5th Joint Meeting with Mayo Clinic
15 -16 october 2009 Turin Italy

Mitral Valve Repair
State of Art

Gian Paolo Ussia, MD, FSCAI

University of Catania

Division of Cardiology

Ferrarotto Hospital - Catania - ITALY

Percutaneous Mitral Valve Repair

I. **La valvola mitrale è una struttura con anatomia e funzione complessa:**
   A. Lembi valvolari mitralici
   B. corde tendinee
   C. muscoli papillari
   D. anulus mitralico
   E. Volumi e contrattilità Vsn

II. **Il trattamento percutaneo della stenosi mitralica mediante valvuloplastica è una tecnica consolidata con indicazioni e risultati codificati**

1. **La riparazione percutanea dell'insufficienza mitralica è in fase pioneristica**

Insufficienza Mitralica

I. **L'incidenza aumenta con l'età**
II. **La corretta quantificazione ecocardiografica è impegnativa**
   A. Diam Vena contracta(>7 mm)
   B. ERO area (> 20, 30, 40 mm2)
   C. Volume rigurgitante (>30, 45, 60 ml)
   D. Flusso sistolico in vena polmonare
III. **Anche asintomatica, l'IM moderata o severa aumenta la mortalità a 5 anni (***Sarano et al NEJM)*
IV. **L'IM funzionale ischemica ha una prognosi peggiore rispetto a quella degenerativa**

ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease

6.3. Mitral Regurgitation

Class I

1. **MV surgery is indicated in the symptomatic adolescent or young adult with severe congenital MR* with NYHA functional class III or IV symptoms. *(Level of Evidence: C)***
2. **MV surgery is indicated in the asymptomatic adolescent or young adult with severe congenital MR* and LV systolic dysfunction (ejection fraction less than or equal to 0.60). *(Level of Evidence: C)***

Class IIa

MV repair is reasonable in experienced surgical centers in the asymptomatic adolescent or young adult with severe congenital MR* with preserved LV systolic function if the likelihood of successful repair without residual MR is greater than 90%. *(Level of Evidence: B)*

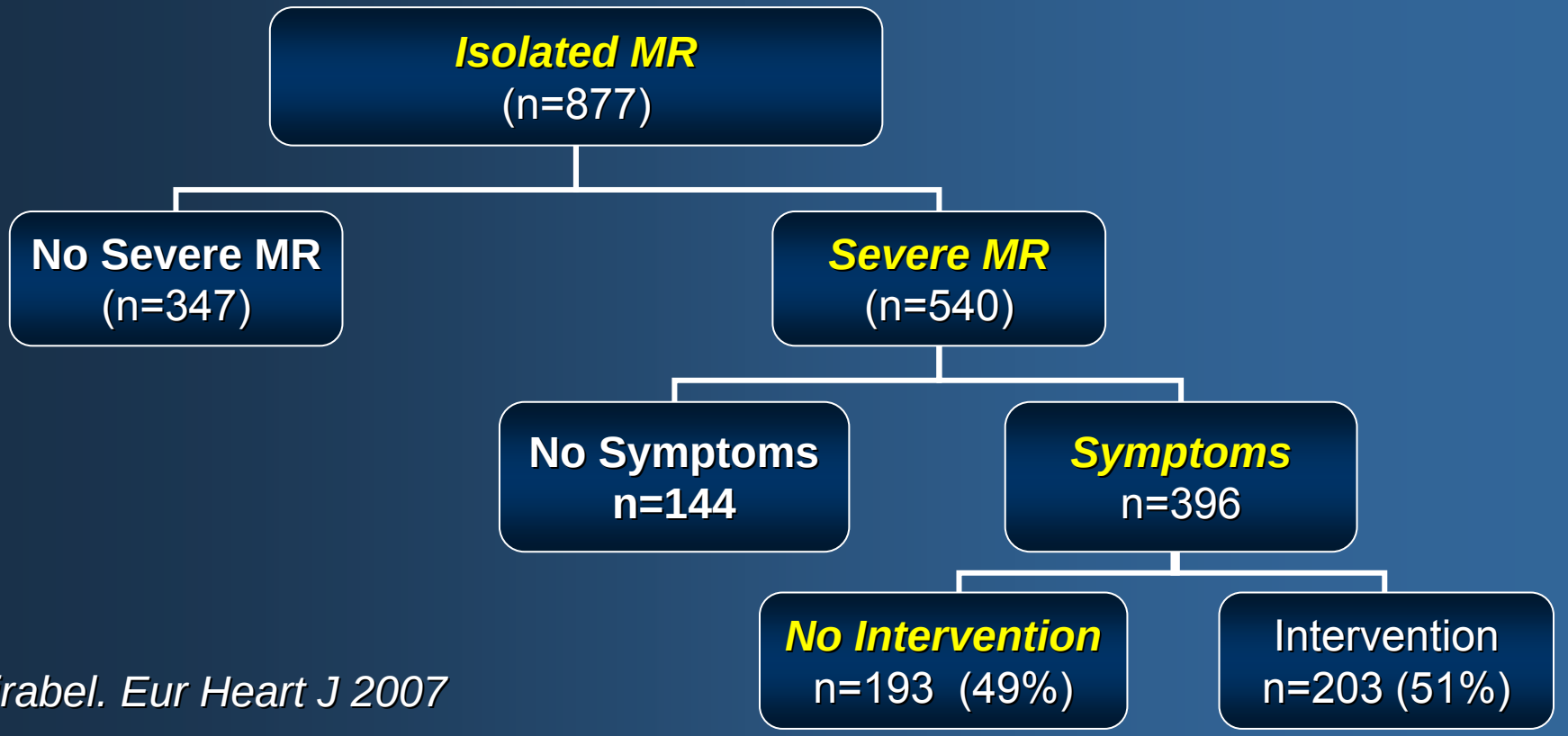
JACC Vol. 48, No. 3, 2006
August 1, 2006:e1–148

Mitral Regurgitation

EUROPEAN SOCIETY OF CARDIOLOGY®

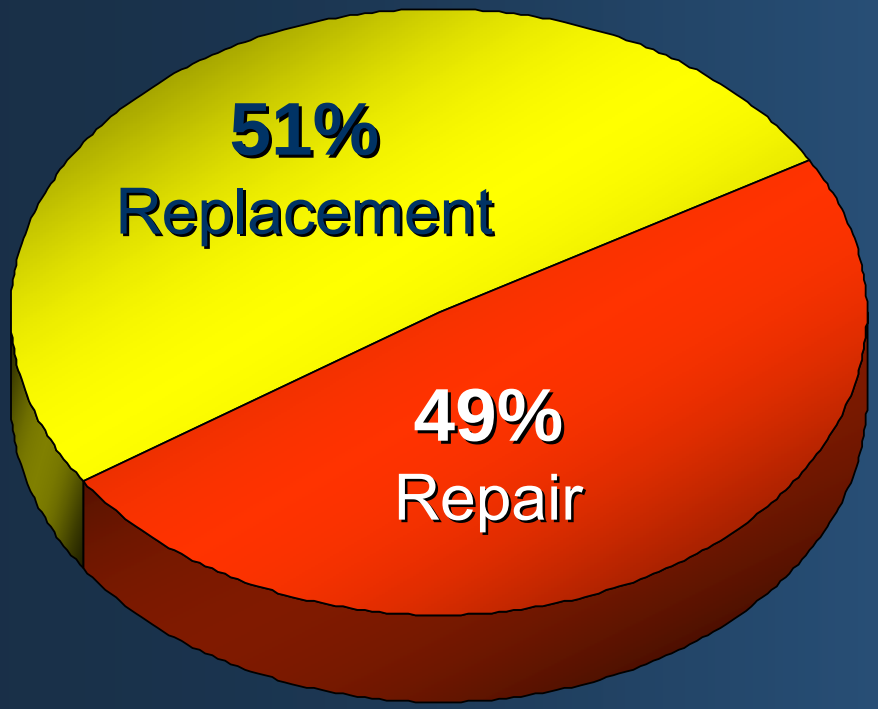
Current Management of MR

Lessons from the Euro Heart Survey

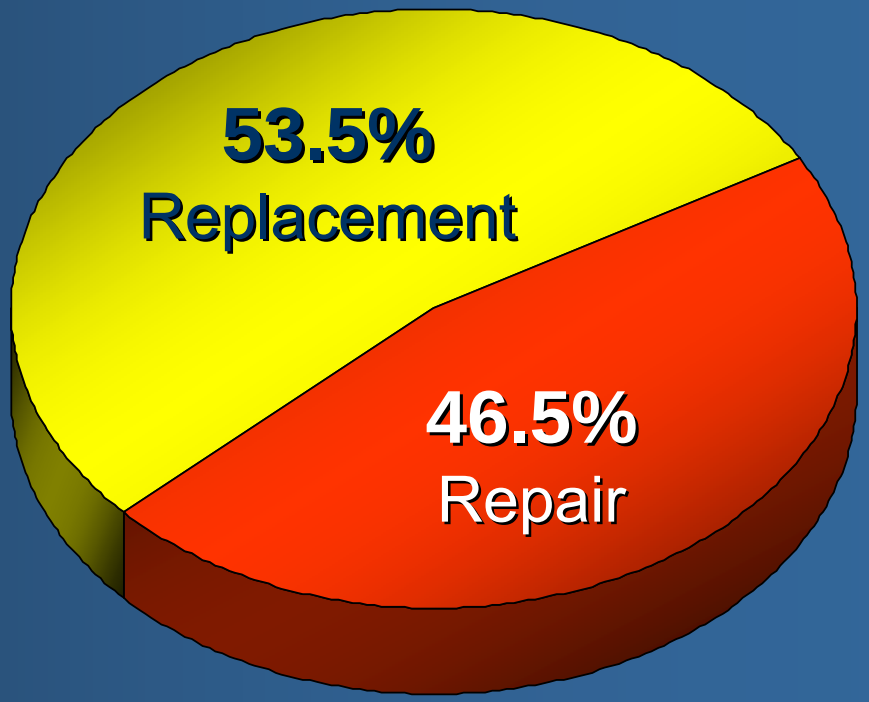


Mirabel. Eur Heart J 2007

Surgery for Mitral Regurgitation



Society of Thoracic Surgeons
Database, 2003

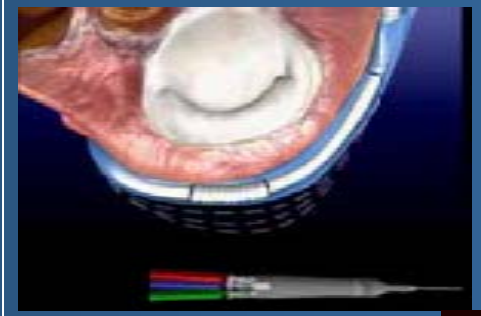


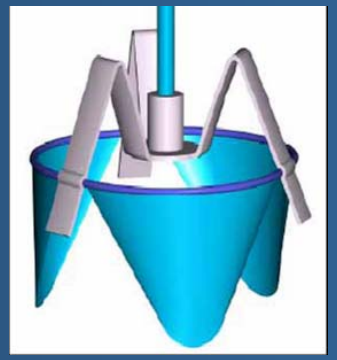
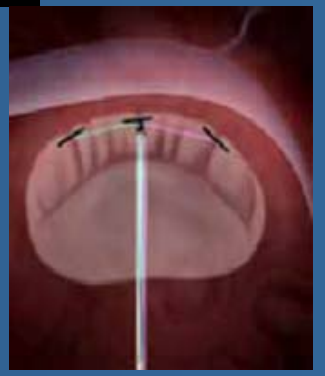
Euro Heart Survey
Iung et al. *Eur Heart J* 2003;24:1231

Percutaneous MV repair

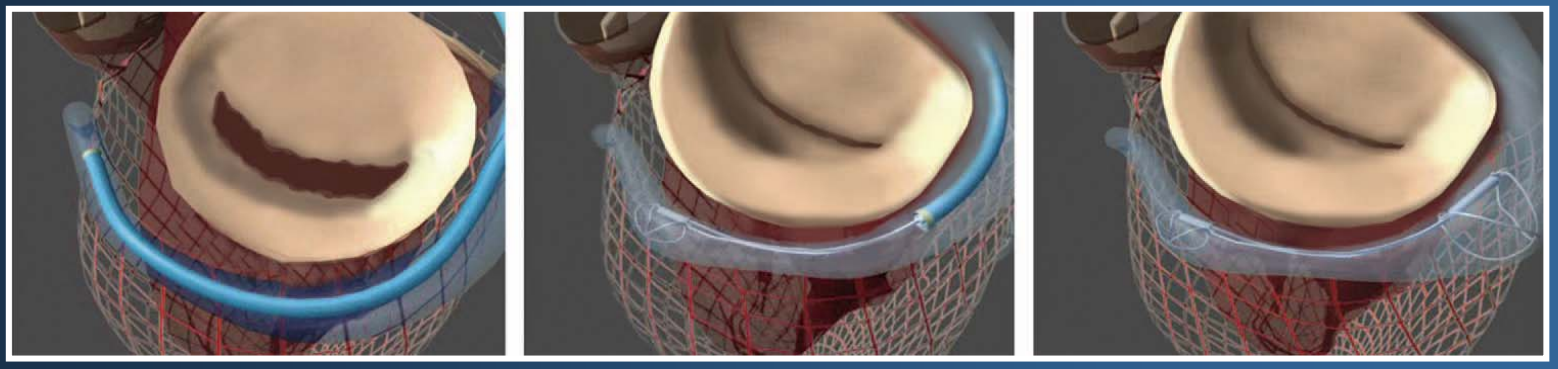
- **Edge-to-Edge**
  - Evalve *Pivotal Completed*
  - Edwards Mobius
- **Coronary sinus annuloplasty**
  - Cardiac Dimensions Carillon
  - Edwards Monarc
  - Viacor PTMA
- **Indirect annuloplasty**
  - Ample PS3
  - St. Jude AAR
  - Mycor i-Coapsys
- **Direct annuloplasty**
  - Mitralign Guided Delivery Systems
  - QuantumCor, Cordis DPA
  - MiCardia
- **Mitral valve replacement**
  - Endovalve



