

# Edwards Balloon Expandable Valve

## Updated techniques and current indication

TAVI Summit, Seoul, Korea, September 2<sup>nd</sup>, 2011



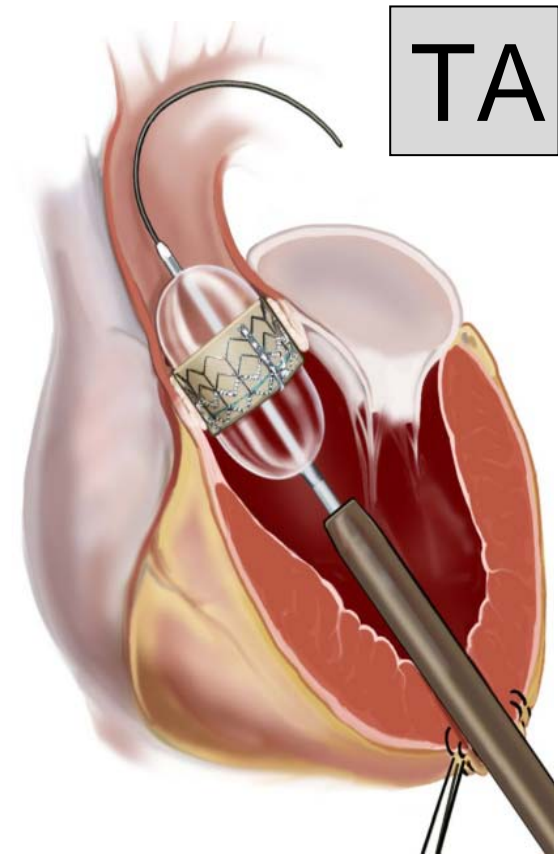
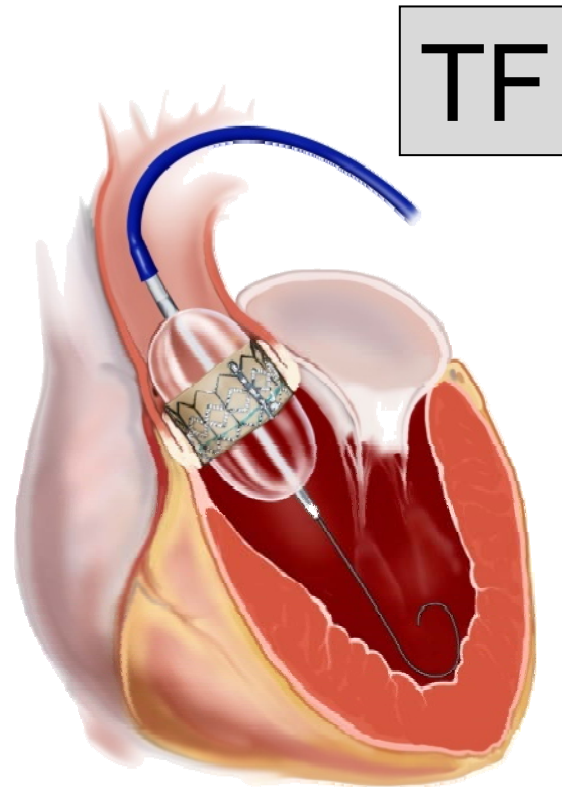
***Alain Cribier, MD***  
***University Hospital Charles Nicolle***  
**Rouen, France**

# Edwards Lifesciences since 2004

New valves, New delivery systems, New techniques



Bovine pericardium  
Anti-Ca Tfx  
Stainless steel frame  
External cuff



Edwards SAPIEN™ 23mm, 26mm



# Subsequent generations of balloon expandable valve

2000 (FIM 2002)

2003

2006

2009

Percutaneous Heart Valve

Cribier Edwards

Edwards Sapien

Sapien XT



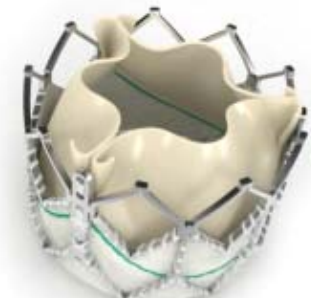
Bovine pericardium  
Stainl. steel frame  
23mm



Equine pericardium  
Stainl. steel frame  
23mm



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



Treated bovine peric.  
Cobalt Chrom. frame  
23, 26, 29mm (TA)  
20mm in evaluation

TF Introducers

24F

22F

22F, 24F

18F, 19F

# 2011: A new Transcatheter Heart Valve

## Edwards SAPIEN XT™ THV



**A Perimount Magna Valve  
within a short stent**

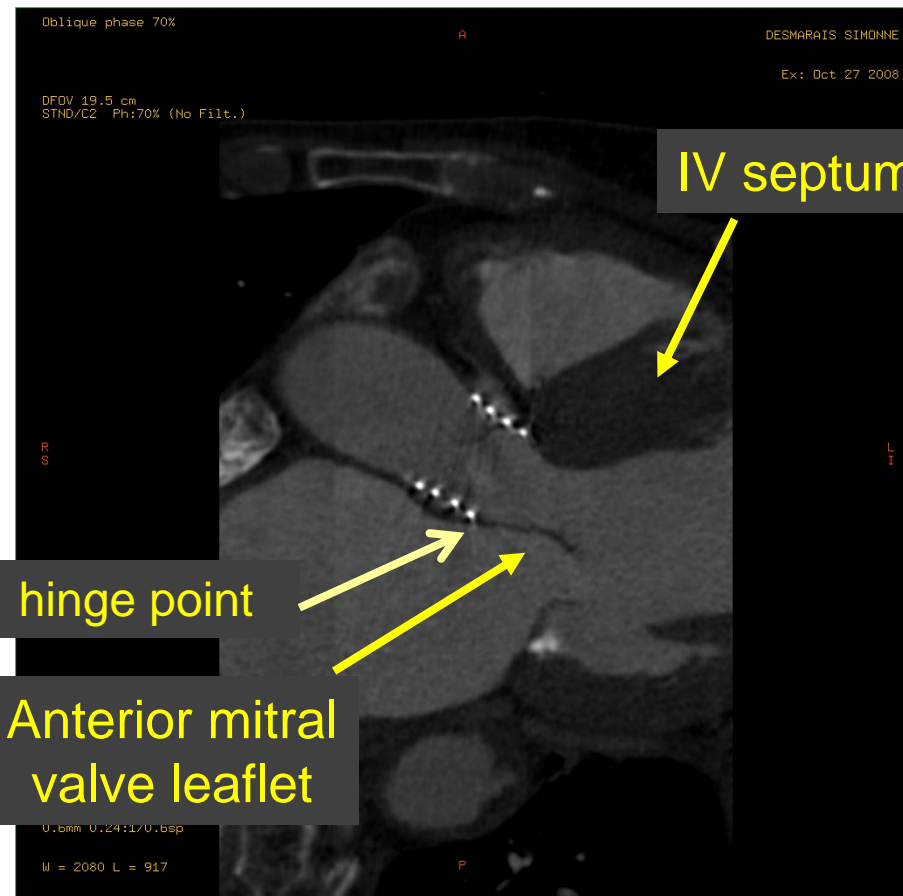
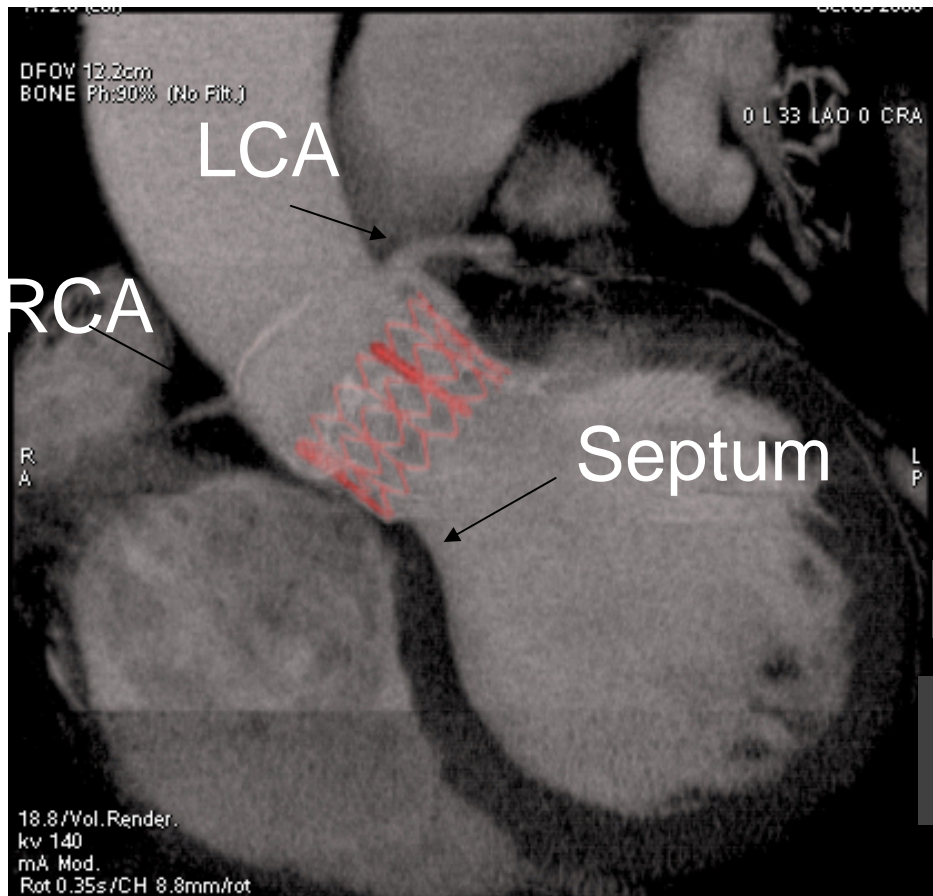
Comparison  
to Edwards

