

Establishing a Program for Structural Heart Interventions

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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, 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*

Structural Intervention

- Balloon valvuloplasty
- Aortic valve replacement
- Mitral repair
- ASD & PFO closure
- L Atrial Appendage occlusion
- Para-valvular leak closure

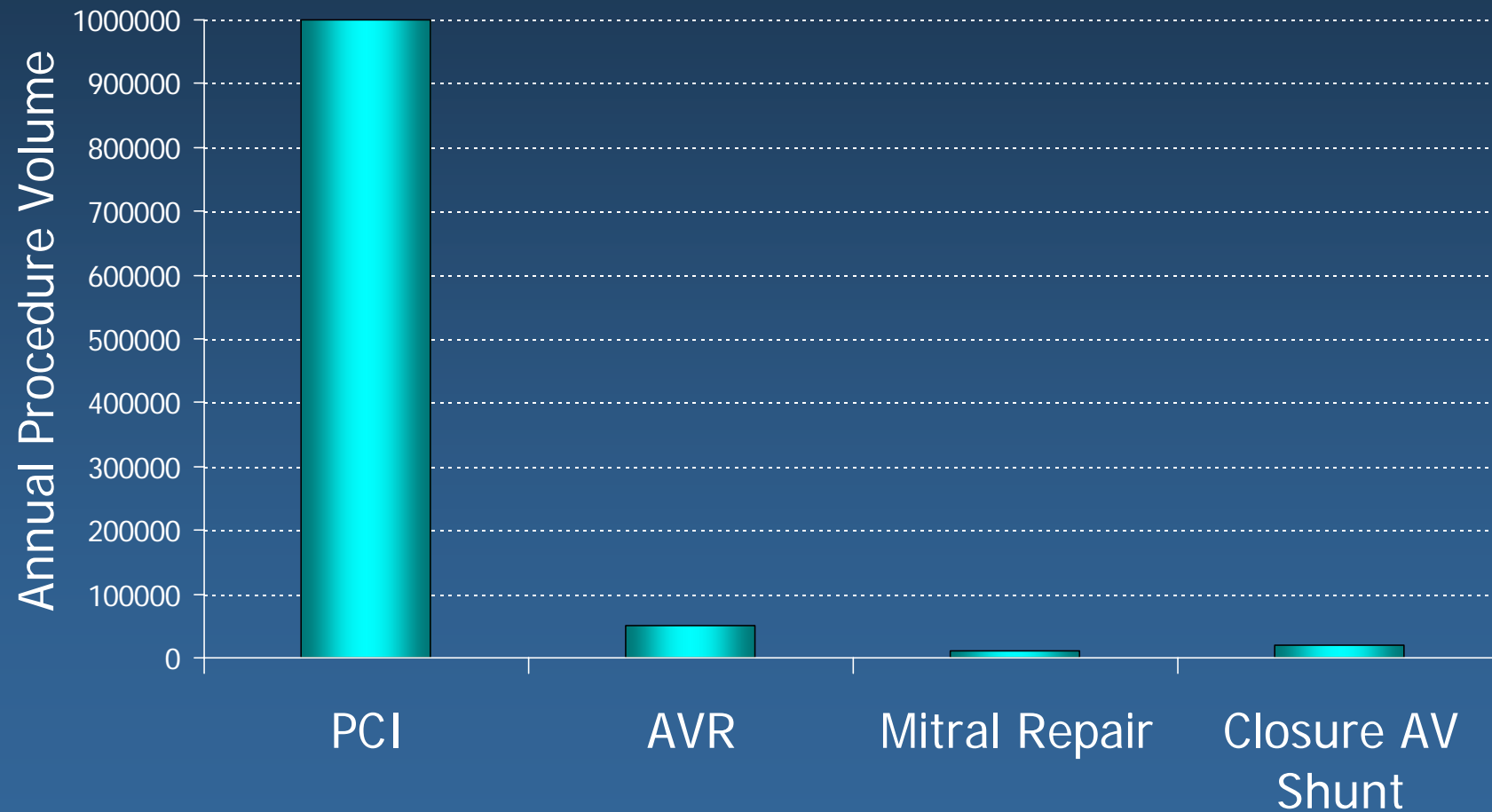
Guidelines for training in adult cardiovascular medicine

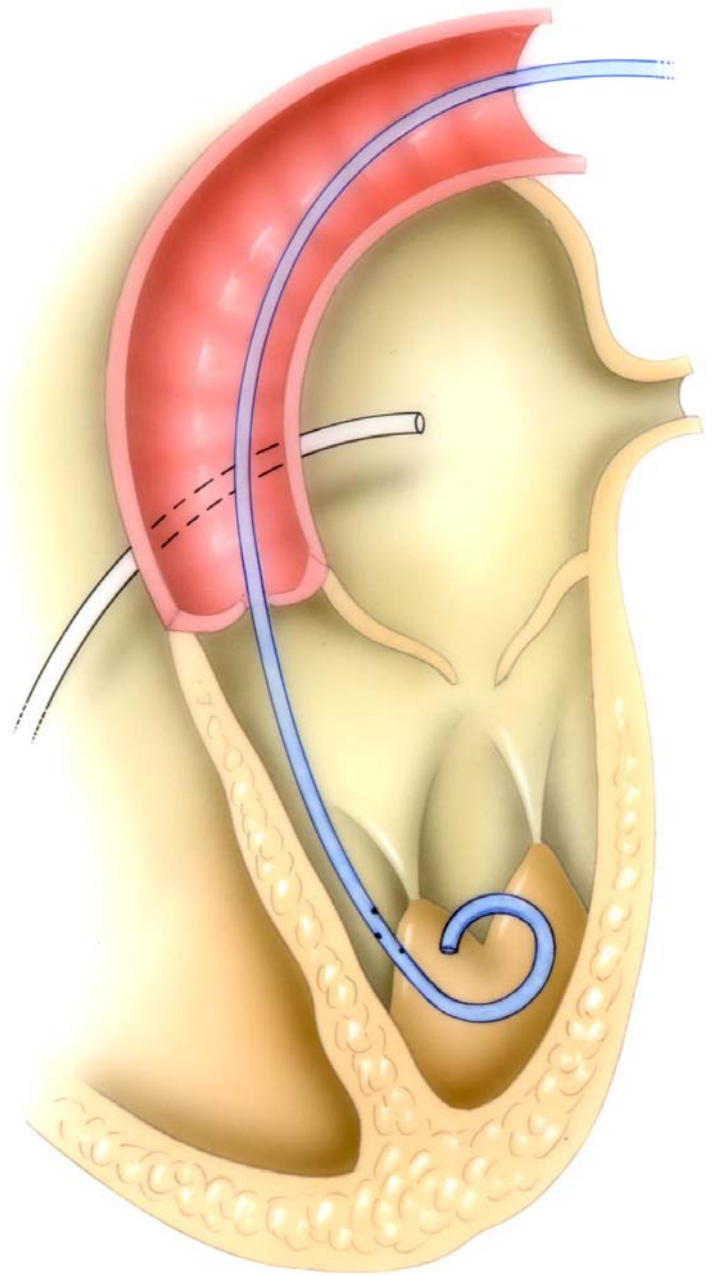
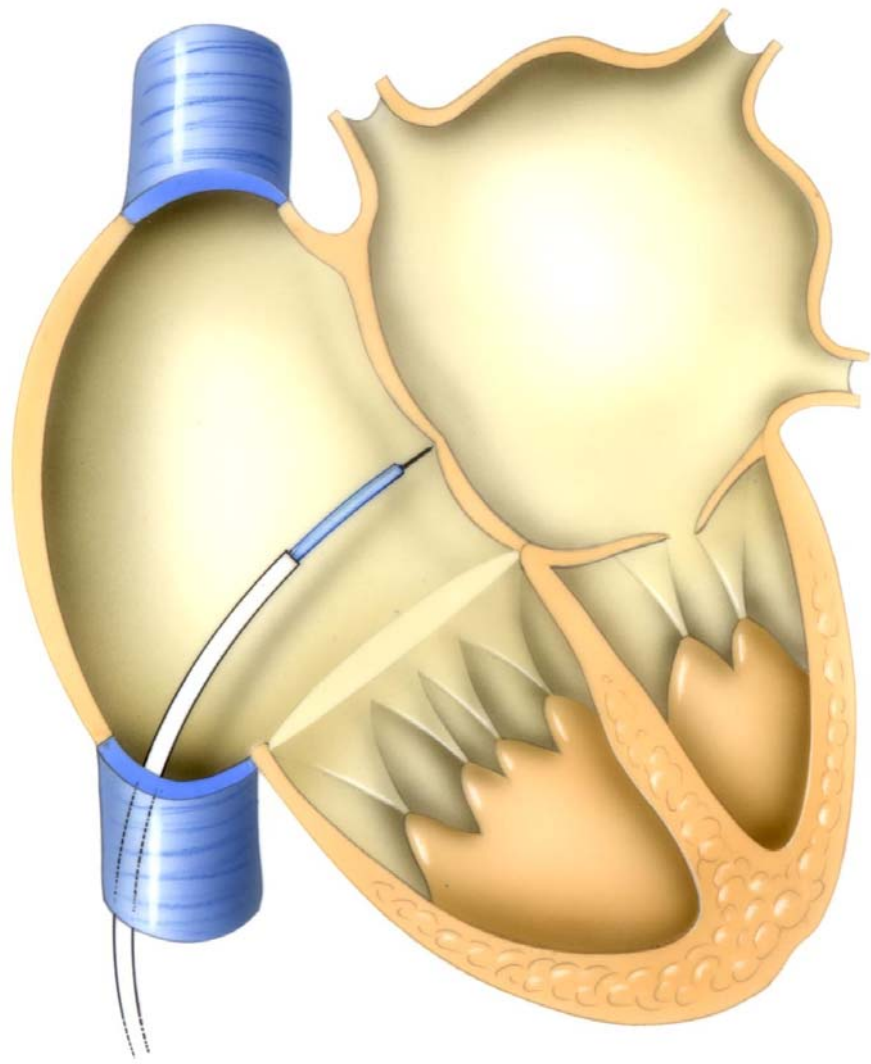
- Level 1
 - 4 months
 - Initial observational role
 - minimum 100 diagnostic procedures
- Level 2
 - 8 months
 - progressive responsibility for diagnostic procedures
 - additional 200 diagnostic procedures
- Level 3
 - 20 months
 - progressive responsibility for interventional procedures
 - 250 interventional procedures