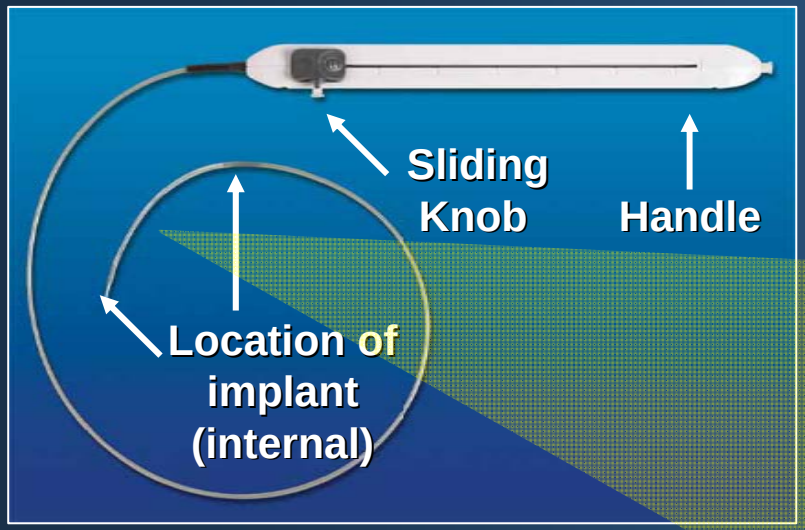


Carillon™ Device

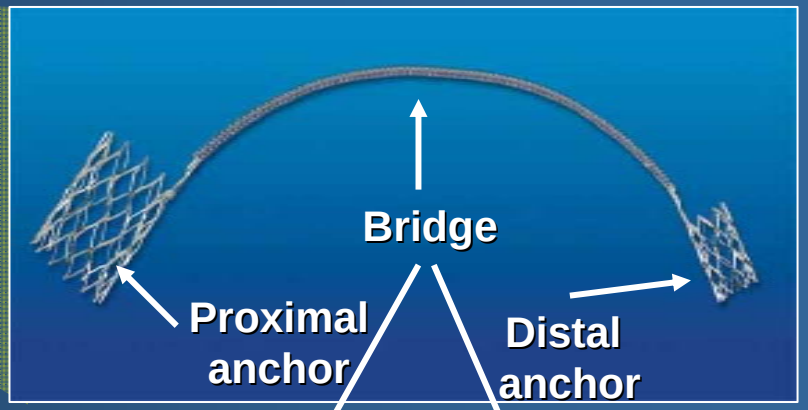


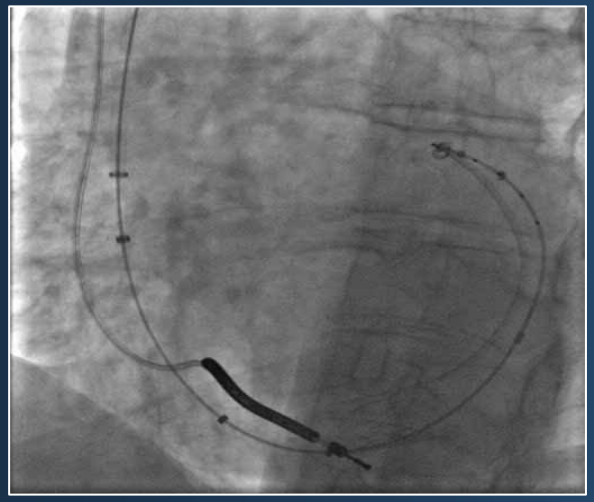
Edwards MONARC System

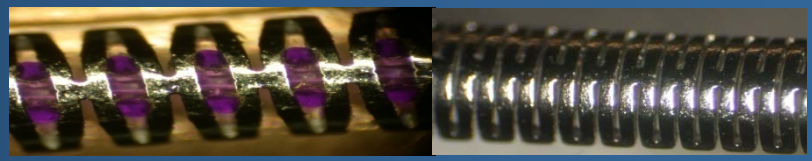


12 Fr guiding catheter

9 Fr delivery system



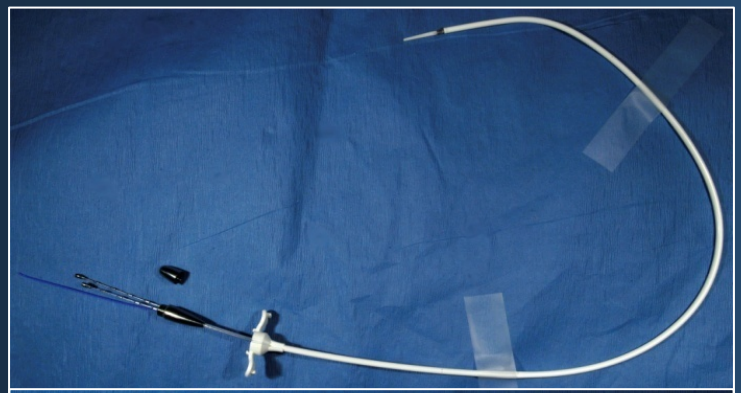


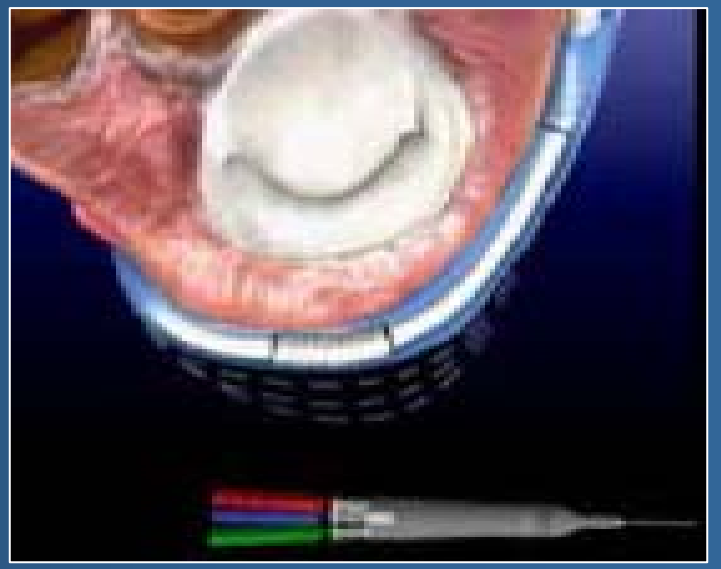


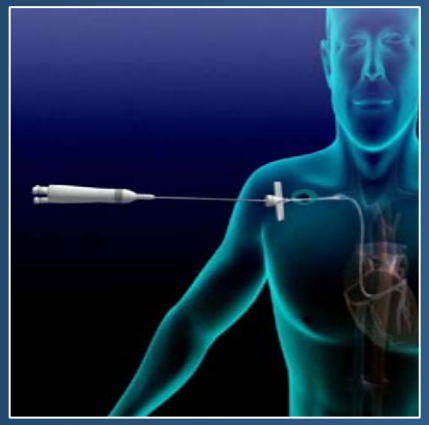
Foreshortening Bridge

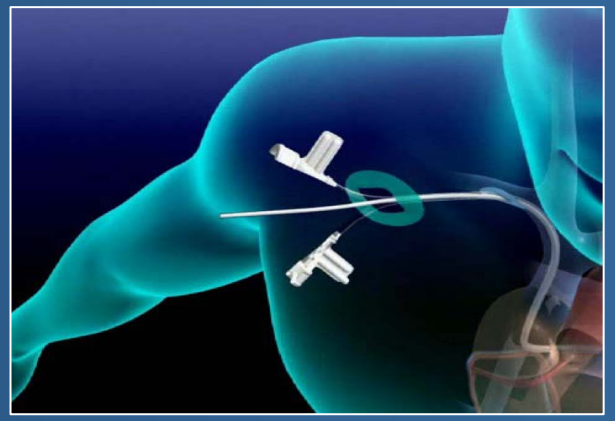
Viacor PTMA™ System

PTMA implant system







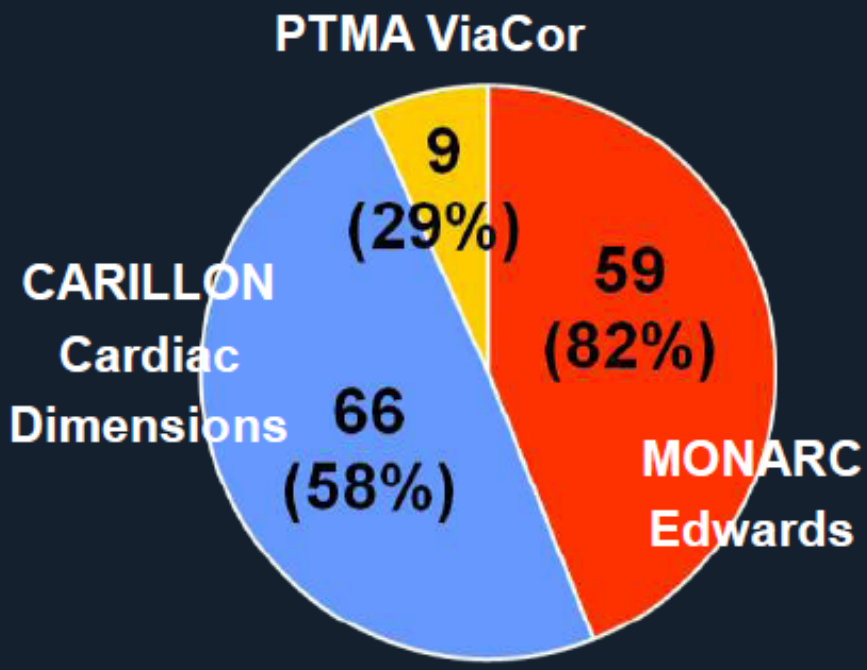


Coronary Sinus Annuloplasty
Summary

n = 136 implanted in 216 attempts (63%)

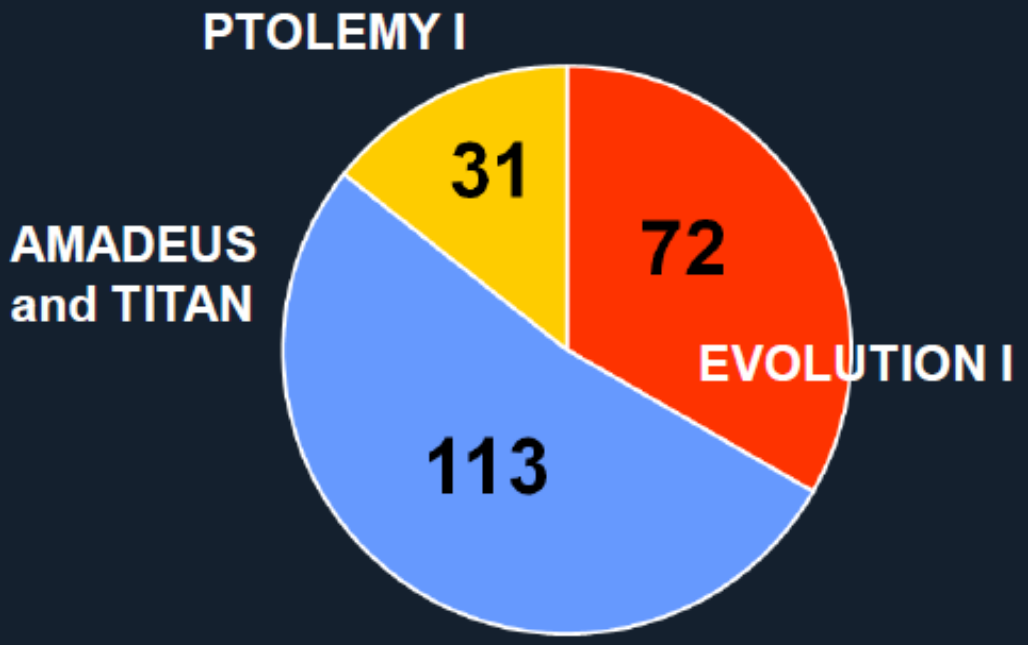
Implanted: n=136

Device name

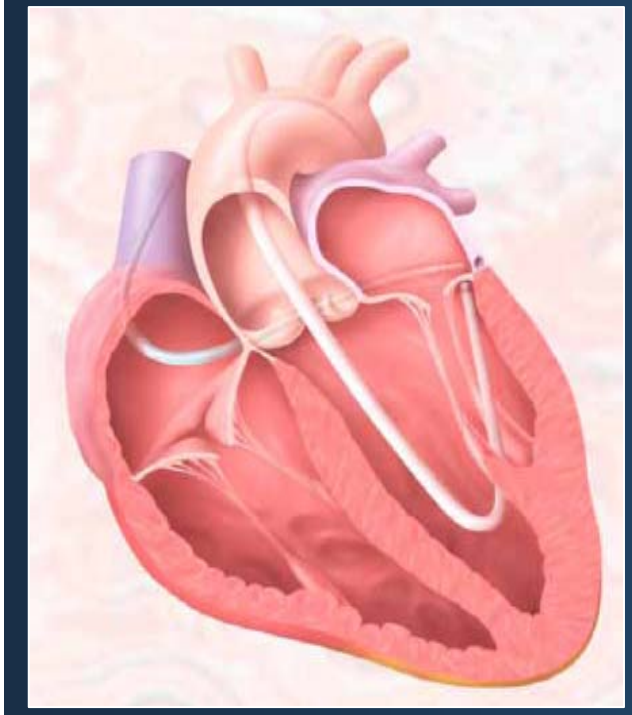


Total attempted: n=216

Trial name



Mitralign System

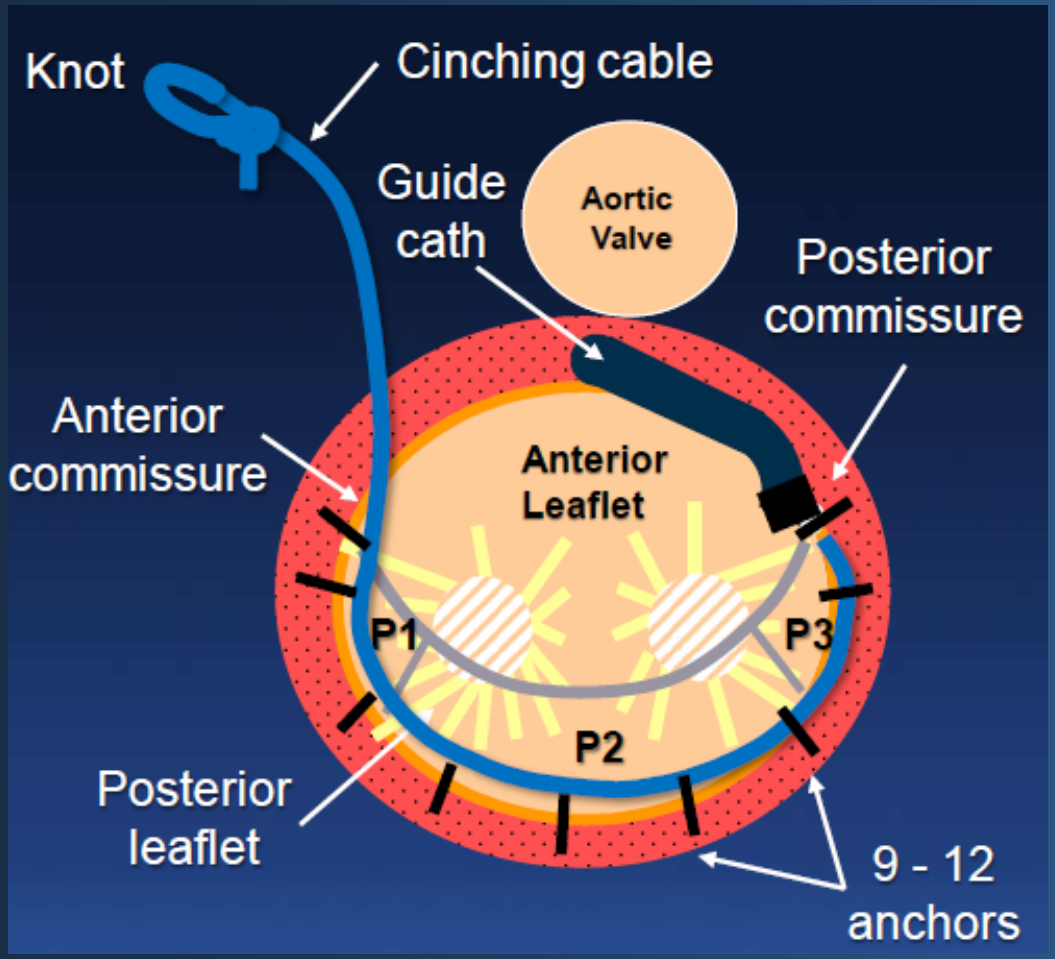


Retrograde approach

Before and After Implant
Atrial View

Direct reduction of the annular SL dimension based on posterior leaflet surgical plication

AccuCinch
Guided Delivery Systems



- Direct reduction of annular dilatation based on <u>proven surgical plication</u>
- Femoral artery access
- 14 Fr delivery system, steerable guide cath
- Retrograde across AoV
- Fluoroscopic guidance
- Reversible, removable, adjustable deployment

QuantumCor

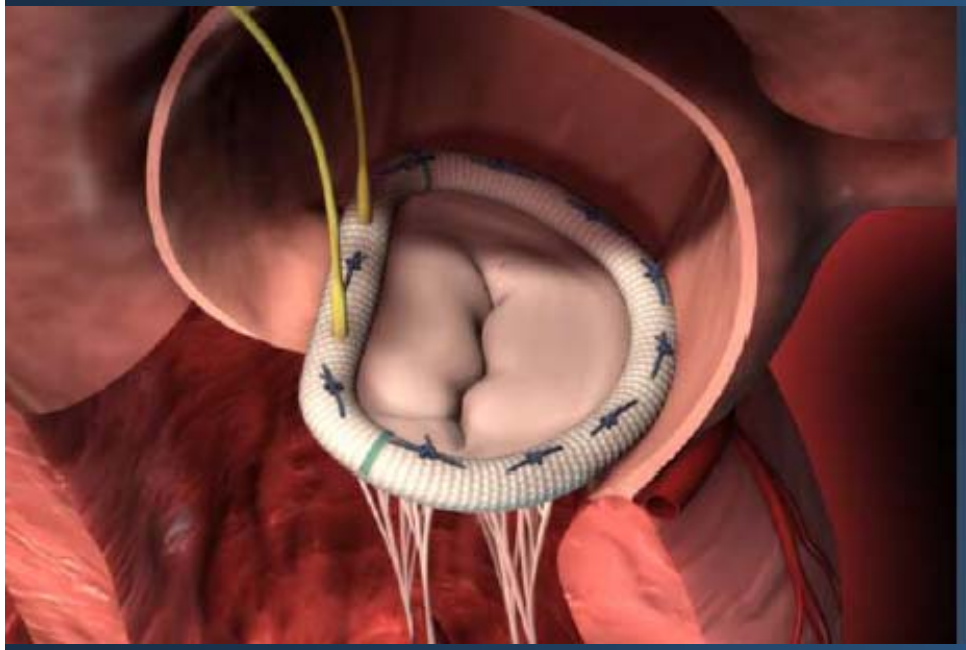
• Sub-ablative radiofrequency energy to induce heating and shrinkage of the collagen of the mitral annulus

