

***Percutaneous mitral valve repair:
leaflet & annuloplasty approaches***

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Disclosure Information

The following relationships exist:

Grant support: Abbott, Atritech, BSC, Cardiac Dimensions, Edwards,
Evalve, Myocor, St Jude

Consultant: Abbott, Cardiac Dimensions, Coherex, Cordis, Myocor

Speaker: Boston Scientific

*Off label use of products and investigational devices
will be discussed in this presentation*

Percutaneous Mitral Repair Approaches

- **Coronary sinus annuloplasty**
 - Edwards Monarc
 - Cardiac Dimensions Carillon
 - Viacor Shape Changing Rods
 - St. Jude Annulus Reshaping

- **Direct annuloplasty**
 - Mitralign Suture-Based Plication
 - Guided Delivery Anchor-Cinch Plication
 - QuantumCor RF Annulus Remodeling
 - MiCardia variable size ring

- **Leaflet repair**
 - EValve Mitraclip
 - Edwards Mobius stitch

- **Chamber + annular remodeling**
 - Myocor iCoapsys
 - Ample PS3

Surgical Correction of Pure Mitral Insufficiency by Annuloplasty Under Direct Vision

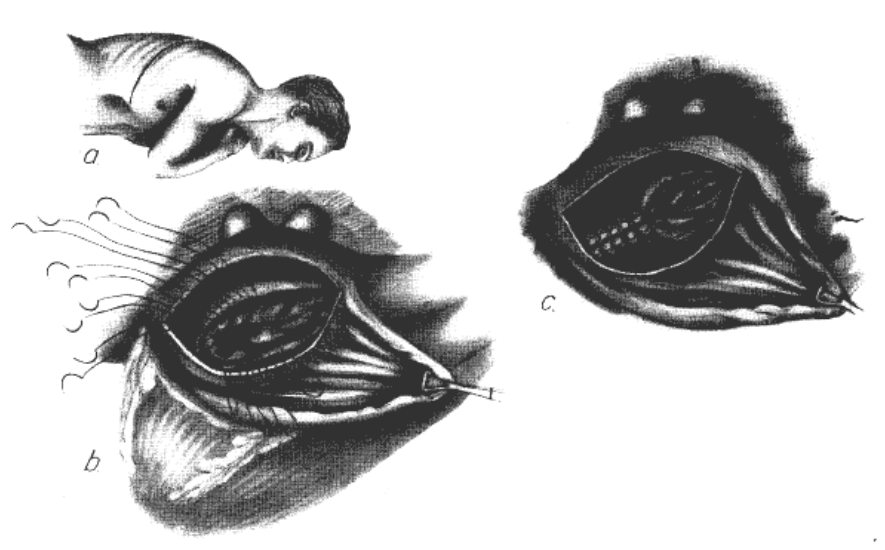
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IN RECENT YEARS, effective surgical measures for treating stenotic lesions of the pulmonary, mitral, and aortic valves have been described.¹⁻⁵ The methods usually described for these operations have been carried out through a thoracotomy with these defective valves exposed without interruption of the patient's circulation.

The development of the technique of routine clinical use of a closed-chest approach for working inside of the heart under direct vision by use of a pericardial flap has removed the barrier of cardiac surgery and has opened the way in the treatment of cardiac disease. In 1955, the rapid increase in the use of our pump-oxygenator^{6,7} for congenital cardiac malformations had resulted in confidence concerning the well-being of the patient during

been before surgical therapy, the greater have been the benefits of open cardiomy

when the



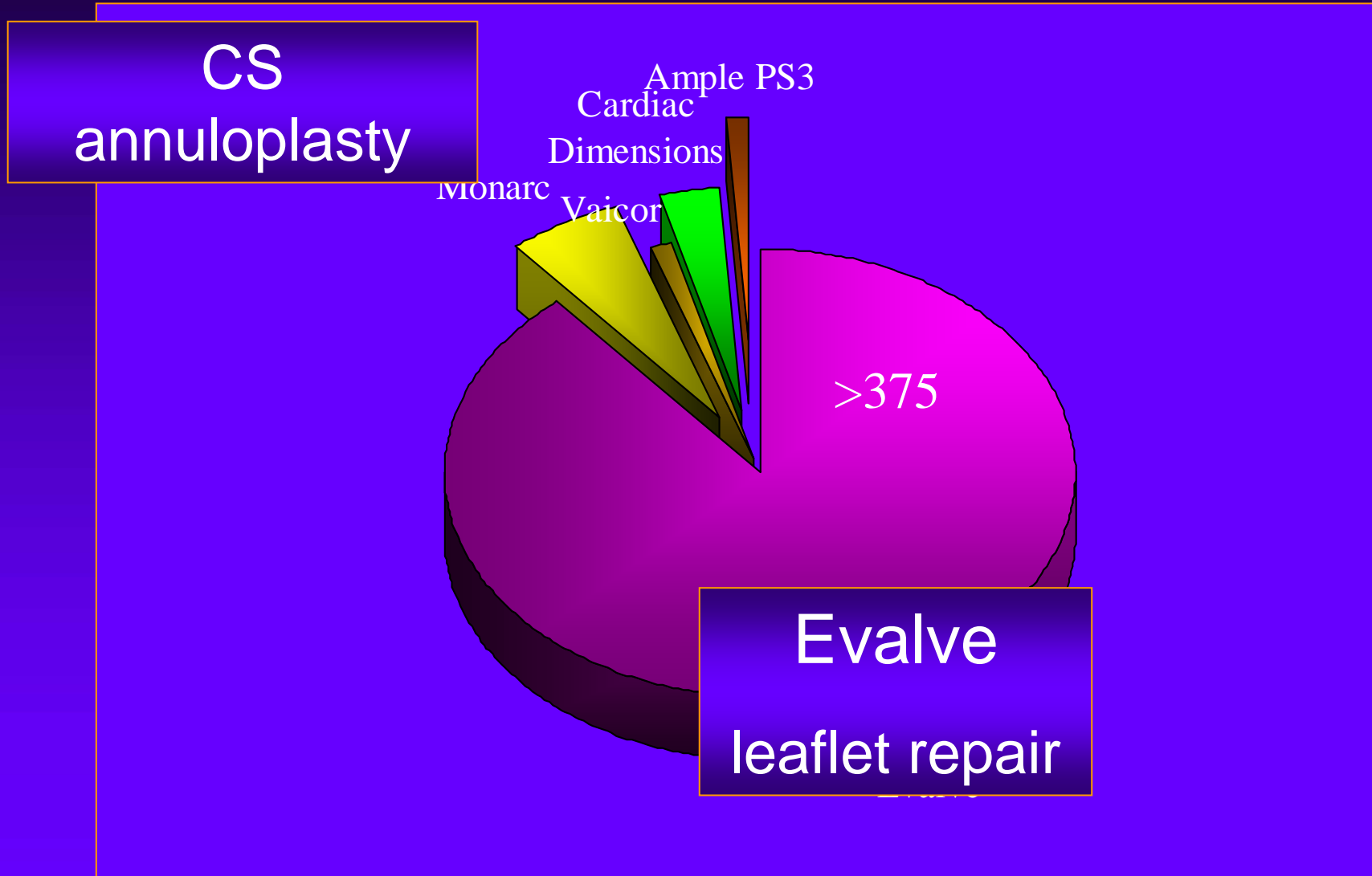
with those obtained by these methods.

It has been shown that patients with regurgitant defects are less well tolerated than those with stenotic defects. Thus, the surgical correction of mitral regurgitation has been one of the major advances in cardiac surgery in the past few years. The pericardial flap approach and the use of the pump-oxygenator, all of these operations have been carried out by closed or blind methods, and none has found general acceptance.

