Transcatheter Aortic Valve Implantation (TAVI)

Early TAVI Experience What We Prepare?

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Indication of TAVI

- Symptomatic Severe AS
- Life expectancy > 1yr
- Contraindication for surgery or High risk for surgery

  Clinical judgement +

  EuroScore(logistic) >20%, STS score >10%

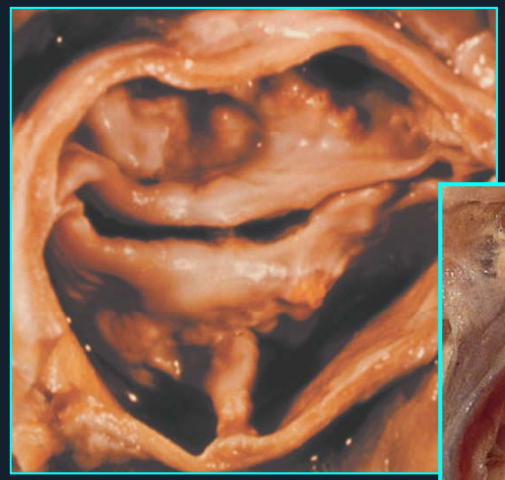
  And/Or Porcelain aorta / History of thoracic irradiation

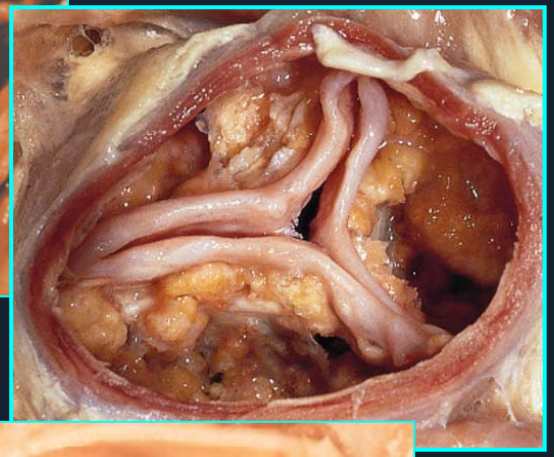
  Severe thoracic deformity / Patent coronary bypass

Eur Heart J, 2008; 29: 1463-1470, Eur J Cardiothorac Surg, 2008; 34: 1-8

Aortic Stenosis

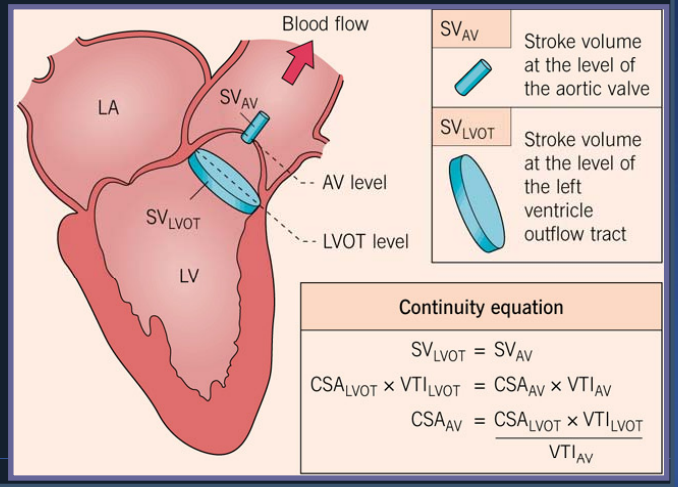
- **Etiology**
  - **Congenital**
    - Bicuspid
  - **Acquired**
    - Degenerative
      - Calcium deposition
      - AR : rare
      - DM, hypercholesterolemia
      - Smoking, HT, low HDL
    - Rheumatic
      - Commissure fusion
      - Cusp retraction & stiffening
      - MV involvement
      - AR : common



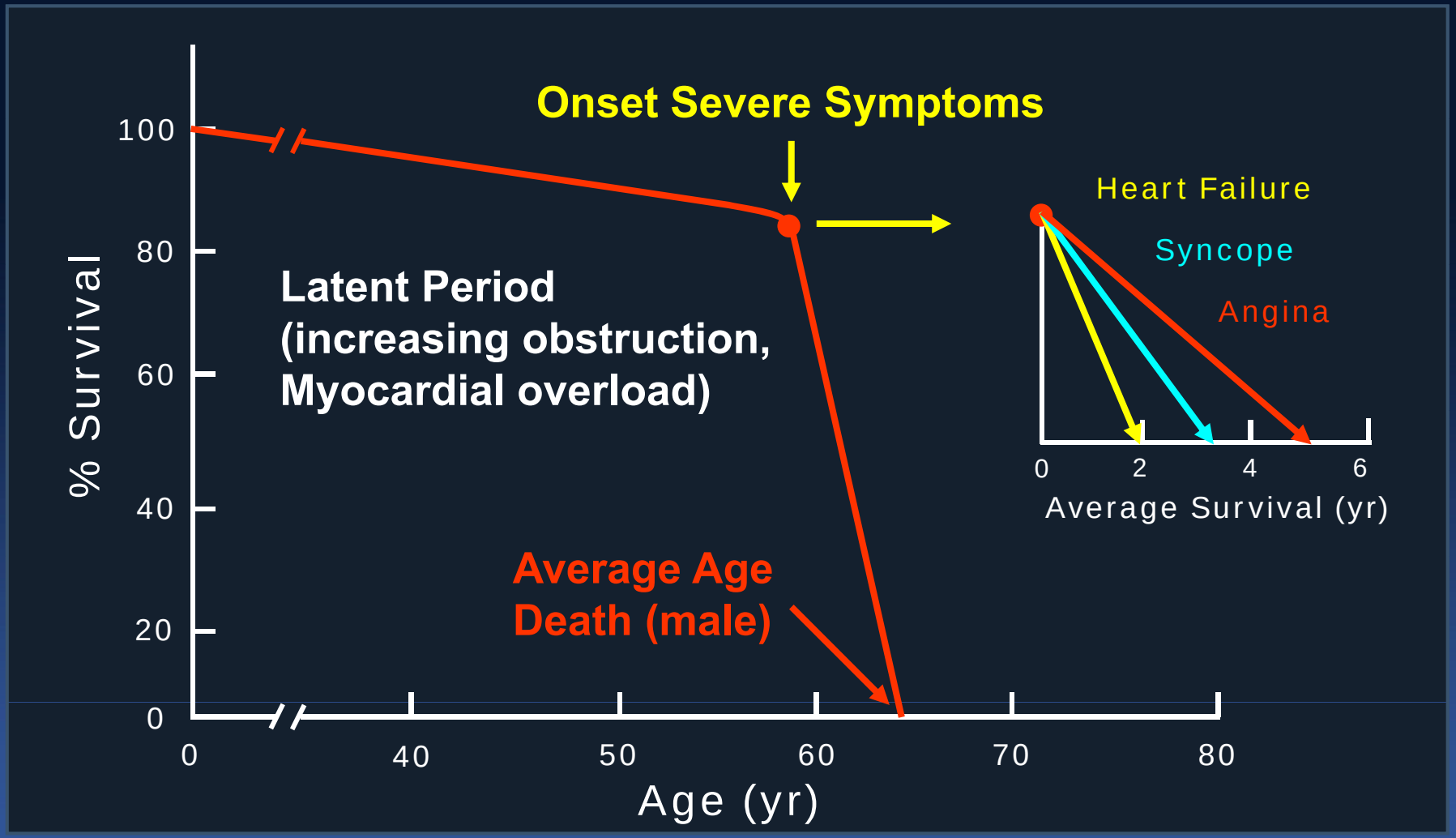


Severity of AS

- **Mild**
  - Mean PG < 20 mmHg
  - AVA > 1.5 cm^2
- **Severe**
  - Mean PG > 40 - 50 mmHg
  - Vmax > 4.5 m/s
  - AVA < 0.75 - 1.0 cm^2



