

# Transcatheter Aortic Valve Implantation with the Balloon expandable Edwards Valve *Past, present and future*

Angioplasty Summit TCTAP 2010



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# From PVT to Edwards Valves

## Edwards Valves

2000: **PVT Valve**

2003-2004

2005-2009

2009

Percutaneous Heart Valve

Cribier Edwards

Edwards Sapien

Edwards Sapien XT



Bovine pericardium  
Stainl. steel frame  
23mm

Equine pericardium  
Stainl. steel frame  
23mm

Treated bovine peric  
Stainl. steel frame .  
23 and 26mm

Next to come  
**20mm / 29mm**

Next generation

24F

22F

22F, 24F

**18F, 19F**

TF sheath sizes

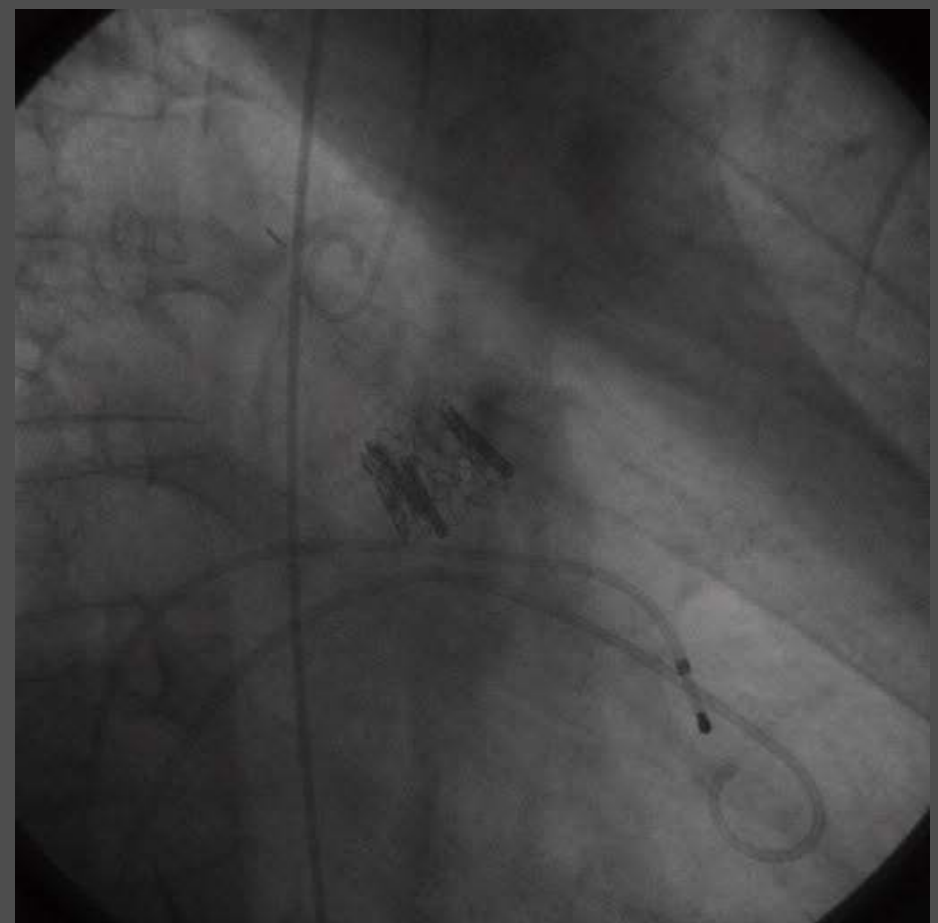
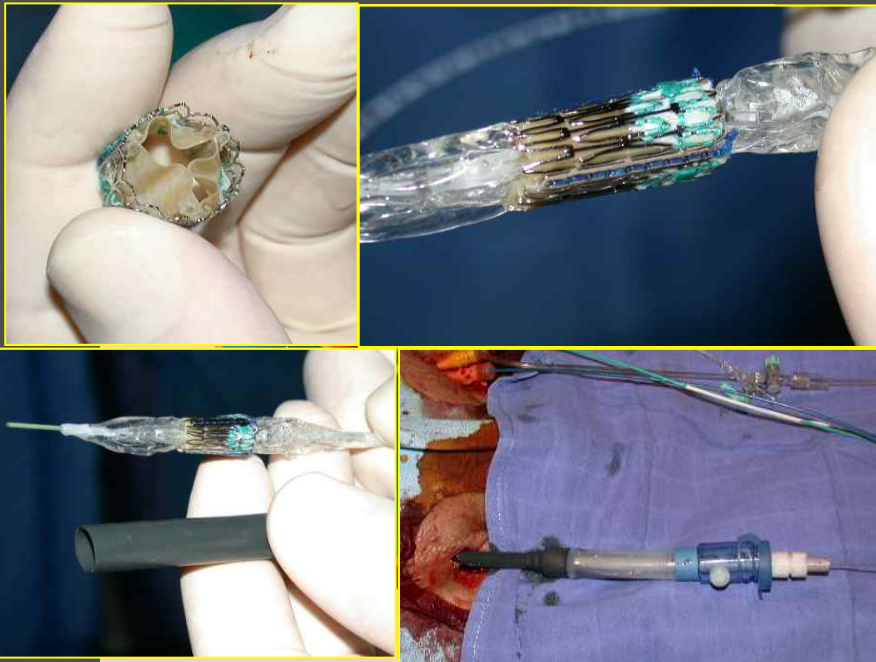


# The past:

## First In Man, Rouen, April 16, 2002

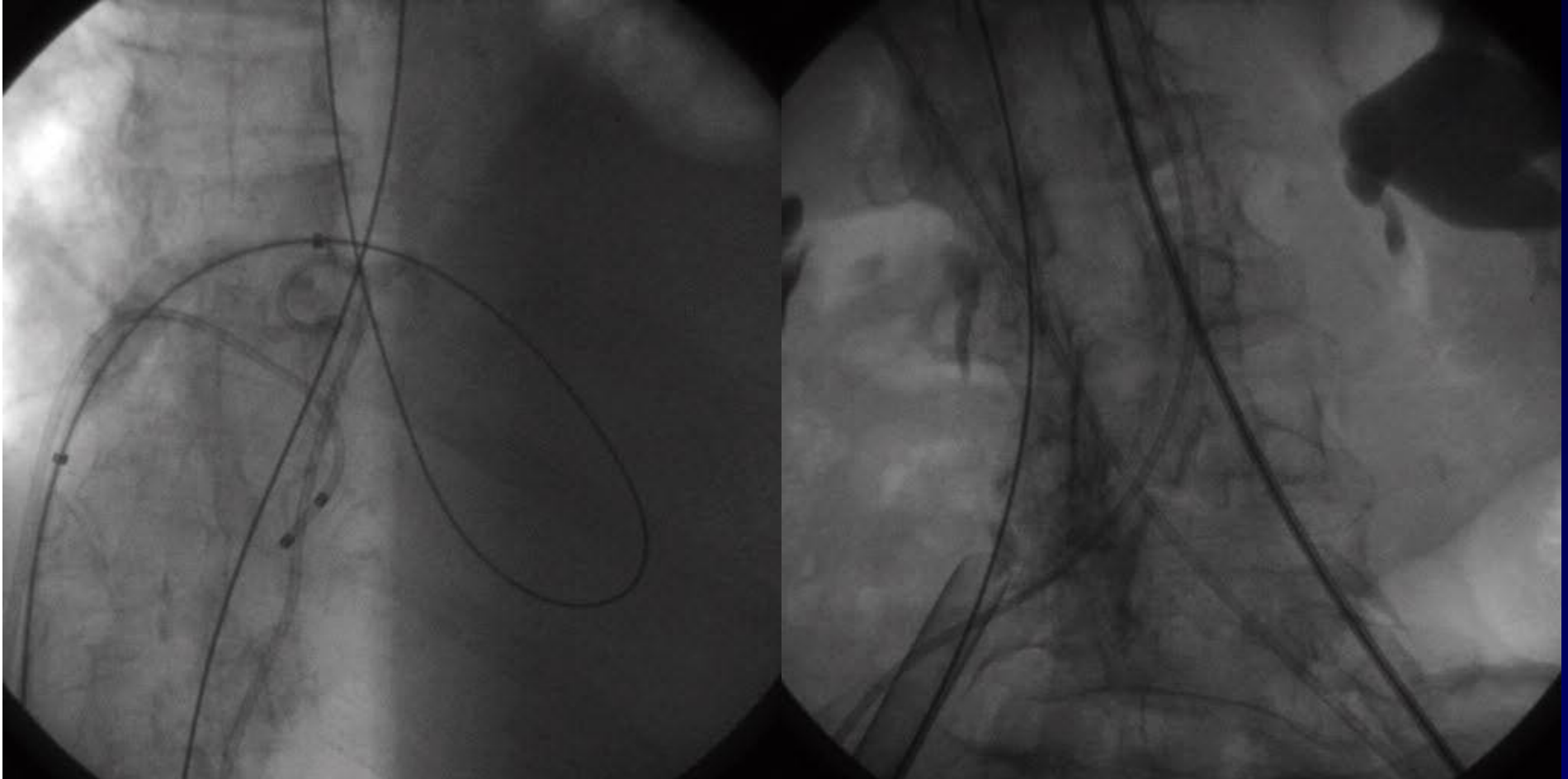
### Trans-Septal Approach; PVT Valve

Man, 57 y-old, severe AS  
Cardiogenic shock , LVEF: 12%  
Multiple comorbidities,  
No arterial access