ACC training statement on recommendations for the structure of an optimal adult interventional cardiology training program: a report of the ACC task force on clinical expert consensus documents. JACC. 34(7):2141-7, 1999

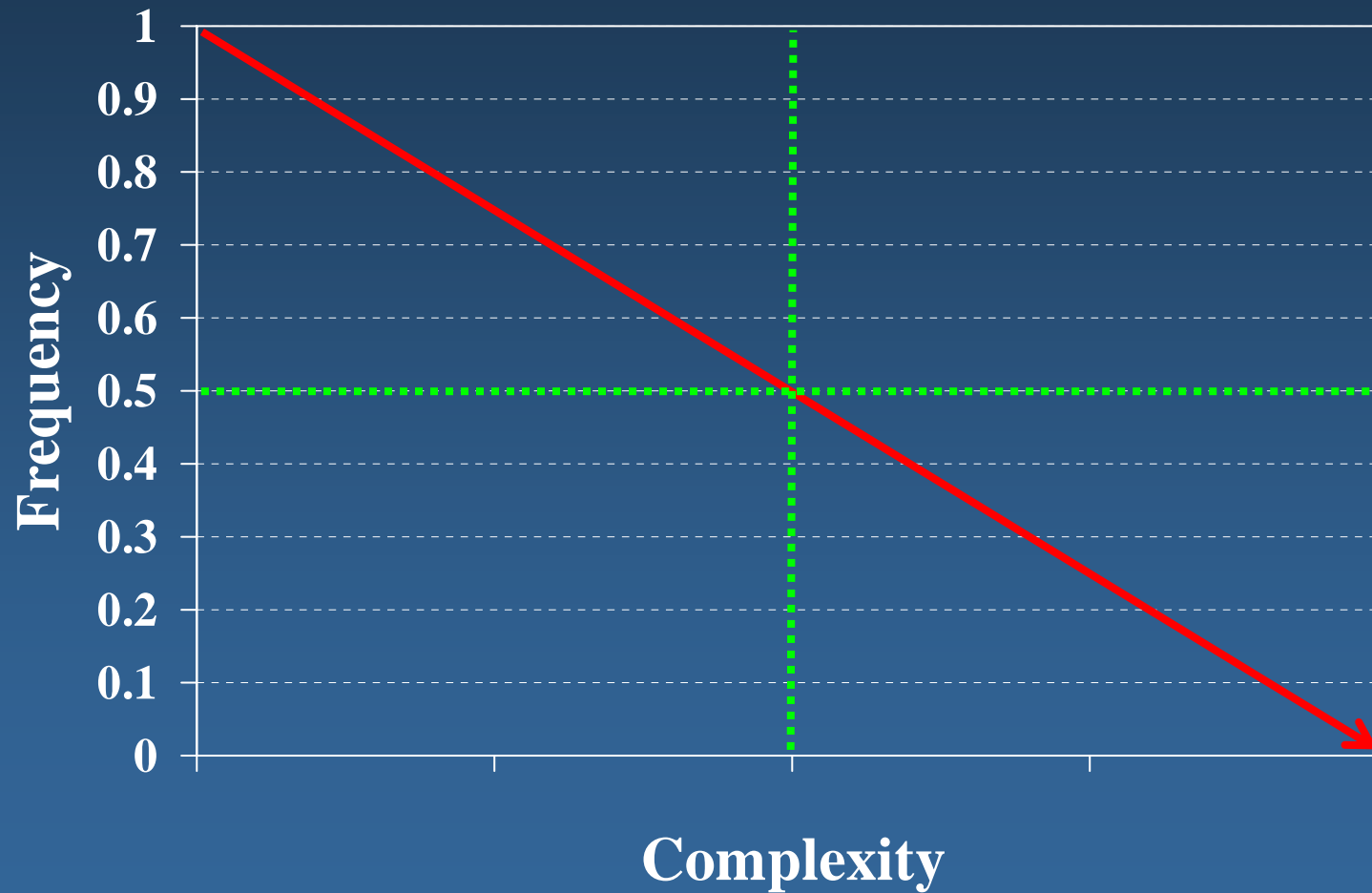
Procedure Volumes

Medicare 2007

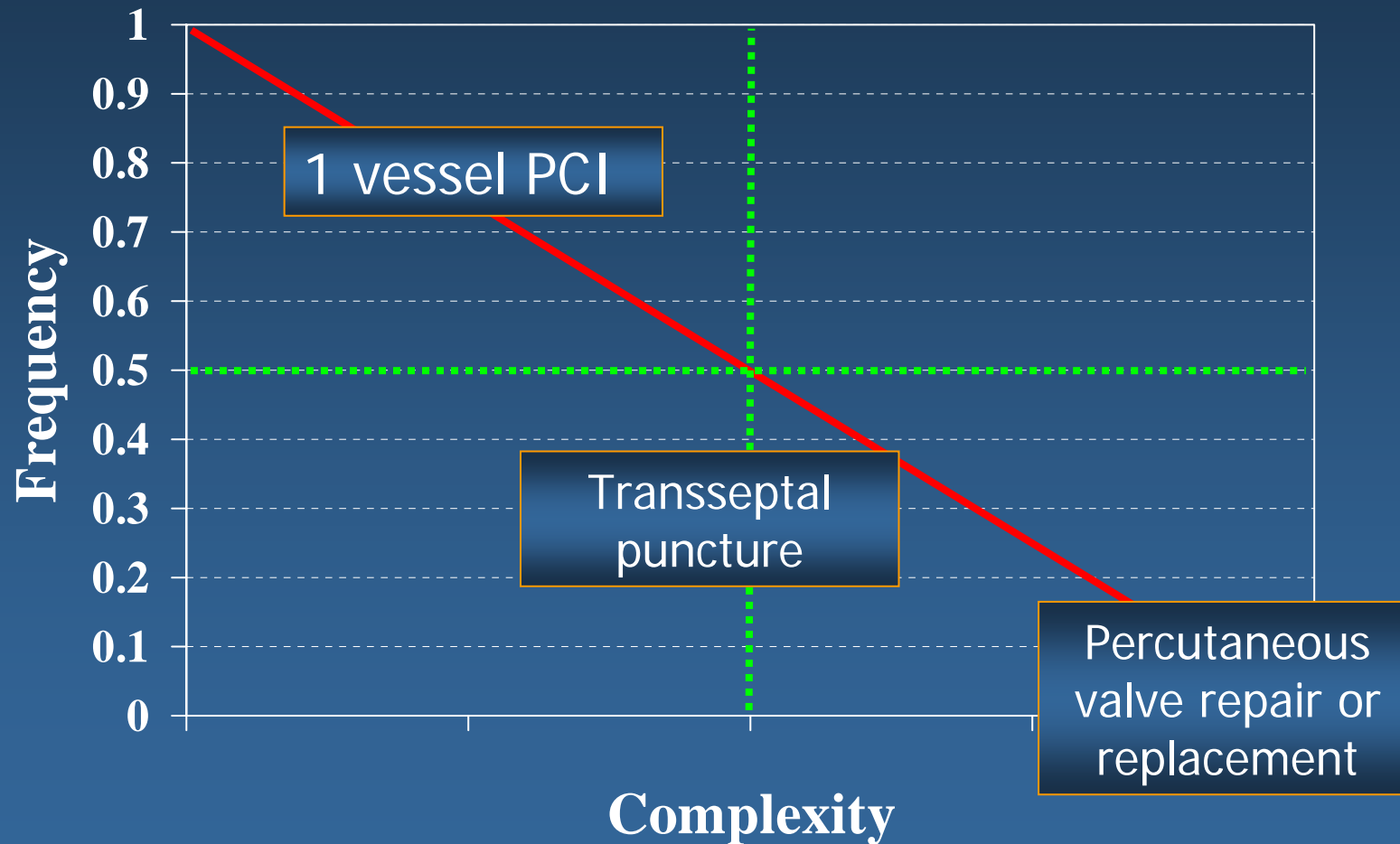




Structural Interventional Procedures



Structural Interventional Procedures



Structural operators

- perform procedure with general anesthesia
- use TEE during an intervention
- use 8-19F ICE catheters
- film the levophase of a R sided injection
- inject contrast into the LA
- place 12-24F sheaths (venous and arterial)
 - use 10F suture pre-closure
- use a 24-30mm diameter balloon catheter
- snare and exteriorize a wire
- implant a vascular plug or coils
- cut or modify a wire, sheath, catheter or guide

AcuNav

Accurate Navigation

GEUSON

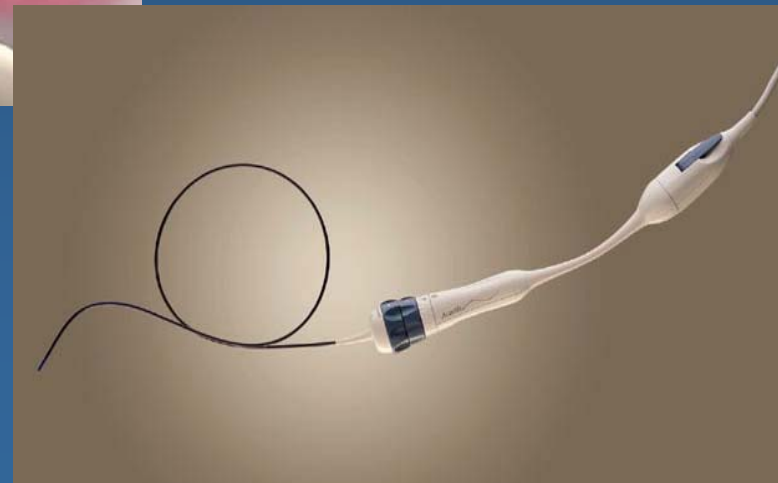
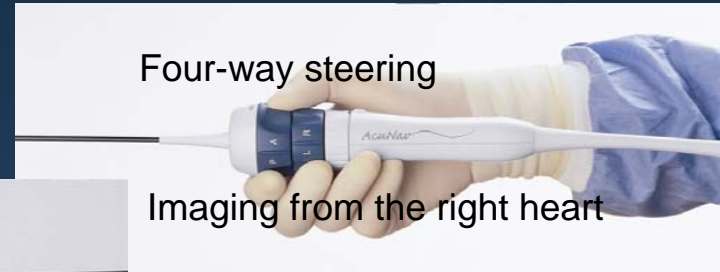
Four-way steering

