

# Percutaneous mitral valve therapies

Ted Feldman MD, FACC, FSCAI

*Evanston Hospital*

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# Ted Feldman MD, FACC, FSCAI

## *Disclosure Information*

The following relationships exist:

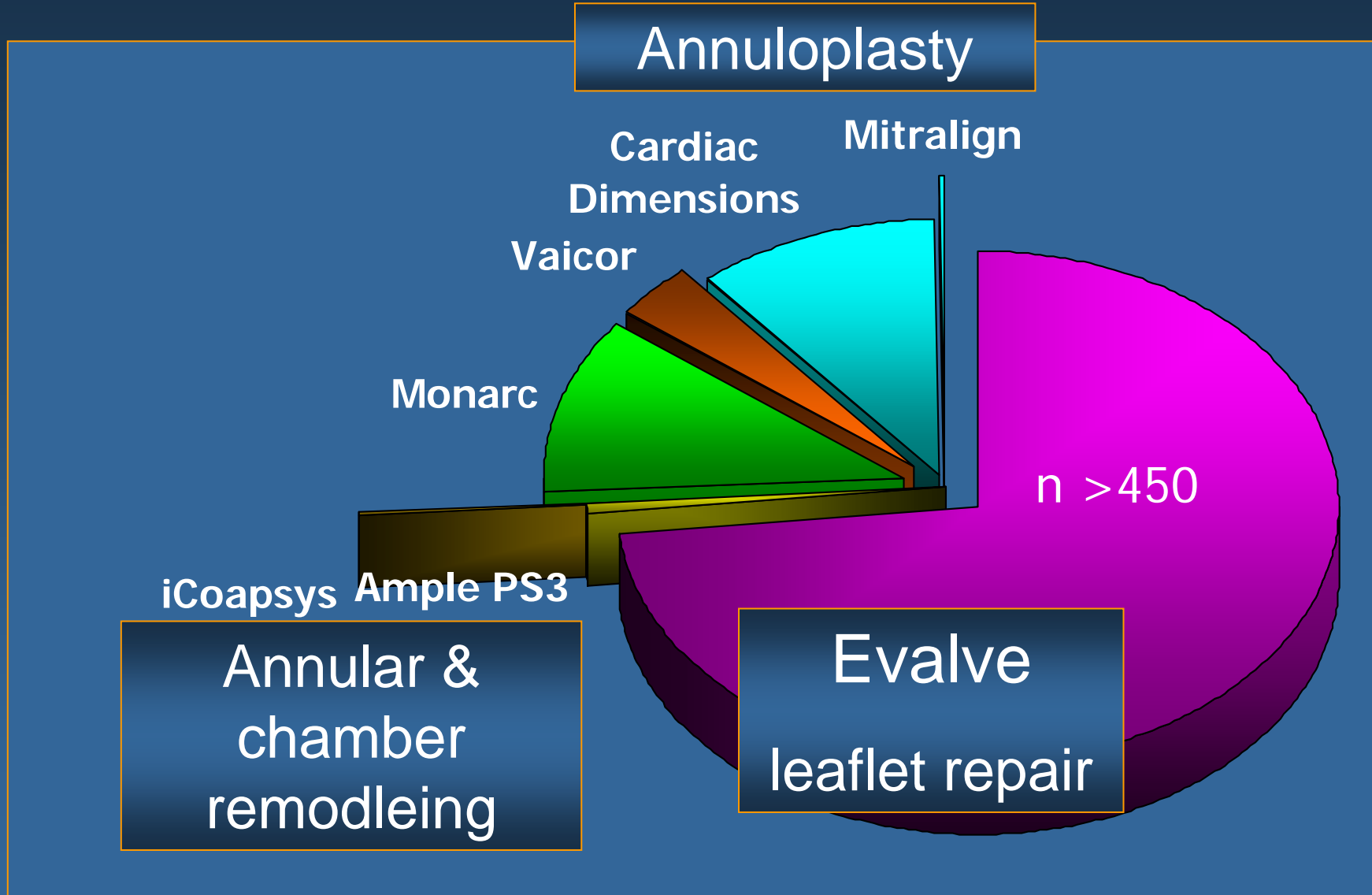
Grant support: Abbott, Atritech, BSC, Cardiac Dimensions,  
Edwards, Evalve, Myocor, St Jude

Consultant: Abbott, Cardiac Dimensions, CoAptus, Coherex, Cordis,  
WL Gore, Myocor, Quantam-Cor