radial strength (>95%  
circular opening)

- Enhanced leaflet design
- Same high quality leaflet processing and manufacturing

# GOAL: Subcoronary implantation

## Respect of surrounding structures



**Minimal risk of coronary occlusion**  
**Free access to LM / RCA on long term**

**No MR on short and long term**  
**Pace-Makers required in < 10%**

# Transfemoral approach Improved delivery system

## RetroFlex 3 (Edwards Sapien)

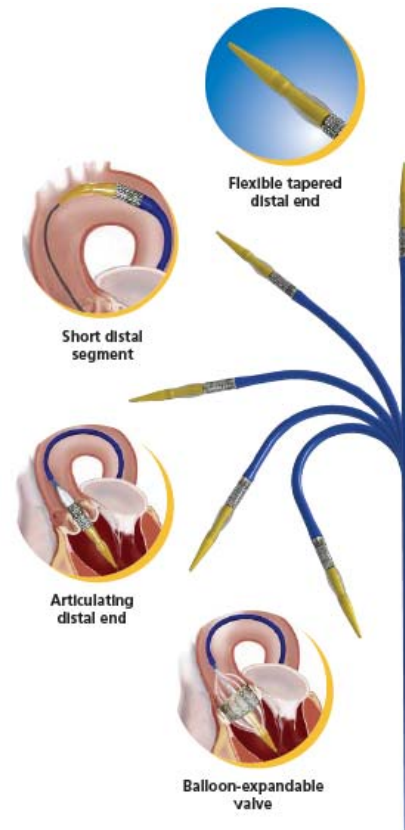


*Sheath size: 22F (23mm), 24F (26mm)*

### Stent like procedure

- Pure percutaneous approach
- Conscious sedation
- Decreased vascular complications
- Discharge at Day-3

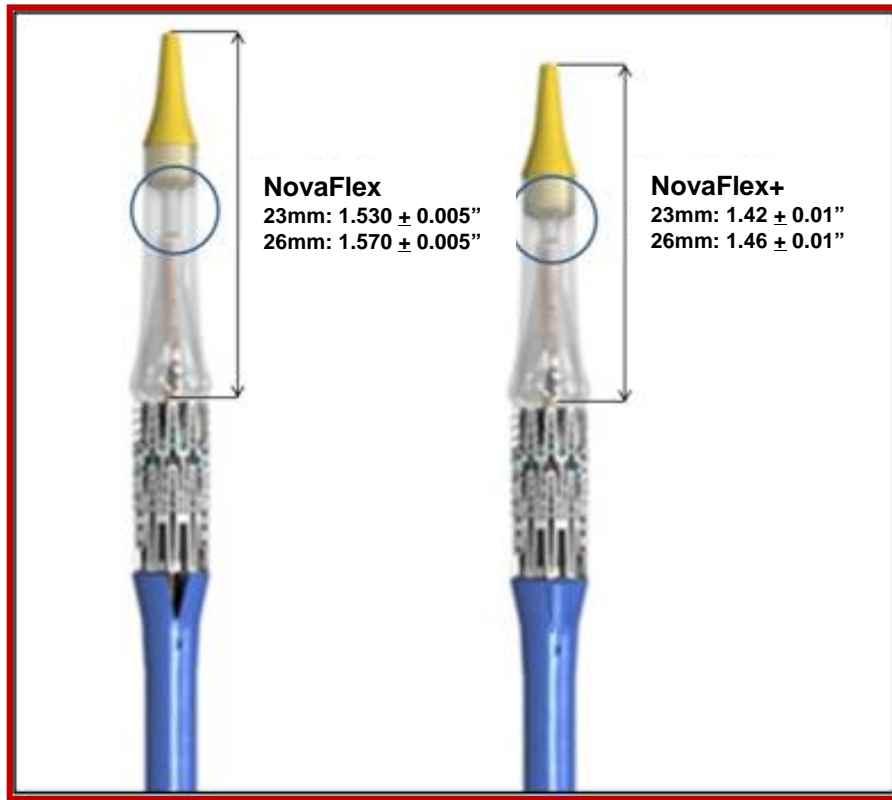
*Sheath size: 18F (23mm), 19F (26mm)*



**Articulated delivery system**

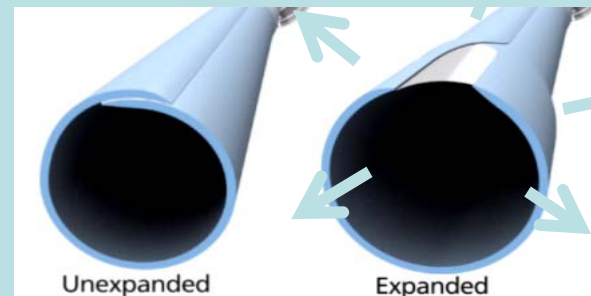
# 2011: New NovaFlex+ TF Delivery System