• Produce contraction of the mitral valve annulus resulting fibrosis and reduction MR

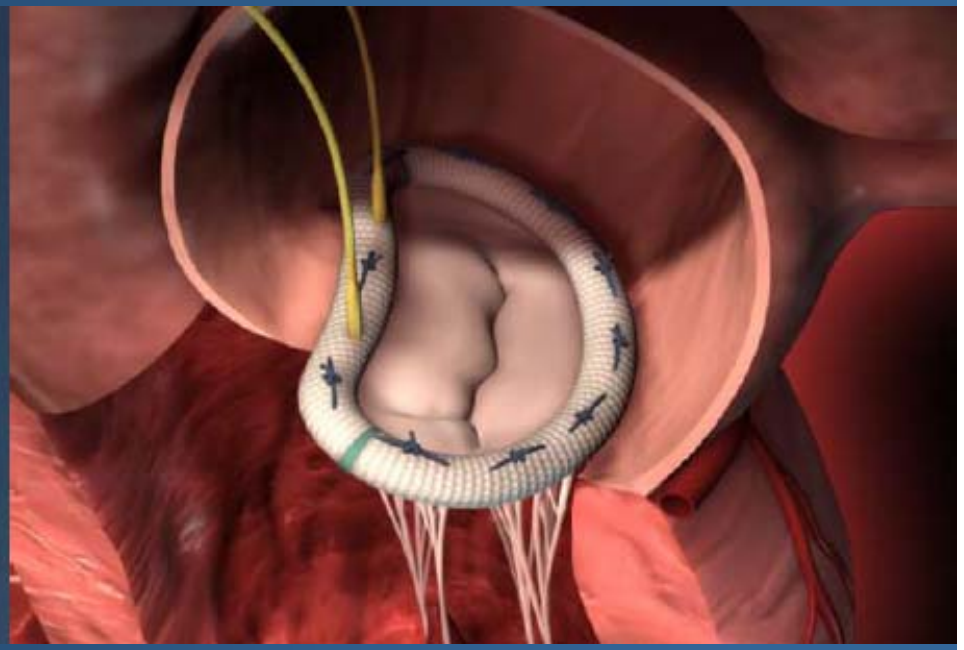
7 electrodes / 14 thermocouples / 40 mm loop dia.

Micardia

Implant shape

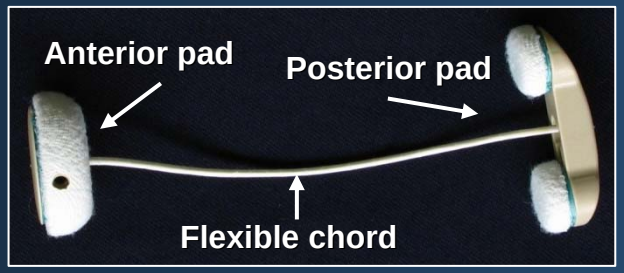


Post-activation shape



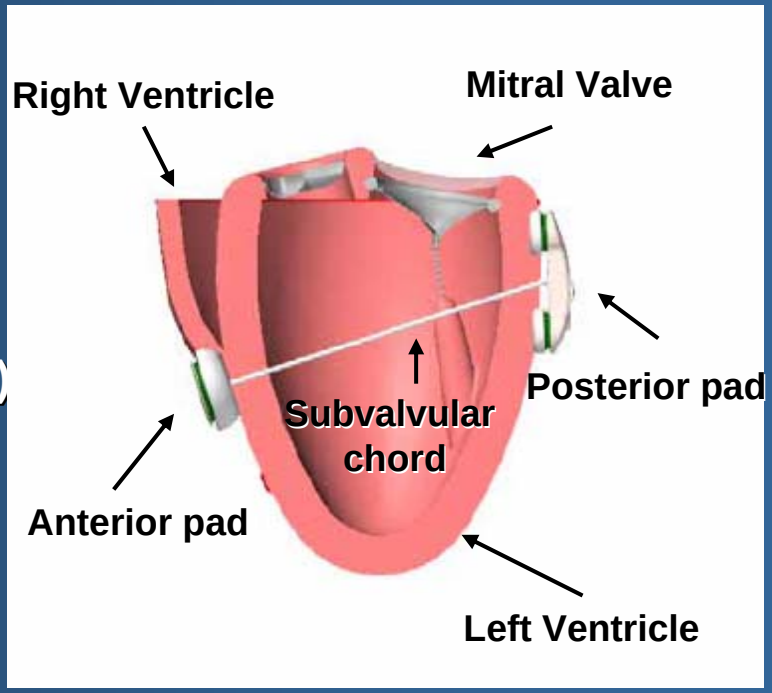
- AP “+” or “-” adjust to improve leaflets coaptation
- Currently actived intraoperatively off CPB on beating heart (40 implanted in EU & US)
- Soon: transcutaneously via access port months later
- PerQ implanted is feasible

*i*Coapsys System



- ***Trans-pericardial access***
- ***External epicardial implant***
- ***ICE, TEE, and fluoro guidance***
- ***Mechanism of action:***
- **Annular reduction (indirect annuloplasty)**
  - **AP dimension**
  - **Cinching**
- **Papillary muscle repositioning**
- **LV remodeling and stress reduction**

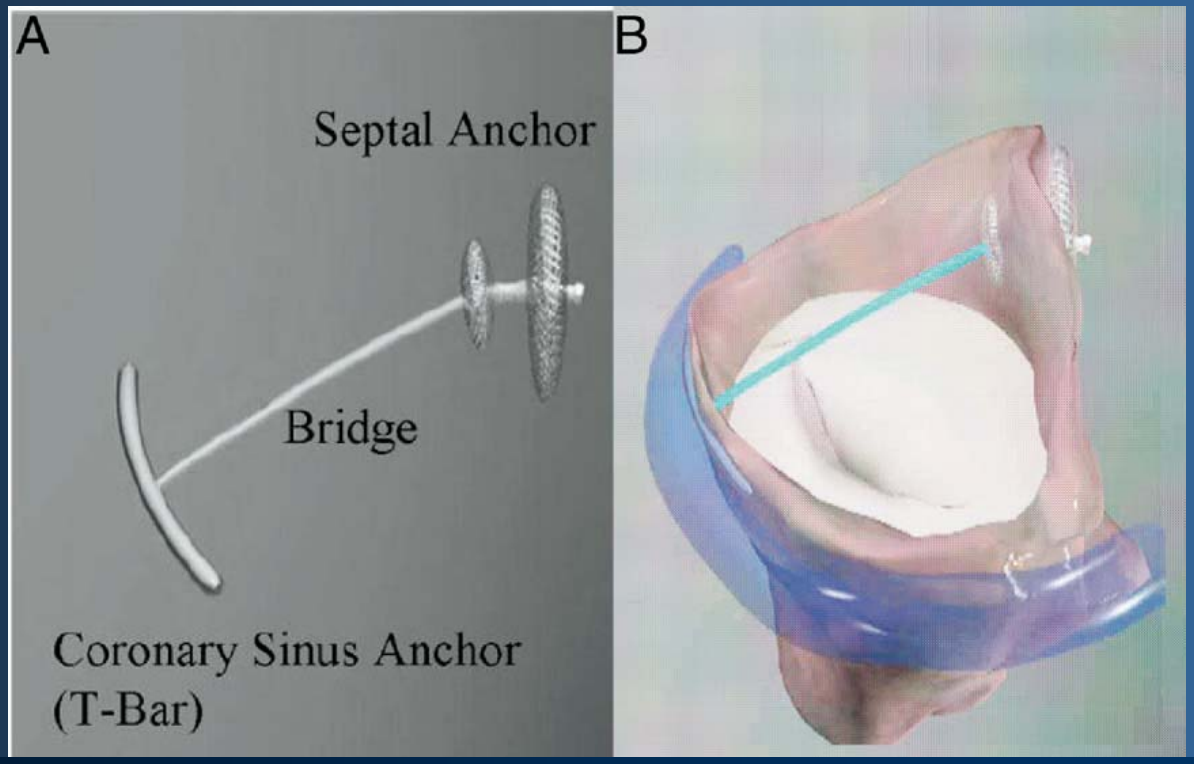
Device Positioning



PS3 System

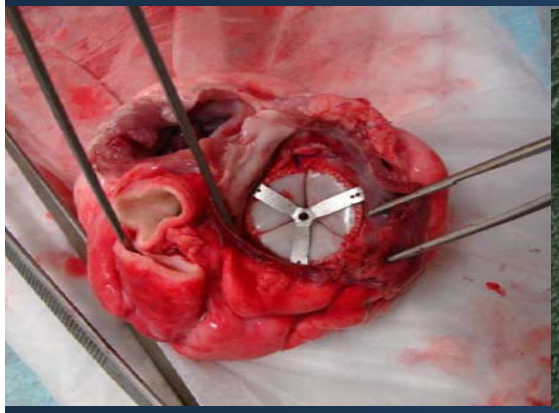
• Percutaneous septal sinus shortening

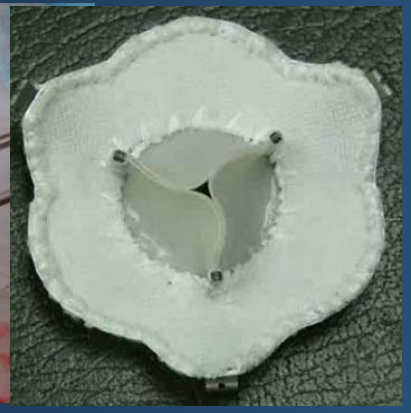
• Consists of an atrial septal occluder device and T-bar element that act as anchors in the interatrial septum and coronary sinus, respectively. A bridging element traversing the left atrium connects the 2 anchors.



Percutaneous Mitral Valve Replacement

endoValve





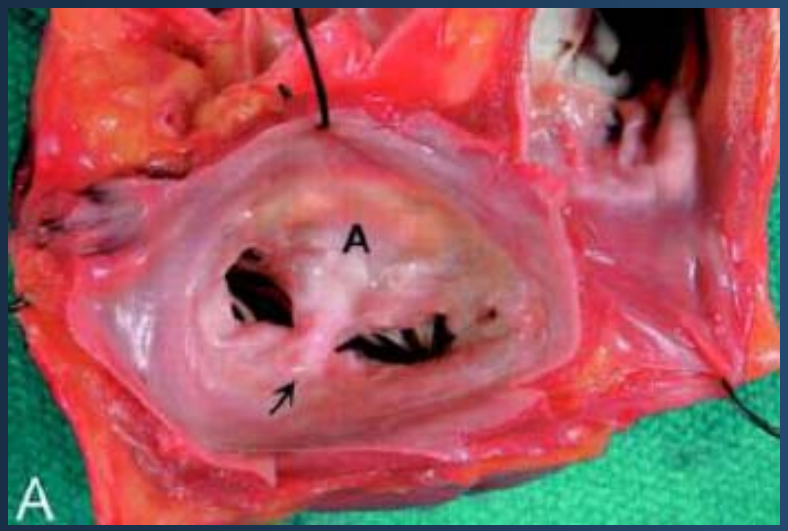
- Trans-septal approach
- Valve sparing (like repair)
- Immediately function
- Repositionable

Mitraclip System

CE 0050

Marzo 2008

Edge-to-edge Technique



Human S/P Surgical Alfieri
Circulation 2002;106:e173

eValve Clip repair in porcine heart (6 mos post)
Circulation 2003;108 (supp IV):493

Clinical Trials since 2003

Study	Population	n
EVEREST I (Feasibility)	Non-randomized	55
EVEREST II (Pivotal)	Pre-randomization	60
EVEREST II (Pivotal)	Non-randomized patients (High Risk Registry)	78
EVEREST II (Pivotal)	Randomized patients (2:1 Clip to Surgery)	279 184 Clip 95 Surgery
REALISM (Continued Access)	Non-randomized patients	135
EUROPE Commercial	Non-randomized patients	219
	Total	731 +95 surgery

MitraClip European Experience

September 2009

Stockholm, SW

Hull, UK

Cambridge, UK

London, UK (2)

Hamburg, DE (2)

Amsterdam, ND

Nieuwegein, ND

Berlin, DE

Gottingen, DE

Aachen, DE

Frankfurt, DE

Essen, DE

Munich, DE

Linz, AS

Zurich, CH

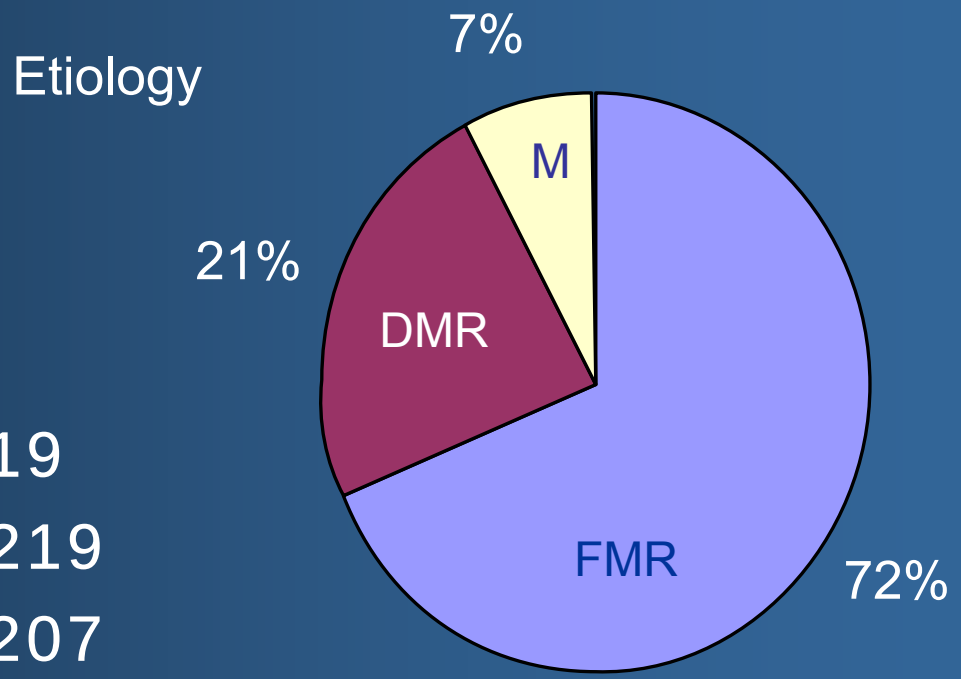
Lugano, CH

Milan, IT

Catania, IT

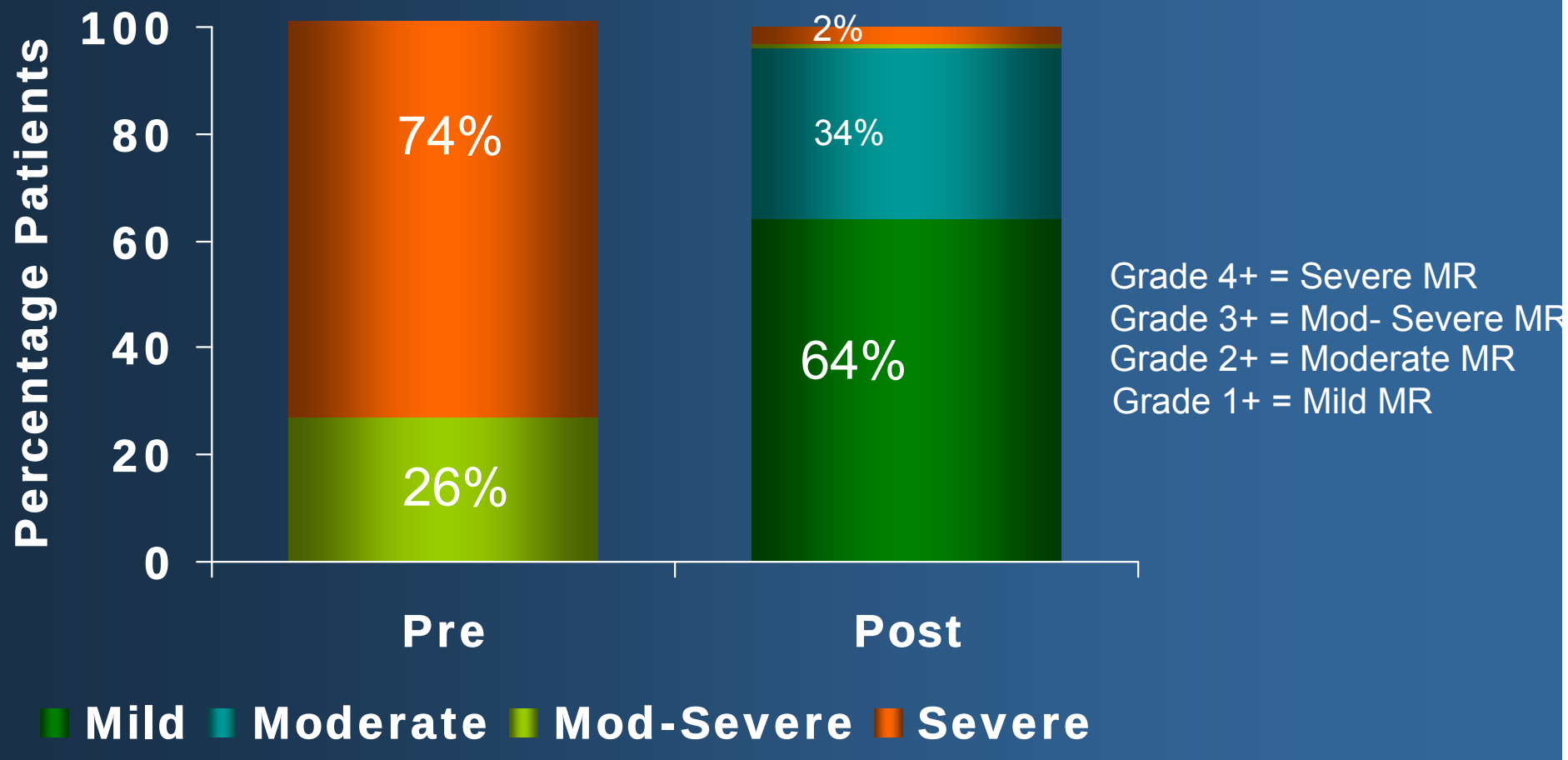
Ferrarotto Hospital
University of Catania

