

TAVR Procedure with Balloon- Expandable (SAPIEN) Valve

Step-By-Step Approach and Complex and Complication Cases Management

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Conflict of Interest Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Consulting Fees/Honoraria

Consulting Fees/Honoraria

Consulting Fees/Honoraria

Company

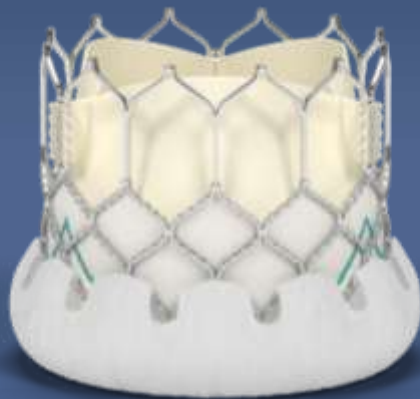
Edwards LifeSciences

Medtronic Inc

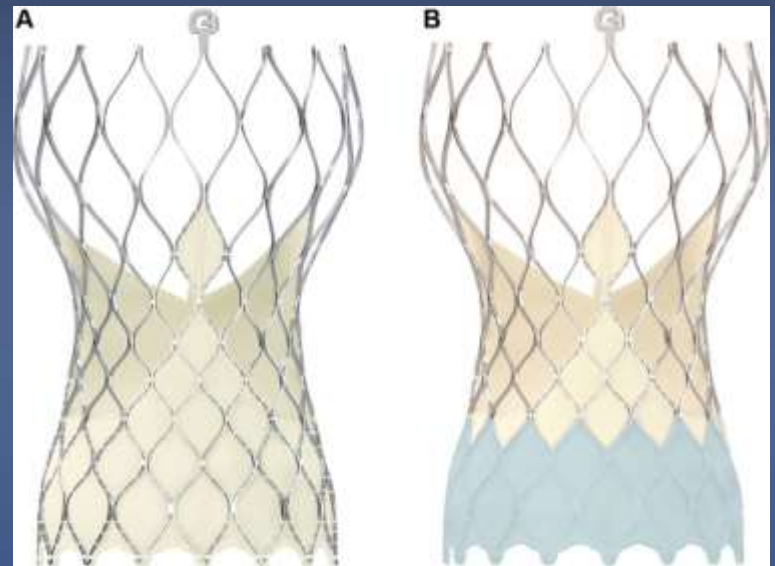
Boston Scientific

Contemporary TAVR Devices in Korea

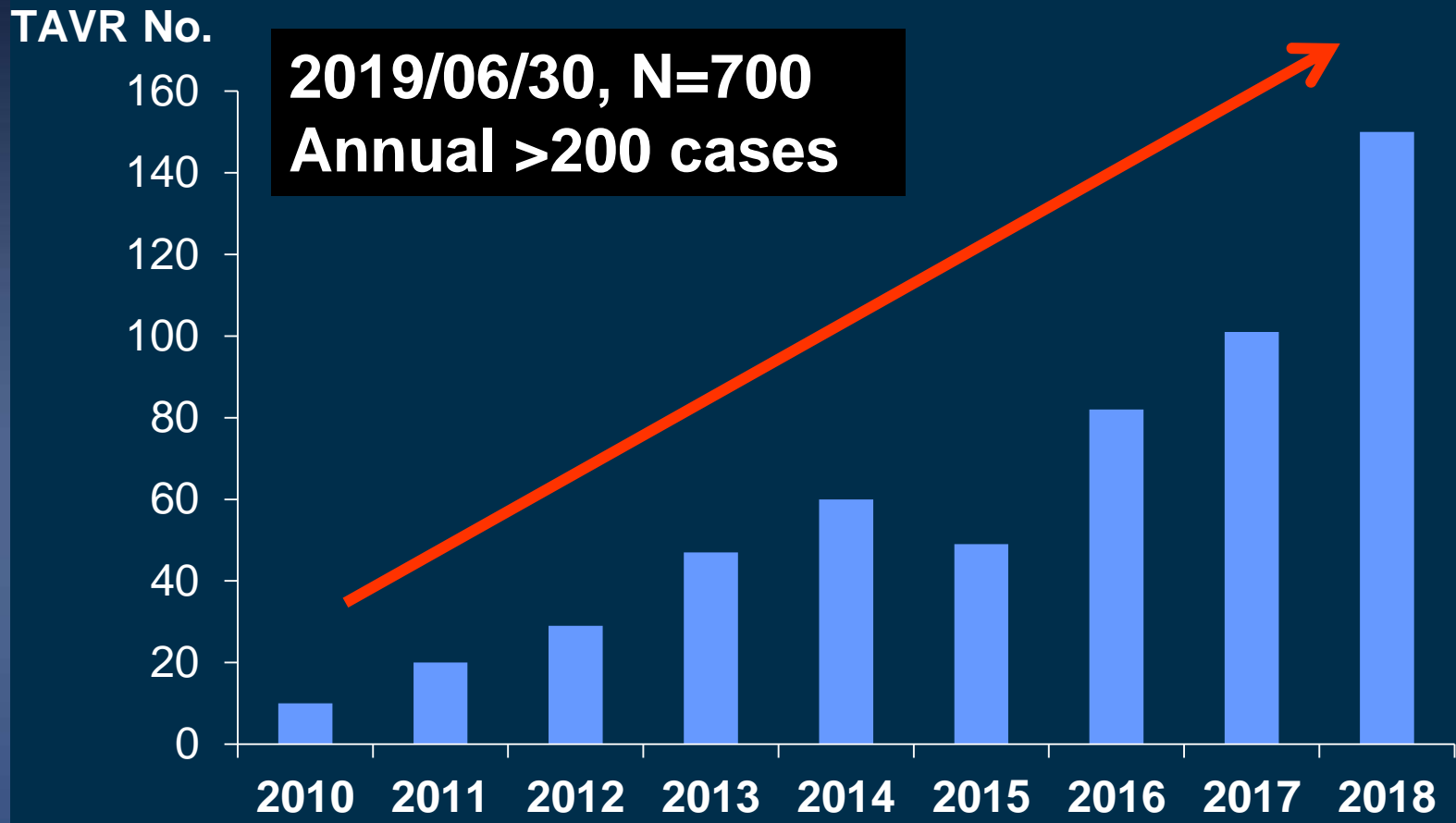
Sapien 3



Evolut R & Pro



TAVR in Asan Medical Center



SAPIEN

Step-By-Step Approach

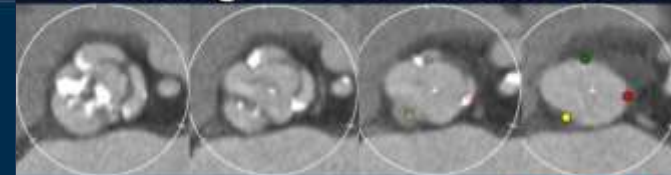
Pre-Procedural Planning

Echo findings

- 71/F, 157 cm, 47.5 kg, BMI 19.27, BSA 1.44
- Chief complaints
 - Dyspnea (NYHA III)
- Medical history
 - ESRD s/p KT (1991), spinal stenosis, osteoporosis
 - Pericardial effusion s/p PCC (2017.3)
- ECG : paroxysmal AF with RVR
- Serum Cr : 1.48
- PFT : FEV1 0.94 (43%) / FVC 1.15 (40%) = 82%
- STS score = 3.081 %
- Euroscore I = 2.68 %, Euroscore II = 2.66 %

- Tricuspid valve
- AVA = 0.55 cm²
- Peak / Mean PG = 119 / 63 mm Hg
- V max = 5.5 m/s
- EF= 71 %
- LVOT diameter, TTE: 19.4 mm
- Severe degenerative AS
- Mild AR
- Pericardial effusion

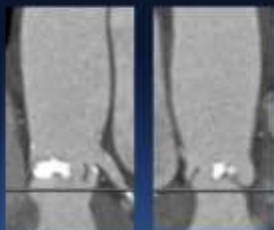
CT findings – Aortic annulus view



Annulus plane

Aortic Annulus parameters	
Annulus short diameter	17.7 mm
Annulus long diameter	29.4 mm
Annulus mean diameter	21.5 mm
Annulus area	353.6 mm ²
Annulus area-driven diameter	21.2 mm
Annulus perimeter	68.6 mm
Annulus perimeter-driven diameter	21.9 mm

CT findings – Coronary Height



Anomalous origin of RCA from LCC

Coronary Height	
LCA	19.5 mm
RCA	13.5 mm

CT findings – Iliofemoral Angio

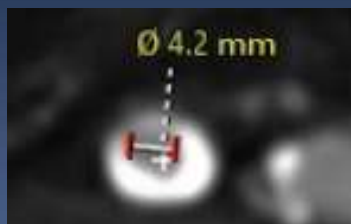
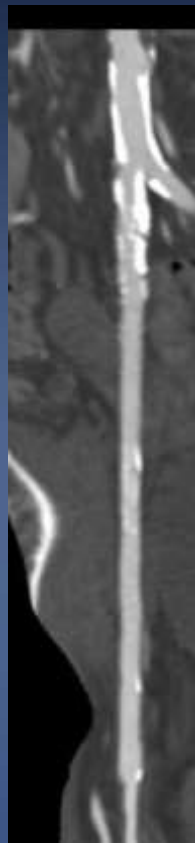


Sizing for Sapien 3

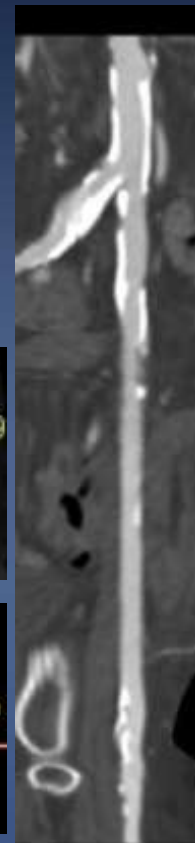
Size	Area_oversize (%)	Perimeter_oversize (%)
23	115.7	104.1
24	126.0	108.6
25	136.7	113.2
26	146.7	117.7
27	158.2	122.2
28	170.1	126.8
29	183.5	131.6

Femoral Access Screening

CTA: 3D reconstruction



R CIA prohibitive

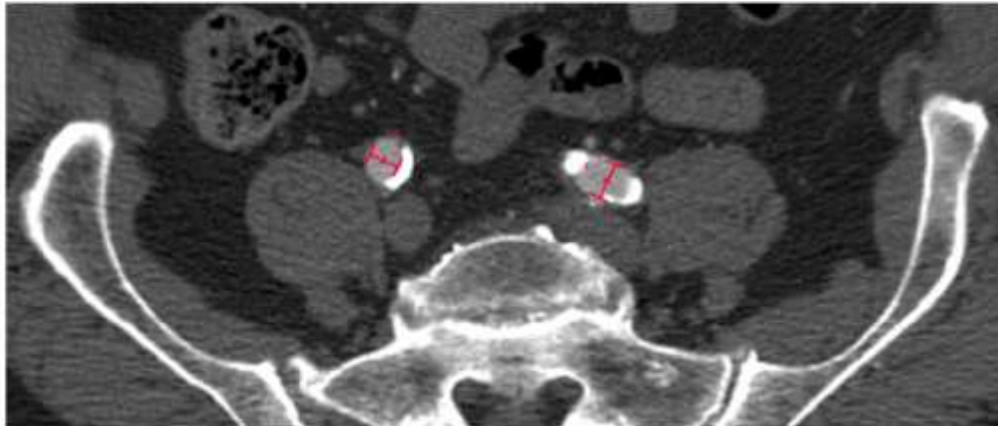


Femoral Access: Sapien

Minimum Vessel Diameter

“Minimum 5.0 is possible”

THV Size	Minimum Vessel Diameter*
23 mm	<u>≥ 5.5 mm</u> (14 Fr)
26 mm	≥ 5.5 mm (14 Fr)
29 mm	≥ 6.0 mm (16 Fr)



Procedural Steps

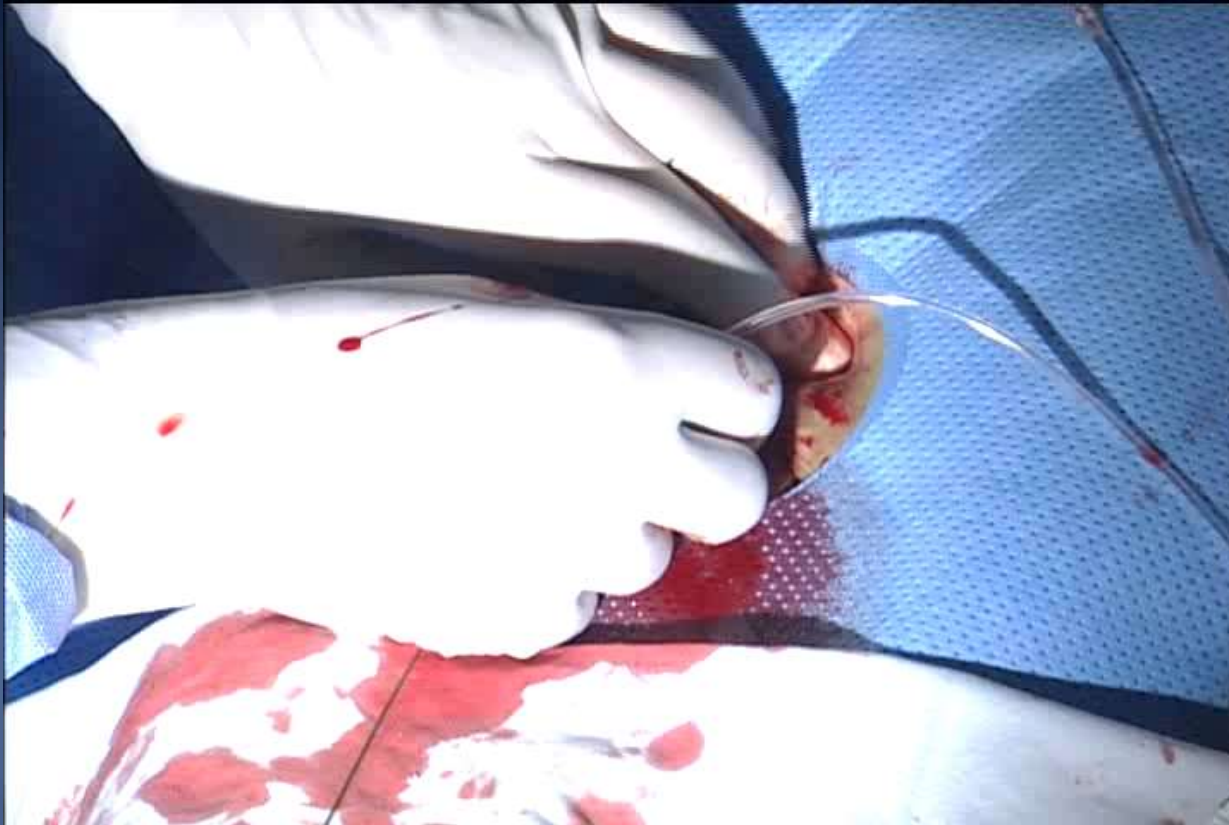
- Femoral artery puncture
- Sheath insertion
- Wire crossing of native AV
- Device crossing of native AV
- Valve positioning
- Valve deployment
- Device retrieval
- Femoral artery closure

Puncture



6 Fr – Pacemaker, 7 Fr – Pigtail Catheter

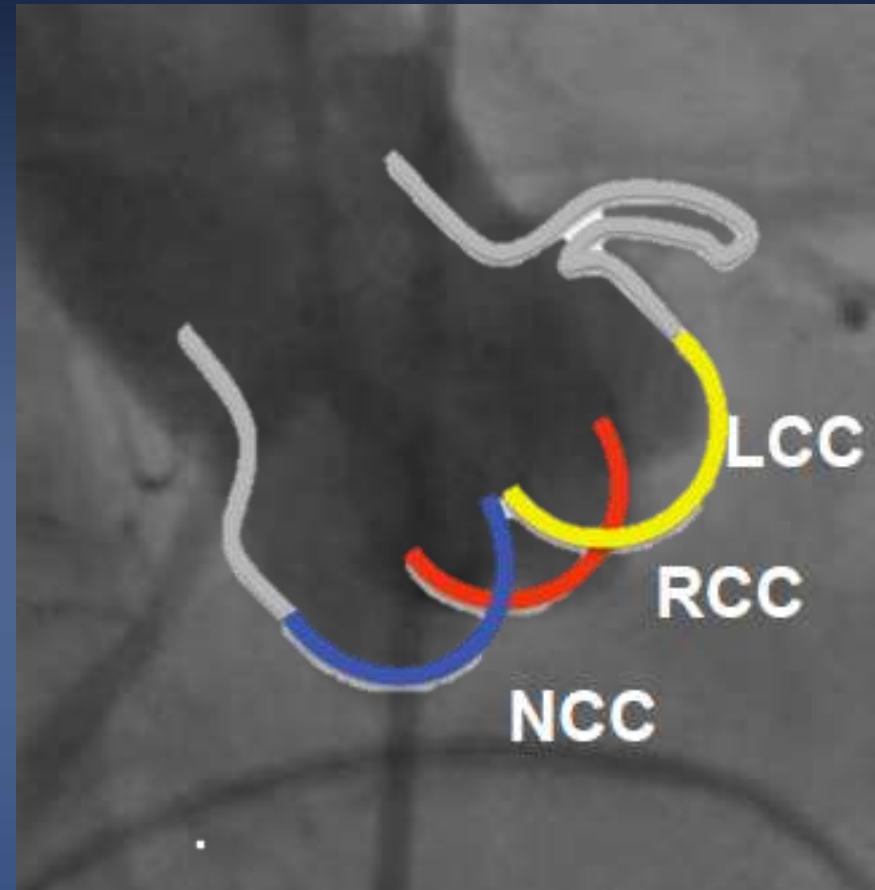
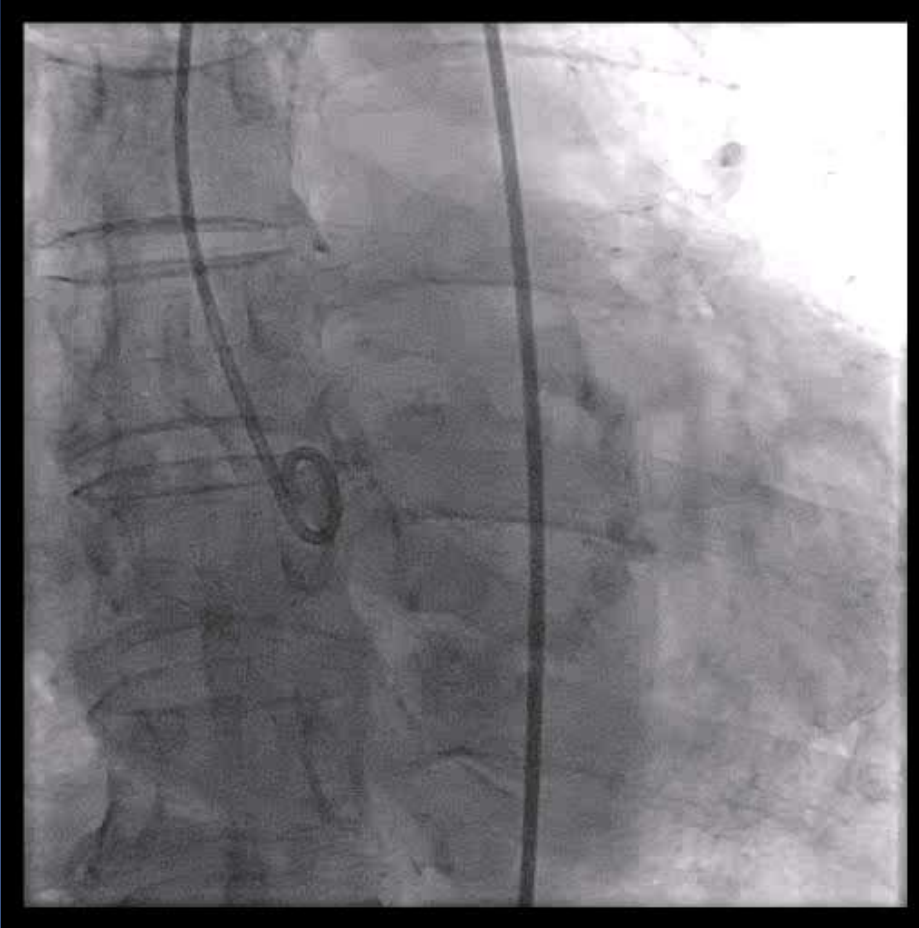
Proglide