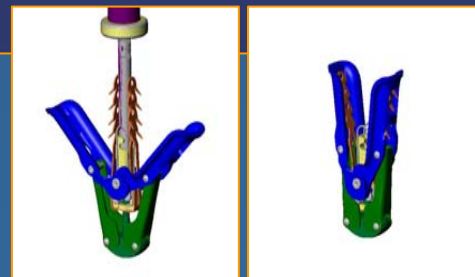
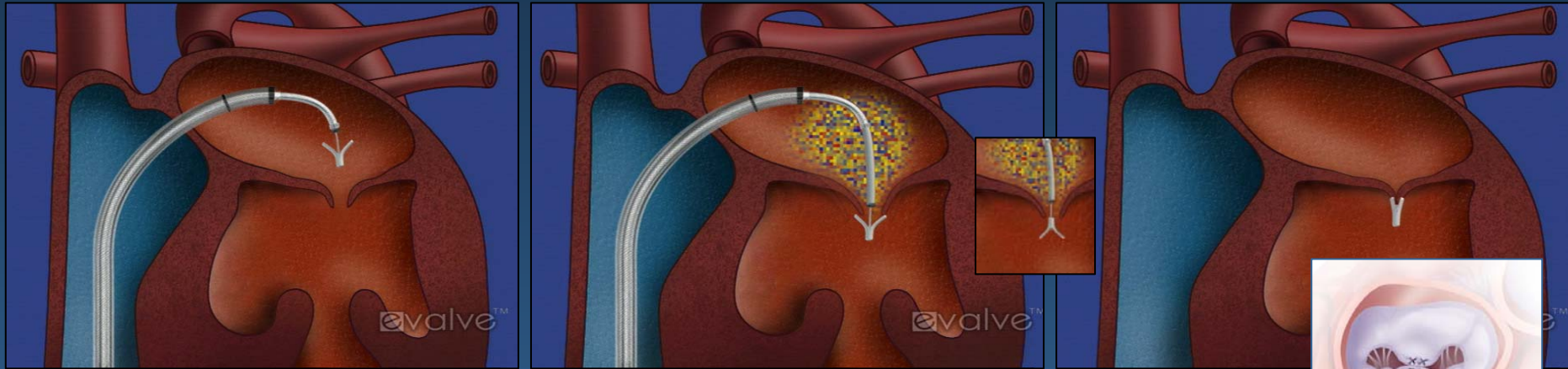
Speaker: Boston Scientific

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

# Percutaneous Mitral Valve Therapies



# Endovascular CVRS for E2E Mitral Repair Cardiovascular Valve Repair System



# EVEREST I & II Enrollment

Randomization 8/5/2005-9/17/2008

Enrollment	Population	n
EVEREST I Feasibility (1 <sup>st</sup> patient 7/2/2003)	Registry patients	55
EVEREST II	Roll-in	60
Randomized n=279	Randomized Clip	184
	Randomized Surgery	95
EVEREST II	High Risk Registry	78
Total enrolled		472