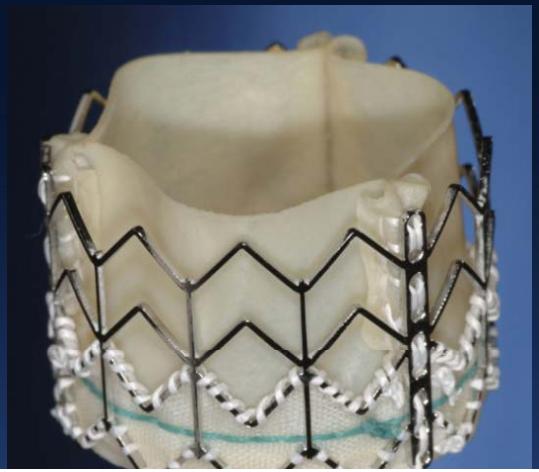
Natural History of AS



Circulation 1968;38[Suppl V]:61

Current Active Devices

Current Generation Devices



	Width	Hight	For annulus diameter	Height of skirt
Edward SAPIEN XT™	23mm	14.3mm	18-22mm	10.1/7.74mm
	26mm	17.2mm	21-25mm	11.4/8.67mm
CoreValve Revalving™	26mm	55mm	20-23mm	12mm
	29mm	53mm	23-27mm	12mm

Table 1 Comparison of the Edwards SAPIEN XT valve and Medtronic CoreValve prostheses

	Edwards SAPIEN XT	Medtronic CoreValve
Frame	Cobalt chromium	Nitinol
Leaflets	Bovine pericardial	Porcine pericardial
Expansion	Balloon-expandable	Self-expanding
Balloon valvuloplasty required	Yes	Yes
Retrievable	No	Prior to release
Annular/valvar fixation	Yes	Yes
Ascending aortastabilization	No	Yes
Manufacturers diameter[a]	23, 26 mm	26, 29 mm
Recommended annulus diameter	18–25 mm	20–27 mm
Length	15–17 mm	53–55 mm
Delivery system diameter	18F&19F	18F
Sheath external diameter	7.3 mm	7.3 mm
Minimum arterial diameter	6 mm	6 mm

Table 1 Comparison of the Edwards SAPIEN XT valve and Medtronic CoreValve prostheses

Cobalt chromium

Nitinol

AMC Registry : Procedure

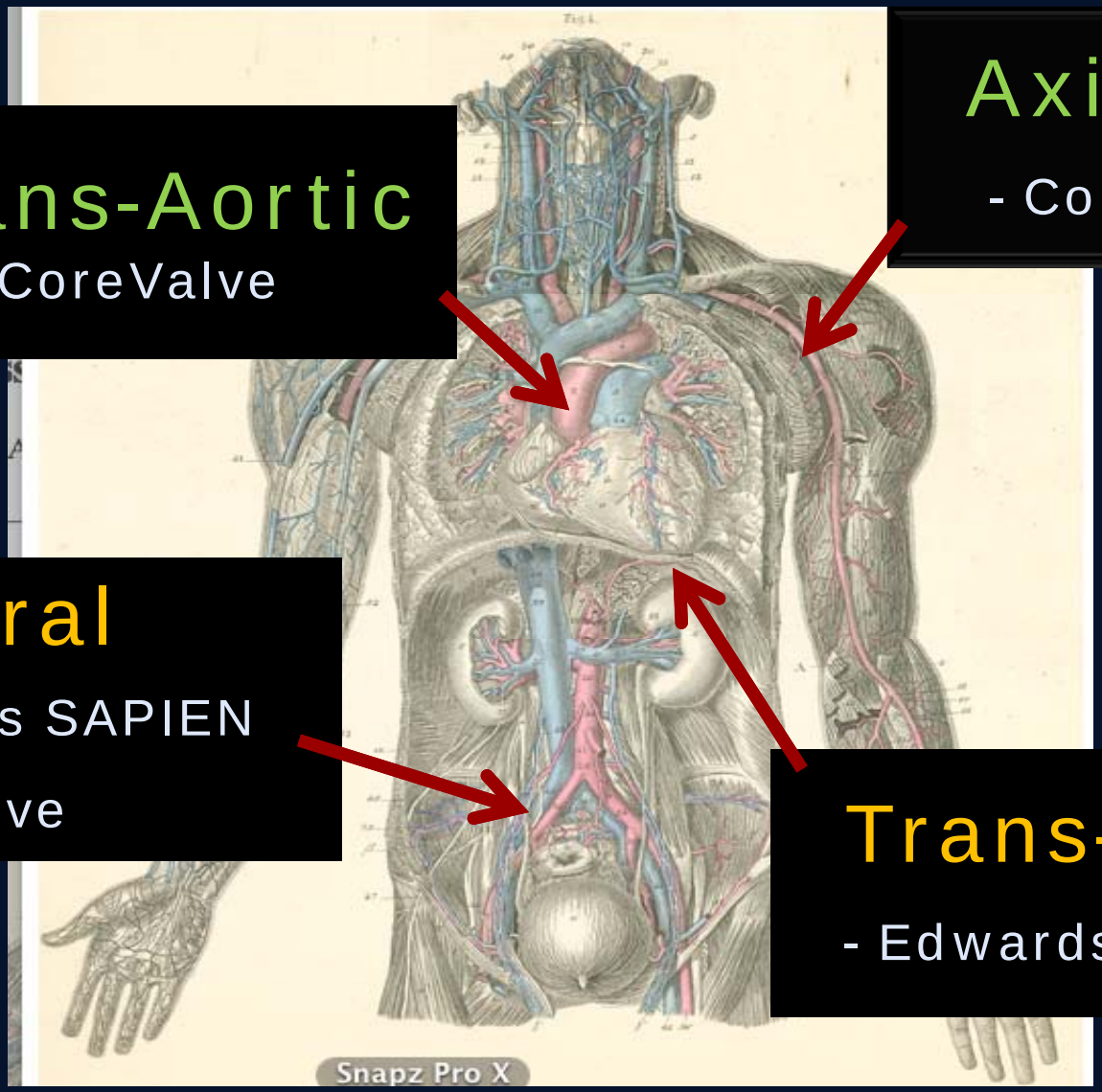
(RF1=5, RF3=5, NovaFlex=19, CoreValve=9)	N=38
Age, years	76.4±5.4
Logistic EuroSCORE, %	25.6±5.1
Implanted valve size, mm	
23 mm	21
26 mm	10 (2*)
29 mm	7*
Transfemoral approach	35
Surgical closure	4
Percutaneous closure	31
Transapical approach	3

* CoreValve

In-Hospital, 30 days

	N=38
Procedural Success	35/38 (92%)
Mortality	0
Major or minor Stoke	0
Permanent Pacemaker	0
Moderate to severe AR (CoreValve)	1
Vascular complication (RF1, Edward Sapien)	2
Access site	1
Iliac artery perforation	1

Access Routes For TAVI



Trans-Aortic
- CoreValve

Axillary
- CoreValve

Femoral
- Edwards SAPIEN
- CoreValve

Trans-apical
- Edwards SAPIEN

Transfemoral Approach

Edwards SAPIEN

Case Presentation

Brief History (82/F, 146cm, 65Kg)