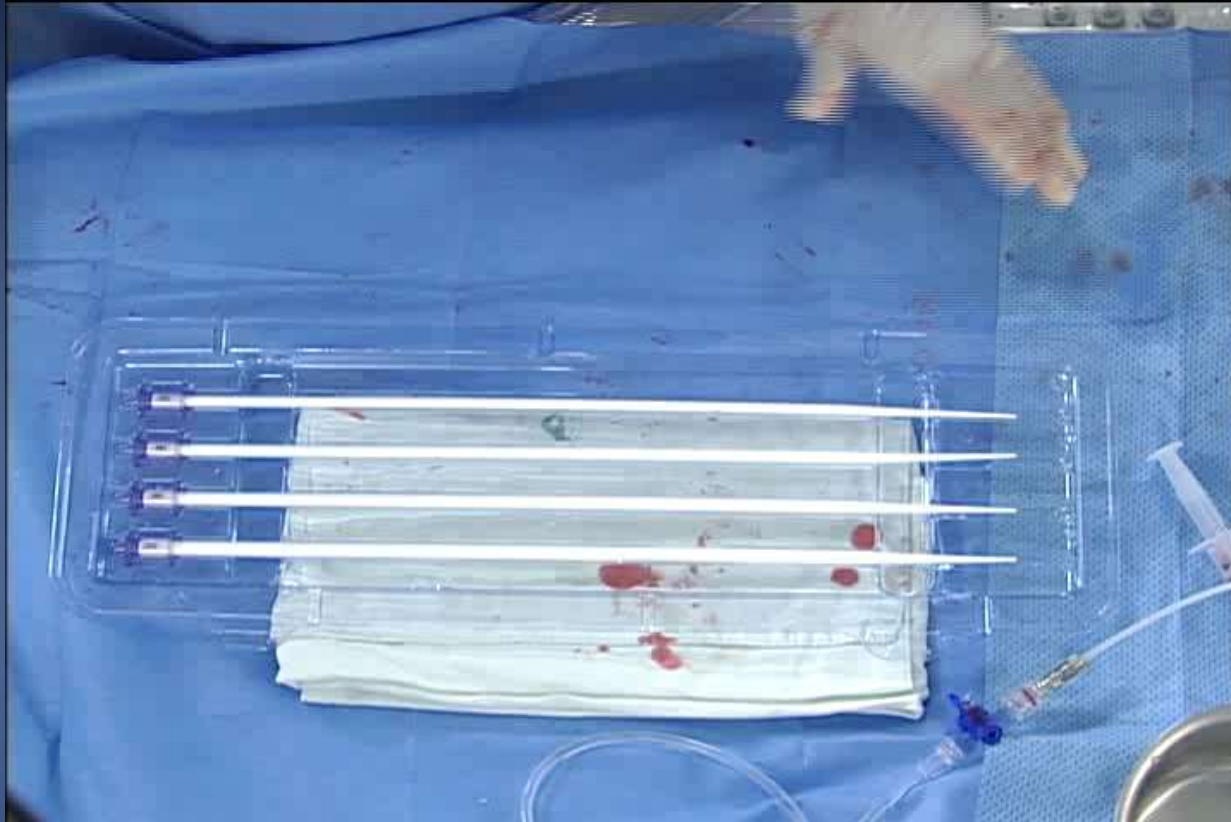
14 Fr – 1 Proglide (S3 23 mm, 26 mm)

16 Fr – 2 Proglides (S3 29 mm)

Baseline Aortogram: Coplanar View



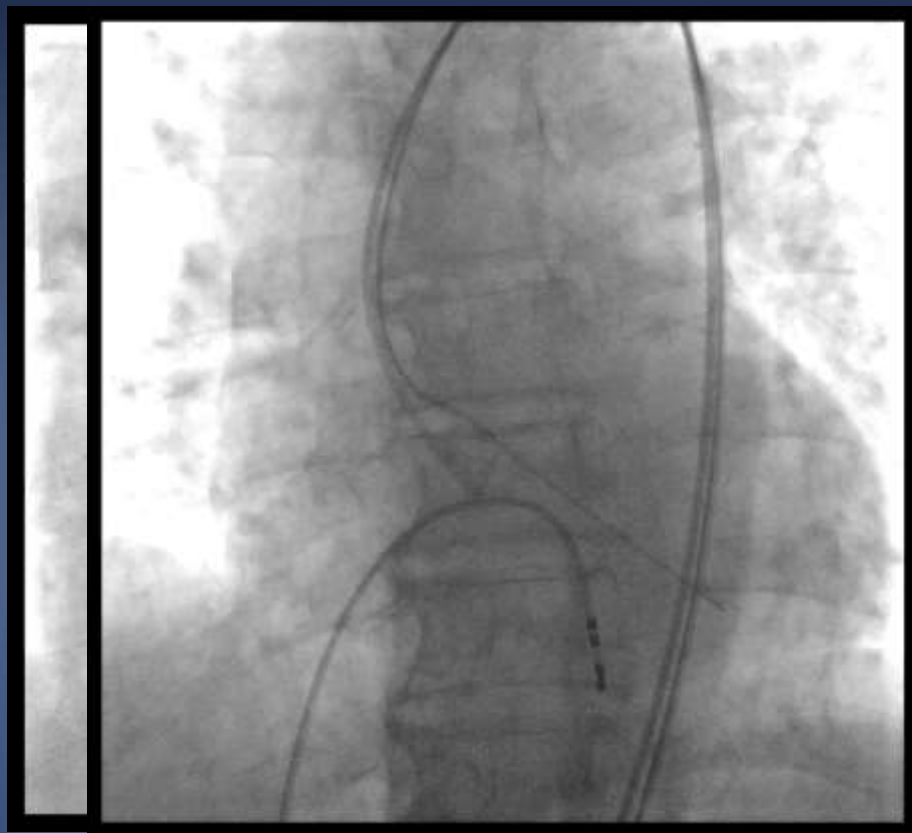
Dilator before Sheath Insertion



Edwards E-Sheath



Wire Crossing



Catheter



AL 1



AL 2



JR

Wire

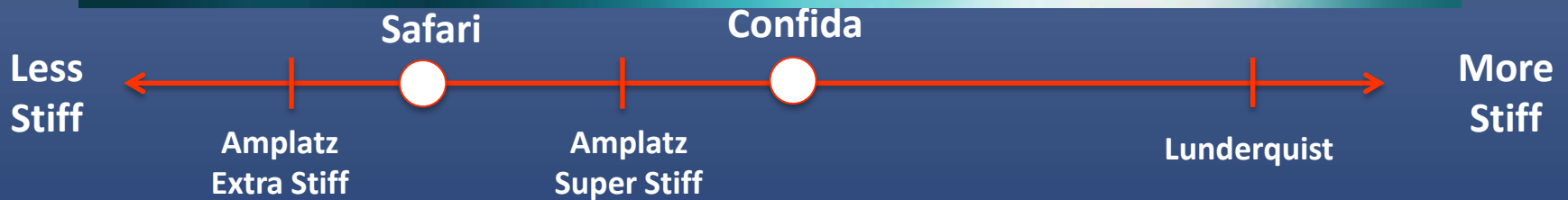
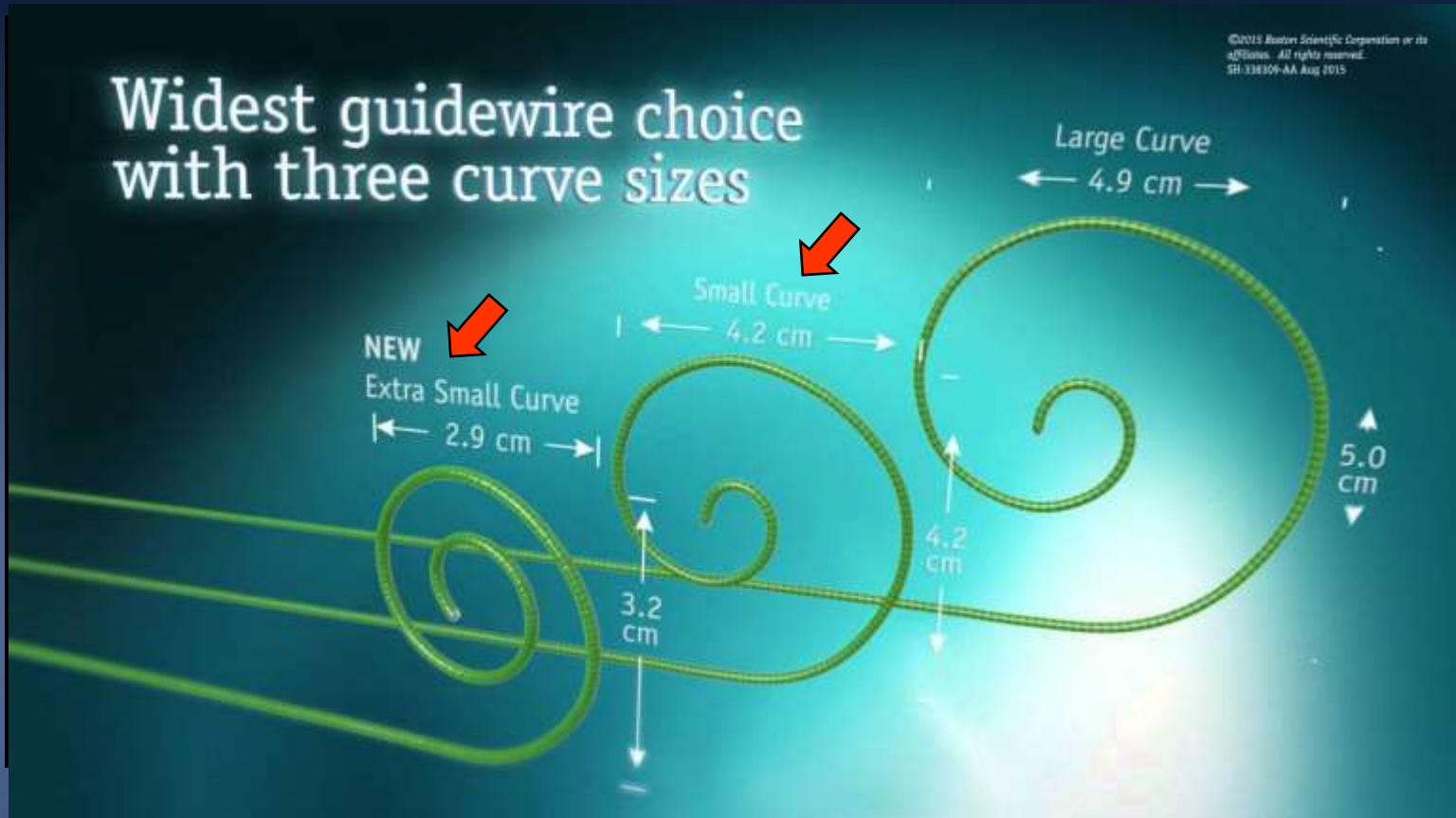


Teflon straight

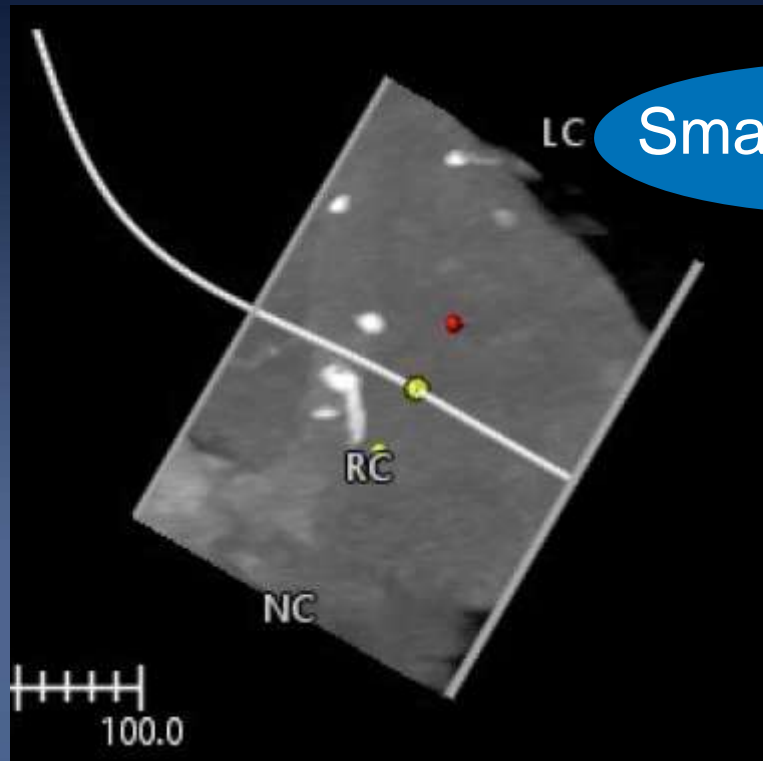


Ring toque

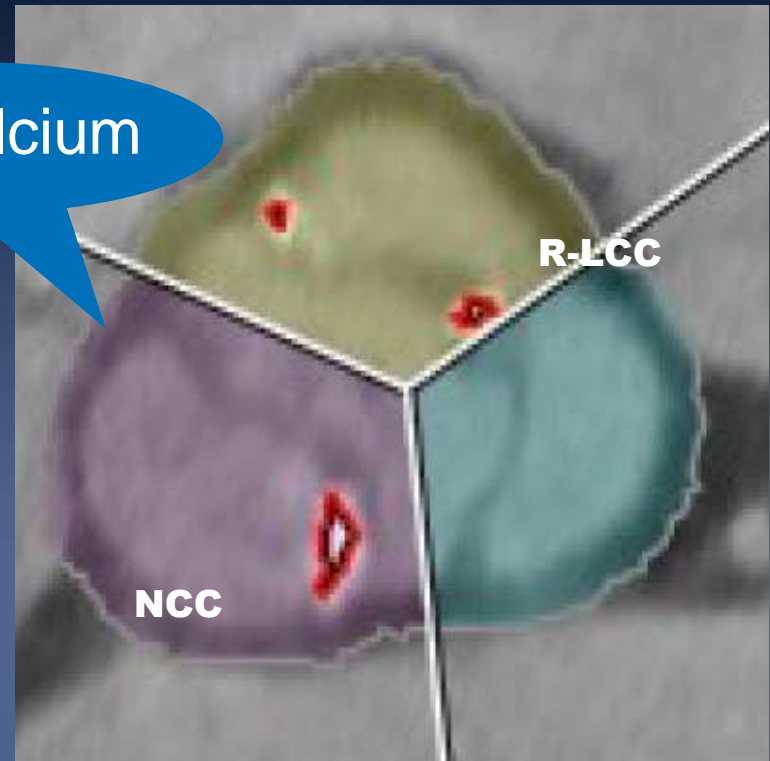
LV Support Wire Exchange



LV Wire Caution 79/F with severe AS



Small calcium

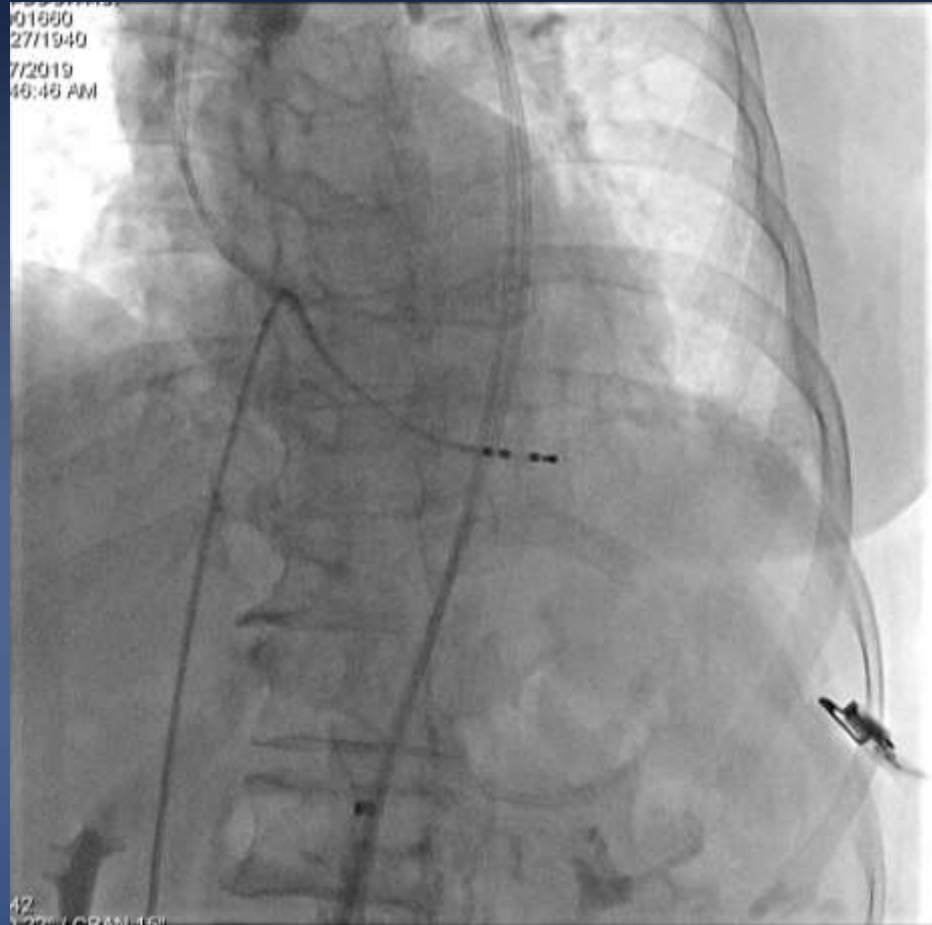
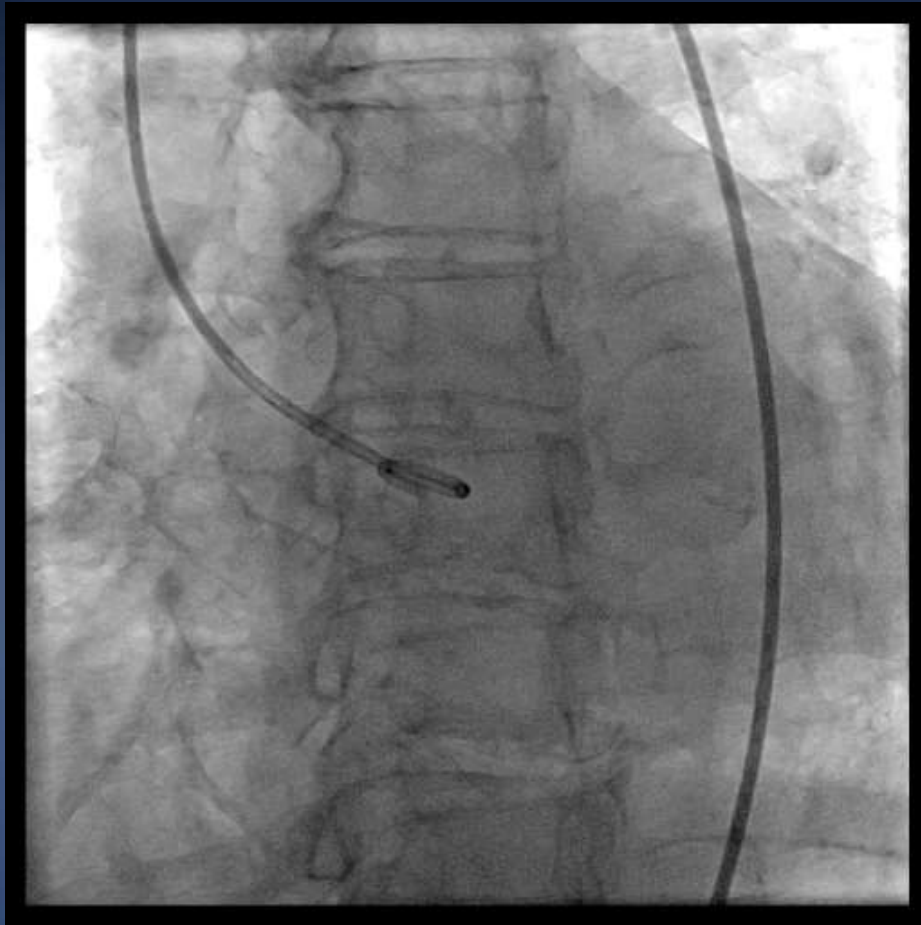


