6th Joint Meeting with Mayo Clinic

GREAT INNOVATIONS IN CARDIOLOGY

Torino – 14-15 October 2009

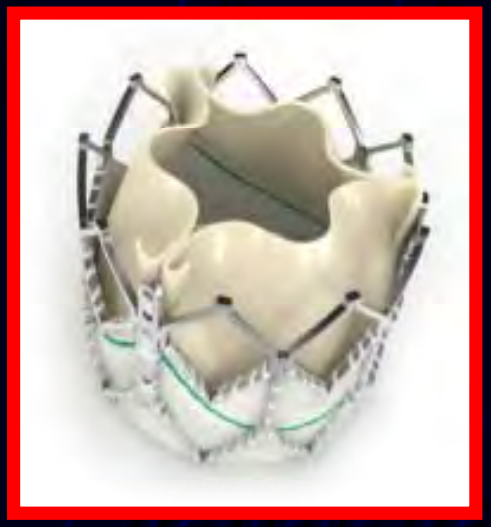
Transcatheter Aortic Valve Implantation implantation: Tips & Trick

Speaker – 20'

Antonio Colombo

Centro Cuore Columbus and
S. Raffaele Scientific Institute, Milan, Italy

Percutaneous Aortic Valve



Edwards SAPIEN XT

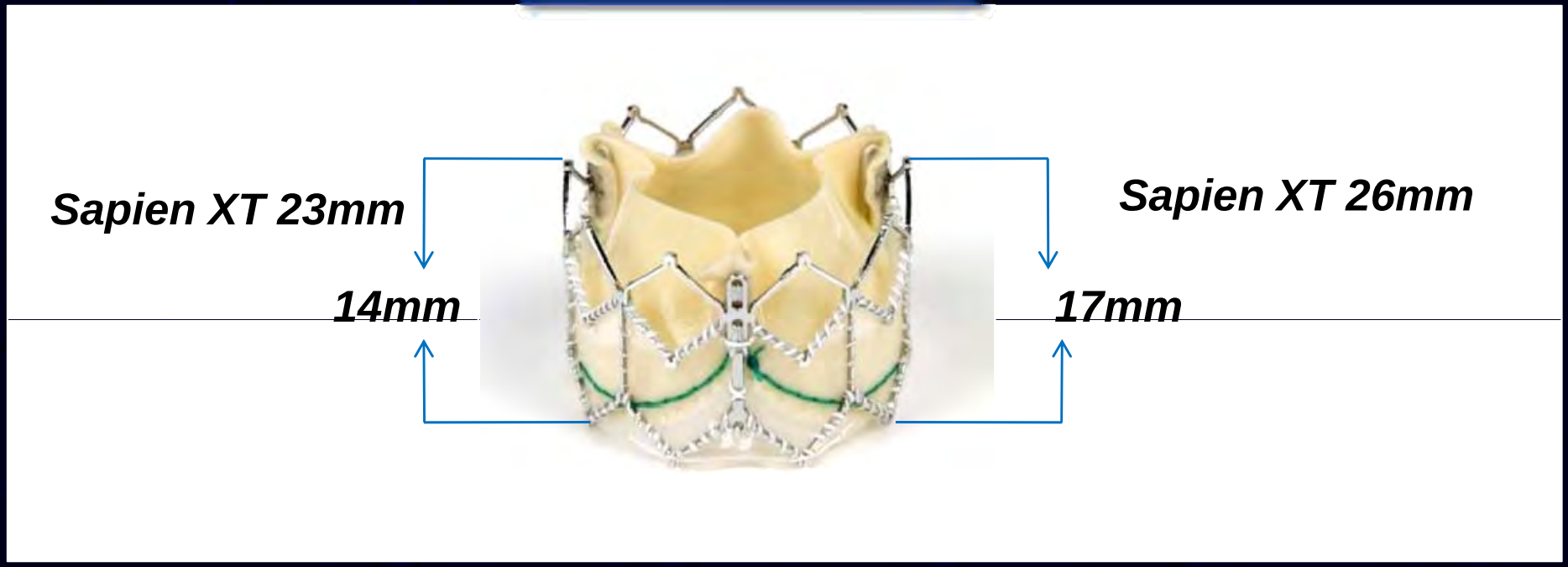
- Bovine valve on balloon-expandable stent frame
- 23 mm and 26 mm
- 18F and 19F (NovaFlex delivery system)
- 26F sheath (Ascendra Transapical delivery system)

CoreValve ReValving® System

- Porcine valve in self-expandable nitinol stent
- 26 mm and 29 mm
- 18F sheath
- Repositionable

SAPIEN XT

SAPIEN XT
Transcatheter Valve



- *High radial strength Cobalt Chromium Frame*
- *Bovine scallop leaflets, similar to those used in Carpentier PERIMOUNT™*
- *ThermaFix™ Anti-calcification Treatment*
- *20mm, 23mm, 26mm, 29mm*
- *Low profile NovaFlex™ Catheter (18F)*

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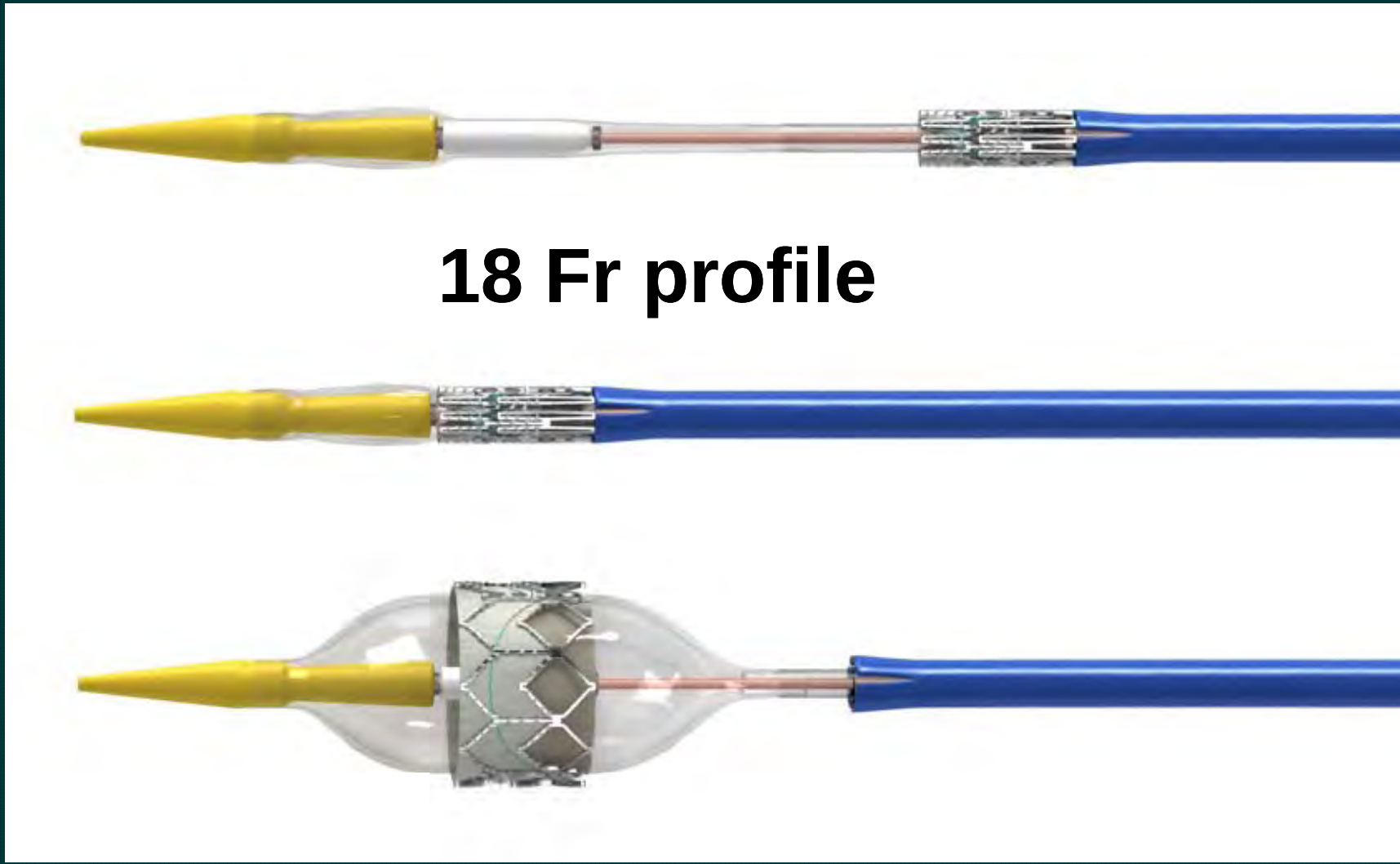
Sapien XT + NovaFlex Delivery System



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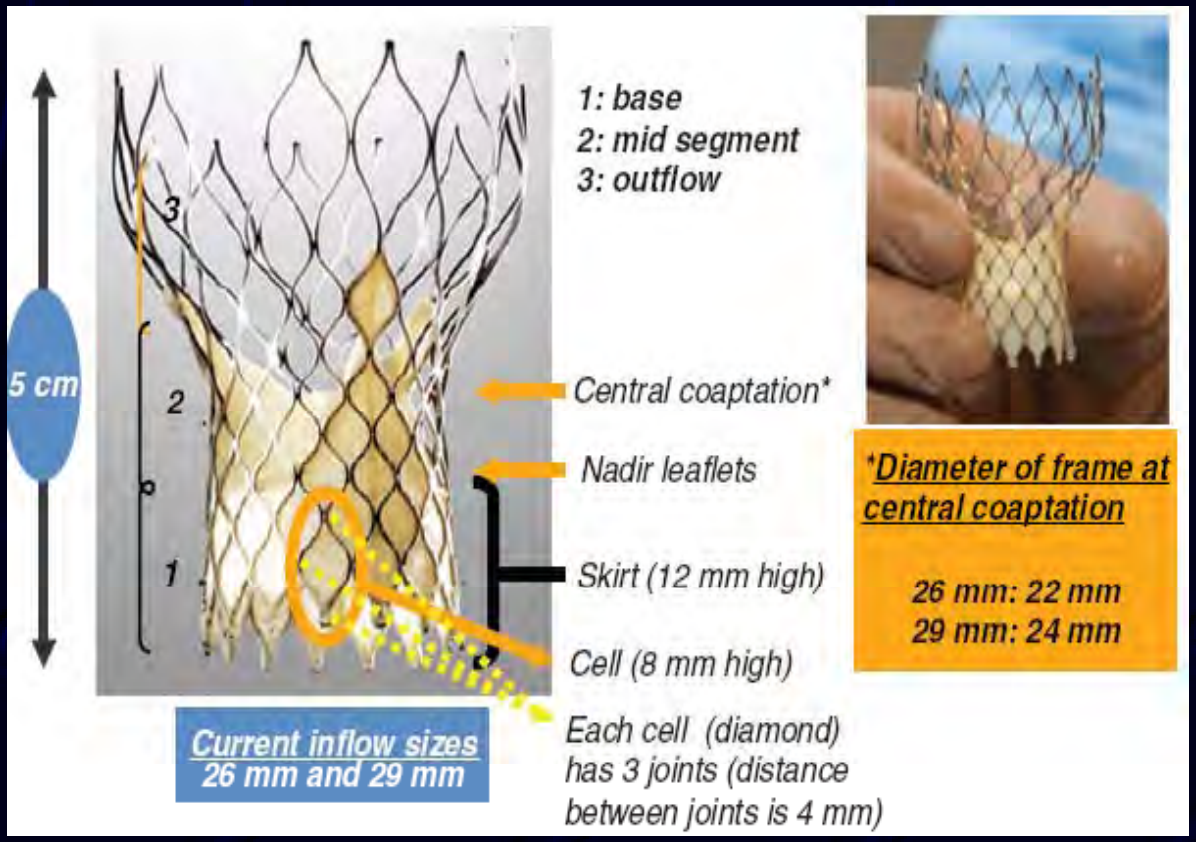
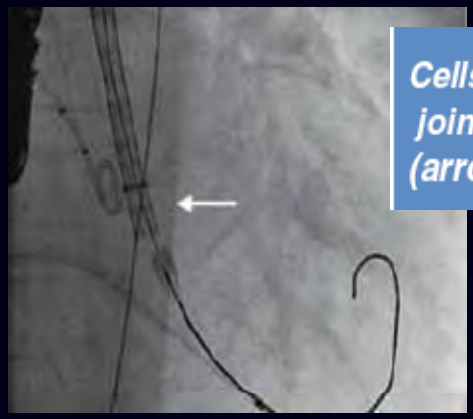
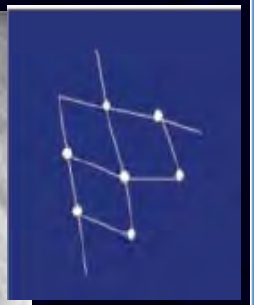
IMPLANTATION OF THE COREVALVE REVALVING SYSTEM





Cells in collapsed state - joints seen as a row (arrow)



Cell = 3 joints:
- at the base
- at the mid segment
- at the top

Joints are 4 mm apart
Total height of cell: 8 mm

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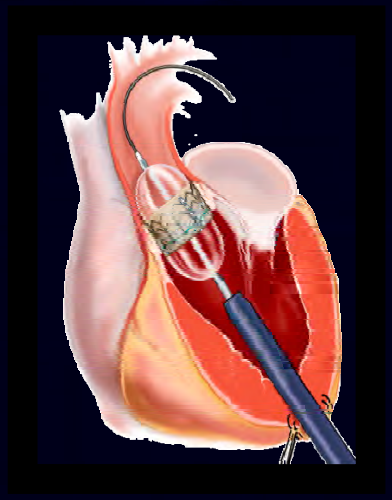
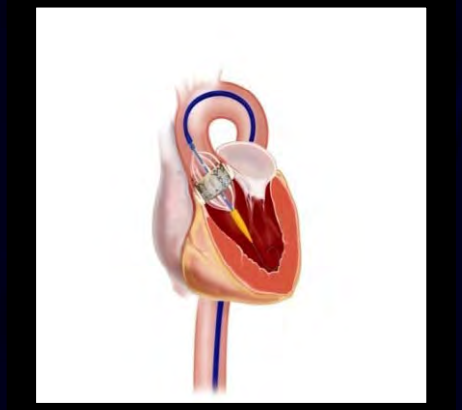
Edwards SAPIEN™/SAPIEN XT

CoreValve ReValving®

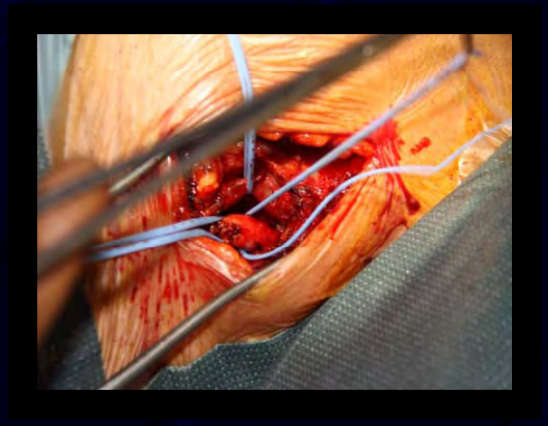
?



Trans-apical



Trans-femoral

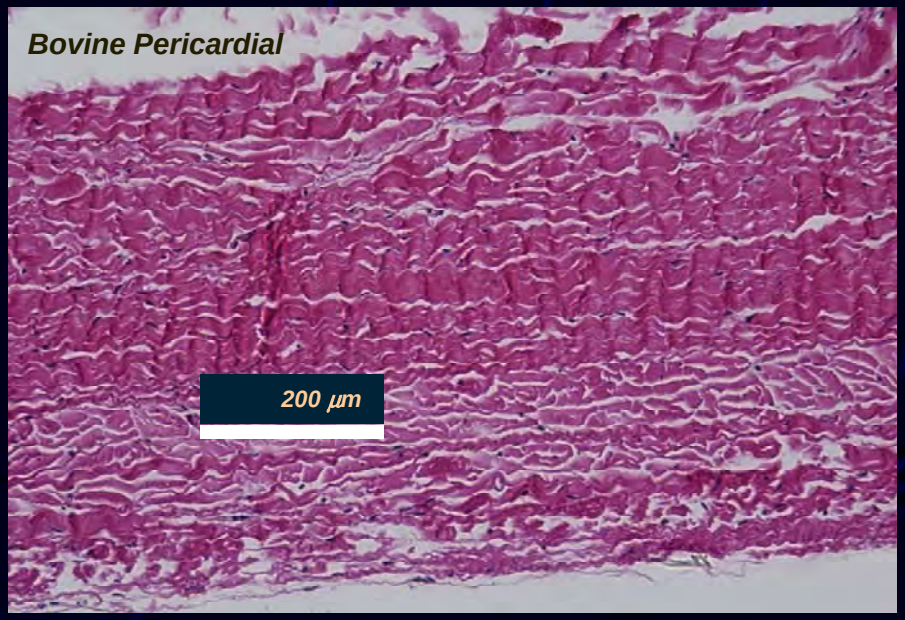


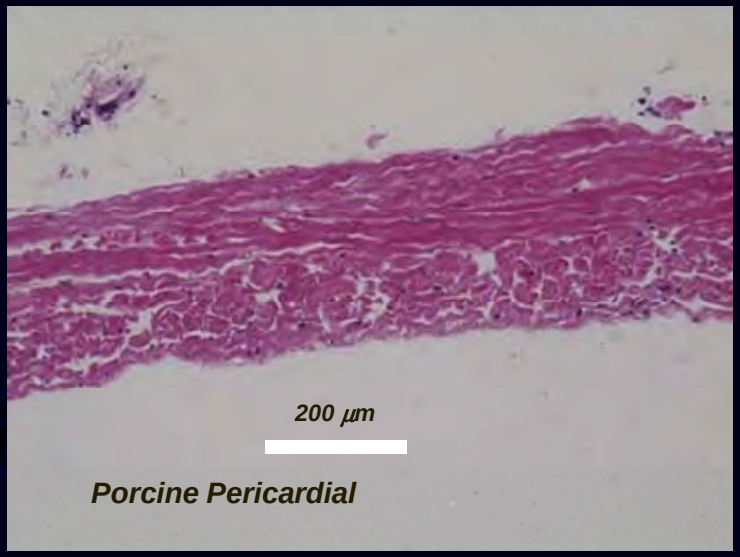
Trans-aortic

Trans-axillary

Bovine Pericardial Tissue with clinically proven long term durability

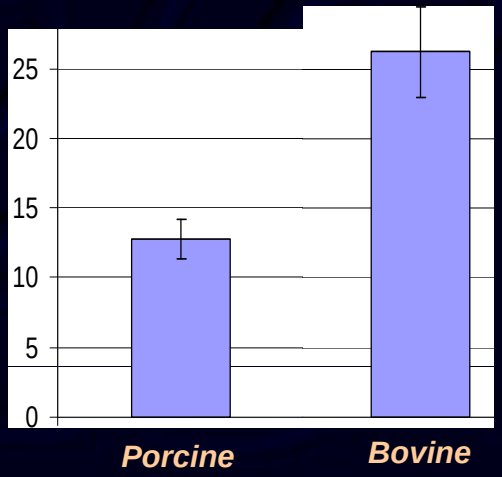
Bovine pericardial tissue contains a uniquely dense, layered collagen structure





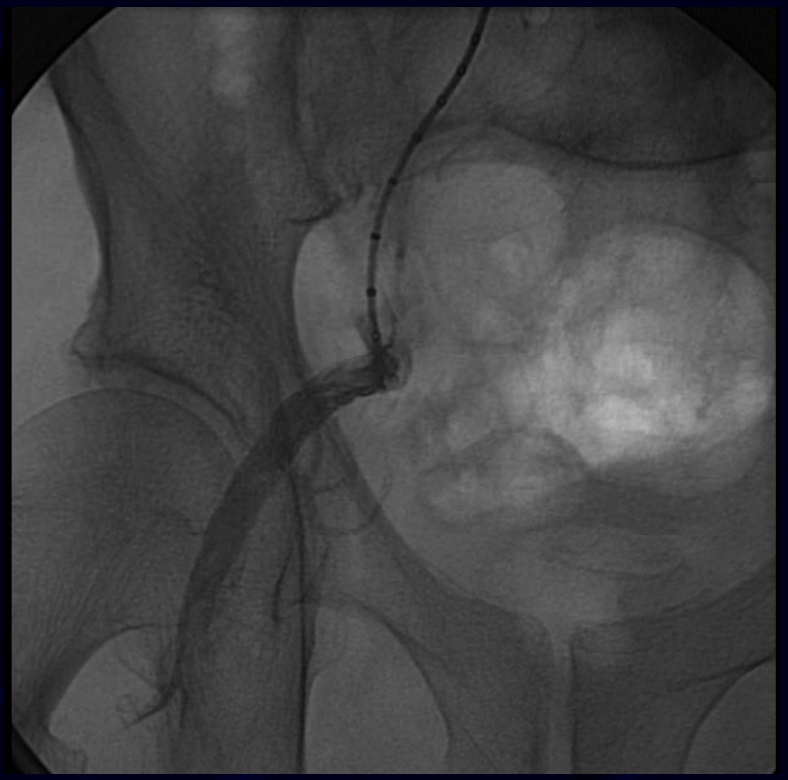
Bovine Pericardial is a strong and resistant tissue

Pericardial Tissue Yield Strength [Newtons]



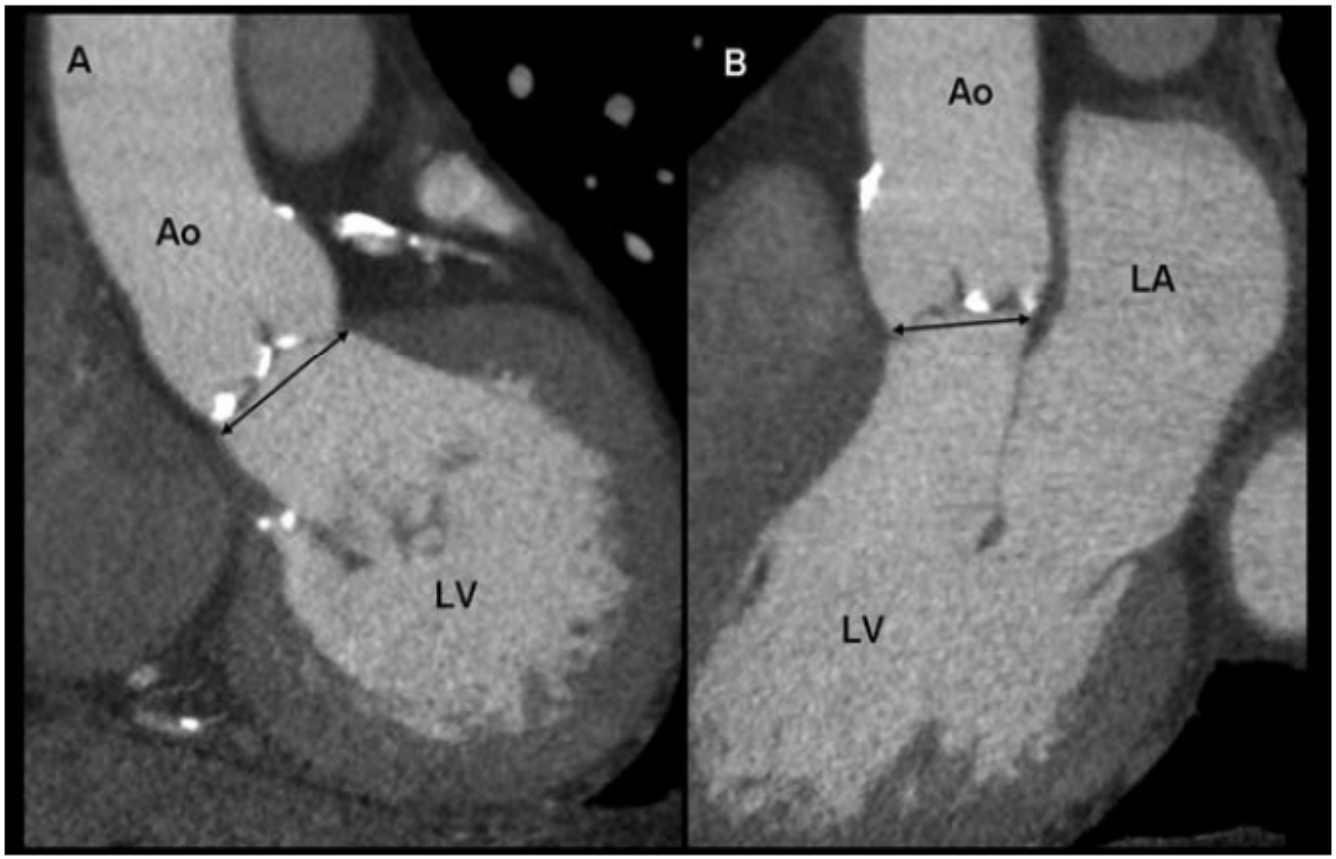
Procedure - Screening

- **Ilio-femoral access assessed by MSCT and by quantitative angiography**
  - ¡ **Femoral artery at the access size:**
  - ¡ **> 6 - 7mm for 18-19 F**
  - ¡ **Evaluate Calcium and possible elasticity of the vessels**



Aortic valve sizing

- ar
-



coronal diameter larger than the sagittal diameter

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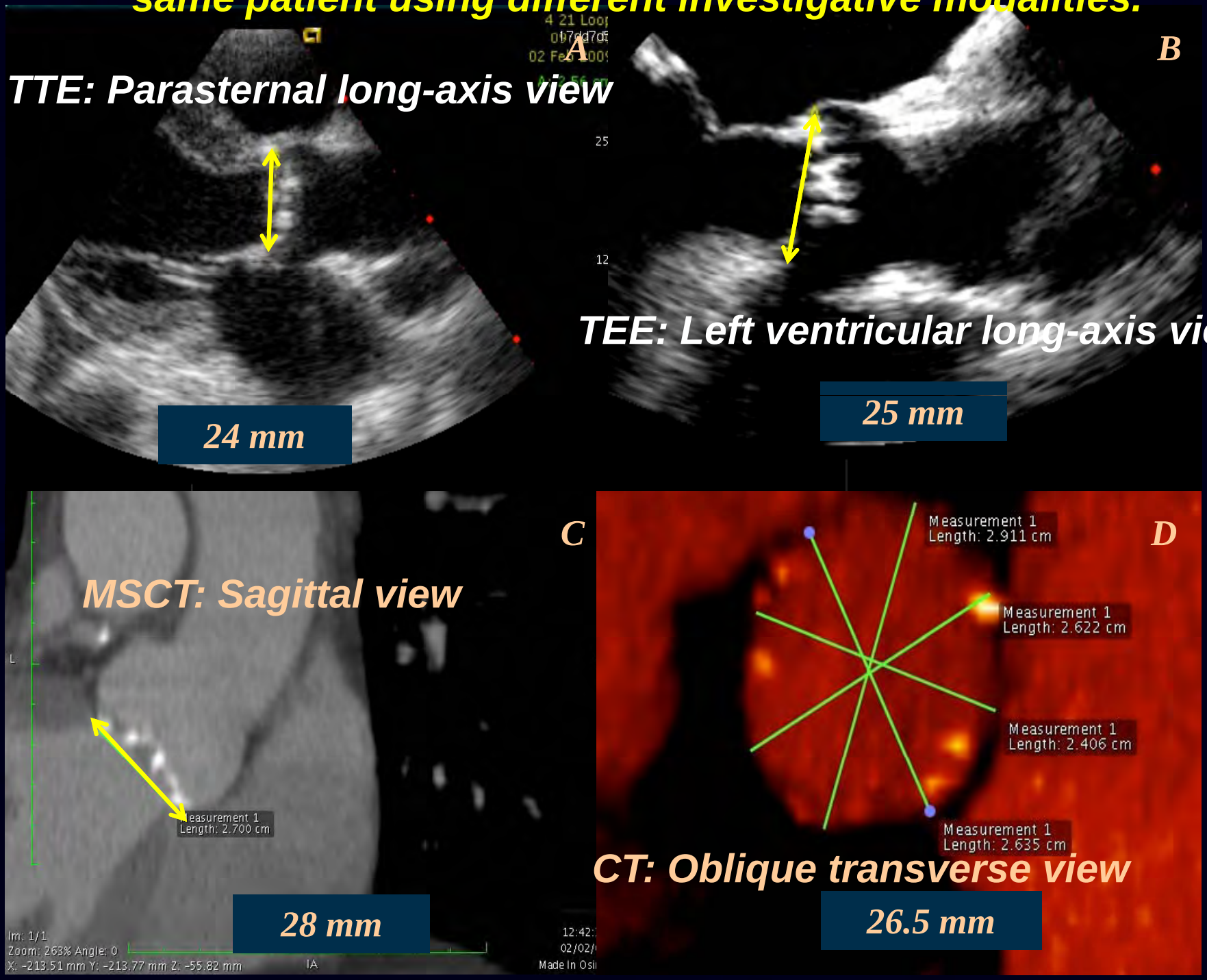
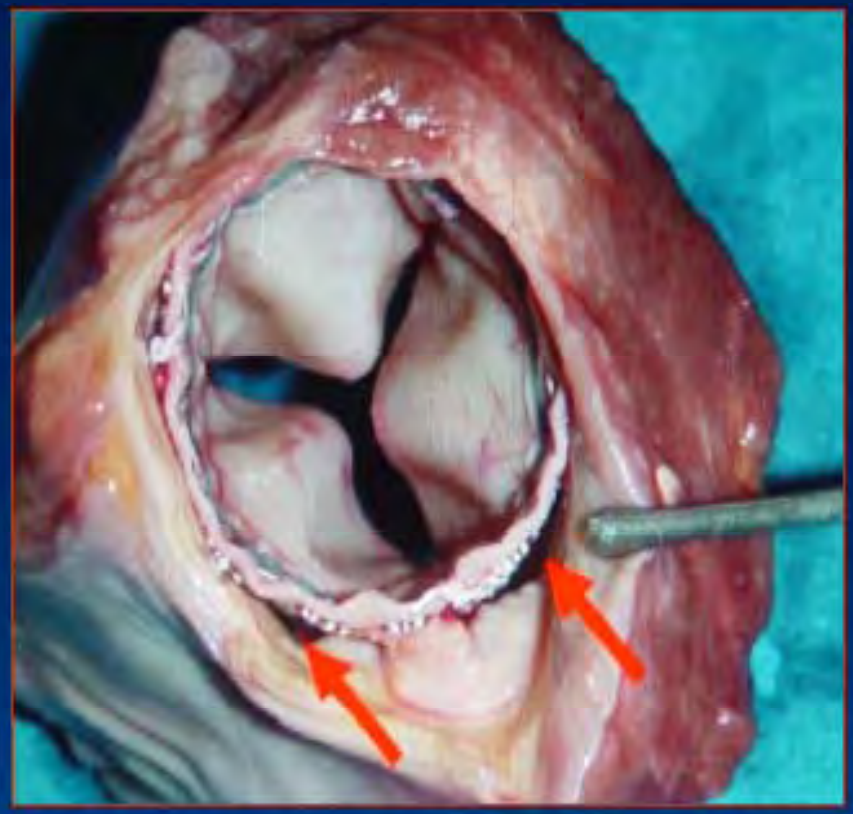
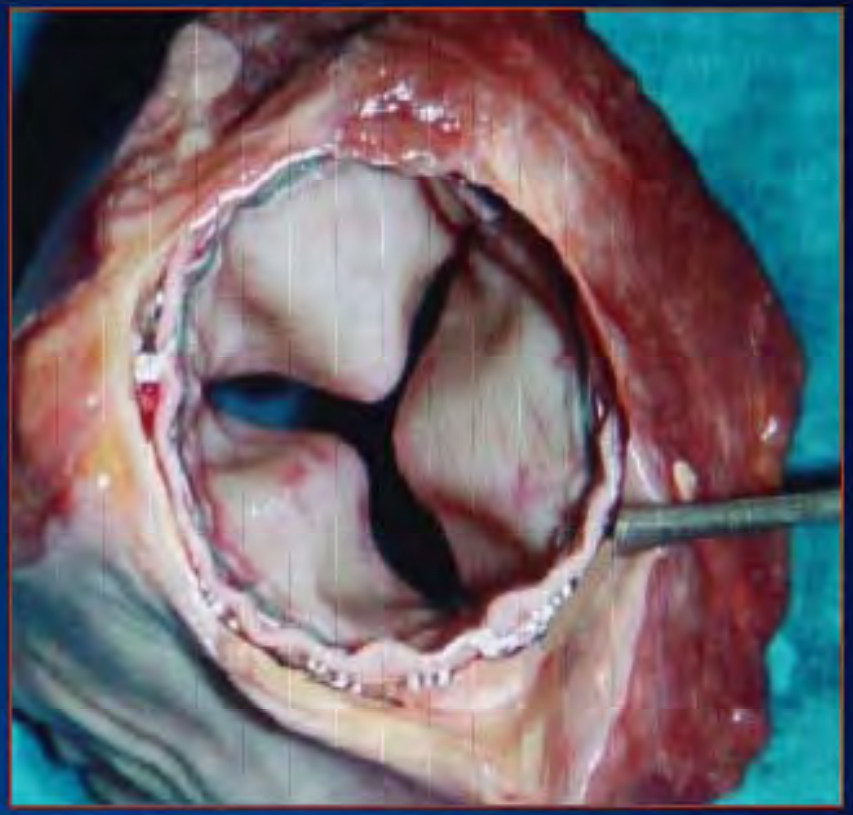
The variation in annulus size measurements made in the same patient using different investigative modalities.



Larger size valve: rationale



PHV23MM



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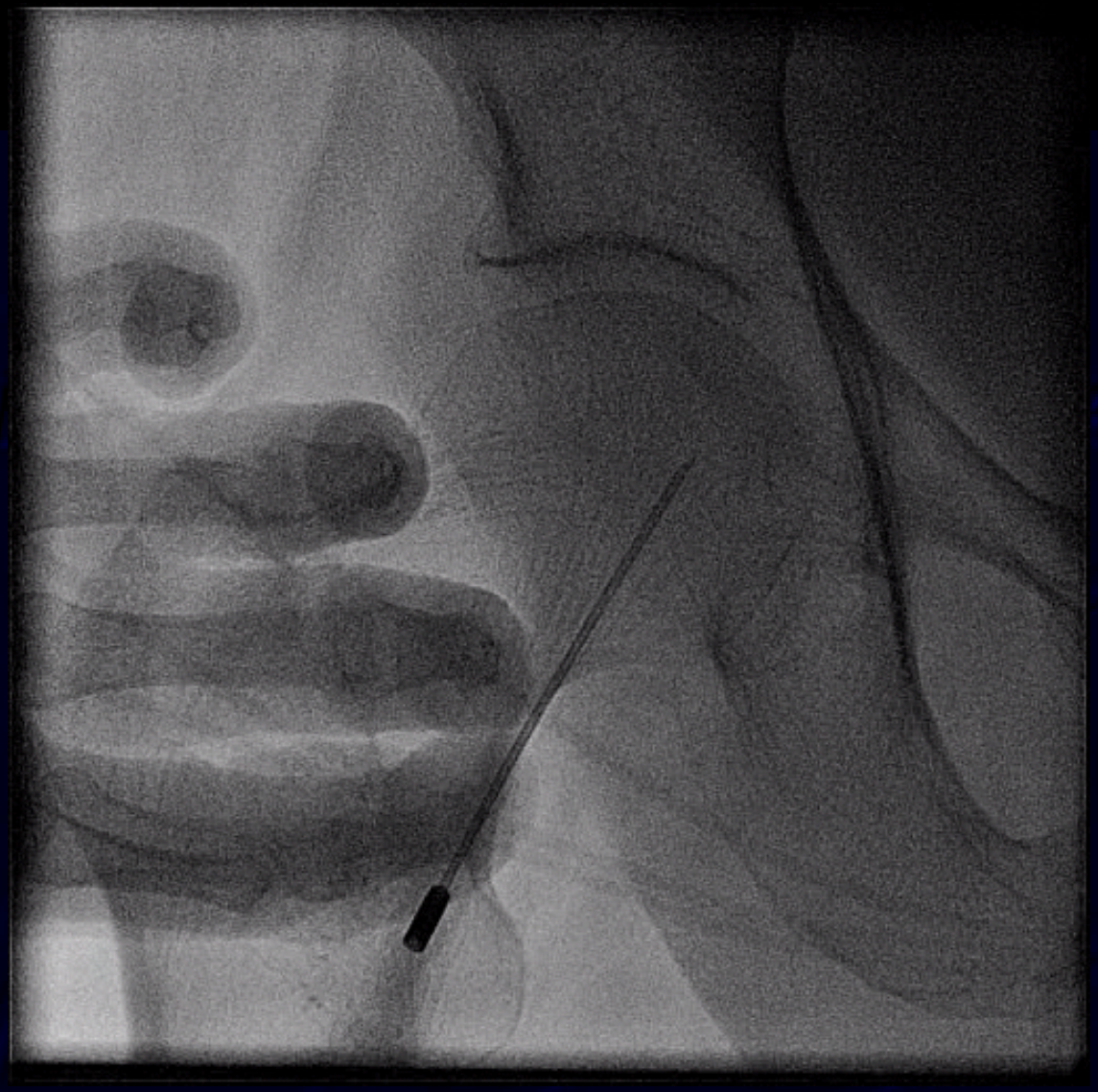
Transcatheter Aortic Valve Implantation(TAVI) Tips and Tricks

1. Femoral access
2. Balloon valvuloplasty
3. Prosthesis positioning
4. Options to correct mal-positioned prosthesis (CoreValve)
5. Treatment options for access site complications

Correct puncture site



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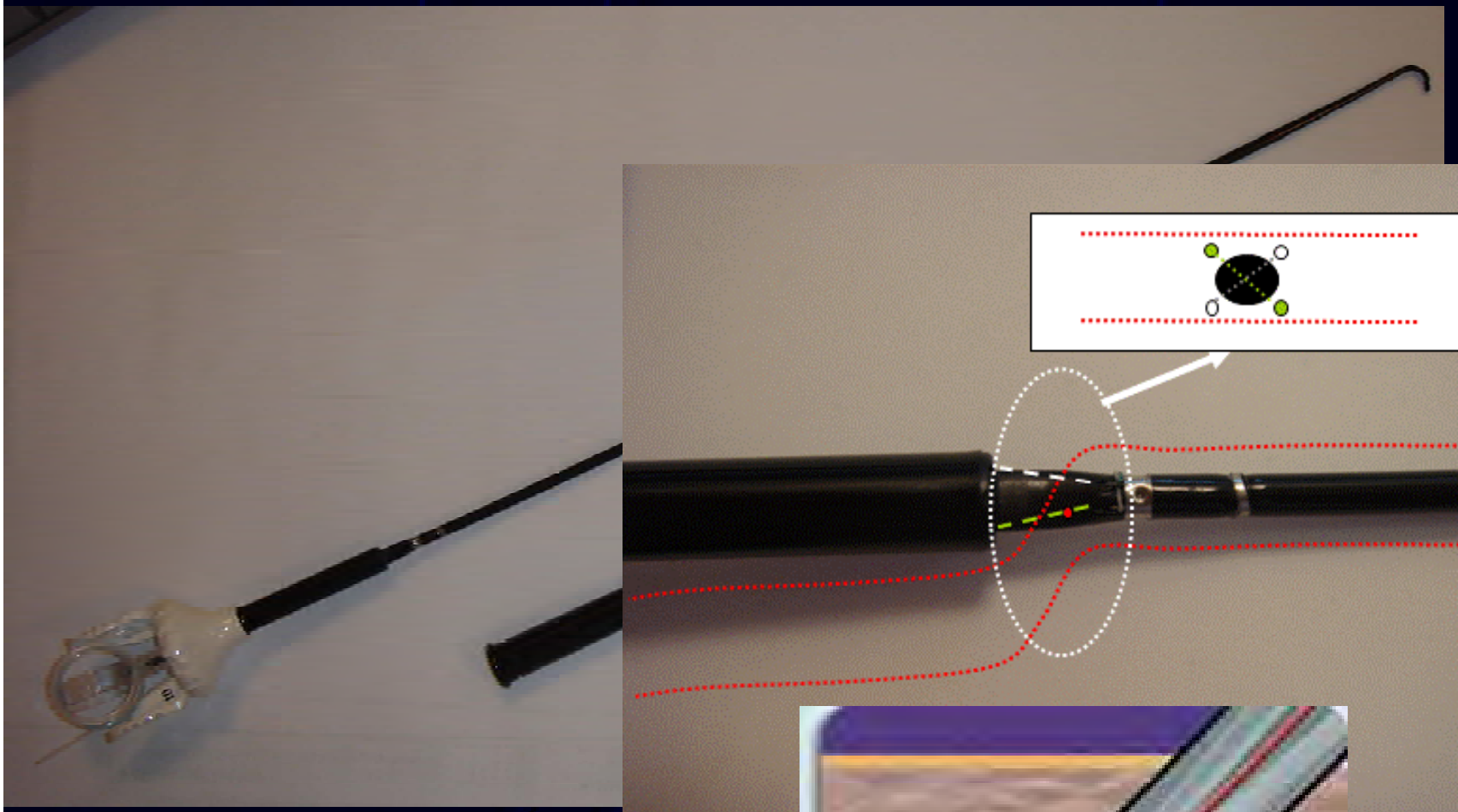
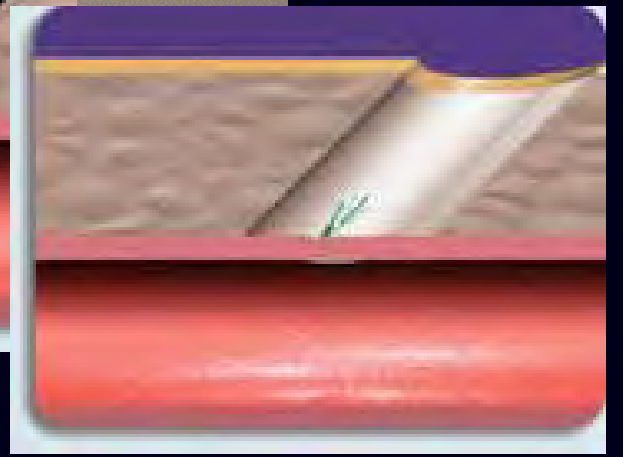
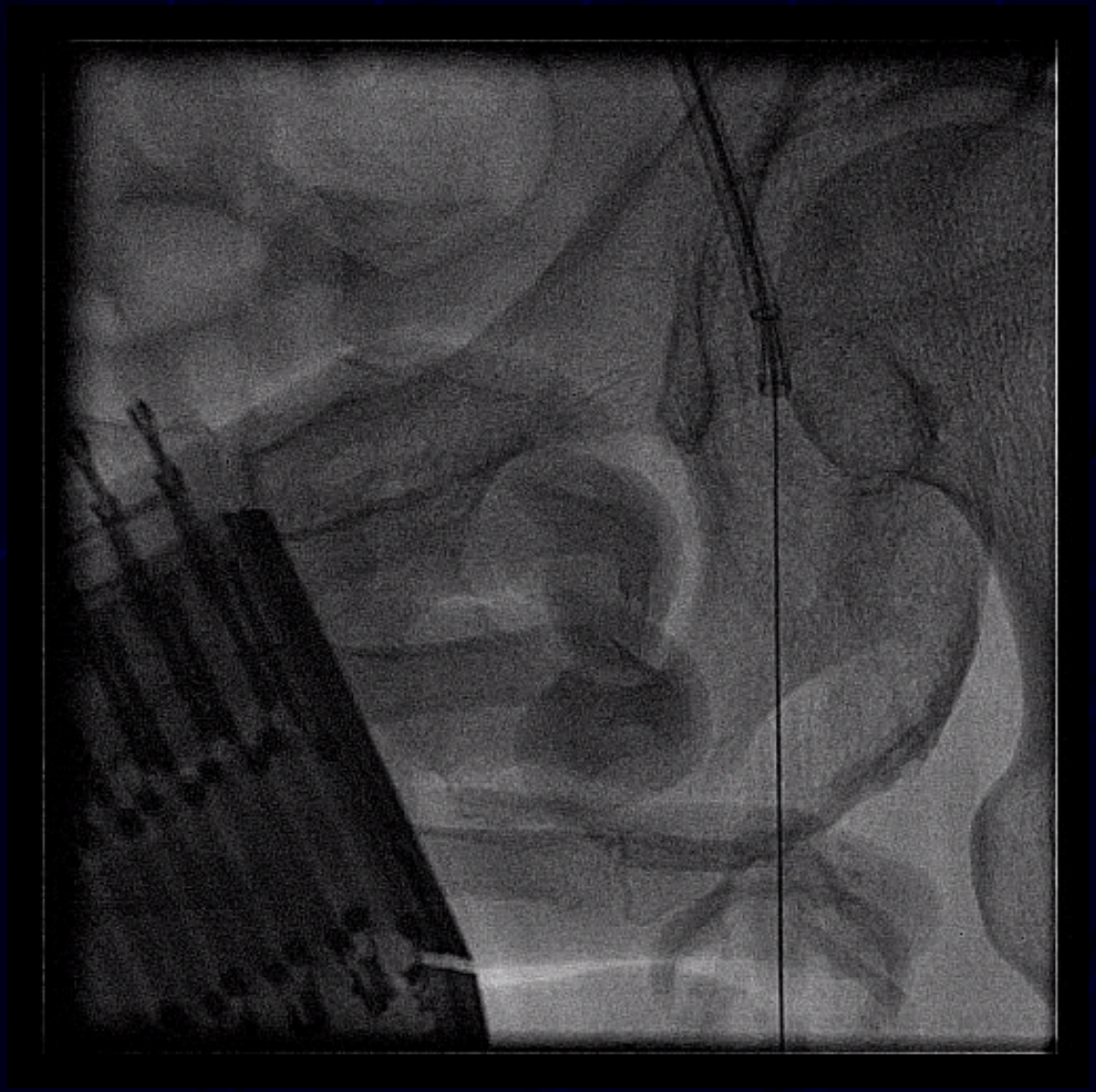
Prostar XL 10 French







Prostar 10XL after 9 F pre-dilatation

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One way to lower vascular complications

14-16 French becomes 18-19 French, the sheaths are available for CoreValve and for Sapien

Onset Medical Corporation

SoloPath™

Wiring the aortic valve

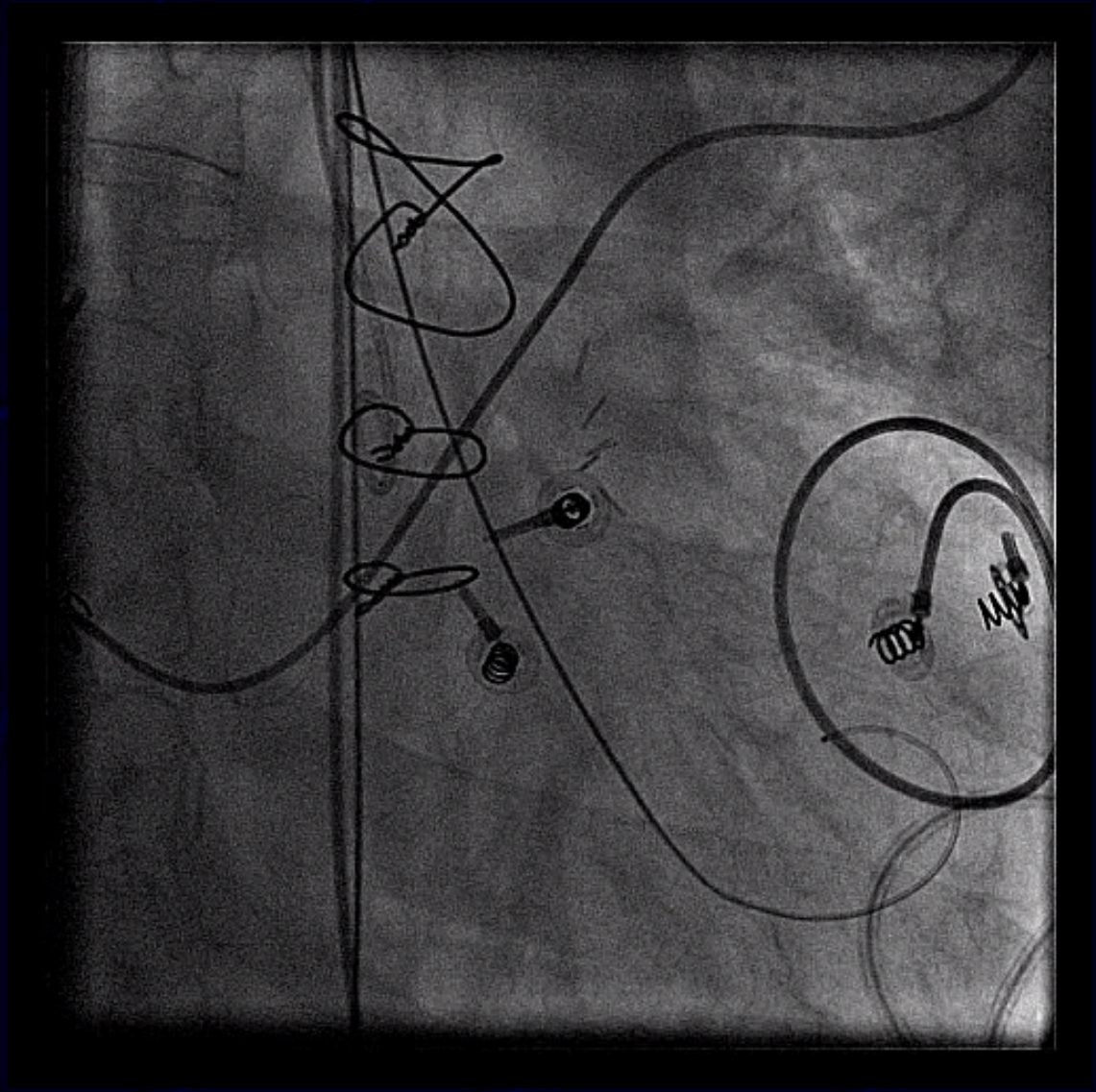
Technique

- with AL1 and straight Terumo (alternativelly straight 0,035“) wire or mouvable core wire

  → CAVE: do not engage the coronaries
- exchange for a 5 F pigtail using a 260 wire
- Simultaneous pressure recording

Placing the stiff wire

- Amplatz Superstiff ST1
  (short floppy tip 1 cm)
- Alternative stiff wires
  Cave: long floppy tips
- →manually bending the stiff part into a pigtail shape
- Next, 18 French sheath (always over the stiff wire)



Balloon valvuloplasty

- Balloon catheters:
  - Nucleus 12 F (Inoue like behavior)

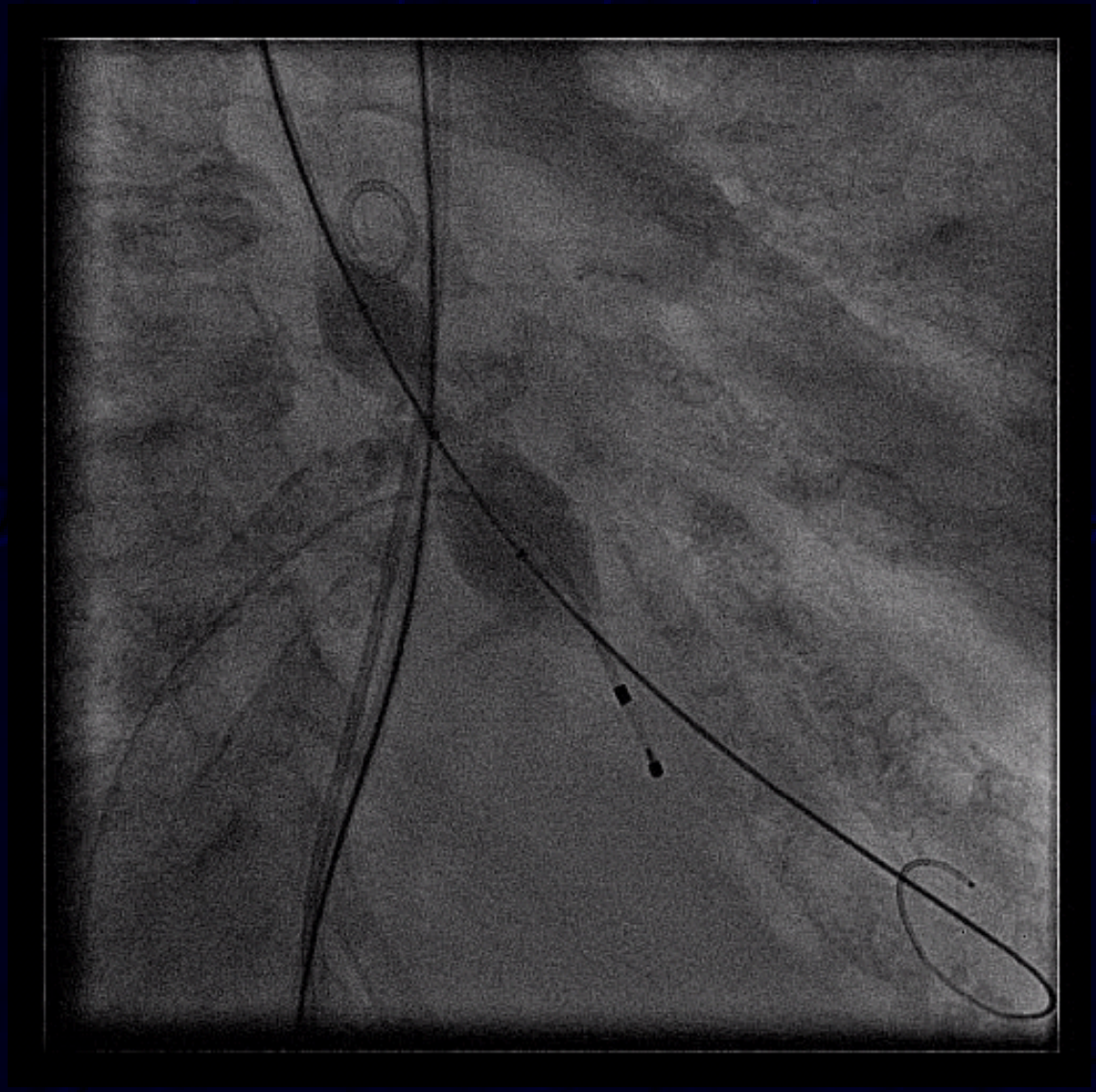
    → Stabilize position
  - Z-med X 12 F
  - Tyshak II (9 F to 25mm) but rated burst 1.0-1.5 atm
  - Or other valvuloplasty balloons possible
  - Ideal balloon length 40-60 mm

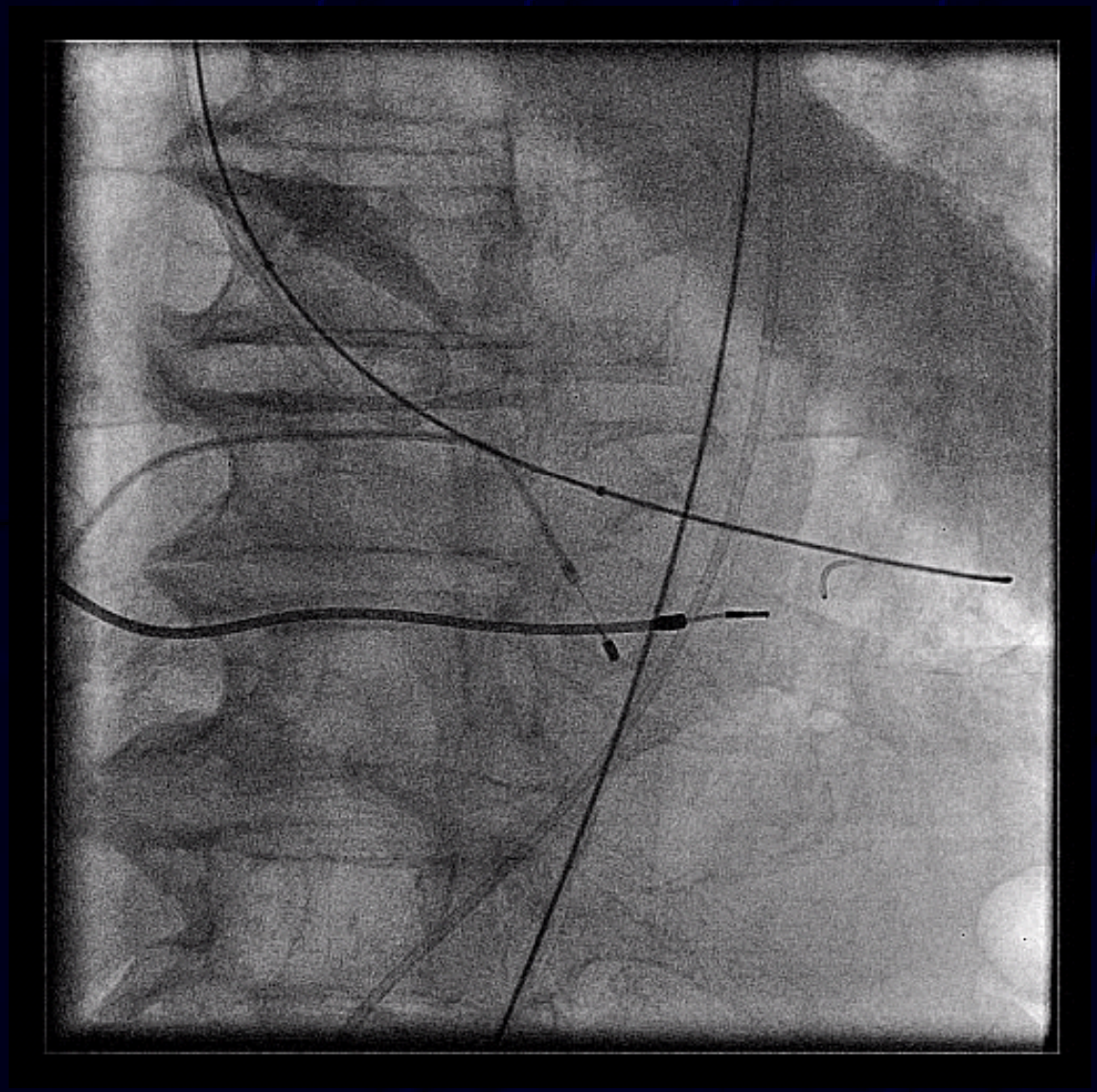
Rapid RV stimulation ~180 - 200 BPM

(systolic pressure <60 mmHg), use lead with tip balloon or lead with screw (be careful of perforations) → Stabilize position, less embolization?

Embolic protection

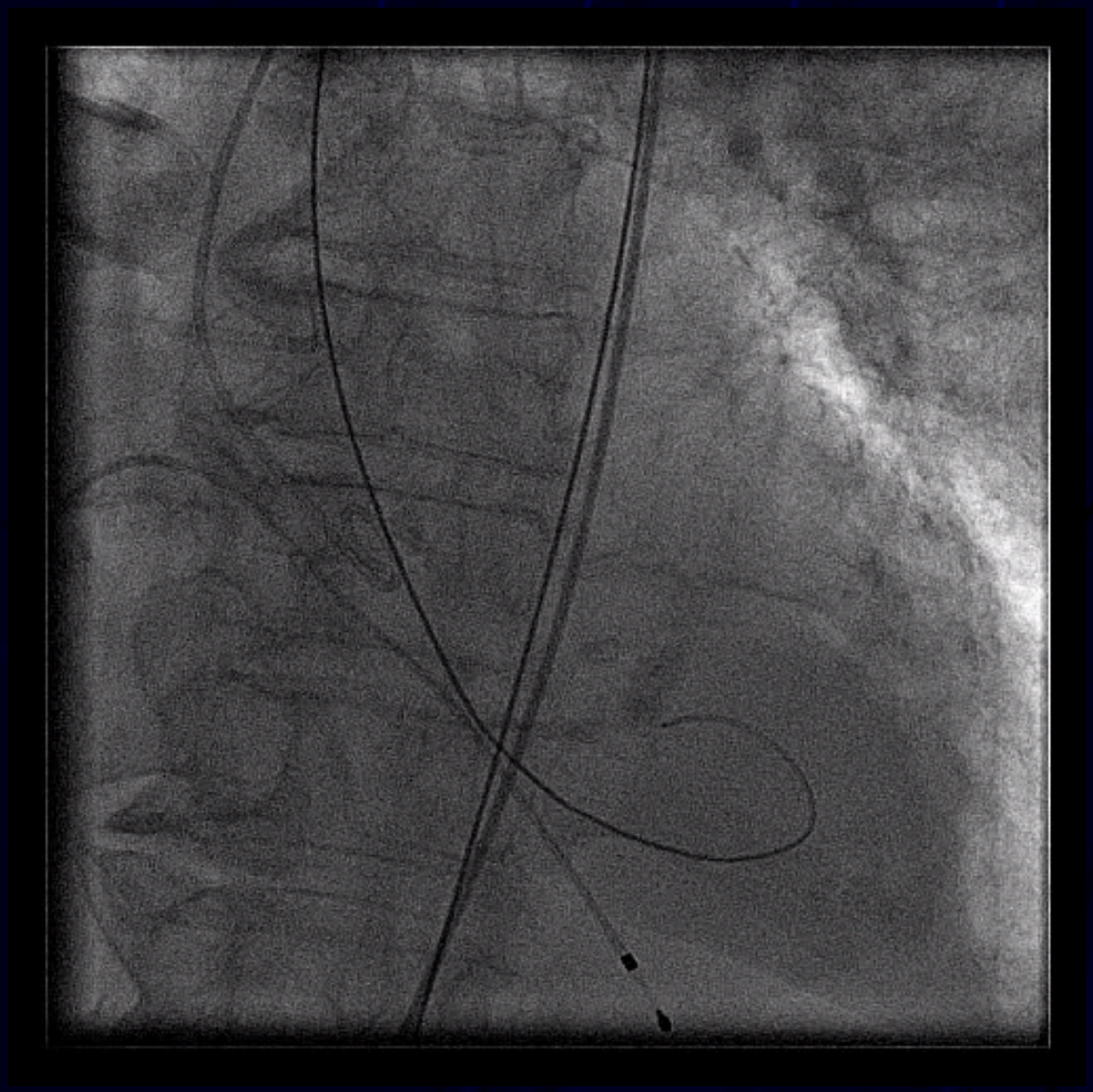
Balloon valvuloplasty with Nucleus (balloon rupture !)





Balloon valvuloplasty

using a 25 mm ZMed balloon and simultaneous dye injection in a 28 mm annulus (measured by CT)

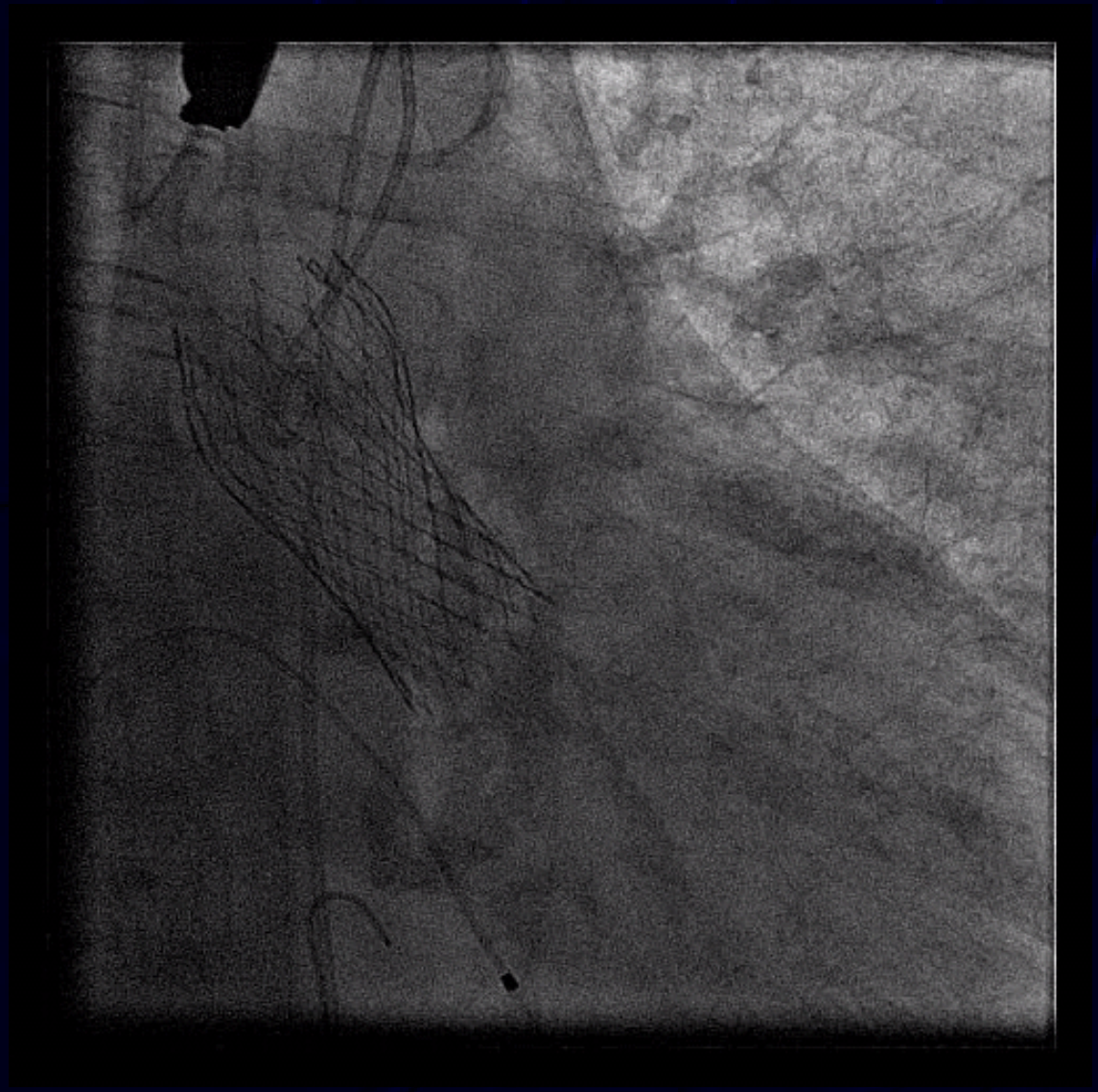


Severe aortic regurgitation

after valvuloplasty (incidence 2-5%)

Acute aortic regurgitation resulting in acute LV overload

Acute LV failure / asystole or VF due to (Volume-loading of the LV)

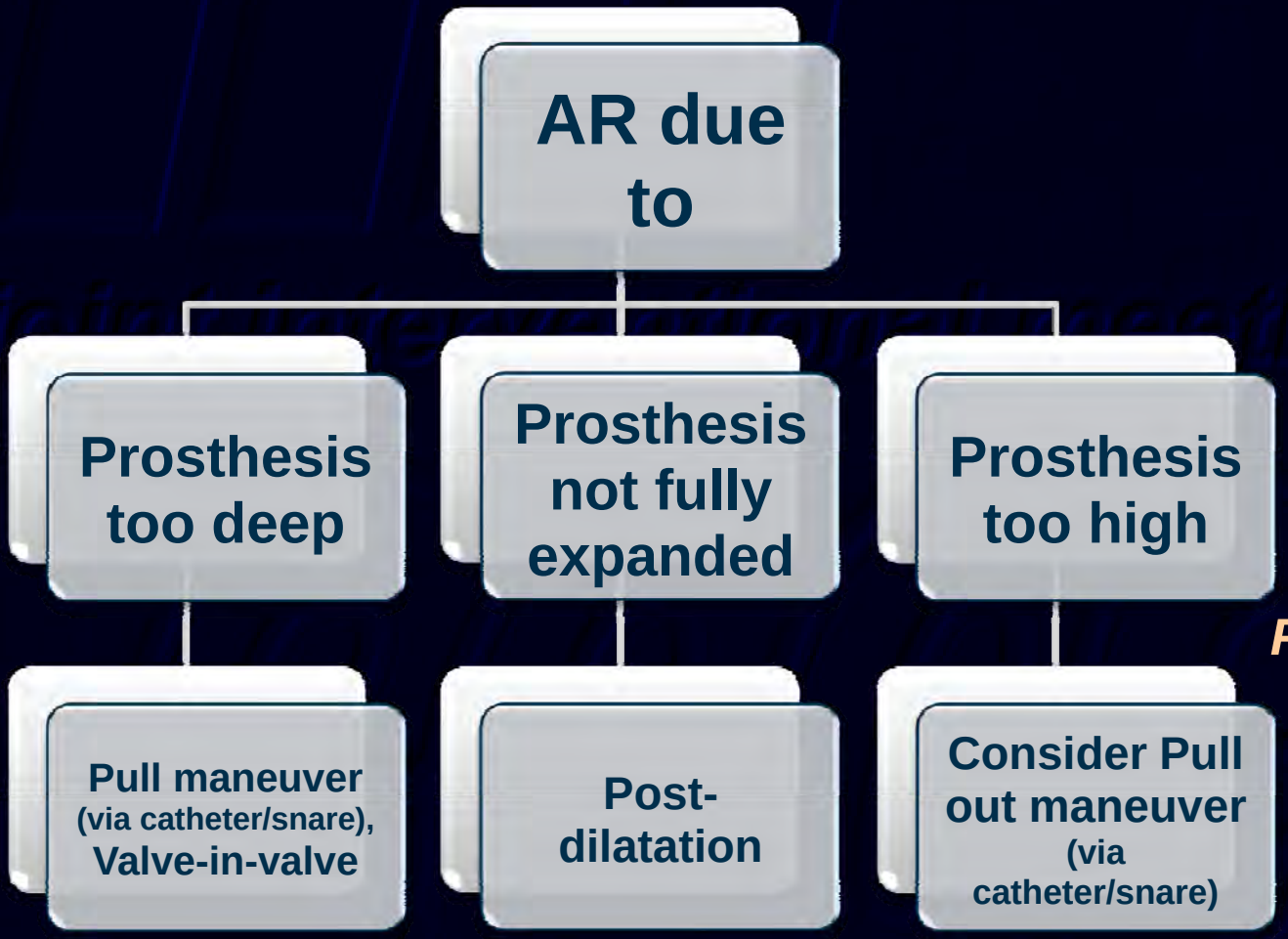


Angiographic result

after 26 mm CV

Always have the prosthesis loaded before valvuloplasty for immediate implantation

Aortic regurgitation after delivery of the prosthesis



For CoreValve

For CoreValve

For CoreValve and for Sapien

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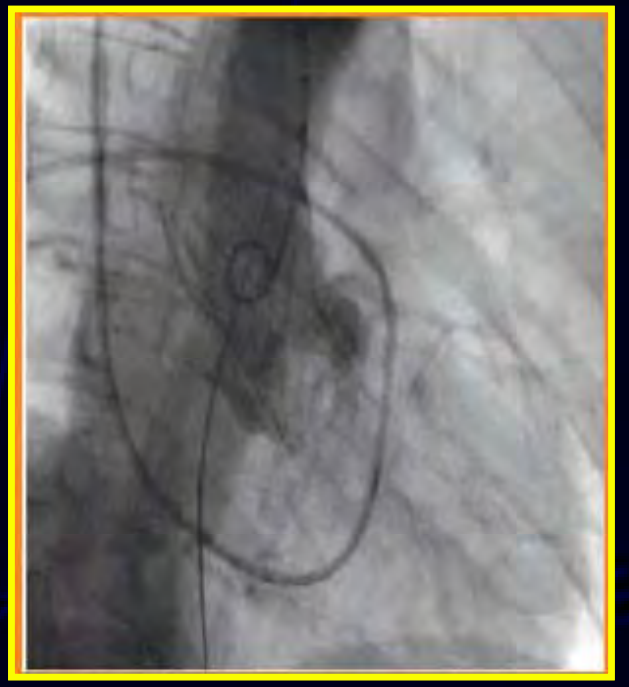
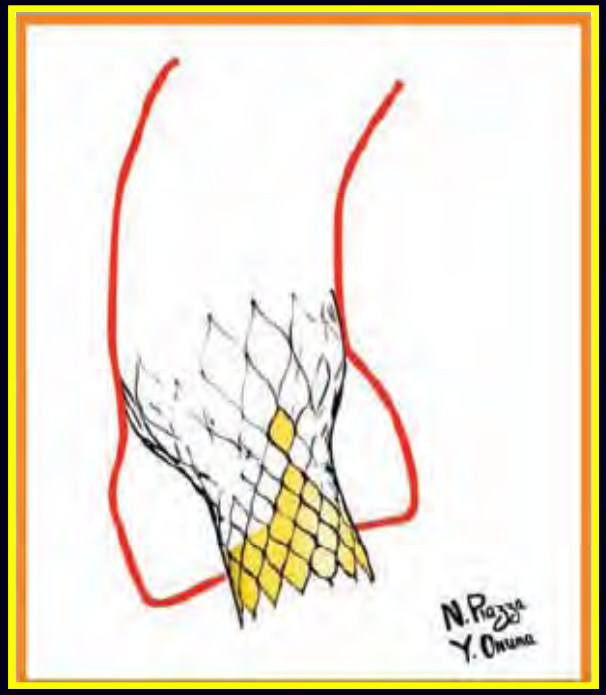
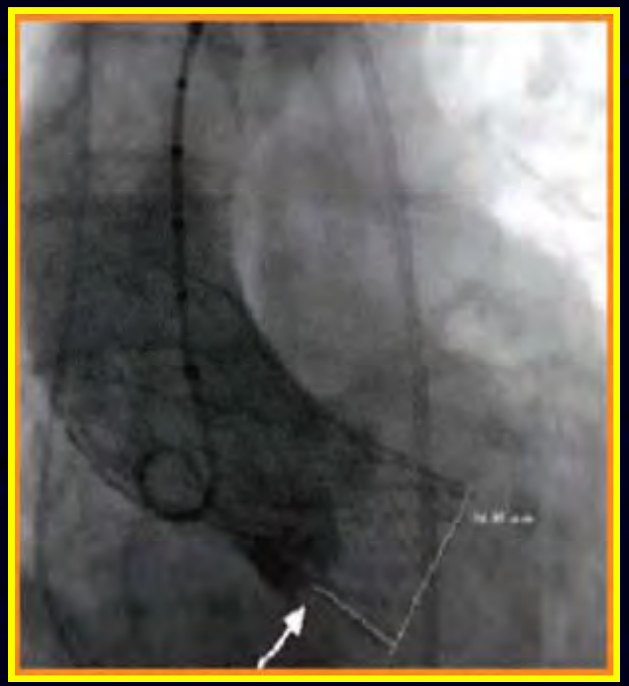
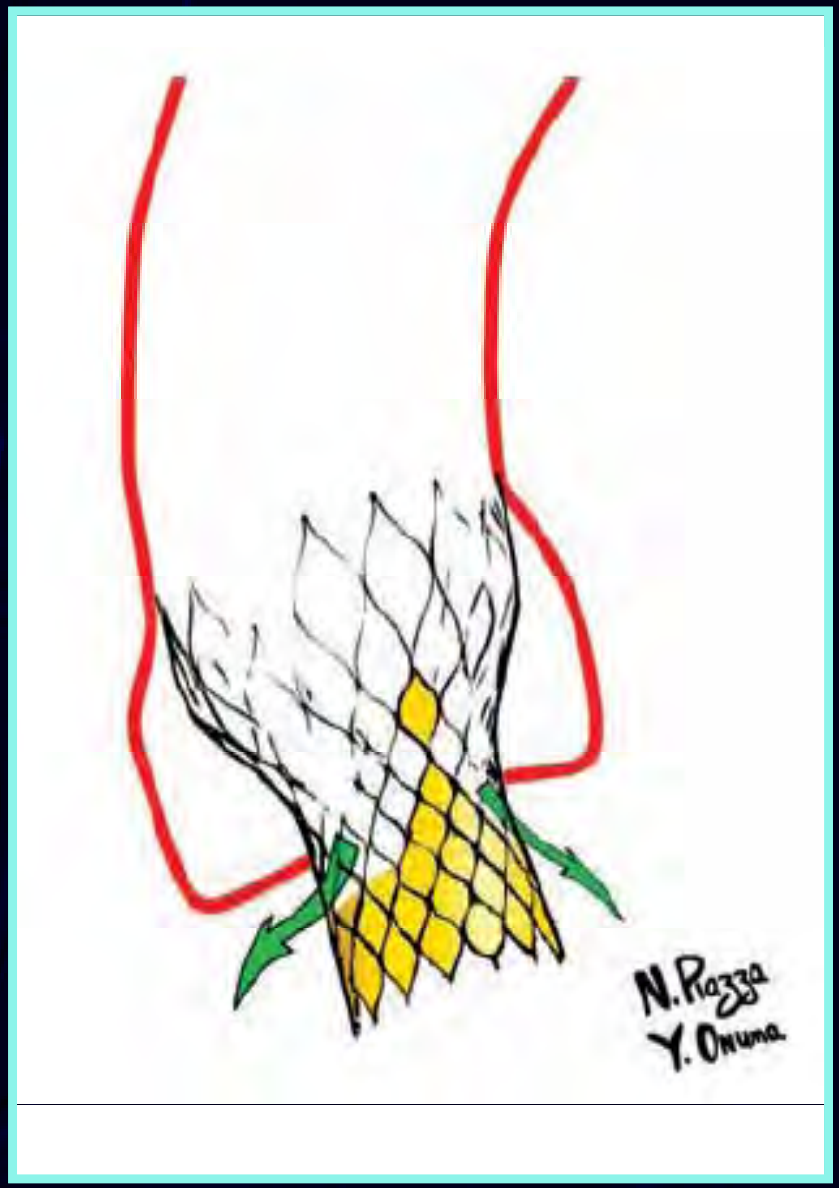
Positioning and depth of implantation of the CoreValve Revalving System ™

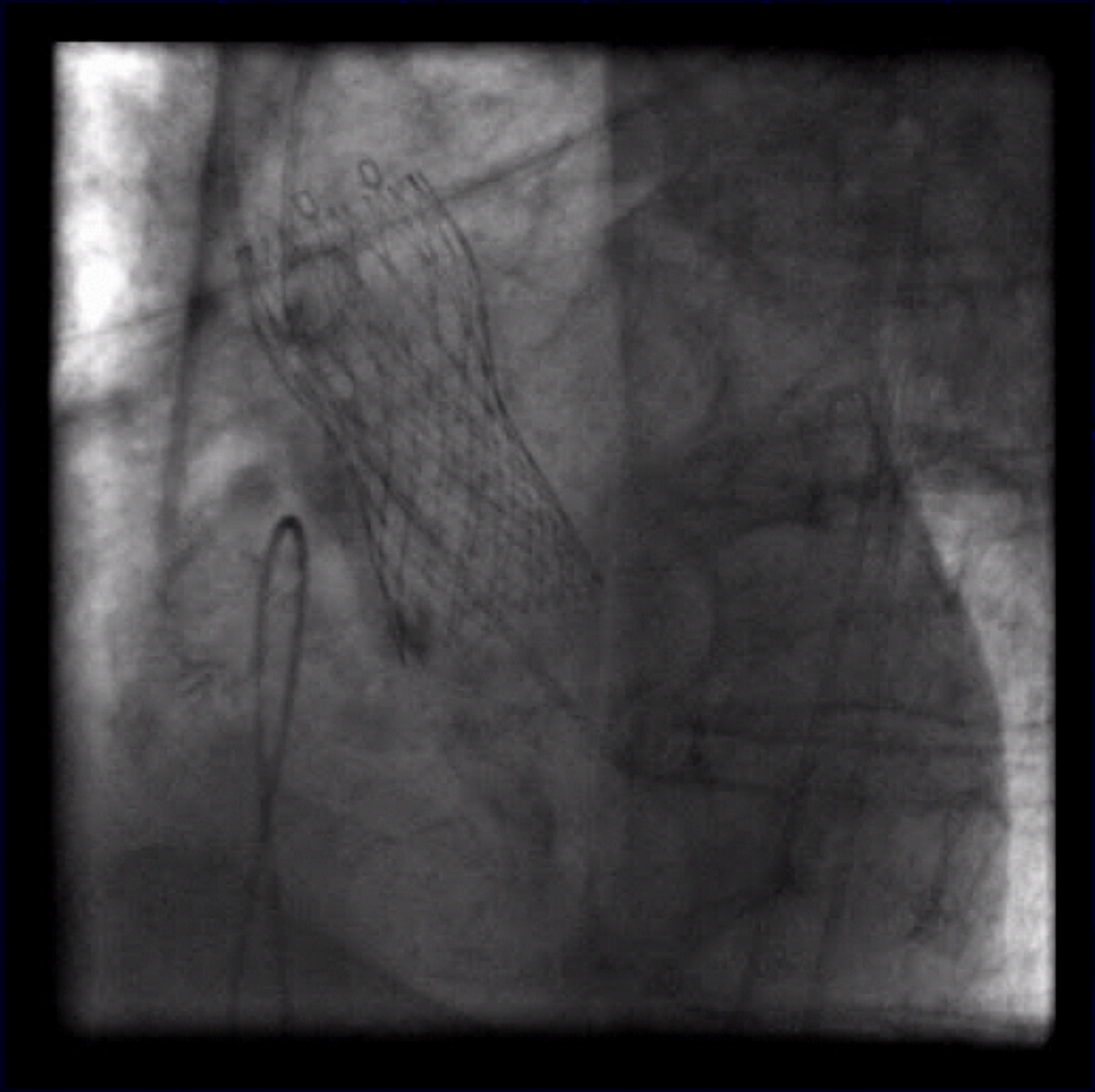






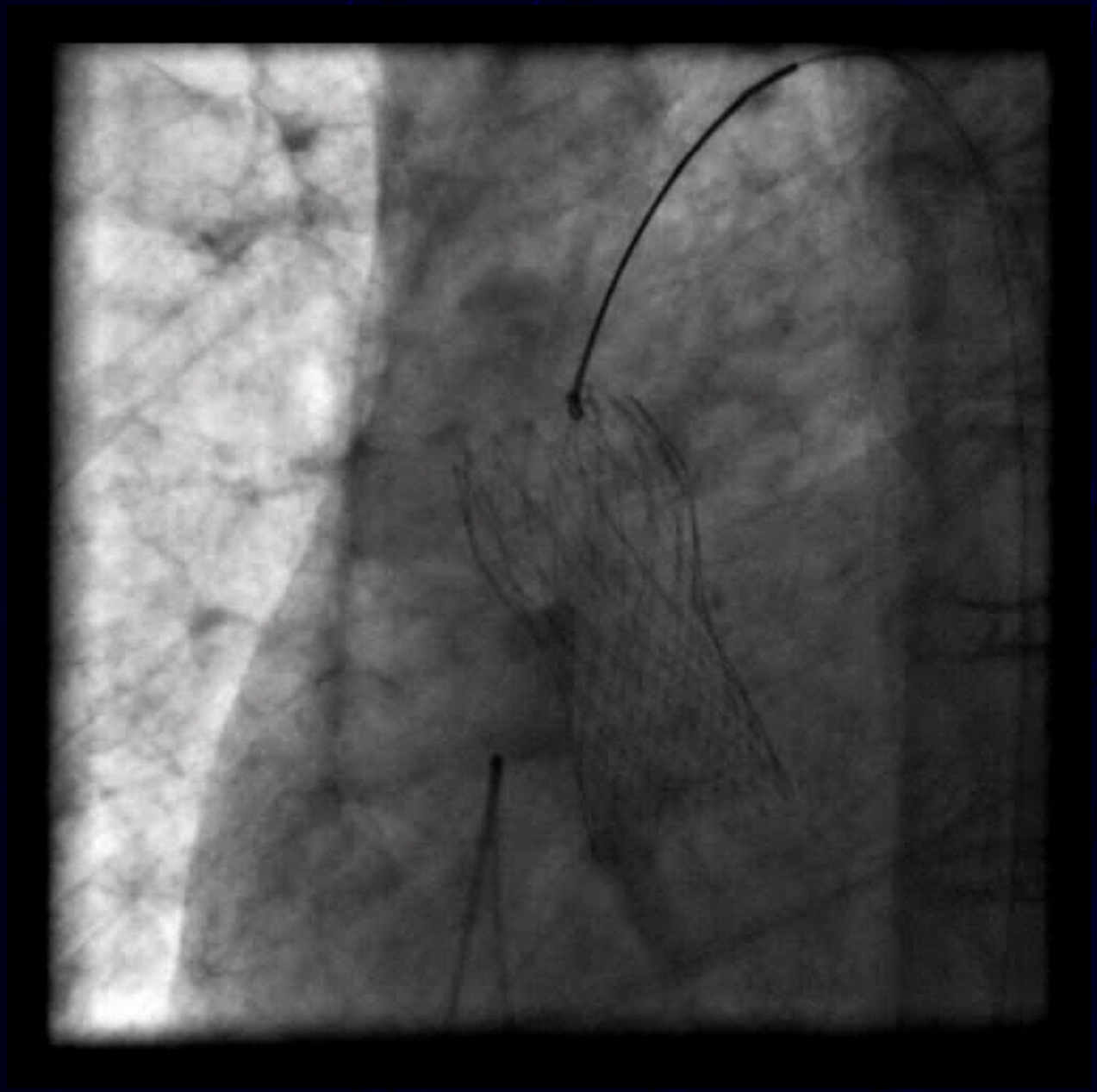
Aortic regurgitation due to a incorrect (too deep) implantation.
The top pericardial skirt is below the base of the aortic root.
As a result there is aortic regurgitation due to operator related misplacement of the valve.





AR due to too deep prosthesis

(paravalvular leakage)



Re-positioning

using
a Goose Neck ‚snare‘
(15/20 mm)
from femoral 6F

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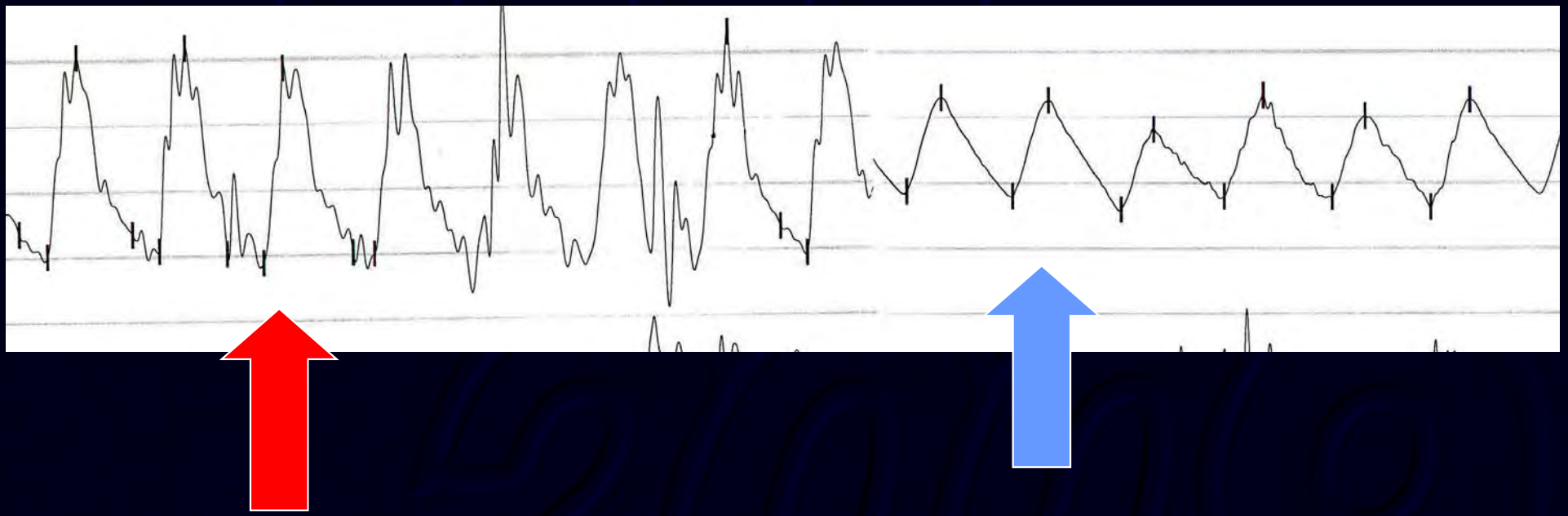
Controlled during continuous pulling by monitoring of the diastolic blood pressure



Cardiac Complications CoreValve

Valve is too low:

1) snare the valve to pull it up

2) implant a second valve.

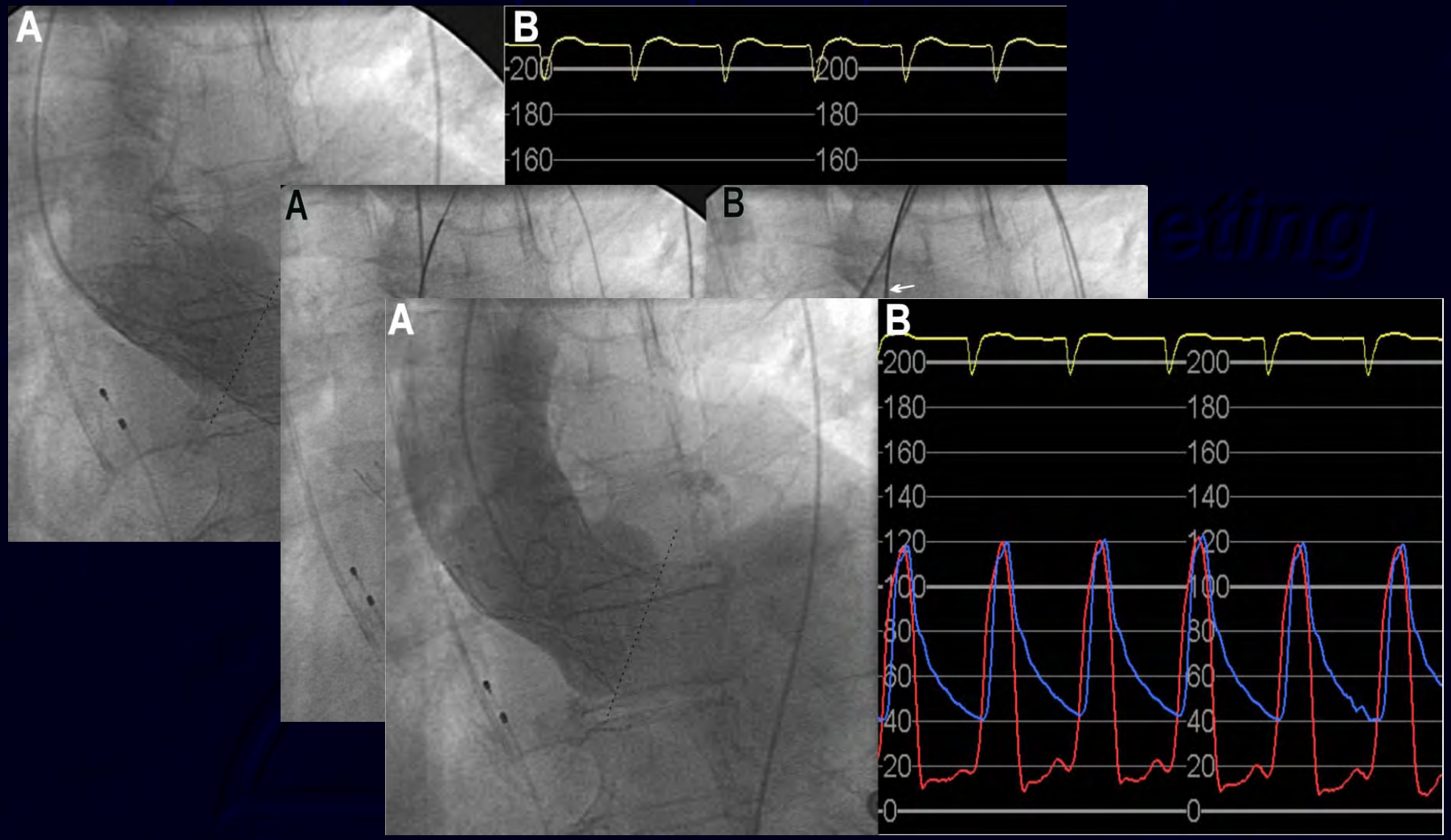
Valve is too high:

Retrival the valve to proximal position, keep the coronary ostial clear and position a second valve.

Cardiac Complications
CoreValve

Valve is too low:

1) snare the valve to pull it up



Cardiac Complications Sapien

Valve is too low:

Implant a second valve

Valve is too high:

Implant a second valve

Generic Cardiac Complications

- ✓ *LV perforation*
- ✓ *Dissection of the Aorta or of the anulus*
- ✓ *Arrhythmias*
- ✓ *AV block: 20% for CoreValve and 5% for Sapien*
- ✓ *Injury to the mitral valve*
- ✓ *Obstruction of coronary ostia*

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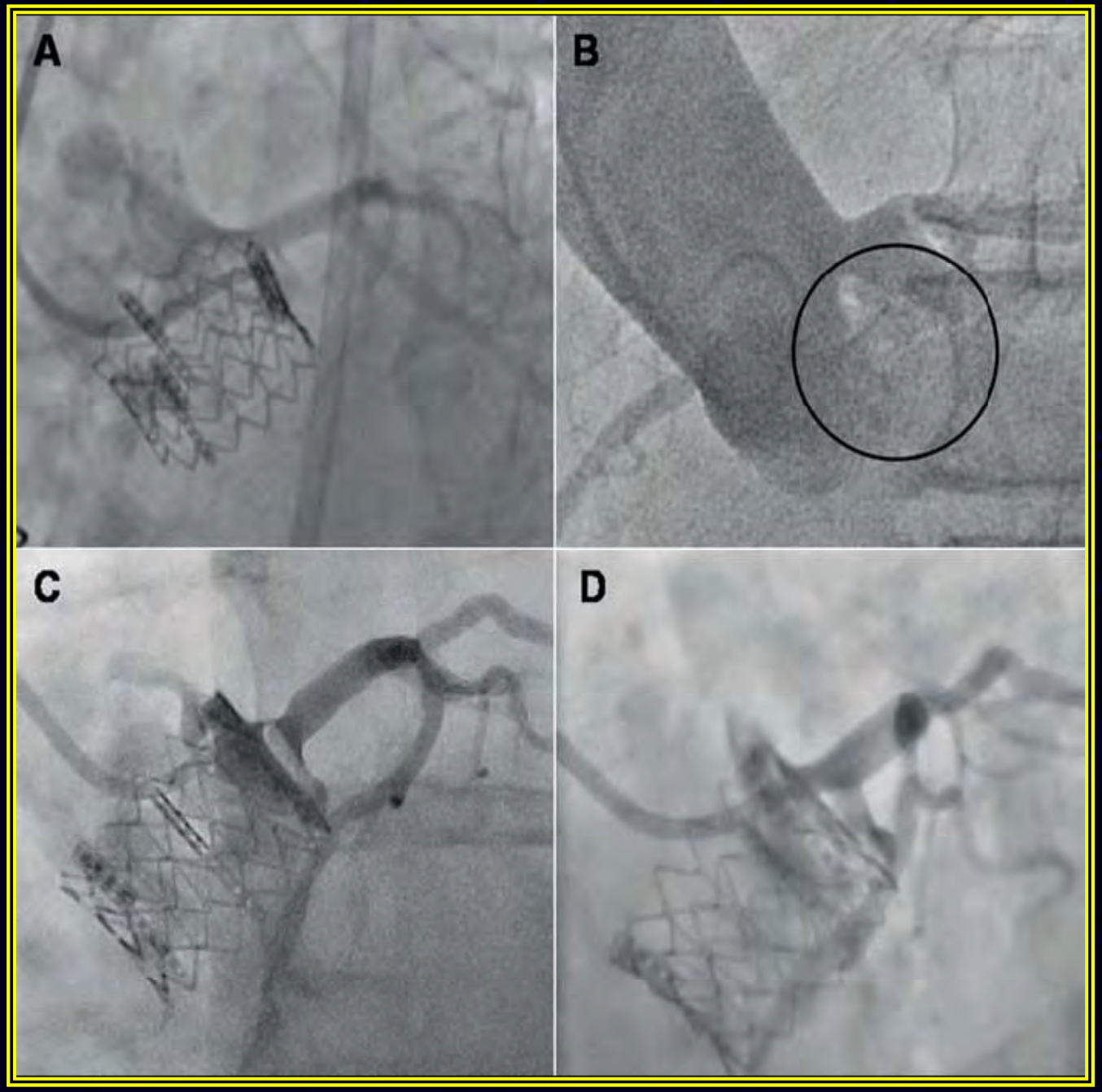
Perforation of the left ventricle

(A) An extra-stiff wire is positioned into the left ventricle but is not well elongated

(B) As the nosecone is advanced, the relationship between the wire and nose-cone suggest perforationof the ventricle

(C) Beating-heart left ventricular patch repair performed under femoro-femoral support

Coronary obstruction



(A) The very uncommon situation of a coronary ostium being obstructed by a stent strut.

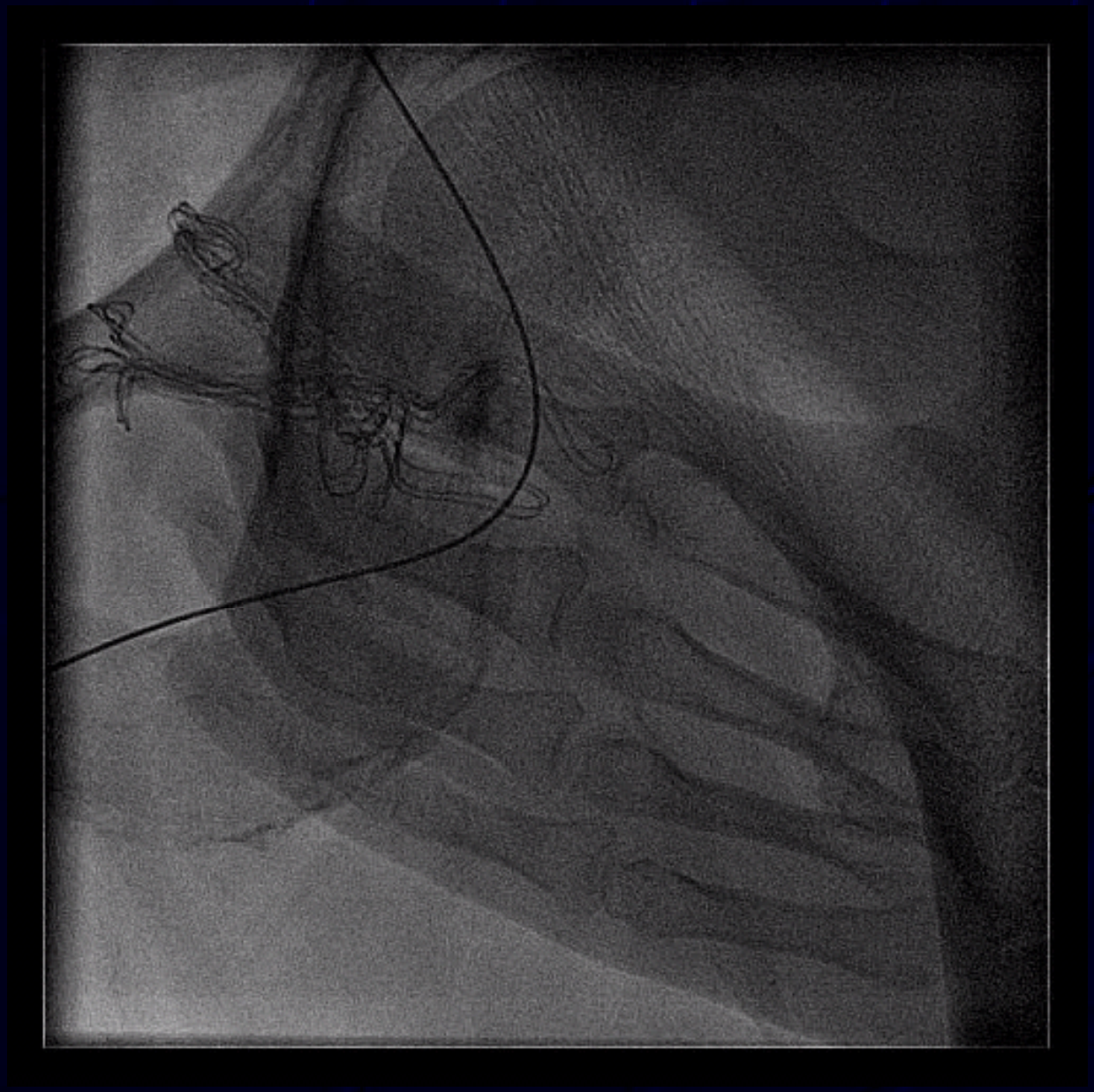
(B) Bulky coronary leaflets that warrants further evaluation.

(C) Left main obstruction by a bulky coronary leaflet.

(D) Successful stenting of the left main coronary through an open cell of the valved stent.

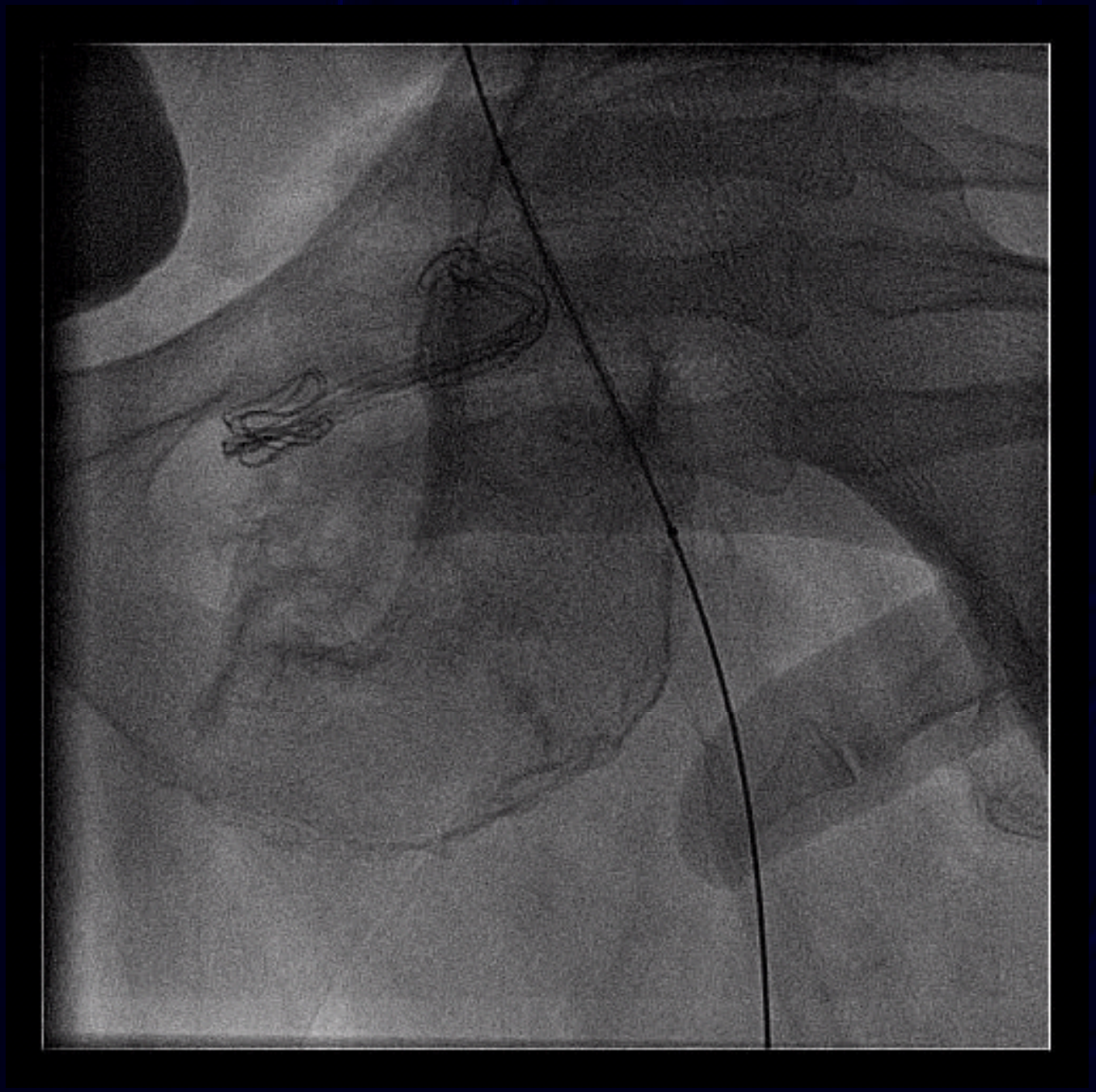
Treatment options for peripheral complications

- Always angio control after access site 18 F sheath
- Vessel occlusion / stenosis after Prostar closure
  - → Re-canalization. Balloon first
- Active Bleeding
  1. Occlusion with balloon
  2. Covered Stent vs vessel repair: it is fondamental that the puncture site was in the common femoral, if a covered stent is needed we will, have no obstruction of superficial and deep femoral arteries

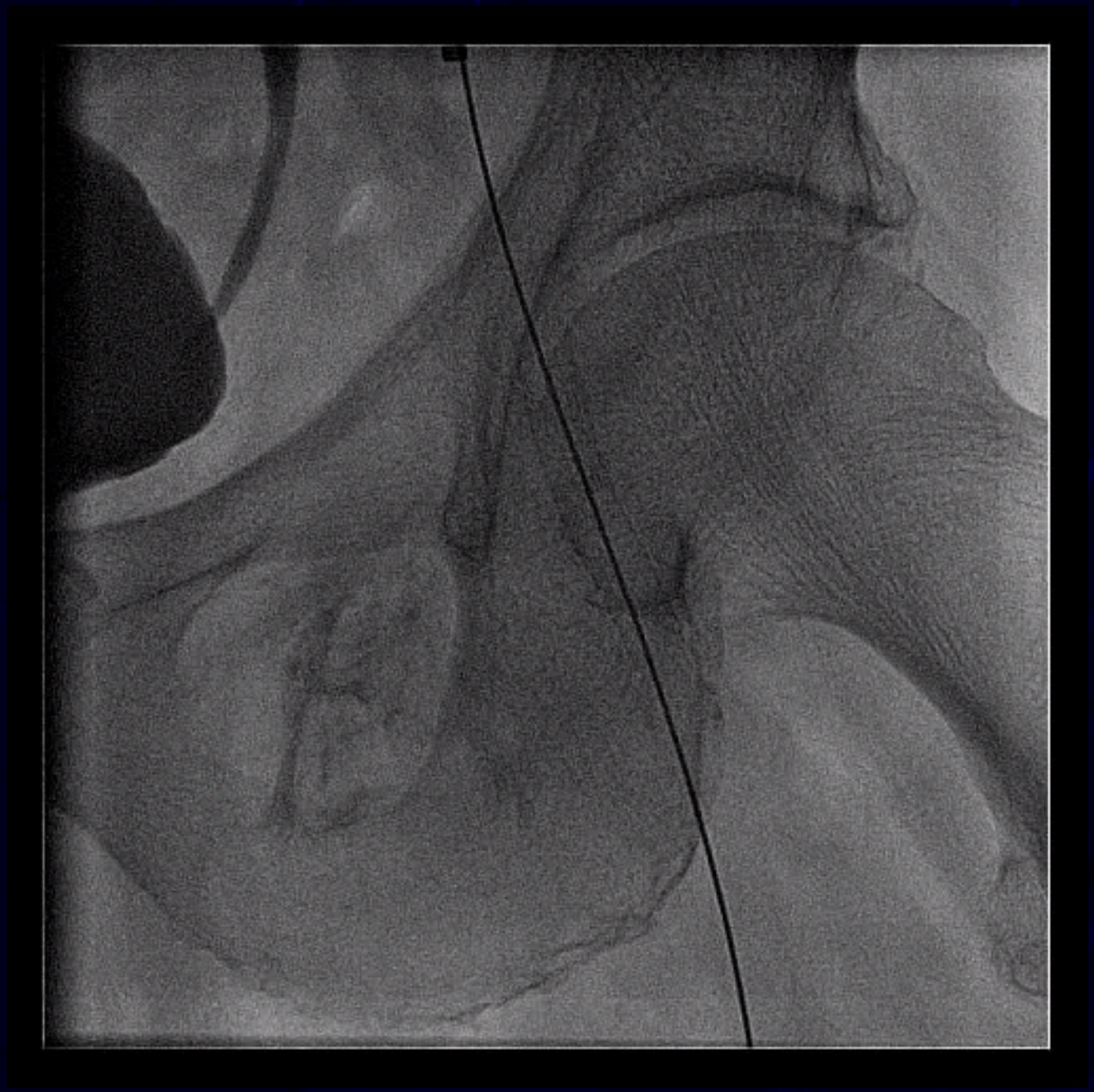


Bleeding

after
unsuccessful
Prostar

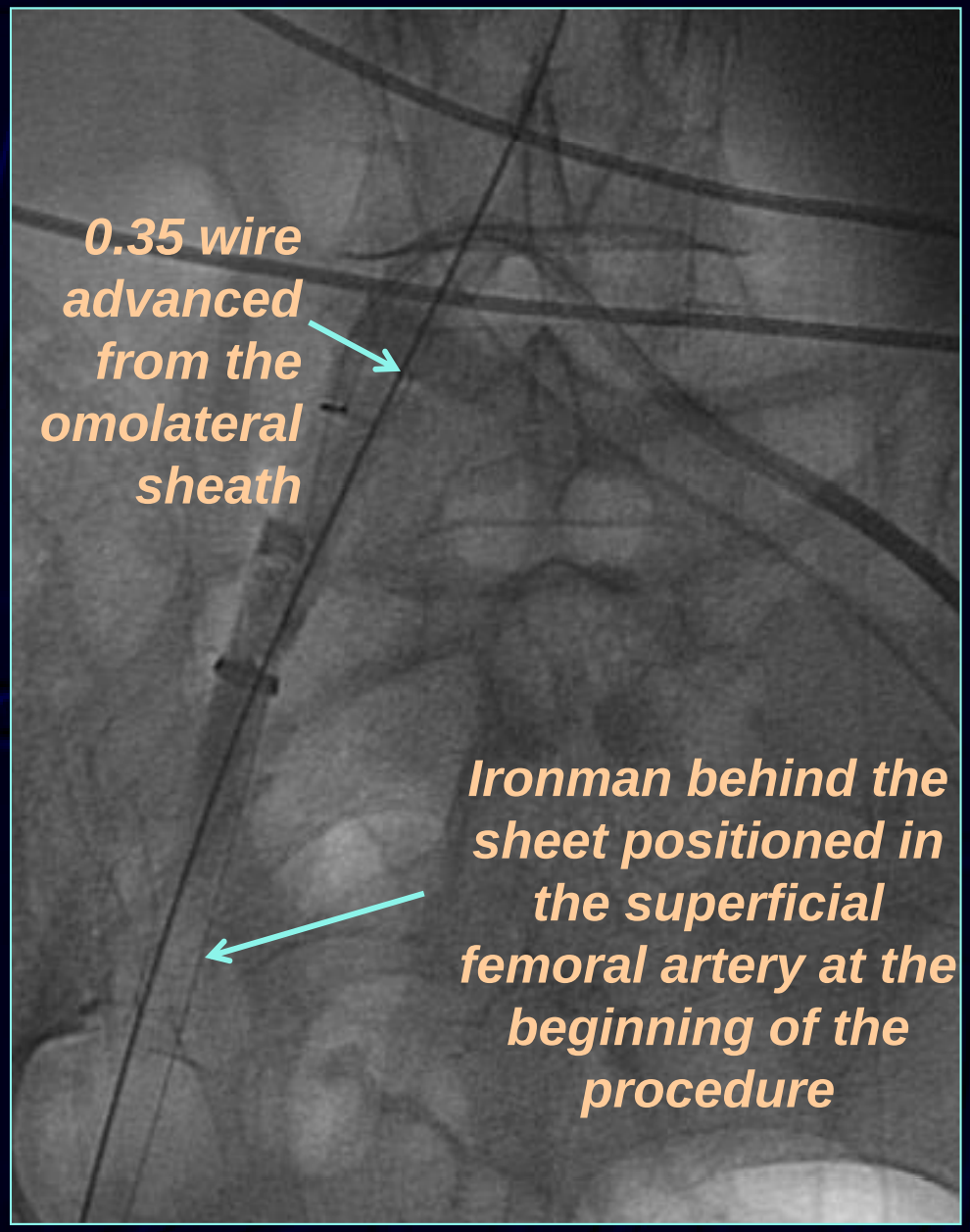


Implantation of a covered self-expandable Viabahn stent 8 / 50 (8 F sheat)

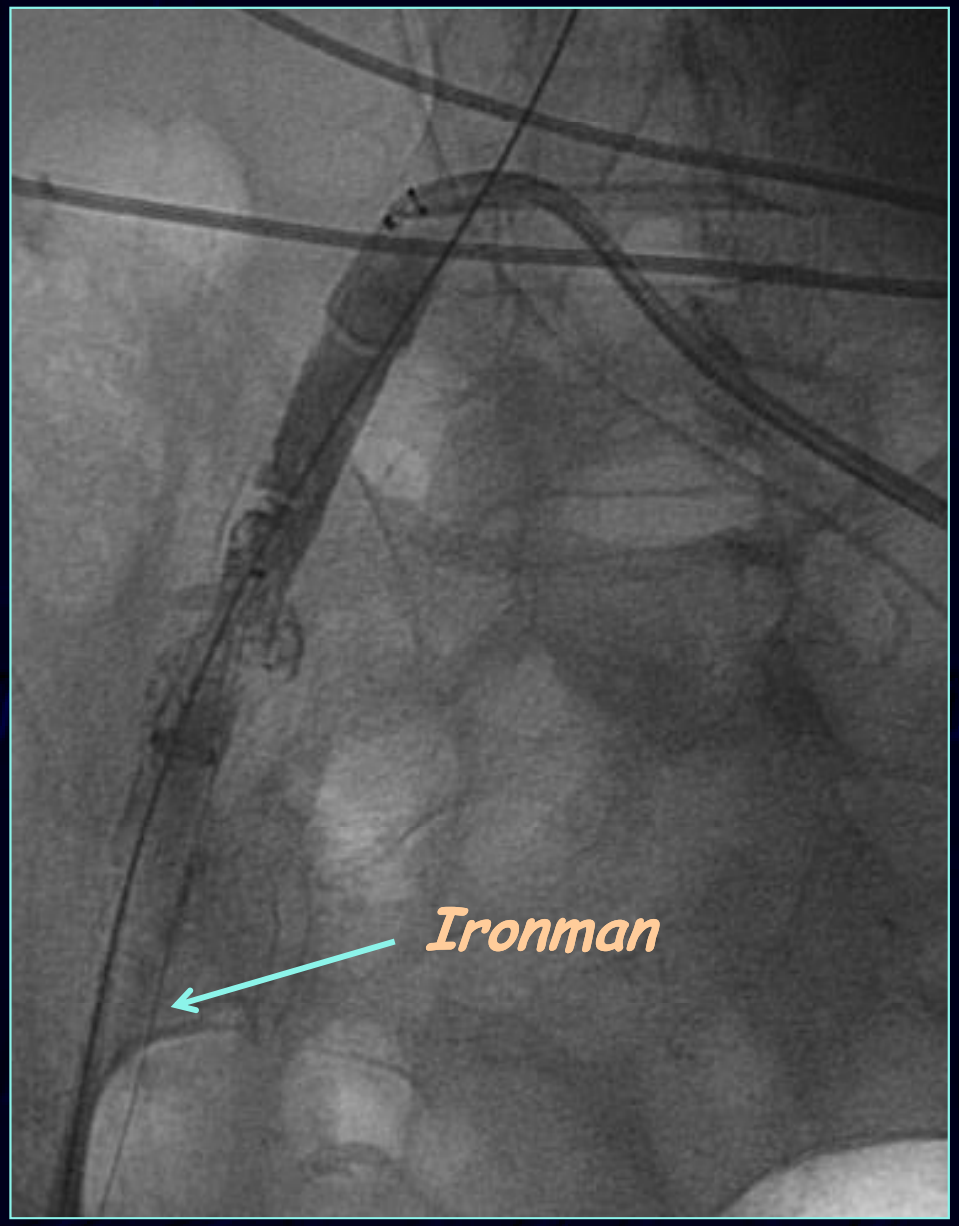


Final result

Puncture of Common Femoral Artery with contra-lateral access



Checking integrity Iliac Vessel with injection from large omolateral sheet



Injection from large contra-lateral sheet to check integrity Iliac Vessel

Inflation of 10x40mm balloon in the Common Iliac Artery to control bleeding from Iliac Rupture

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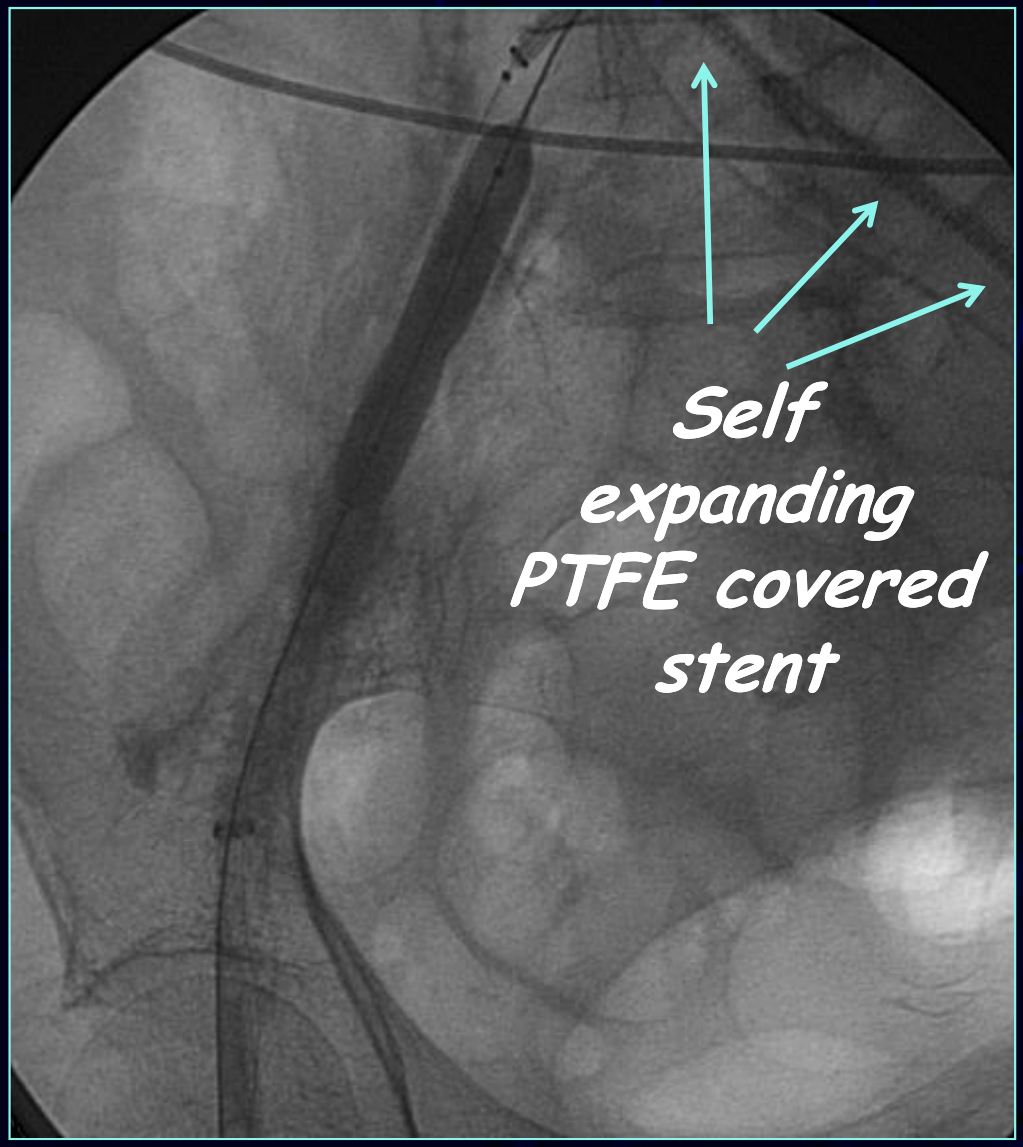
Extravasation from Iliac Rupture beginning at the point of sheath insertion. Control of this problem only be achieved if two requirement have been met:

1) *Puncture in the Common Femoral Artery above bifurcation*
2) *A wire already present in the distal vessel extending below the puncture site*

56703/09HSR

Balloon sealing provided by balloon inflation. The balloon has been advanced over the 0.35 wire inserted from the large omolateral sheath.

The iron man wire in the controlateral sheat will be used to advanced the self expanding covered stent



Emobahn (self expanded PTFE covered stent) ready to go from contra-lateral sheath over iron man wire.

The inflated balloon provides sealing during advancemt. This balloon is deflated when the stent is advanced distally

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Deployment of Emobahn

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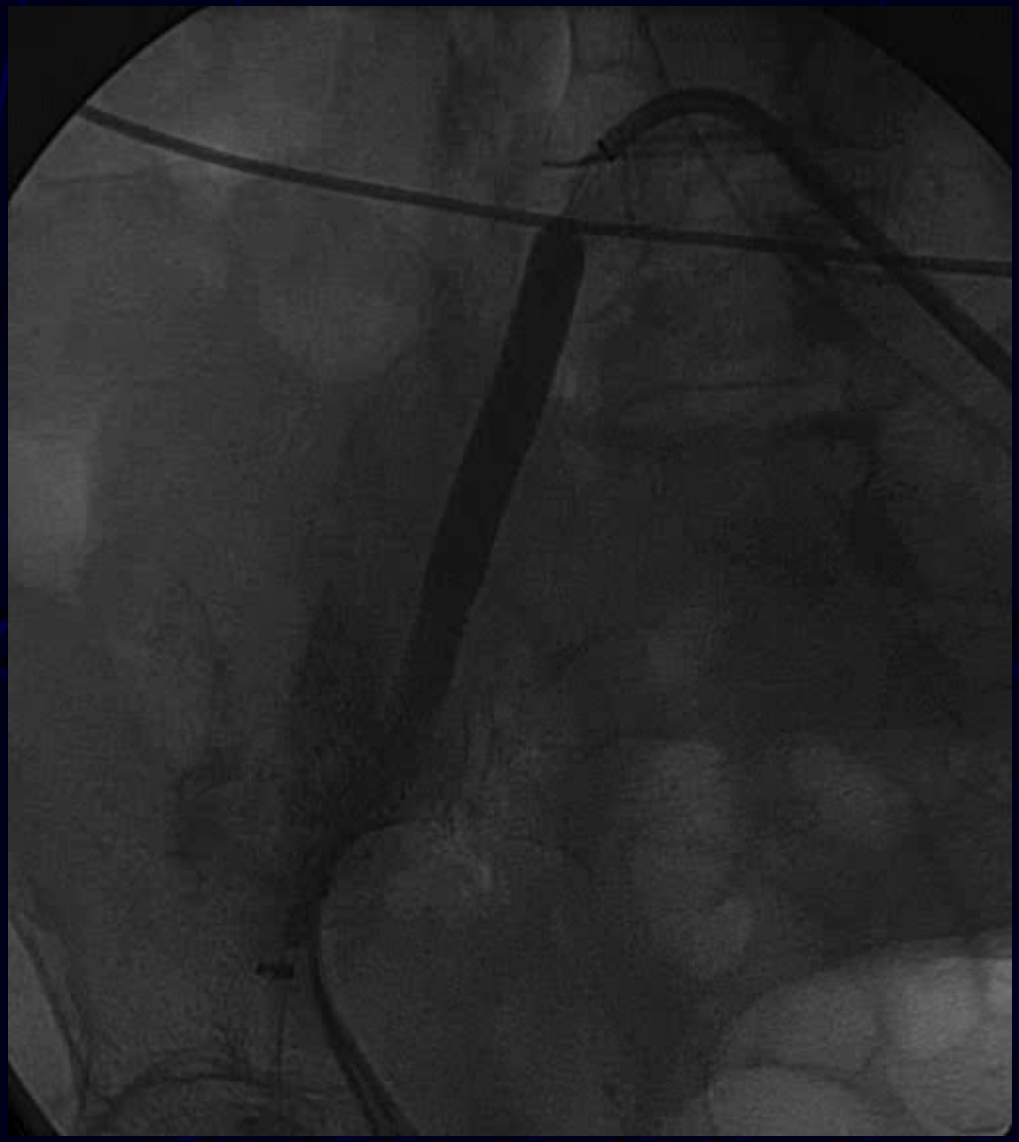
Deployment of Emobahn

Post-dilatation

56703/09HSR

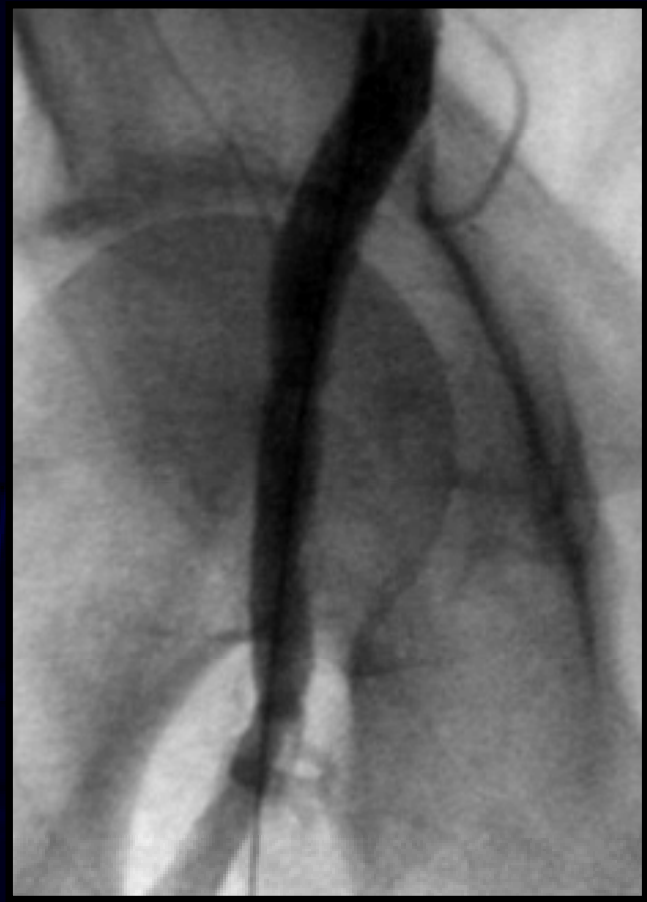


Incomplete distal sealing

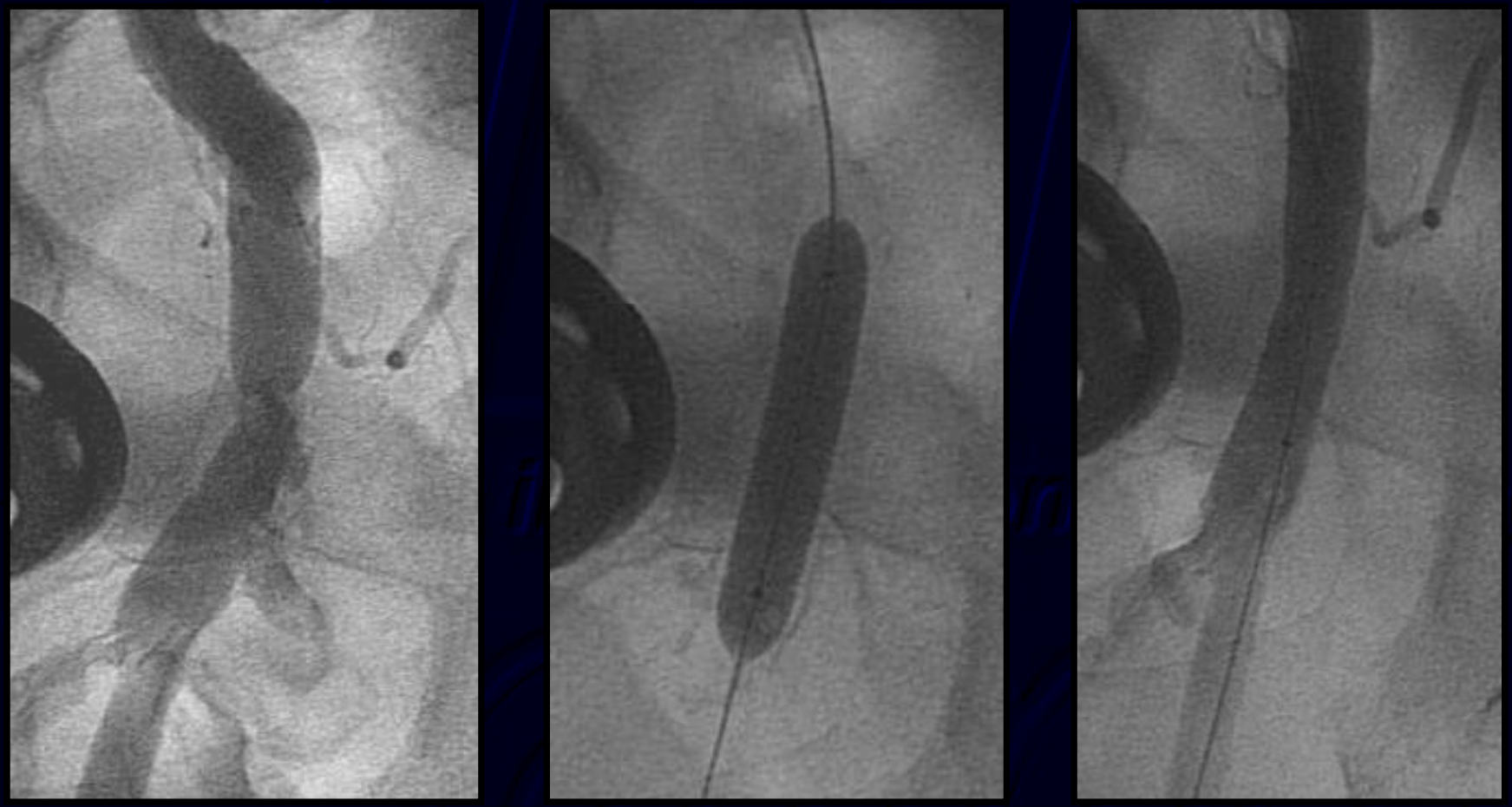
Deployment of second Emobahn covering the puncture site. Essential is to have the ironman wire already advanced in the distal vessel

Post-dilatation

Final check



Extravasation at the puncture site treated with a balloon inflation with a good final result.



In the left hand picture, a stenosis caused by excessive tension on the Prostar sutures is seen in the common femoral artery. Distal extravasation is also evident. Balloon inflation at two atmospheres for 5 minutes improved both issues significantly.

Conclusions

Patients undergoing TAVI are very frail, most of the complications considered minor become major when they occur in these patients

There is the need for meticulous attention to any detail even the minor ones

Be always ready to take action when there is a complication and acknowledge that an inappropriate solution to the first complication will not be forgiven