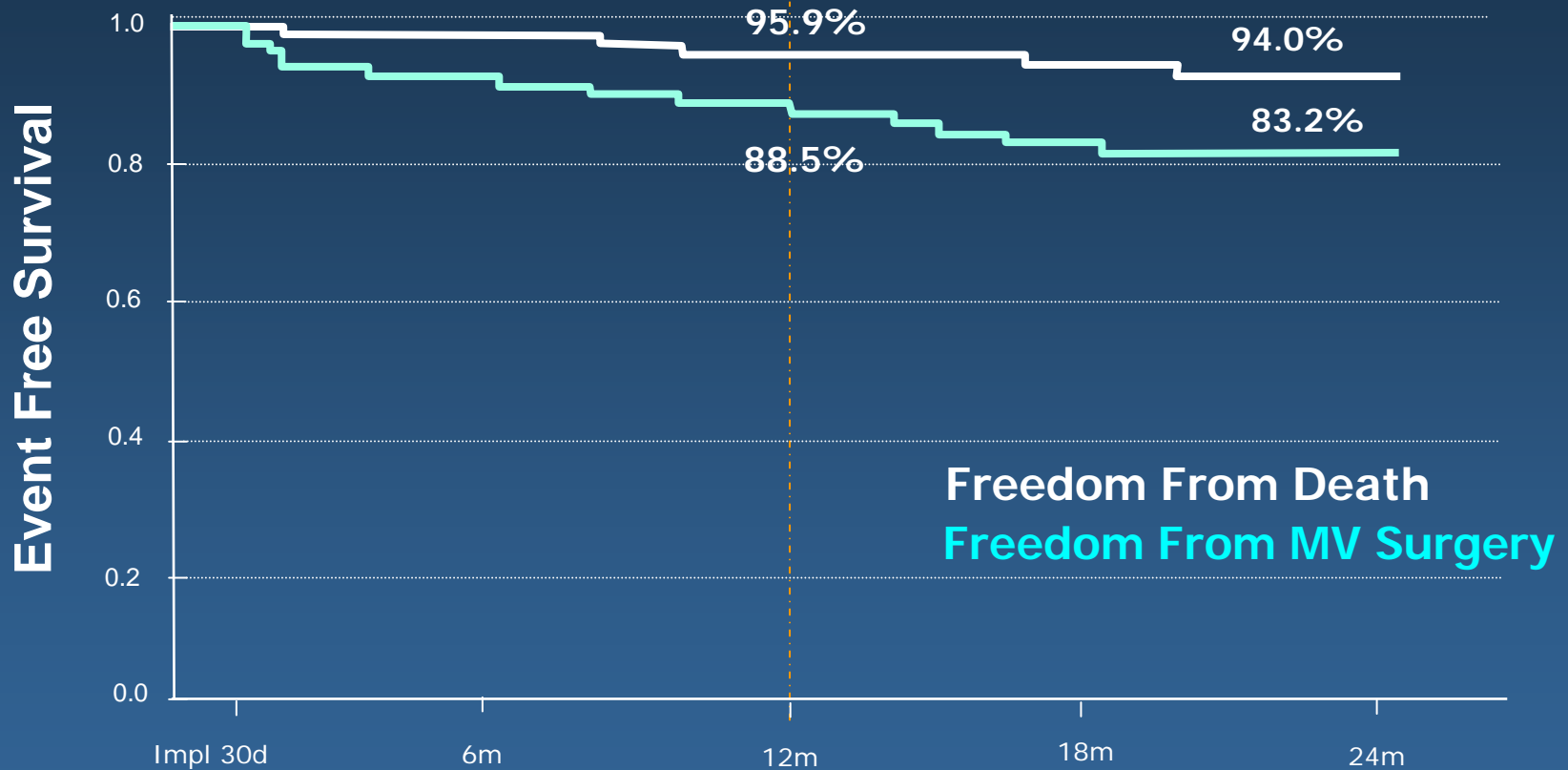
# EVEREST Preliminary Cohort

Study	Population	n
EVEREST I (Feasibility)	All patients enrolled	55
EVEREST II (Pivotal)	Non-randomized patients (Excluding High Risk Registry)	52
Total		107

- *Preliminary Cohort analysis per EVEREST II definitions*
- *30 North American sites*
- *70% are 1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup> procedure at a site*

# Kaplan-Meier Freedom from Death and MV Surgery


## Preliminary Cohort - Per Protocol



n at risk Death	79	79	73	69	63	56
n at risk Surgery	79	79	72	67	59	51

# EVEREST I & II Enrollment

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# EVEREST HRR

## Study Algorithm

### KEY INCLUSION CRITERIA

- Predicted procedural mortality  $\geq 12\%$ 
  - STS or Surgeon estimated
- Symptomatic 3+ or 4+ MR
- Degenerative or Functional

### KEY EXCLUSION CRITERIA

- EF  $\leq 20\%$  and/or LVESD  $>60\text{mm}$
- MVA  $<4\text{cm}^2$
- Leaflet anatomy unsuitable