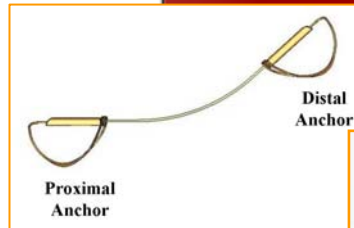
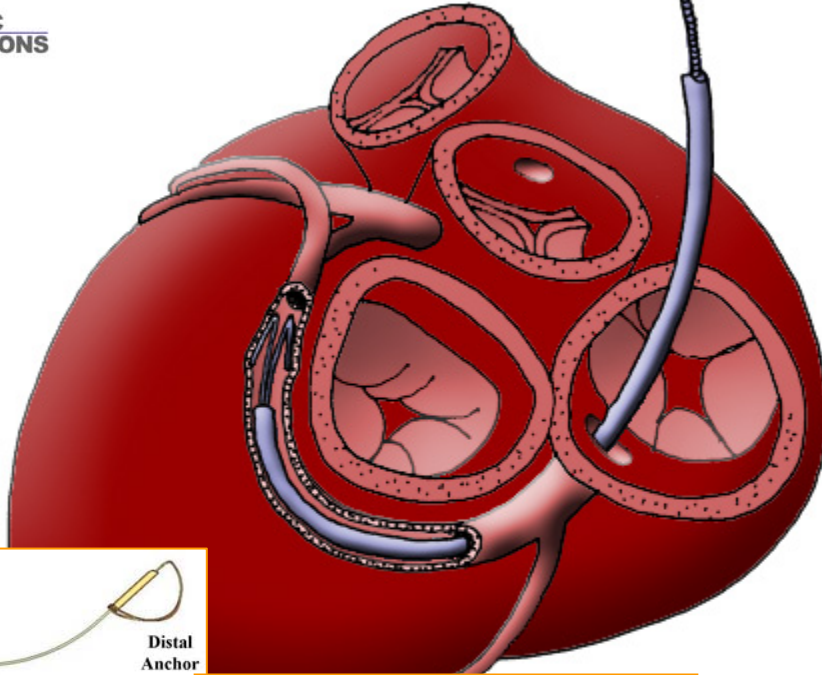
that they have been carried out by closed or blind methods, and none has found general acceptance.

	Annuloplasty	Leaflet Repair
Functional CHF	✓	
Functional Ischemic	✓	
Degenerative Prolapse	✓	✓

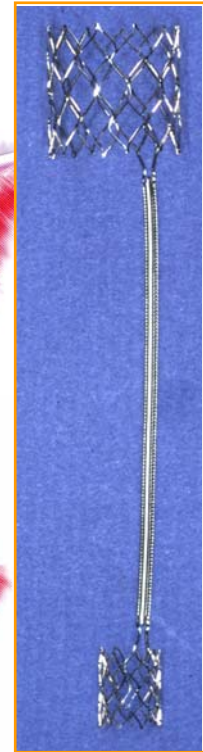
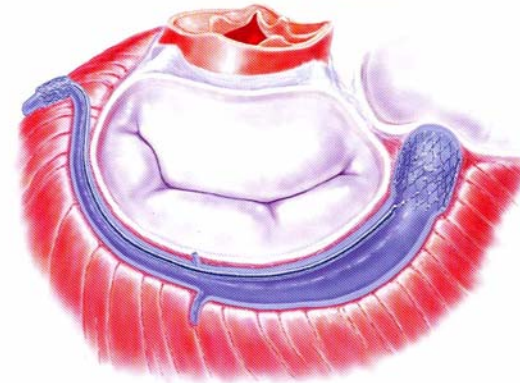
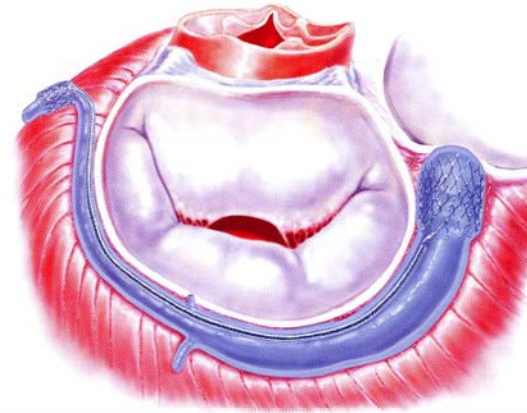
Percutaneous Mitral Valve Therapies