# The past: Trans-Septal Approach

(Rouen, 2002-2004: 40 patients, 80% success)

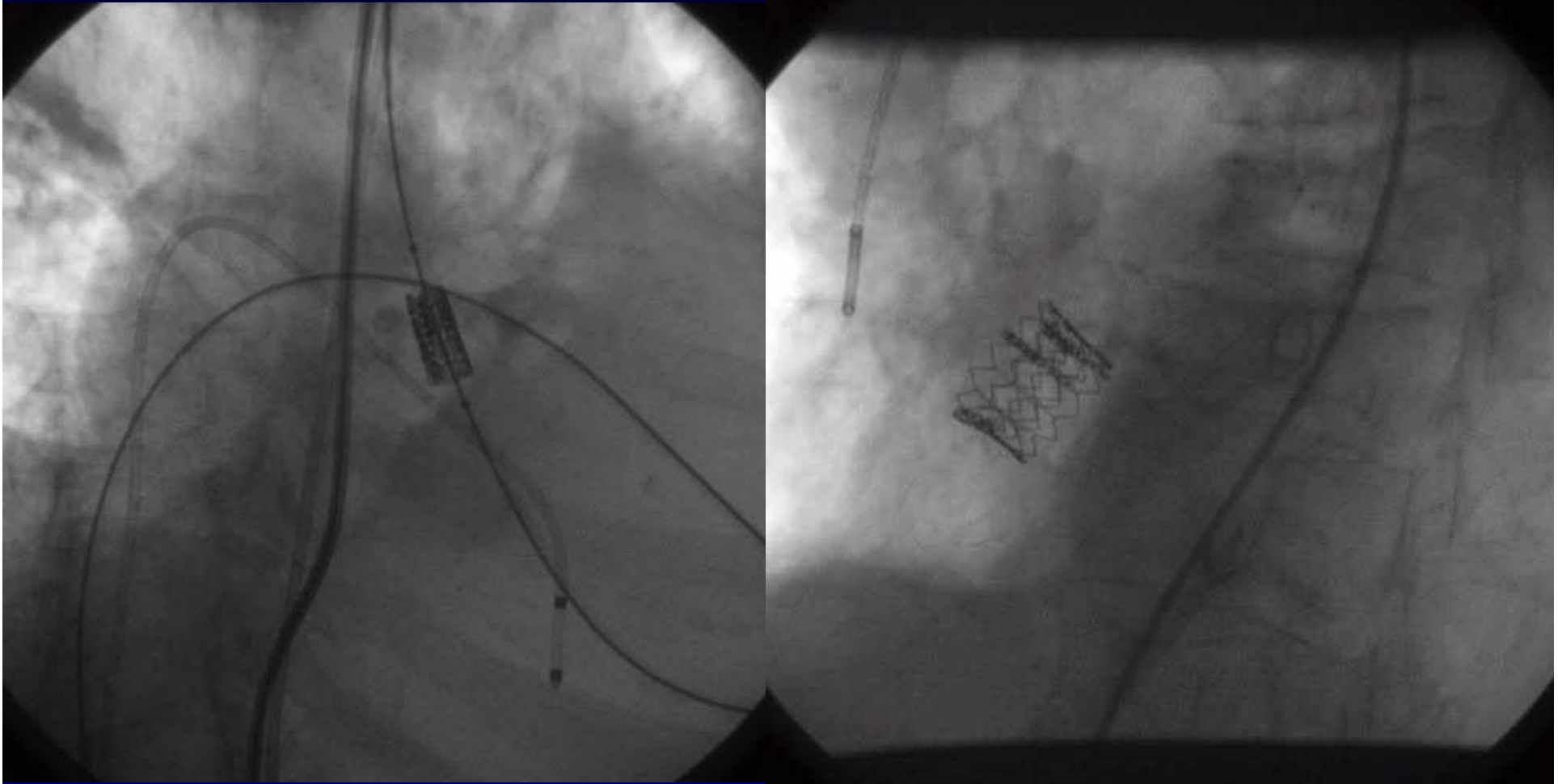


- Guidewire from femoral vein to contra-lateral femoral artery
- Dilatation of atrial septum with a 8mm balloon

- THV advanced from femoral vein to native aortic valve

# The past: Trans-Septal Approach

(2002-2004: 40 patients, 80% success)



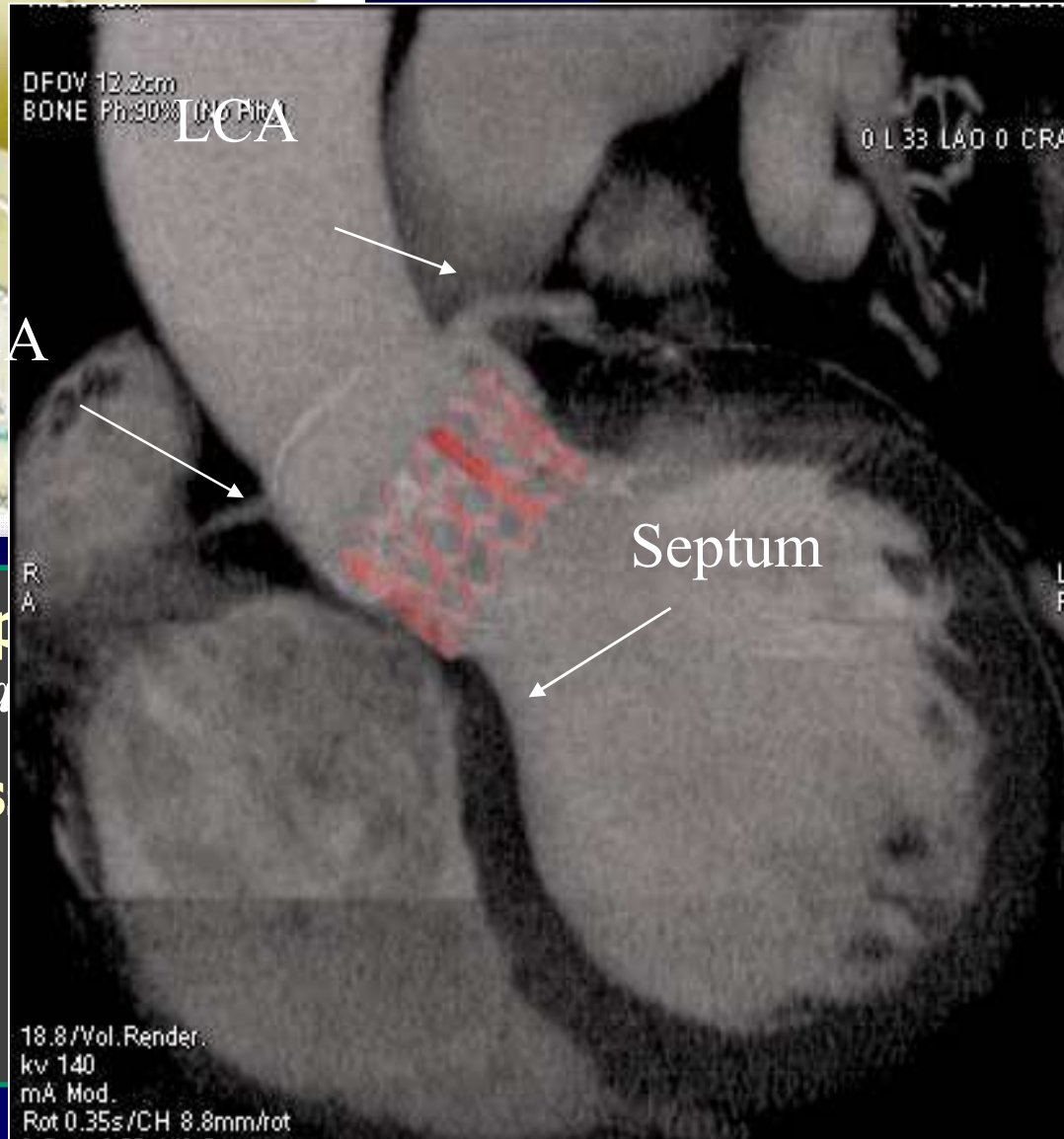
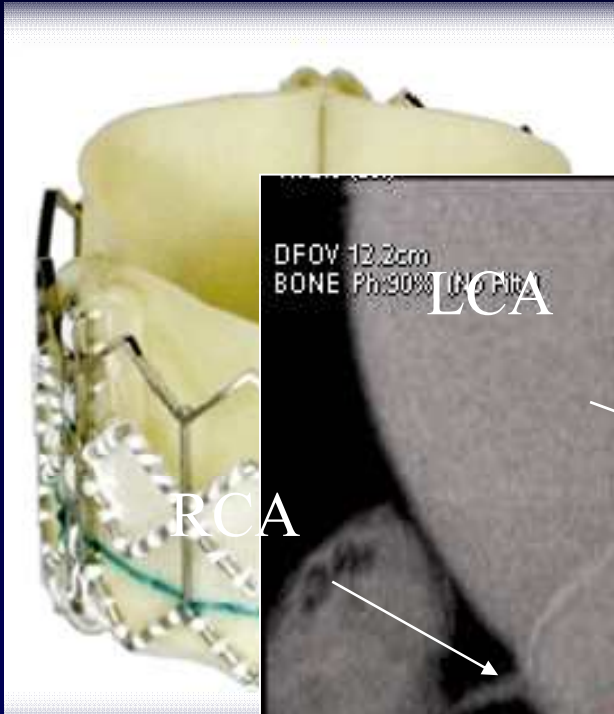
- THV delivered under rapid pacing
- Sones catheter from femoral artery to hold the THV in place during inflation