Imaging from the right heart

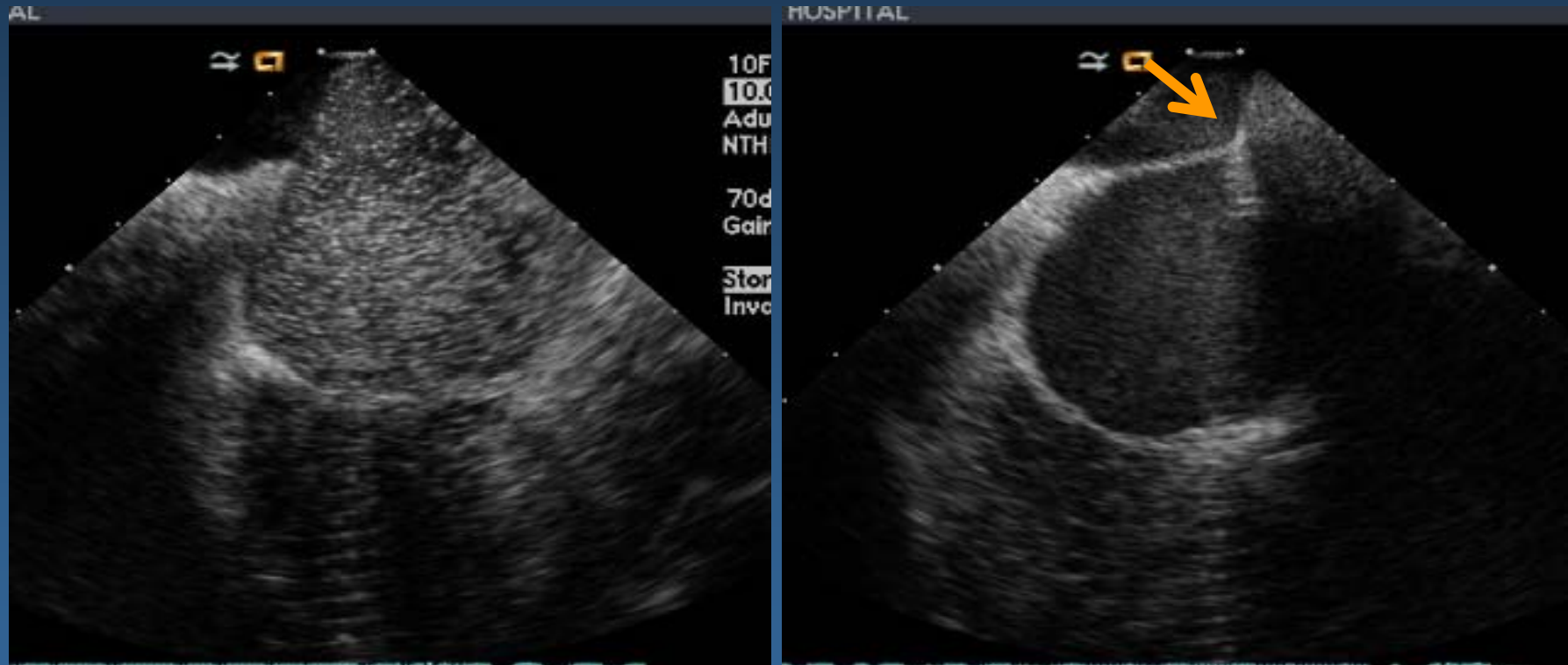


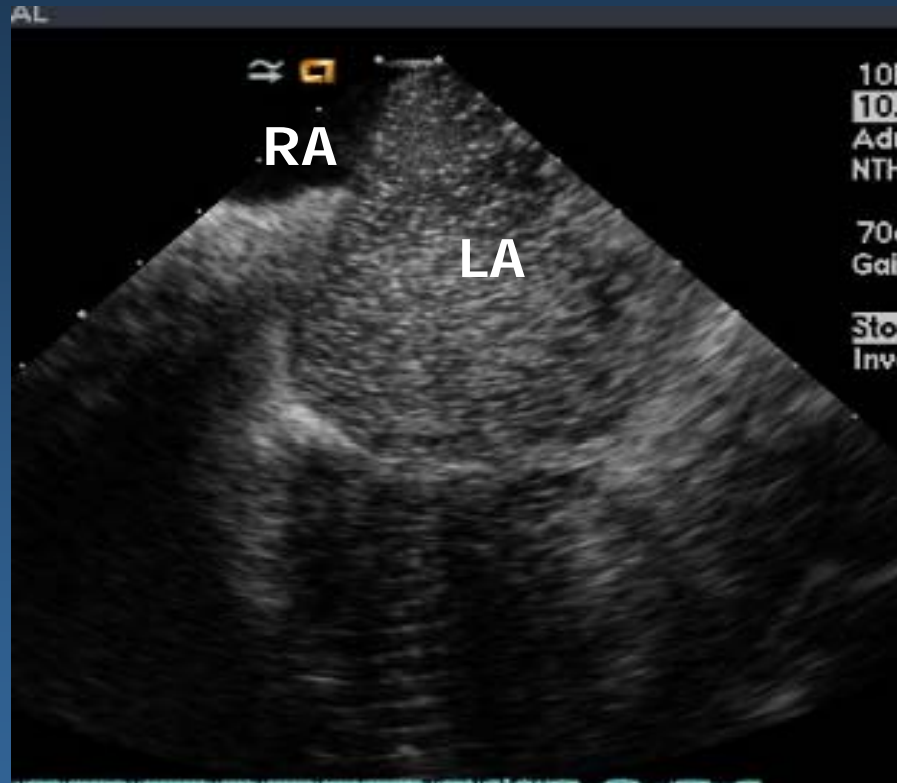
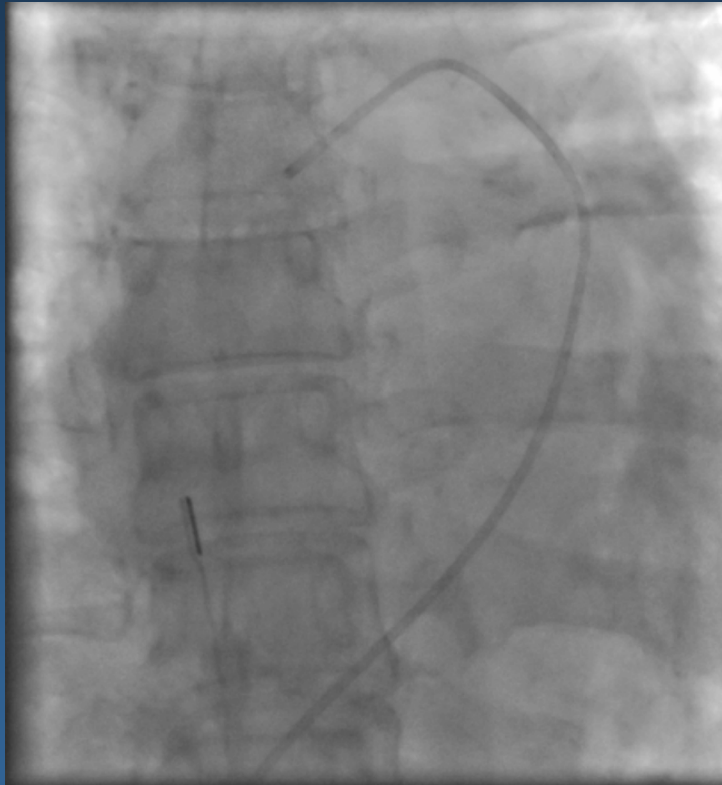
10 French / 3.3 mm