Shortened tip for reduced material in LV



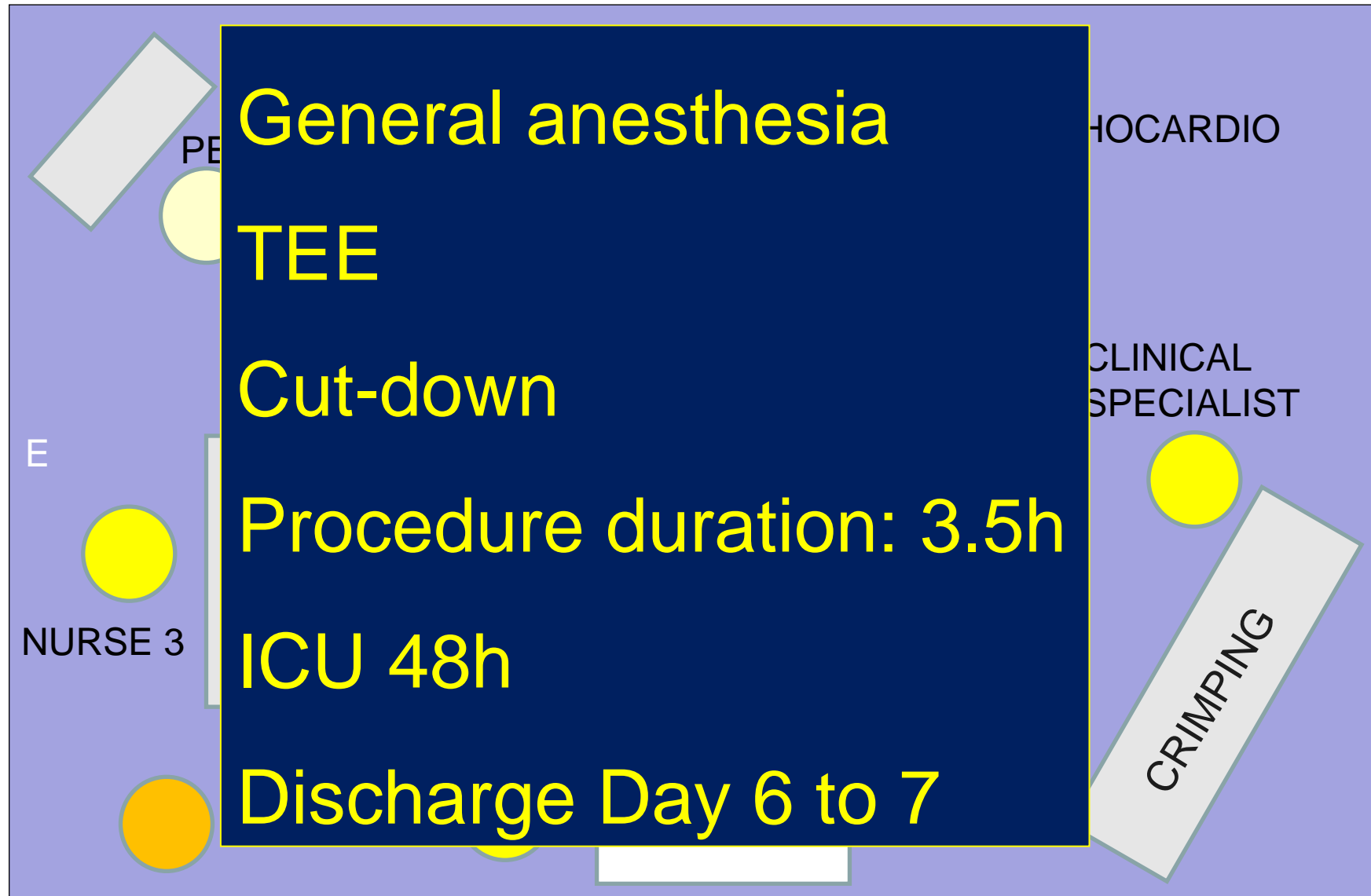
- Same innovative catheter tip, enhances ability to smoothly cross the native valve
- Now overall 3mm shorter

## New Edwards e-sheath



**16F /18F for 23mm and 26mm THV sizes**

# Room set-up: Edwards Sapien « Maximalist » environment





Oslo  
Dec 12nd, 2010  
Hybrid Room  
17 persons



# 2010: Room set-up: Edwards Sapien XT, TF

Local anesthesia

No TEE

Percutaneous approach

Preclosure (ProStar 10F)

Procedure duration: 45 min

ICU < 24h

Discharge Day 3

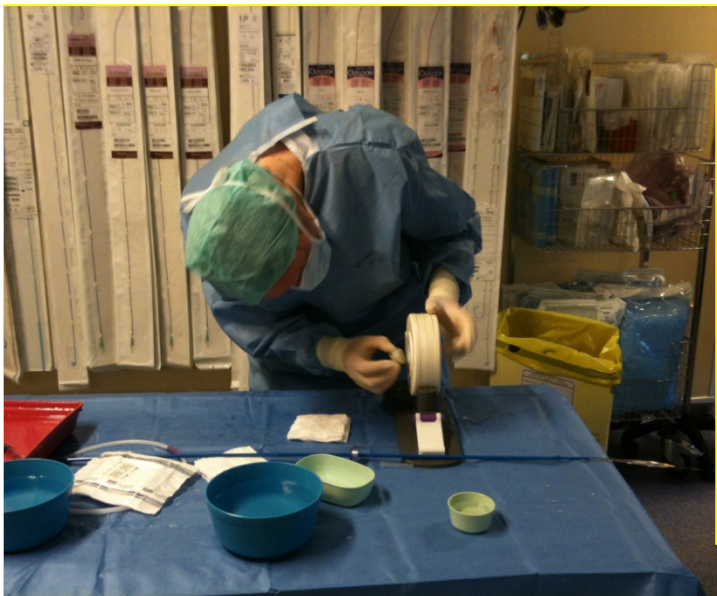
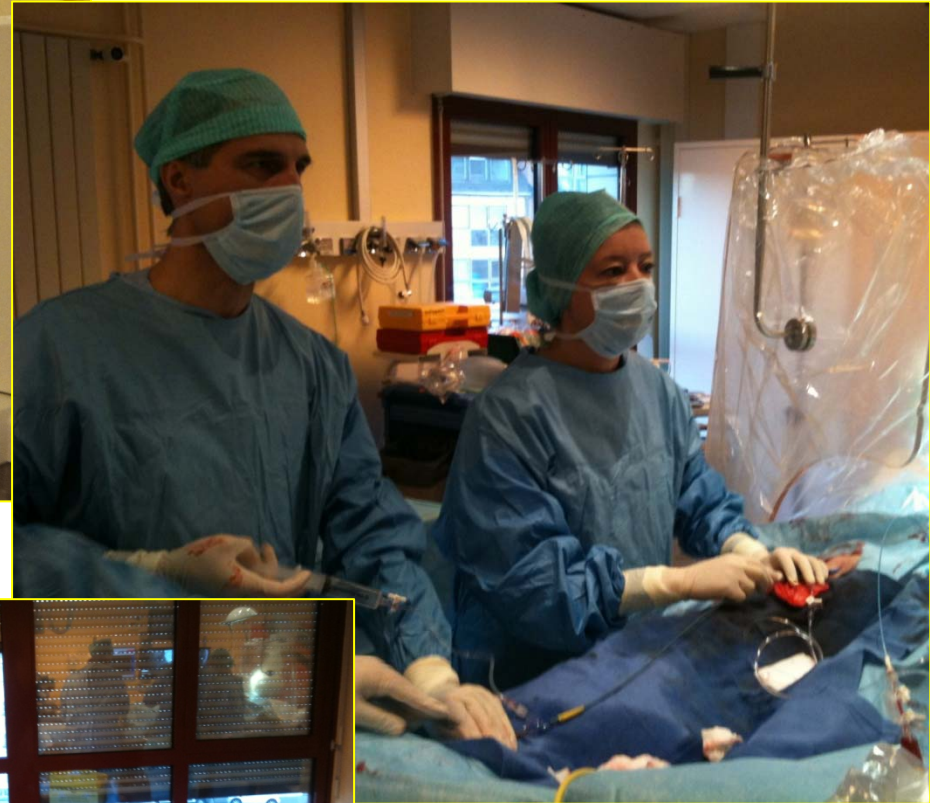
Echo

g 1

CRIMPING



# Rouen, since 2010 Cardiac Cath setting Limited team



Near by:  
Anesthetist  
Echocardiographer  
Cardiac surgeon



# Transfemoral approach: vascular access

- Surgical cut-down (access calcification)
- **Percutaneous in 95% of cases:**  
*Preclosing with Prostar 10F*