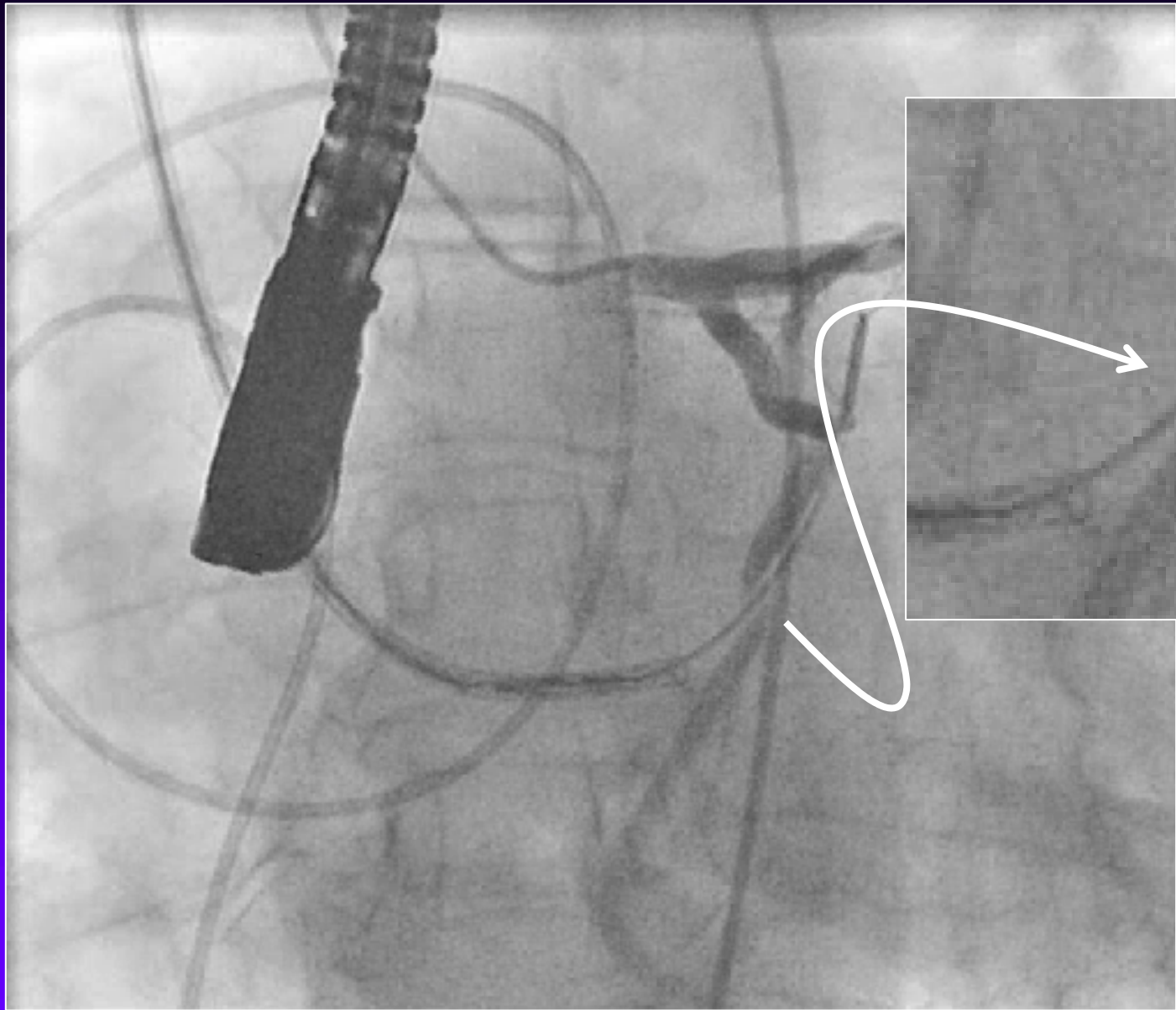


CARILLON Mitral Contour System



The MONARC system Delayed Release-*in situ*





Cumulative MACE events

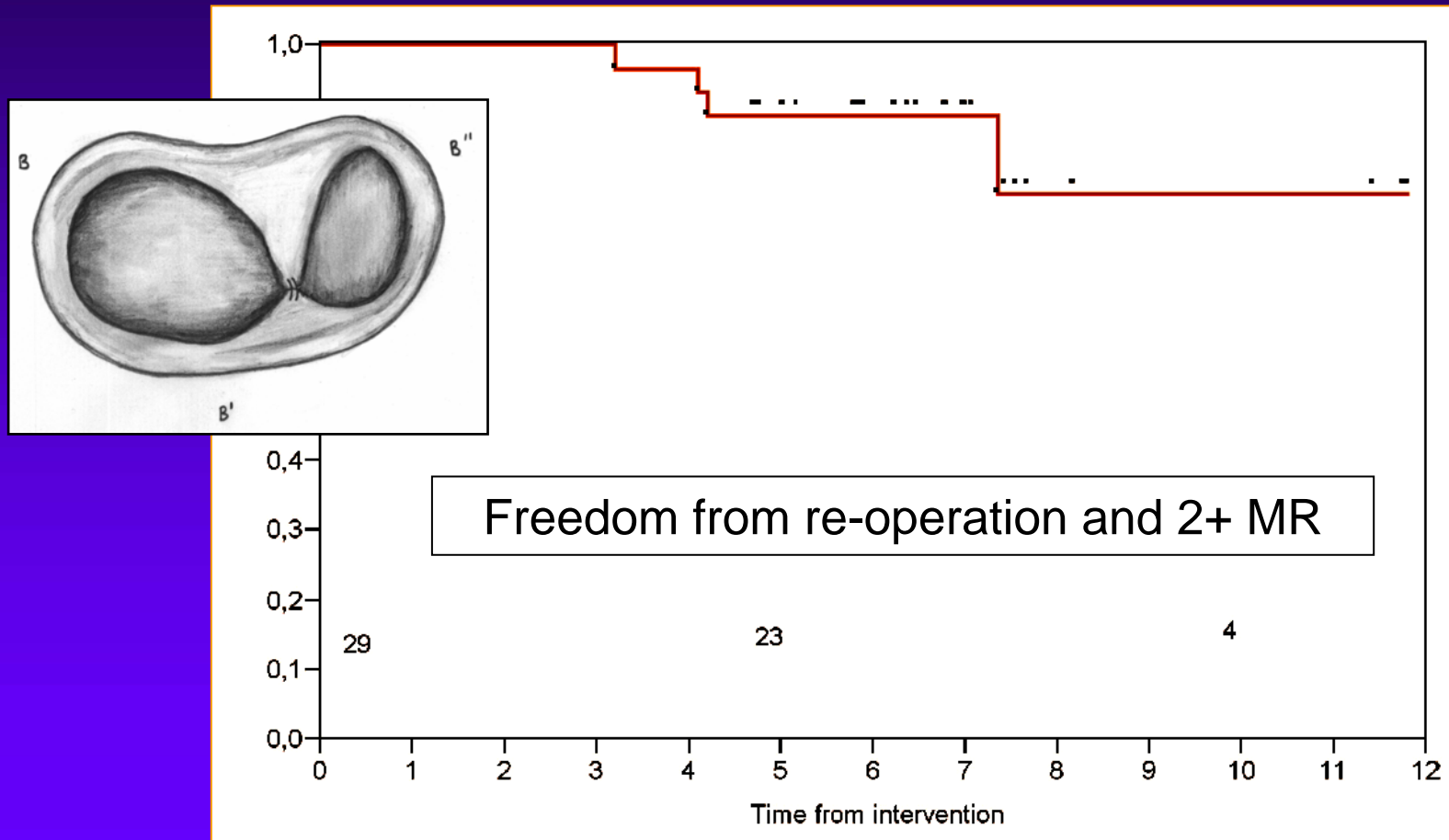
Event	Cause
Day 1	Probable Cause: Use of non-J-Tip Guidewire *
Day 6	Probable Cause: Use of non-J-Tip Guidewire *
MI (3)	
Day 16	Distal Anchor Positioned at first Diagonal Branch *
Day 19	LCx occlusion, pre-existing disease *
Day 551	OM1 Occlusion &
Death (9)	
Day 22	Arrhythmia
Day 24	Heart failure
Day 51	Bacterial infection
Day 52	Fall Leading to Cranial Hemorrhage &
Day 61	Pulmonary Embolism
Day 96	Multi-Organ System Failure – Post MV Surgery
Day 141	Heart Failure
Day 280	Worsening for Cardiopulmonary Disease
Day 552	Left Heart Failure due to MI &

N=59 implants

TCT 2007

Surgical isolated edge-to-edge mitral repair without annuloplasty

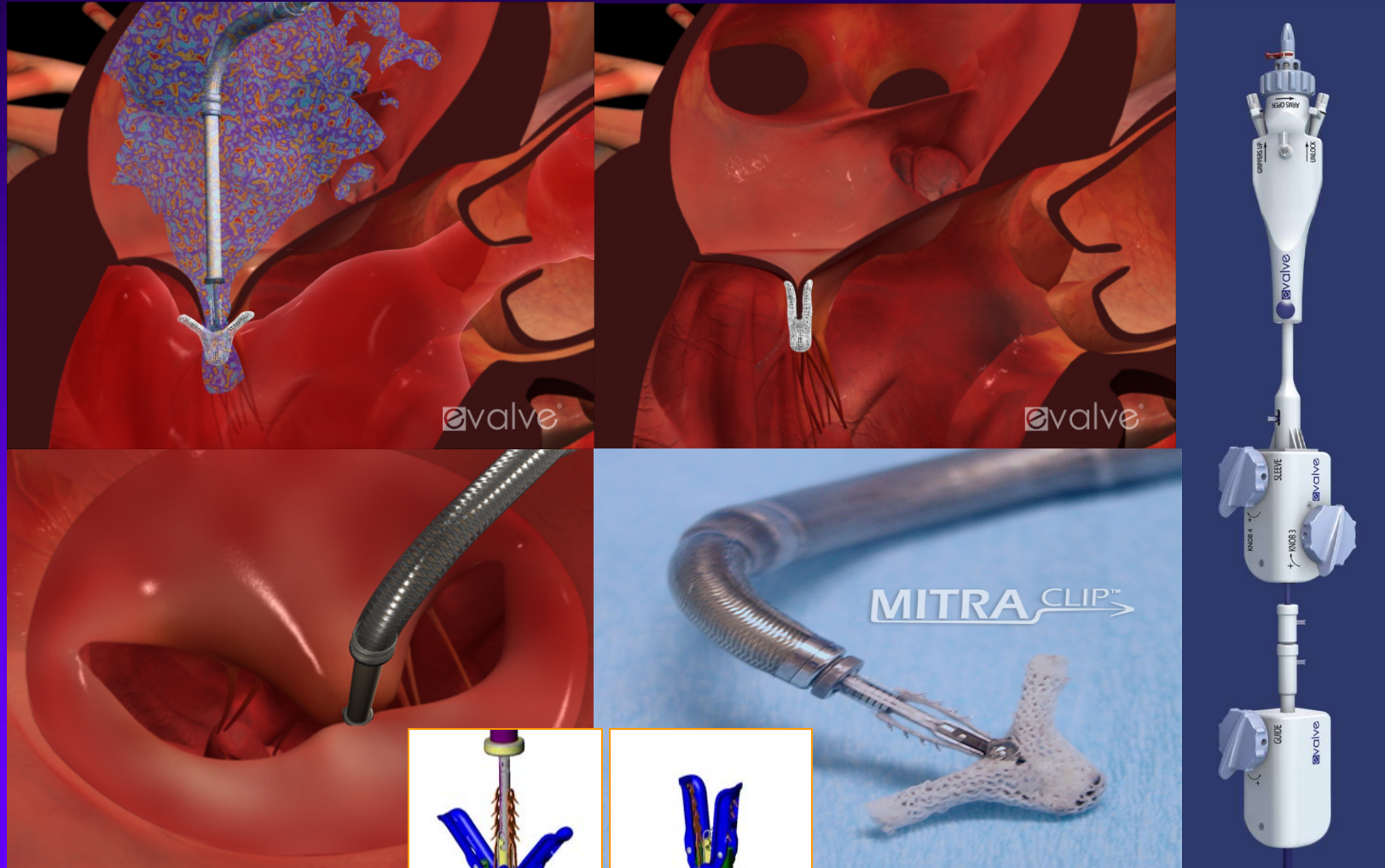
clinical proof of principle for an endovascular approach