European Implant Experience



- Customers: 19
- Procedures: 219
- Implants: 207
- Implant % 96%
- MR reduction: 98% of implants

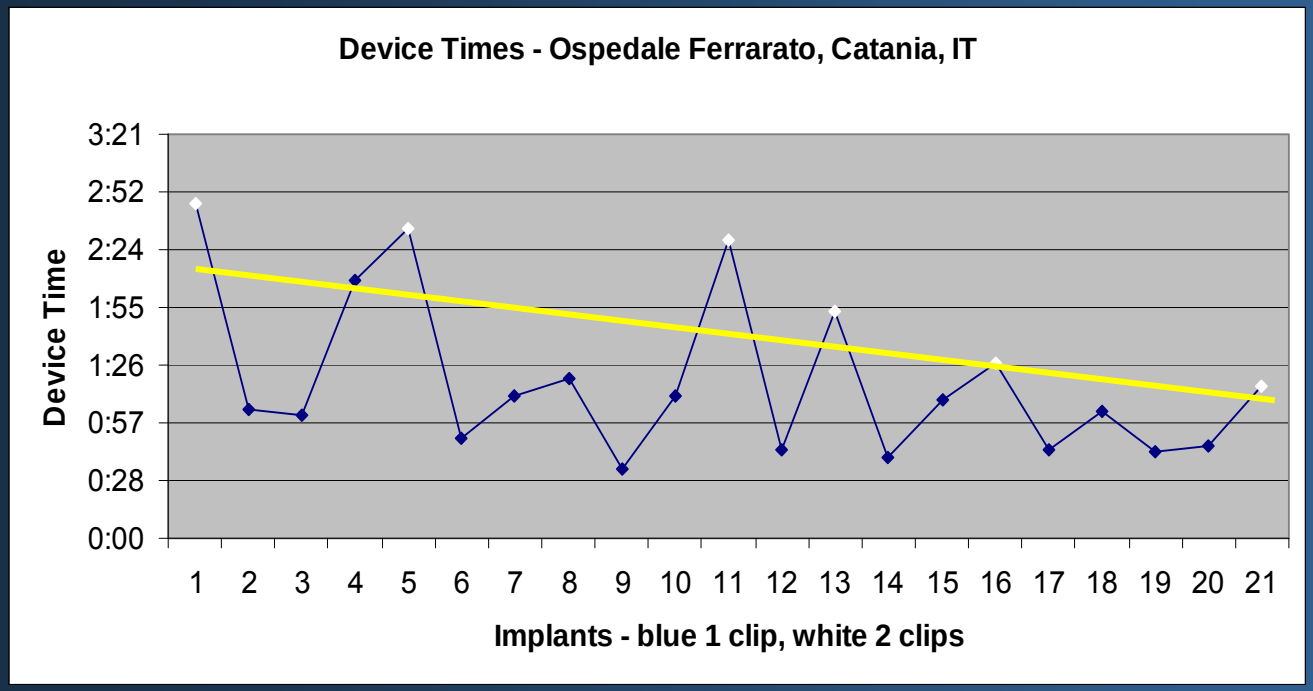
MR reduction after MitraClip implant



Ferrarotto Hospital
University of Catania

Data for 207 implant

Learning Curves



	Avg.
1 clip	1:00
2 clips	2:04

European & REALISM Experience

	Europe	REALISM
Patient Treated	219	128
Hospitals/Sites	19	26
Etiology: FMR/DMR (%)	72%/28%	60%/40%
Average Device Time (hr)	1:58	2:03
Clip Implant Rate (%)	96%	92%
1 Clip/2 Clip (%)	71%/29%	64%/36%
Site Reported MR Reduction (%) (in patients receiving a Clip)	98%	100%
Clip Embolization (%)	0%	0%

Ferrarotto Experience

First implant 7th October 2008

	n = 24
Mean age, mean±SD	69±14
Diabetes mellitus	10 (32)
Chronic Renal Insufficiency, n (%)	6 (27)
Chronic Pulmonary Disease, n (%)	8 (36)
History of congestive heart failure	11 (36)
History of coronary artery disease	14 (45)
Previous cardiac surgery	3 (6)
Atrial fibrillation	8 (26)
Ejection fraction, %±SD	31±24
Logistic EuroSCORE (% ± SD)	28 ± 9.1

Percutaneous MV repair

Inclusion criteria
Age 18 years or older
Moderate to severe (3+) or severe (4+) chronic mitral valve regurgitation with symptoms or without symptoms but left ventricular ejection fraction (LVEF) < 60% or left ventricle end systolic diameter >
High risk candidate for mitral valve surgery including cardiopulmonary bypass
Primary regurgitant jet originating from malcoaptation of the A2 and P2 scallops of the mitral valve.
Presence of sufficient leaflet tissue for a mechanical coaptation
Non-rheumatic/endocarditic valve morphology
Trans-septal catheterization determined to be feasible by the treating physician.

Percutaneous MV repair

Exclusion criteria
Acute myocardial infarction in the prior 12 weeks of the intended treatment
Need for any other cardiac surgery
Mitral valve orifice area <4.0 $cm^{2/}$Severe mitral annular calcification
Non eligible anatomy
Hemodynamic instability or cardiogenic shock
Need for emergency surgery for any reason
Systolic anterior motion of the mitral valve leaflet
Hypertrophic cardiomyopathy
Echocardiographic evidence of intracardiac mass, thrombus or vegetation
History of, or active, endocarditis
History of, or active, rheumatic heart disease
History of atrial septal defect, whether repaired or not
History of a stroke or documented TIA within the prior 6 months
Patients in whom transesophageal echocardiography is contraindicated.

Percutaneous MV repair

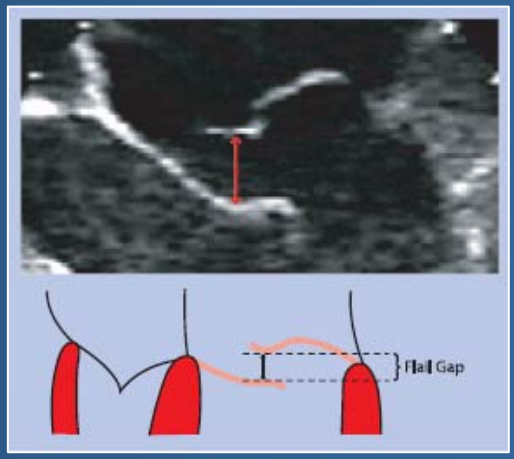
Anatomic Eligibility

Sufficient leaflet tissue for mechanical coaptation

Non-rheumatic/endocarditic valve morphology

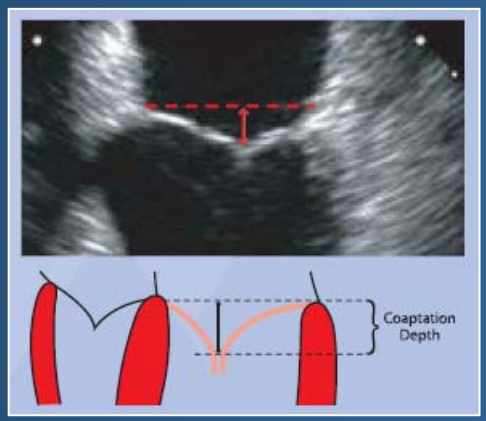
Absence of severe LV dysfunction

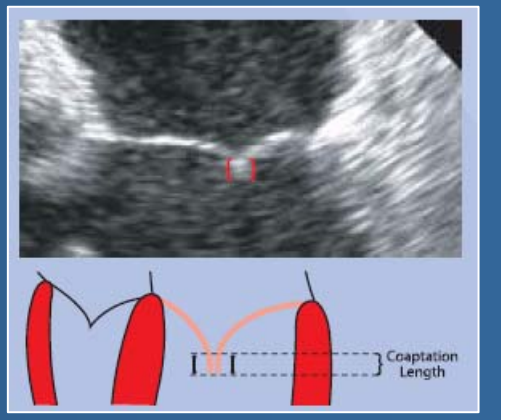
Absence of severe calcification



Protocol anatomic inclusion

- Flail gap <10mm
- Flail width <15mm
- LVIDs < 55mm
- Coaptation depth <11mm
- Coaptation length > 2mm





Ferrarotto Experience

MR Characteristics	Pts 24
Mitral Regurgitation ≥ 3 +, n(%)	24 (100)
Degenerative MR , n(%)	10 (45)
P2 prolapse/flail	6 (6%)
Bi-leaflets prolapsed	2 (2%)
A2 flail	2 (2%)
Functional MR, n(%)	14 (55)
NYHA Functional Class II, n (%)	5 (21)
NYHA Functional Class III-IV, n (%)	19 (79)

Ferrarotto Experience

Procedural Data	Pts 24
General Anaesthesia/TOE guidance, n (%)	23 (95)
Conscious Sedation/TOE guidance, n (%)	1 (4.5)
1 Clip, n (%)	18 (75)
2 Clips, n (%)	6 (25)
Acute Procedural Success, n (%)	24 (100)
Procedural Complications, n (%)	0 (0)
Procedural Death, n (%)	0 (0)
Device time One clip	65±19
Device time Two clips	145±25
Device time Functional etiologies	88±41
Device time Degenerative etiologies	107±52

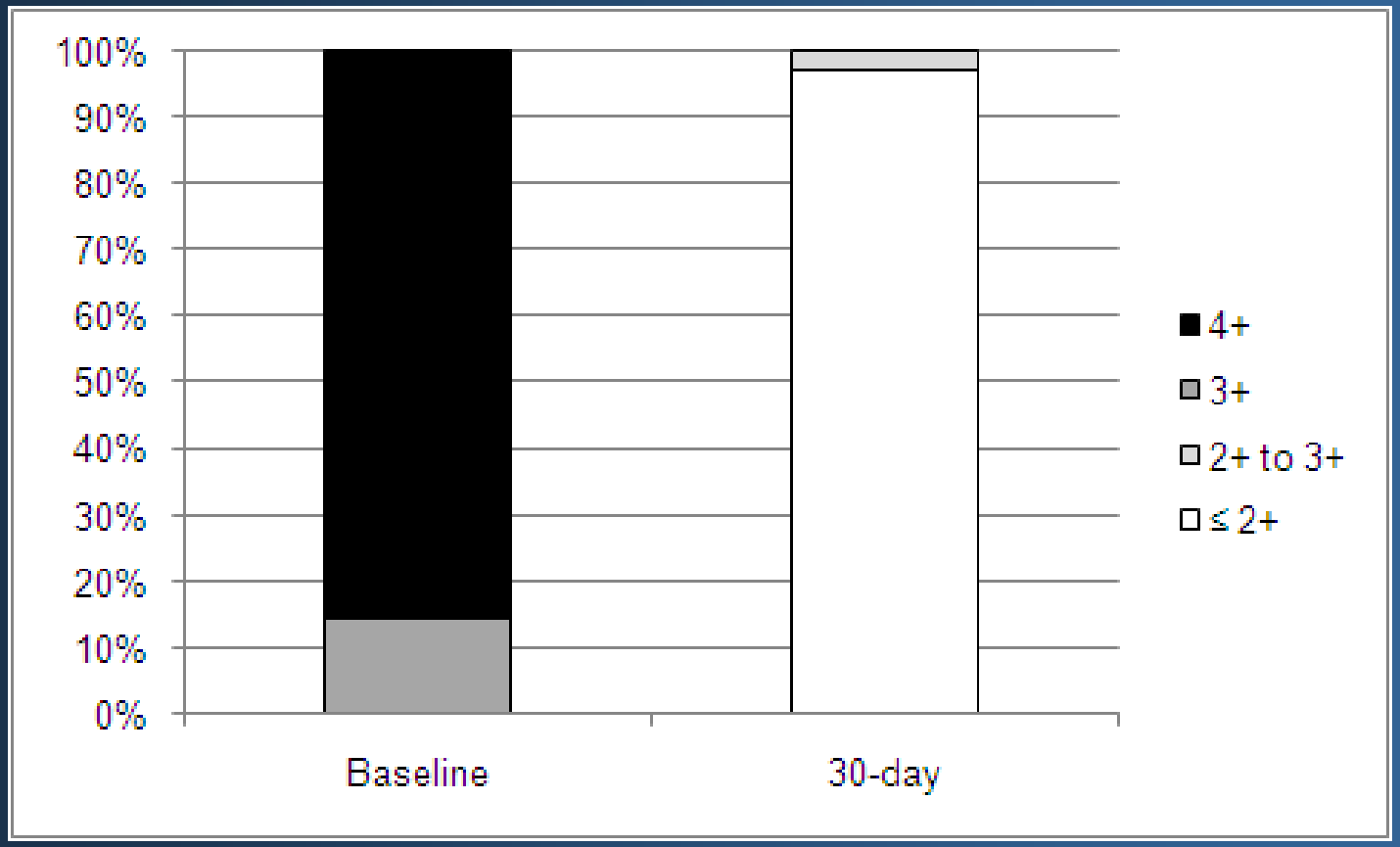
Ferrarotto Experience

30 days MACE

	n = 24
Death	1 (3.2)
Myocardial infarction	0
Stroke	0
Non-elective cardiac surgery for adverse events	0
Clip detachment	0
Clip embolization	0
Transfusion of > 2 units of blood	1 (3.2)
Ventilation for >48 hours	0
Deep wound infection	0
Septicemia	0
New onset of atrial fibrillation	0
NYHA Functional Class I-II, n (%)	24 (90)