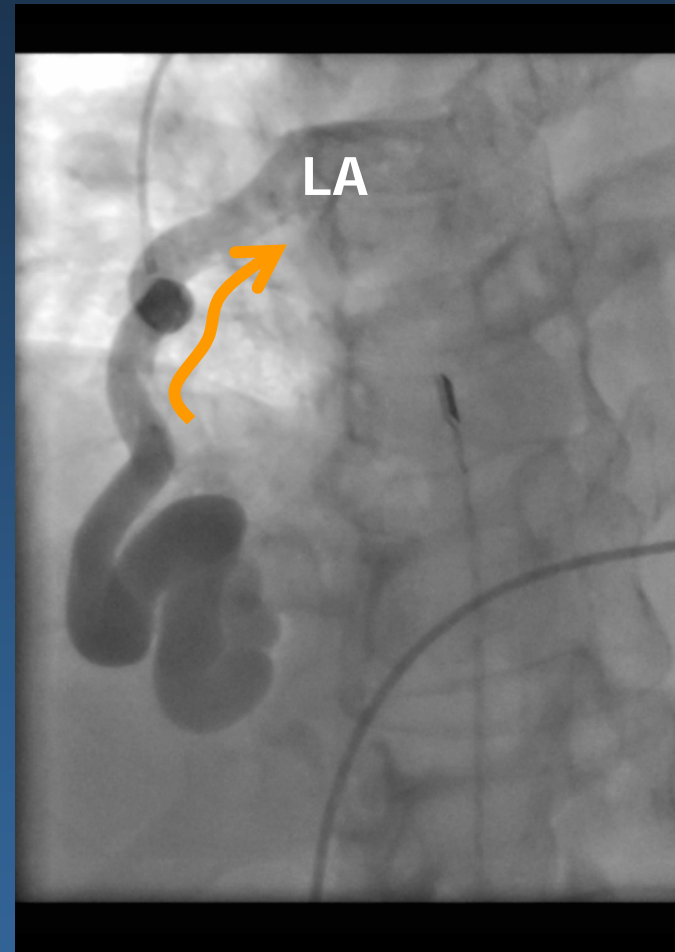
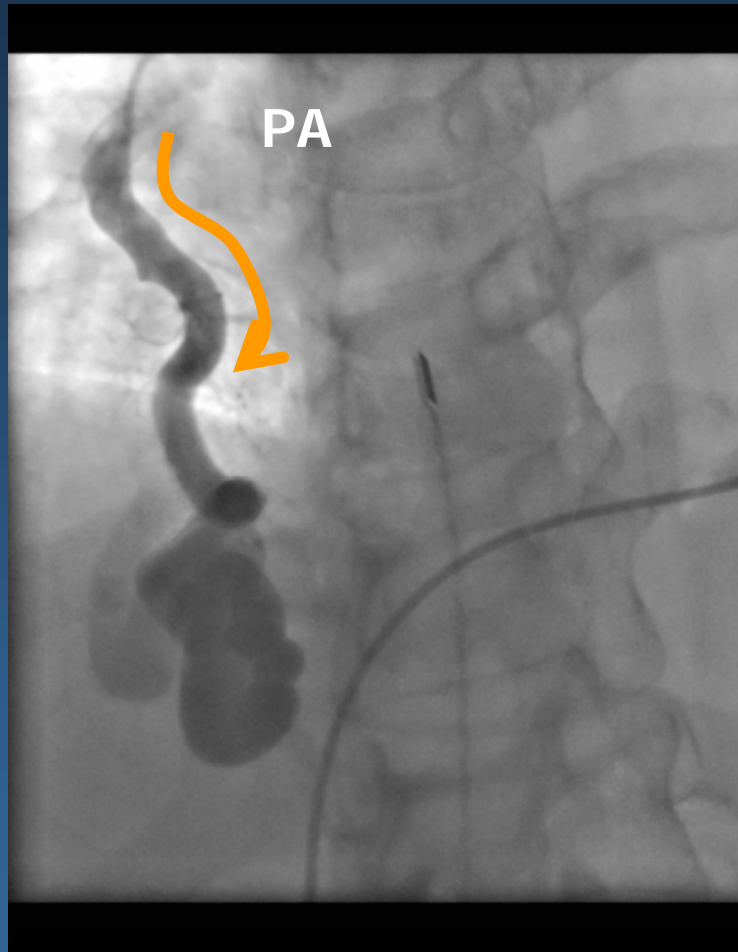
90 cm length

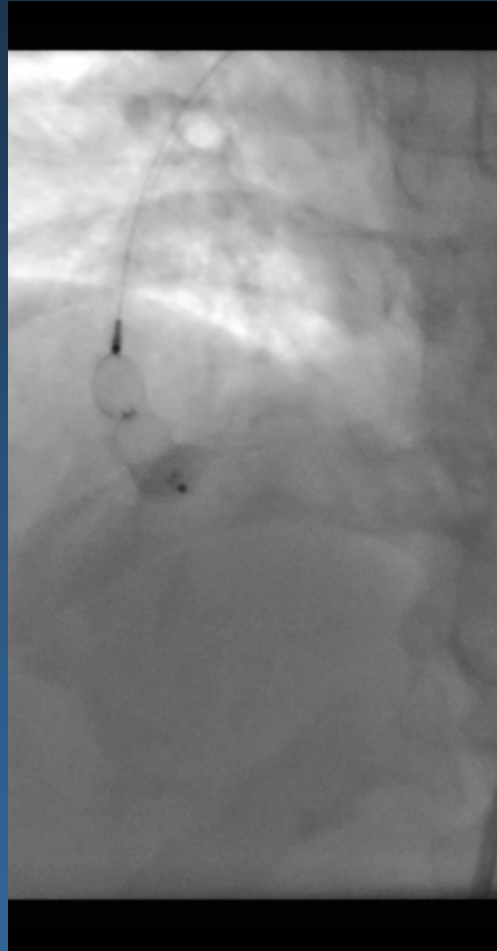
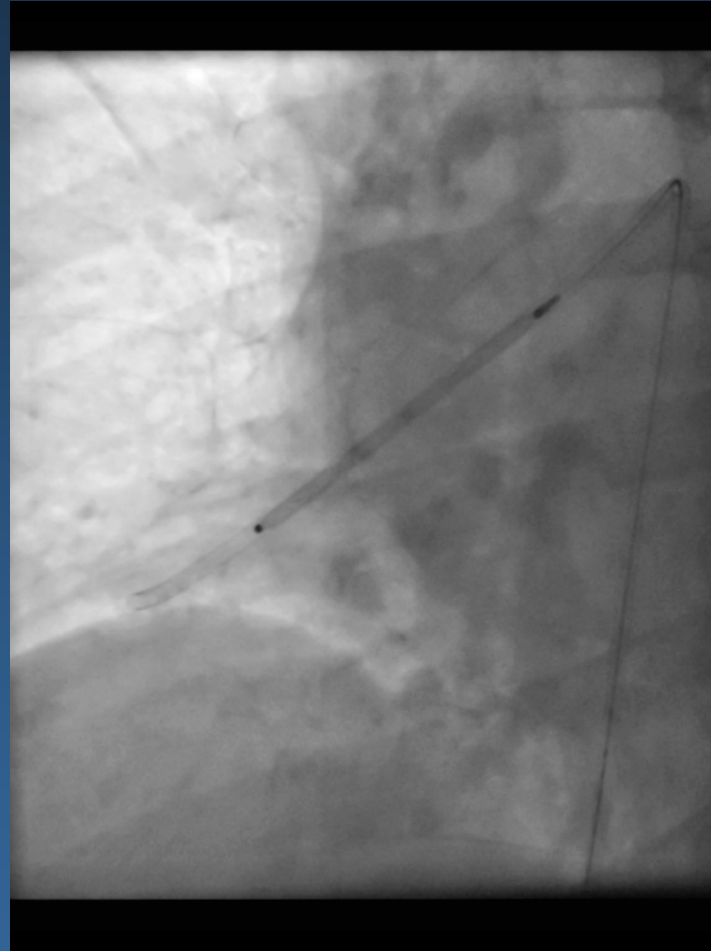