Calcium volume	
NCC	18 mm ³
R-LCC	5 mm ³
Total	23 mm ³

Mean Amount of total Calcium 355.4 ± 289.9

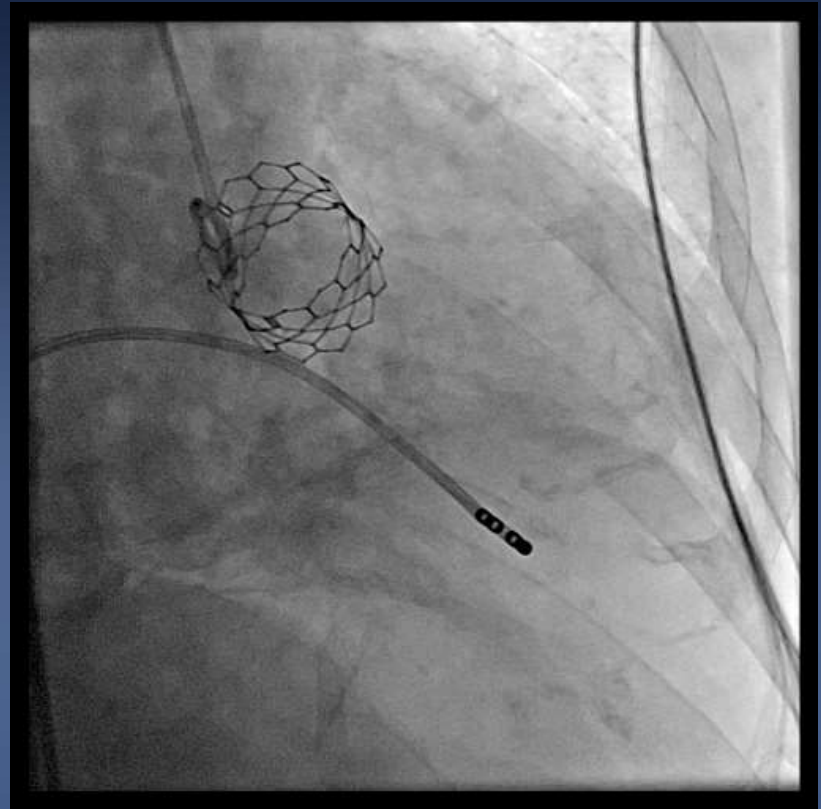
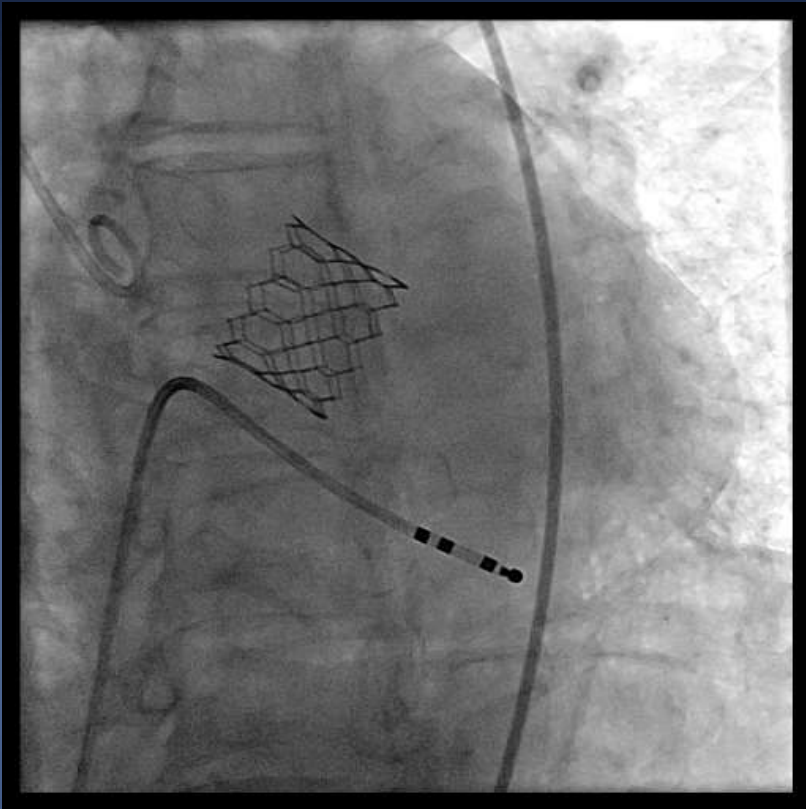
Sapien 23mm with 1.5cc underfill

BP drop due to big and deep SAFARI wire position



Sapien 23mm with 1.5cc underfill

Mild PVL

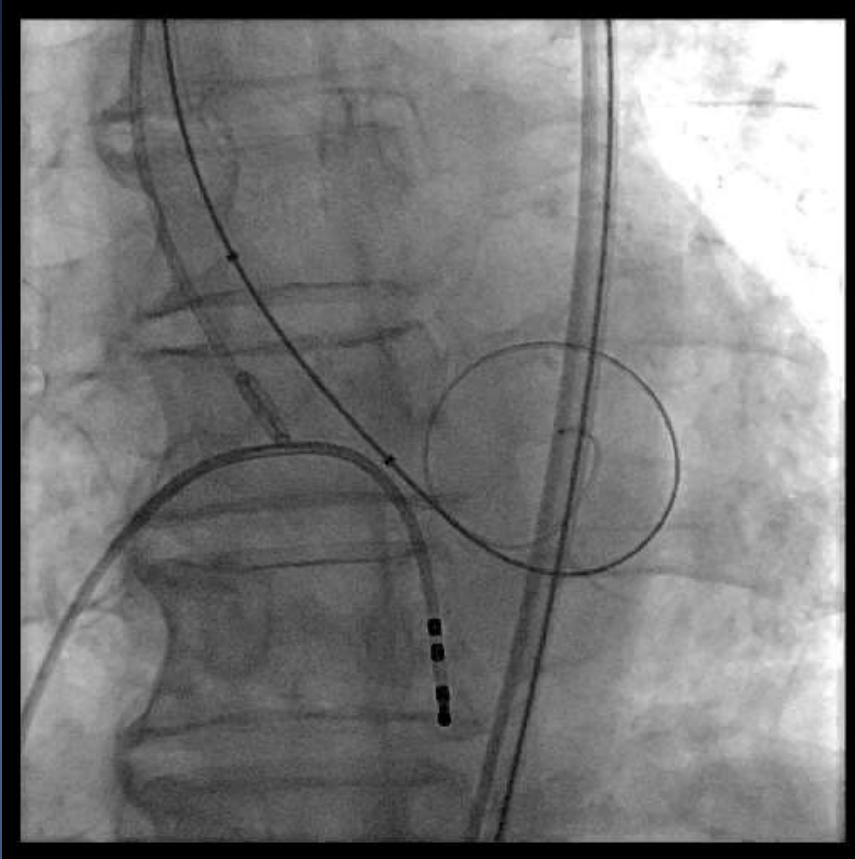


LV Wire Caution:

One Size Does Not Fit All

Use extra-small safari for small LV

Pre-Balloon



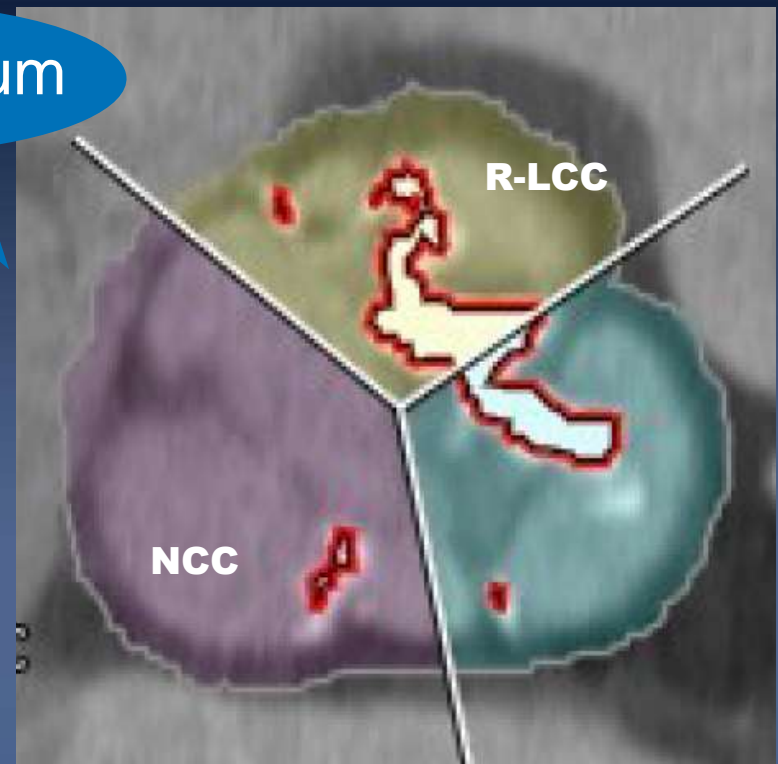
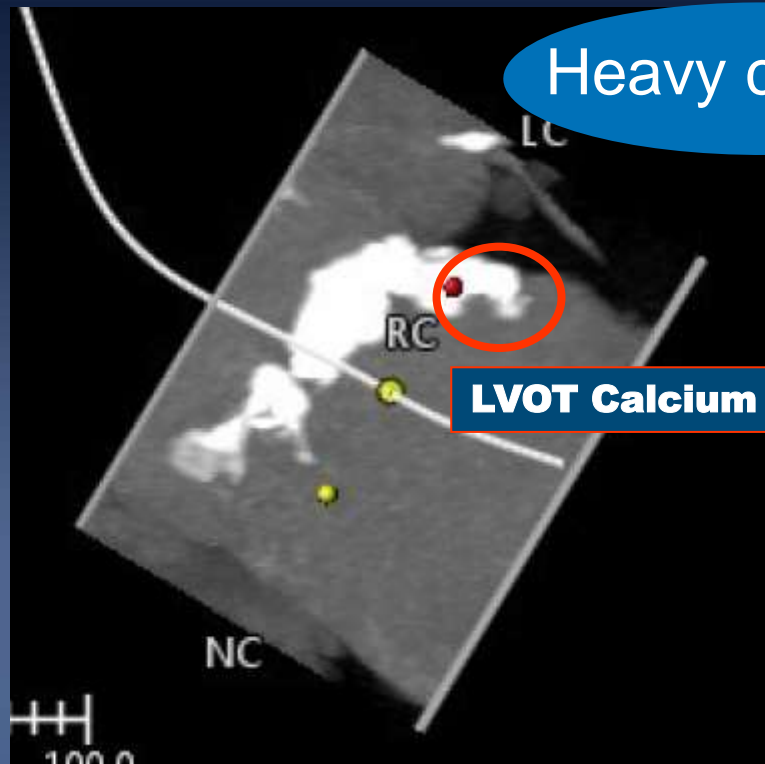
- **Risk**
 - Embolization
 - Aortic root injury
 - Acute AR
- **Benefit**
 - Procedural stability
 - Exact positioning
 - Valve sizing estimation

Our routine is...

Pre-dilation: calcium volume $>400 \text{ mm}^3$

Pre-Balloon Caution

88/M with severe AS

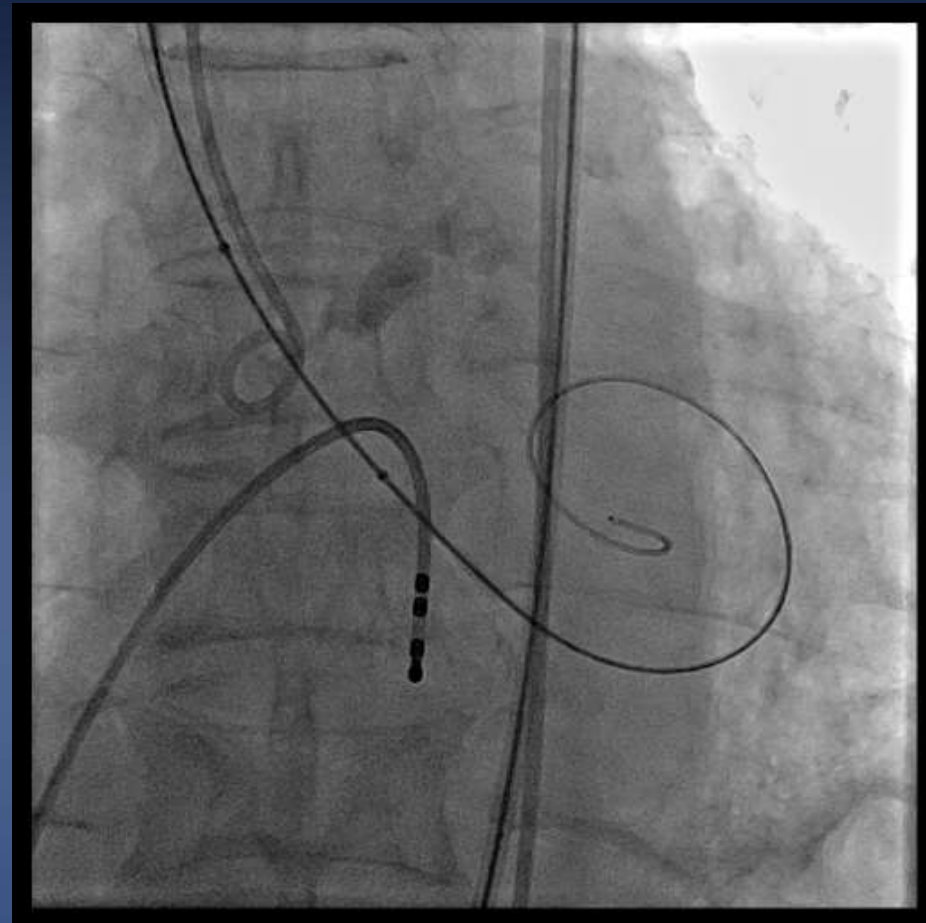
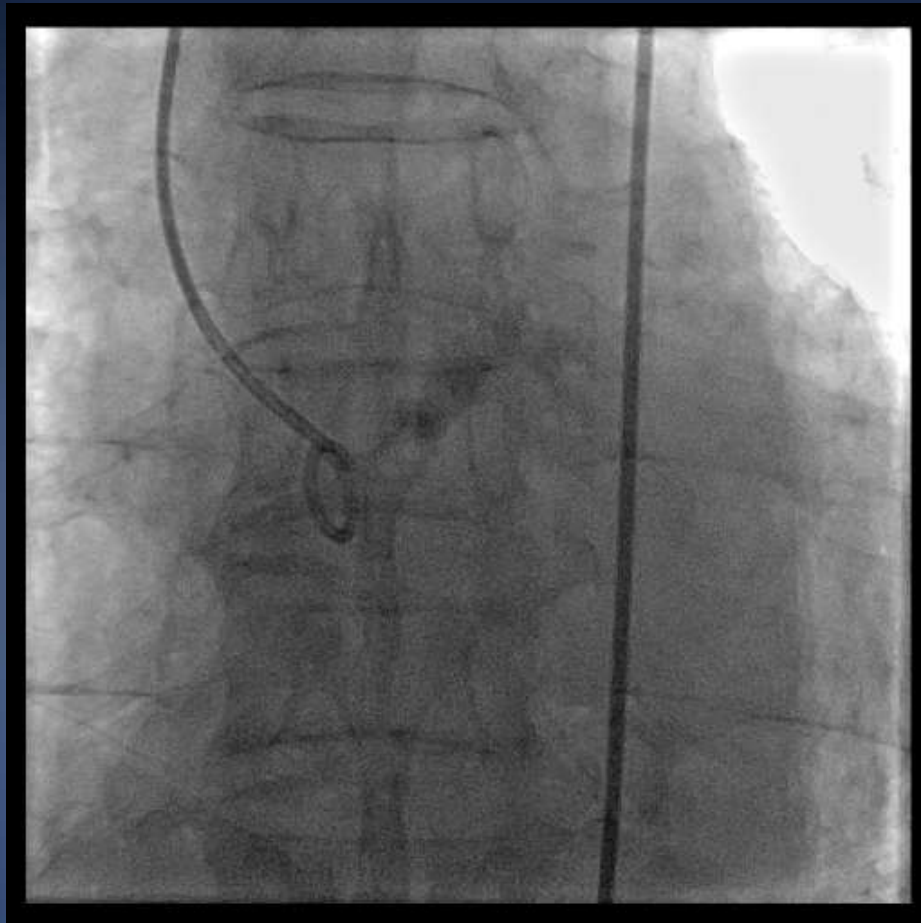