Maisano F, Vigano G, Blasio A, Columbo A, Calabrese C, Alfieri O

Eurointervention 2:181-186, 2006

Percutaneous Mitral Repair



Caution: Investigational

Not for sale under Federal (US) Law to Investigational Use

EVEREST Preliminary Cohort

Surgery Following Clip Procedure

N = 107

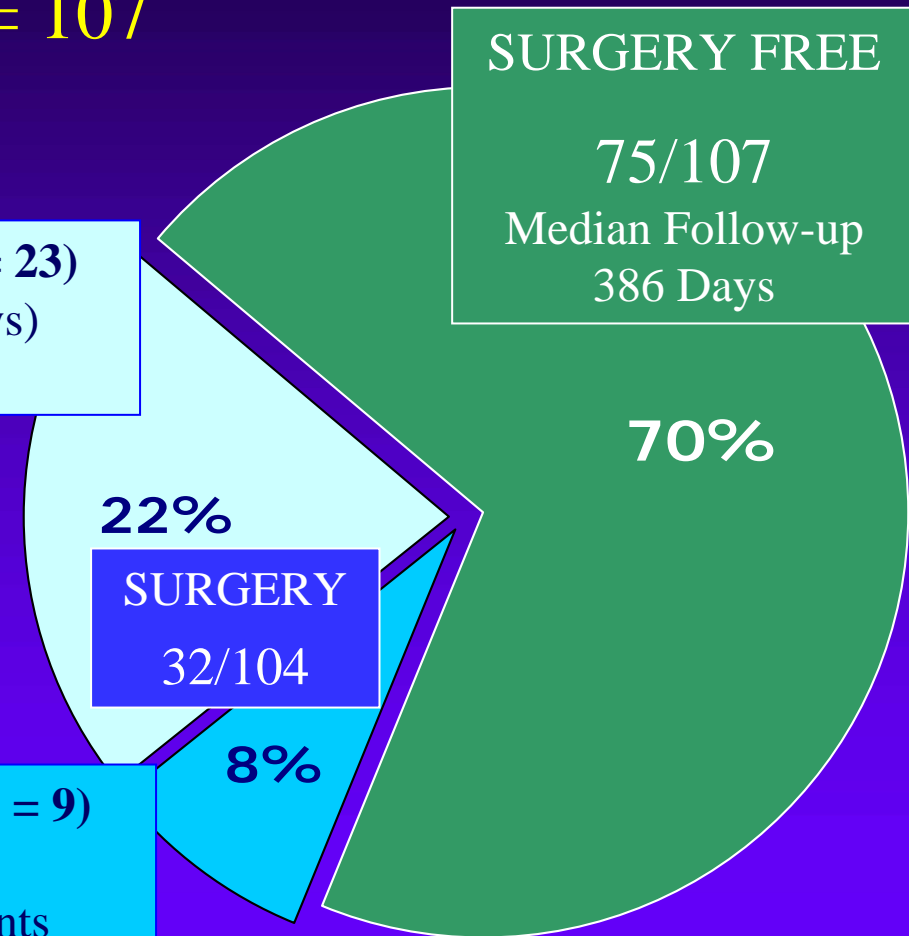
Surgery After Clip Implanted (n = 23)

- 16 (70%) Repairs (0 - 562 days)
- 7 (30%) Replacements

66% Repaired

Surgery After No Clip (n = 9)

- 5 (56%) Repairs
- 4 (44%) Replacements



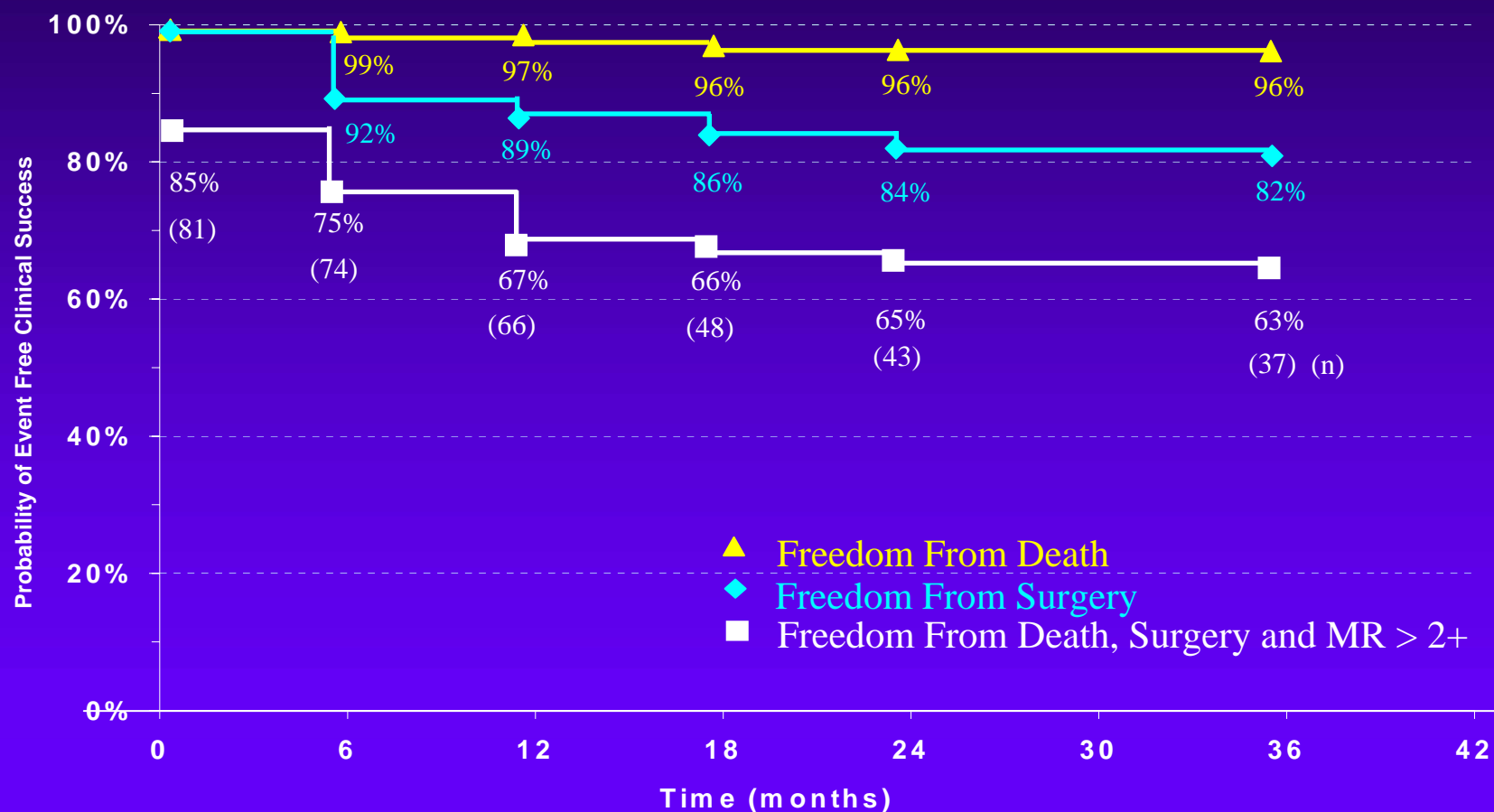
84% (21/25) attempted repairs successful