78  
Enrolled

46 FMR  
Patients -  
59%

36  
Concurrent  
Control

50% met all  
inc/exclusion criteria

50% met all but clip  
anatomical criteria

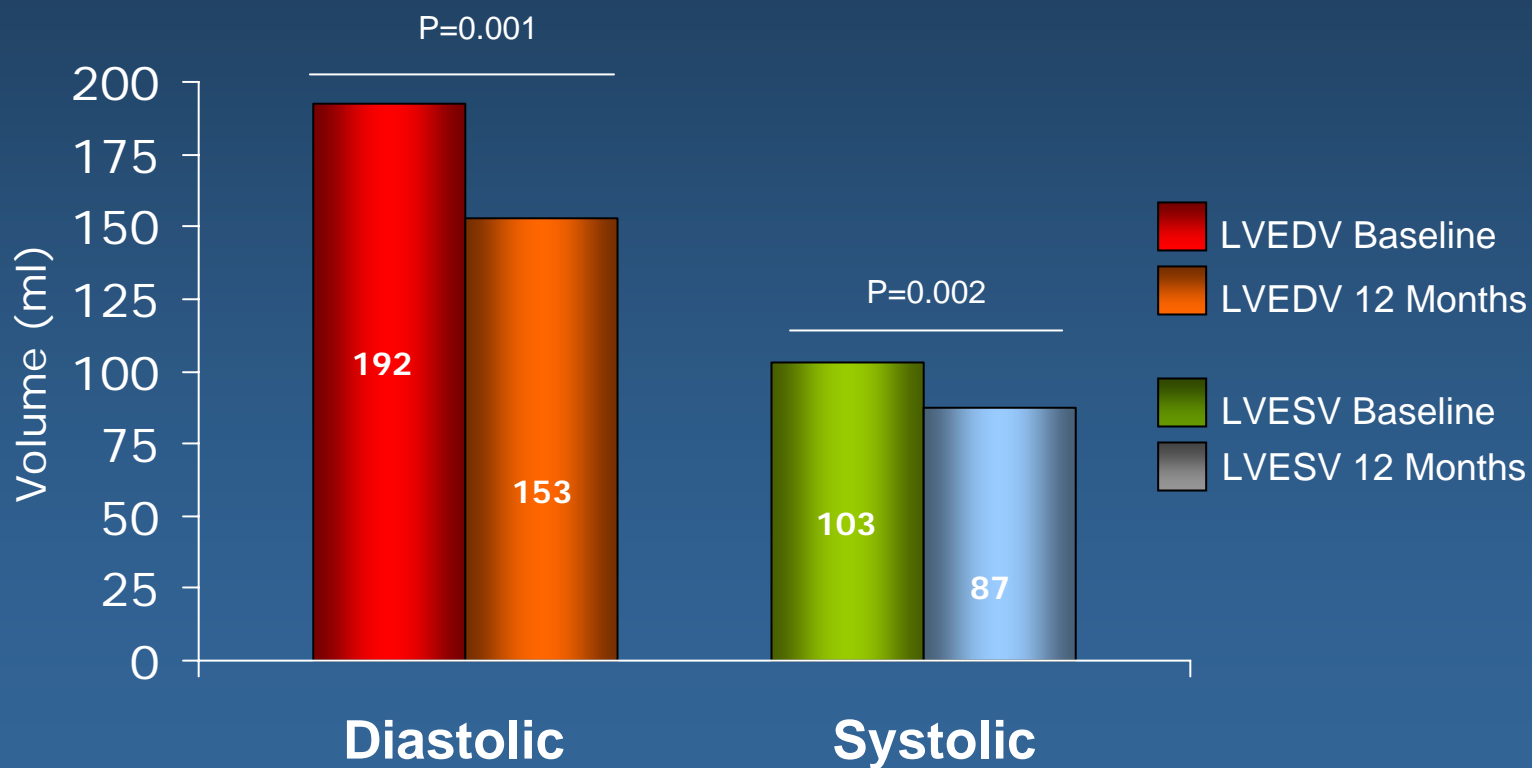
# HRR FMR: Baseline Demographics

	HRR, FMR(n=46)	Euro Heart Survey*		STS Database 2007**	
		Not Operated (n=193)	Operated (n=203)	Isolated Repair	Isolated Replacement
Age	73	69	63	59	61
≥ age75	56%	65% (est)	35% (est)	35%(>65)	45%(>65)
Male gender	63%	47%	53%	60%	42%
Diabetes mellitus	52%	21%	10%	11%	21%
Hypertension	91%	53%	47%	55%	61%
COPD / Chronic lung disease	35%	21%	11%	16%	27%
Moderate to Severe Renal Failure	26%	n/a	n/a	4%	12%
History CHF	100%	49%	29%	34%	53%
History CAD	87%	60%	38%	n/a	n/a
History Atrial Fibrillation	77%	36%	32%	n/a	n/a
Prior Cardiac Surgery	63%	7% CABG	3% CABG	11%	31%
STS Score	17%	n/a	n/a	n/a	n/a
MR Grade (mean)	3.2	n/a	n/a	n/a	n/a
Ejection Fraction	47%	48%	56%	55%	55%
NYHA III or IV	91%	70%	65%	43%	55%
LV EDD (mm)	59	57	59	n/a	n/a
LV ESD (mm)	44	41	40	n/a	n/a