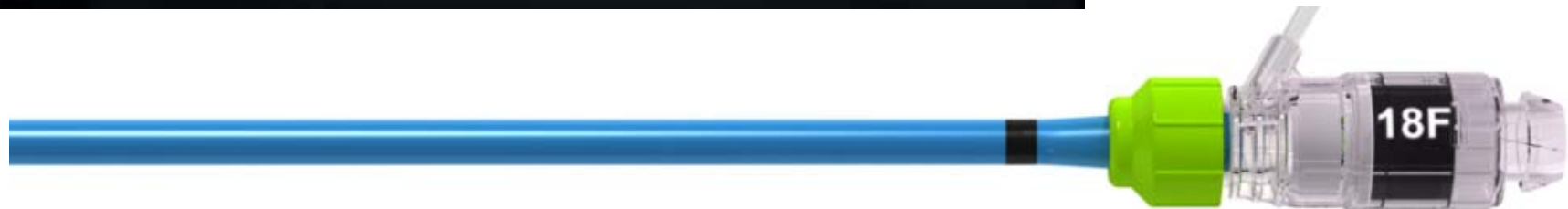




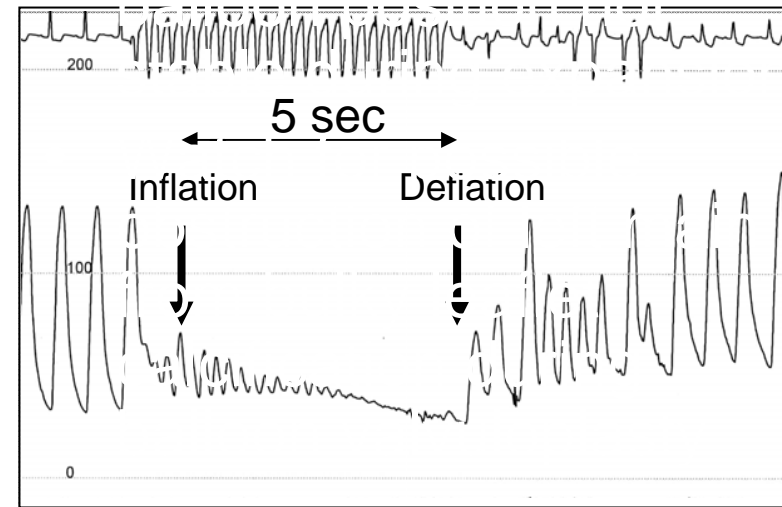
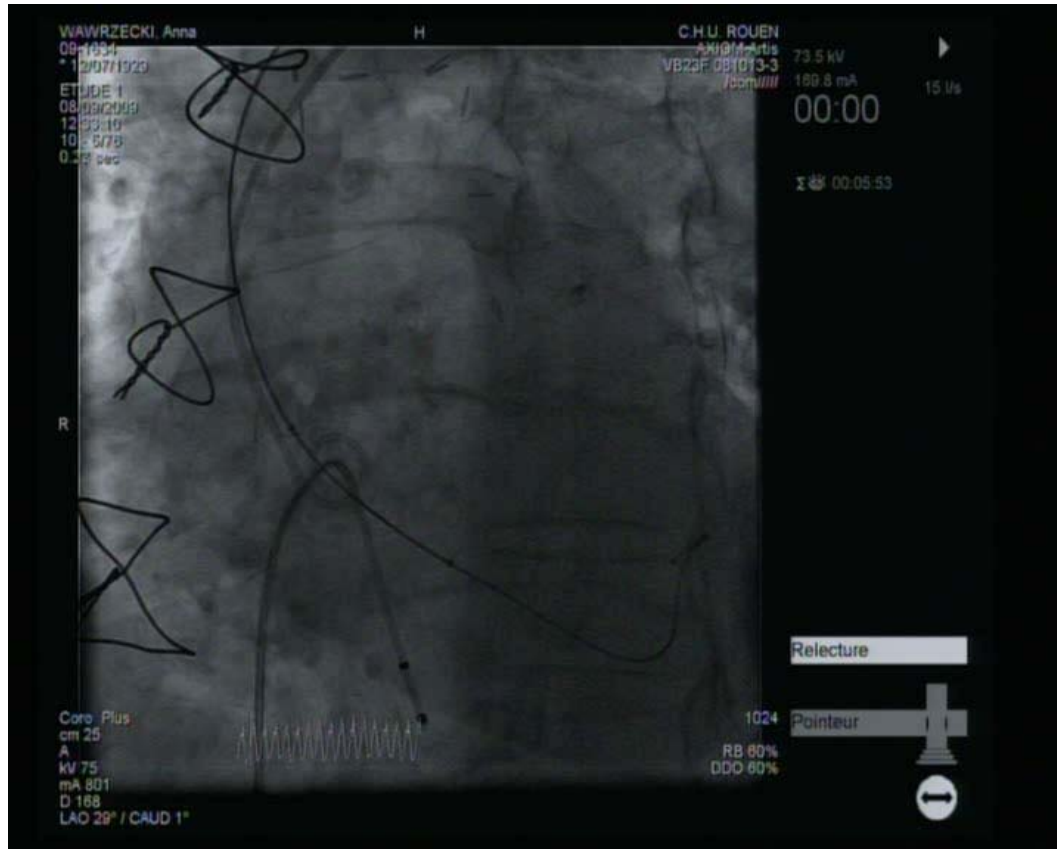
# Transfemoral approach Access Dilatation and Introducer Sheath



Edwards SAPIEN XT Valve	NovaFlex Sheath	Minimum Vessel Diameter	NovaFlex Sheath OD
23 mm	18F	6.0 mm	7.2 mm
26 mm	19F	6.5 mm	7.5 mm



