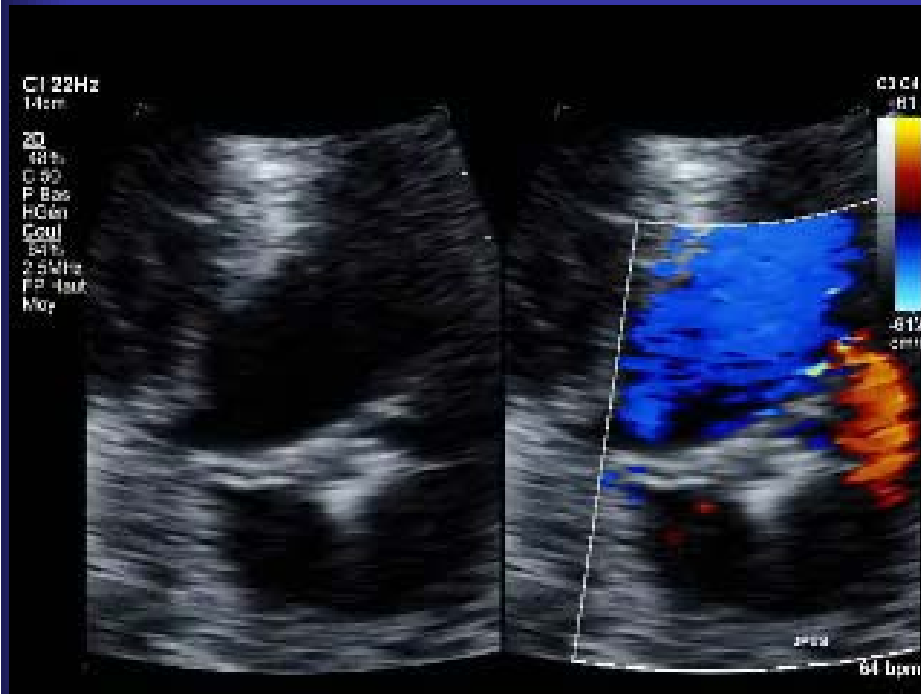
- **3+ MR (1 grade reduction)**
- **MR from flail is eliminated, but ischemic MR remains**
- **Double suture repair**



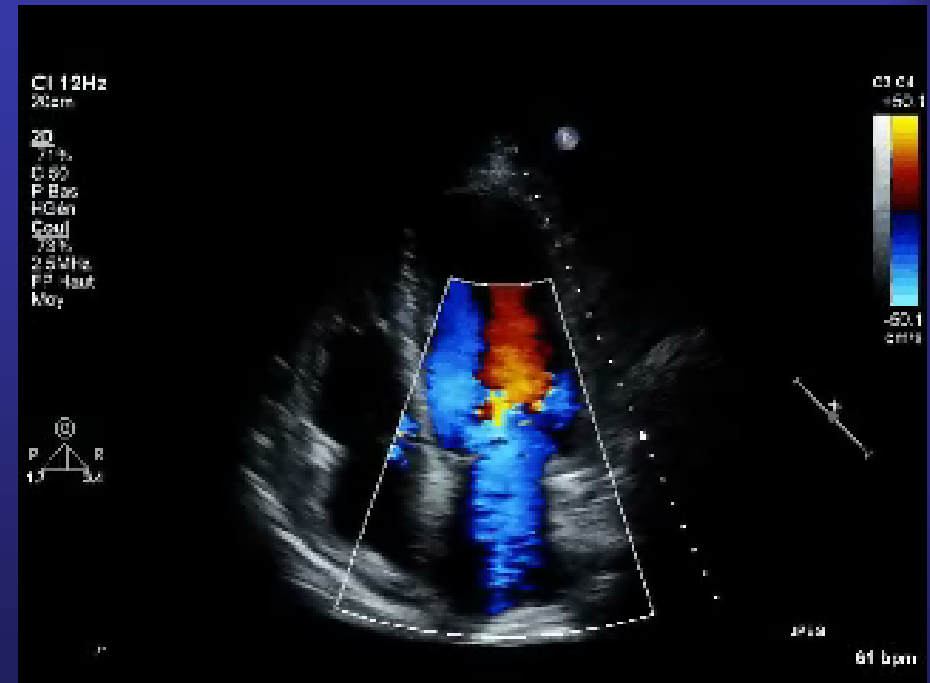
Discharge vs. Pre-Procedure: Echo Views

Jet direction altered

Discharge



Pre-Procedure



Case # 3: Summary

- **Anatomy: Flail P2 with dilated atrium, ventricle and annulus**
- **Repair: Double suture**
- **MR Reduction: 1 grade at discharge (flail MR), ischemic MR remains**

Clinical Results : 30 DAY outcome F.I.M.

15 patients enrolled

Acute procedural success
(9)

Stitch- 3 single, 5 double,
1 triple

Acute reduction MR 2 grade

Figure of "8" at 30days
Present- 5
Absent- 4

Procedural failure (6)

Surgical Repair (6)

Safety Results: 30 days

● MI	0
● CVA	0
● Death	0
● Worsening MR	0
● Pericardial effusion	1
● Clip Embolism	1

Conclusion

- **Experience to date has confirmed a reproducible procedure with a reliable rate of primary success and no acute complications.**
 - ▶ **Echo visualization and guidance remains a significant challenge...**
 - ▶ **From this very early experience careful selection of patients with specific Valvular pathologies seems critical**
 - ▶ **Extent of MR reduction and long term durability of the repair remains the primary goal of our ongoing investigation.**