# HRR FMR (ITT)

## Reverse LV remodeling

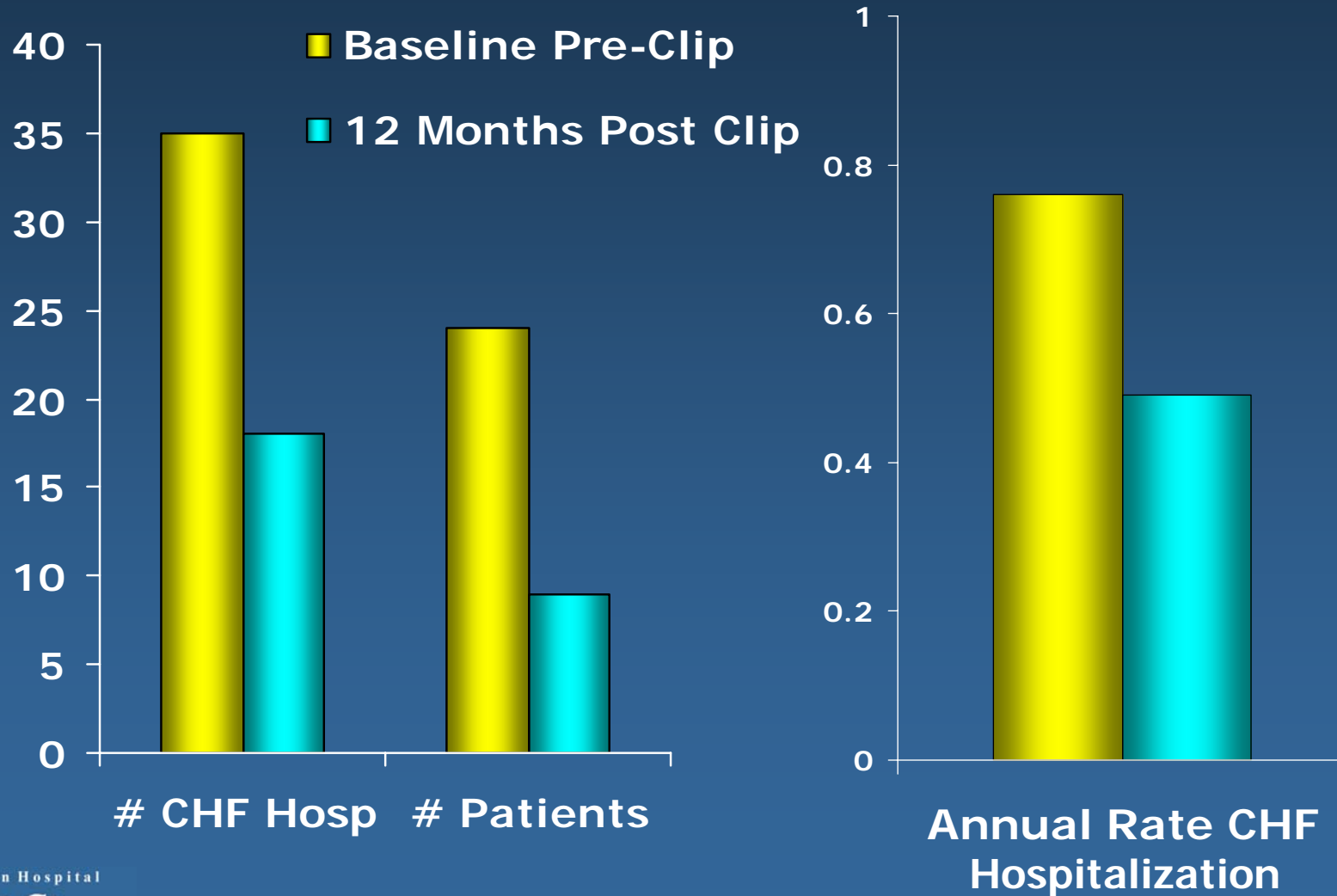
### LV End Diastolic & Systolic Volumes



n=34, Matched Data

# HRR FMR (ITT)

## Hospitalization for CHF



# European Sites

**71**  
**procedures at**  
**10 sites**  
**FMR 66%**

Cottingham, GB

London, GB

Hamburg, DE

Amsterdam, NE

Essen, DE

Aachen, DE

Frankfurt, DE

Lugano, CH

Milan, IT

Catania, IT



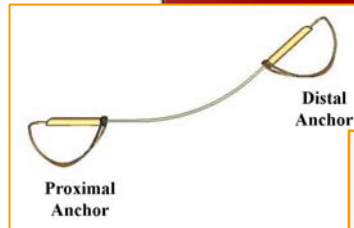
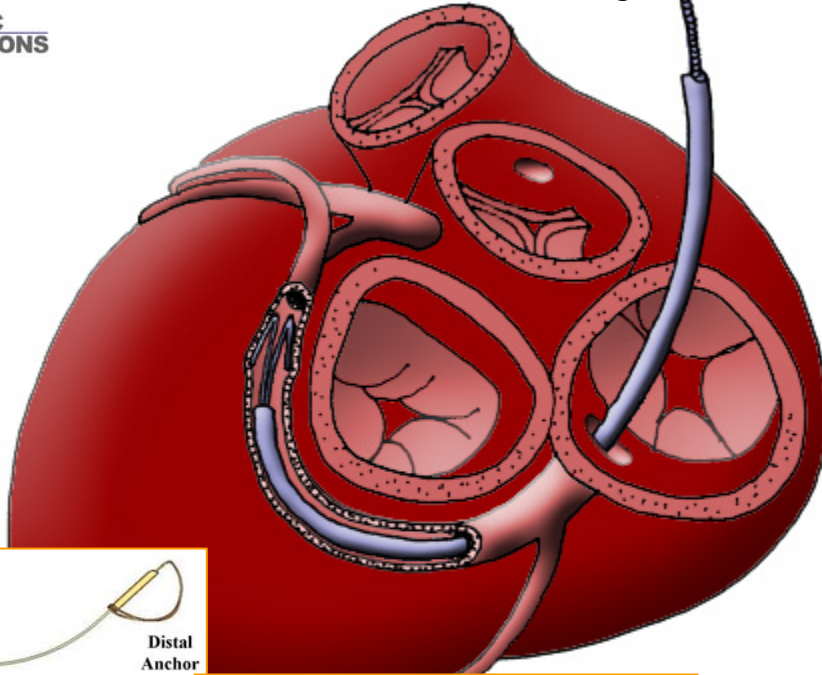
# EVEREST Conclusions