- Good angiographic result

2004: PVT



Edwards Lifesciences



➤ **Bovine p**  
*Treated a*

➤ **Stainles**

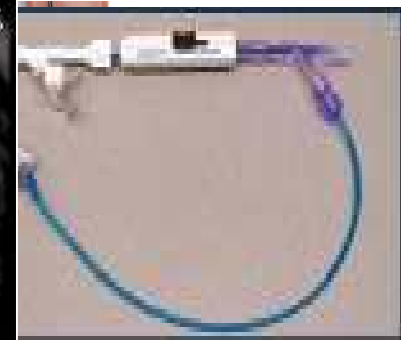
➤ **2 sizes:**

➤ **Sheath:**

Is Valve  
en Valve



Ascendra



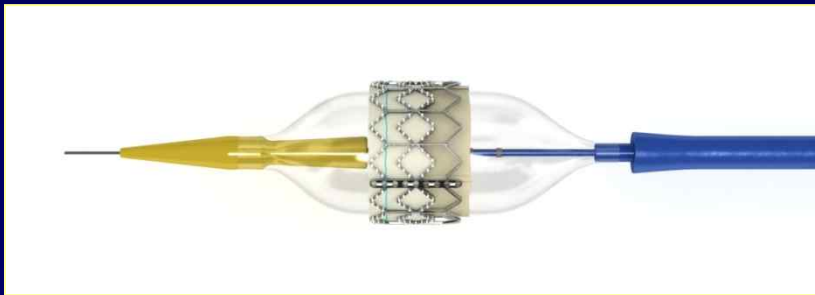
stems

Transapical

# The present: Retrograde approach Edwards Sapien Valve

## The Retroflex III

*Third generation of delivery system*



# Rouen: Clinical example: 89 y/o female

- **NYHA functional class 3**
- **Severe AS:**
  - EOA:  $0.46 \text{ cm}^2/\text{m}^2$ , Mean gradient: 46 mm Hg
  - LVEF: 75%, normal coronary arteries
- *Breast cancer, pulmonary insufficiency*
- *Bilateral hip prosthesis, arthritis (chronic corticotherapy)*

**EuroSCORE: 22.37%**

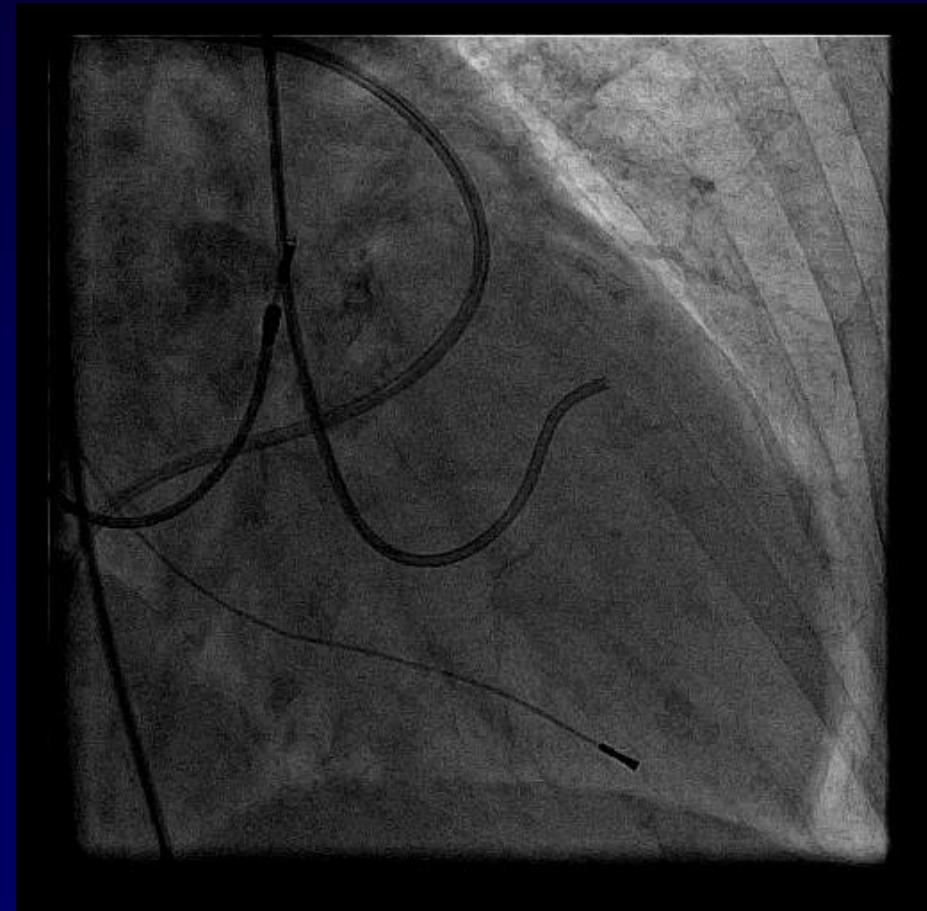
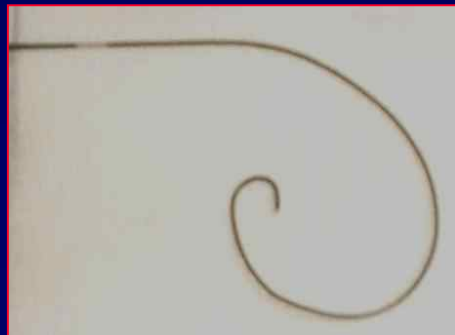
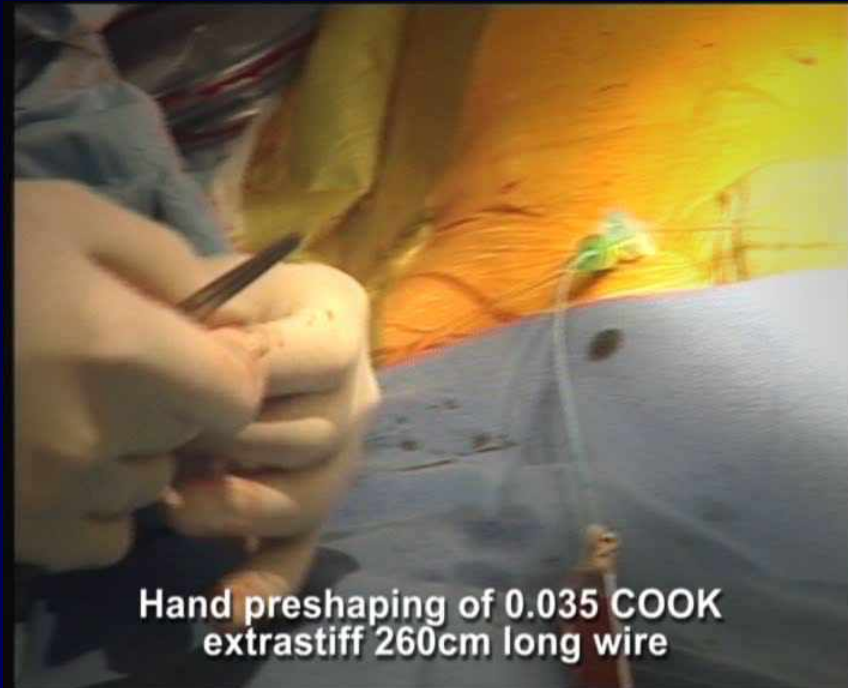
**Annulus diameter: 20.2mm**