Calcium volume	
NCC	135 mm ³
R-LCC	638 mm ³
Total	773 mm ³

Mean Amount of total Calcium 355.4 ± 289.9

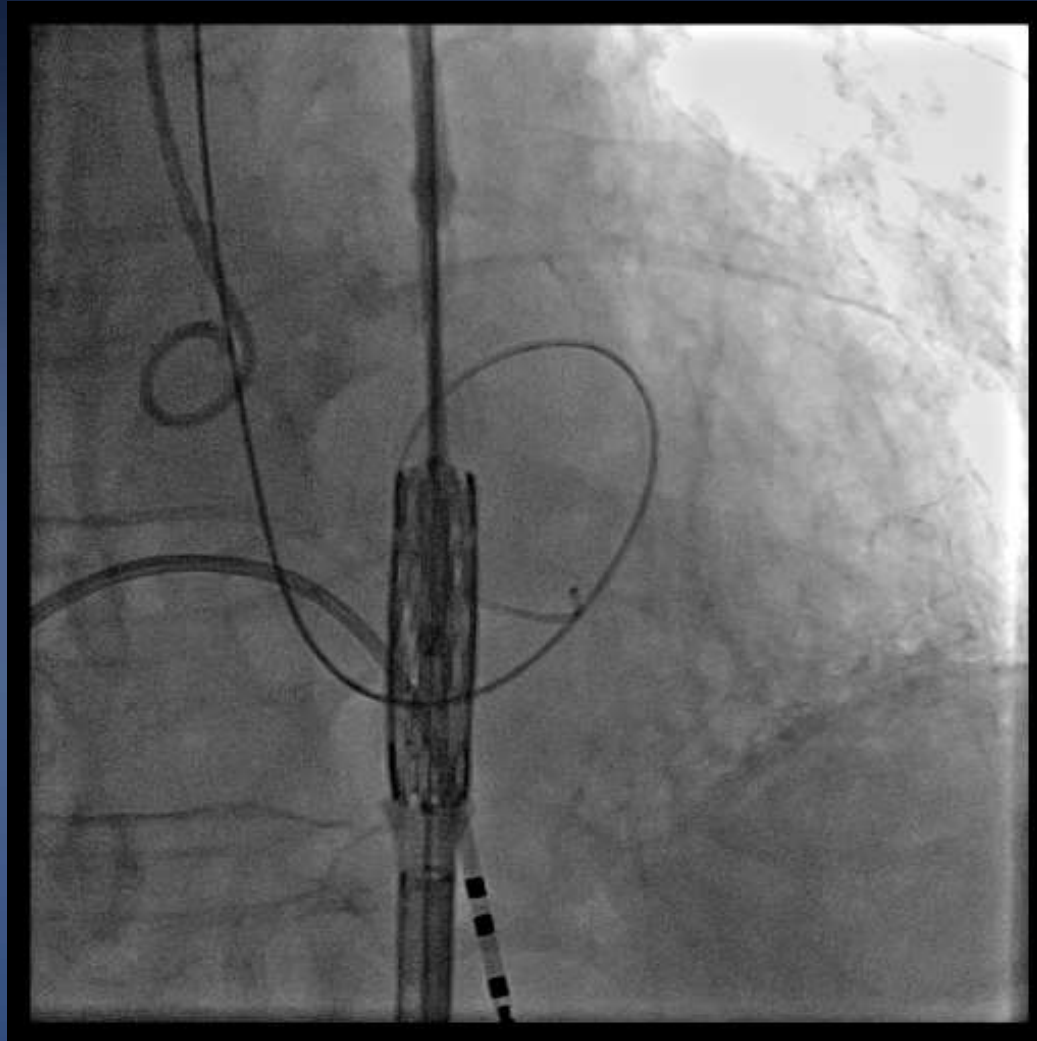
Sapien 29mm with 2cc underfill

Pre-dilation with 23mm



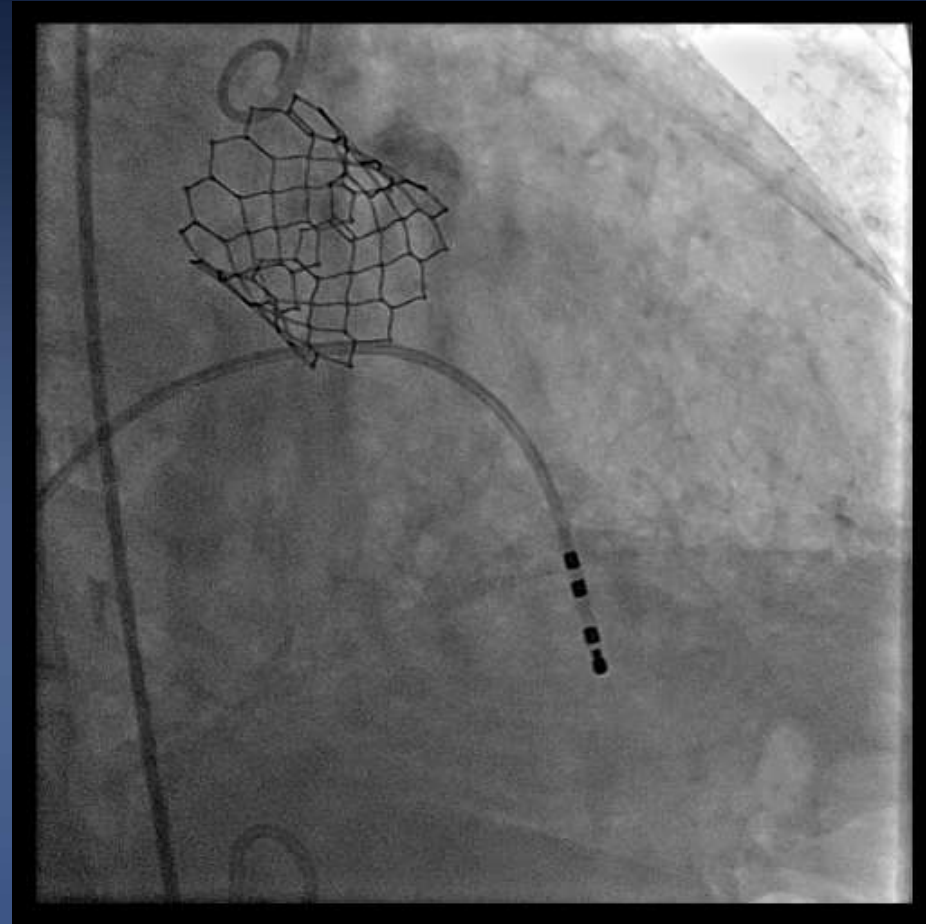
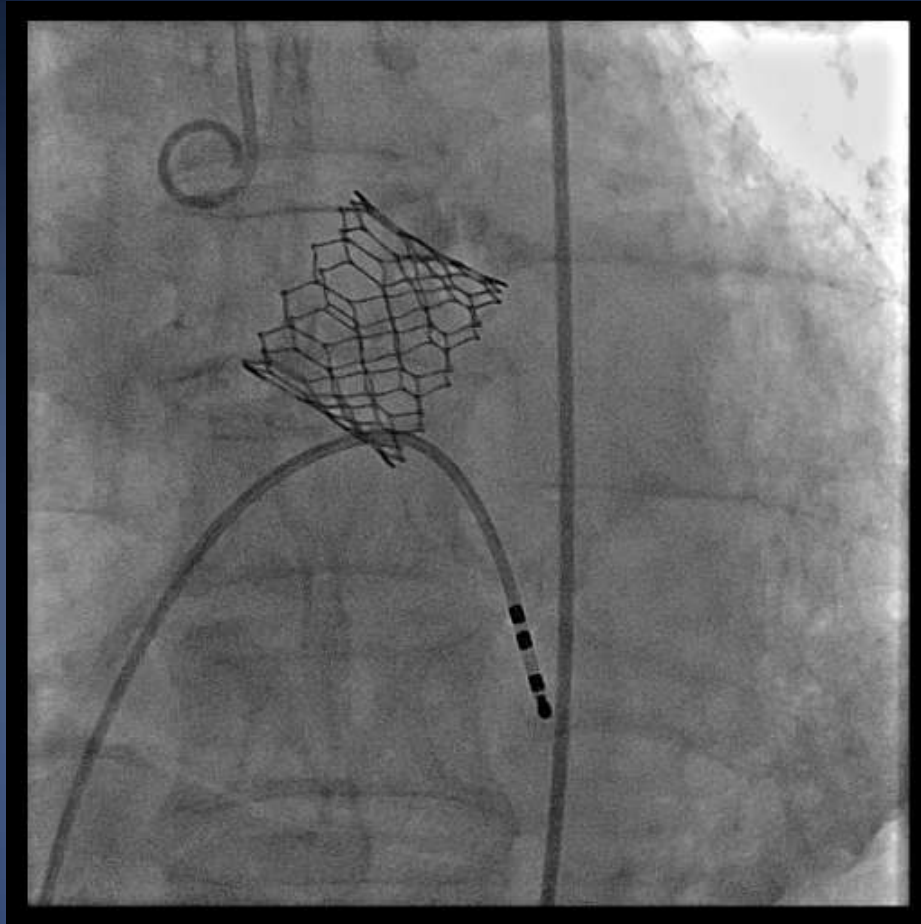
Sapien 29mm with 2cc underfill

Hemodynamics collapse due to acute severe AR



No Mercy!! Urgent Valve Implantation

Trivial PVL



Pre-Balloon Caution:
Valve mounting should be prepared

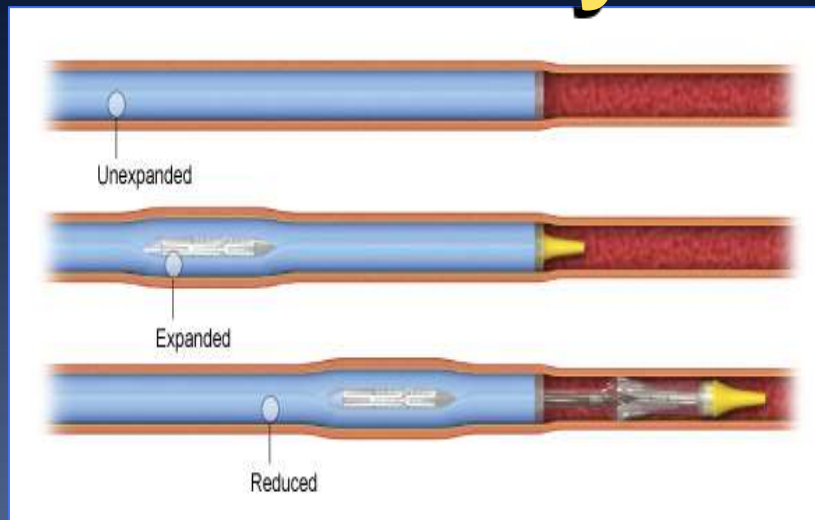
Valve Mounting: In-House Staff (skilled nurse) or Not



Valve Mounting Caution:

Valve mounting should be completed before predilation 

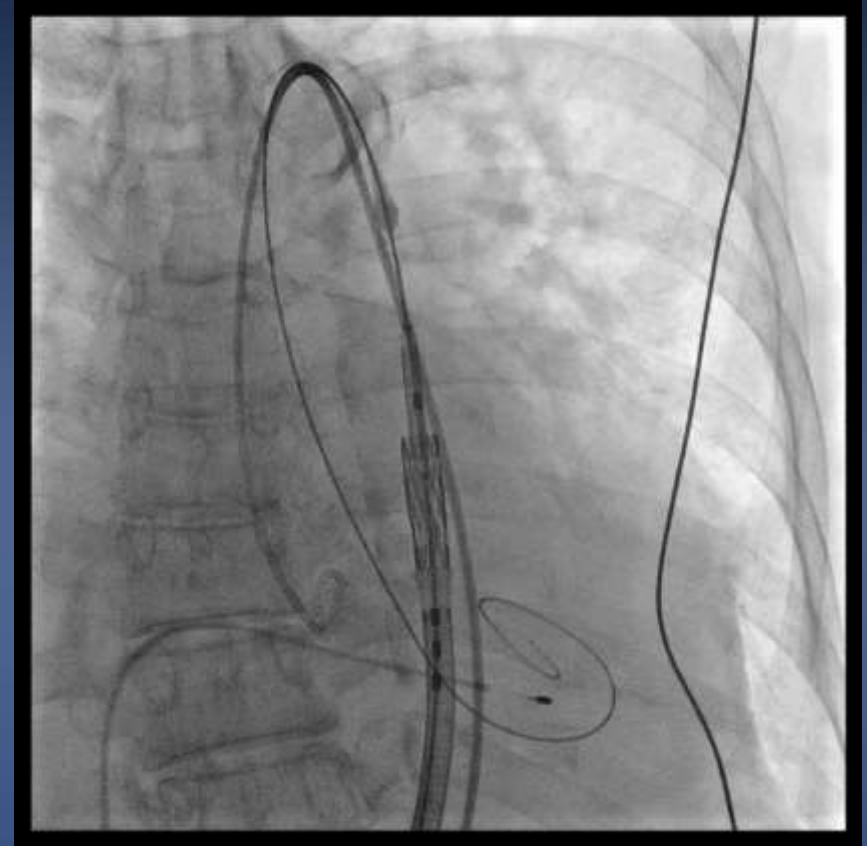
E-Commander: valve delivery



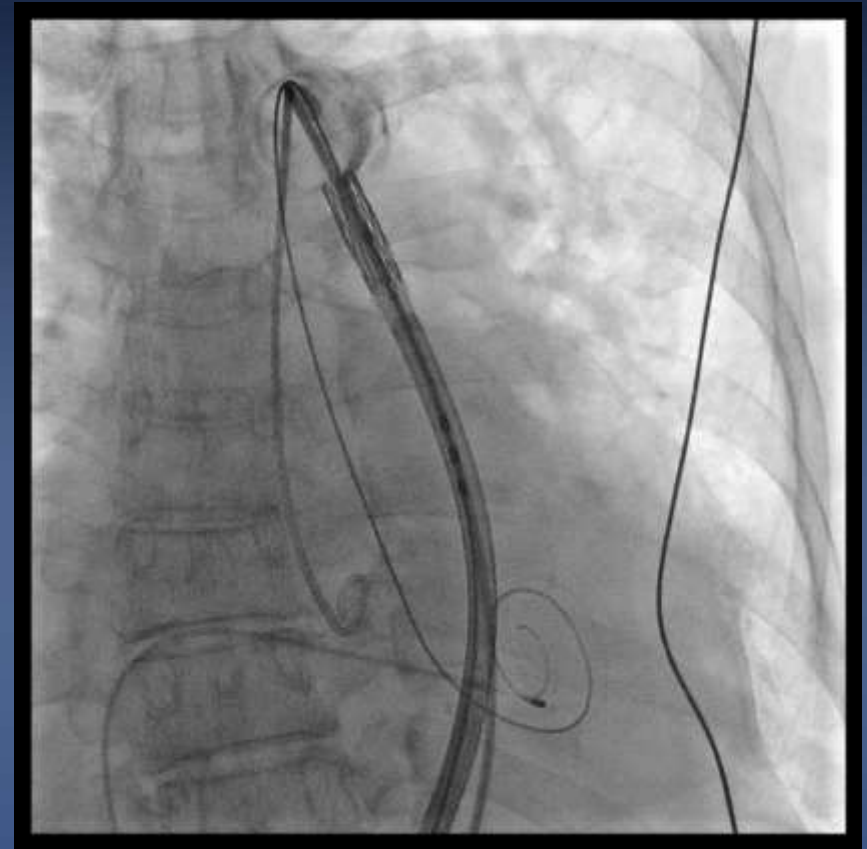
DEM: Dynamic Expansion mechanism

- Allows for transient sheath expansion during valve delivery
- Reduces the time the access vessel is expanded

Balloon Retraction: Valve-on-Balloon



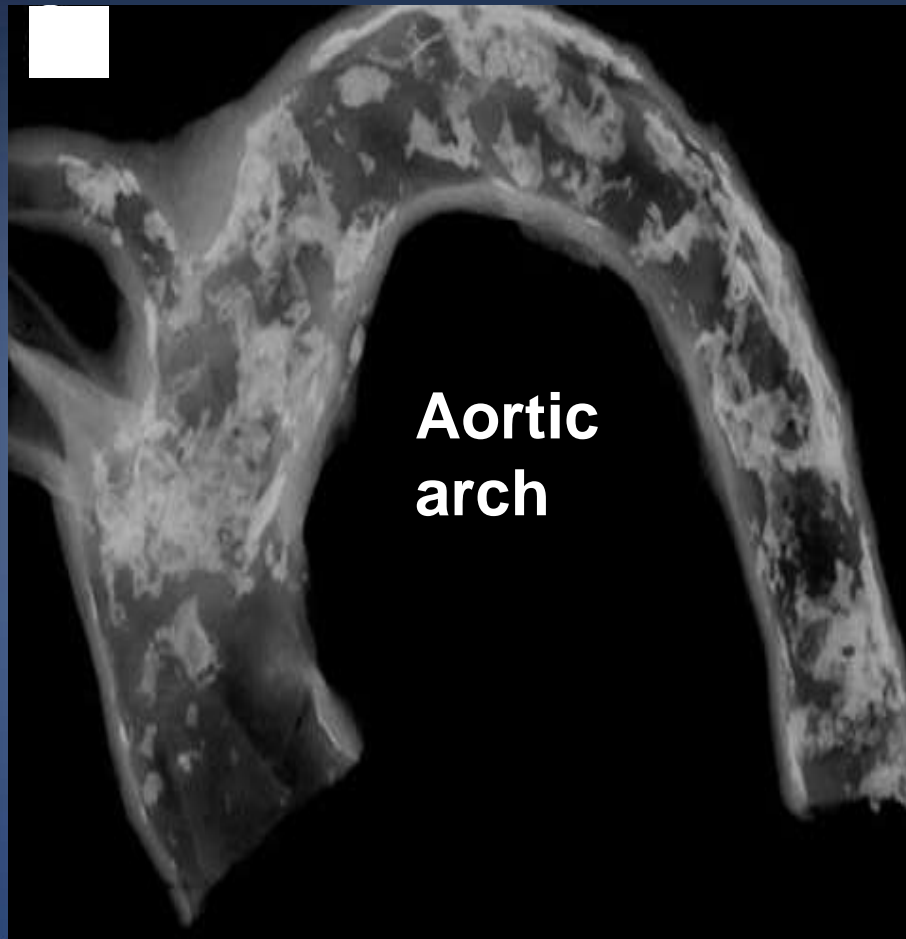
Ascending Aorta and Valve Pass



Gentle Valve Passage Is Important
Make Sufficient Curve

Why Gentle Valve Passage Is Important?

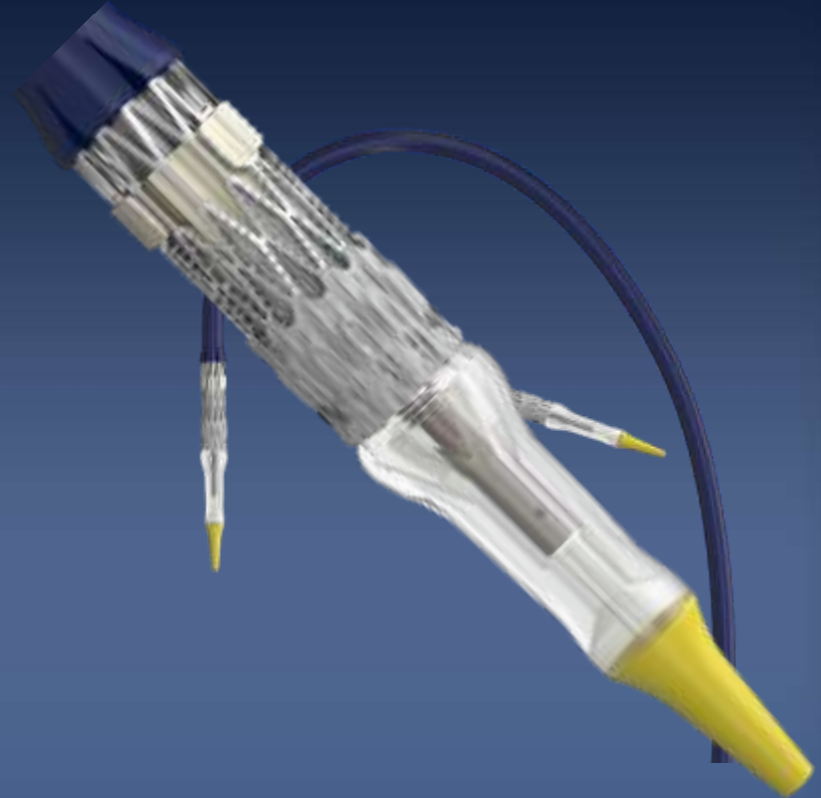
Mechanism of Stroke after TAVR



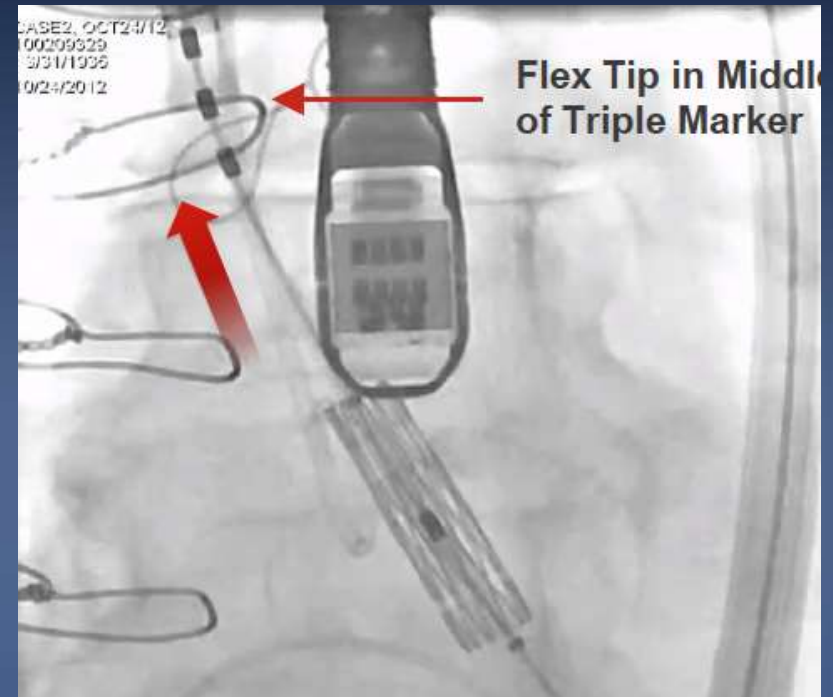
- Primarily ischemic in nature due to either embolic events or cerebral hypoperfusion
- Embolic events
 - Aortic atheroma
 - Gaseous emboli
- Cerebral hypoperfusion
 - Watershed infarcts on CPB
- Multiple other etiologies postulated including atrial fibrillation, hyperglycemia, cerebral hyperthermia, etc.

Why are stroke rates low?

- Delivery catheter allows atraumatic passage around arch
- Distal tip allows easier crossing of the native valve
- Use of less aggressive or no BAV during procedure

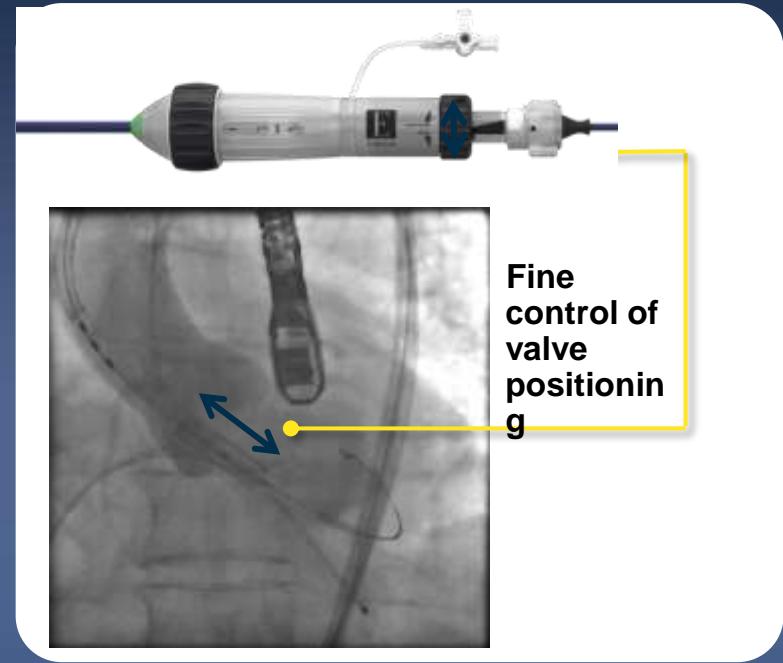
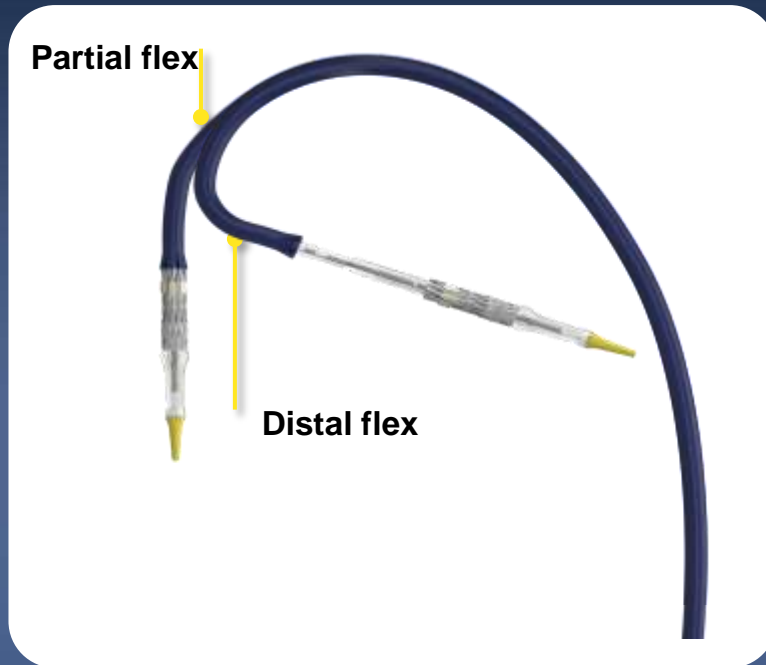


Pull Back Flex Catheter



Making Coaxial Alignment

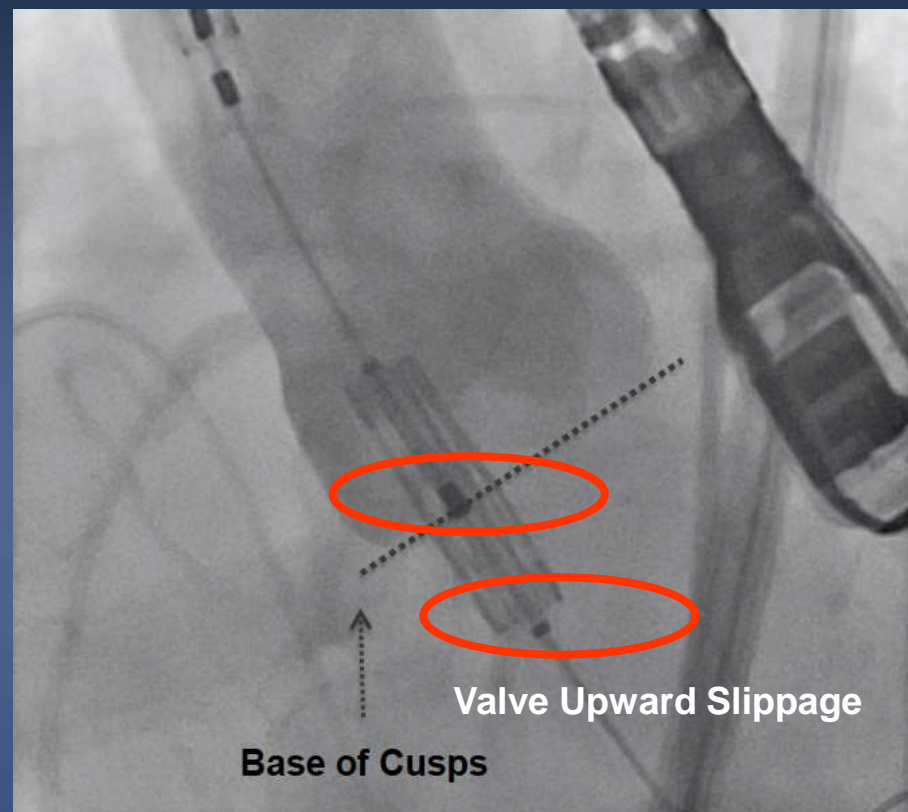
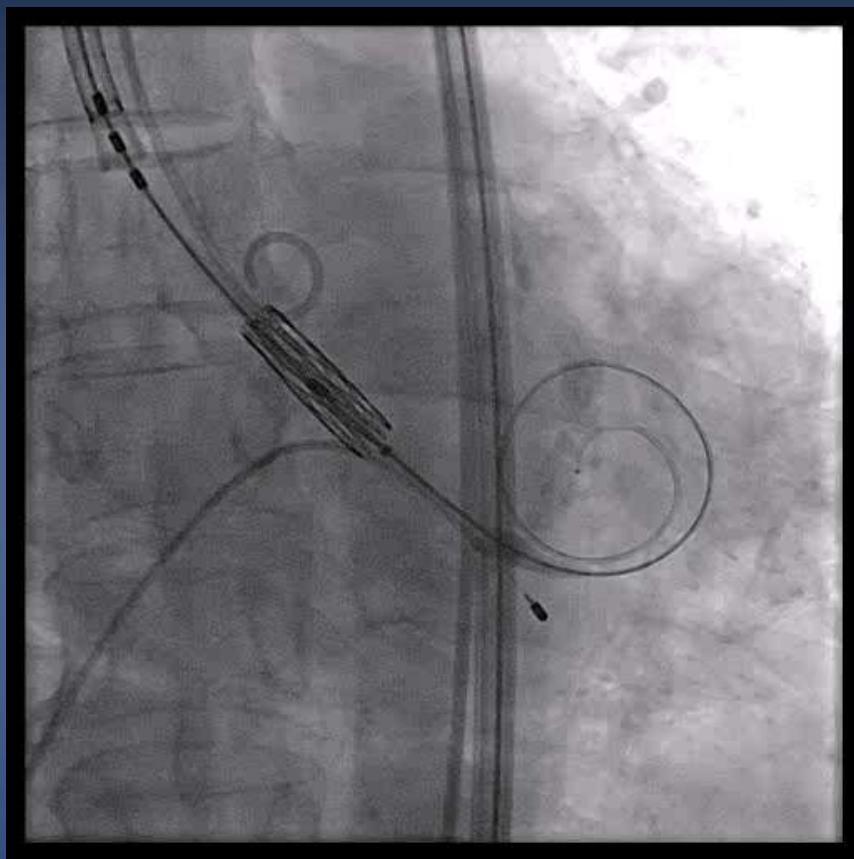
Distal hyperflexion, push/pull of delivery system, and fine control knob



Nice Coaxial Guarantee Nice Valve Positioning
Spend time for coaxial alignment

Valve Positioning and Implantation

Bottom of Center Marker at Base of Cusps



S3 Sizing Algorithm

Based on the CT Assessment in AMC

Severe AS with Tricuspid

10~15% Area Oversizing

Severe AS with Bicuspid

0-5% Lesser Oversizing

**Heavy Calcification
(Ca volume > 400 mm³)**

0-5% Lesser Oversizing

**Small Sinus of Valsalva to
Annulus Area ratio**

0-5% Lesser Oversizing

Small LVOT

**Consider Lesser
Oversizing**

84/M, STS 7.8

LVOT Calcification

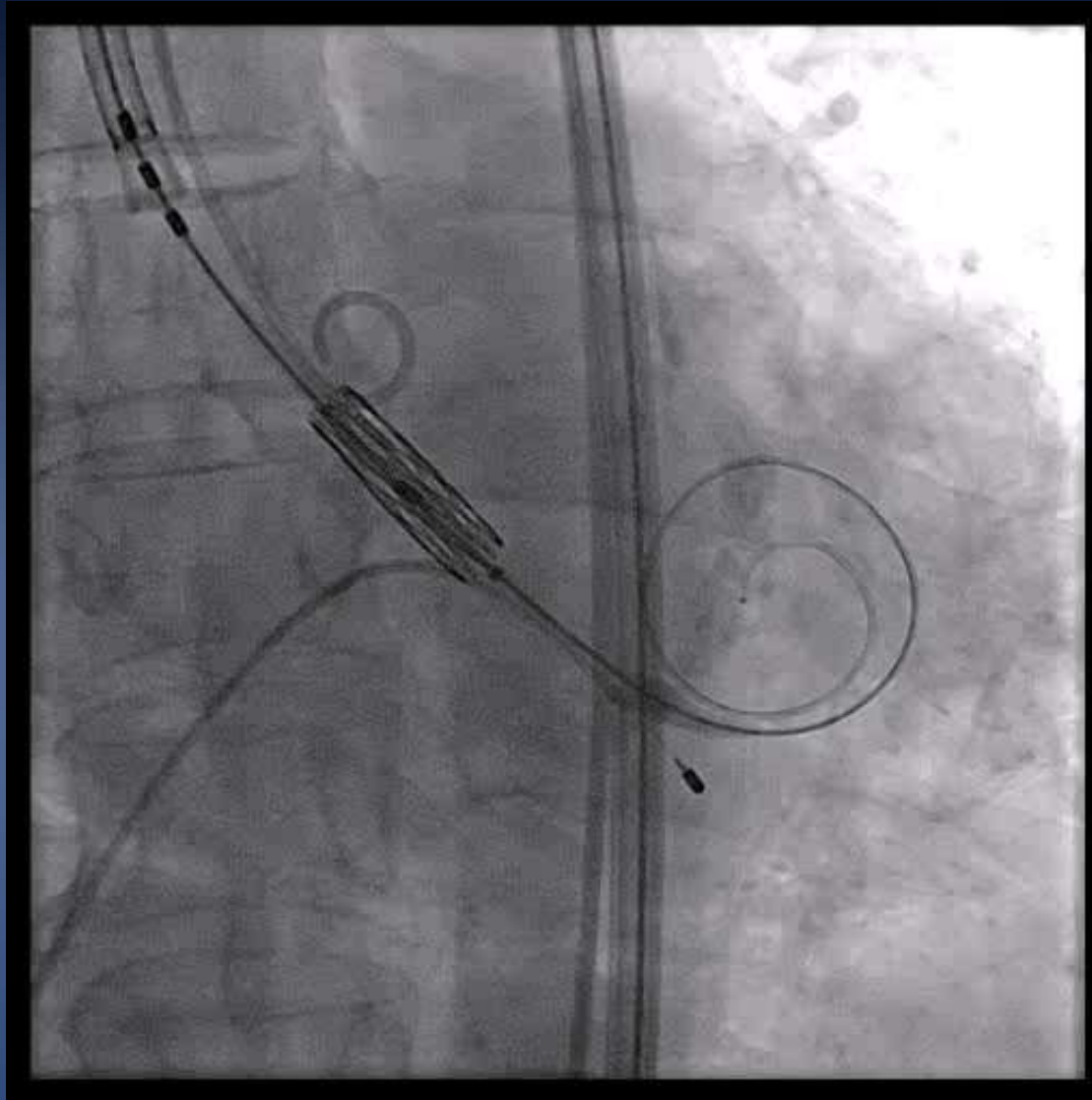


Annulus Rupture

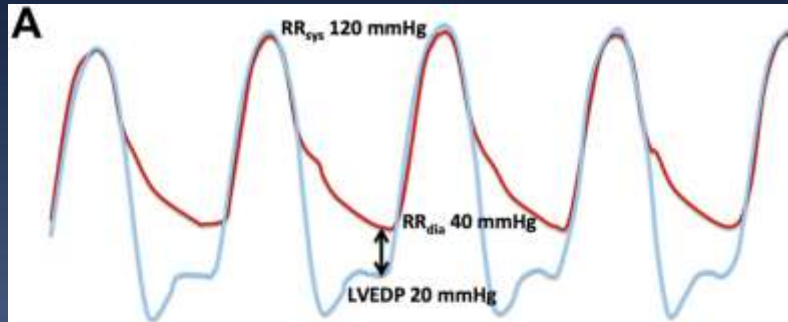
Edwards-Sapien 29mm
18% Oversize



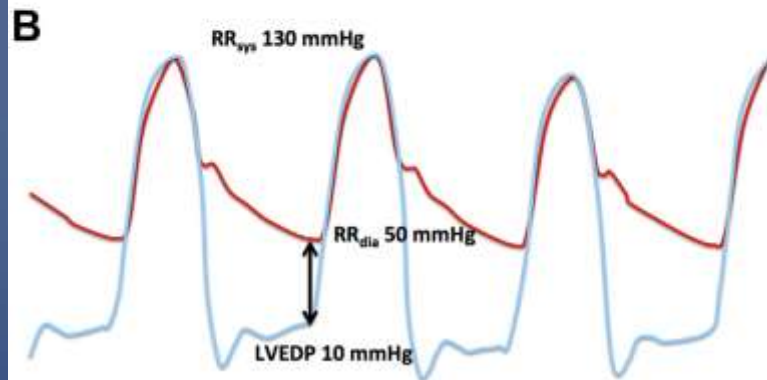
After Successful Implantation



Final hemodynamics

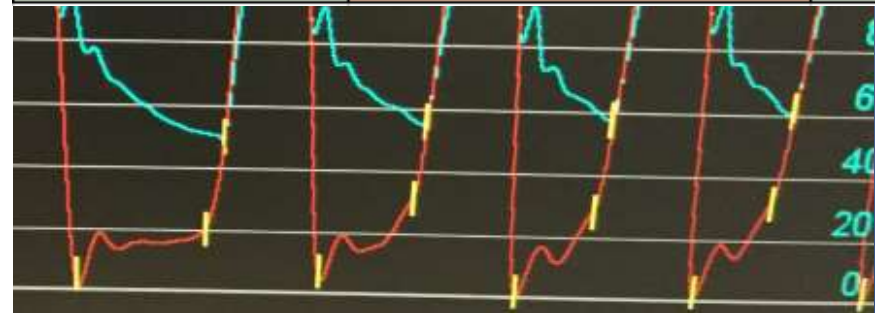


$$\begin{aligned}\text{Aortic Regurgitation Index} &= [(RR_{\text{dia}} - \text{LVEDP}) / RR_{\text{sys}}] \times 100 \\ &= [(40 - 20) / 120] \times 100 = \underline{16.7}\end{aligned}$$



$$\begin{aligned}\text{Aortic Regurgitation Index} &= [(RR_{\text{dia}} - \text{LVEDP}) / RR_{\text{sys}}] \times 100 \\ &= [(50 - 10) / 130] \times 100 = \underline{30.8}\end{aligned}$$

PVL AR Grade	AR Index (DBP - LVEDP)/SBP	Rough Value
None	31.7 ± 10.4	40s
Mild	28.0 ± 8.5	30s
Moderate	19.6 ± 7.6	20s
Severe	7.6 ± 2.6	10s



IF Significant PVL, How Do We Do?

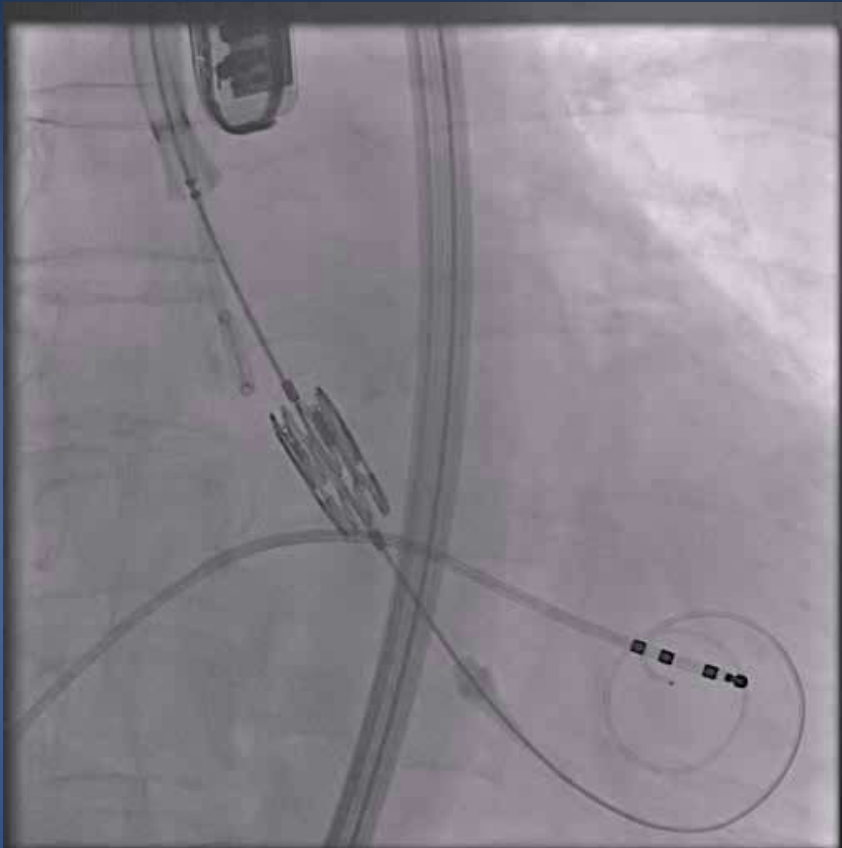
Complex and Complication PVL

Cases Management

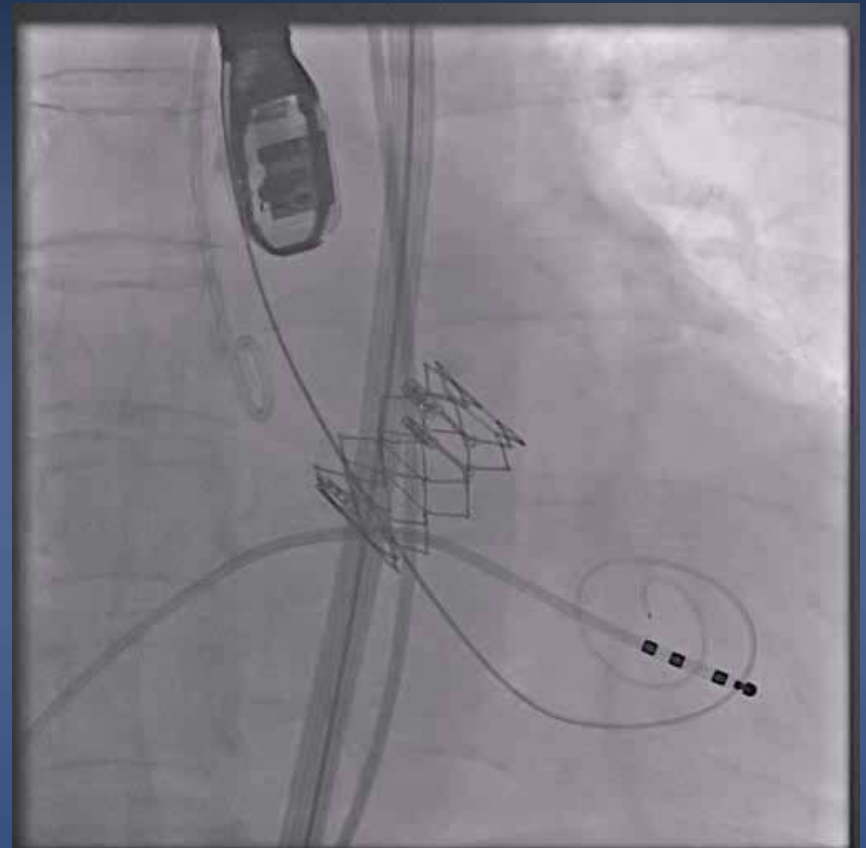
78/F, Severe AS, Severe PVL

TF TAVR with Sapien XT 26mm

Valve Implantation



Immediate after Implantation



Severe AR

TF TAVR with Sapien XT 26mm

Post-dilation (2cc overfill)

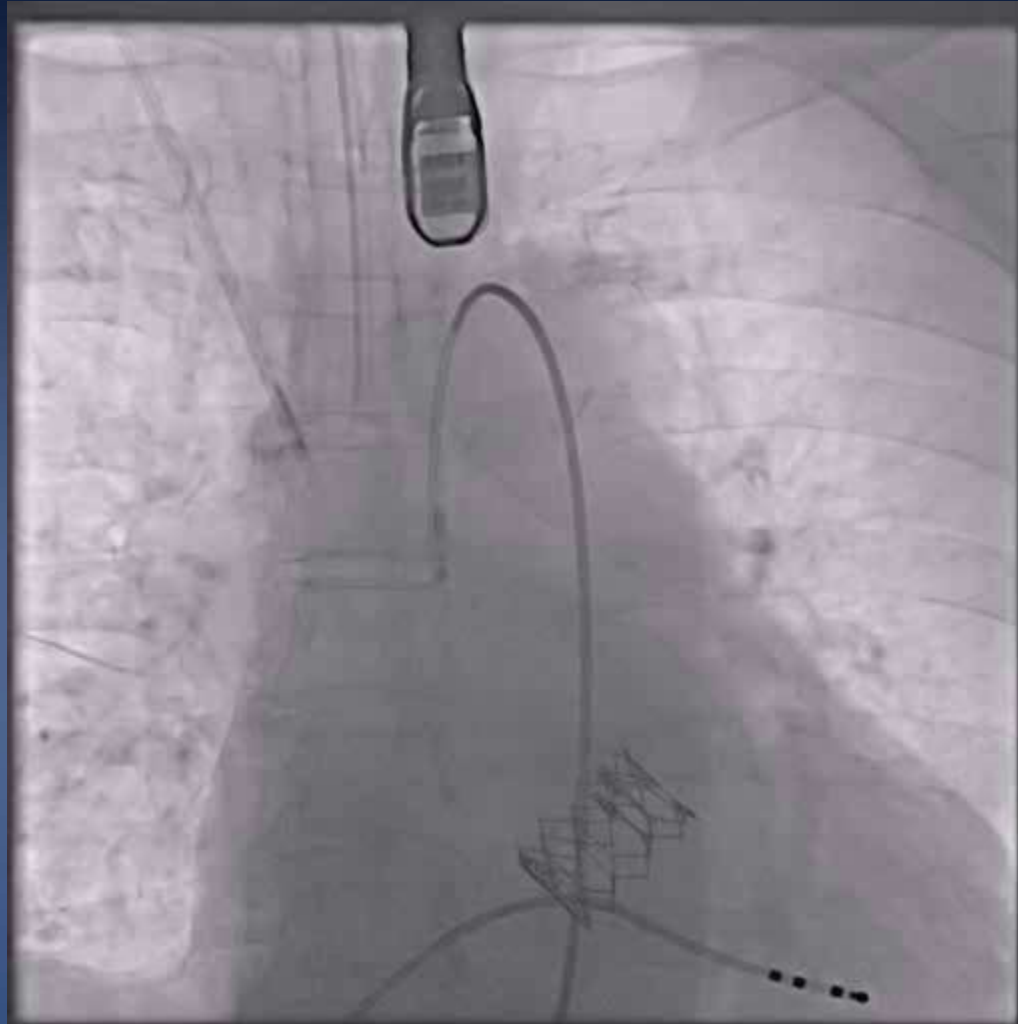


Aortography after post-dil



Mild AR

Aortography - aortic dissection



TEE finding – Aortic dissection



Follow-up CT

1 POD

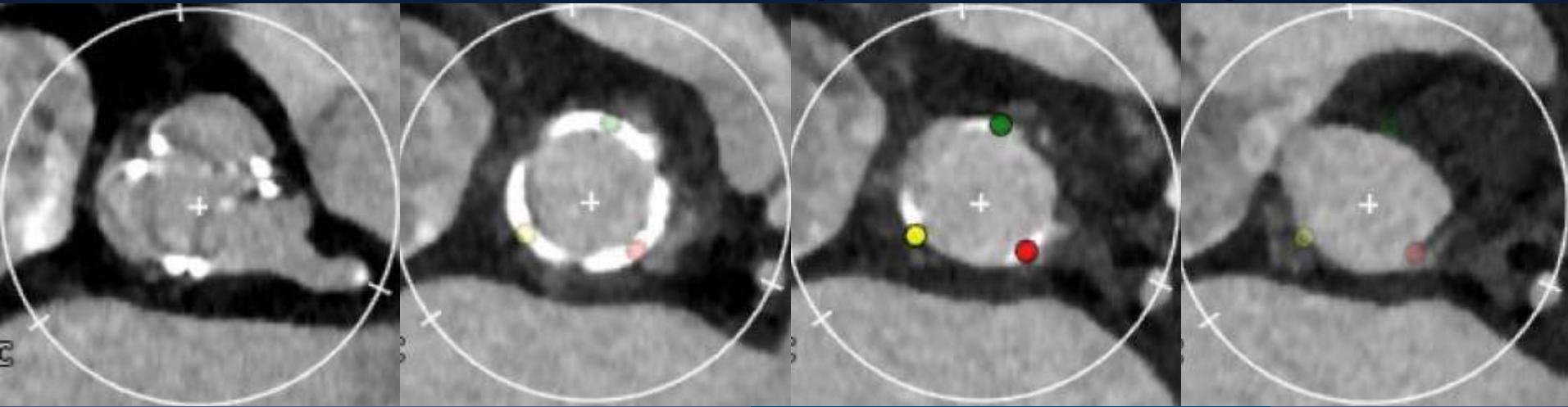


7 POD



2018 AP-Valve Live Case

80 F, ViV case: AVR(C-E 19mm) (2009)



Base of the surgical valve

Bioprosthetic valve parameters	
Valve internal short diameter	16.6 mm
Valve internal long diameter	18.1 mm
Valve internal mean diameter	17.3 mm
Valve internal area	238 mm ²
Valve internal area-derived diameter	17.4 mm
Valve internal perimeter	54.9 mm
Valve internal perimeter-derived diameter	17.5 mm

Fracturing, Cracking, Fracking



Perimount

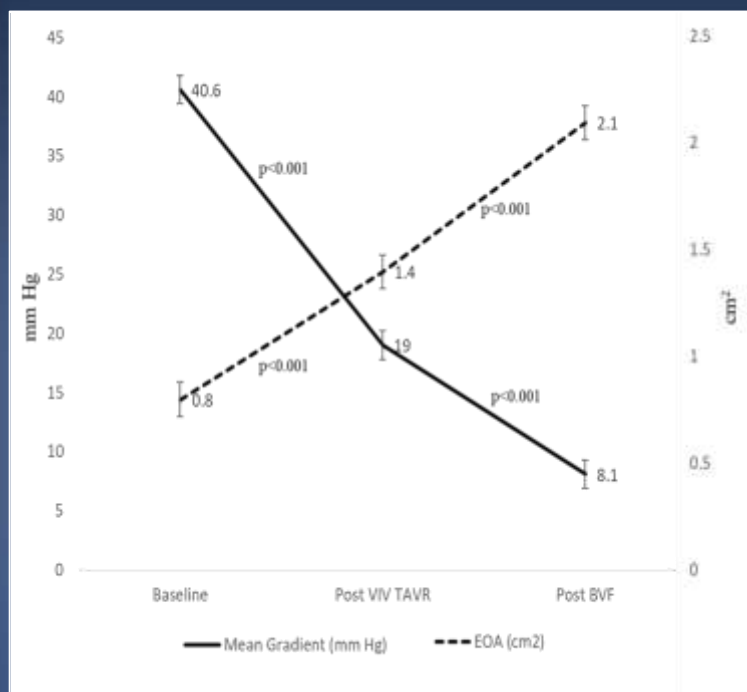
Figure 2: Fractured 21 mm Mitroflow Bioprosthesis Valve



The Dacron sewing cuff has been partially removed to display the single separation of the polymer ring. x indicates the surgical ring which has been fractured.

Mitroflow

Bioprosthetic Valve Fracture (BVF)



Manufacturer/Brand	Valve Size	Bard TRU Balloon Fracture/Pressure
St. Jude Triecta	19 mm	NO
	21 mm	NO
St. Jude Biocor Epic	21 mm	YES / 8 ATM
	21 mm	YES / 8 ATM
Medtronic Mosaic	19 mm	YES / 10 ATM
	21 mm	YES / 10 ATM
Medtronic Hancock II	21 mm	NO
	21 mm	NO
Sorin Mitroflow	19 mm	YES / 12 ATM
	21 mm	YES / 12 ATM
Edwards MagnaEase	19 mm	YES / 18 ATM
	21 mm	YES / 18 ATM
Edwards Magna	19 mm	YES / 24 ATM
	21 mm	YES / 24 ATM

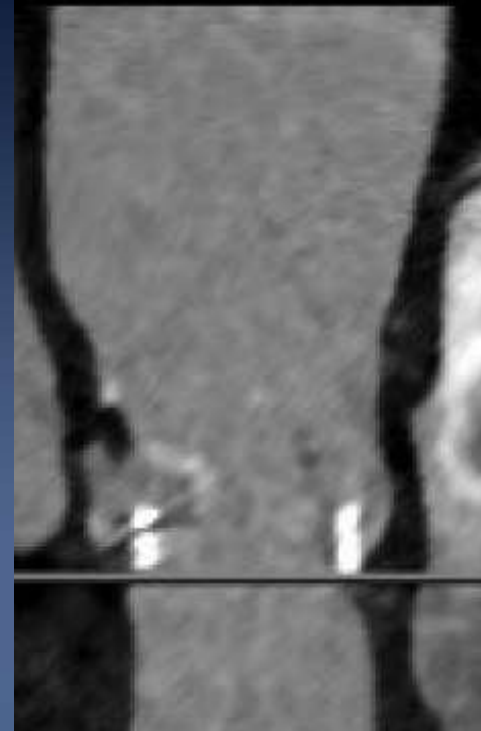
- Balloon 1mm larger than surgical valve
- Pressures 8 to 24mmHg
- Some valve with metal rings won't fracture (Triecta, Hancock)

CT – Coronary heights

LCA



RCA



Coronary Height	
LCA	6.8 mm
RCA	8.8 mm

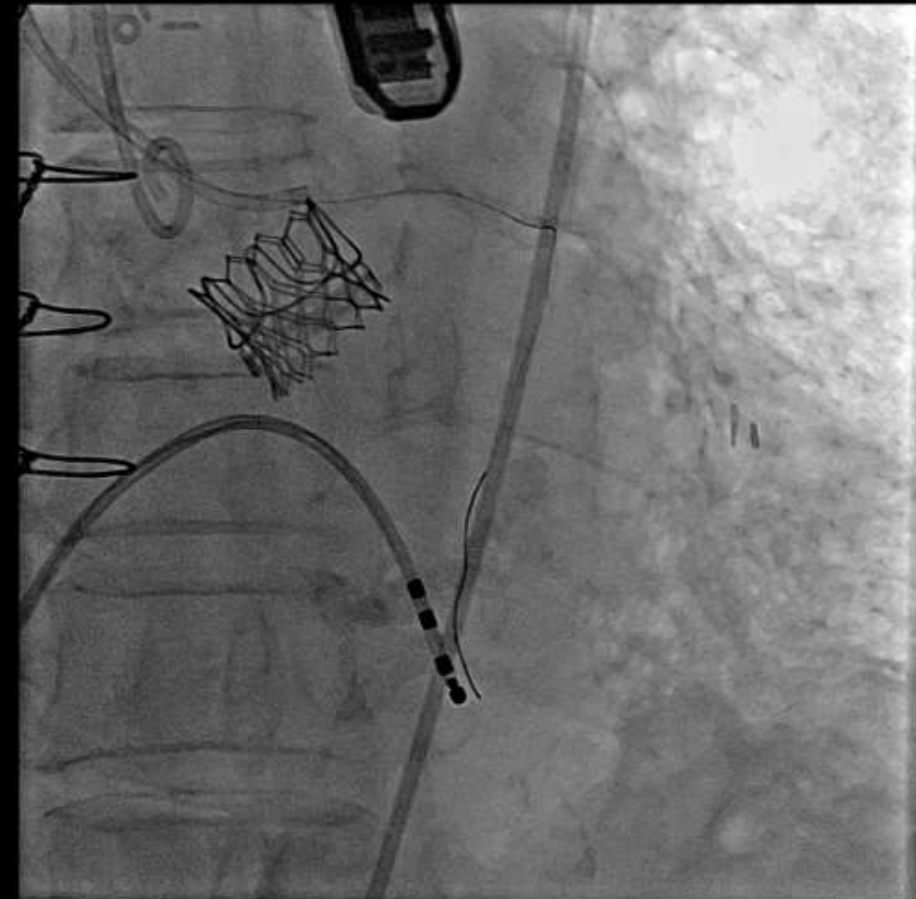
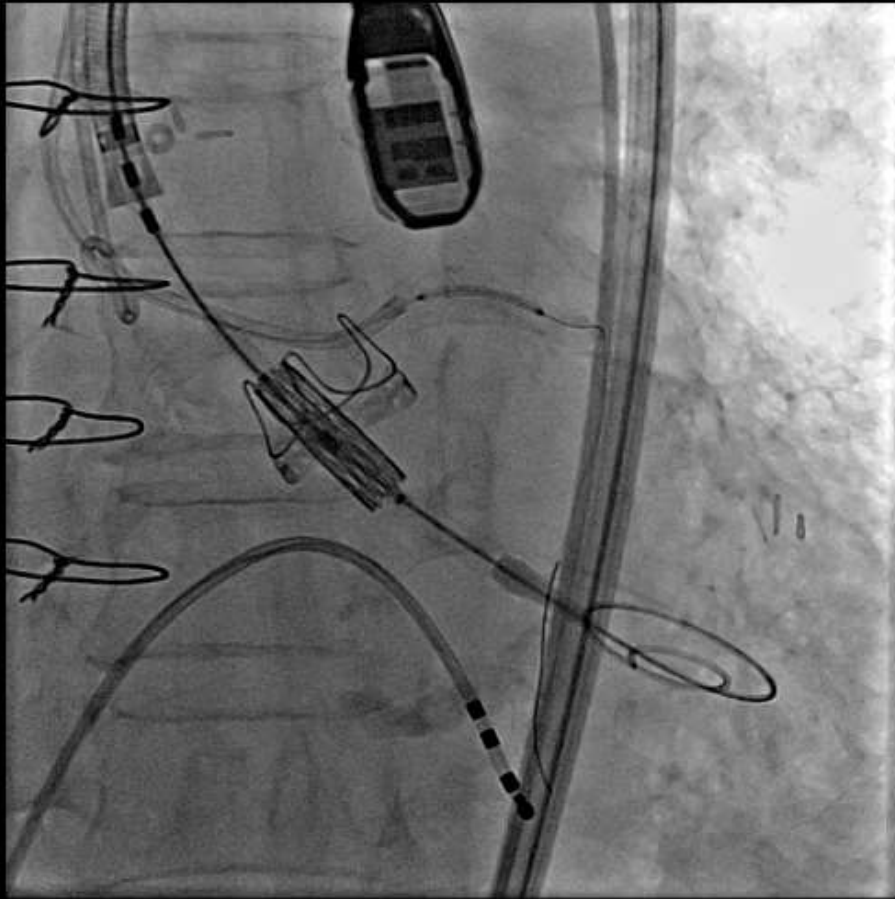
BVF Caution:

Initially, Valve fracturing Is Not Planned

2018 AP-Valve Live Case

**SAPIEN 3: 20mm with
coronary protection**

> Moderate PVR

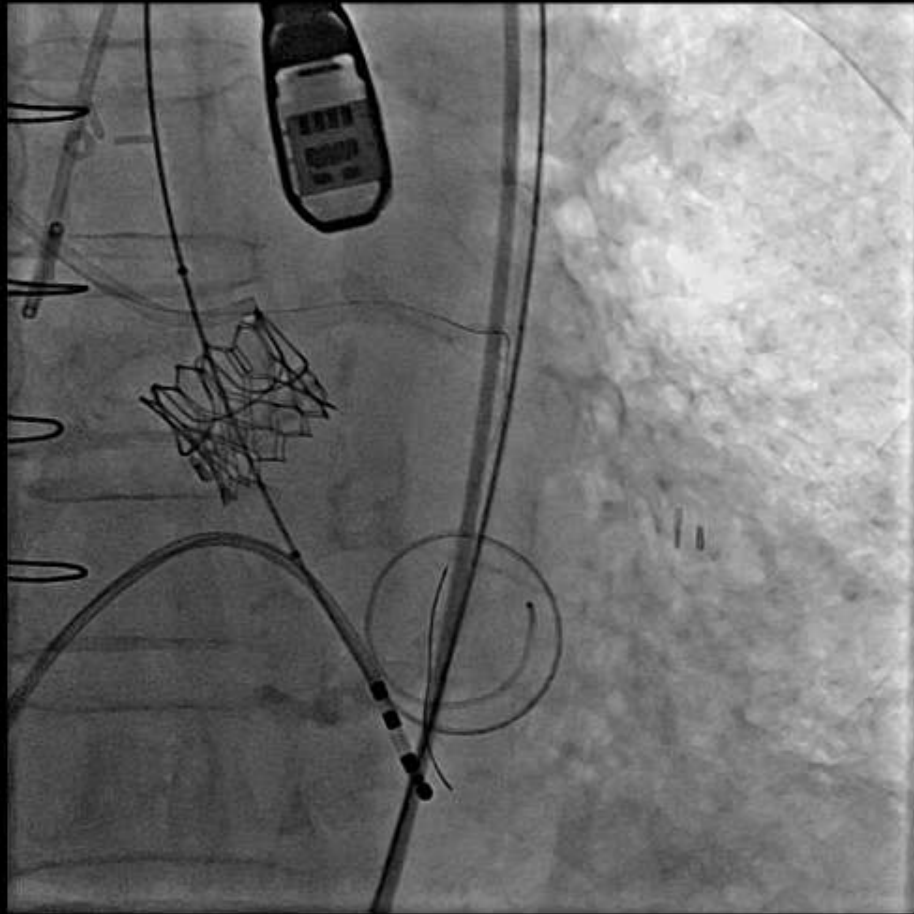


BVF Caution:

Initially, Valve fracturing Is Never Planned

Z-Med Post-dilation with 20mm

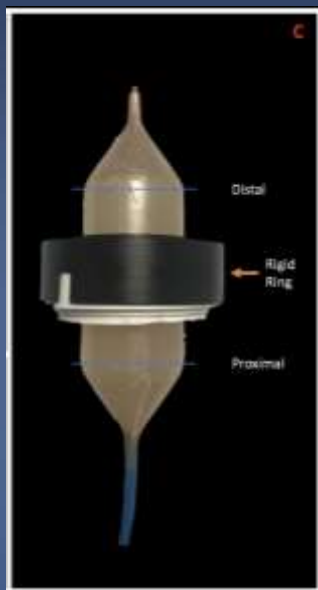
PVR did not reduce



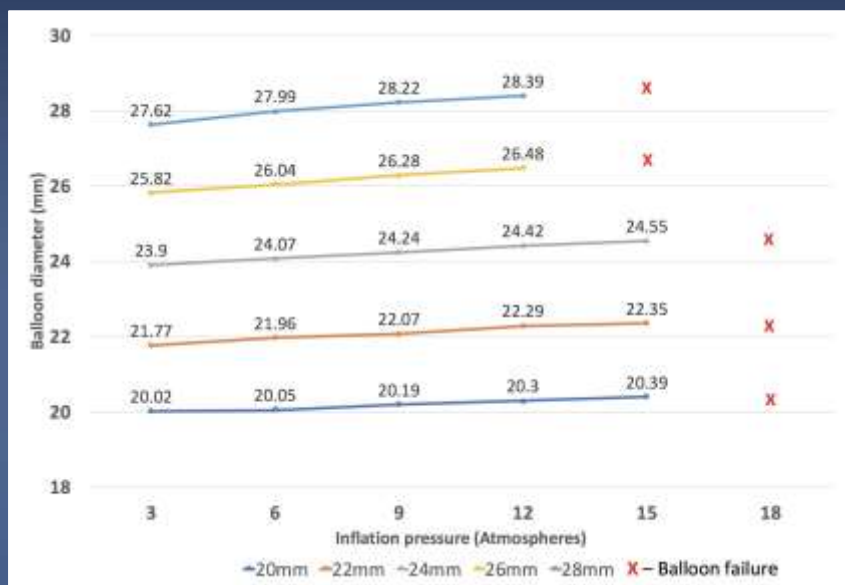
**Initially, Valve fracturing Is Never Planned.
However....**

A non-compliant balloon is necessary

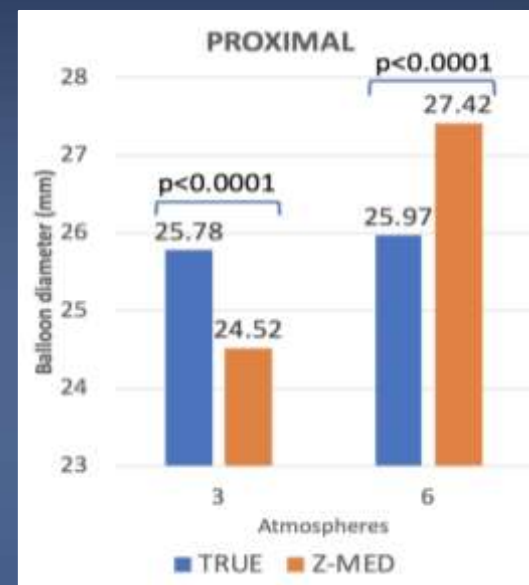
True Balloon



Extremely non-compliant

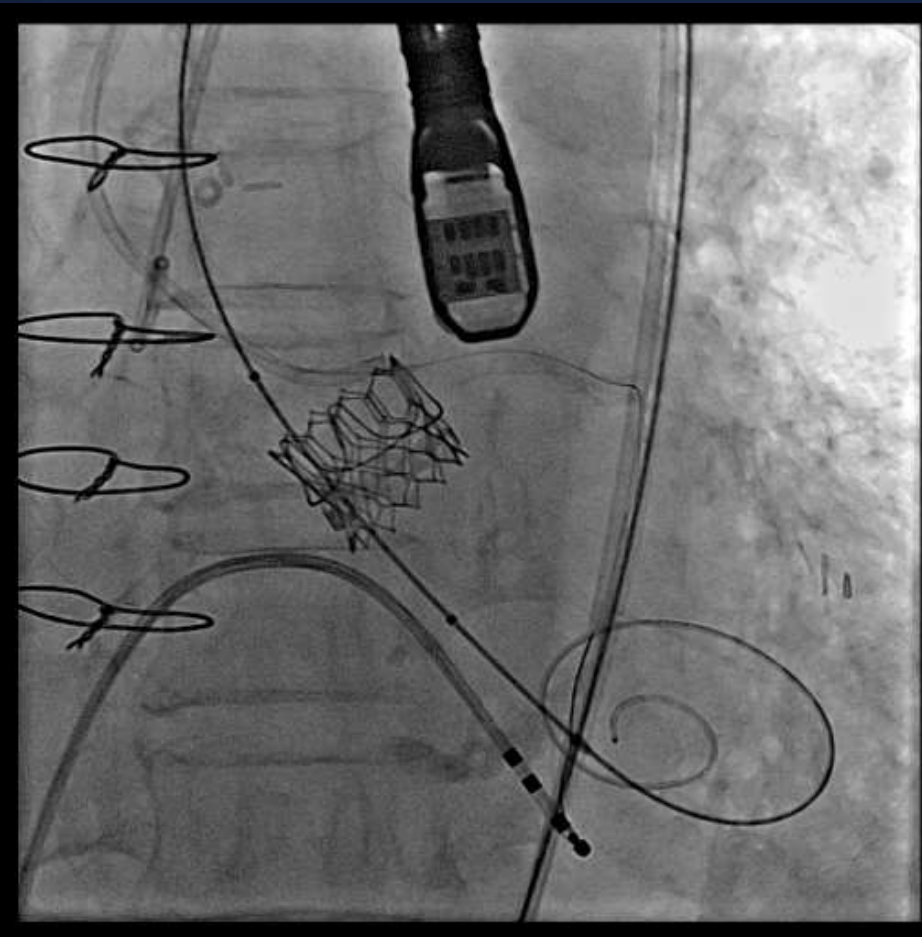


Comparison to Z-Med



Valve Fracture with 20mm ATLAS GOLD

Tight stenosis between S3
and STJ by surgical leaflet

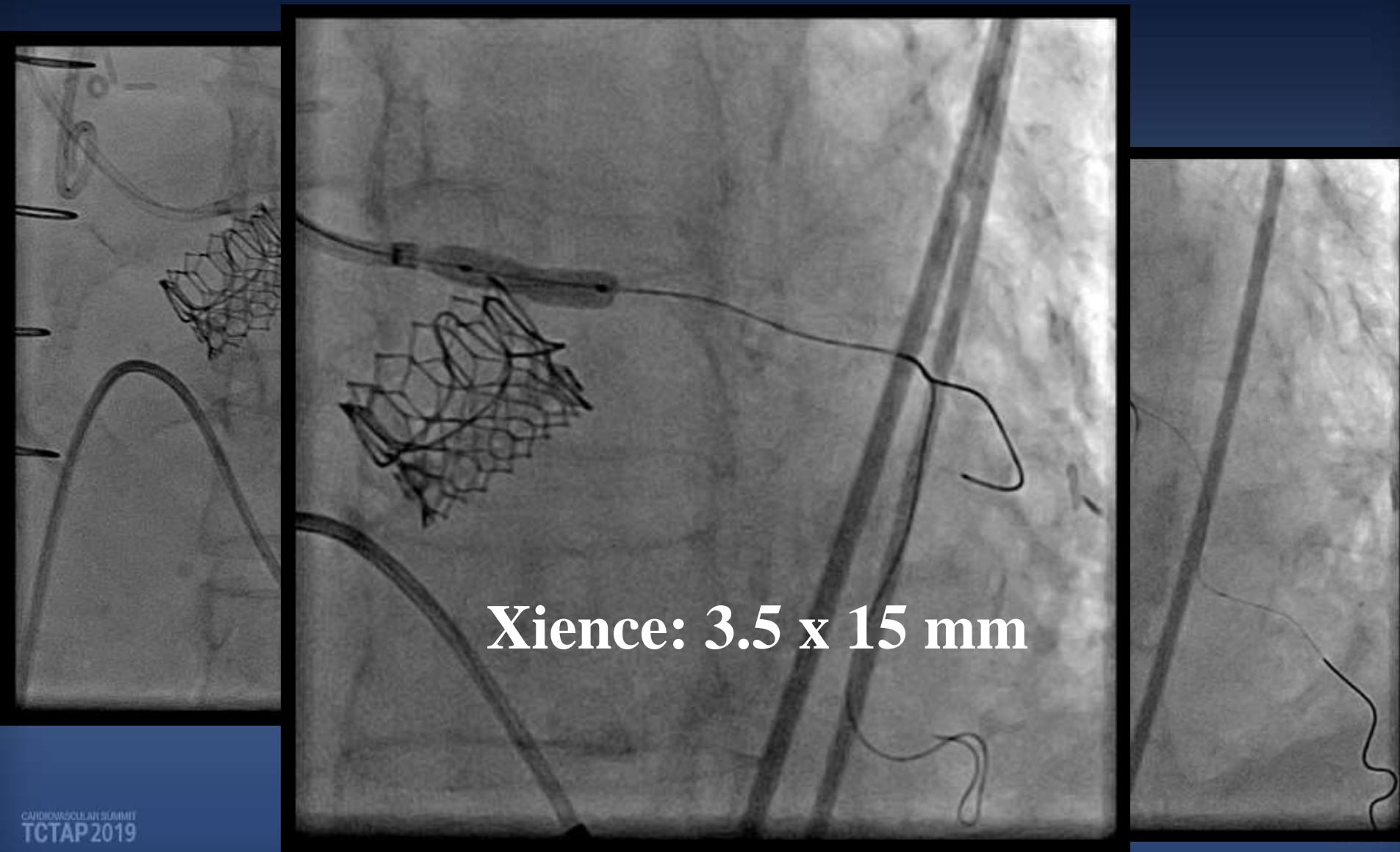


**Initially, Valve fracturing Is Not Planned.
However....Unavoidable BVF**

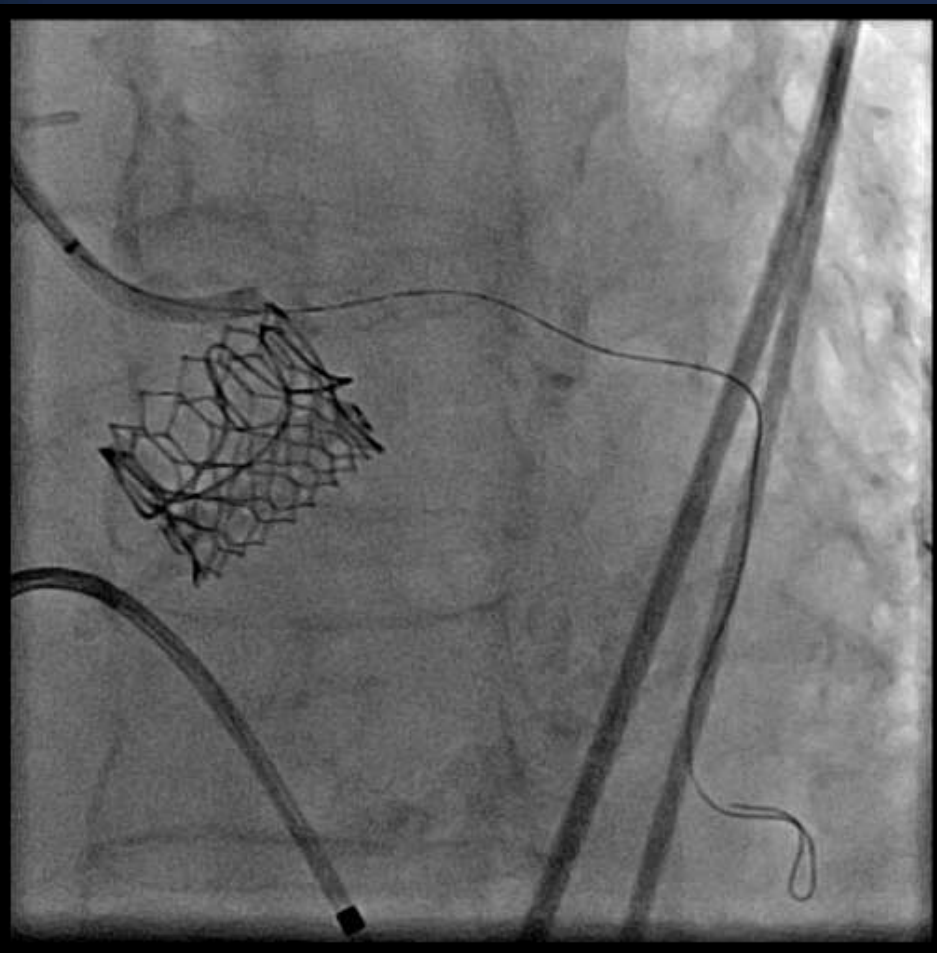
Initially, Valve fracturing Is Not Planned.

However....Unavoidable BVF

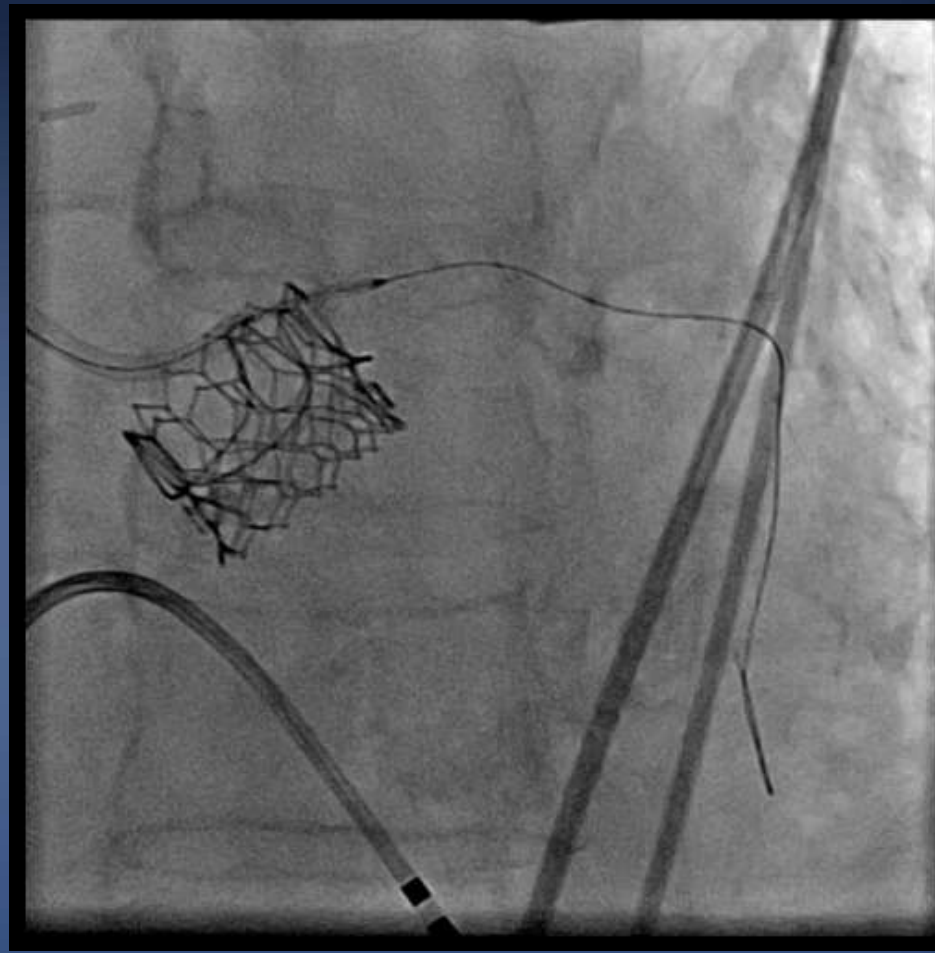
Dilation with several size of balloon under Guidzilla support



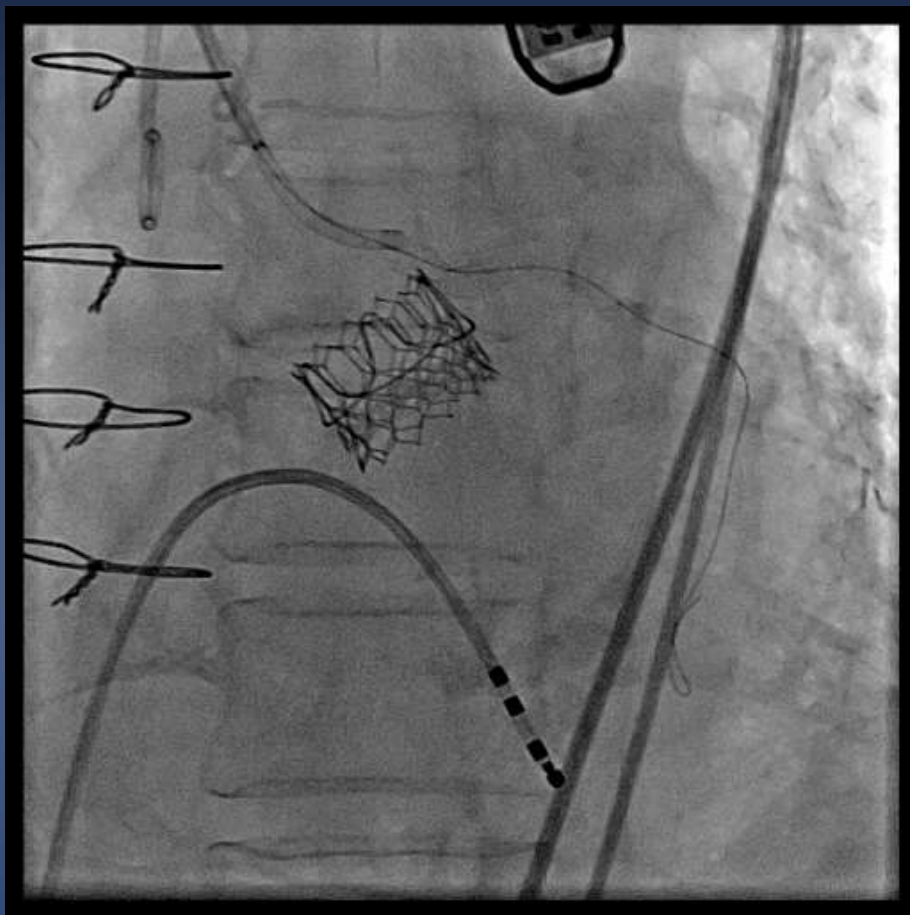
Acute recoil after 1st stent



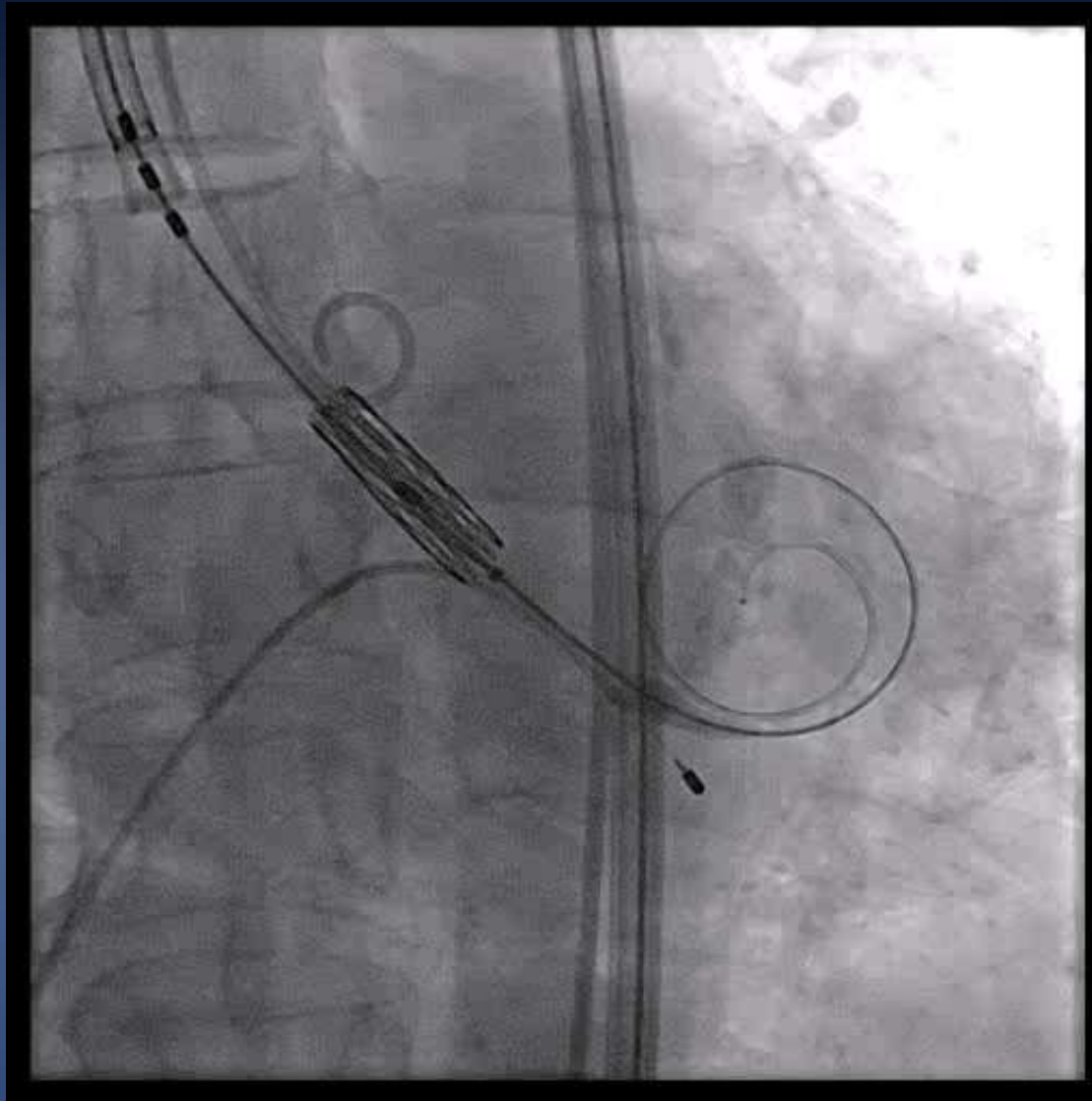
Stent-in-Stent to increase radial force



Final angiography after BVF



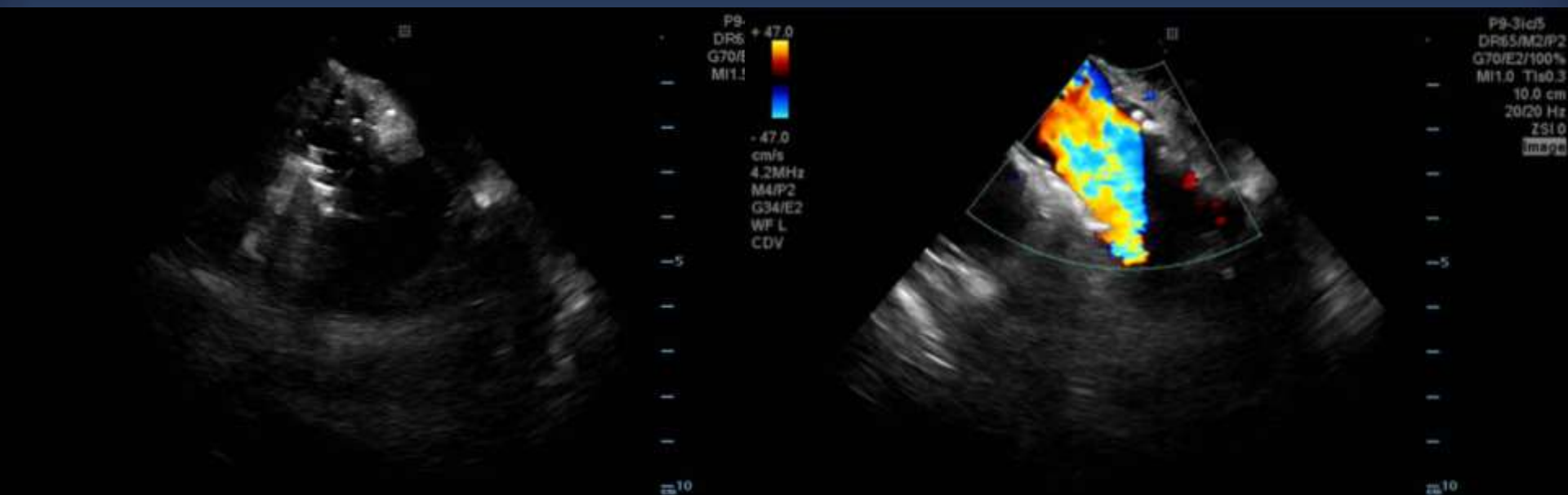
After Successful Implantation



Sapien 29 mm with 3cc underfill

Post-procedural ICE

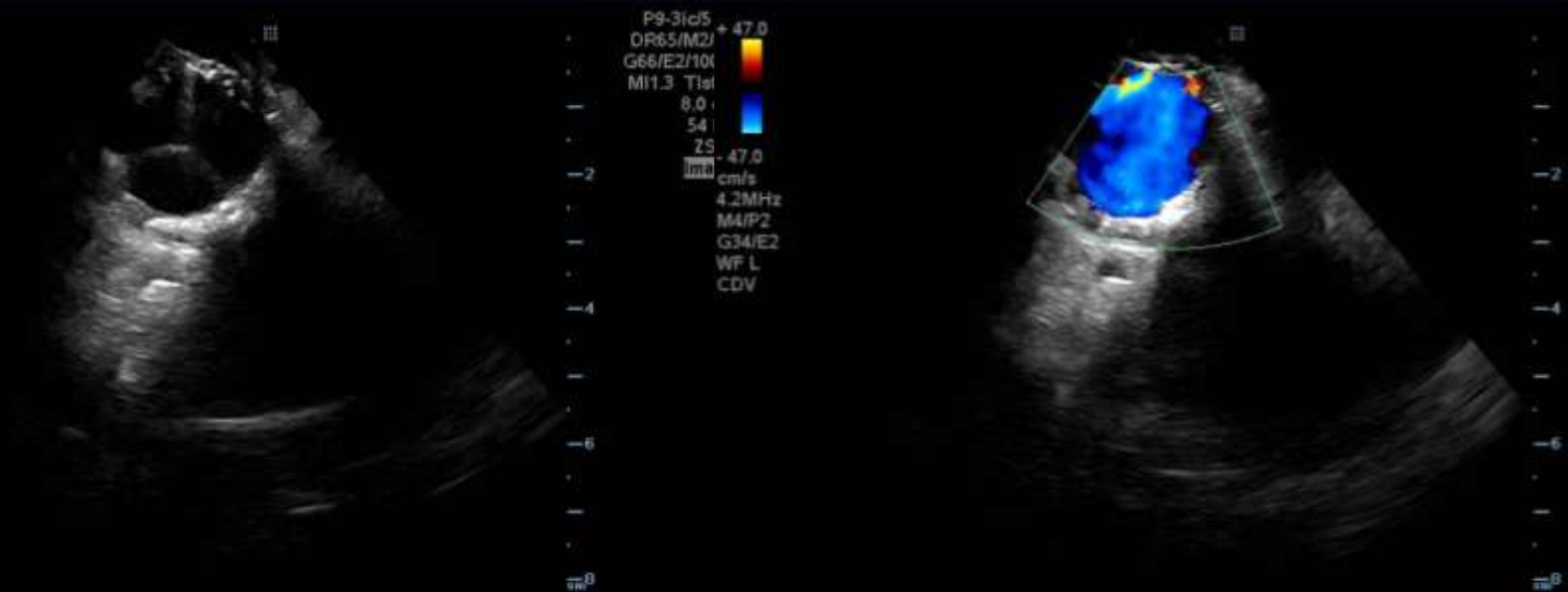
Long Axis View



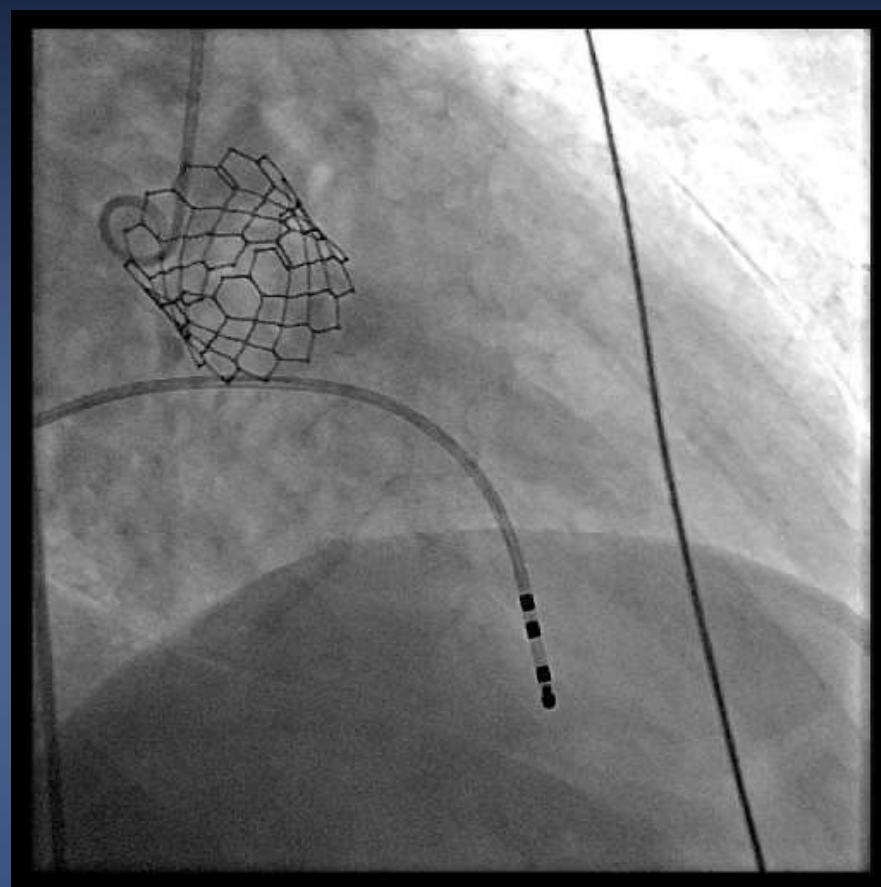
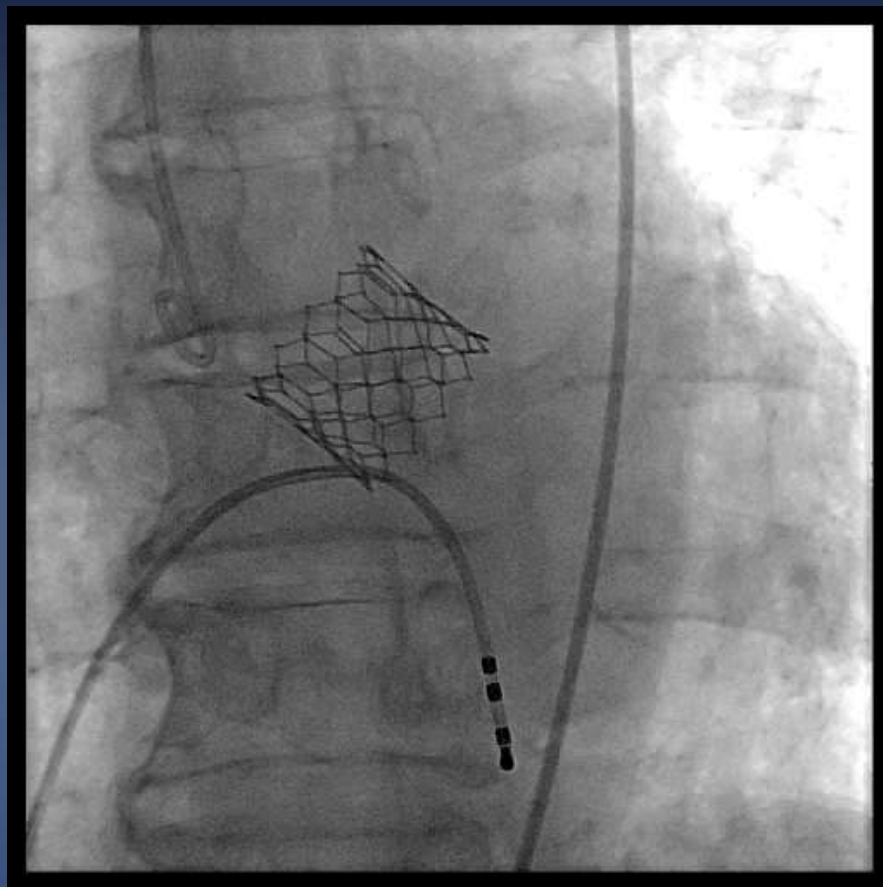
Sapien 29 mm with 3cc underfill

Post-procedural ICE

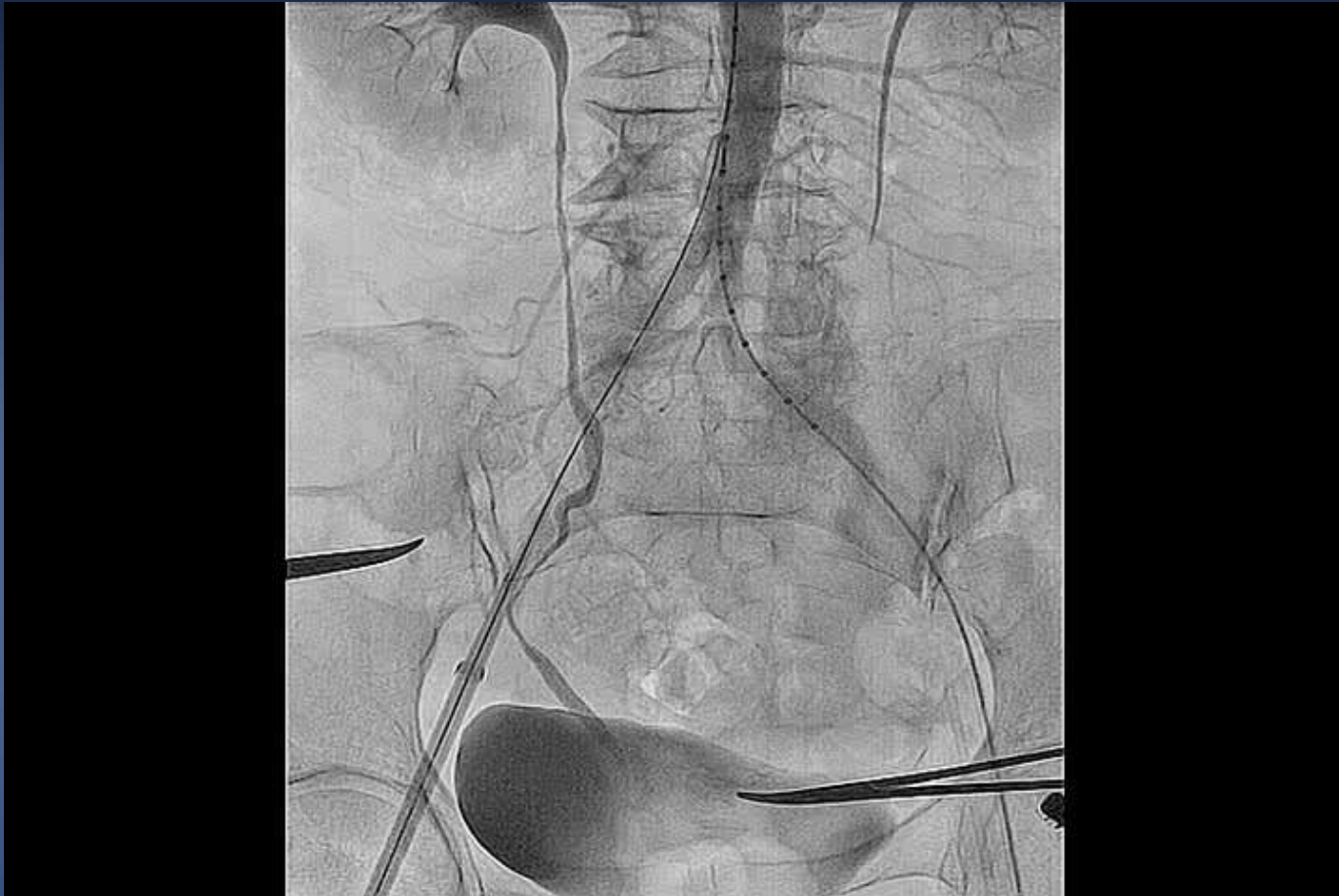
Short Axis View



Final Aortogram



Completion Angiogram and Sheath Removal



TAVR with SAPIEN

- TAVR with SAPIEN is one of standard procedure for high-, intermediate- or even low-risk patients with severe AS
- Optimal patient selection (heart-team discussion) and procedural planning (CT and echo) is key steps for successful TAVR.
- More developed devices and more experienced expertise are associated with a lower procedural complications.
- We should also concern different complications per different patient.