- Proof of principle for both degenerative & functional MR
- High Risk Registry
  - Unmet need for poor surgical candidates
  - Reverse LV remodeling, Increased Stroke Volume, Decrease in Septal-Lateral Annular Dimension
  - Improved NYHA Class, Reduction in hospitalization for CHF
  - Clinical benefits sustained for at least one year
- Enrollment complete in EVEREST II
  - role for patients with surgical option
- Surgical options preserved
- Randomized trial results in 1 year
  - Landmark results with 1<sup>st</sup> percutaneous repair technology to complete a trial
  - Prospective evaluation of current mitral valve surgery

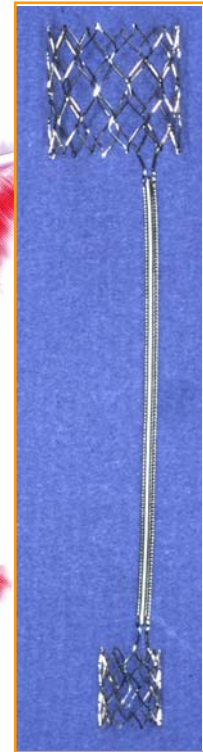
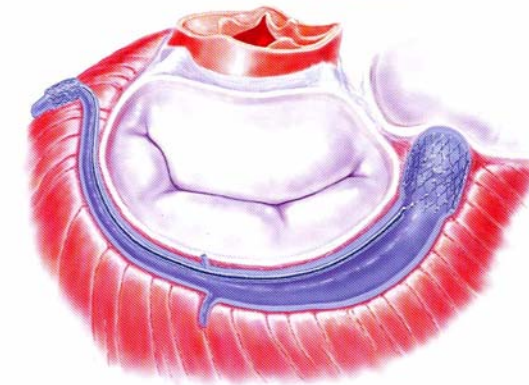
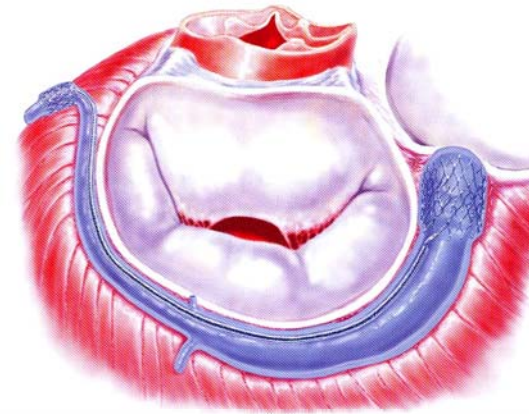
# Percutaneous Mitral Approaches

- **Coronary sinus annuloplasty**
  - Edwards Monarc
  - Cardiac Dimensions Carillon
  - Viacor Shape Changing Rods
- **Direct annuloplasty**
  - Mitralign Suture-Based Plication
  - Guided Delivery Anchor-Cinch Plication
  - Quantum Cor
- **Chamber + annular remodeling**
  - Myocor iCoapsys
  - Ample PS3
- **Leaflet repair**
  - EValve Mitraclip
- **Chordal replacement**
- **Mitral valve replacement**