# Transfemoral approach: Balloon valvuloplasty

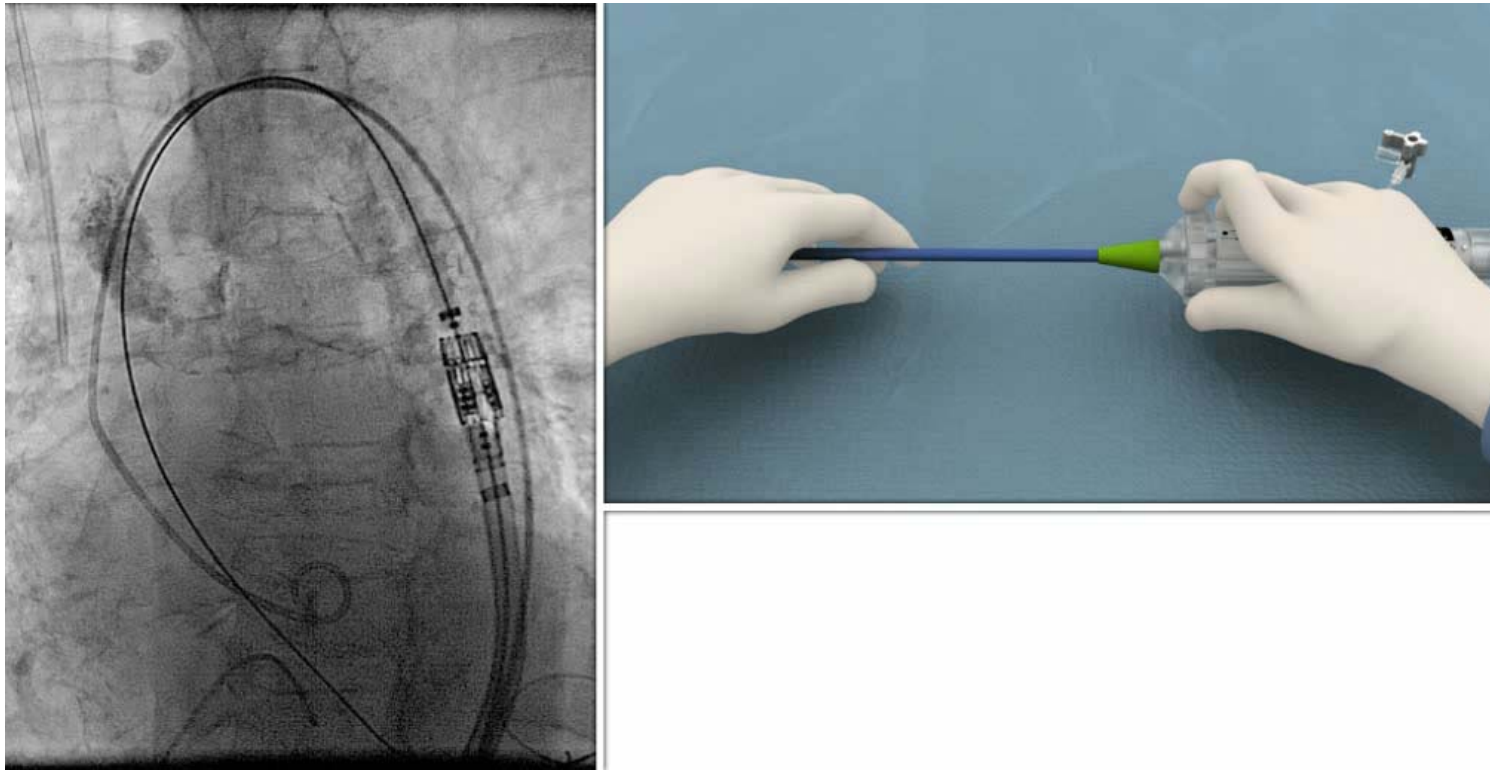


Aortogram during  
valvuloplasty

- 20 mm size for the 23mm XT valve
- 23 mm size for 26mm XT valve

- Balloon inflation during RVP

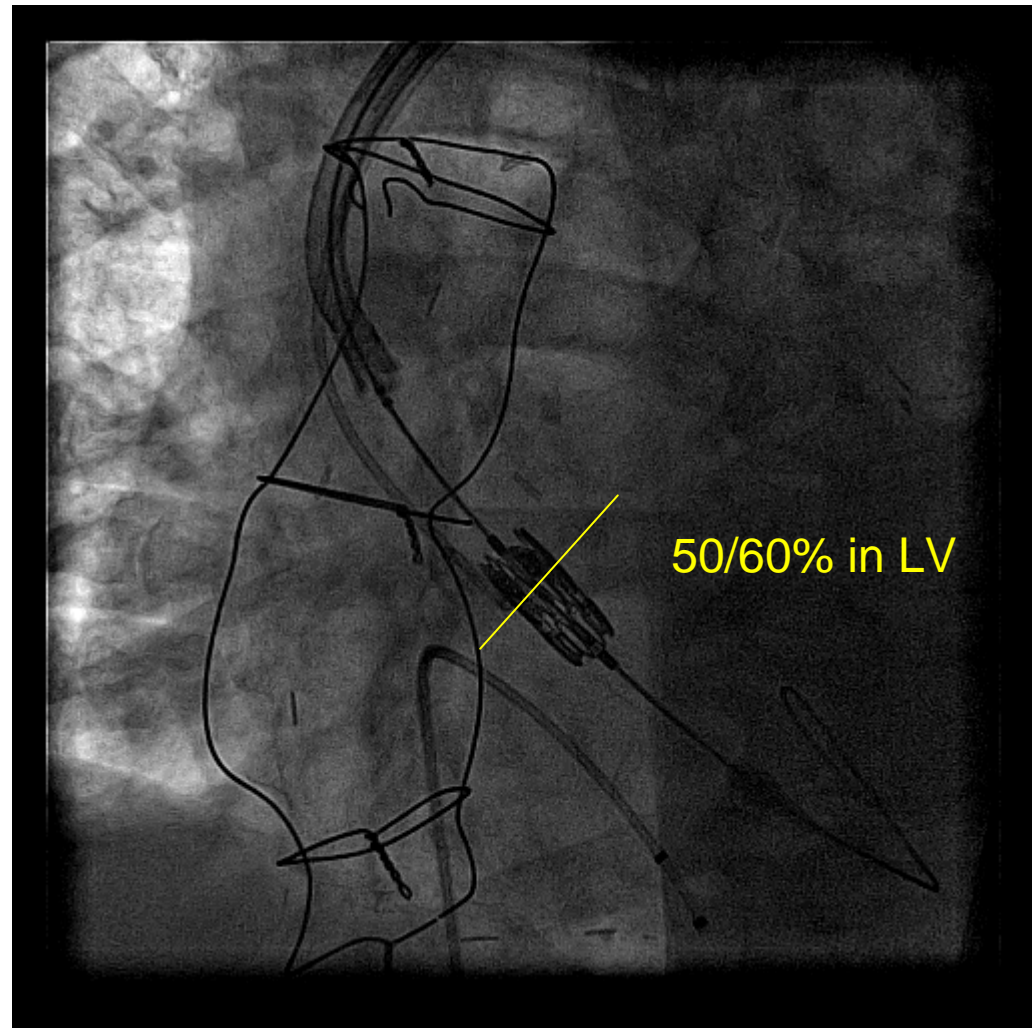
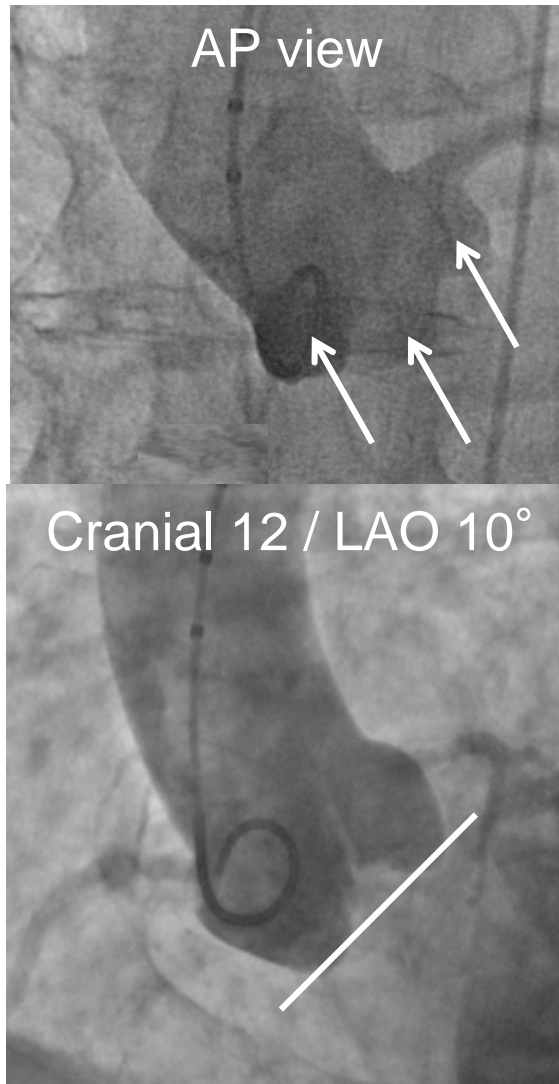
# Transfemoral approach: Tracking Over Aortic Arch



Use LAO 30 to 40 to provide  
view of aortic arch

Three rotations of the Flex  
wheel for full flex

# Transfemoral approach: THV positioning





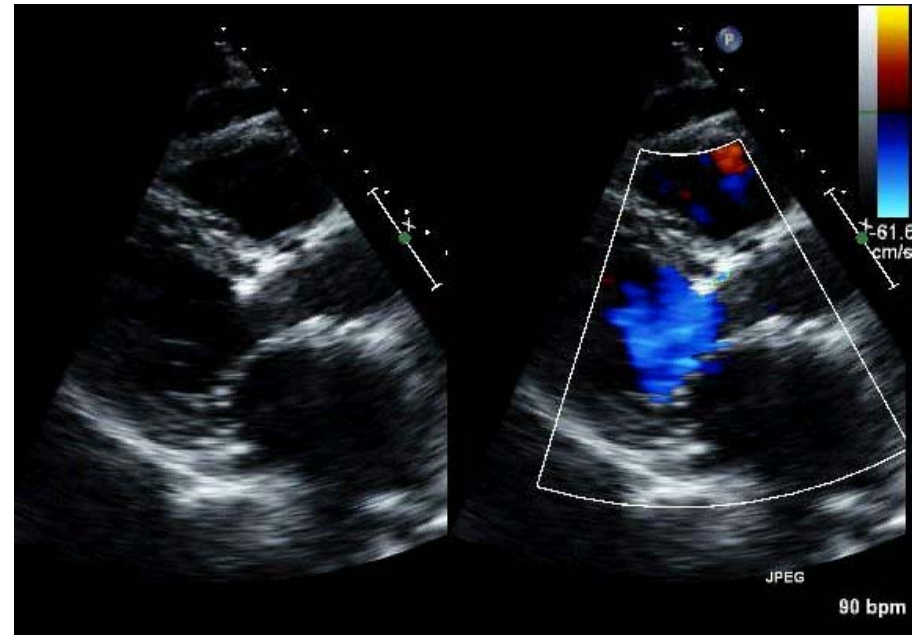
# Transfemoral approach: Valve delivery

- Sheath at the level of the double marker on novaflex (stability)
- Holding the balloon fully inflated **5 sec**

- 1: Stimulation on
- 2: Balloon inflation
- 3: Balloon deflation
- 4: Stimulation off