64% (7/11) replacements planned (complex disease, age, co-morbidity)

EVEREST Preliminary Cohort

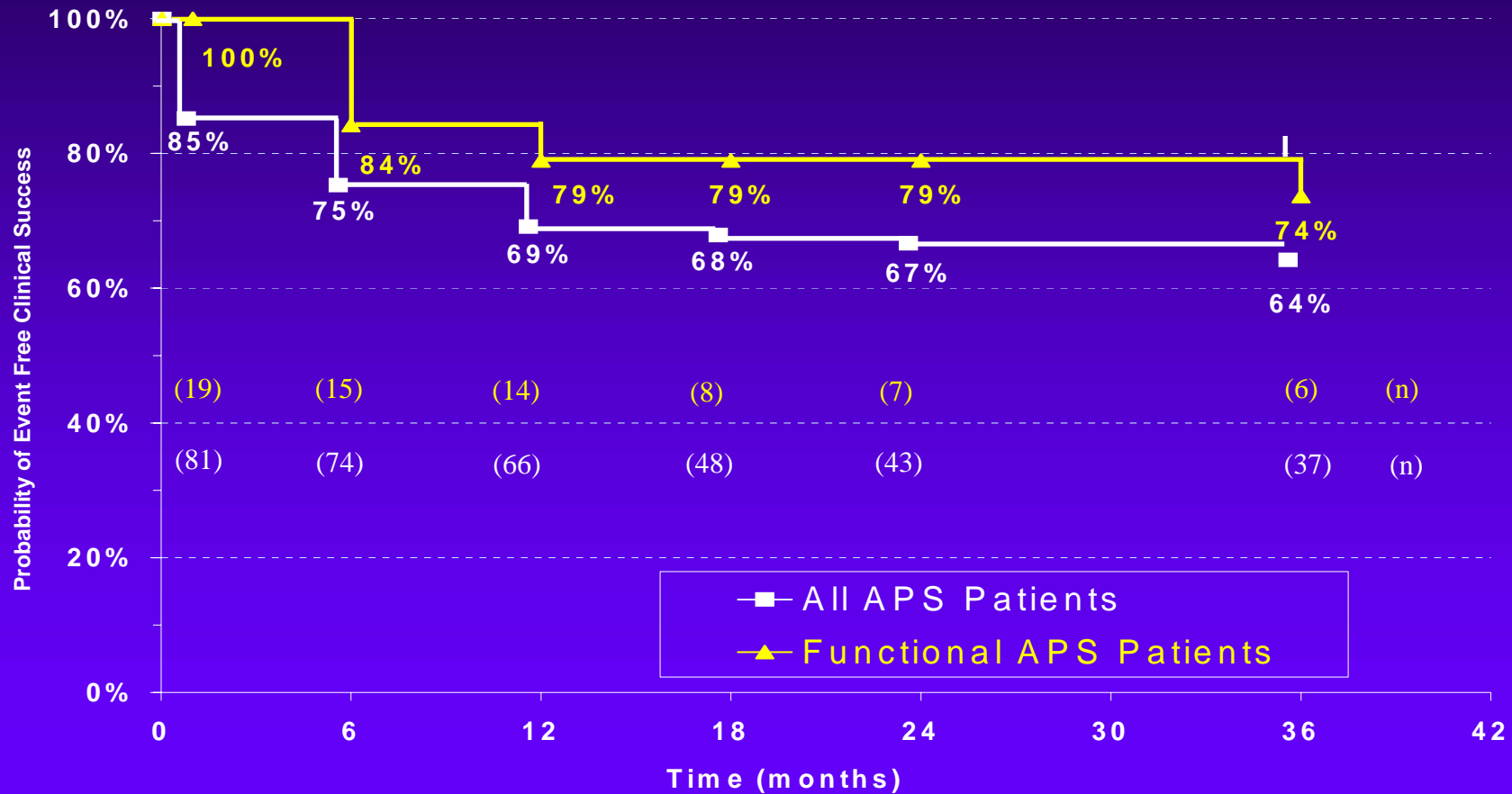
Event Free Clinical Success Kaplan-Meier

Acute Procedure Success Patients $n = 81$



Freedom from death, mitral valve surgery, & MR>2

EVEREST Preliminary FMR Cohort: Event Free Clinical Success Kaplan-Meier Acute Procedure Success Patients $n=19$



Freedom from death, mitral valve surgery, & MR > 2+

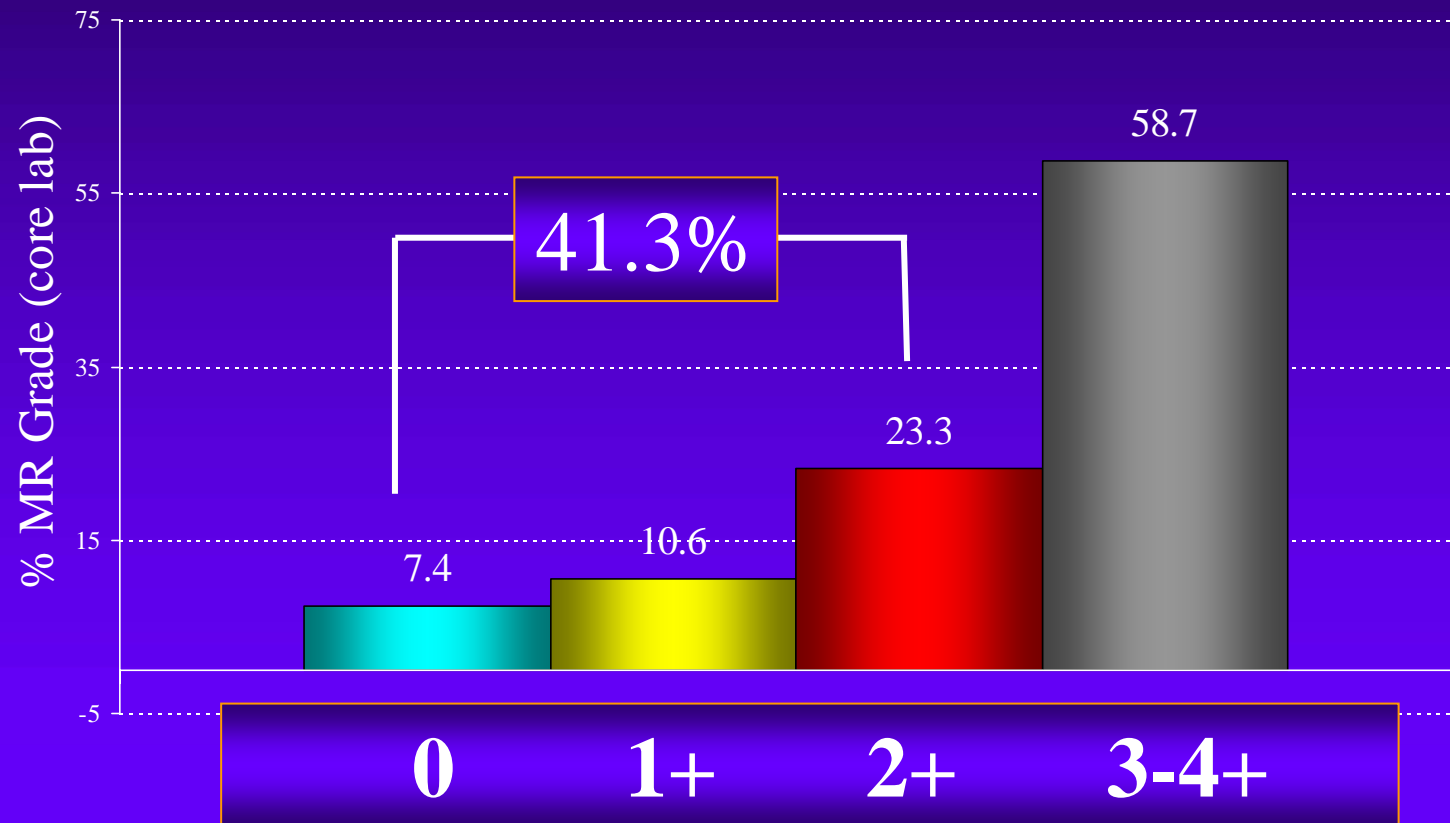
Surgery for Mitral Valve Disease

- Intention to treat reporting
 - Frequency of conversion to MVR highly variable
- Severity of MR
 - Results better in moderate MR
 - Trials include more severe grades than usual practice
- Core lab MR assessment
 - Challenges for MR grading substantial
 - Post-operative vs pre discharge vs 1 month
- Endpoints
 - Recurrent MR not well characterized
 - Functional status difficult to characterize
 - Results not so great for functional MR

Mitral valve surgery in heart failure

Insights from the Acorn Clinical Trial

Baseline MR grade



High Risk :Inclusion Criteria

- STS surgical risk calculator $\geq 12\%$
- *or* judgment of surgeon investigator the patient is considered high risk due to one of the following:
 - Porcelain aorta or mobile ascending aortic aneurysm
 - Post-radiation mediastinum
 - Previous mediastinitis
 - Functional MR with EF<40
 - Over 75 years old with EF<40
 - Re-operation with patent grafts
 - Two or more prior chest surgeries
 - Hepatic cirrhosis
 - Three or more of the following STS high risk factors:
 - Creatinine > 2.5 mg/dL
 - Prior chest surgery
 - Age over 75
 - EF<35

Medical Decision Making

Technique

Metric

- | | |
|-----------------------------|-------------------------|
| ■ Eminence -based | white hair |
| ■ Vehemence -based | level of stridency |
| ■ Eloquence -based | smoothness of tongue |
| ■ Providence -based | religious fervor |
| ■ Nervousness -based | risk of litigation |
| ■ Confidence -based | bravado (surgeons only) |
-
- | | |
|--------------------------|--|
| ■ Evidence -based | Statistically-valid inferences from well-designed RCTs |
|--------------------------|--|

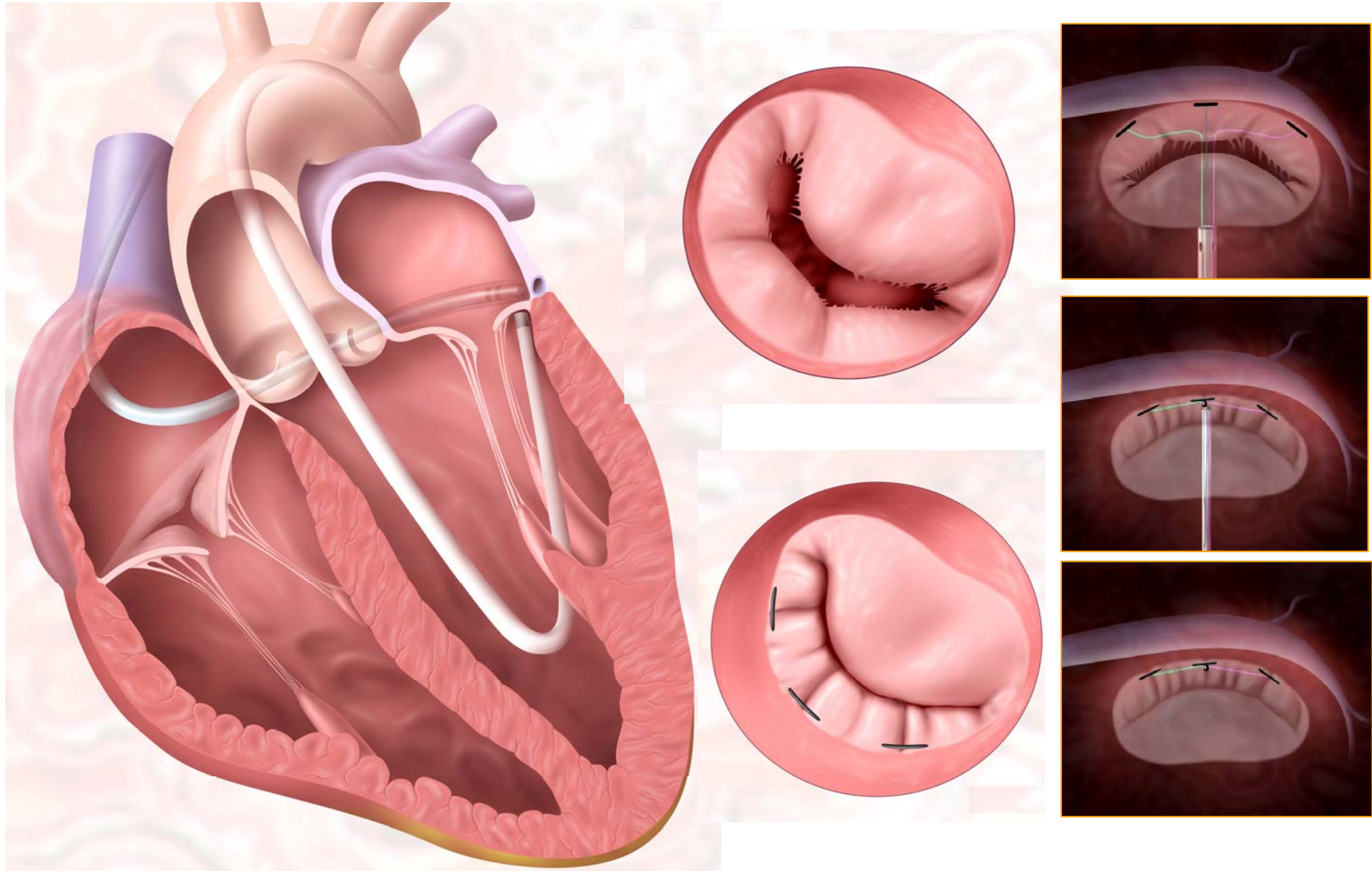
EVEREST I & II Enrollment

(3/20/08)

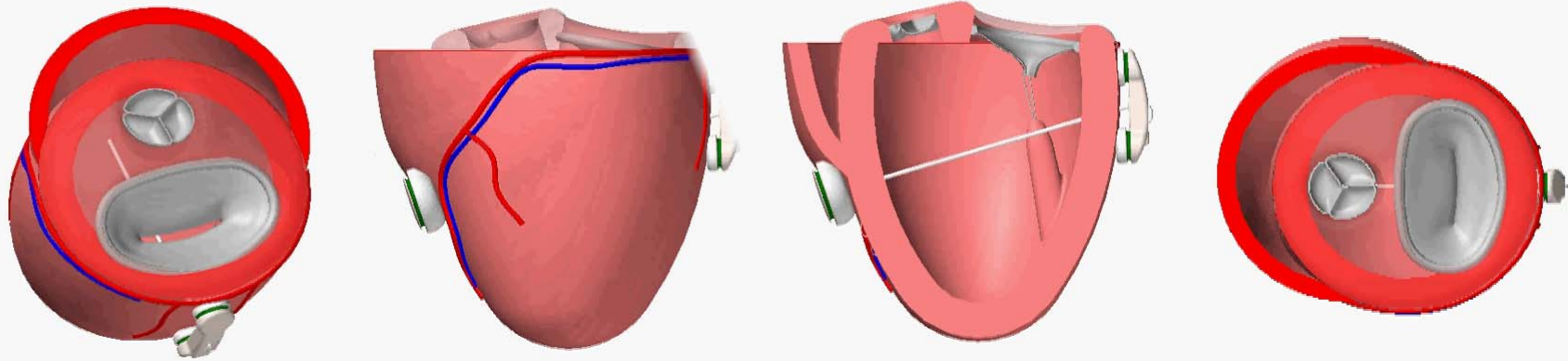
Enrollment	Population	n
EVEREST I Feasibility (completed)	Registry patients	55
EVEREST II	Roll-in	59
Randomized n=131	Randomized Clip	129
	Randomized Surgery	61
EVEREST II	High Risk Registry (completed)	78
Total enrolled		382