Ferrarotto Experience

30 days follow up

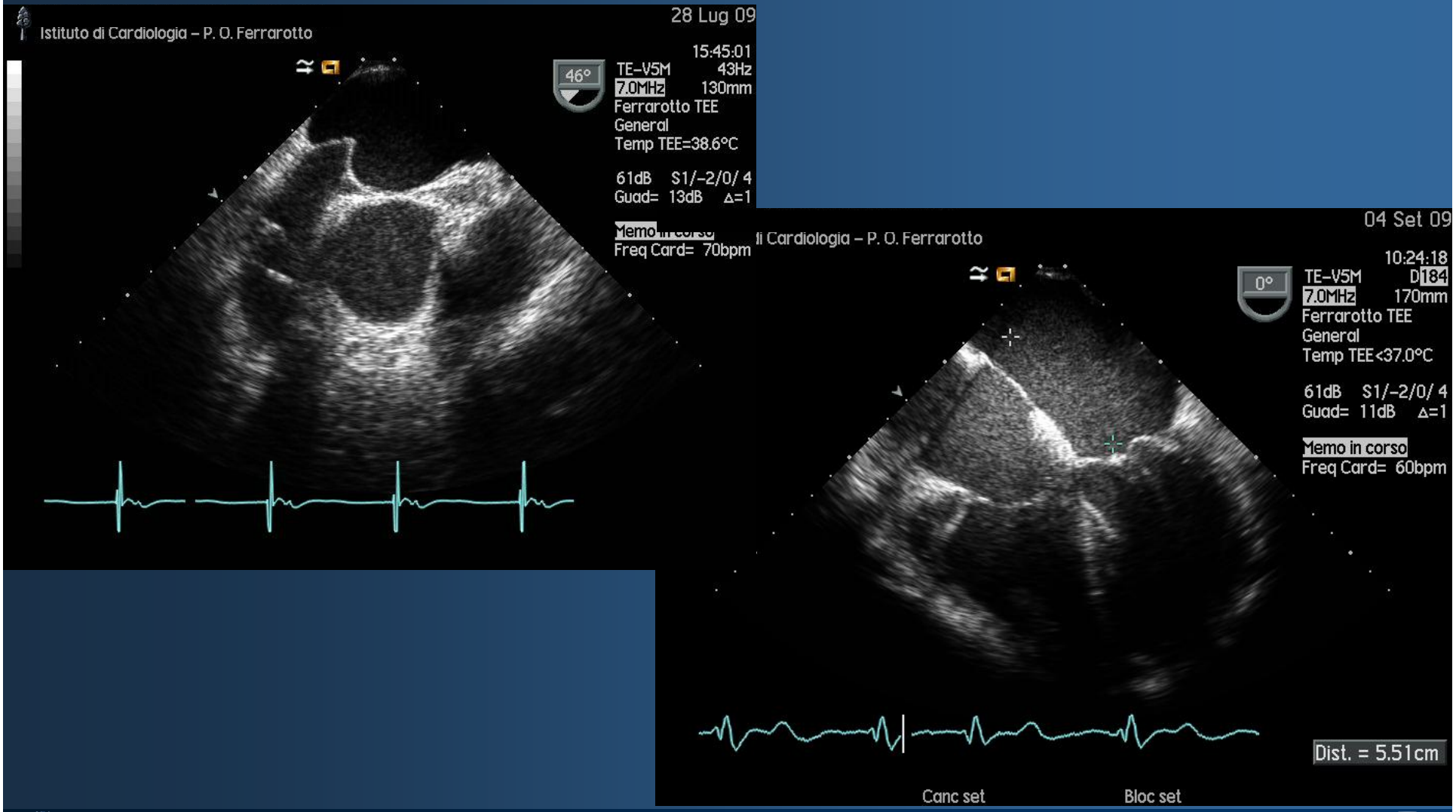


* One in-hospital death, after 8 days for GI bleeding (pt with 2 clips)
One patient died for liver cirrhosis complication after 2 months

Edge-to-Edge Technique

- General Anesthesia
- TOE guidance
- Right femoral vein access
- Transeptal puncture
- Introduction 24 Fr guide catheter in LA
- Introduction DCS with the clip
- Clip orientation in LA and than above mitral regurgitation
- Checking enduring MR using TOE
- Clip deployment

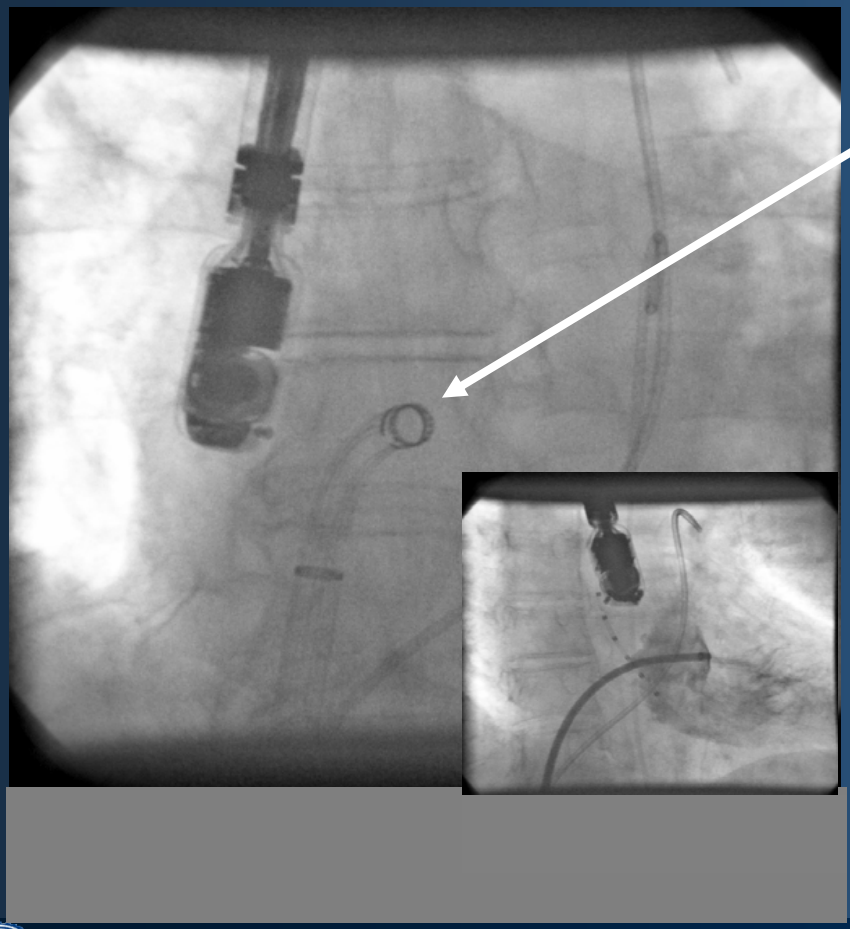
Procedure


Istituto di Cardiologia – P. O. Ferrarotto
28 Lug 09
15:45:01
46°
TE-V5M 43Hz
7.0MHz 130mm
Ferrarotto TEE
General
Temp TEE=38.6°C
61dB S1/-2/0/ 4
Guad= 13dB Δ=1
Memo
Freq Card= 70bpm
Istituto di Cardiologia – P. O. Ferrarotto
04 Set 09
10:24:18
0°
TE-V5M D184
7.0MHz 170mm
Ferrarotto TEE
General
Temp TEE<37.0°C
61dB S1/-2/0/ 4
Guad= 11dB Δ=1
Memo in corso
Freq Card= 60bpm
Dist. = 5.51cm
Canc set
Bloc set