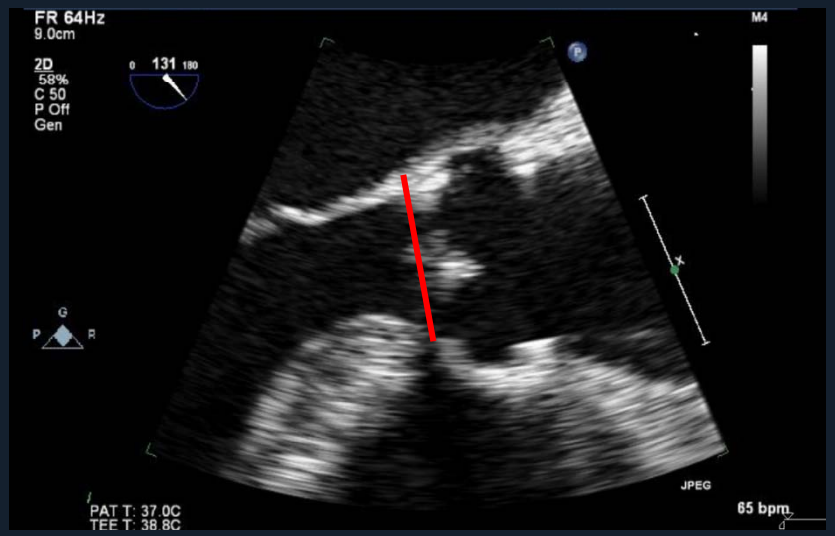
Chief Complaints :

- Recurrent Syncope
- DOE (NYHA III)
- Chest discomfort for 2 years

Medical Comorbidities :

- HTN/ DM/ previous CABG/ COPD
- Euroscore = 32%

Severe Degenerative Aortic Stenosis



Aortic valve area: 0.8 cm^2

Max gradient: 50 mmHg

Mean gradient: 35 mmHg

Vmax: 3.8 m/sec

Annulus: 20 mm

EF: 60%

TR Vmax: 2.1 mmHg

CT Measurement

Coronal view

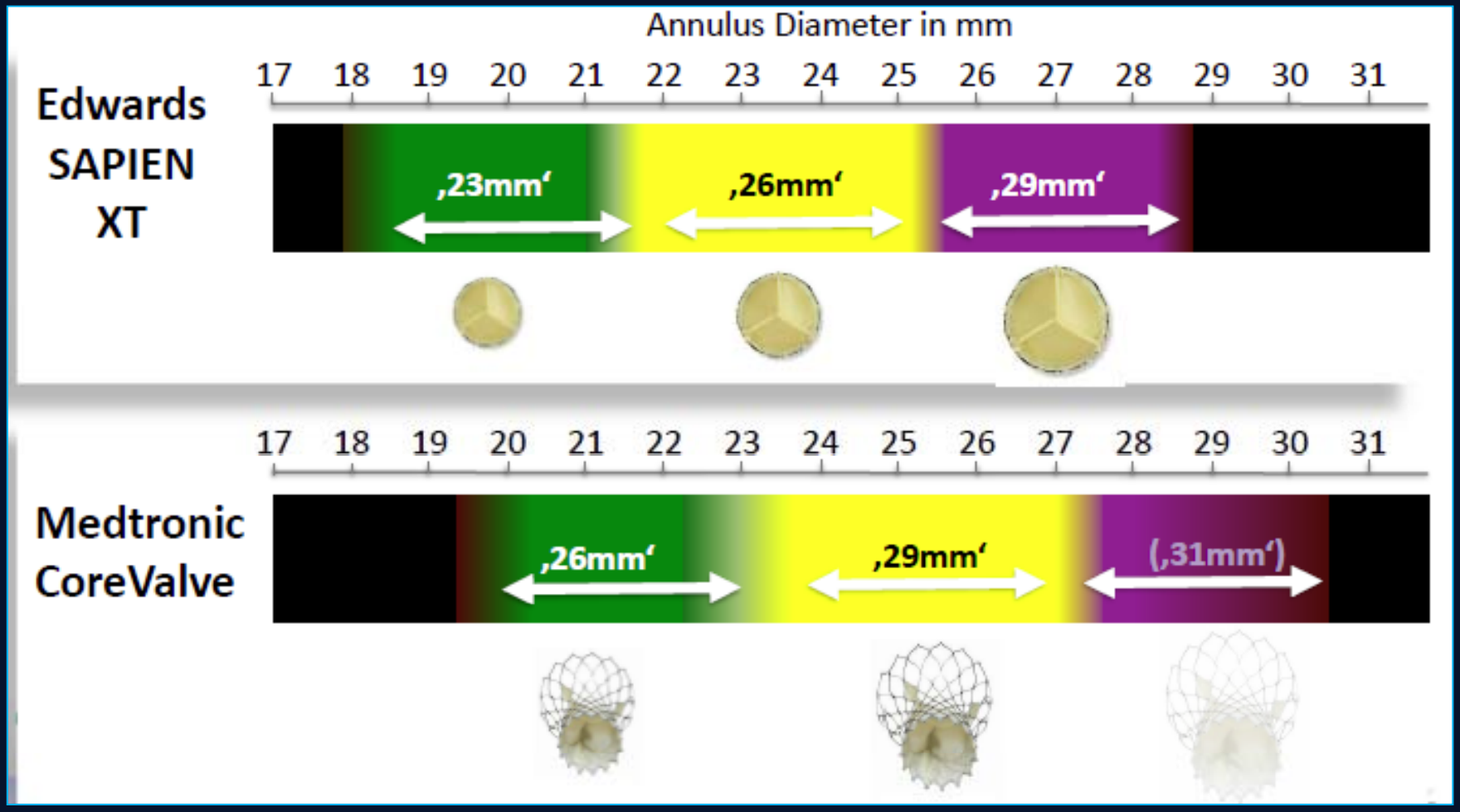
Sagittal view
= Parasternal long-axis view