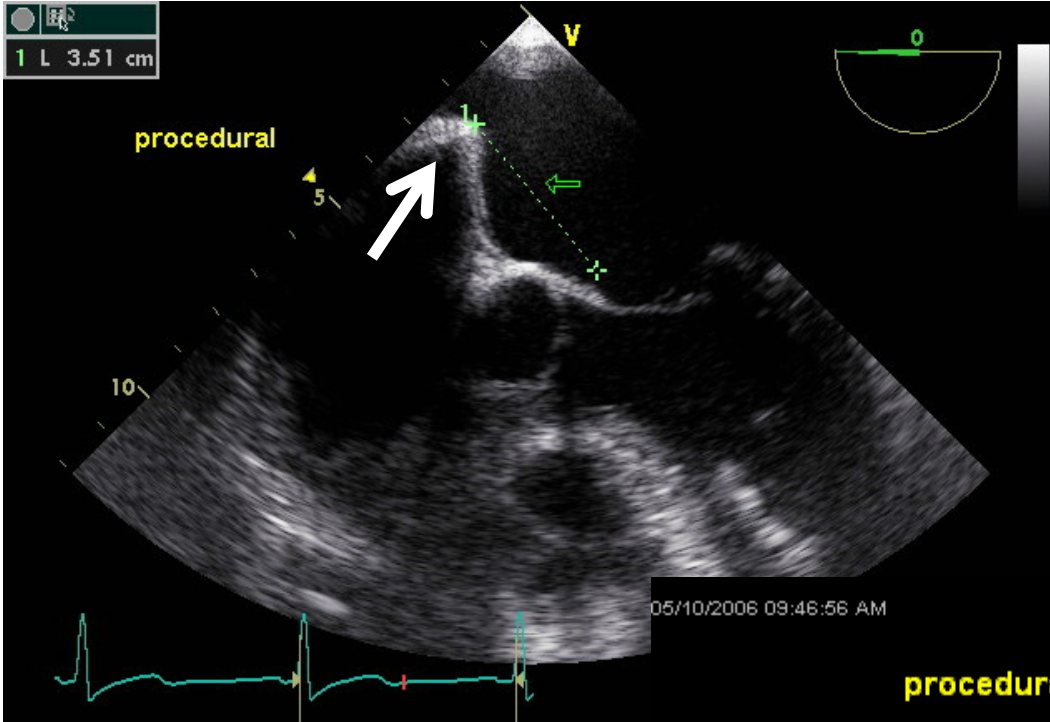
PFO??