# Assessing Aortic Regurgitation Angiography, TTE/TEE



# 2011: Transapical approach Improved delivery system



SAPIEN XT Transcatheter Heart Valve



Ascendra2 System



Ascendra2 Introducer Sheath Set



Ascendra Balloon Aortic  
Valvuloplasty Catheter



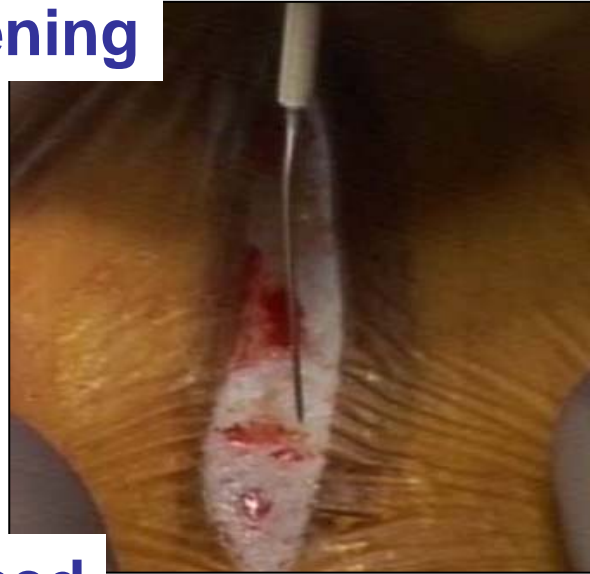
Crimper



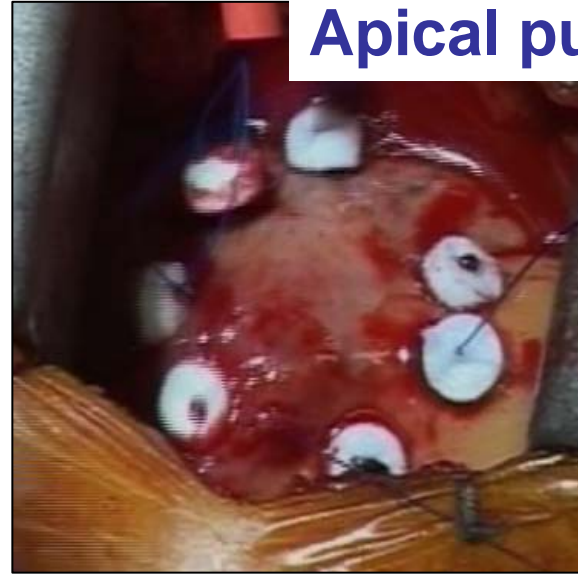
Atrion QL2530 Inflation Device

# Transapical approach: first steps

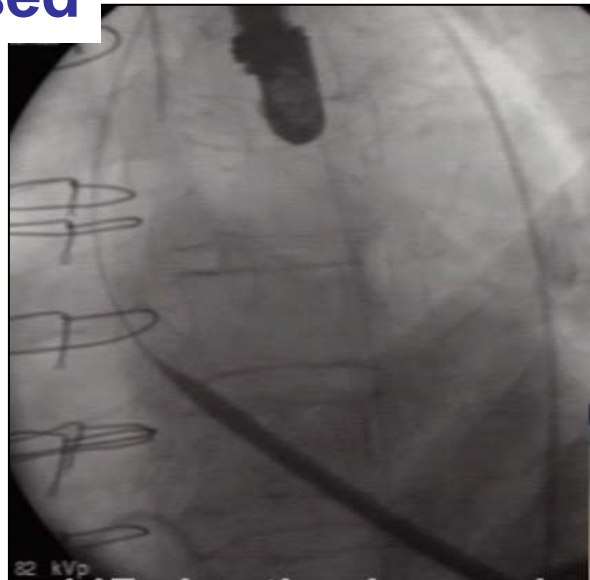
Chest opening



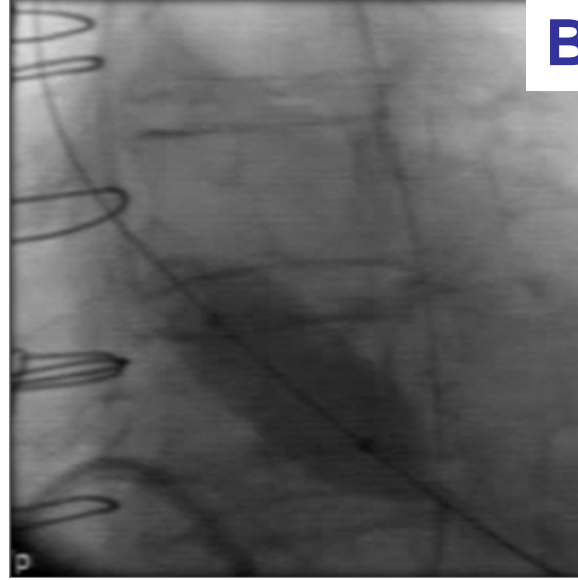
Apical pursestring



Valve crossed

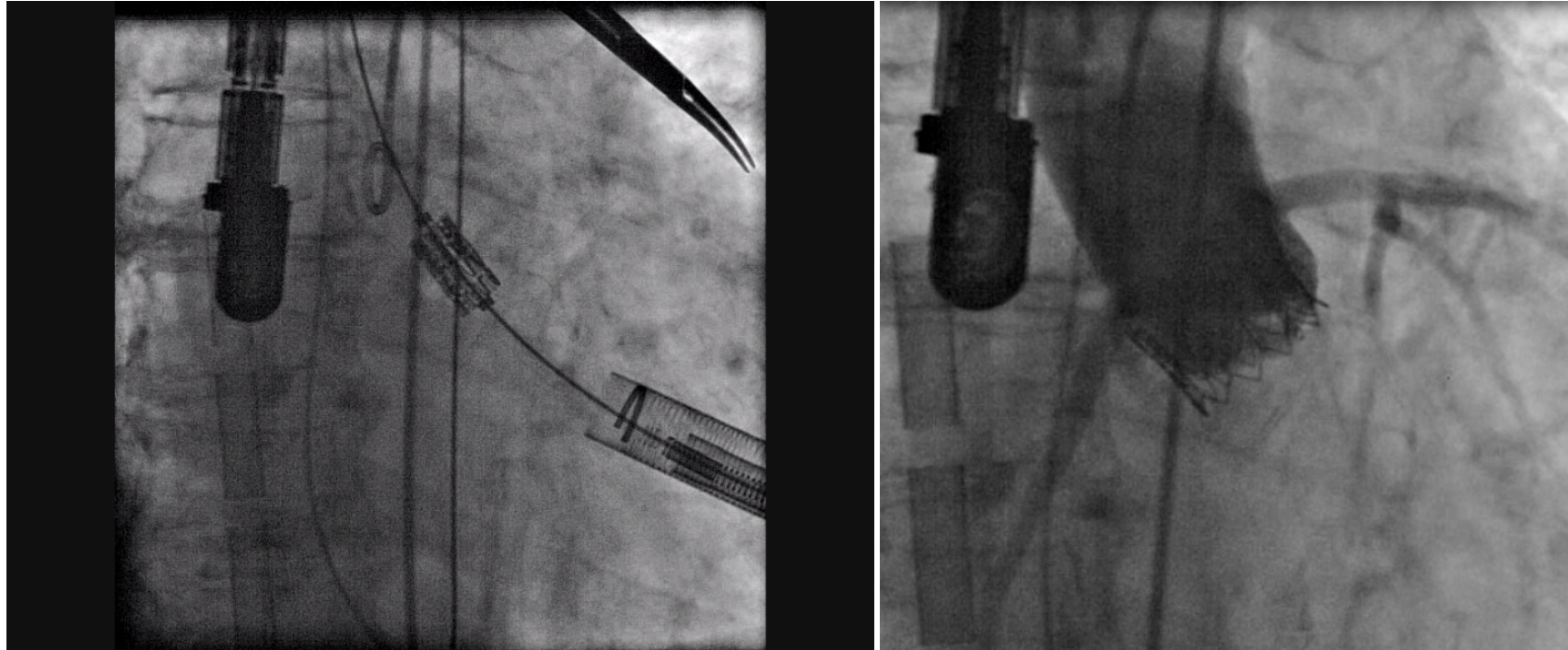


BAV





# Transapical approach: THV positioning and delivery

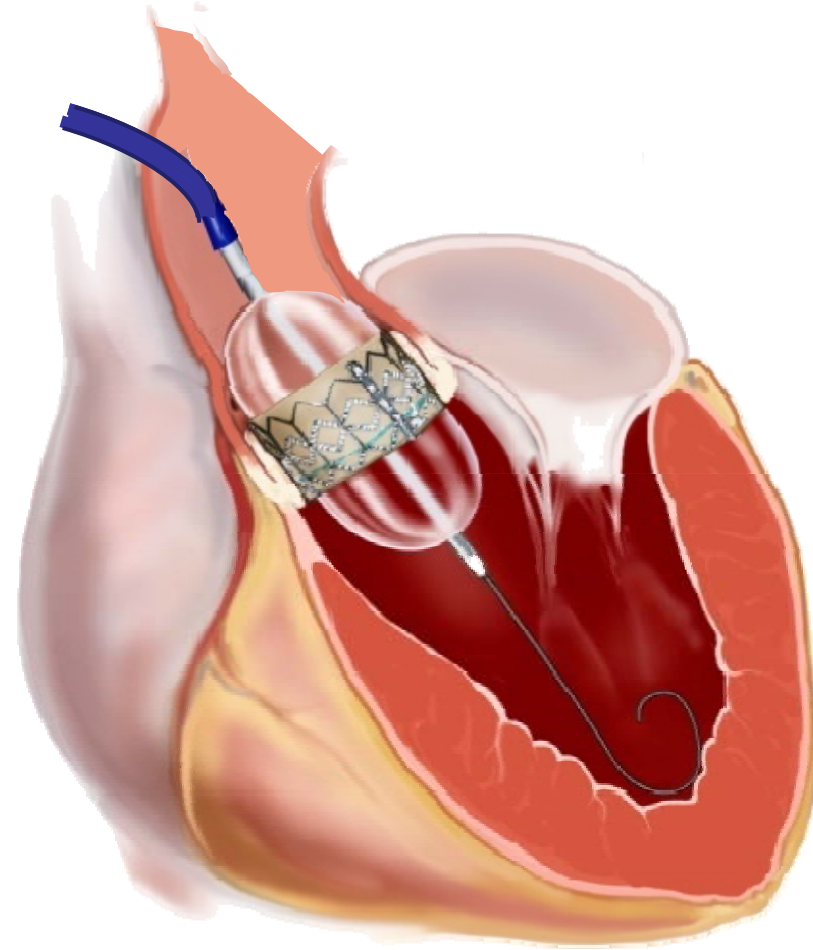


Same as for TF approach

# 2011: Trans-aortic approach

A new promising approach under investigation:

- Less invasive
- Easier technique
- No injury to LV
- Decreased risk of bleeding & infection
- Faster recovery