19~21 mm

Double oblique view
at annular level

Annular Sizing for TAVI

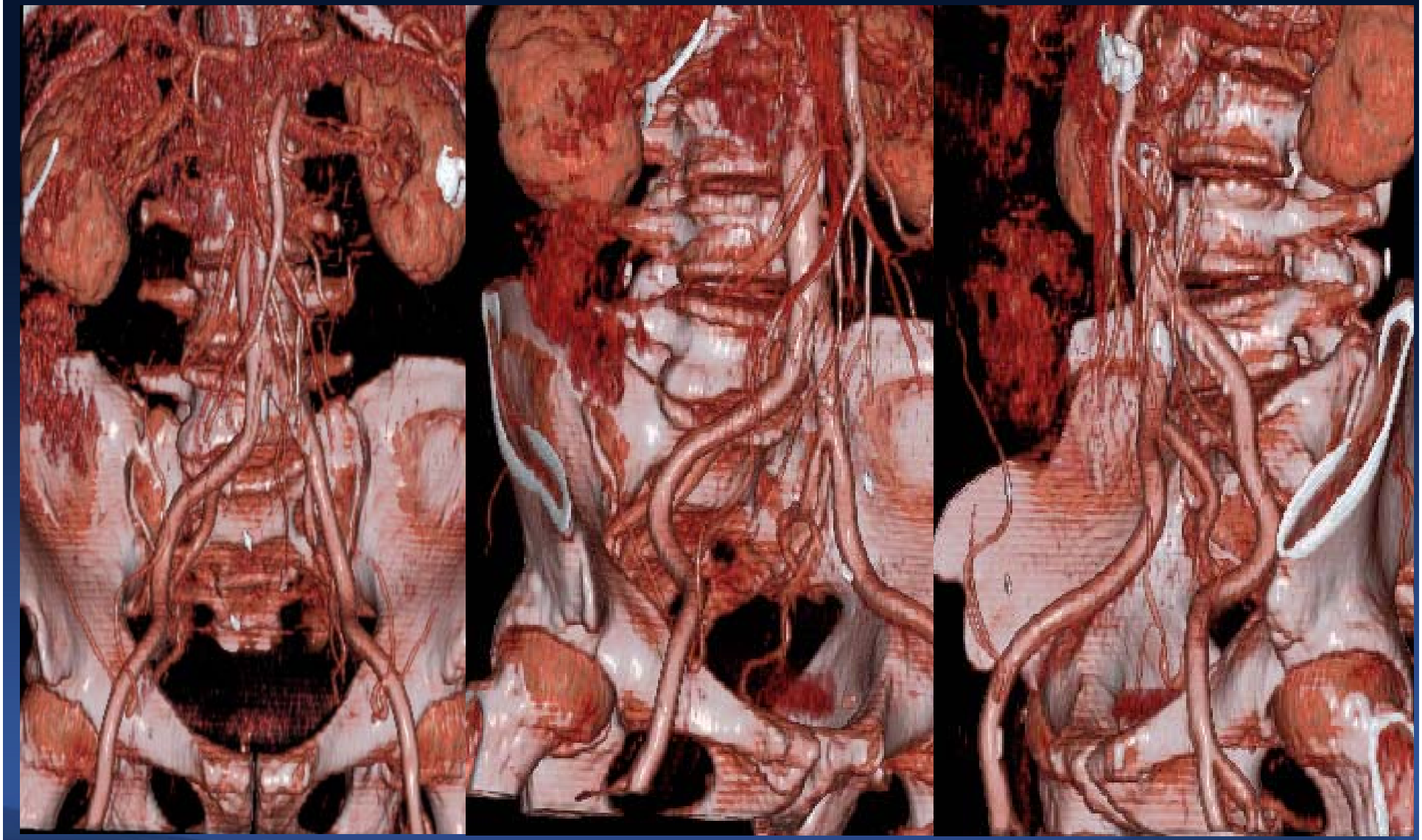
Measurement of Annulus Dimensions



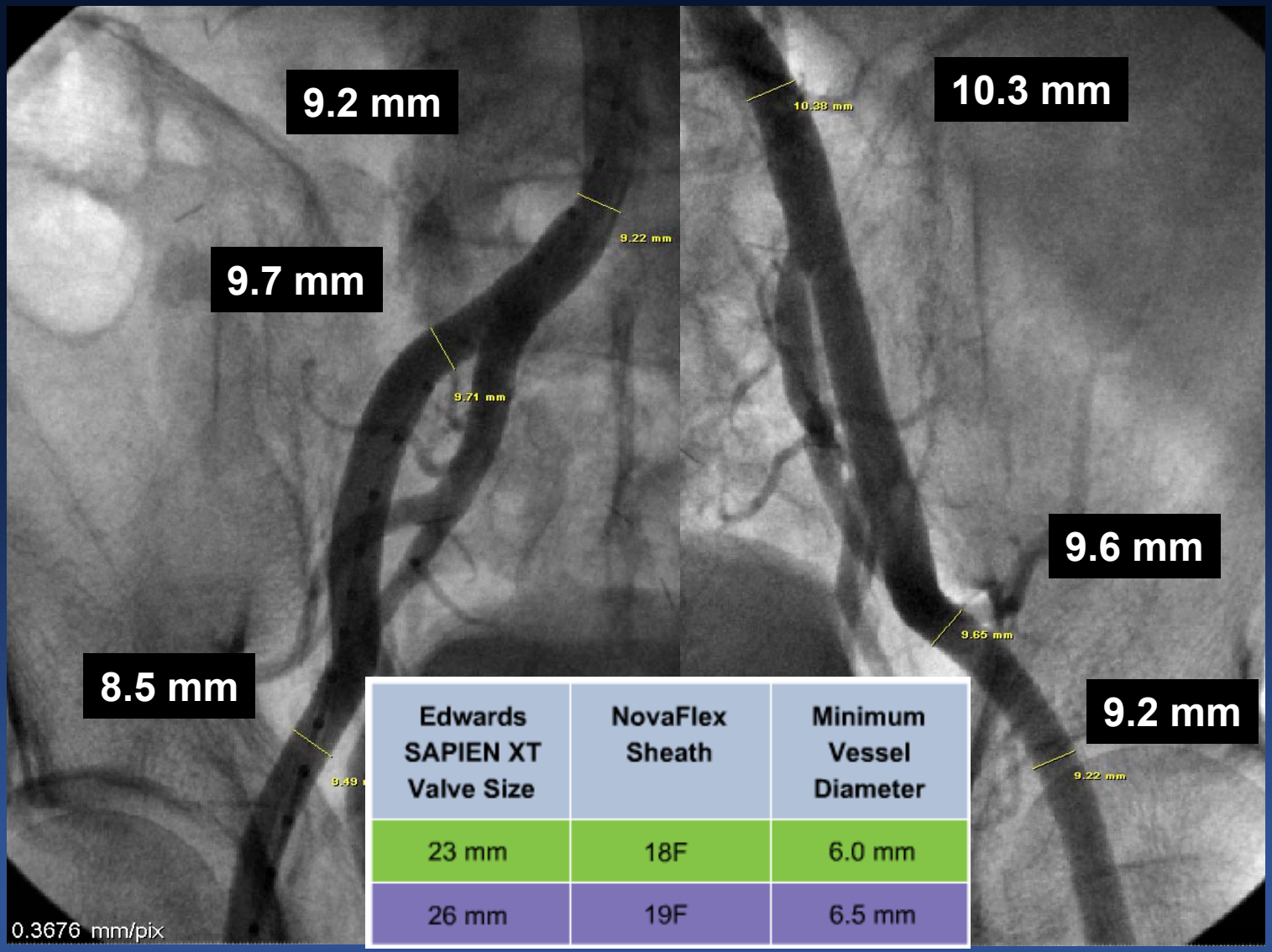
CT Angiography

No severe calcification in access route
No severe tortuosity

CT Angiography



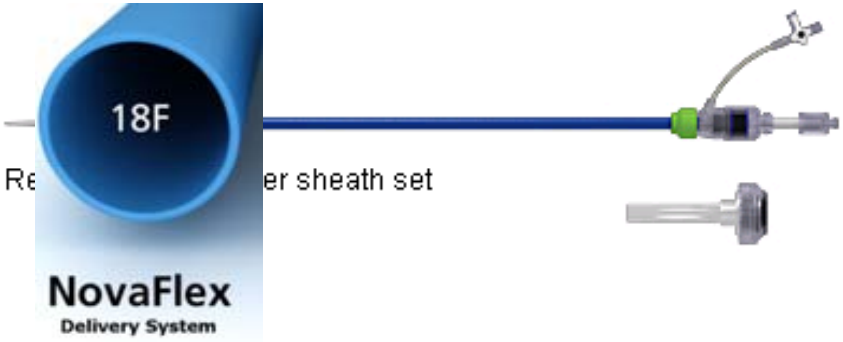
Ilio-femoral angiogram



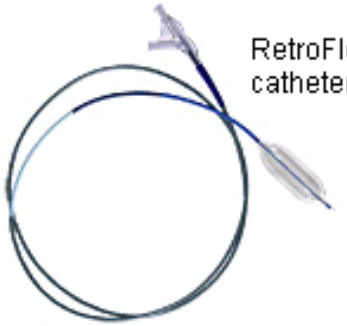
Edwards SAPIEN XT Valve Size	NovaFlex Sheath	Minimum Vessel Diameter
23 mm	18F	6.0 mm
26 mm	19F	6.5 mm