Indication to THV 23 mm, transfemoral approach



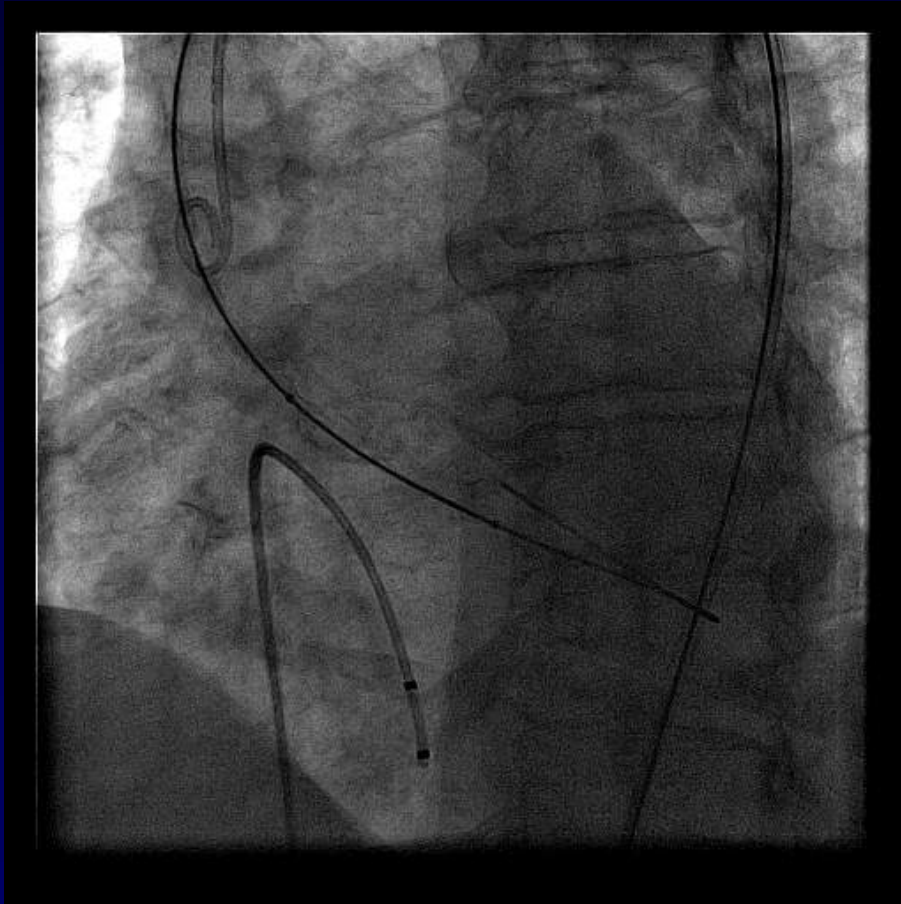
# Pre-shaping the exchange extra-stiff wire

**260cm long COOK 0.035"**  
**« *Extra-Stiff Guidewire* »**

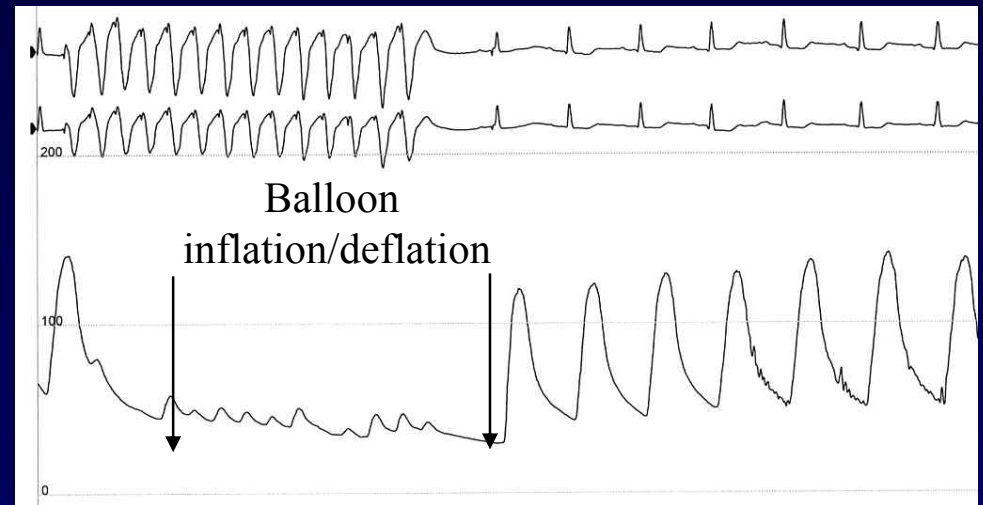


RAO View

# 20mm Edwards balloon: 20mm (23mm THV)



Two inflations, one with aortogram

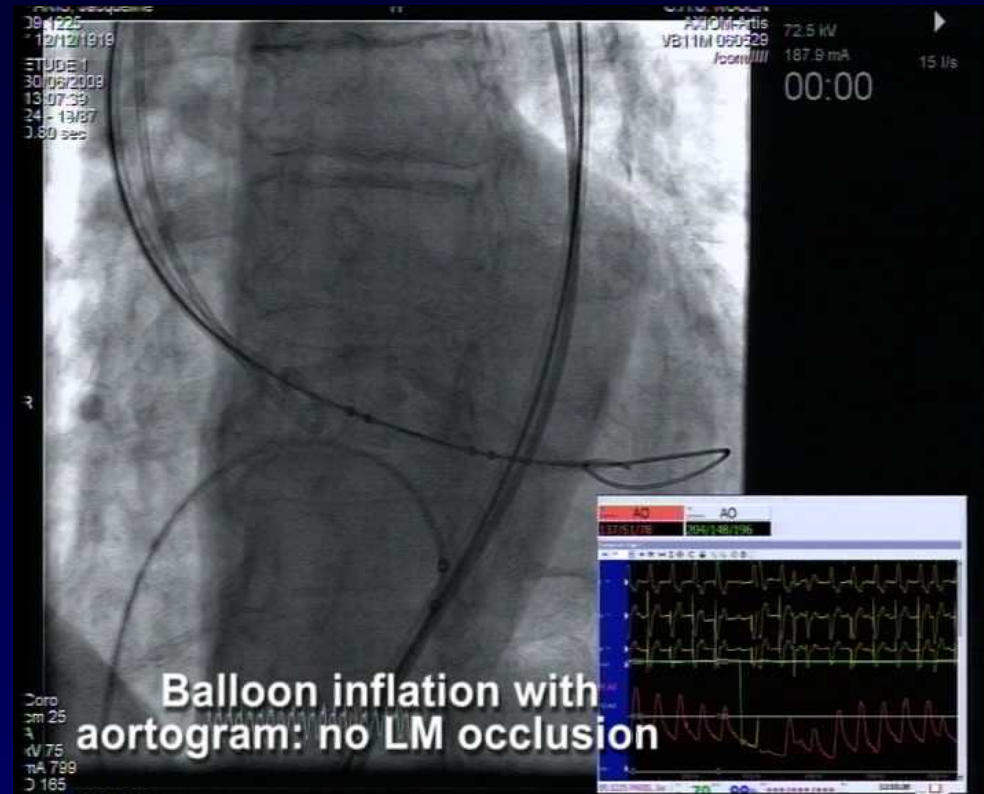


**Rapid Ventricular Pacing**

(200 to 220 bpm)

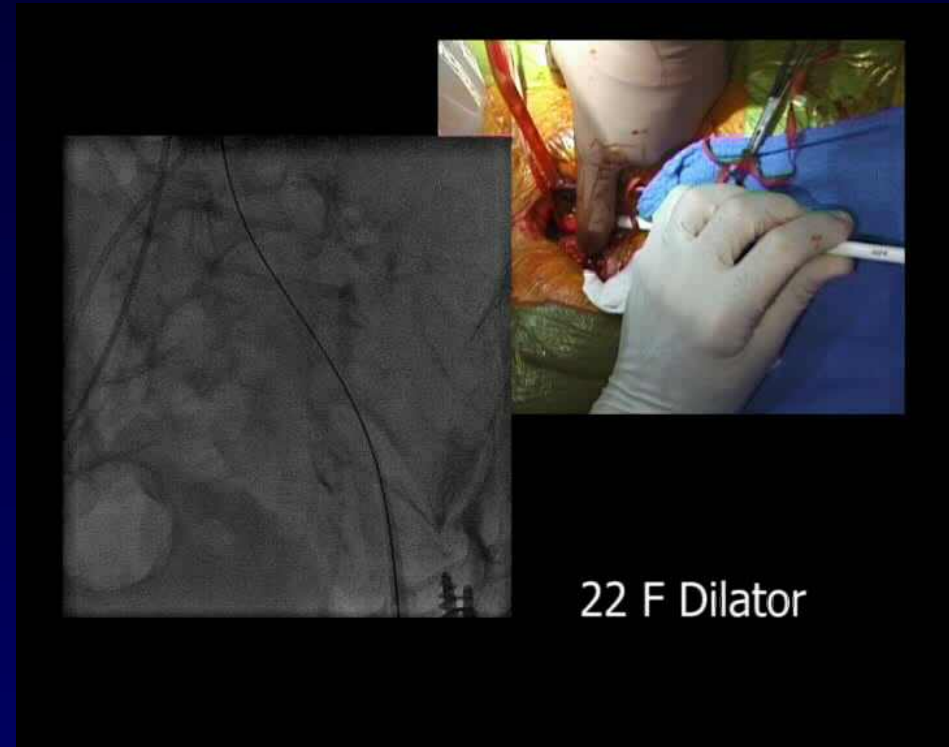
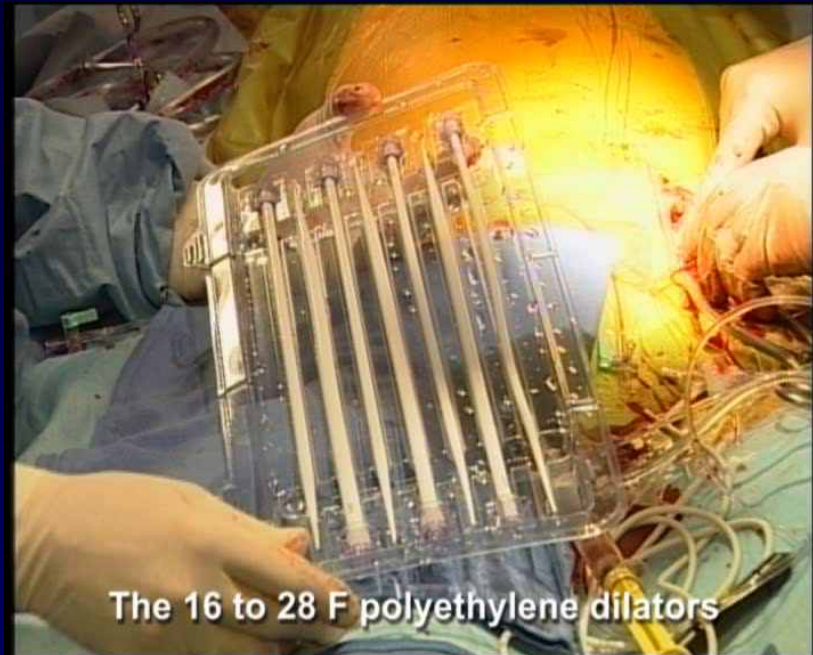
Helps stabilizing the balloon  
during inflation