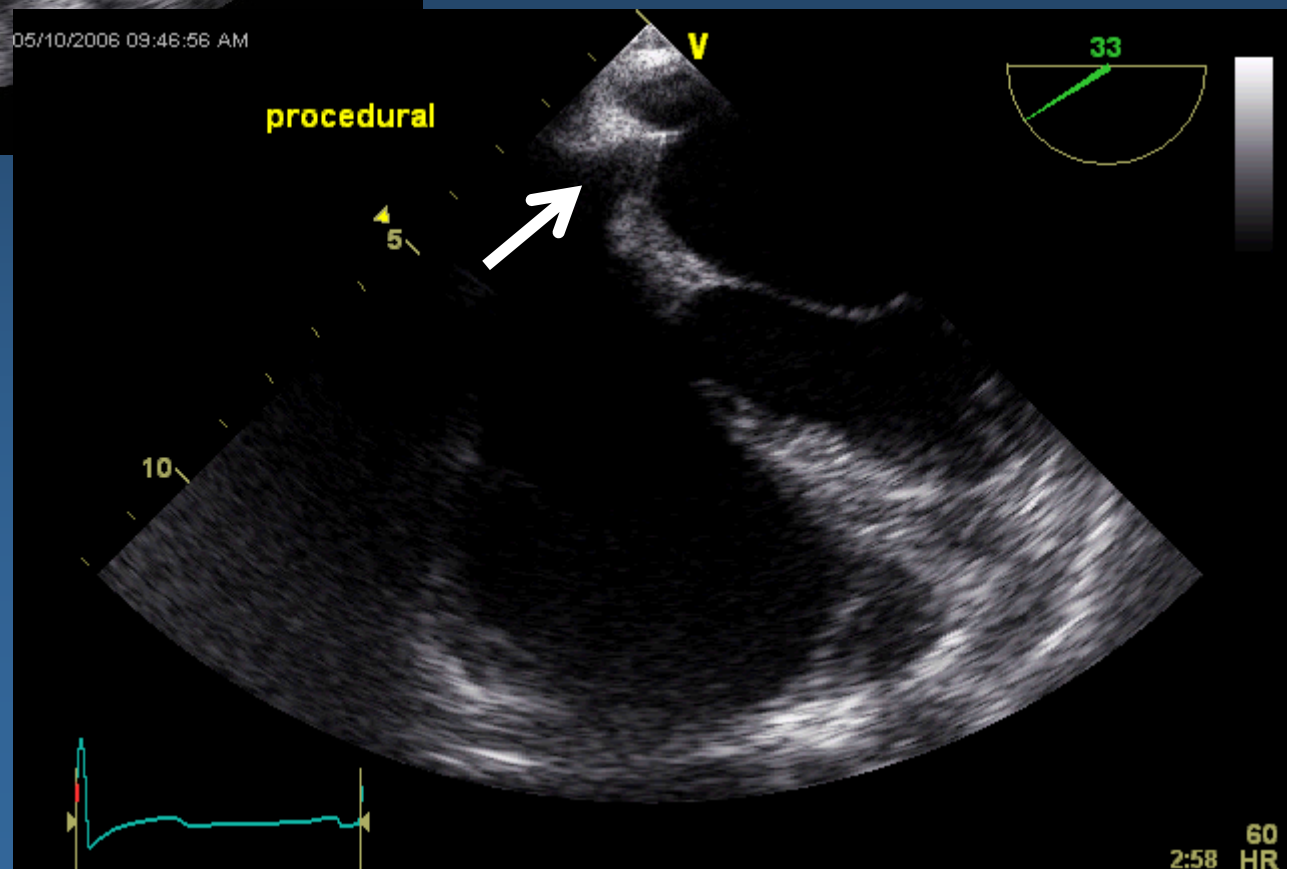


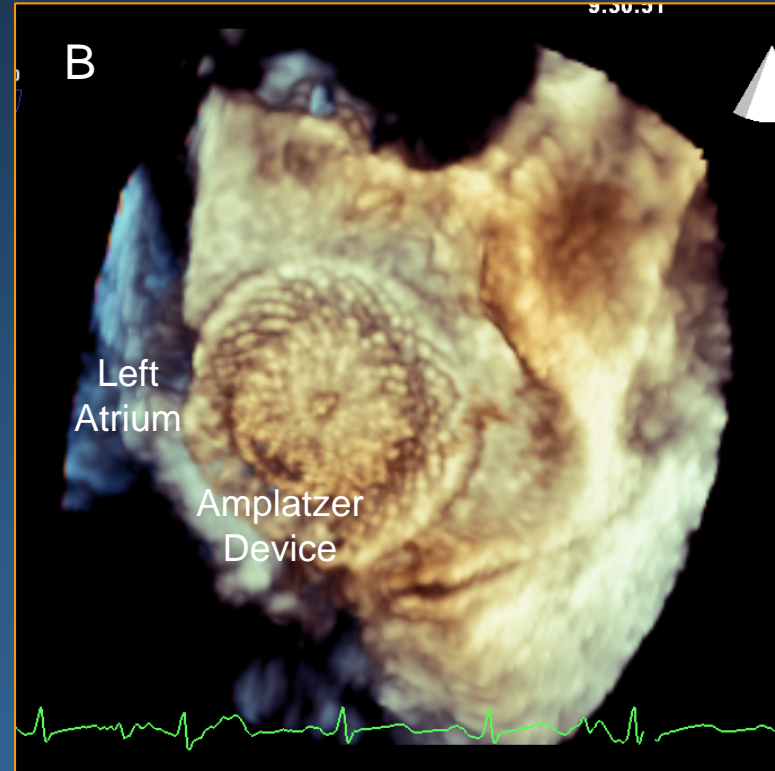
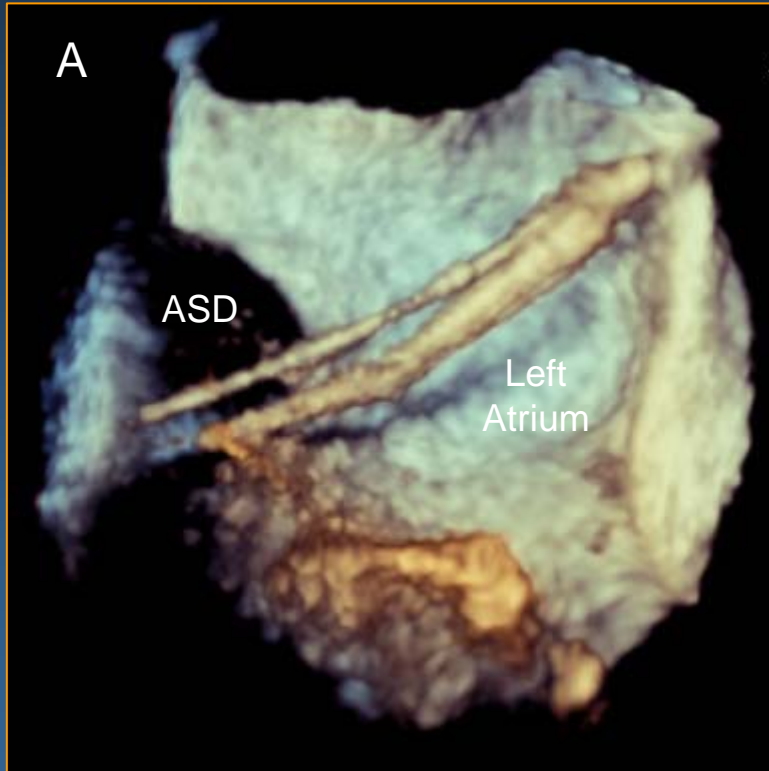