- 38 sites

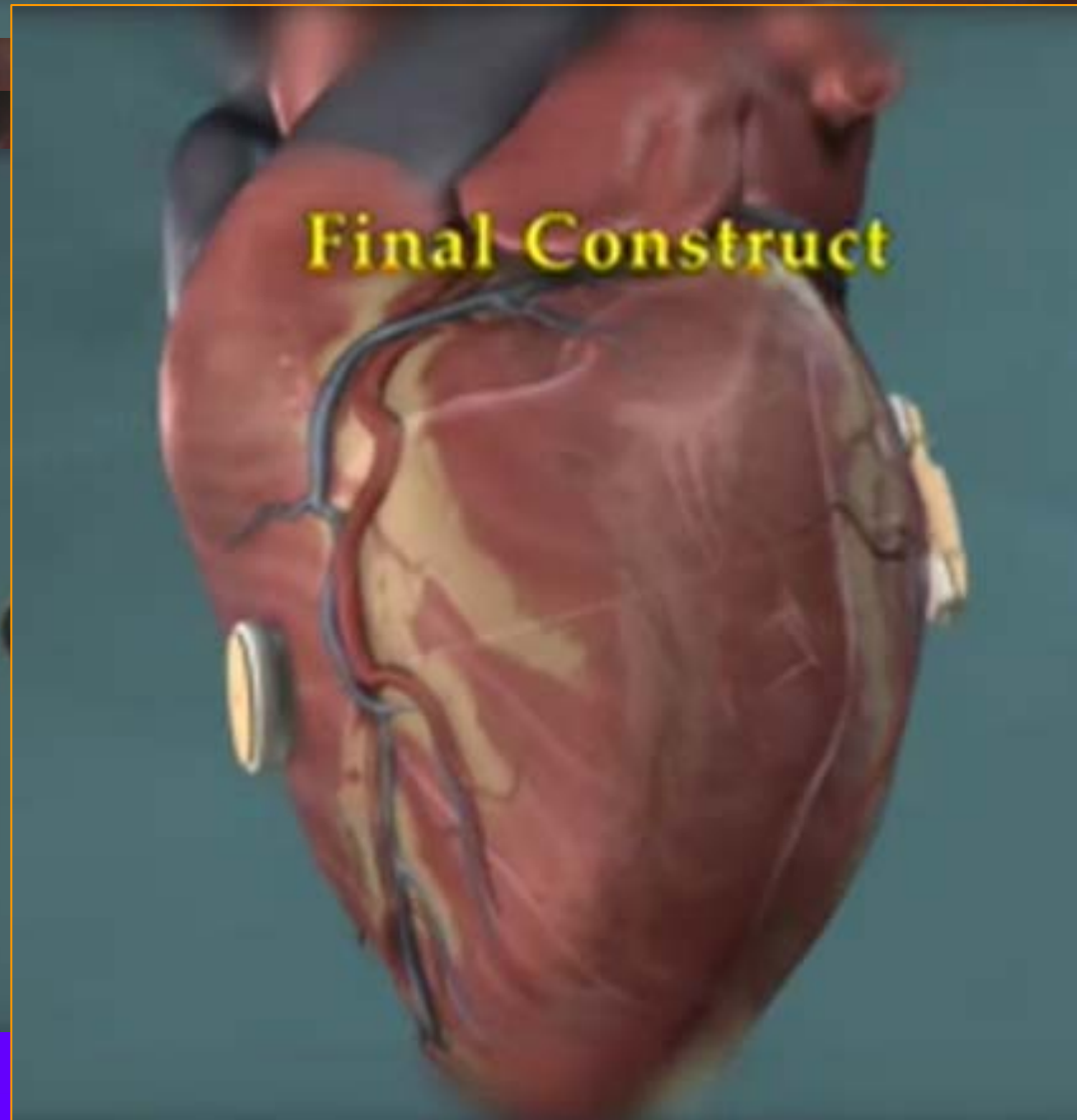
Retrograde-LV Direct Suture Annuloplasty

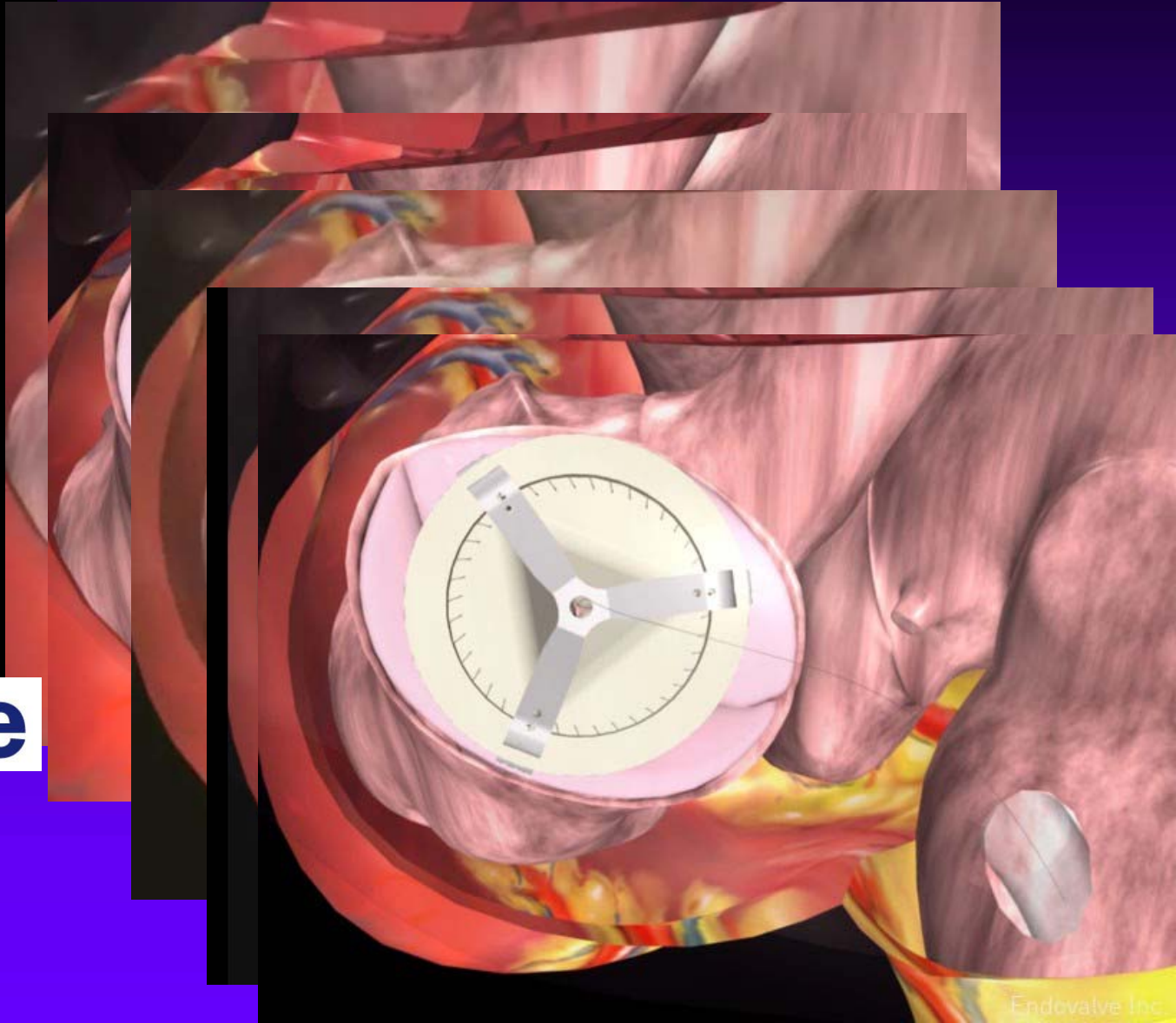


The Myocor Surgical Coapsys System



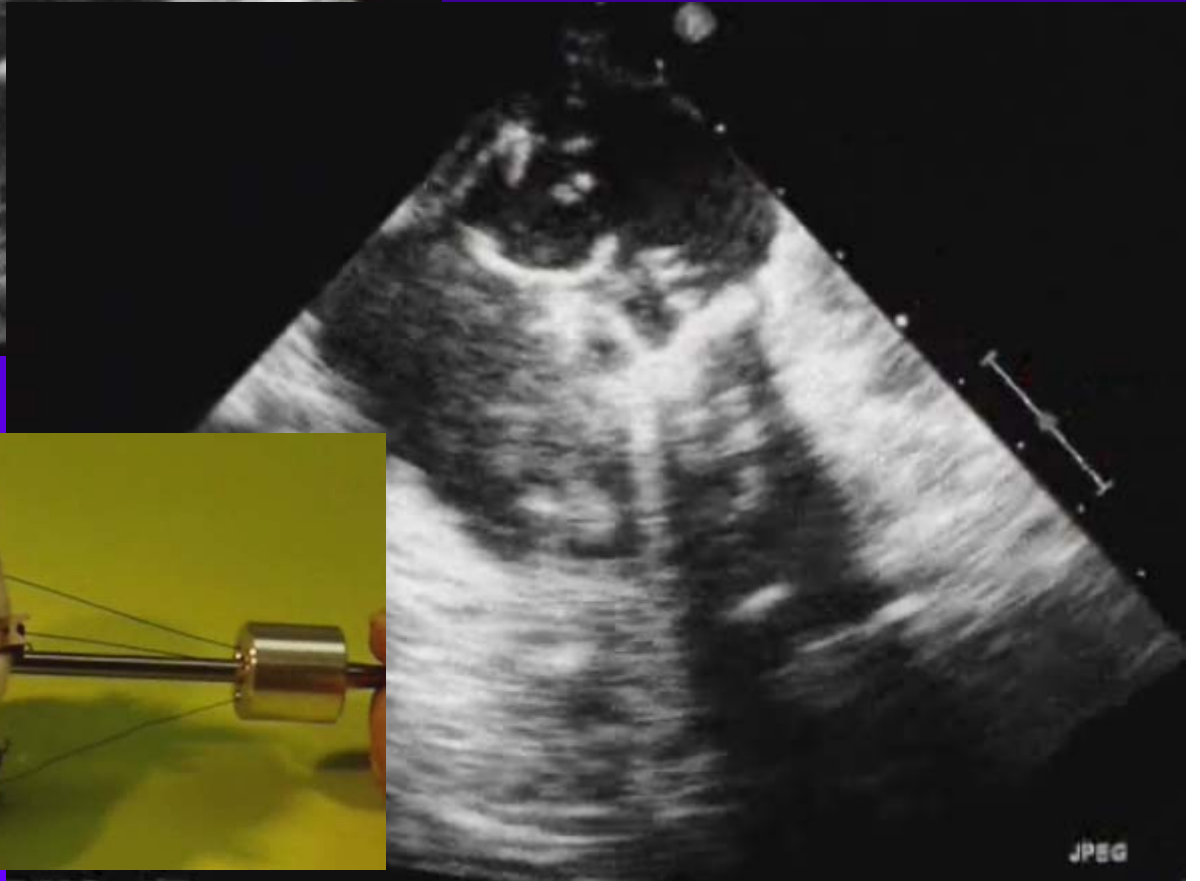
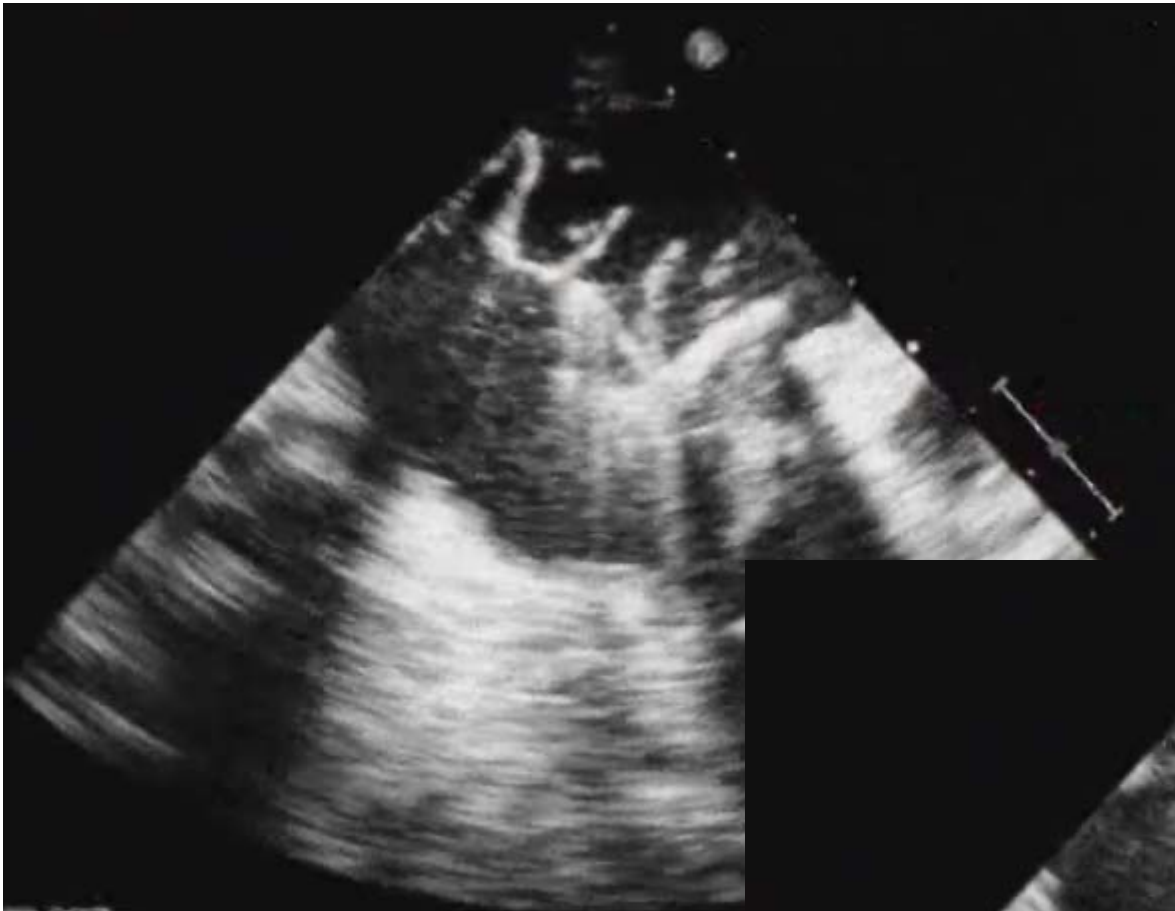
iCoapsys



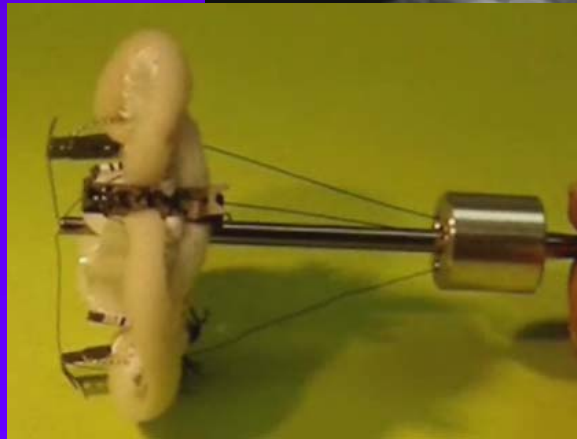


endo**Valve**

endo**Valve**



JPEG



Interventionalist meets Valve Surgeon 1970-2000



Circa 2010