Edwards SAPIEN Device

NovaFlex System



Re er sheath set



RetroFlex balloon catheter

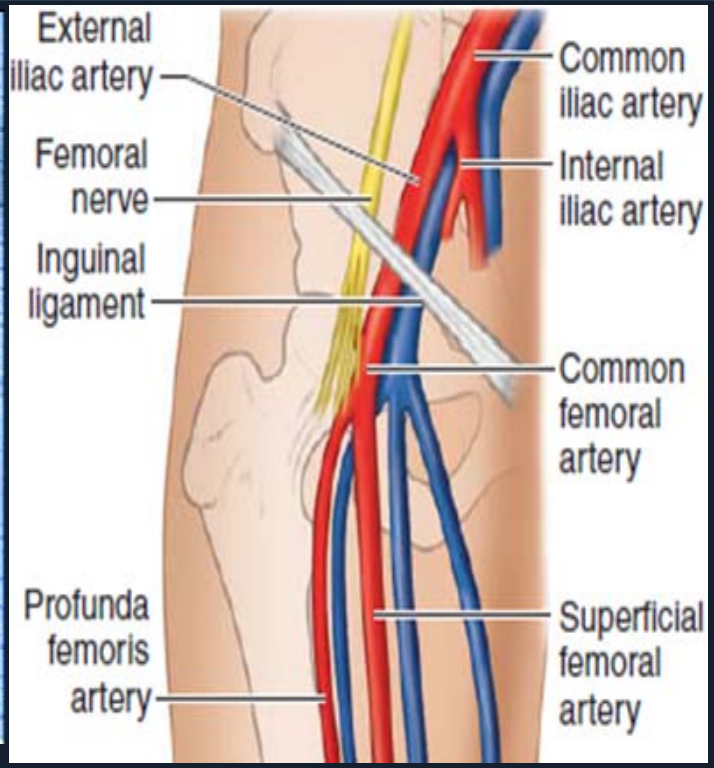
RetroFlex dialator kit

Atrion inflation device

Crimper

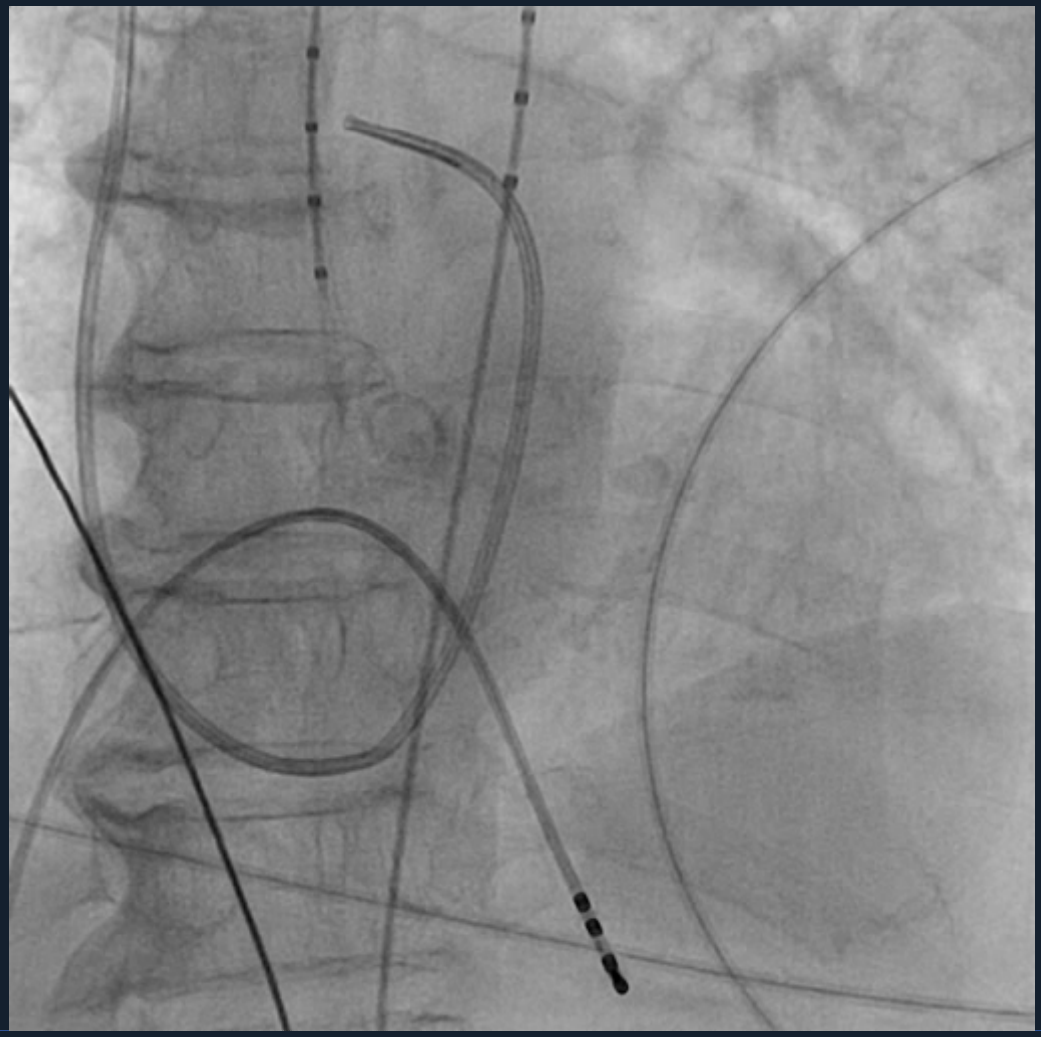
Conscious Sedation

Puncture (Rt. Approach)

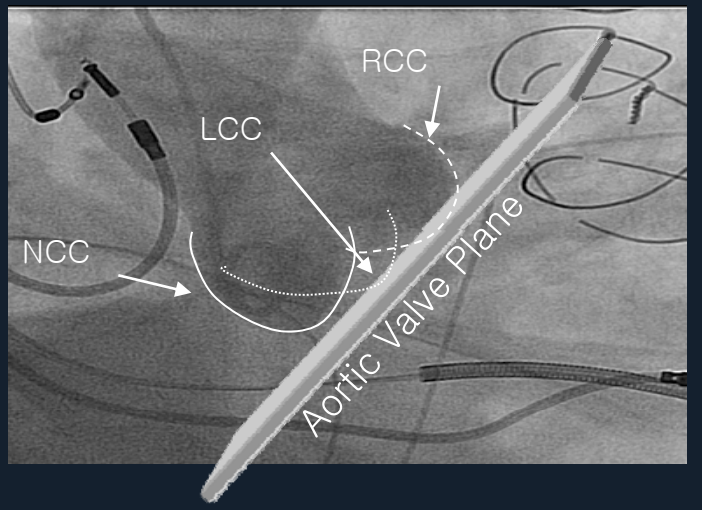


- Lt. femoral artery 7Fr for pigtail catheter
- Lt. femoral vein 6Fr for Pacing catheter
- Pacing Cath into the RV & Check the pacing
- Rt. femoral artery puncture 7Fr sheath
  (Femoral Head Upper Position)