# Balloon inflation with aortogram



Aortography during balloon inflation used to confirm the **optimal valve size** required and assesses **the risk of Left Main occlusion** by bulky calcified leaflet

# Edwards Polyethylene dilators



**16 to 25F dilators to dilate the arterial access**

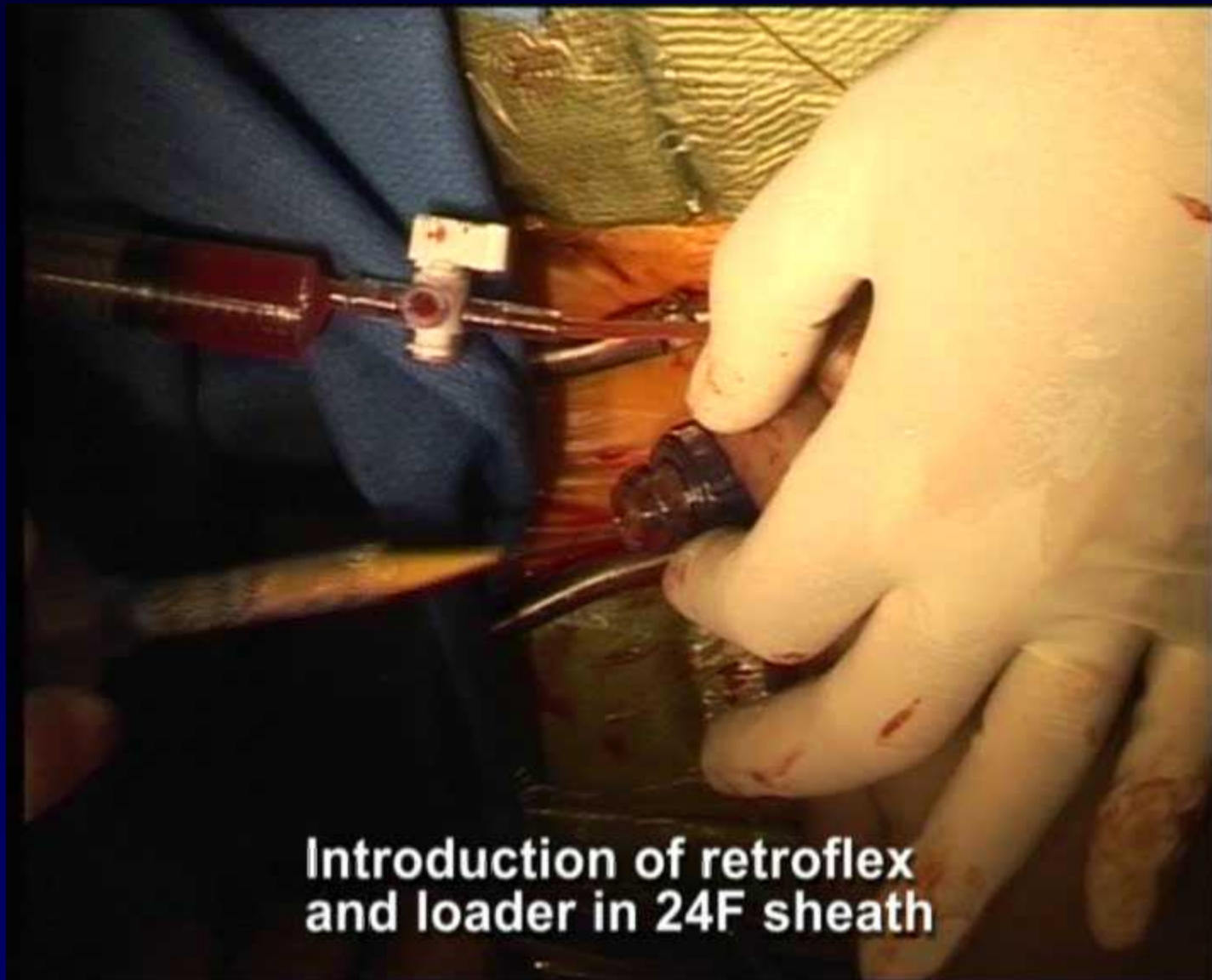


# The 22F Sheath

(a 24F sheath is required for the 26mm valve)



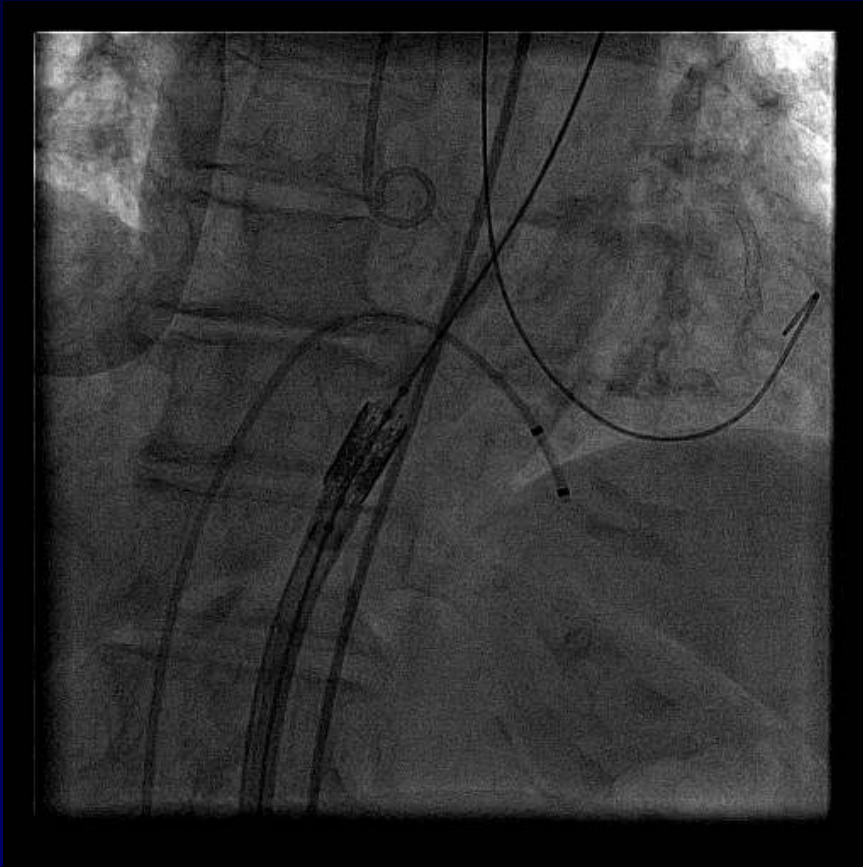
Catheterization of the LFA with the 22F sheath