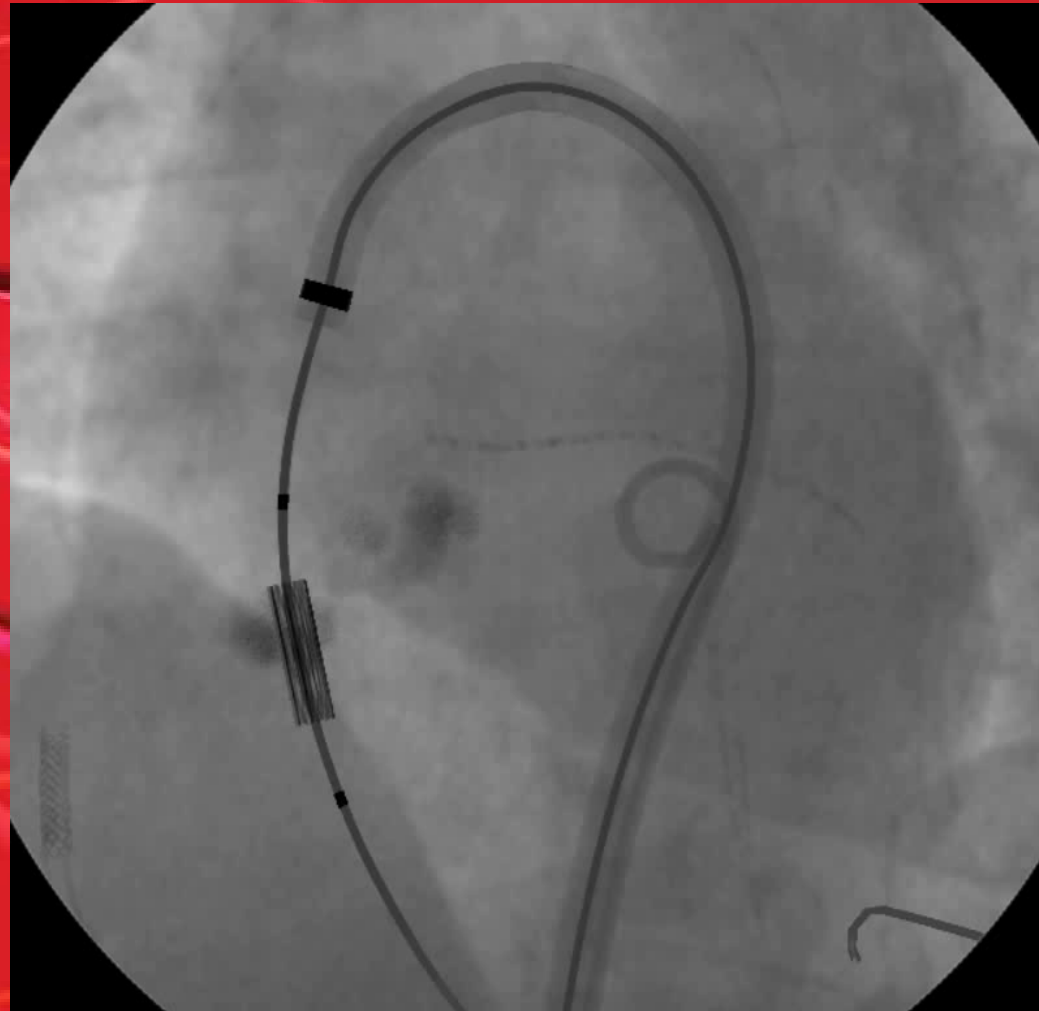
Evalue

High Posterior Stick
>3cm Height





*Itzhak Kronzon, James Slater
New York University School of Medicine*



Transcatheter Valve Replacement
Physician Training Program

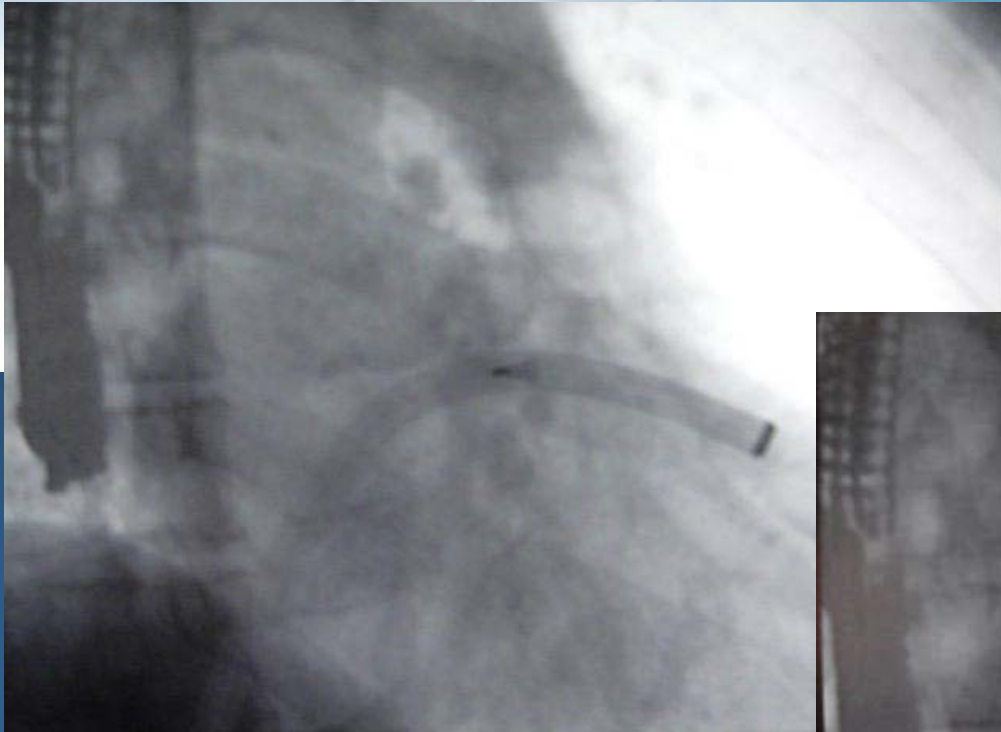


Edwards

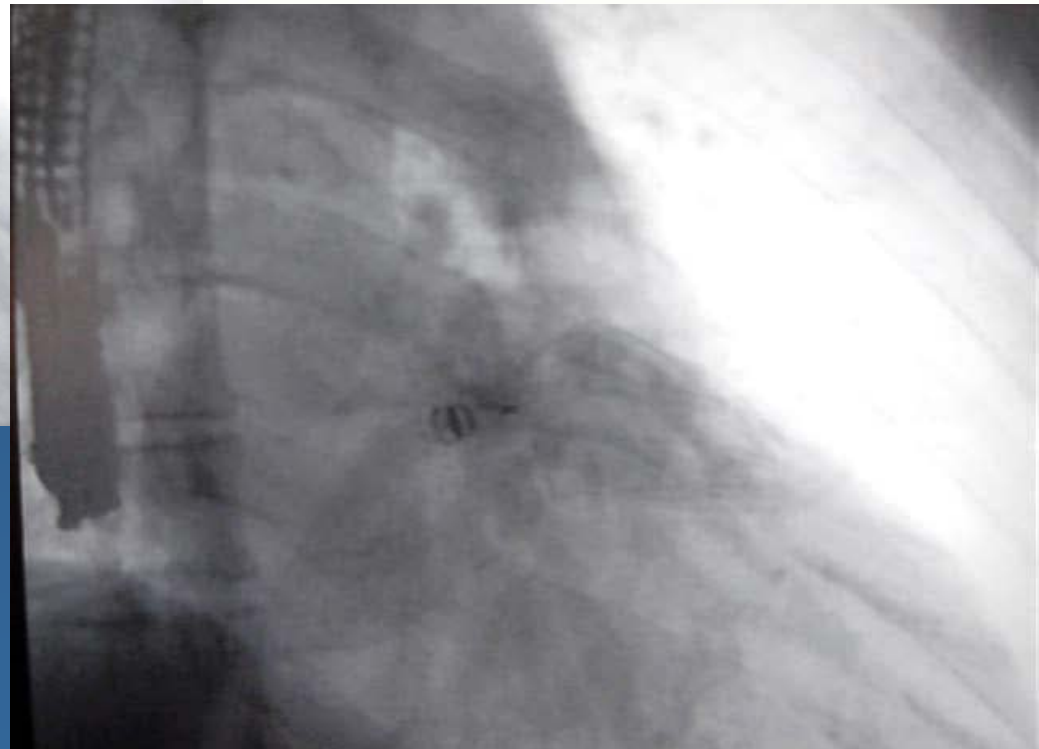


Medical Simulation – Proctoring / training implanting physicians...

Preventing AF Related Stroke Through Technology