Baseline Aortogram

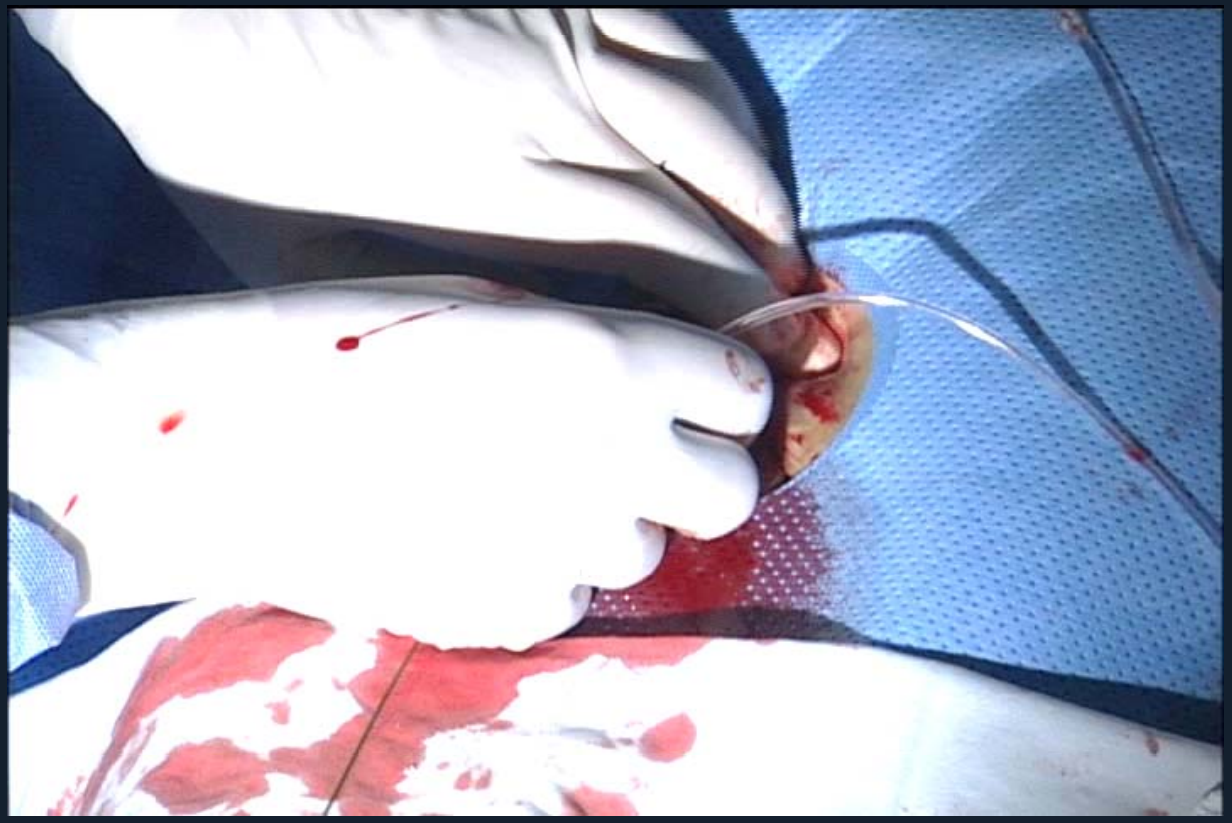


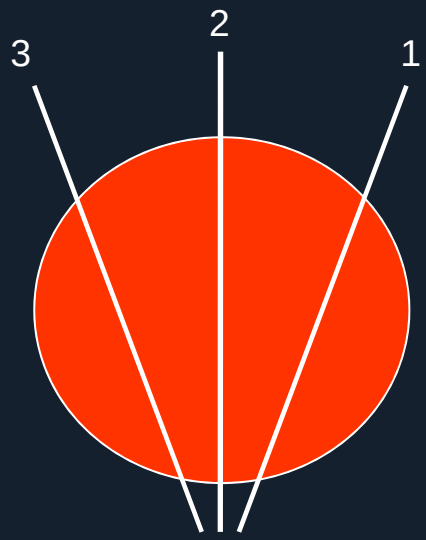
LAO 18 CAU 12



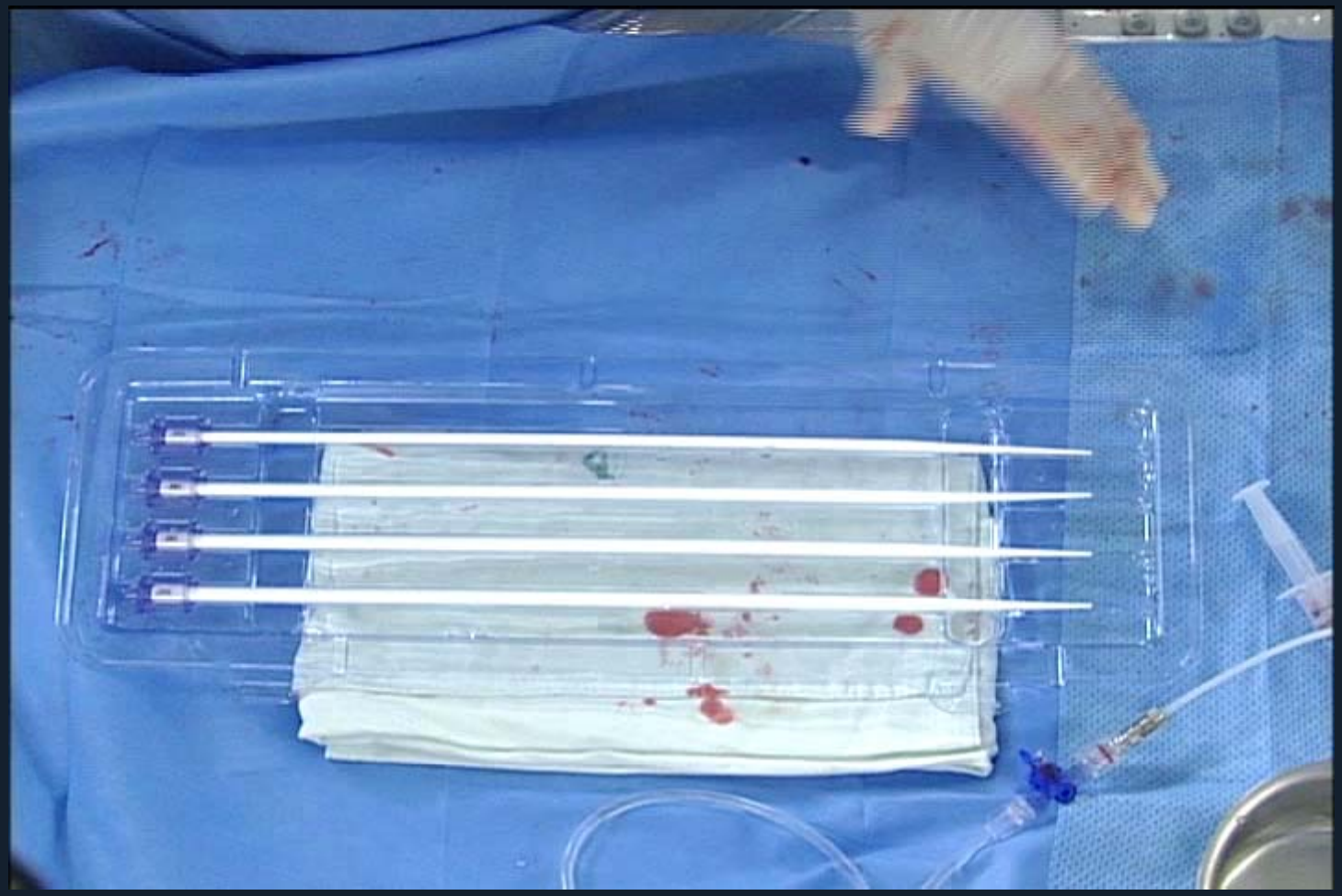
Three cusps in same plane

Pre-close (Proglide)