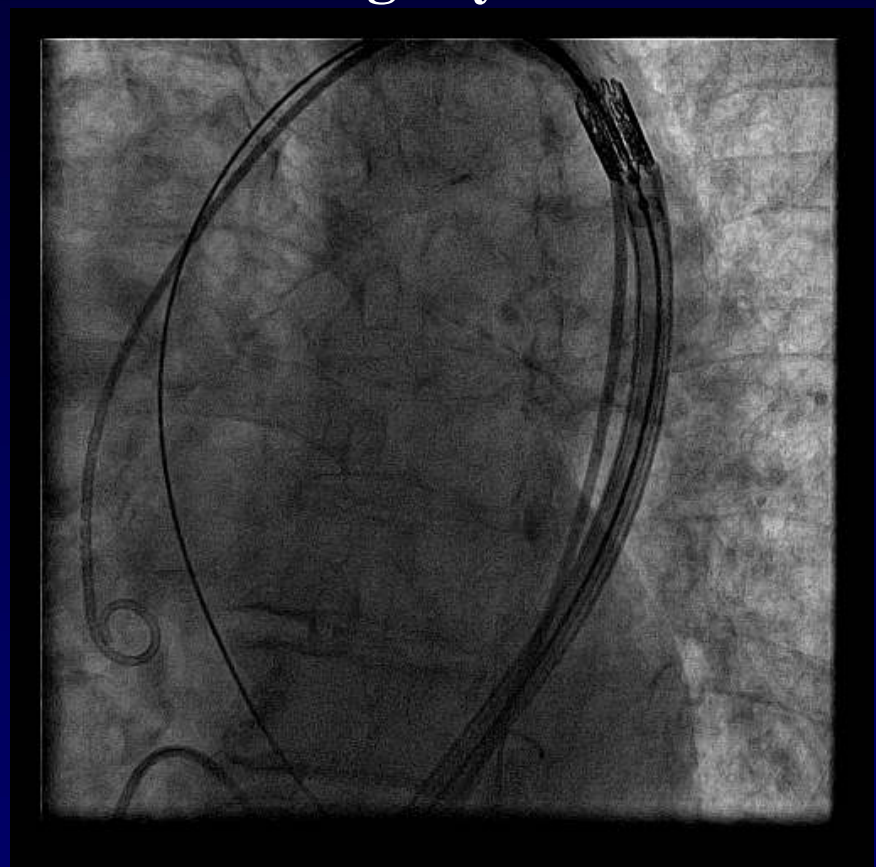
**Introduction of retroflex  
and loader in 24F sheath**

# THV advanced in aorta

RetroFlex slightly deflected



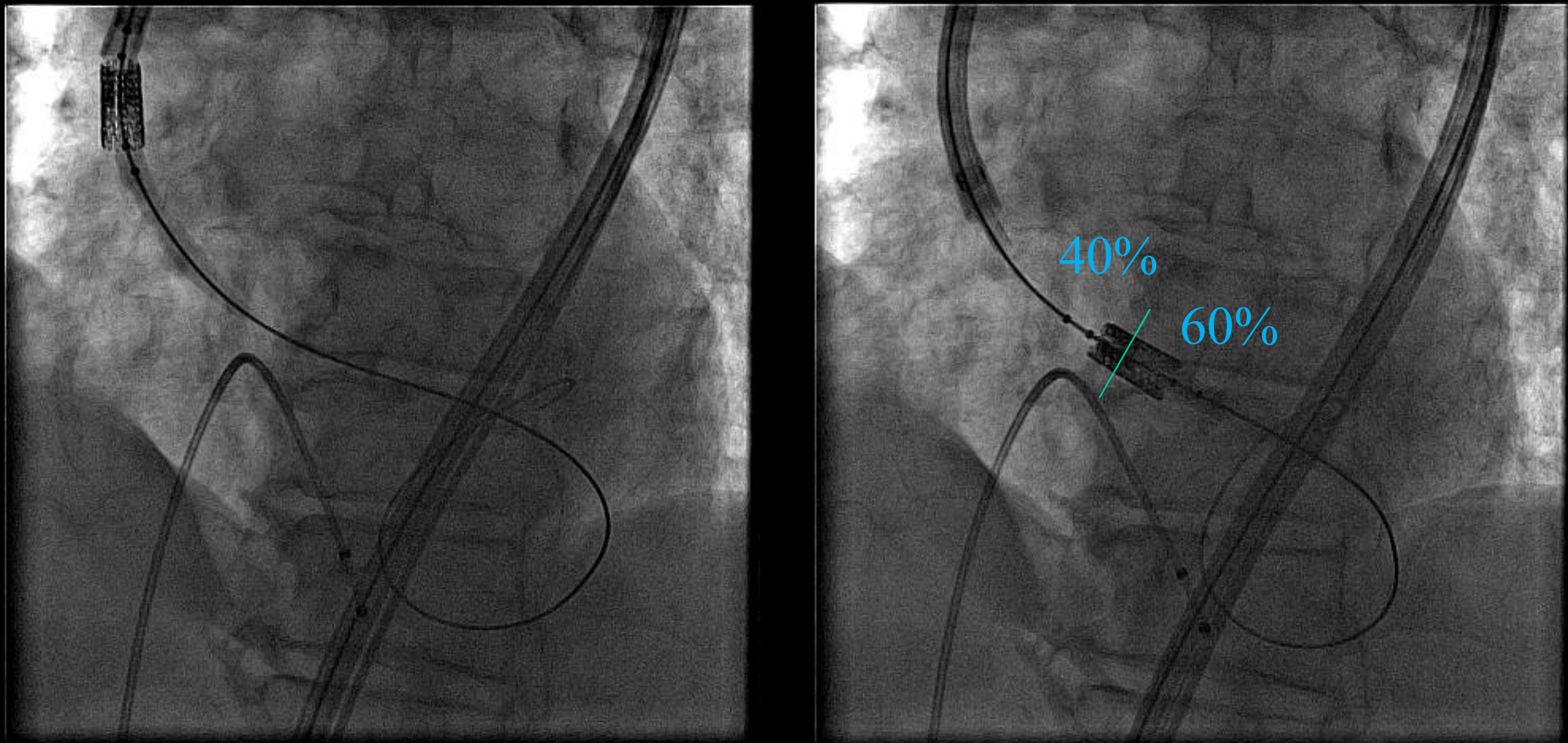
AP view



LAO view 40°



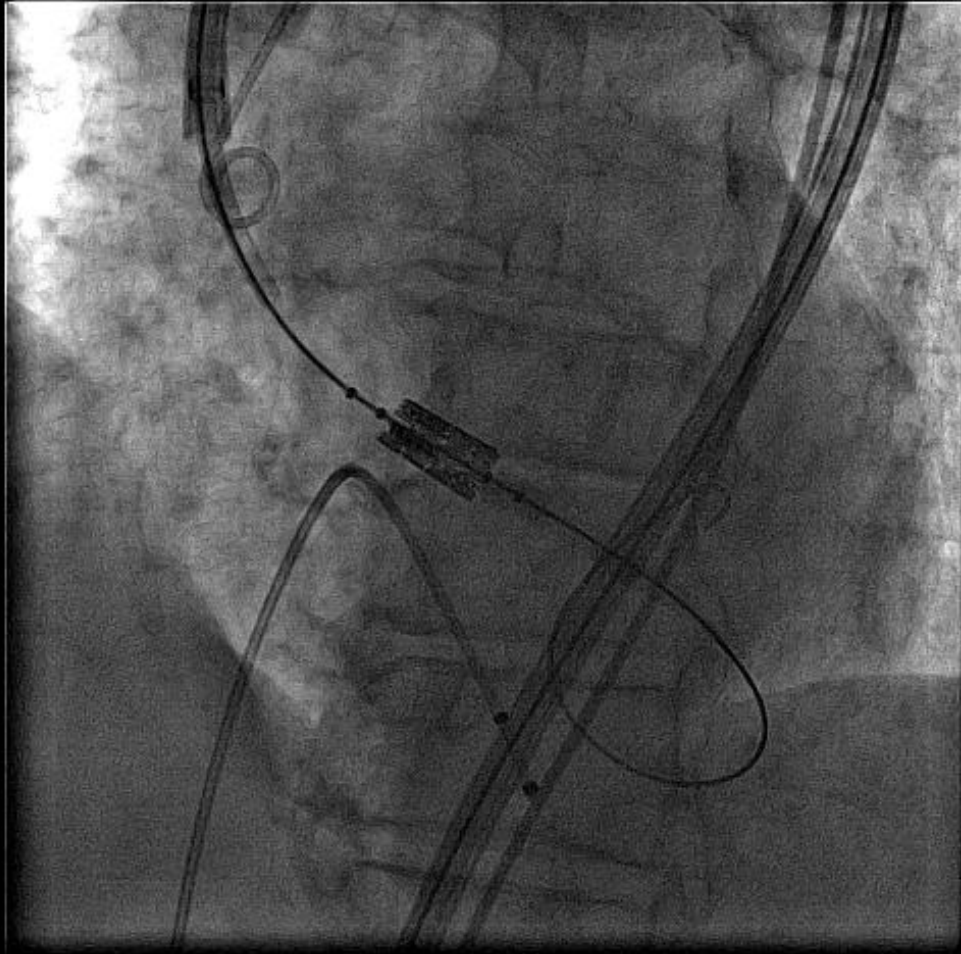
# Crossing the native valve and positioning



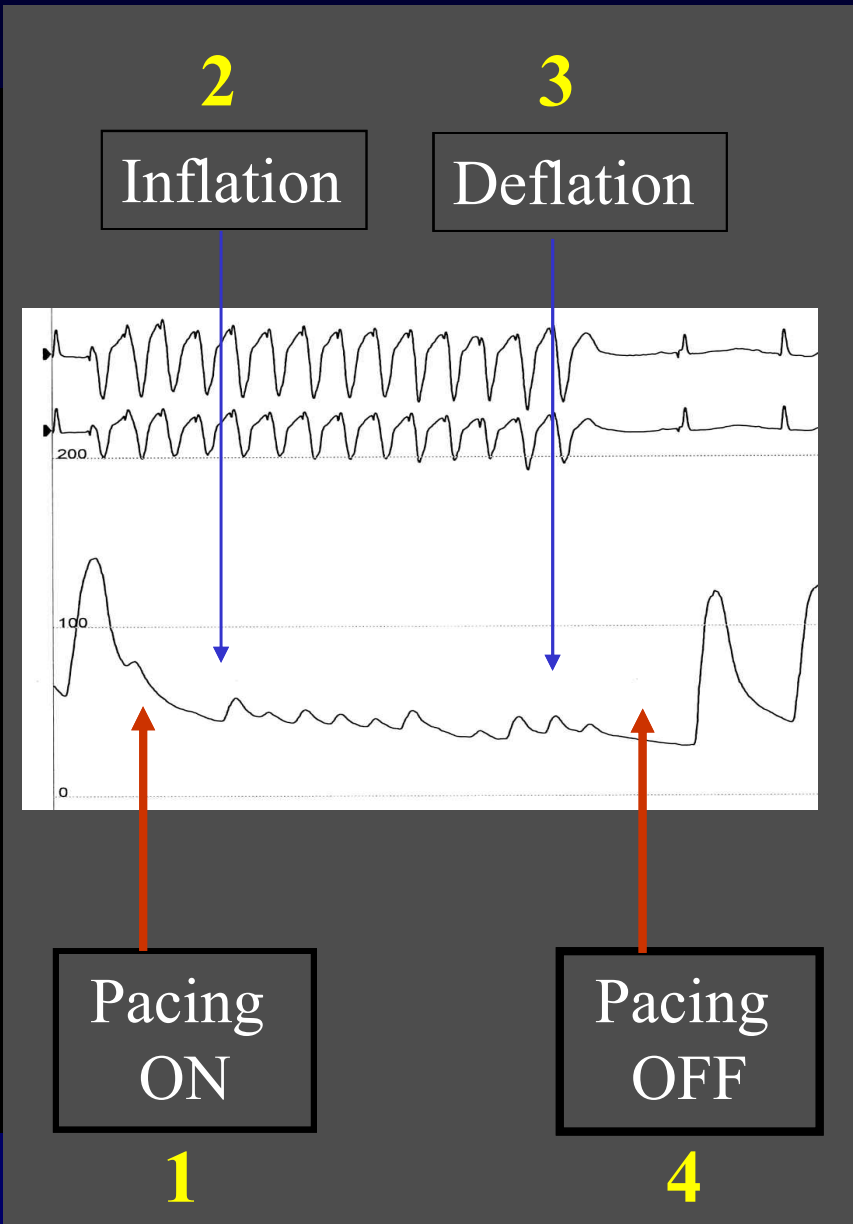
Reference view (LAO 10° / Cranial 10°)  
(aortic annulus seen perpendicular to screen)



# THV delivery under RVP

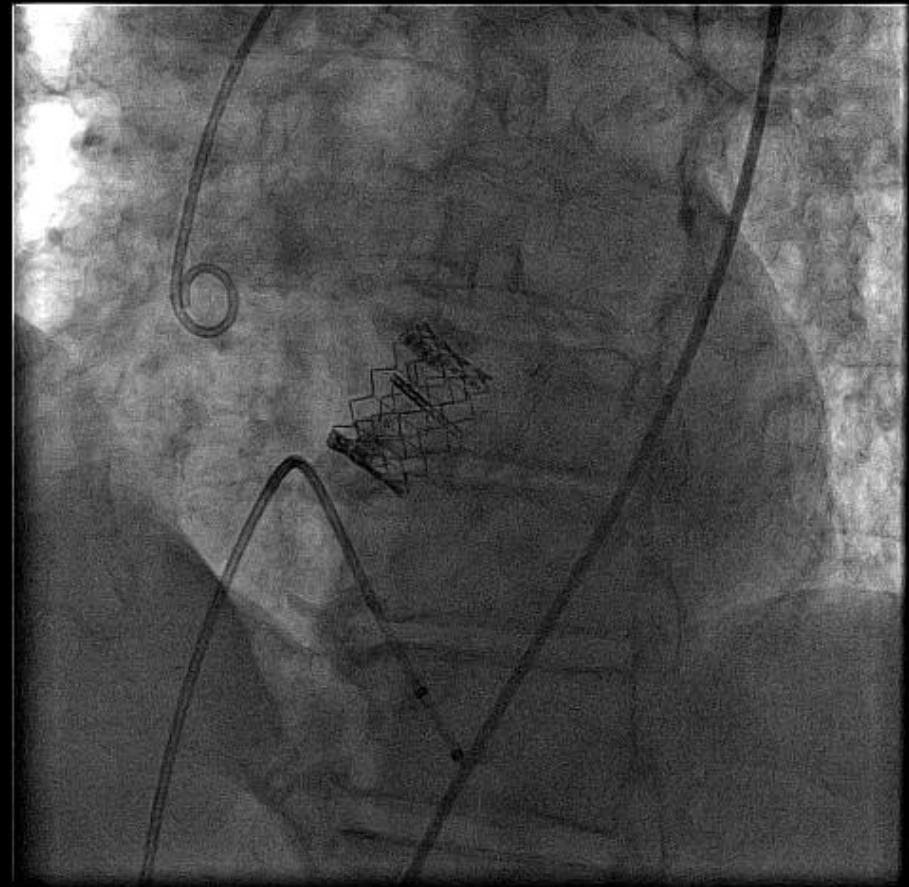
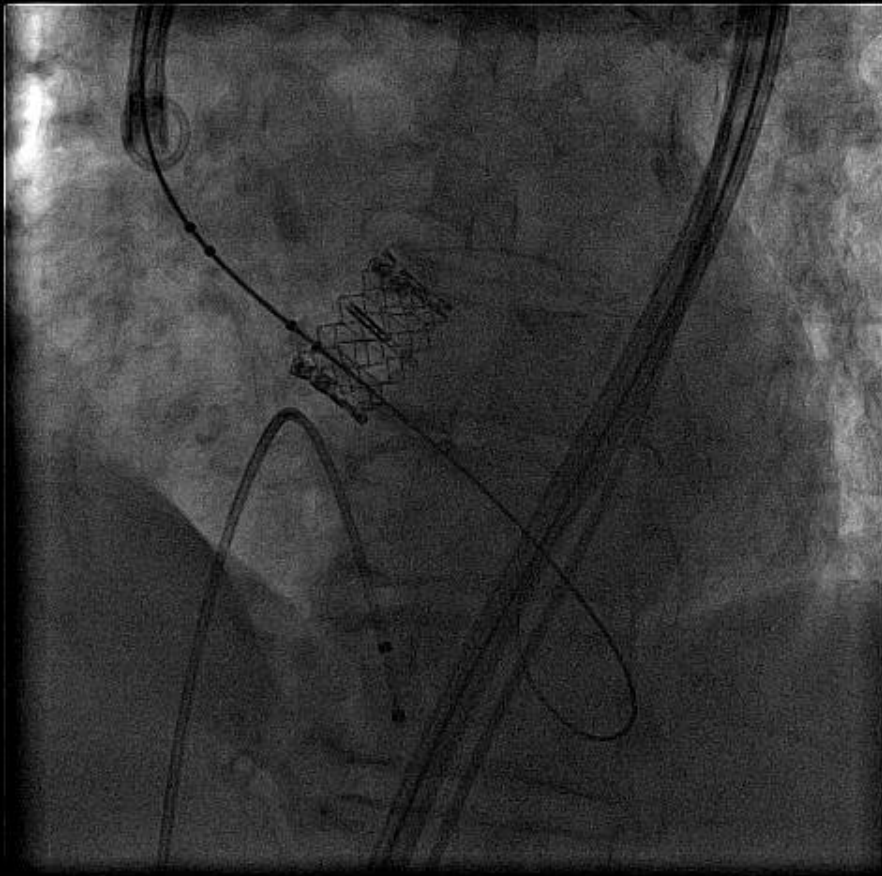


Full inflation maintained 3 sec



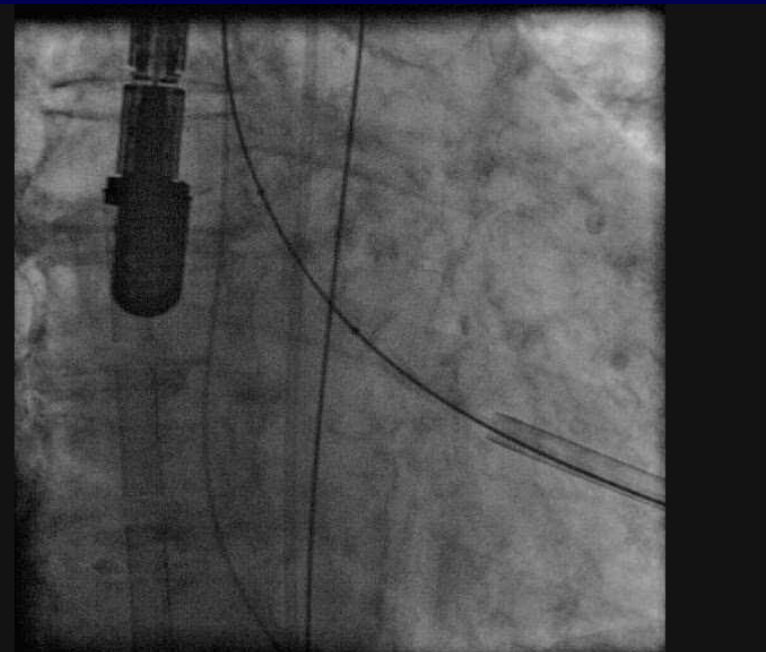
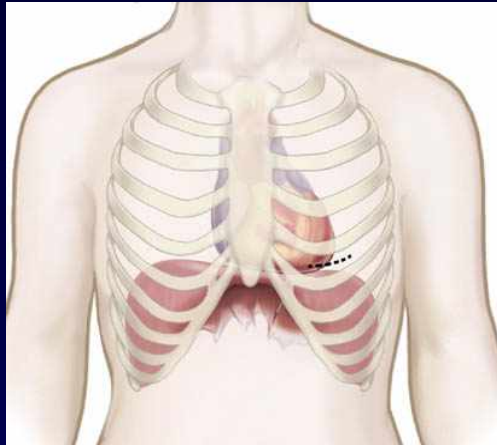
# **Retroflex straightened and retrieved**

## **Final angiographic control**



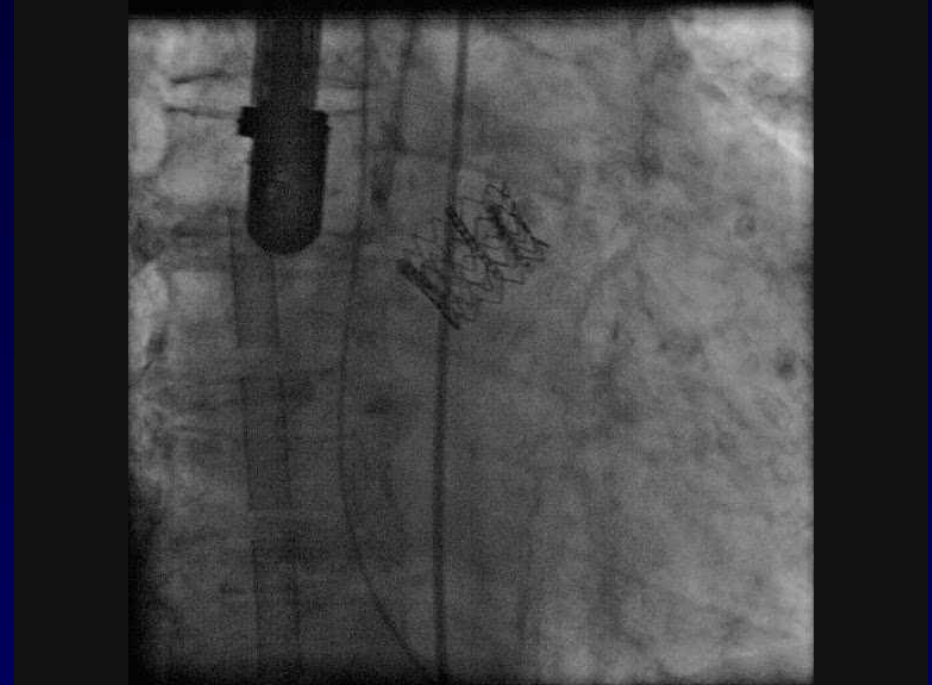
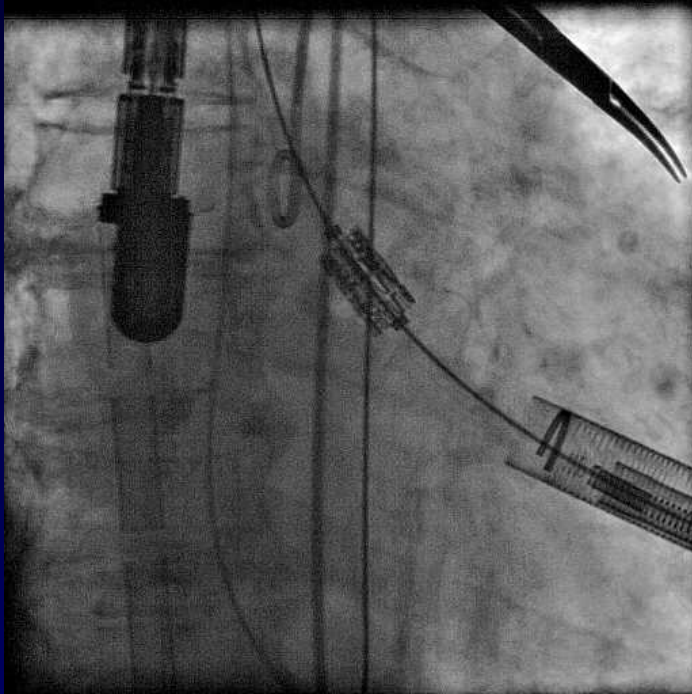
# TA Procedure: Edwards Sapien

## Chest opening, purse string and LV puncture

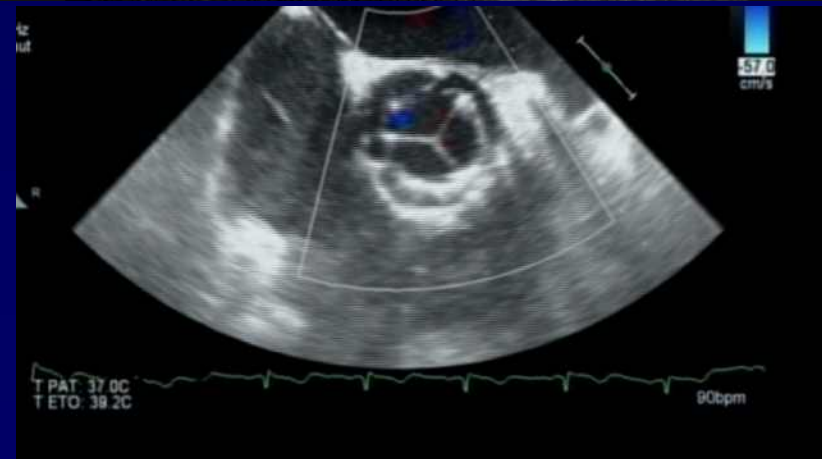




# TA Procedure: Edwards Sapien THV deployment and controls



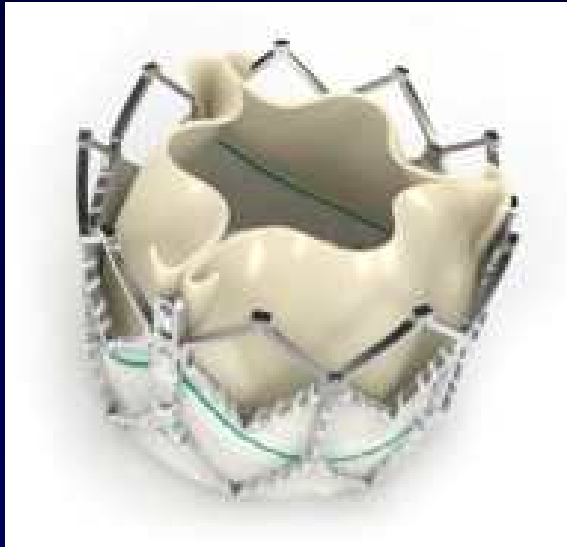
- Balloon inflated under RVP and kept inflated 5 sec
- Results assessed on aortography and TTE or TEE





# The future: is already there !

## EDWARD SAPIEN XT



- New Frame Design
  - Cobalt-chromium Material
- New Valve and Leaflet
- 23 and 26 mm valves
- 29 & 20mm to come

### Sheath size

18F: 23mm valve

19F: 26mm valve



**Percutaneous approach**  
**Local anesthesia**  
**Preclose technique (PROSTAR)**

# The future: is already there !

## EDWARD SAPIEN XT



THV delivery



Aortogram post-THV

# Conclusions

- Major technological advancements have been made over the last years, making TAVI procedure simpler, faster, safer, and more efficient
- In the next future, with the decreased sheath sizes, TAVI will be performed in 70 to 80% of the cases using the transfemoral approach, as a stent like procedure.
- Optimal training and proctoring for patients selection and procedure, and excellent partnership within the teams are crucial for the success of TAVI