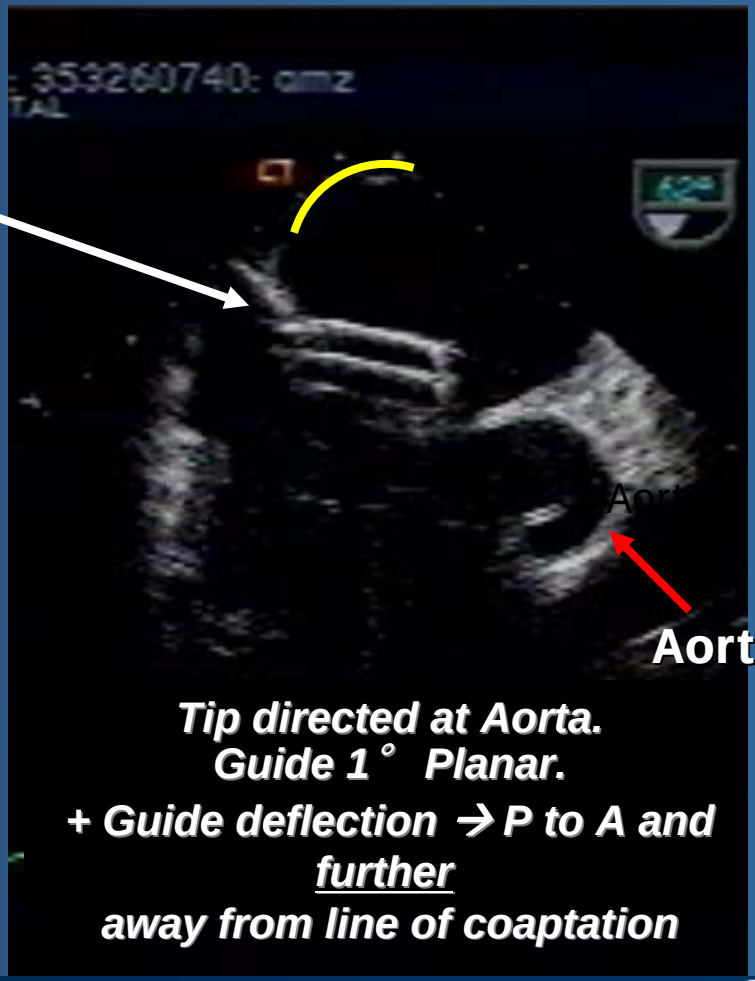
Procedure

Edge to Edge Technique

Guide position

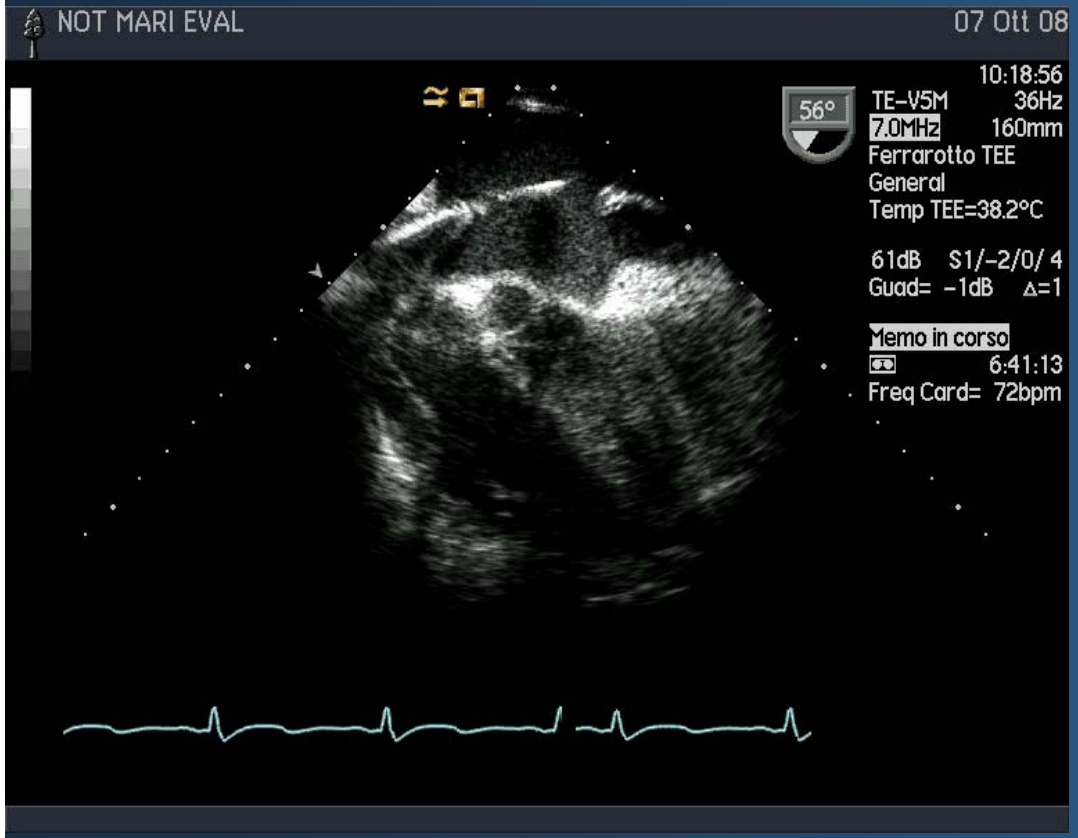


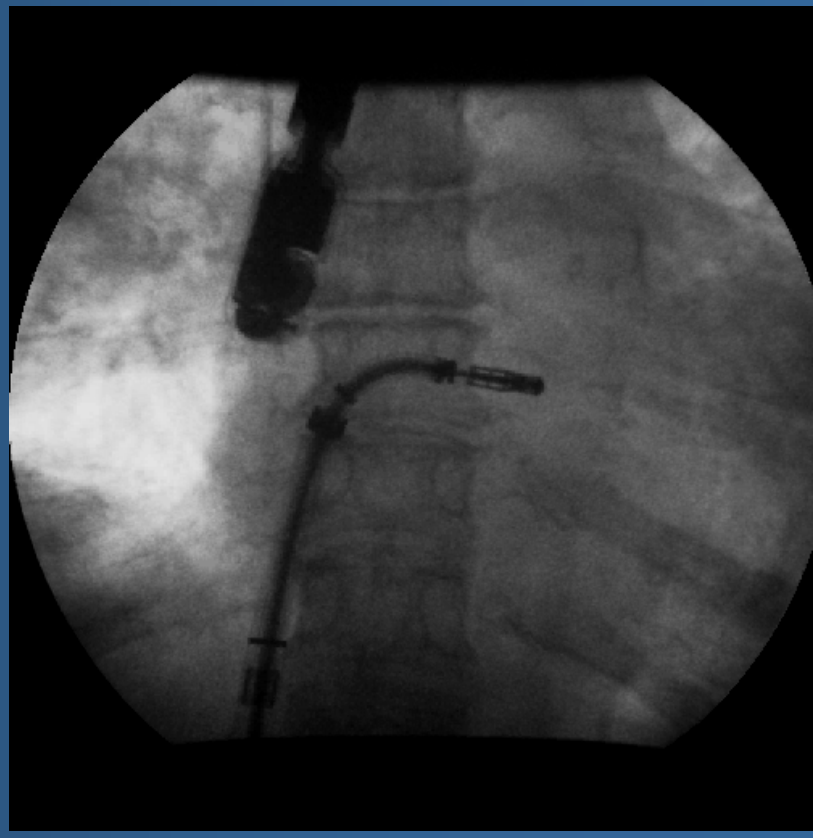
Echo answer

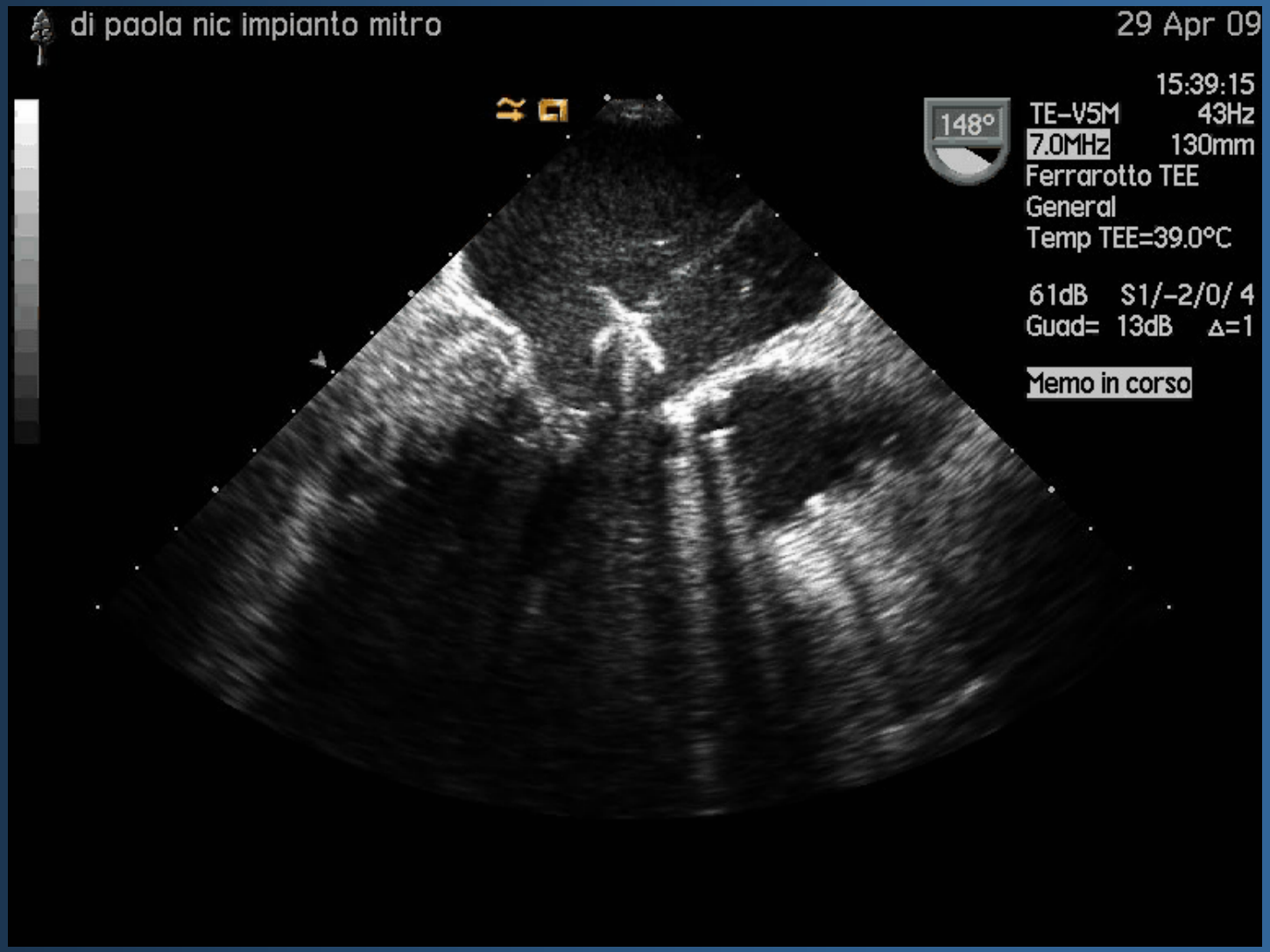


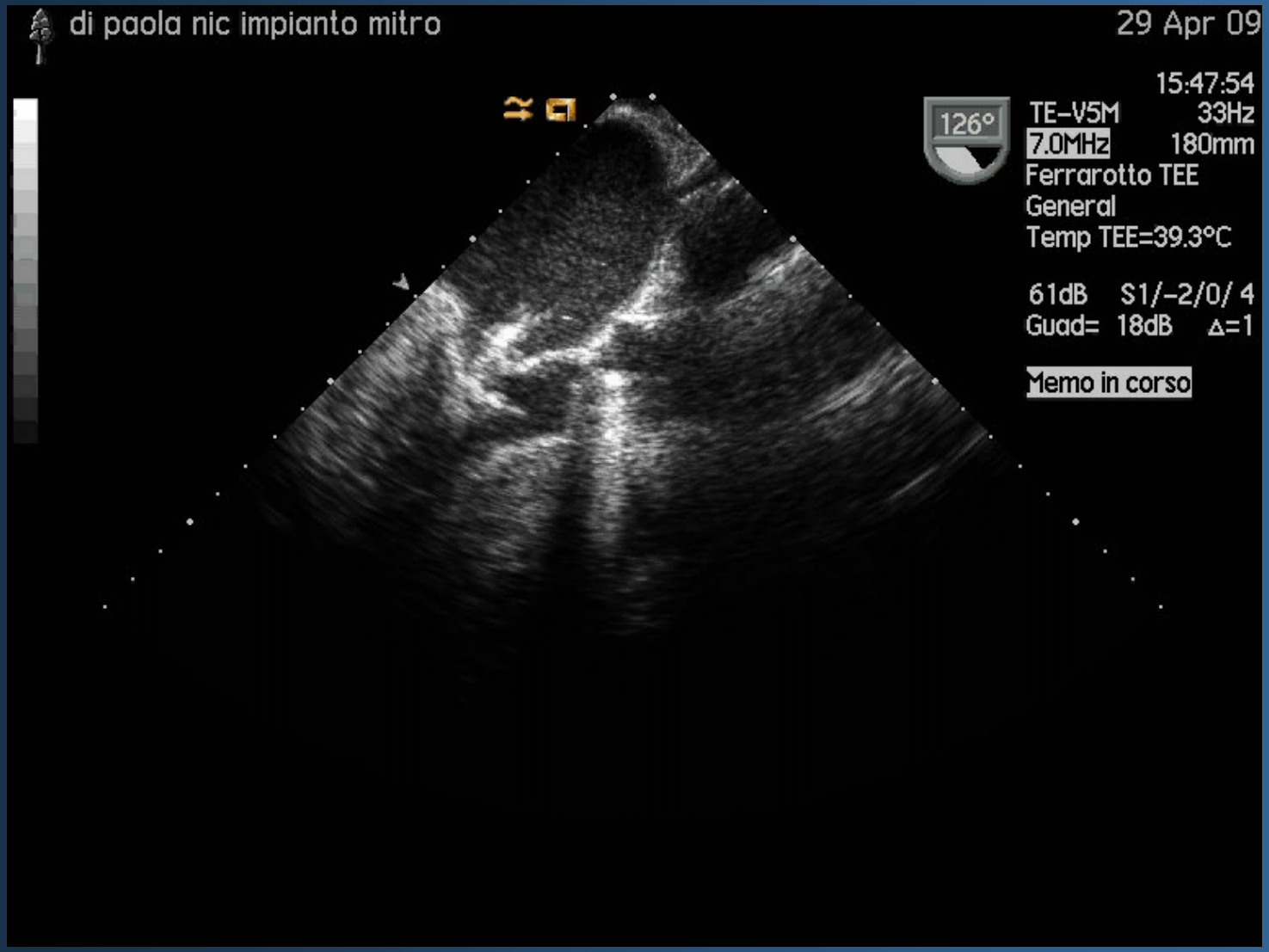
Tip directed at Aorta.
Guide 1° Planar.
+ Guide deflection → P to A and <u>further</u>
away from line of coaptation

Procedure

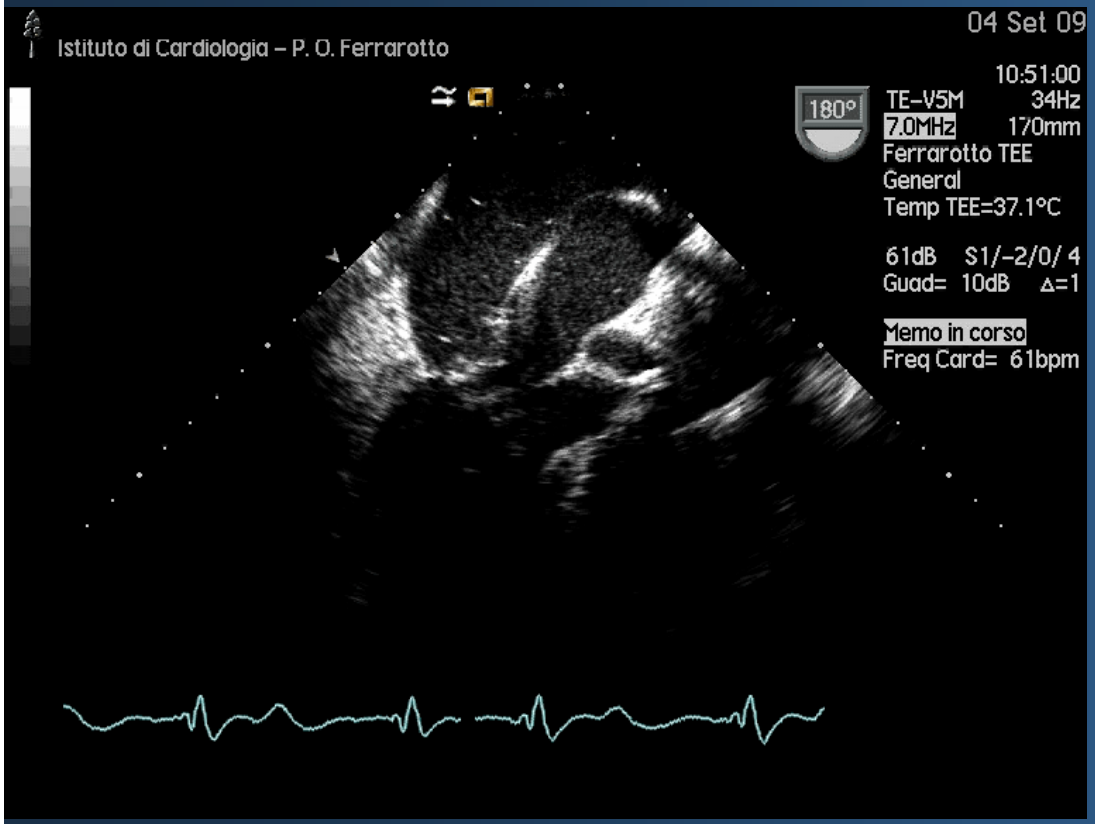

NOT MARI EVAL
07 Ott 08
10:18:56
56°
TE-V5M 36Hz
7.0MHz 160mm
Ferrarotto TEE
General
Temp TEE=38.2°C
61dB S1/-2/0/ 4
Guad= -1dB Δ=1
Memo in corso
6:41:13
Freq Card= 72bpm

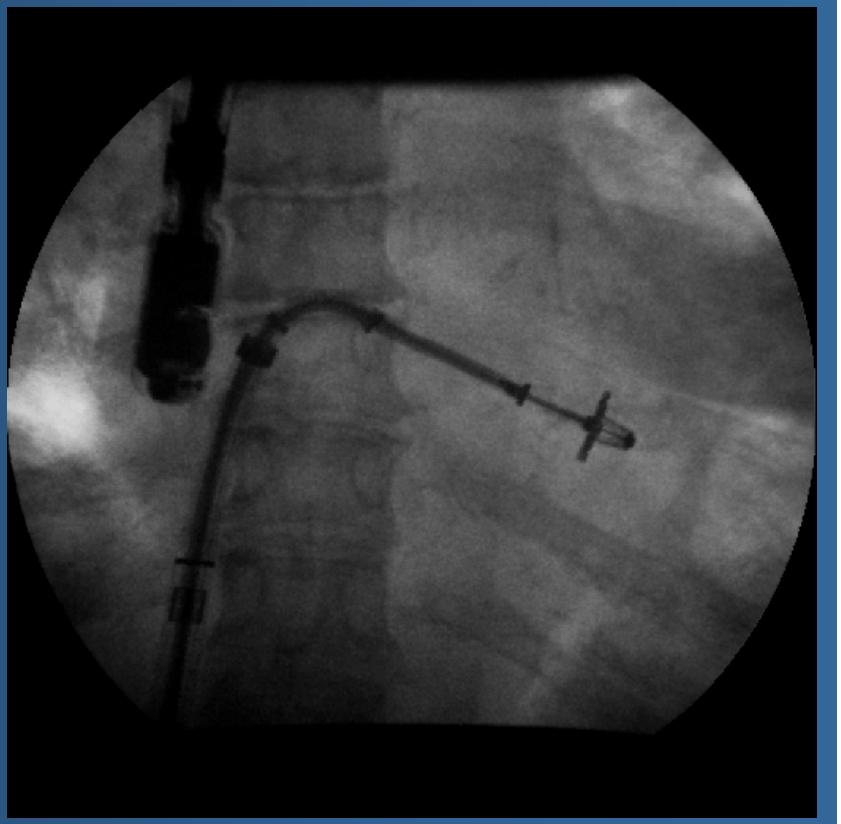



di paola nic impianto mitro
29 Apr 09
15:39:15
148°
TE-V5M
43Hz
7.0MHz
130mm
Ferrarotto TEE
General
Temp TEE=39.0°C
61dB S1/-2/0/ 4
Guad= 13dB Δ=1
Memo in corso

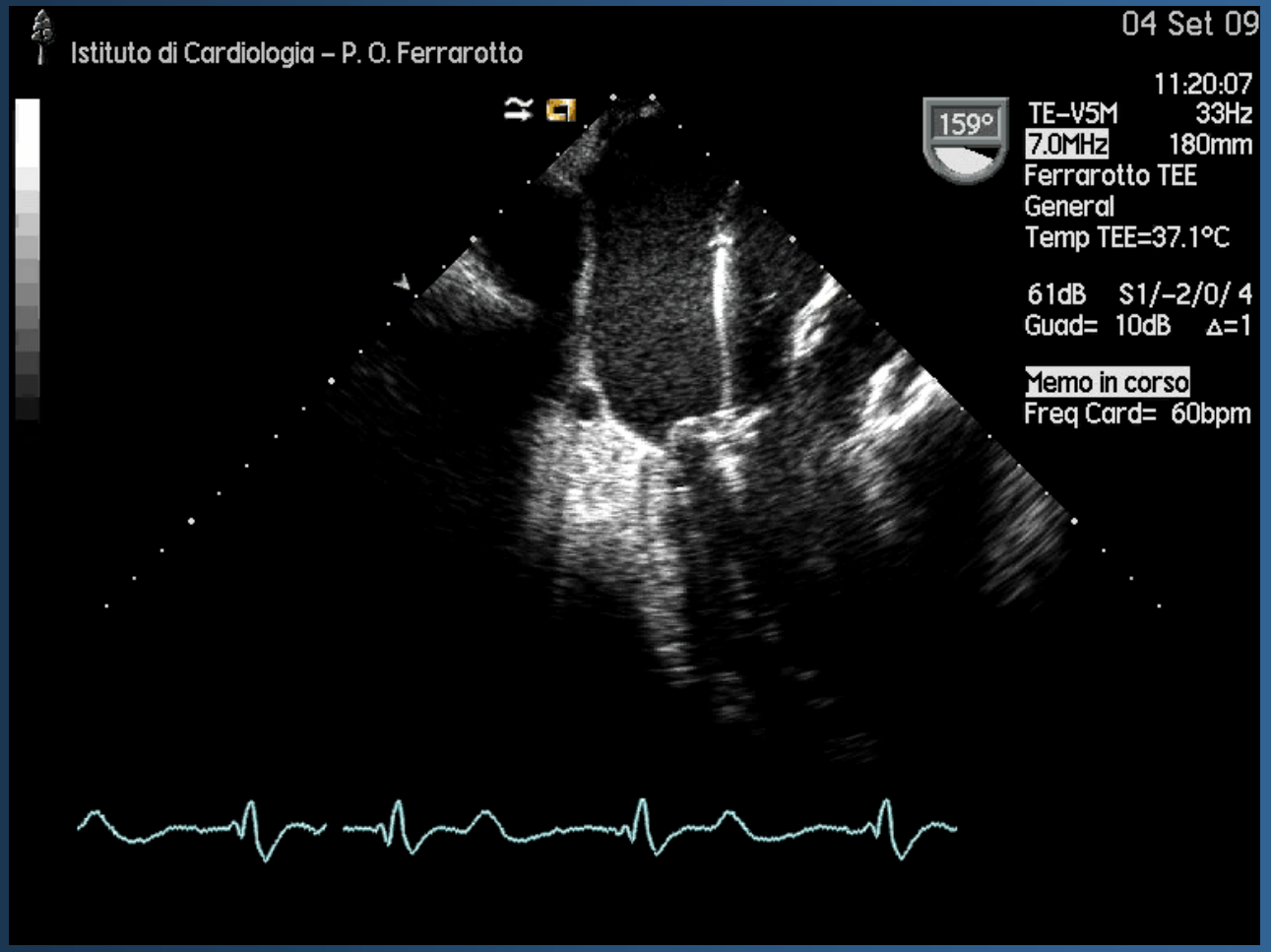

di paola nic impianto mitro
29 Apr 09
15:47:54
126°
TE-V5M 33Hz
7.0MHz 180mm
Ferrarotto TEE
General
Temp TEE=39.3°C
61dB S1/-2/0/ 4
Guad= 18dB Δ=1
Memo in corso

Procedure

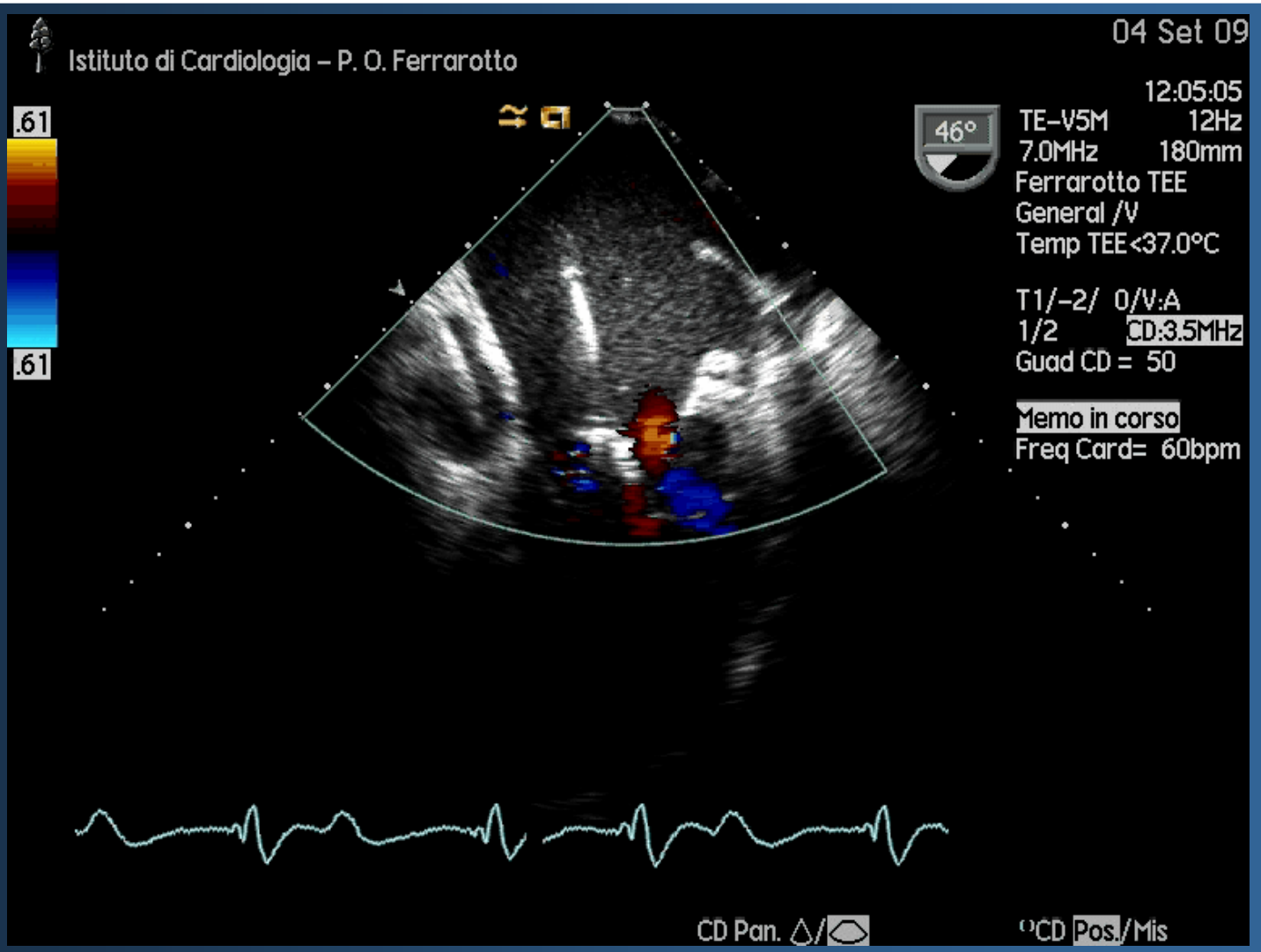

Istituto di Cardiologia – P. O. Ferrarotto
04 Set 09
10:51:00
180°
TE-V5M 34Hz
7.0MHz 170mm
Ferrarotto TEE
General
Temp TEE=37.1°C
61dB S1/-2/0/ 4
Guad= 10dB Δ=1
Memo in corso
Freq Card= 61bpm

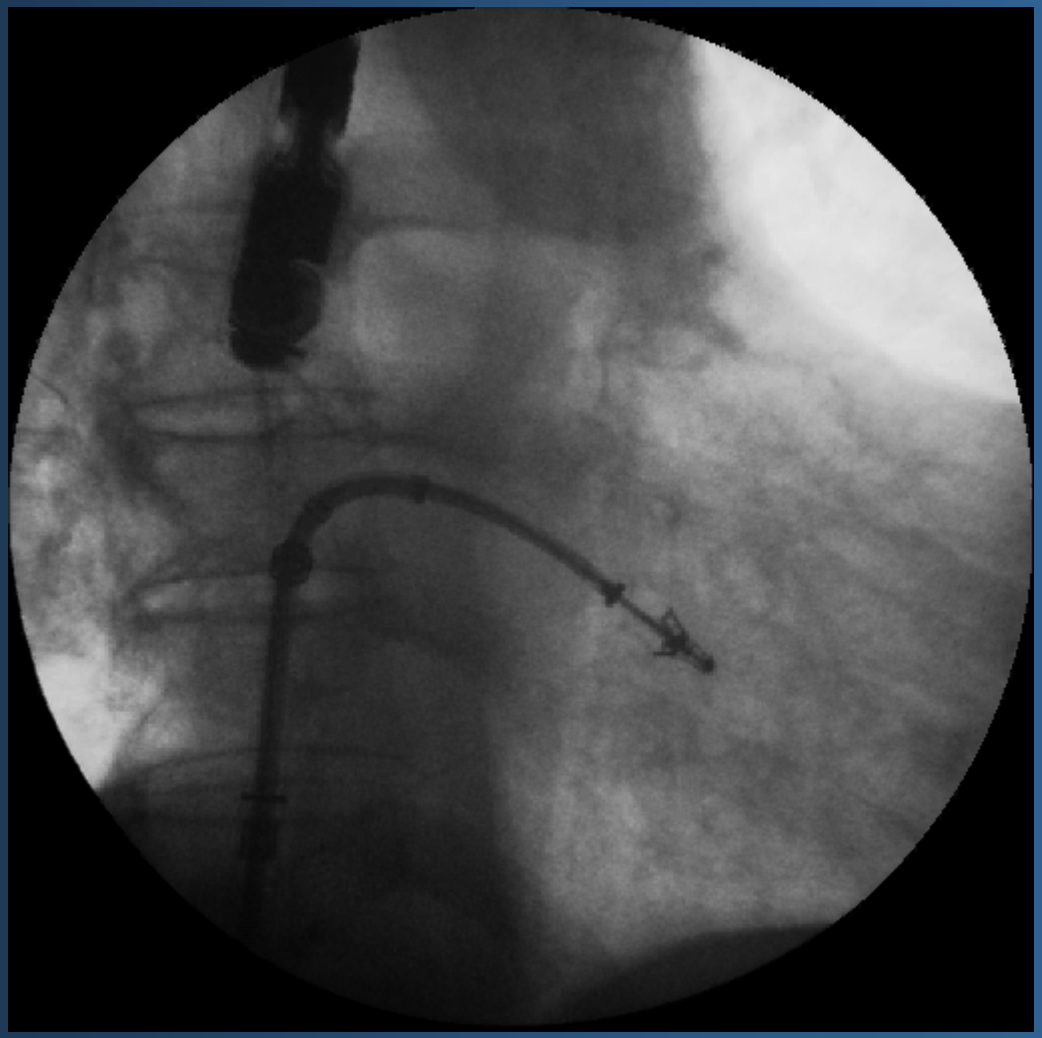


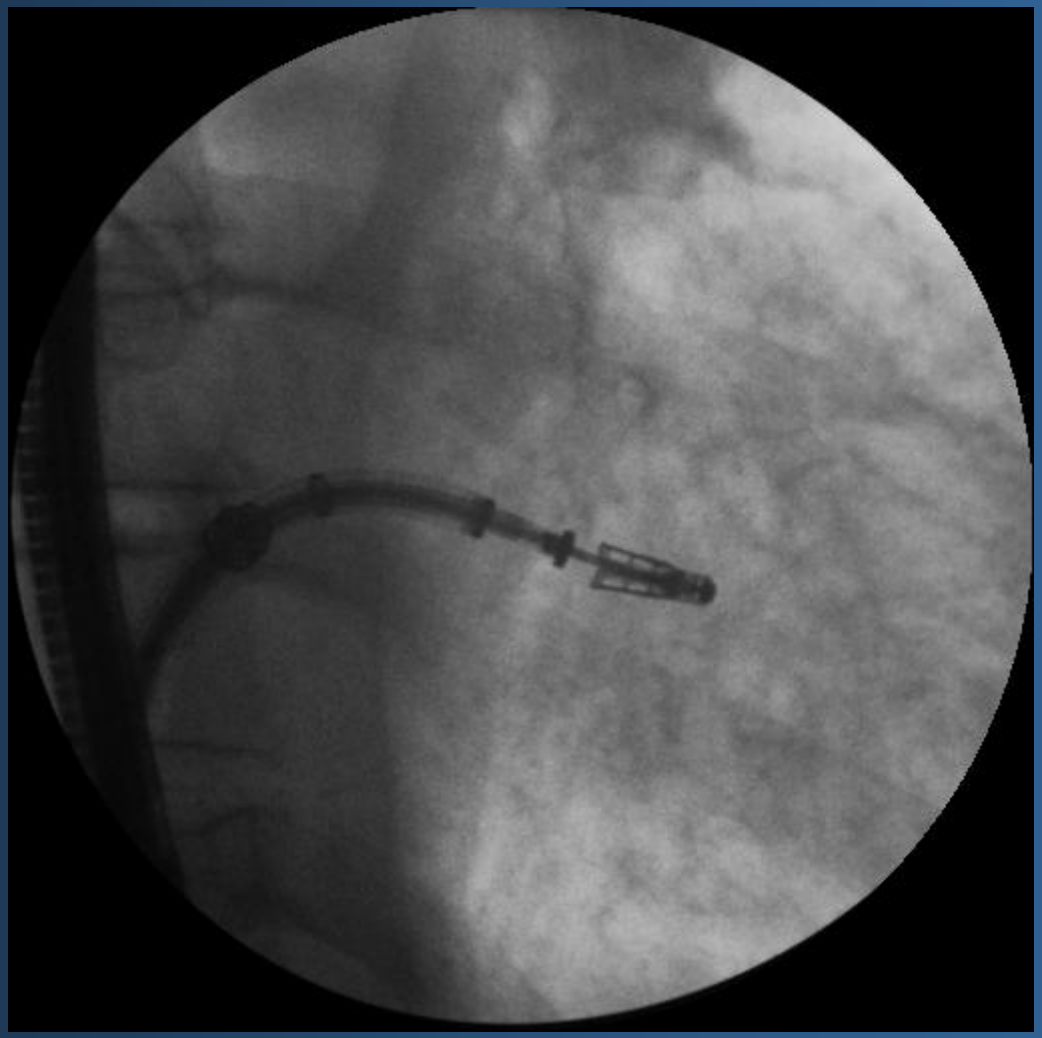
Procedure

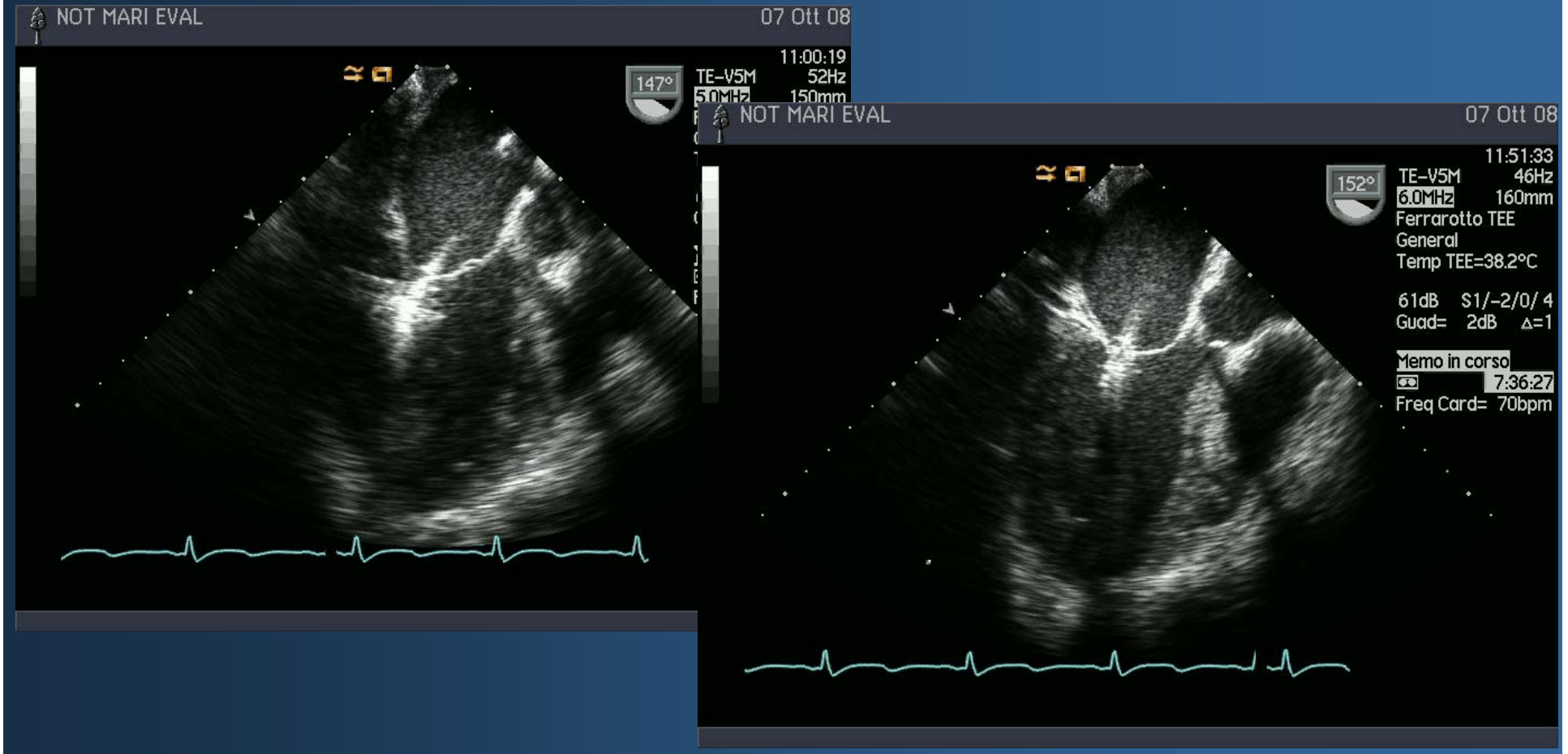

Istituto di Cardiologia – P. O. Ferrarotto
04 Set 09
11:20:07
159°
TE-V5M
33Hz
7.0MHz
180mm
Ferrarotto TEE
General
Temp TEE=37.1°C
61dB S1/-2/0/ 4
Guad= 10dB Δ=1
Memo in corso
Freq Card= 60bpm

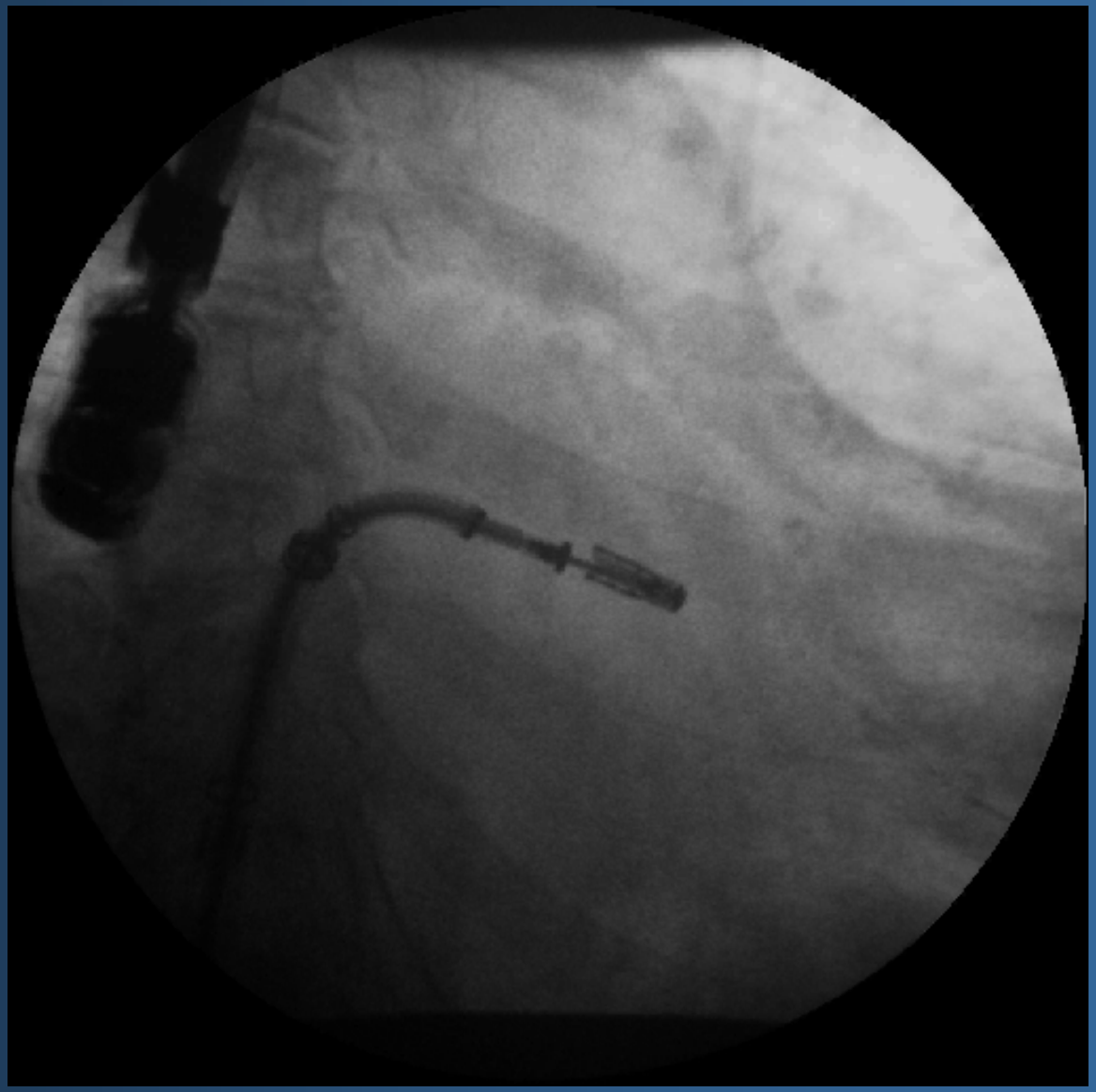
Procedure

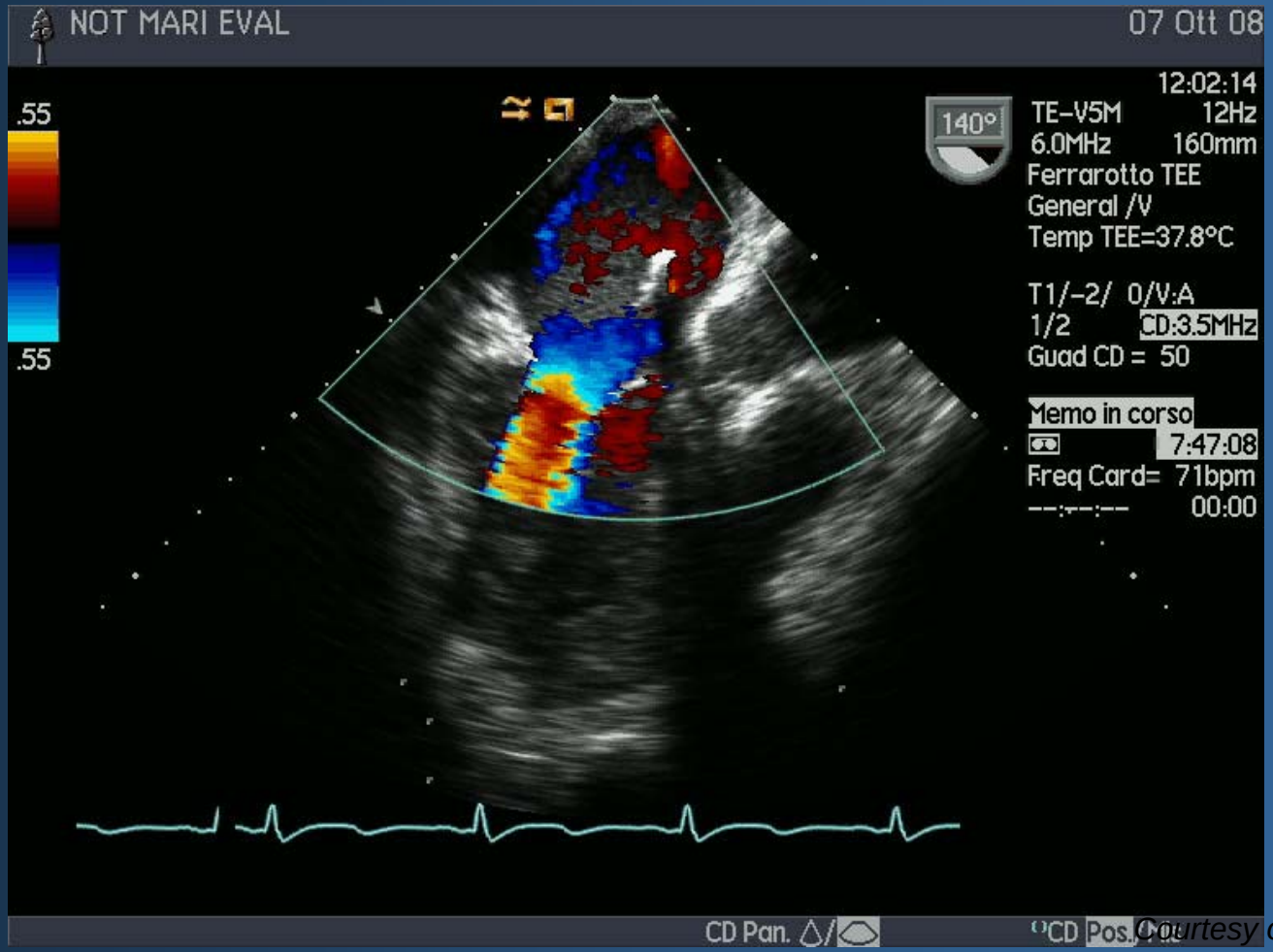

Istituto di Cardiologia – P. O. Ferrarotto
04 Set 09
12:05:05
.61
.61
46°
TE-V5M 12Hz
7.0MHz 180mm
Ferrarotto TEE
General /V
Temp TEE<37.0°C
T1/-2/ 0/V:A
1/2 CD:3.5MHz
Guad CD = 50
Memo in corso
Freq Card= 60bpm
CD Pan.
CD Pos./Mis



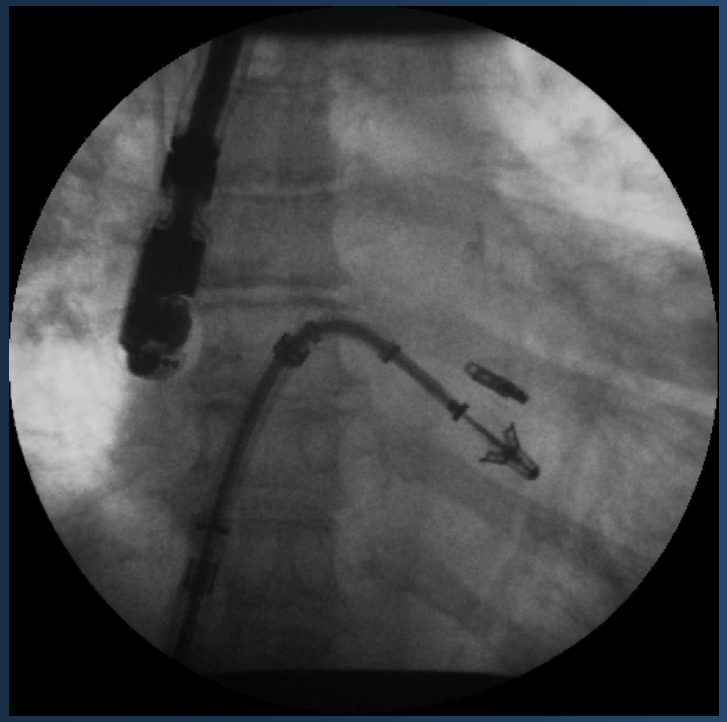


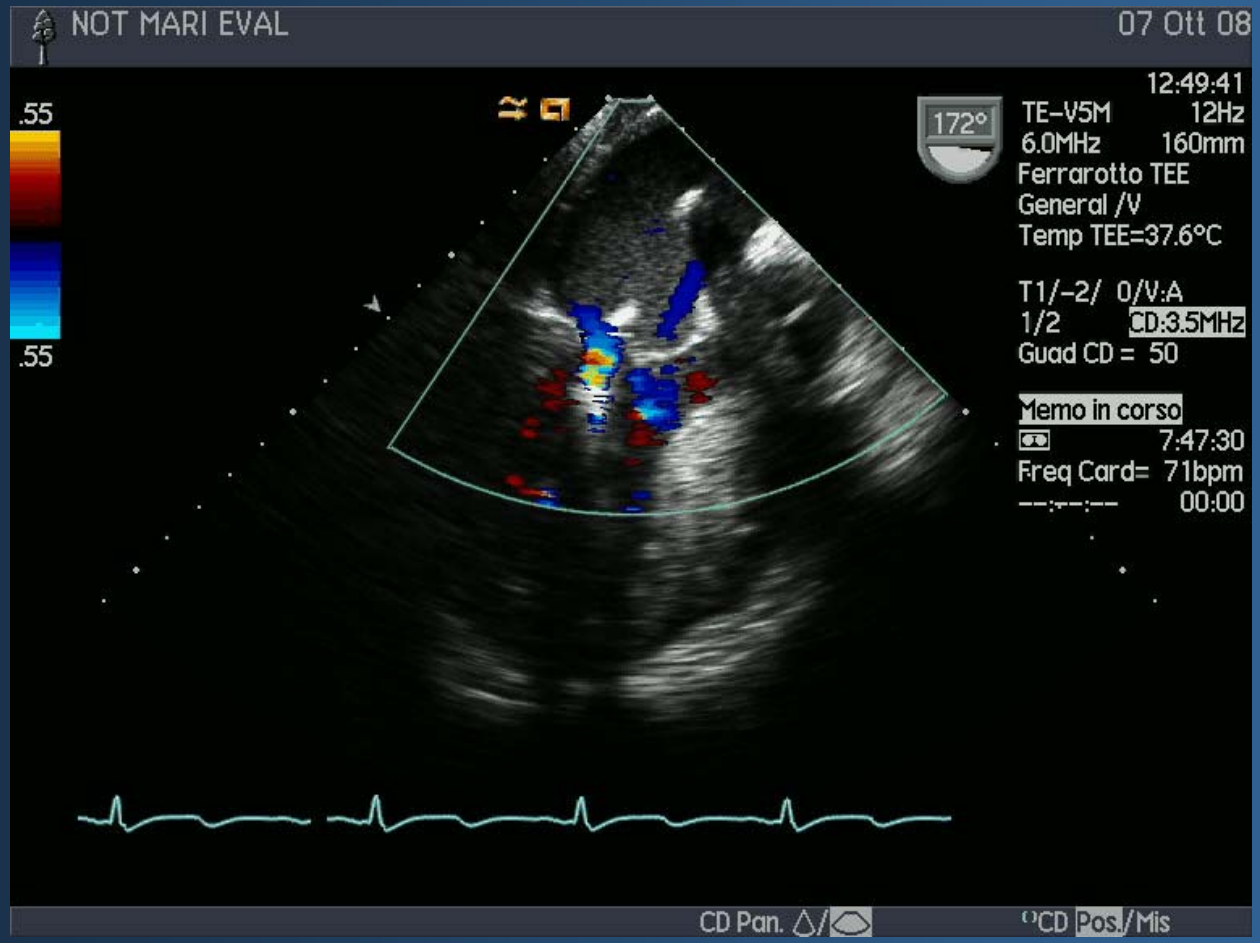

NOT MARI EVAL
07 Ott 08
11:00:19
147°
TE-V5M
52Hz
5.0MHz
150mm
NOT MARI EVAL
07 Ott 08
11:51:33
152°
TE-V5M
46Hz
6.0MHz
160mm
Ferrarotto TEE
General
Temp TEE=38.2°C
61dB
S1/-2/0/ 4
Guad=
2dB
Δ=1
Memo in corso
7:36:27
Freq Card= 70bpm





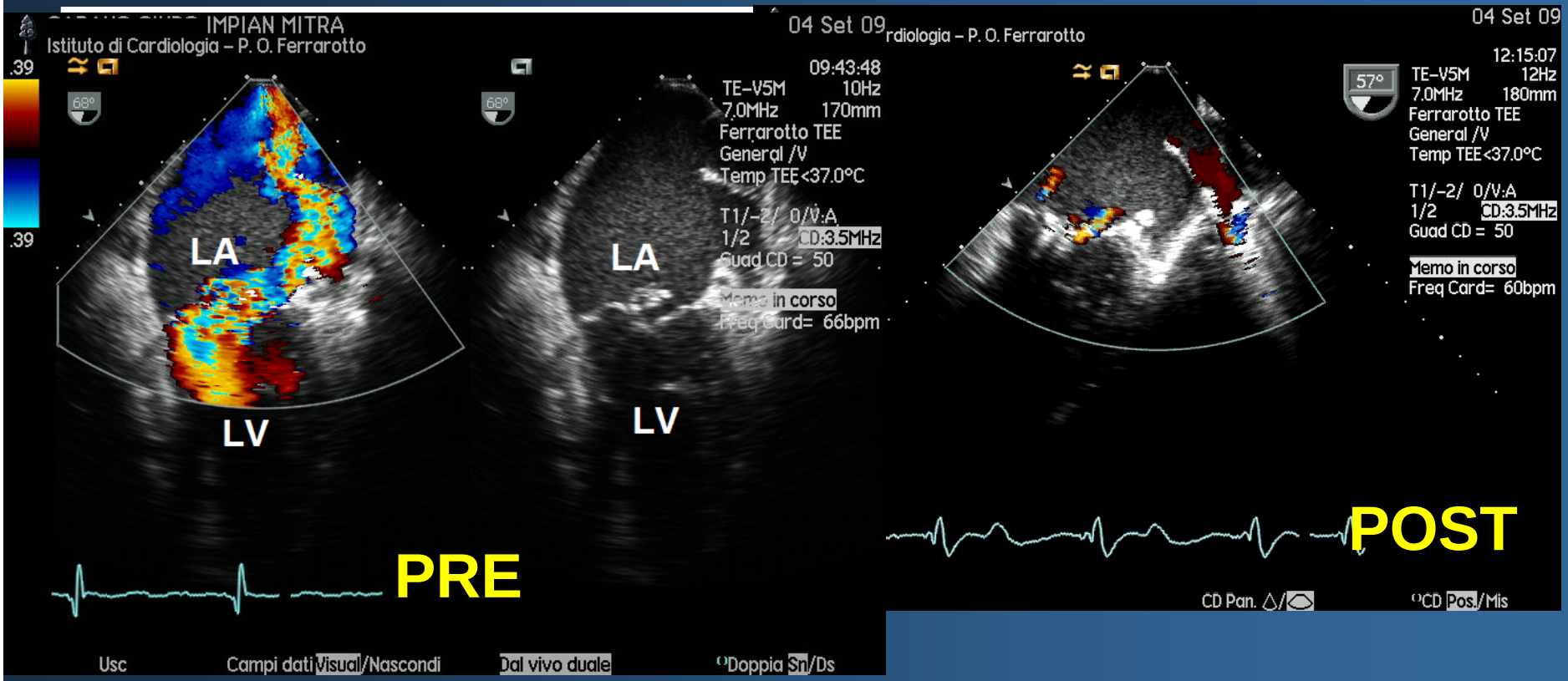
Courtesy of Dr S Scandurra





Courtesy of Dr S Scandurra

Procedure


IMPIAN MITRA
Istituto di Cardiologia – P. O. Ferrarotto
04 Set 09
09:43:48
TE-V5M 10Hz
7,0MHz 170mm
Ferrarotto TEE
General /V
Temp TEE<37.0°C
T1/-2/ 0/V:A
1/2 CD:3.5MHz
Guad CD = 50
Memo in corso
Freq Card= 66bpm
LA
LV
PRE
Usc
Campi dati Visual/Nascondi
Dal vivo duale
Doppia Sn/Ds
rdiologia – P. O. Ferrarotto
04 Set 09
12:15:07
TE-V5M 12Hz
7.0MHz 180mm
Ferrarotto TEE
General /V
Temp TEE<37.0°C
T1/-2/ 0/V:A
1/2 CD:3.5MHz
Guad CD = 50
Memo in corso
Freq Card= 60bpm
POST
CD Pan.
CD Pos./Mis

Edge-to-Edge Technique

- *Mitraclip System has procedural and short term results better than expected*
- *The learning curve is steep*
- *The “real world” is expanding the use in functional MVR*
- *The procedure is safe in Pts with low LVEF*
- *Waiting for other devices …*


Thank You