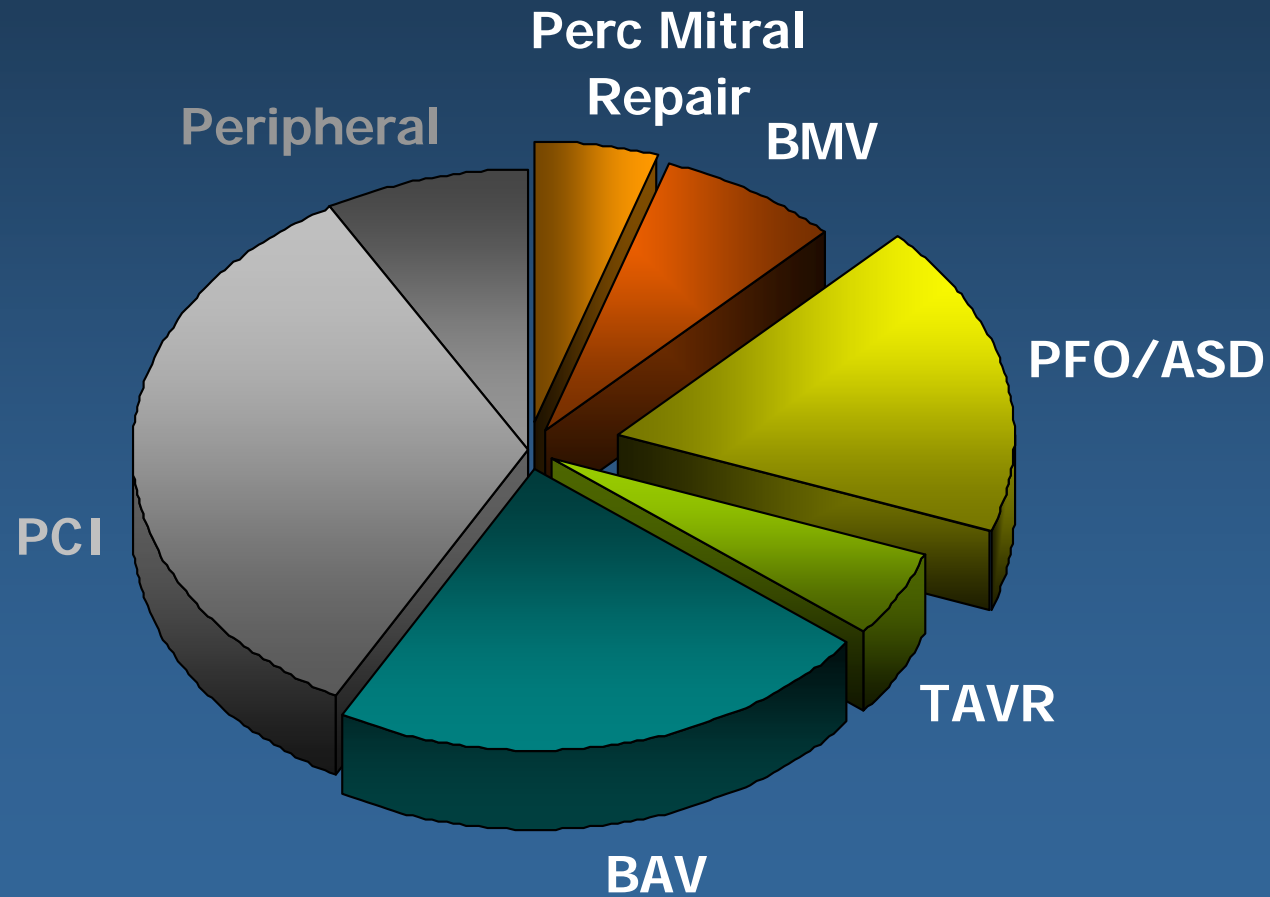
Deploying the
WATCHMAN



Checking release criteria

Interventions 2008

2/3 Structural



Challenges: Phase 2 Trials

from proof of concept to proof of efficacy

- LAA occlusion
 - *Watchman follow-up completed*
- Mitral regurgitation
 - *EVEREST II enrollment completed*
- Aortic stenosis
 - *PARTNER still enrolling*

Projected Number of Adults with Atrial Fibrillation in the US up to 2050