- Less pain
- No secondary pleural effusion



# Objectives of TAVI

1- Successful procedure

2- No complication

3- Short hospital stay

4- Rapid rehabilitation

5- Improved symptoms and quality of life

6- Improved survival

**Optimal patient selection is crucial**

# **Ideal candidate for TAVI**

## **3 questions**

### **1- Clinical evaluation**

Will the patient benefit from TAVI ?

### **2- Is the anatomy suitable?**

(Need to decrease the risk of complications)

### **3- What is the safest approach?**

Transfemoral ? Transapical (or Transaortic?)



# In 2011, candidates for TAVI remain inoperable and high risk patients with severe/symptomatic AS

## ➤ High surgical risk:

– Logistic Euroscore > 15%

– STS score > 10%

## ➤ Contraindications to AVR

– Anemia

(consensus of Heart Team)

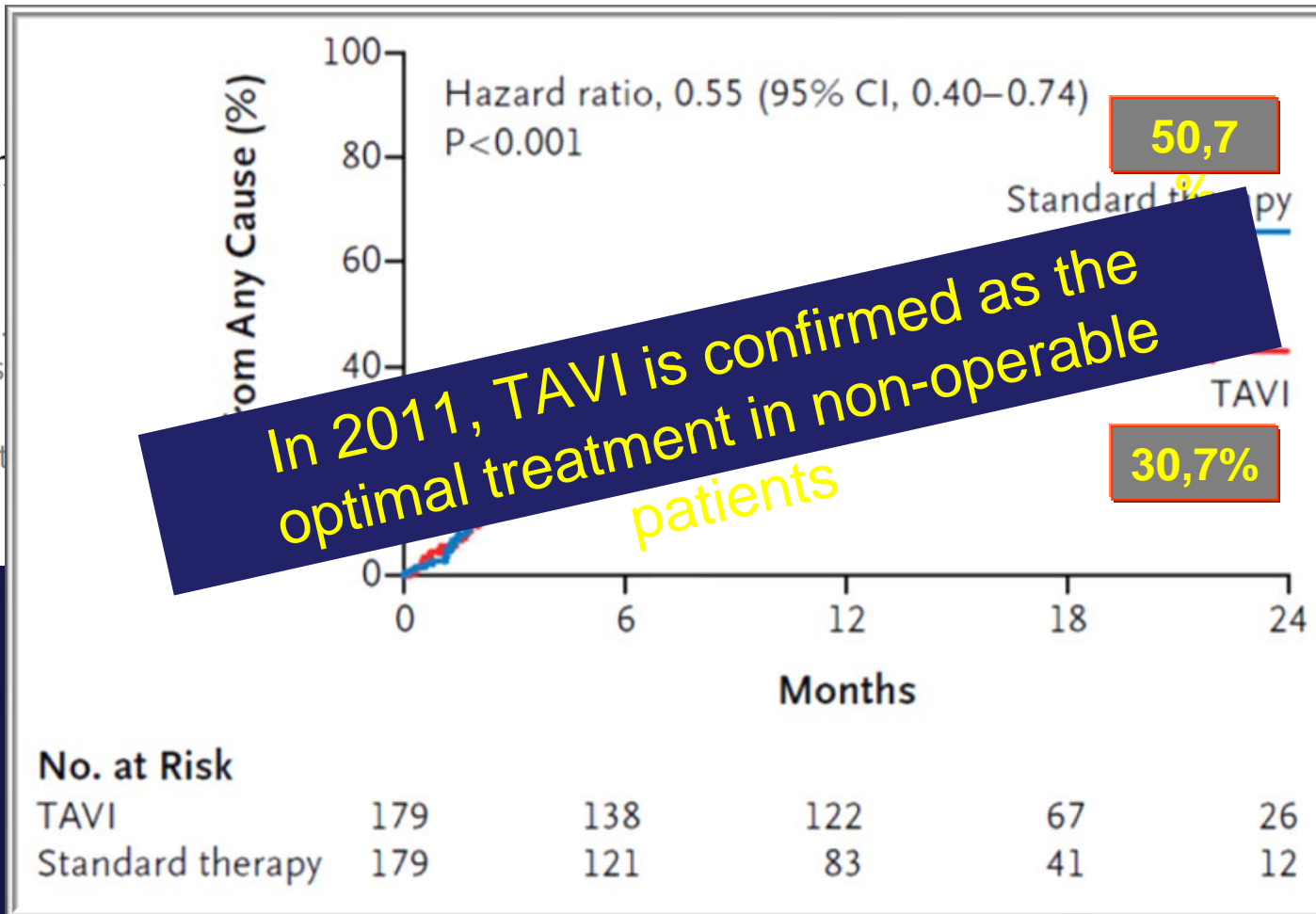
**In 2011, age « per se » and refusal of AVR do not constitute indications of TAVI**