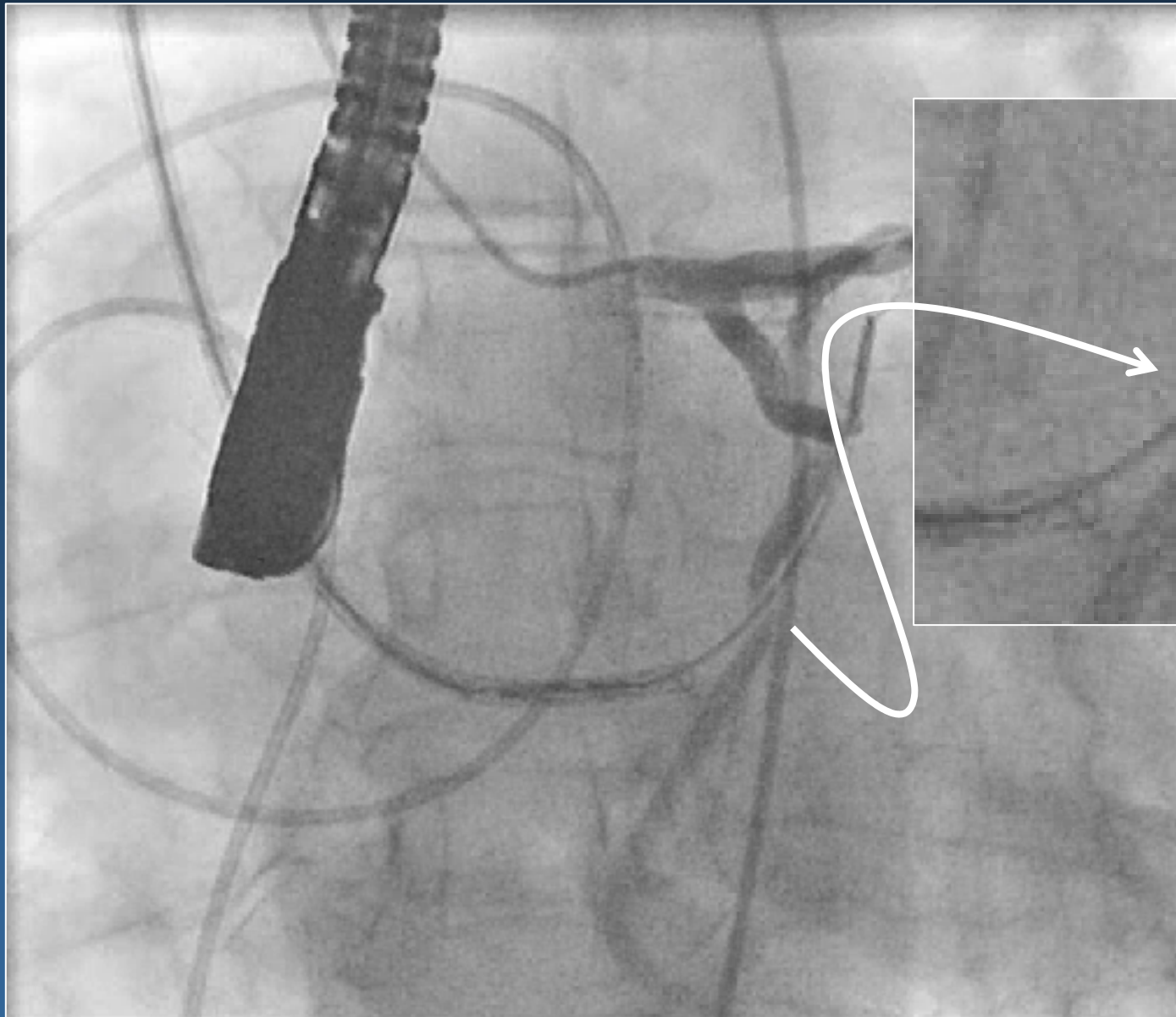
# CARILLON Mitral Contour System



The MONARC system  
Delayed Release-*in situ*







# MONARC

## 12 - Month Cumulative Responder Rates

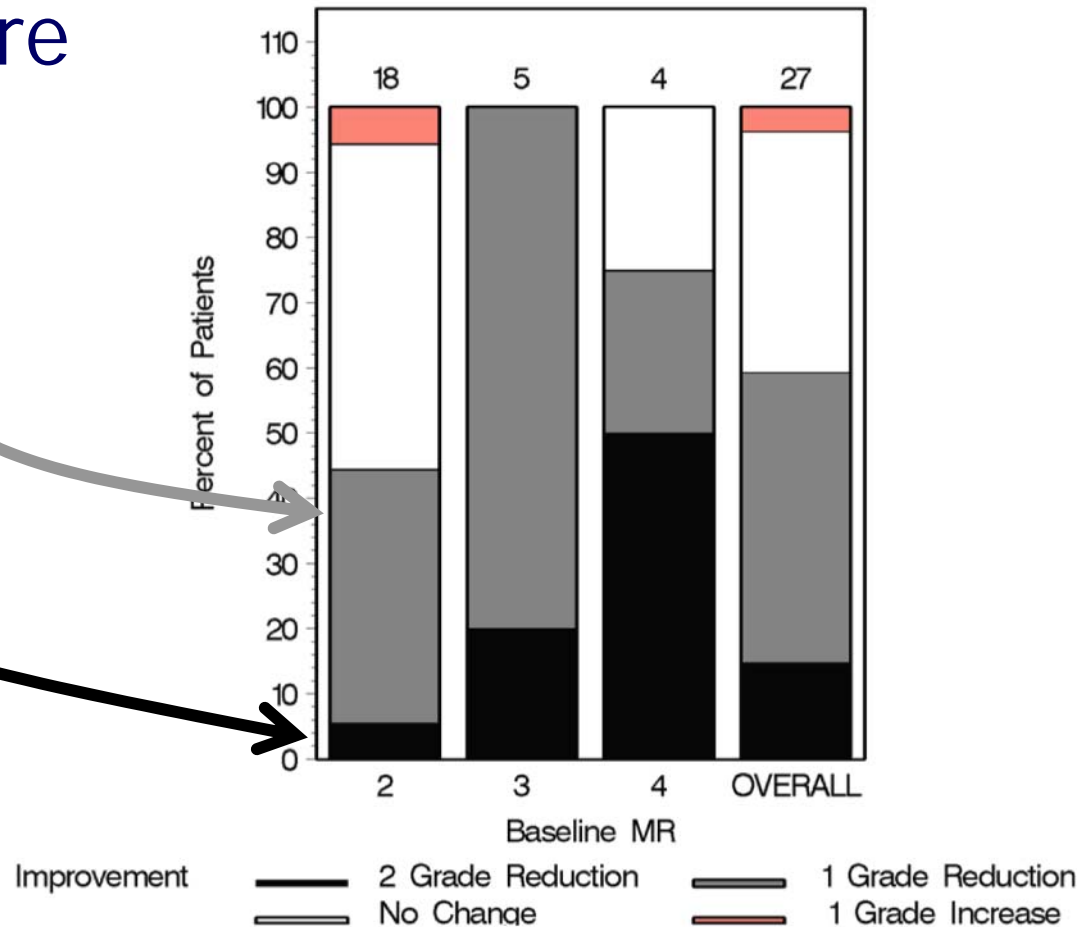
59% of patients are responders:

- 44% 1 grade
- 15% 2 grades

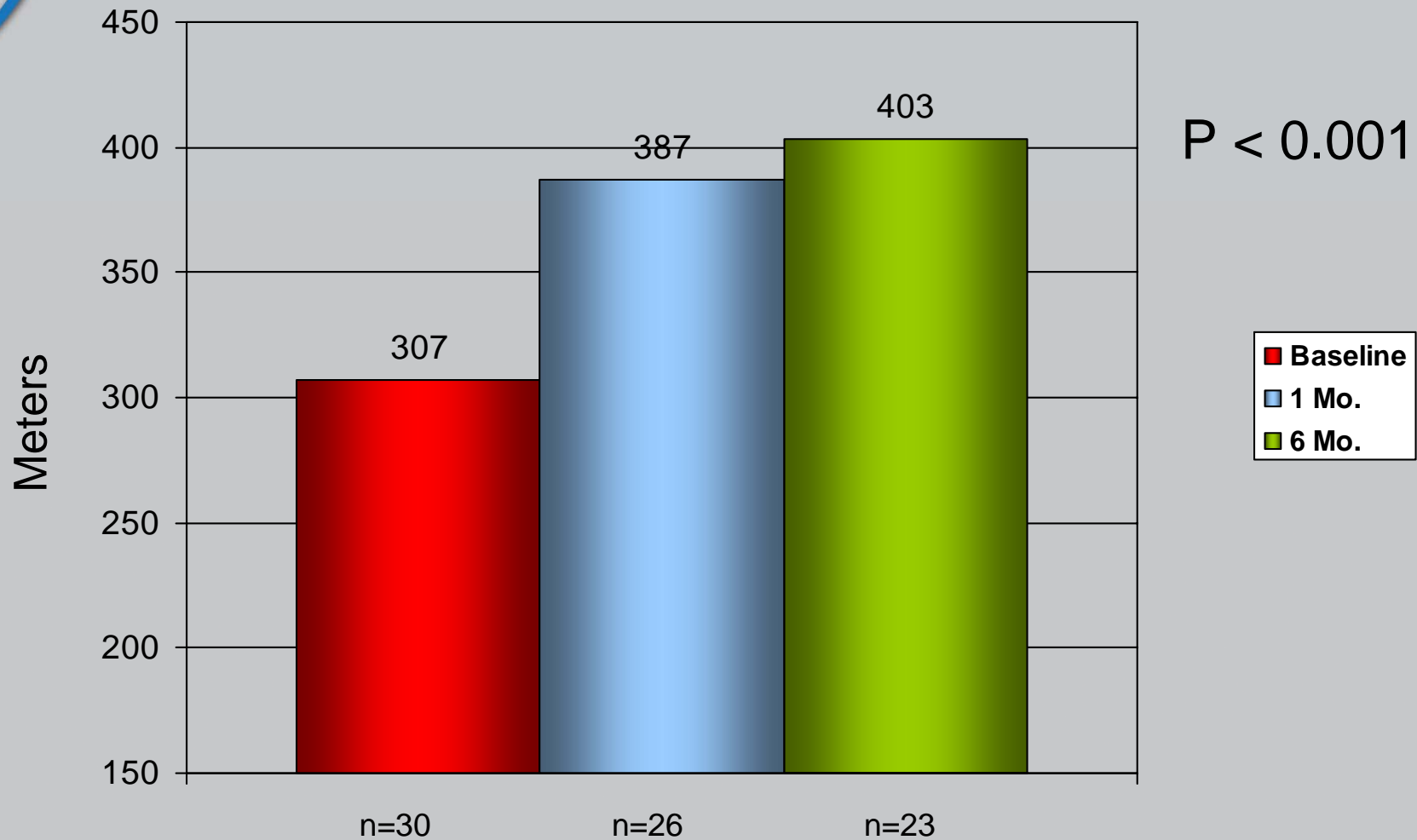
n=72

TCT 2008

Percent of Evaluable Patients with Improved MR  
Baseline MR > 1 and Implanted with Device  
Follow Up Visit: 1 YEAR



# Six Minute Walk Test - AMADEUS™



Caution: Investigational Device: Limited by US Law to European Investigational Use

CAUTION:



