

B O R D E A U X

# PERSPECTIVES

Friday, June 17, 2022

My most didactic/ nightmarish cas and my most promising and innovative technique

## ORGANIZATION

Eric Ducasse & Maxime Sibé

## CONTACT & INFORMATION

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[www.congresperspectives.com](http://www.congresperspectives.com)





## CLINICAL CASE

*SAPIEN 3 Valve Balloon Rupture During  
Transcatheter Aortic Valve Replacement*

Bailout measures to manage peri-procedural complications

*Eric Maupas*

*Hôpital Privé Franciscaines*

*Nîmes*



Je déclare les liens d'intérêt potentiel suivants :  
Consultant : Boston Scientific, Biotronik



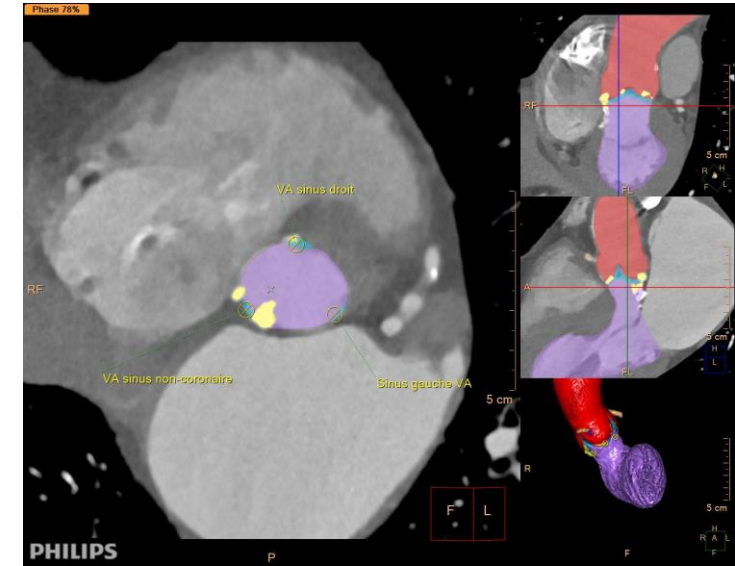
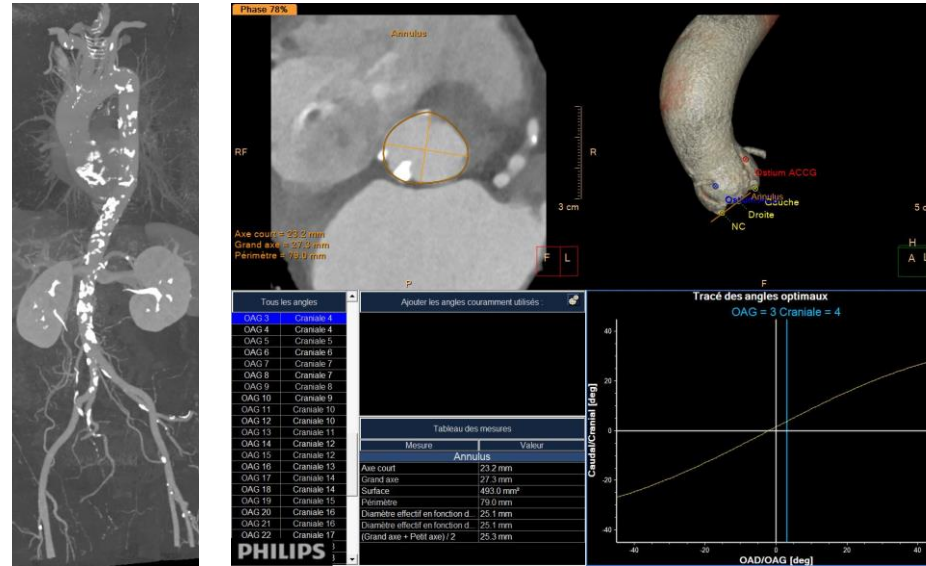
## Clinical Case

- 84-year-old man admitted stage 4 NYHA
- Critical aortic valvular stenosis: mean gradient 70mmHg, aortic valve area < 0,7 cm<sup>2</sup>
- EF 60 %. PAH (systolic 70 mmHg). Annular calcifications +++ and protrusive LVOT calcifications
- BNP > 5000; severe COPD, EKG: AF + RBBB; early cognitive disorders (EBIXA)
- Coronarography: calcified atheroma without significant lesion
- STS Score: 5,88 % ; EUROSCORE log: 20,15 % . EUROSCORE 2: 3,88 %
- TAVI procedure

# Clinical Case

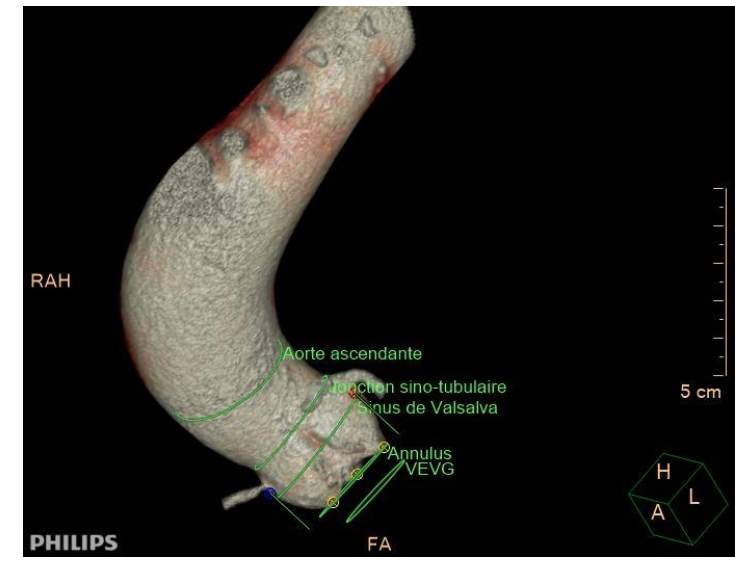
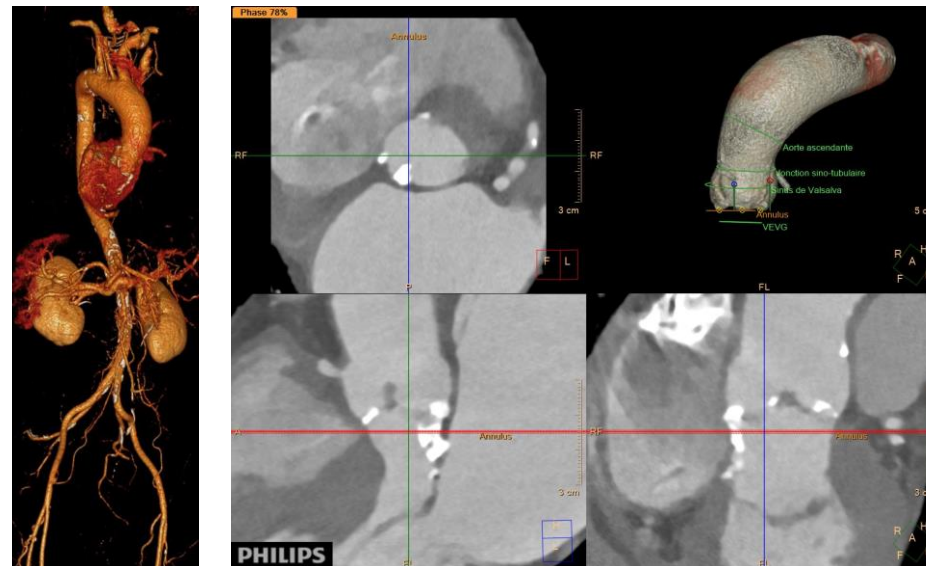
## Pre TAVI CT scan

- Tricuspid aortic valve (Scoring Ca+++ = 4892)
- Annular and LVOT protrusive calcifications
- Aortic angulation = 37°
- Annular area = 493 mm<sup>2</sup>, perimeter 79 mm
- Moderate aortic and ilio femoral axis calcifications



## STANDARD TAVI PROCEDURE Annular protrusive calcifications

EDWARDS S3 26 mm







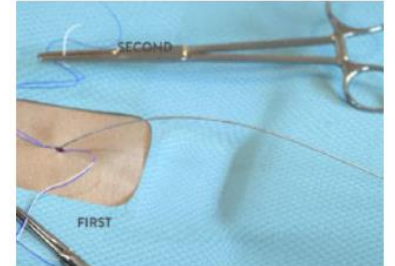
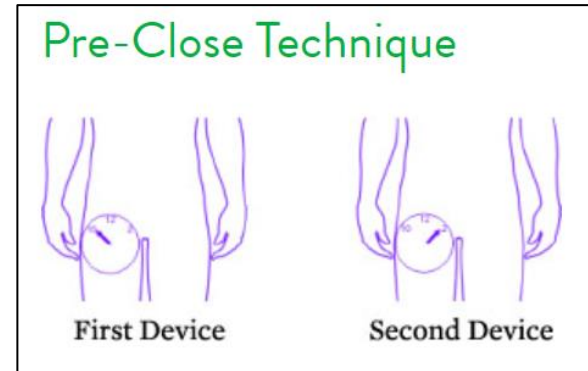
## Procedure (Valve ES3 - 26 mm)



Ultrasound-guided puncture (100%)  
ANGIO before percutaneous approach



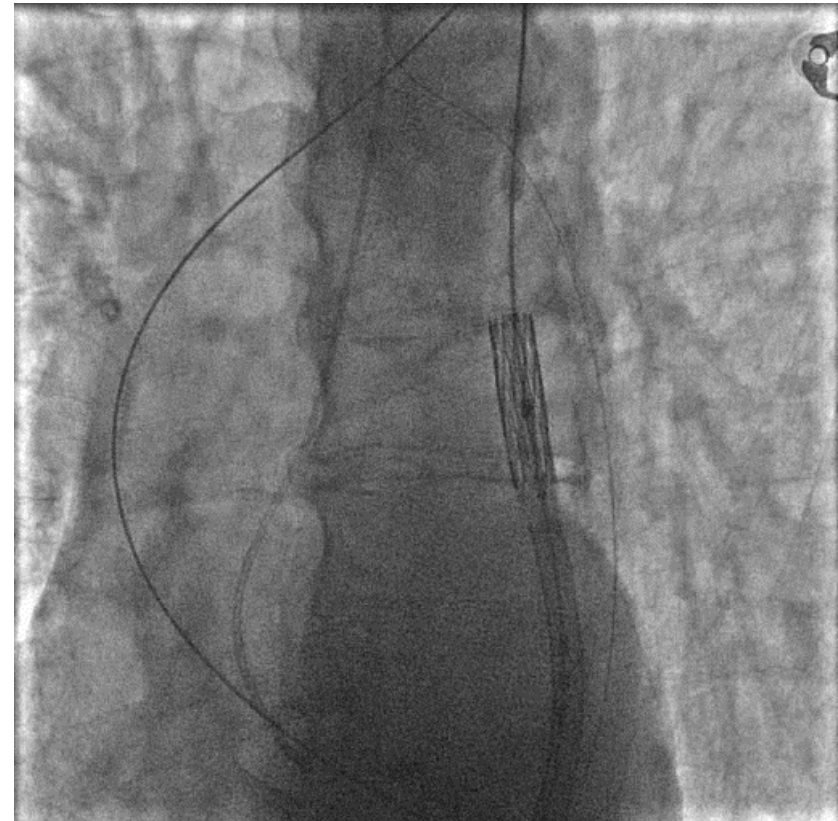
First Device Deployment



Second Device Deployment



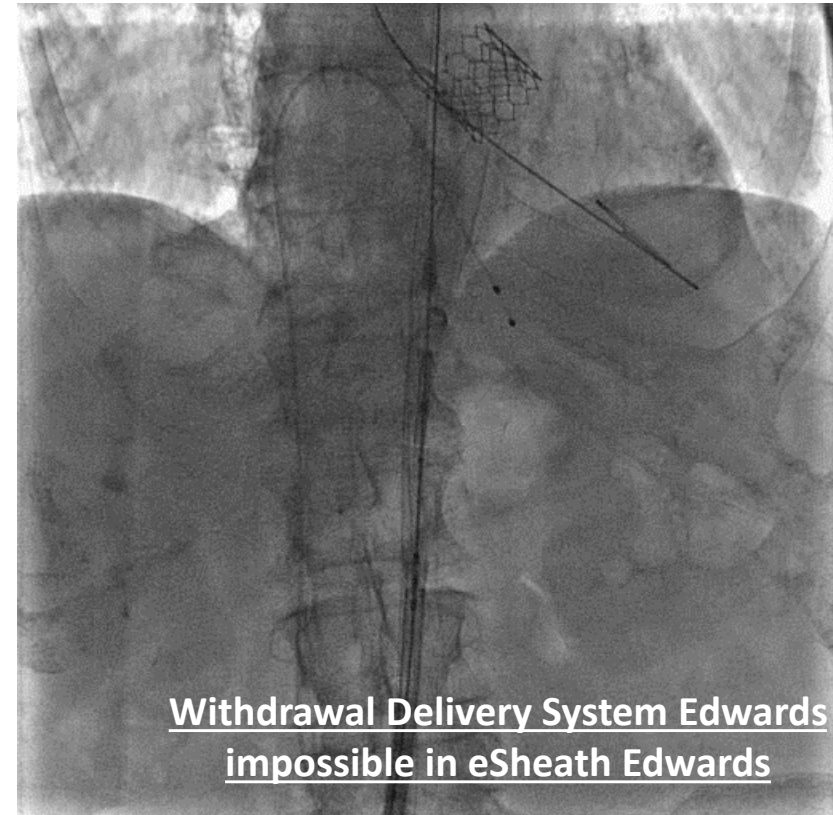
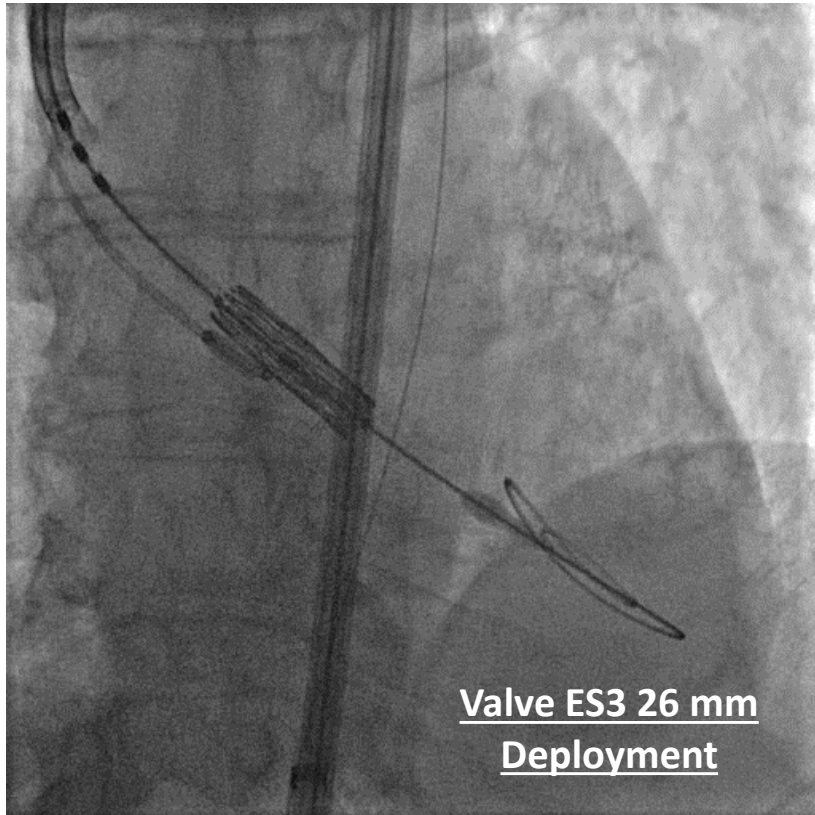
Procedure (Valve ES3 - 26 mm)







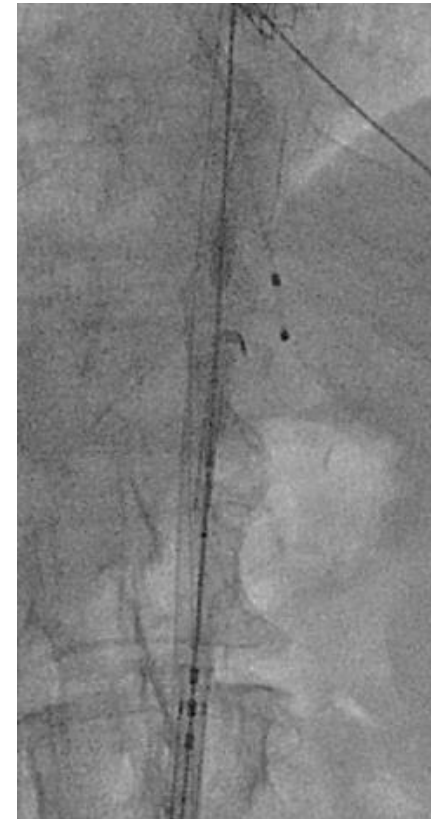
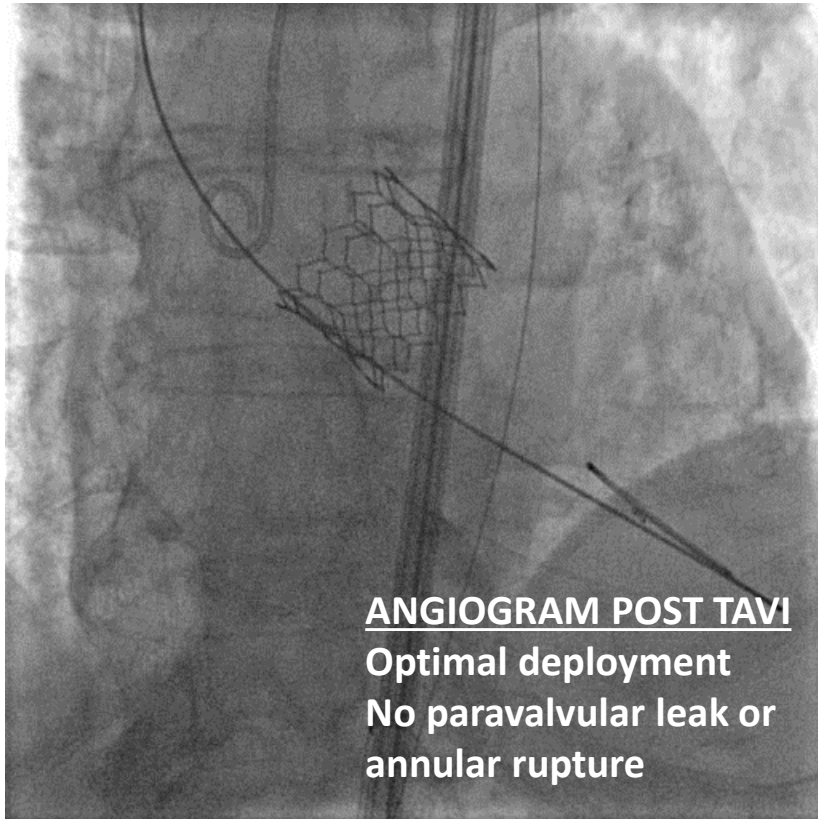
## Procedure (Valve ES3 - 26 mm)





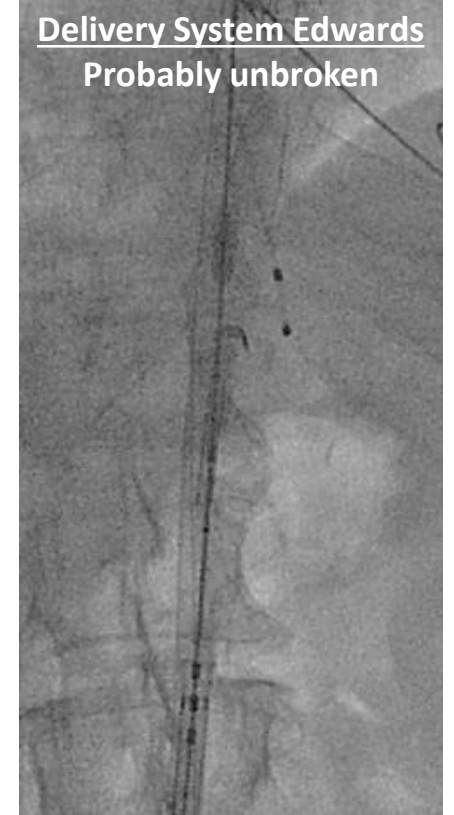
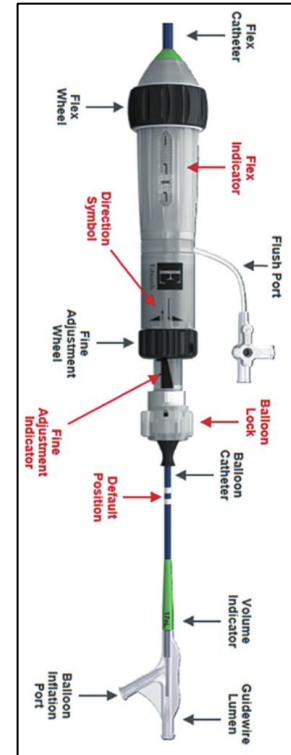
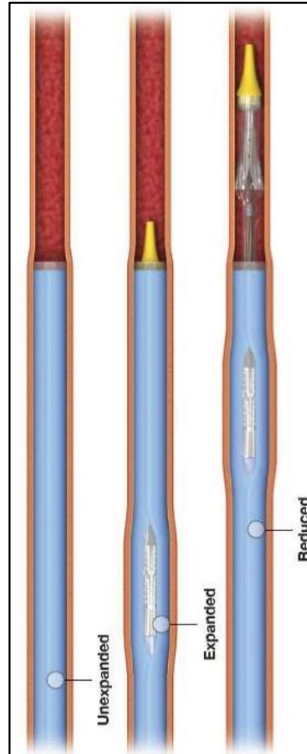
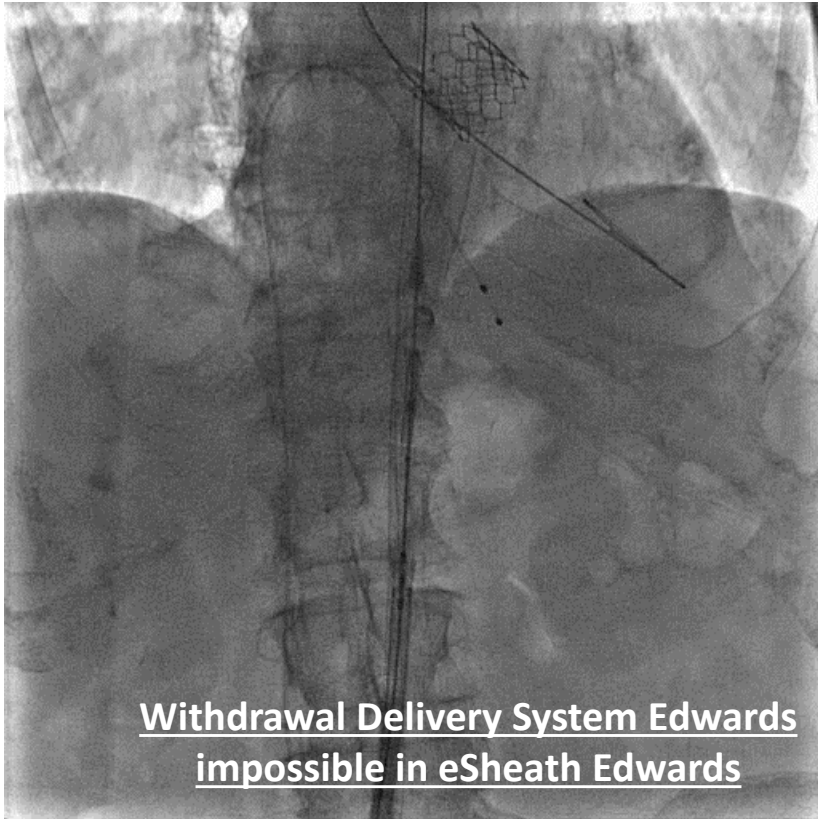


## Procedure (Valve ES3 - 26 mm)



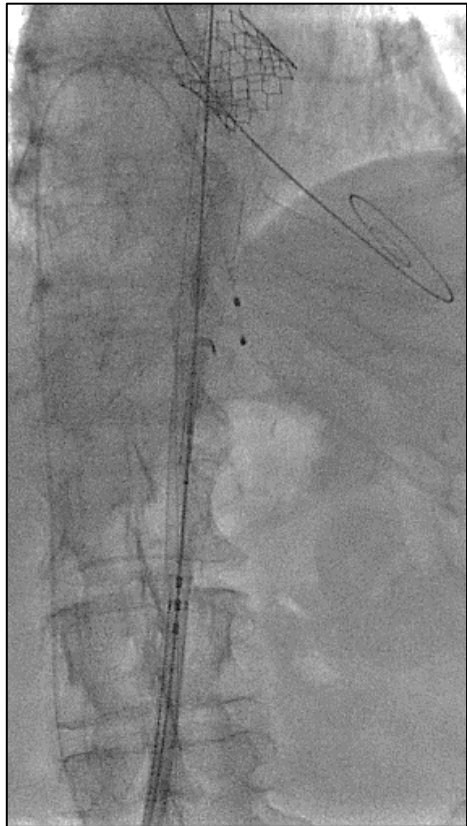
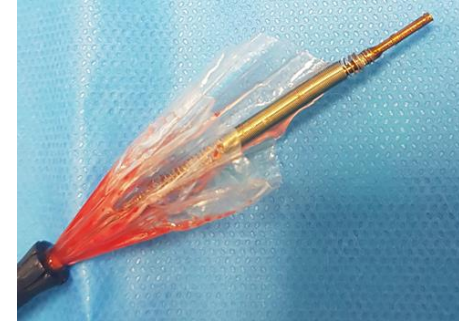


## Procedure (Valve ES3 - 26 mm)





# Procedure (Valve ES3 - 26 mm)

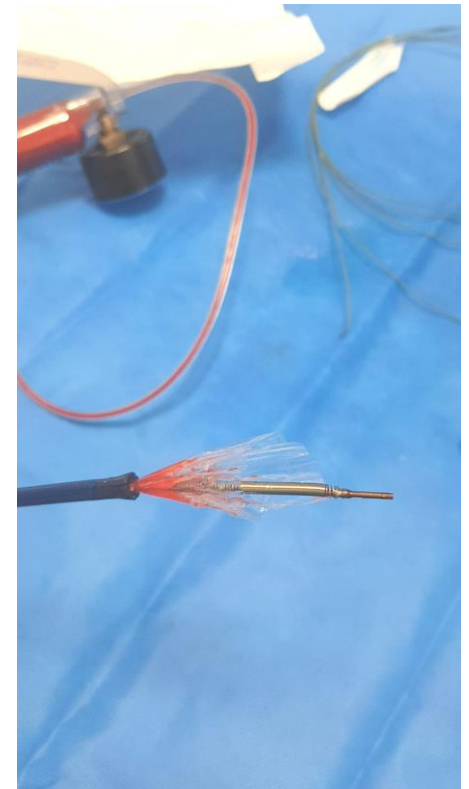
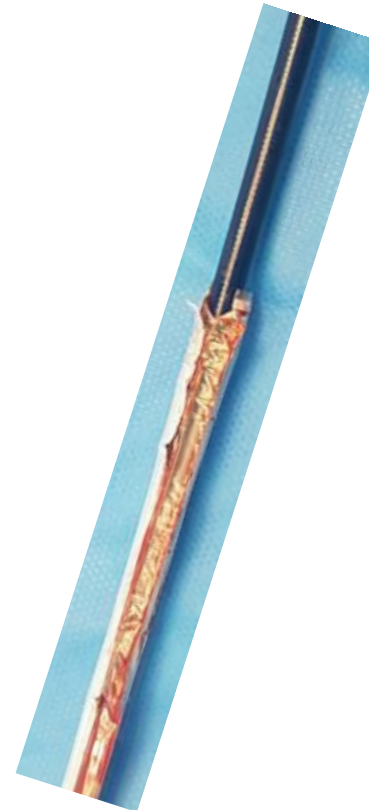


Removal of eSheath EDWARDS + Delivery System and valve balloon and as 1 unit

**but...**

The Nose Cone was stuck at the iliac level and was unable to be retrieved

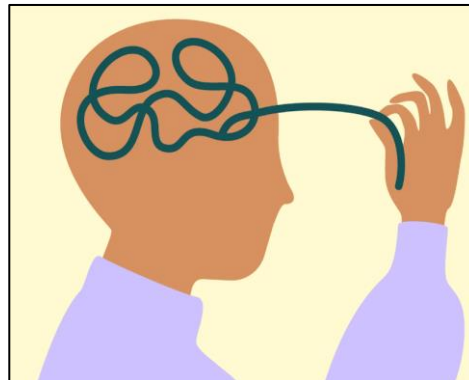
The eSheath was exchanged for a larger 18F sheath (COOK)







## Procedure (Valve ES3 - 26 mm)



Help !!!



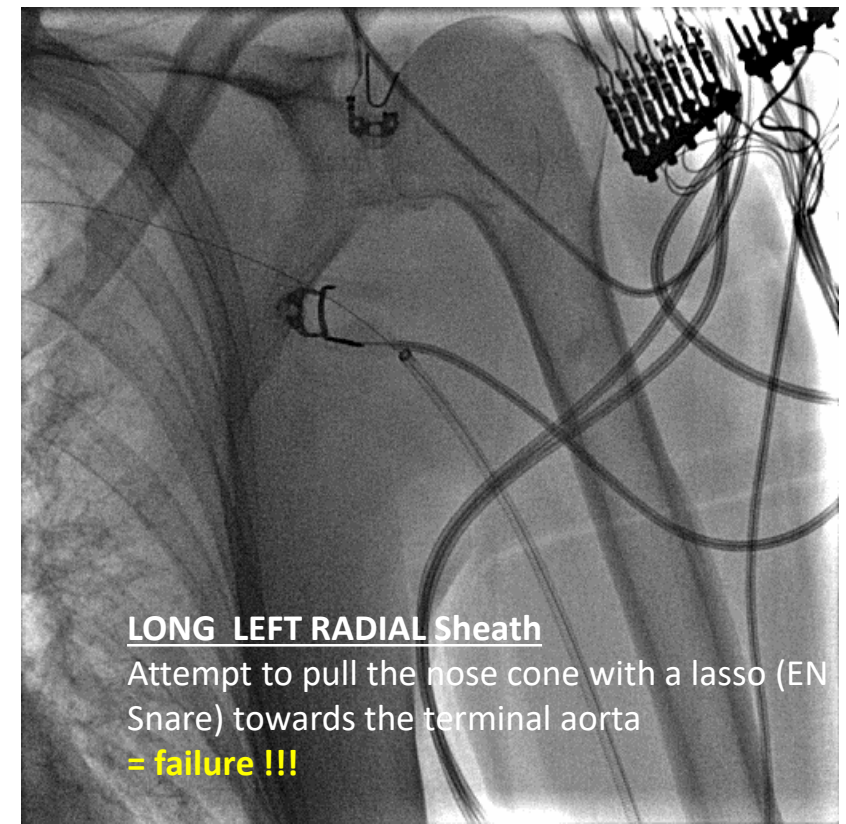
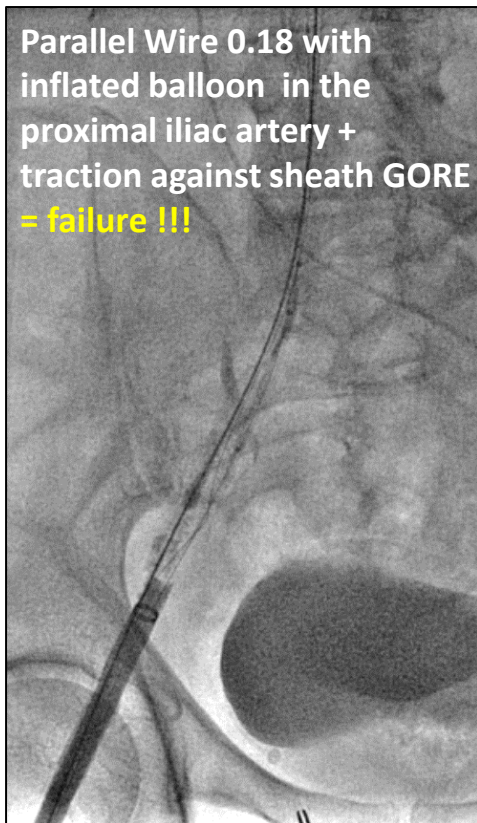
Dr L.. N..



Dr D.. E..



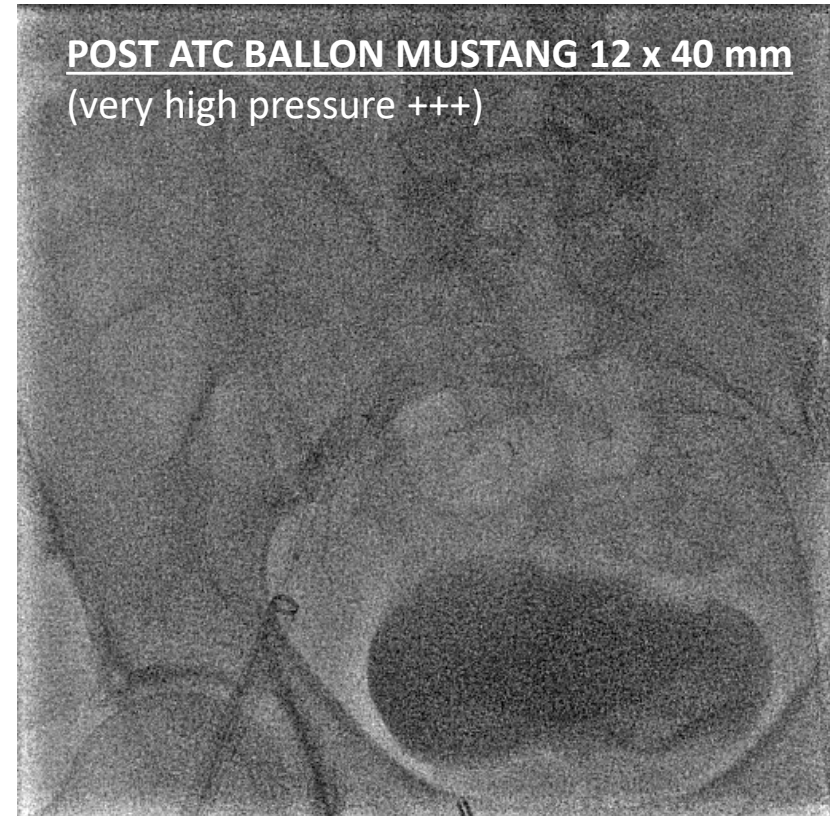
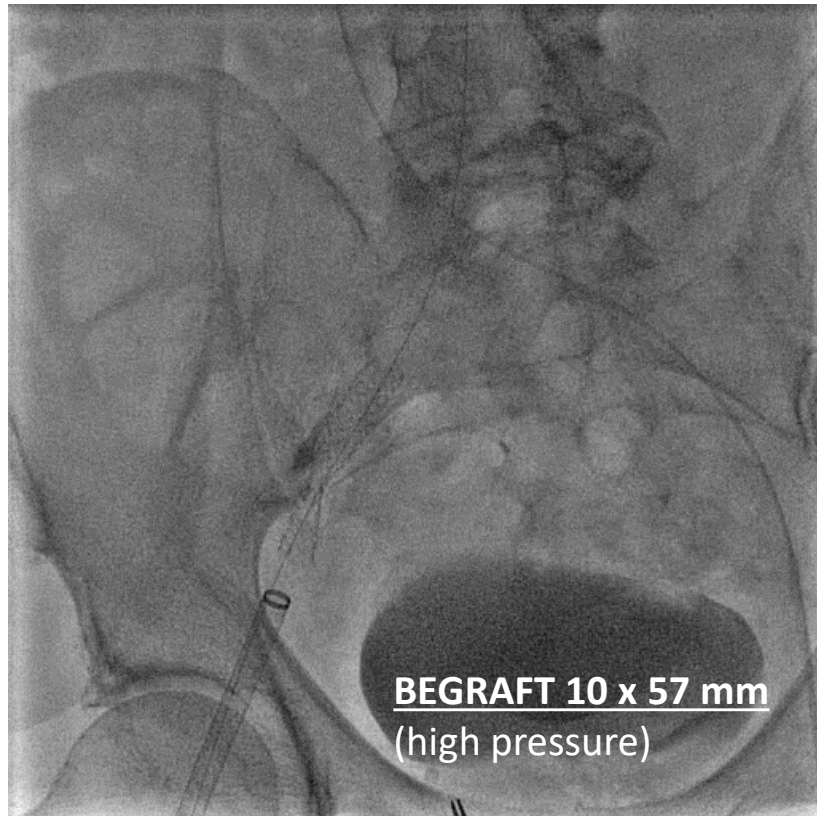
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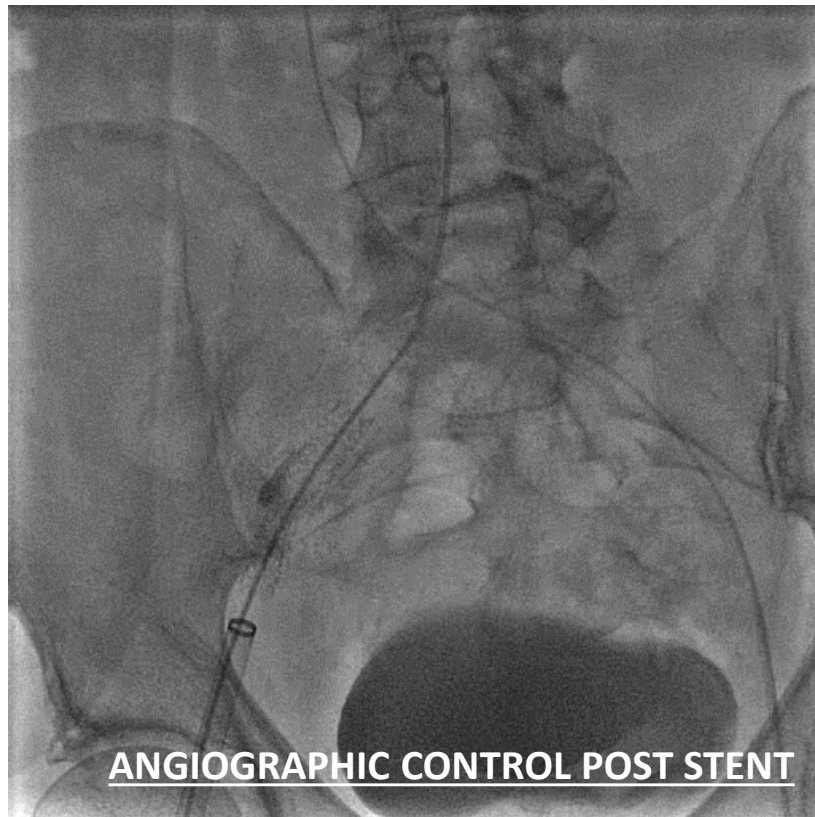
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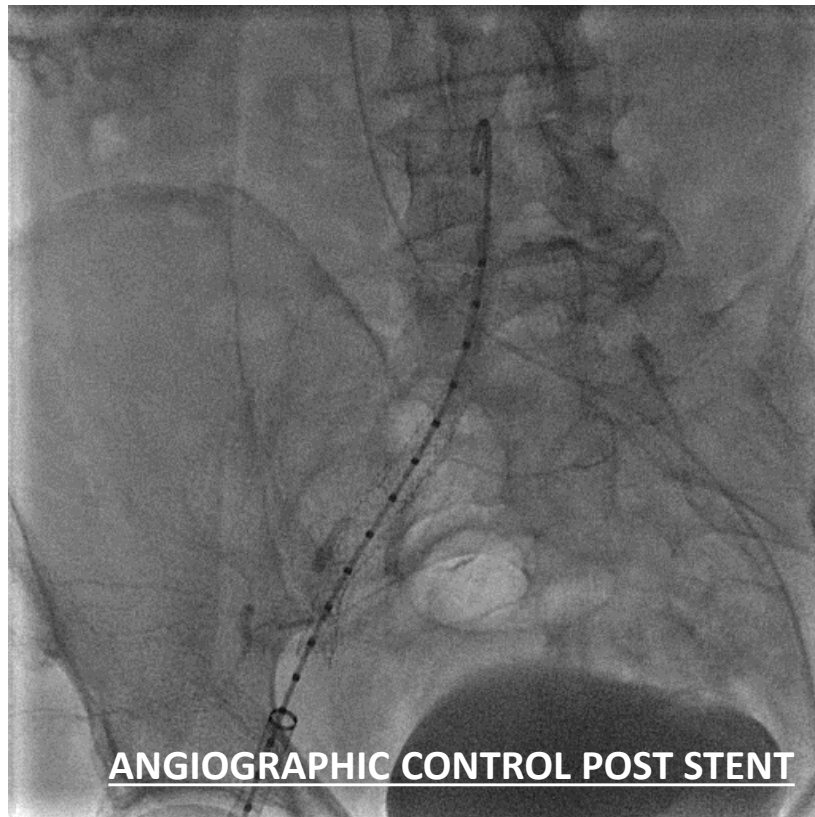


Procedure (Valve ES3 - 26 mm)



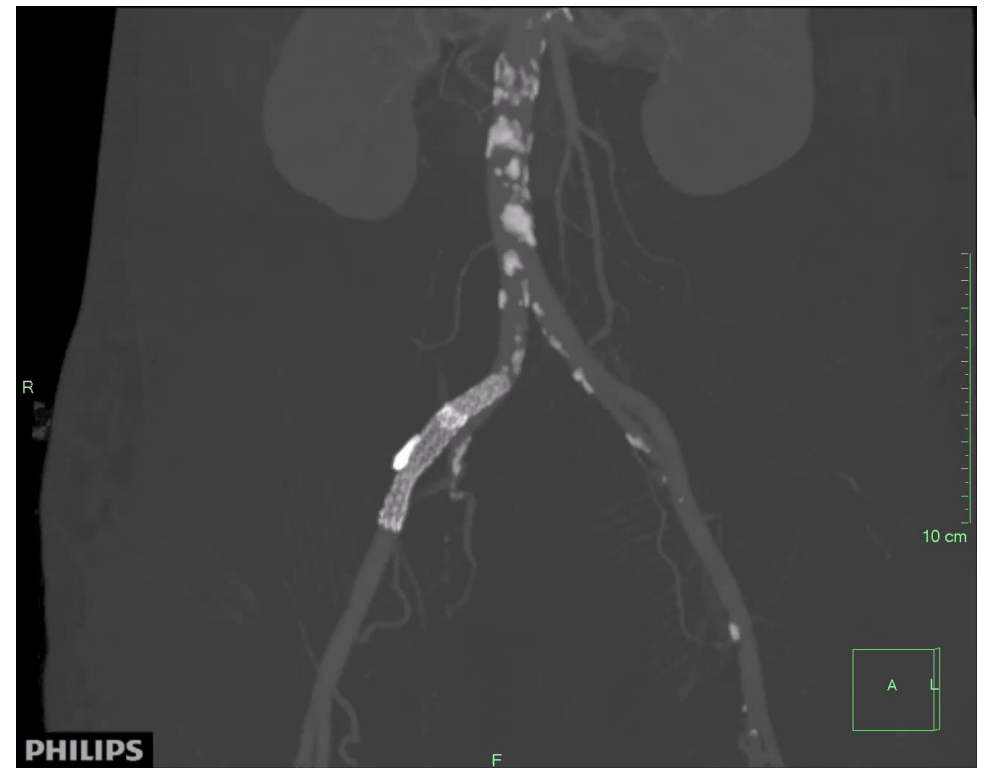


Procedure (Valve ES3 - 26 mm)





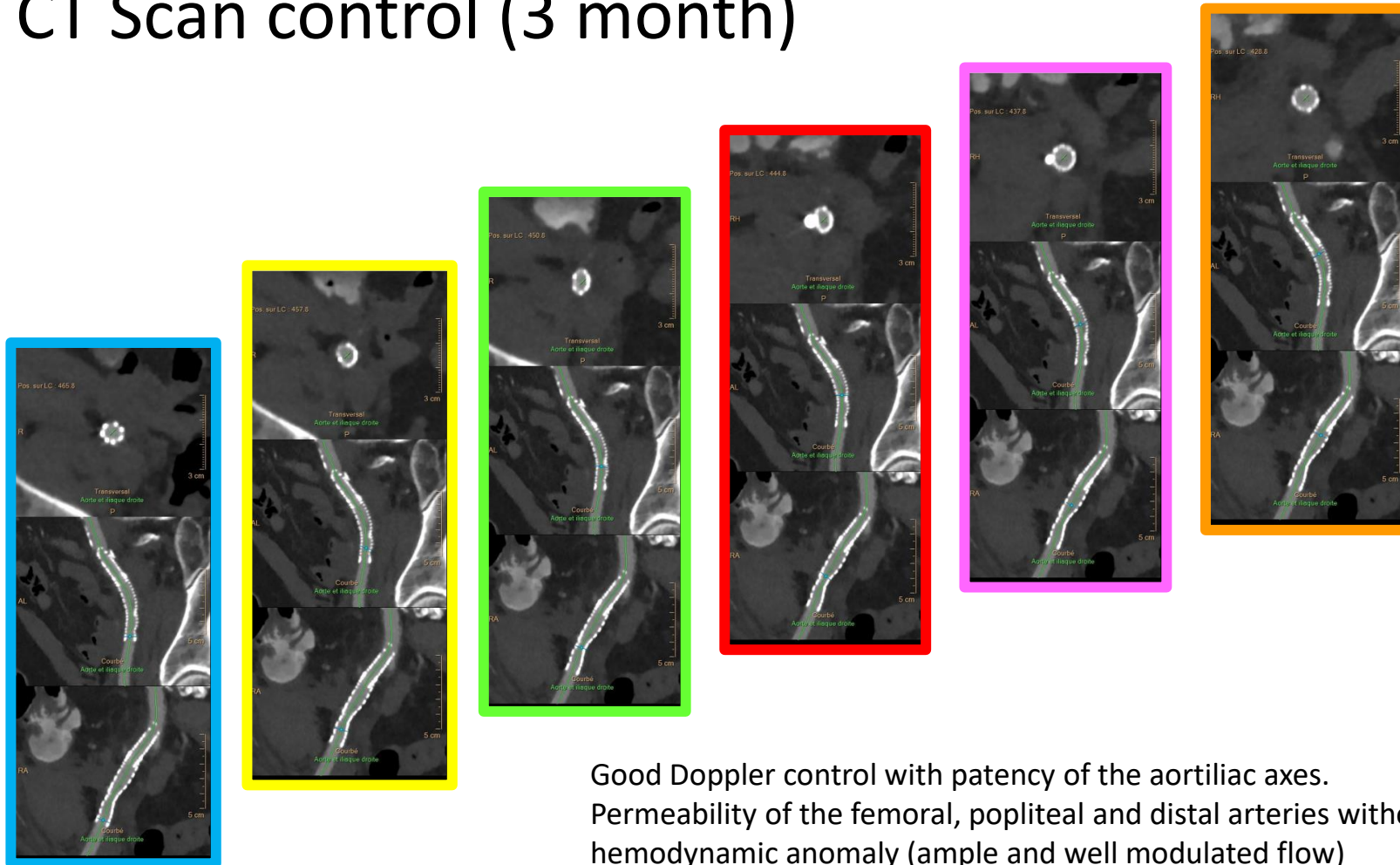
## CT Scan control (3 month)



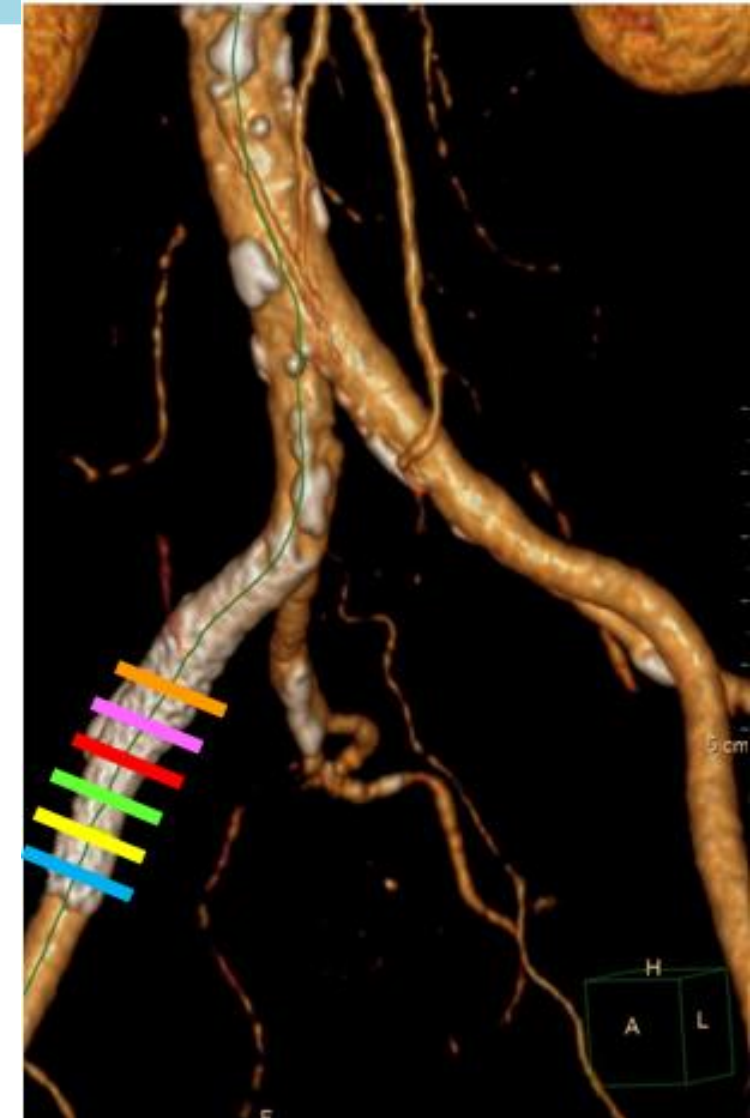




## CT Scan control (3 month)



Good Doppler control with patency of the aortiliac axes.  
Permeability of the femoral, popliteal and distal arteries without hemodynamic anomaly (ample and well modulated flow)



# Similar clinical cases

## Percutaneous Management of Retro-Flex 3 Balloon Rupture and Separation of the Edwards SAPIEN Delivery System

We report the case of an 85-year-old woman with severe aortic stenosis who underwent transcatheter aortic valve replacement with use of the Edwards SAPIEN® valve system. The procedure was complicated by rupture of the valve-deployment balloon, with separation and retention of the nose cone of the RetroFlex 3® delivery system in the iliac artery. Our endovascular retrieval of the equipment was successful, and we achieved access-site hemostasis by deploying a covered stent. To our knowledge, this is the first report of the endovascular retrieval of a malfunctioning delivery system during transcatheter aortic valve replacement. (*Tex Heart Inst J* 2014;41(6):641-4)

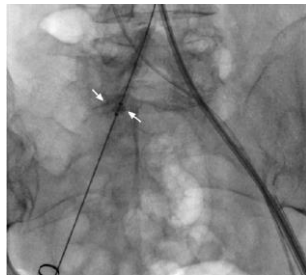


Fig. 3 Fluoroscopic image shows the nose cone, lodged within the common iliac artery. The two dots mark the proximal end of the nose cone.

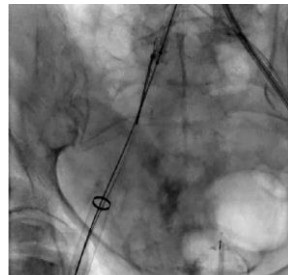


Fig. 4 Fluoroscopic image shows the ENSnare® device, advanced through the Terumo® sheath, securing the nose cone.

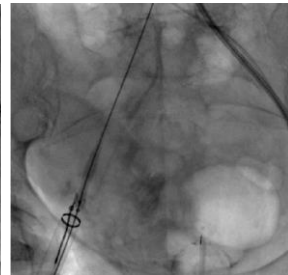


Fig. 5 Fluoroscopic image shows extraction of the nose cone.

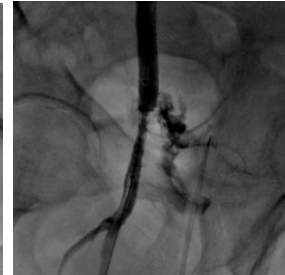


Fig. 6 Angiogram shows extravasation of contrast medium from the external iliac artery after removal of the instruments.

- ✓ Rupture during the deployment of a 23-mm Edwards Sapien valve
- ✓ The valve was well seated with only trace perivalvular aortic insufficiency
- ✓ The ruptured balloon would not enter the distal end of the 22F sheath and the nose cone became lodged in the common iliac artery. With further traction, the nose cone and the distal portion of the balloon separated from the shaft and were retained in the common iliac artery.
- ✓ The LCFA sheath was emergently exchanged for a larger 14F sheath to accommodate a Coda® Balloon
- ✓ A 26F Gore® DrySeal was inserted into the RCFA and into the right external iliac artery. An 18- to 30-mm ENSnare® device was used to capture the retained nose cone. **The nose cone, snare and DrySeal sheath were removed as a unit** over the Super Stiff wire
- ✓ An angiogram revealed **contrast extravasation from the right external iliac artery = covered stent**

JACC: Cardiovascular Interventions  
Volume 9, Issue 8, 25 April 2016, Pages e79-e81

Images in Intervention

### An Unusual Complication After Rupture of the SAPIEN 3 Valve Balloon During Transcatheter Aortic Valve Replacement

Fadi J. Sawaya MD, Andrew Roy MD, Antoinette Neylon MD, Marco Spaziano MD, Thomas Hovasse MD

FIGURE 7 Pictures of the 26 mm Balloon After Surgical Retrieval

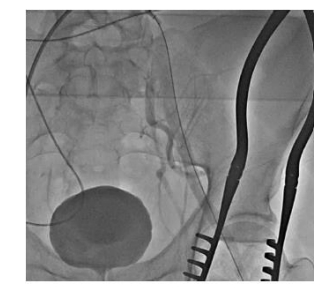
Ruptured and dismantled 26-mm valve balloon.



Nose cone of the commander delivery catheter stuck at the level of the left common femoral artery.



A 9 40-mm Passeo balloon (Biotronik) inflated in the left external iliac for adequate hemostasis.



Final angiogram showing successful repair of left common femoral artery (Online Video 2).


- ✓ Rupture during the end of deployment of a 26-mm Edwards Sapien valve
- ✓ Angiogram showed adequate valve deployment with mild paravalvular regurgitation
- ✓ An attempt to remove the commander delivery system through the 14-F expandable sheath was unsuccessful and met a lot of resistance, which led to splitting of the sheath. It was then decided to remove the sheath and the valve balloon as 1 unit.
- ✓ **The nose cone of the delivery system was stuck at the common femoral level** and was unable to be retrieved
- ✓ **Bleeding from the common femoral access** = crossover balloon was inflated to ensure adequate hemostasis
- ✓ The vascular team was consulted and performed a **surgical cut down with successful retrieval of the Edwards delivery system**



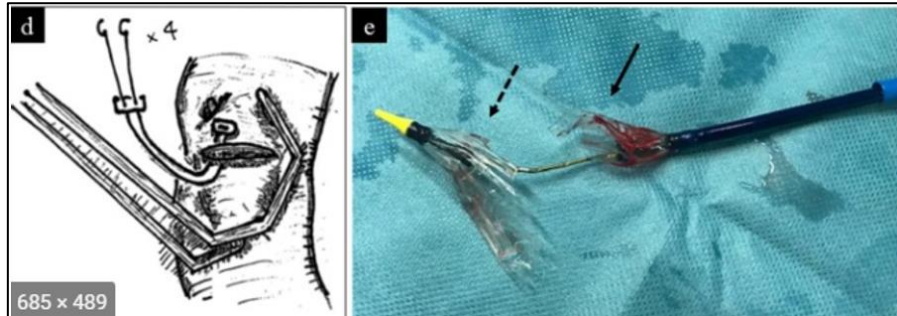
# Similar clinical cases

Images in Cardiovascular Intervention | Published: 19 November 2019

## Successful bailout of Sapien 3 valve balloon rupture during transcatheter valve implantation via transaortic approach

Takeshi Takamura , Ryosai Inoue, Tetsuya Seko, Toshiya Tokui, Atsunobu Kasai & Masaaki Ito

*Cardiovascular Intervention and Therapeutics* 35, 415–416 (2020) | [Cite this article](#)



- ✓ Rupture during the deployment of a Edwards Sapien valve (calcifications STJ)
- ✓ Angiogram showed adequate valve deployment with mild paravalvular regurgitation
- ✓ It was decided to **remove the certitude sheath and delivery system as one unit**
- ✓ Distal balloon shoulder of the certitude delivery system was unable to be retrieved because of great resistance at the ascending aorta
- ✓ After removing the guidewire, we **performed transverse incision by approximately 3 cm with side biting clamp of ascending aorta, and successfully retrieved the certitude delivery system while rapid ventricular pacing**

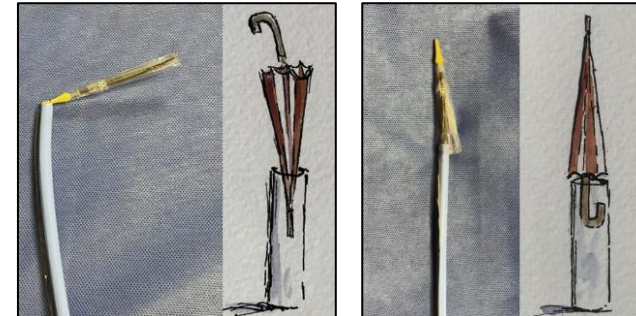
[JACC Cardiovasc Interv.](#) 2022 Jan 24;15(2):e17-e19. doi: 10.1016/j.jcin.2021.10.028. Epub 2021 Dec 29.

## Percutaneous Retrieval of a Ruptured SAPIEN Ultra Balloon: The Reverse Umbrella Technique

Craig Basman <sup>1</sup>, Arber Kodra <sup>2</sup>, Ahmad Mustafa <sup>2</sup>, Garvey Rene <sup>2</sup>, Denny Wang <sup>2</sup>, Luigi Pirelli <sup>2</sup>, Chad A Kliger <sup>2</sup>

Affiliations + expand

PMID: 34973908 DOI: 10.1016/j.jcin.2021.10.028

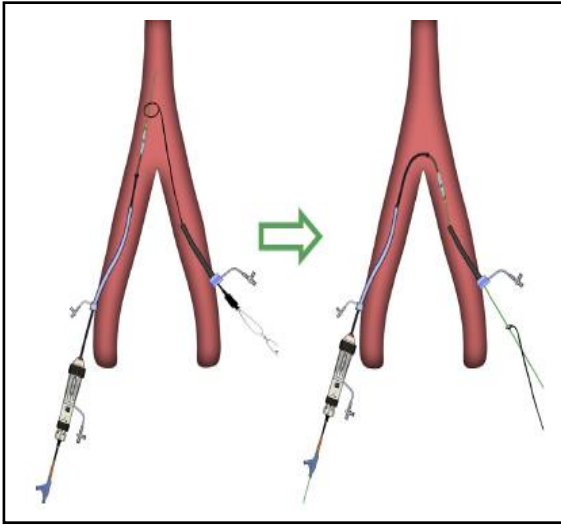


- ✓ During deployment, the THV balloon ruptured, likely from focal spiculated calcium at the STJ
- ✓ Transthoracic echocardiography showed no paravalvular leak with a well-functioning valve
- ✓ During removal of the Commander delivery system, the balloon disrupted and caught onto the E-sheath, separating it from the delivery shaft
- ✓ **The proximal delivery system was removed from the E-sheath**
- ✓ **The wire was therefore removed and the nose cone was snared after losing the wire. The nose cone was then reoriented downward, allowing retraction into the sheath**

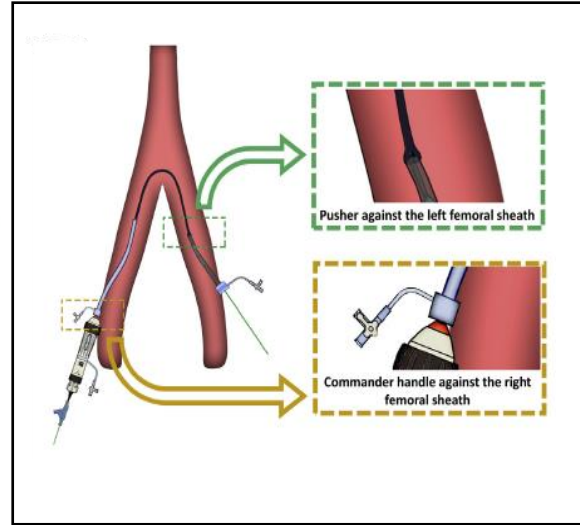


# Similar clinical cases

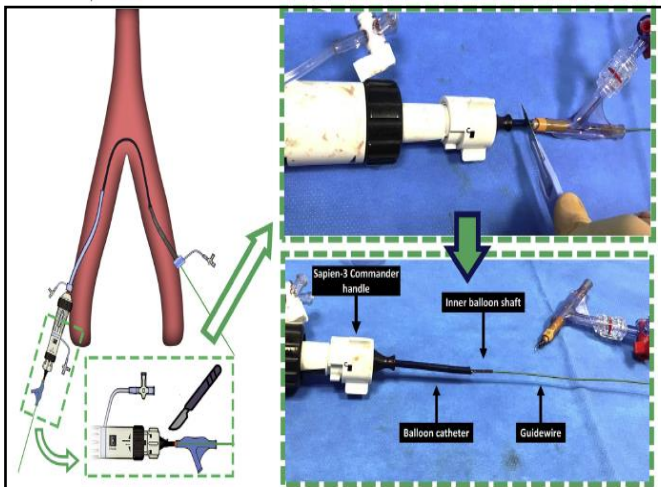
**STEP 1: snare and externalize the wire**



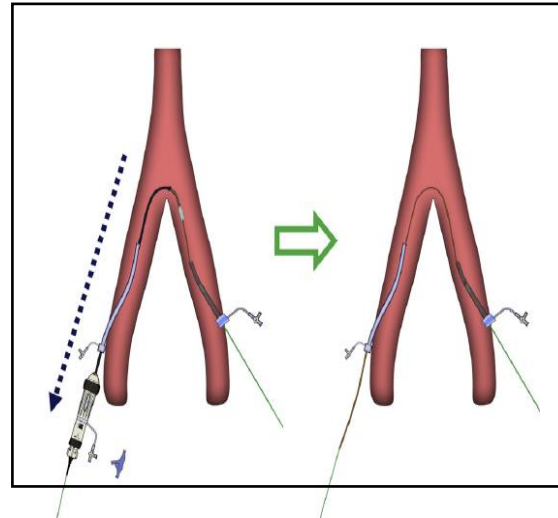
**STEP 2: push the Commander across the aortic bifurcation**



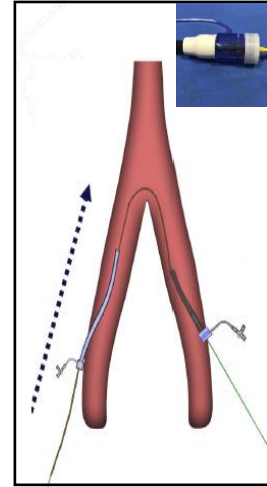
**STEP 3: cut the commander at the proximal end: this will separate the pusher/balloon catheter system from the inner balloon shaft**



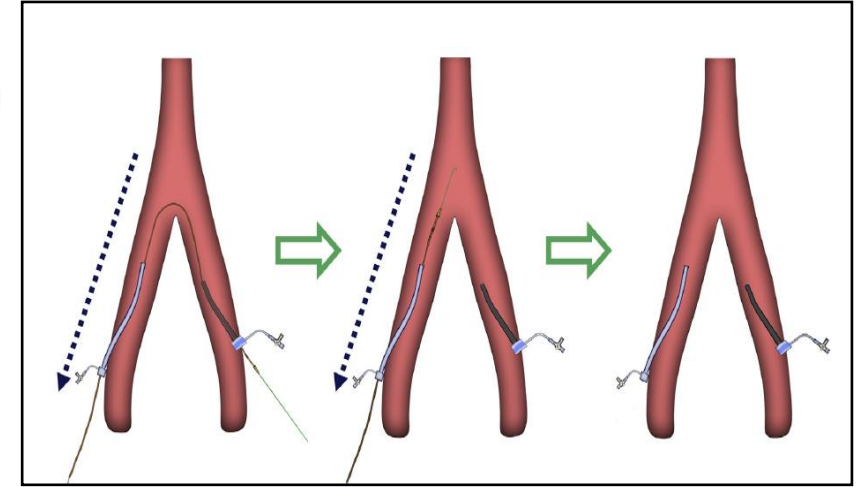
**STEP 4: remove the Commander pulling it from the right femoral sheath. After this maneuver only the inner balloon shaft with the distal part of the balloon will remain in place**



**STEP 5: push the inner balloon shaft to externalize it through the left femoral sheath**



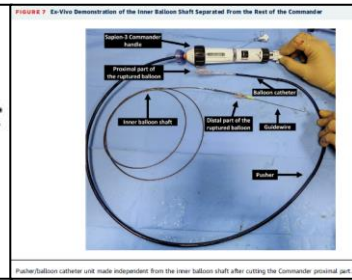
**STEP 6: remove the inner balloon shaft with the distal part of the balloon by pulling it with the wire from the right femoral sheath**



> JACC Cardiovasc Interv. 2021 Aug 9;14(15):e183-e187. doi: 10.1016/j.jcin.2021.04.032. Epub 2021 Jul 14.

## Recapture of the Sapien-3 Delivery System After Transversal Balloon Rupture Using a Whole Percutaneous Femoral Approach

Antonio Giulio Bruno <sup>1</sup>, Nevio Taglieri <sup>1</sup>, Francesco Saia <sup>1</sup>, Rodolfo Pini <sup>2</sup>, Enrico Gallitto <sup>2</sup>,



- ✓ Transcatheter valve replacement with a 29-mm Edwards Sapien-3 valve
- ✓ At the end of the deployment the balloon ruptured and could not be retrieved from the e-Sheath

step-by-step algorithm for retrieval of a ruptured SAPIEN delivery system



- BALLOON RUPTURE DURING TAVR HAS RARELY BEEN REPORTED BUT THE RISK OF SERIOUS COMPLICATIONS IS HIGH
- SEVERAL SIMILAR CASES OF BALLOON RUPTURE DURING VALVE DEPLOYMENT HAVE BEEN DESCRIBED. IN ALL CASES, SEVERE AORTIC ANNULAR OR STJ CALCIFICATIONS WAS PRESENT AND IS POSTULATED TO HAVE CAUSED THE BALLOON RUPTURE
- THE MEDICAL LITERATURE REVEALED **NO OR POOR DISCUSSION REGARDING THE PREVENTION OR MANAGEMENT OF NOSE CONE SEPARATION AFTER BALLOON RUPTURE**
  - **Prevention** :
    - preferential use of self-expanding valve in case of protrusive calcifications
  - **Management**:
    - do not remove the delivery system and valve balloon and as 1 unit in the eSheath Edwards
    - attempt to capture the nose cone (snare) in the aorta (and not in the iliac axis)
    - Reverse umbrella technique