# The NEW ENGLAND JOURNAL of MEDICINE

Tran

Martin B.  
Lars

August

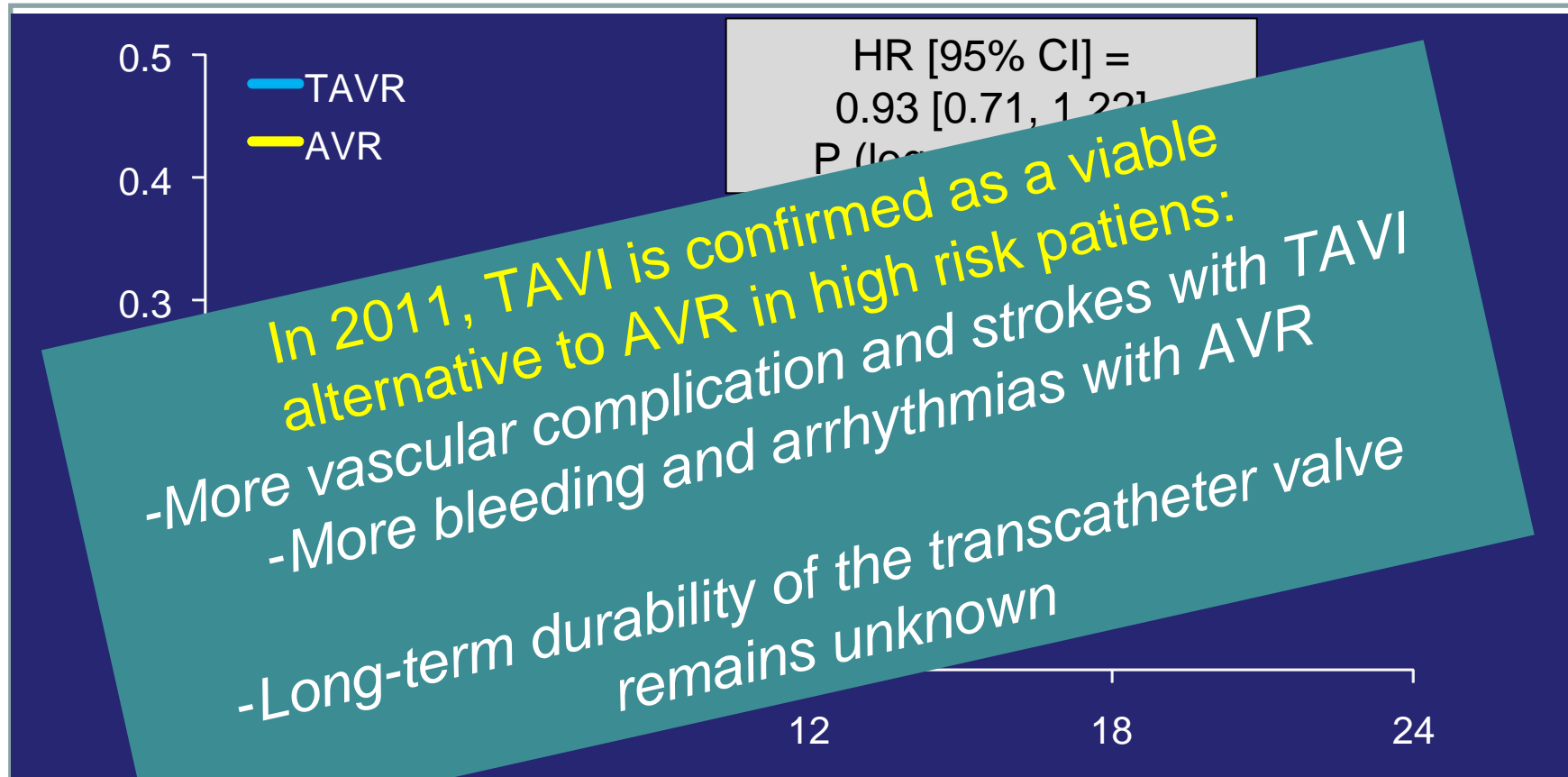


stenosis

Moses, M.D.,  
na, M.D.,  
D.,  
glas, M.D.,  
D.,

# PARTNER Cohort A: High Risk patients

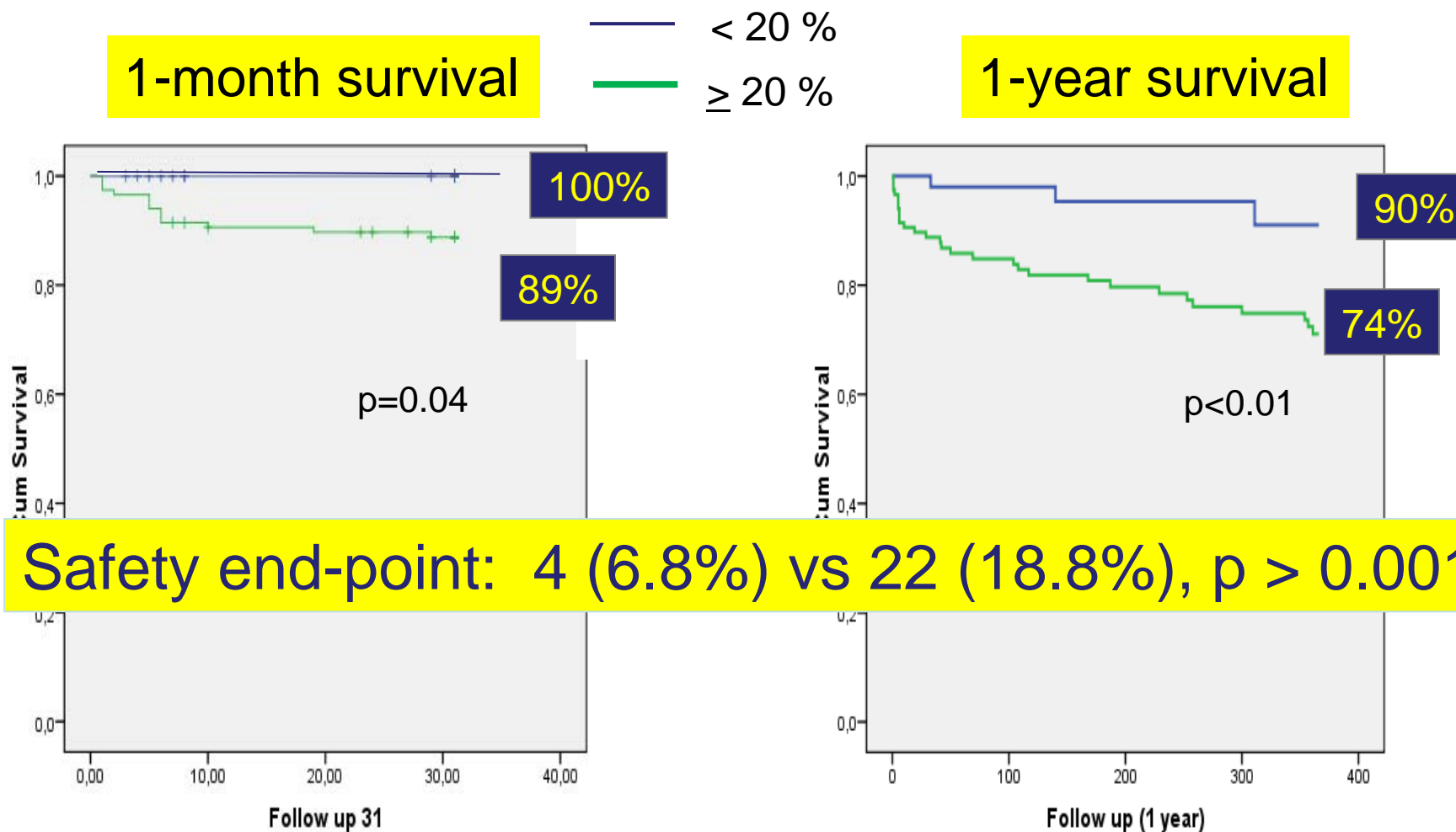
ACC 2011



# Low Score in non operable pts vs High Score

EuroSCORE < 20 (n= 60) vs  $\geq 20$  (n= 117)

Rouen series (ACC / ESC 2011)





# Difficult decision in borderline cases

- Alteration of cognitive functions
- Depressed LV function
- Low gradient
- Bulging septum



Think about « TEST »  
balloon aortic dilatation  
and +/- staged TAVI

# Screening process is crucial

➤ Are the native valve and LV suitable for THV?

- **Echocardiography: TTE ± TEE**

➤ How are: 1- **the coronary arteries:**

Coronary Arteriography

2- **the aortic root:**

Aortogram

3- **the femoro-iliac access:**

Abdominal Aortogram

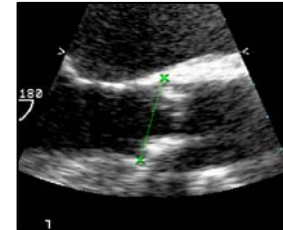
CT-Scan

CT-Scan ?

CT-Scan

CT-Scan

# Close cooperation of team specialists in valve disease



Radiologist

Echocardiographer

Anesthesiologist

Successful TAVI

Nurses  
Technicians



Cardiac surgeon

Geriatrician

Cardiologist



# Conclusions

- Over the last years, devices and procedures have been steadily improving and continue to improve, making TAVI simpler, safer and more efficient. With lower sheath sizes, « stent-like » TF approach can be used in > 70% whereas TransAortic appears a new alternative to TA in other patients
- In 2011, the indications expands to less severely sick patients, but should remain limited to *non-optimal candidates* to surgical valve replacement
- The success and safety of the procedures rely on the quality of screening, the respect of protocols and recommendations.
- An optimal partnership within the team is crucial for both patient selection and procedure