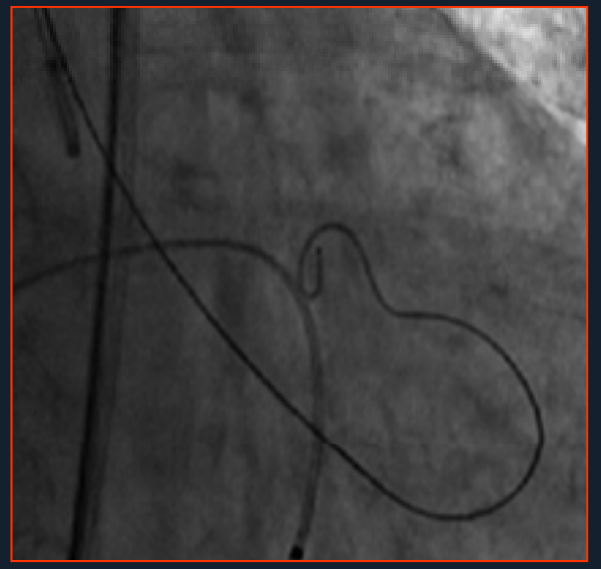




Dilation & Sheath Insertion

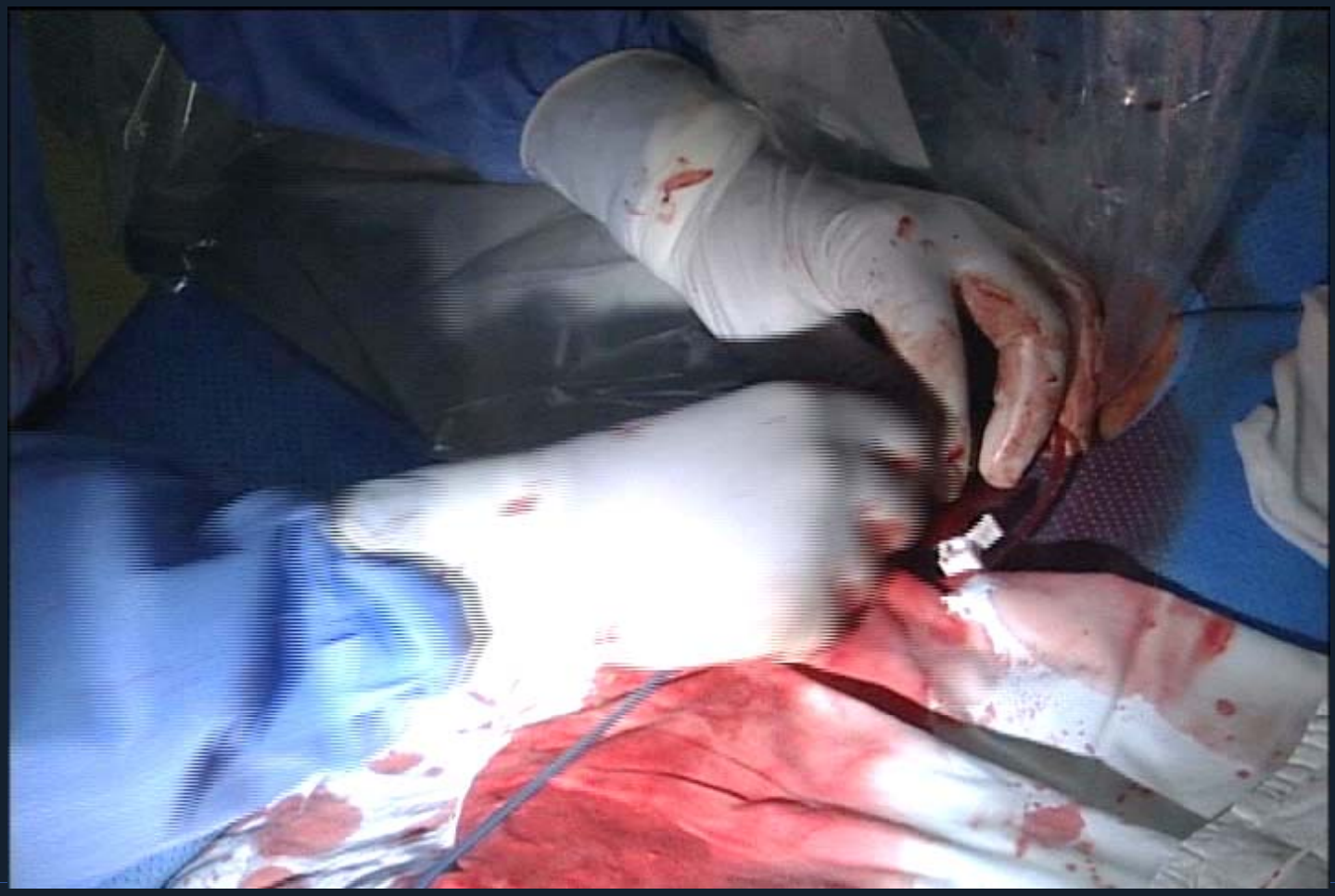


Crossing the Stenotic AV with Wire



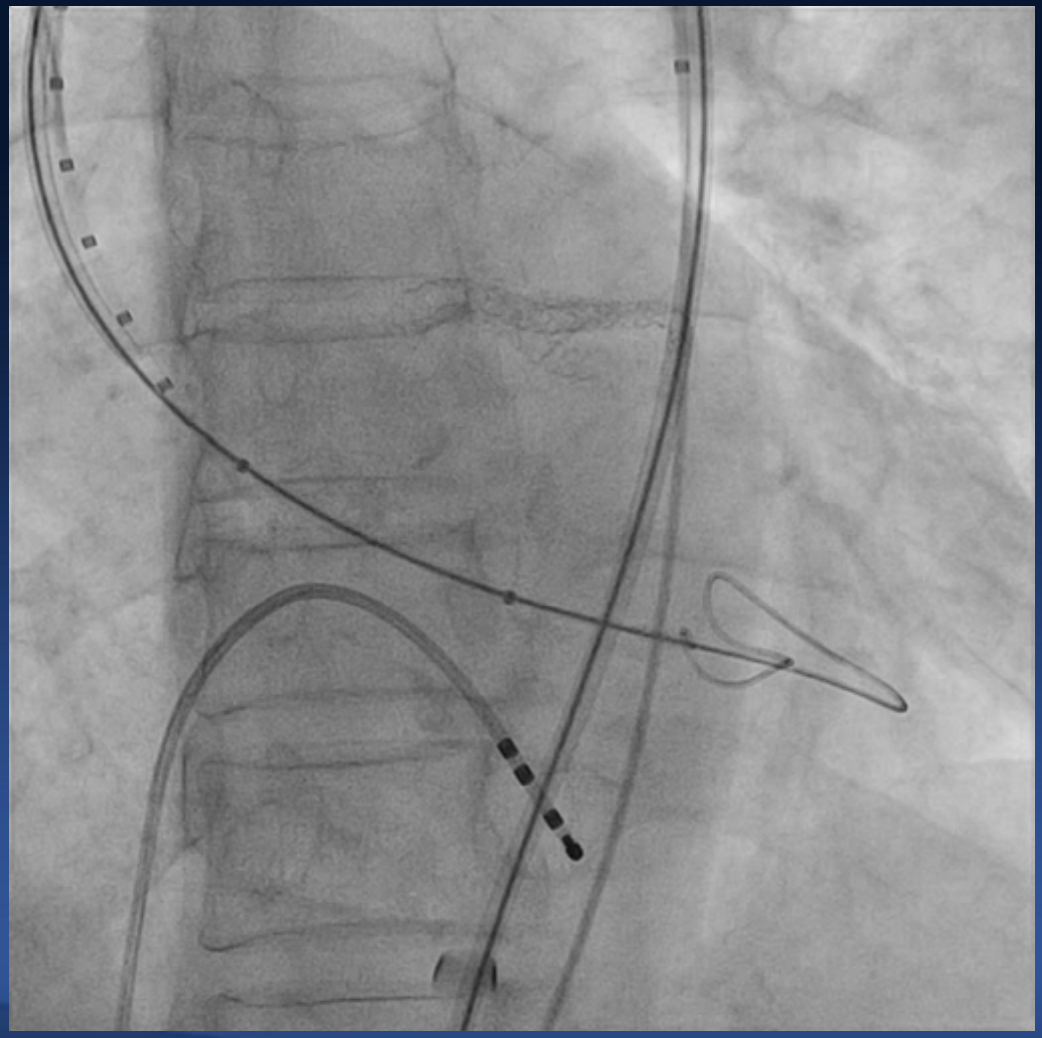
- AL I Diagnostic Catheter
- 035” Fixed Core Wire Straight - TSF (COOK)
- 035” Amplatrz Super Stiff Wire (Boston)
- Pigtail Catheter

Pre-dilatation Ballooning under rapid pacing



20 mm balloon

Pre-dilatation Ballooning under rapid pacing

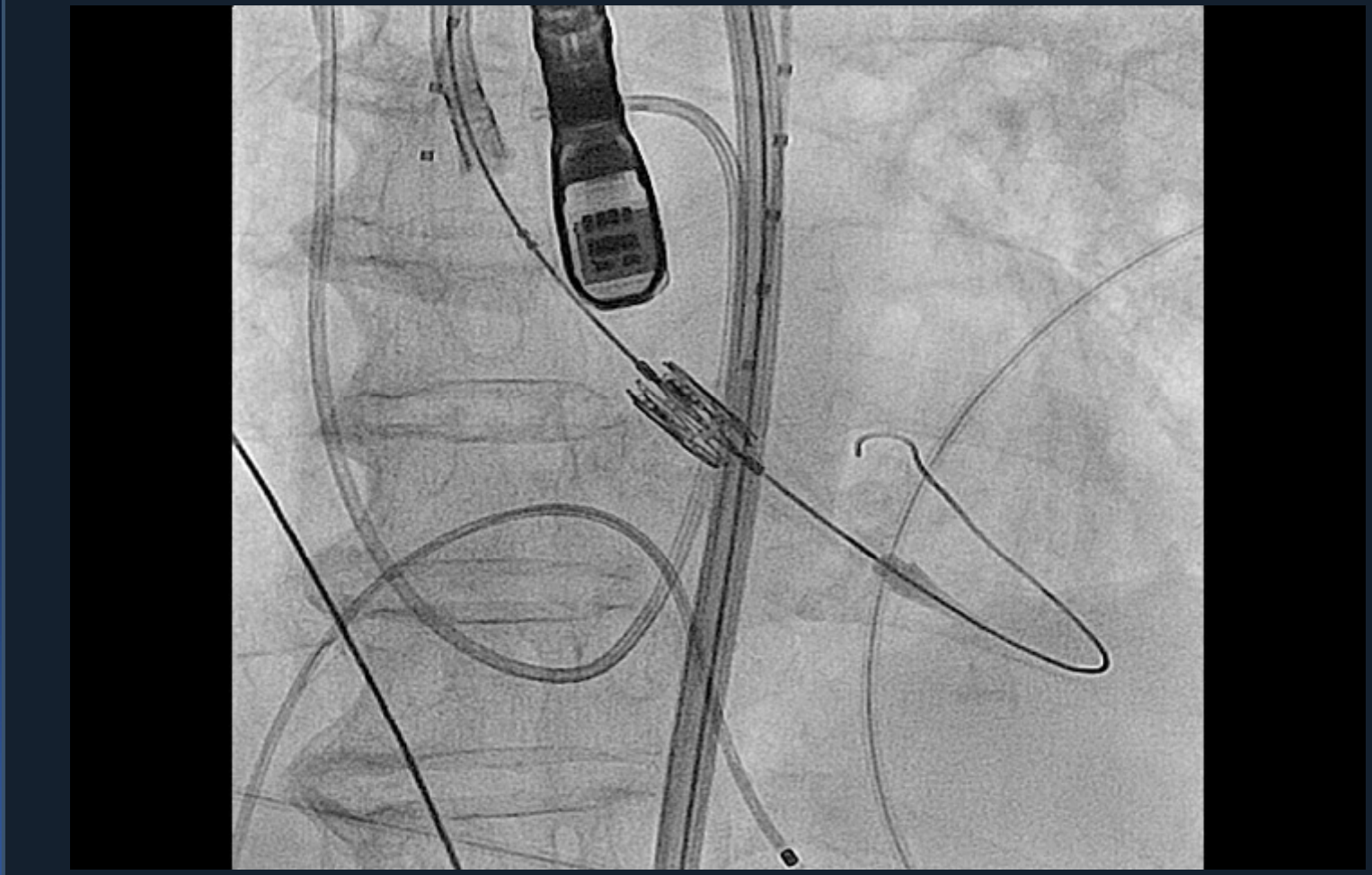


- Pacing On
- Balloon Inflation
- Contrast Injection
- Balloon Deflation
- Pacing Off

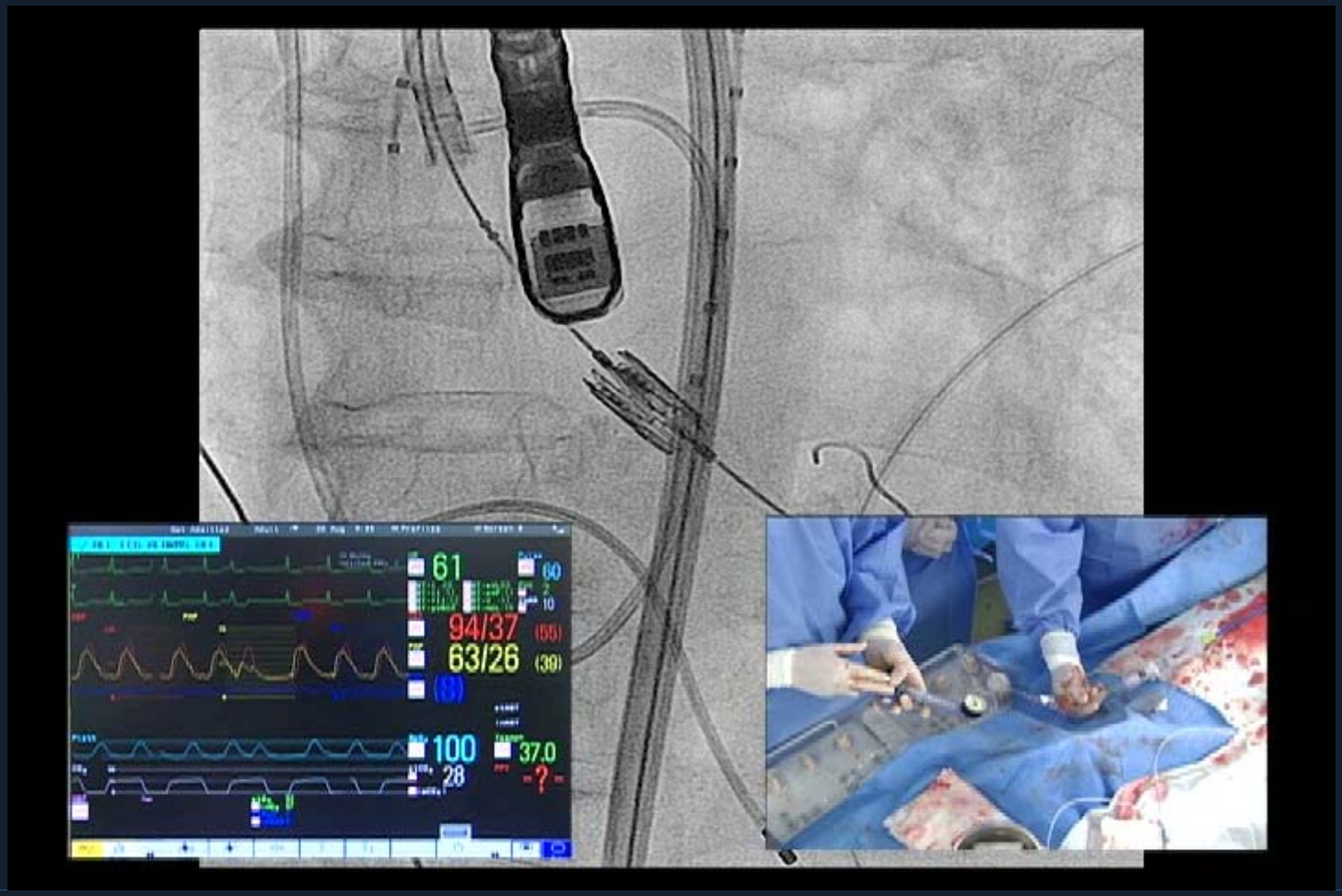
Valve Preparing & Mounting

Introduction of the Flex catheter and Edward Valve

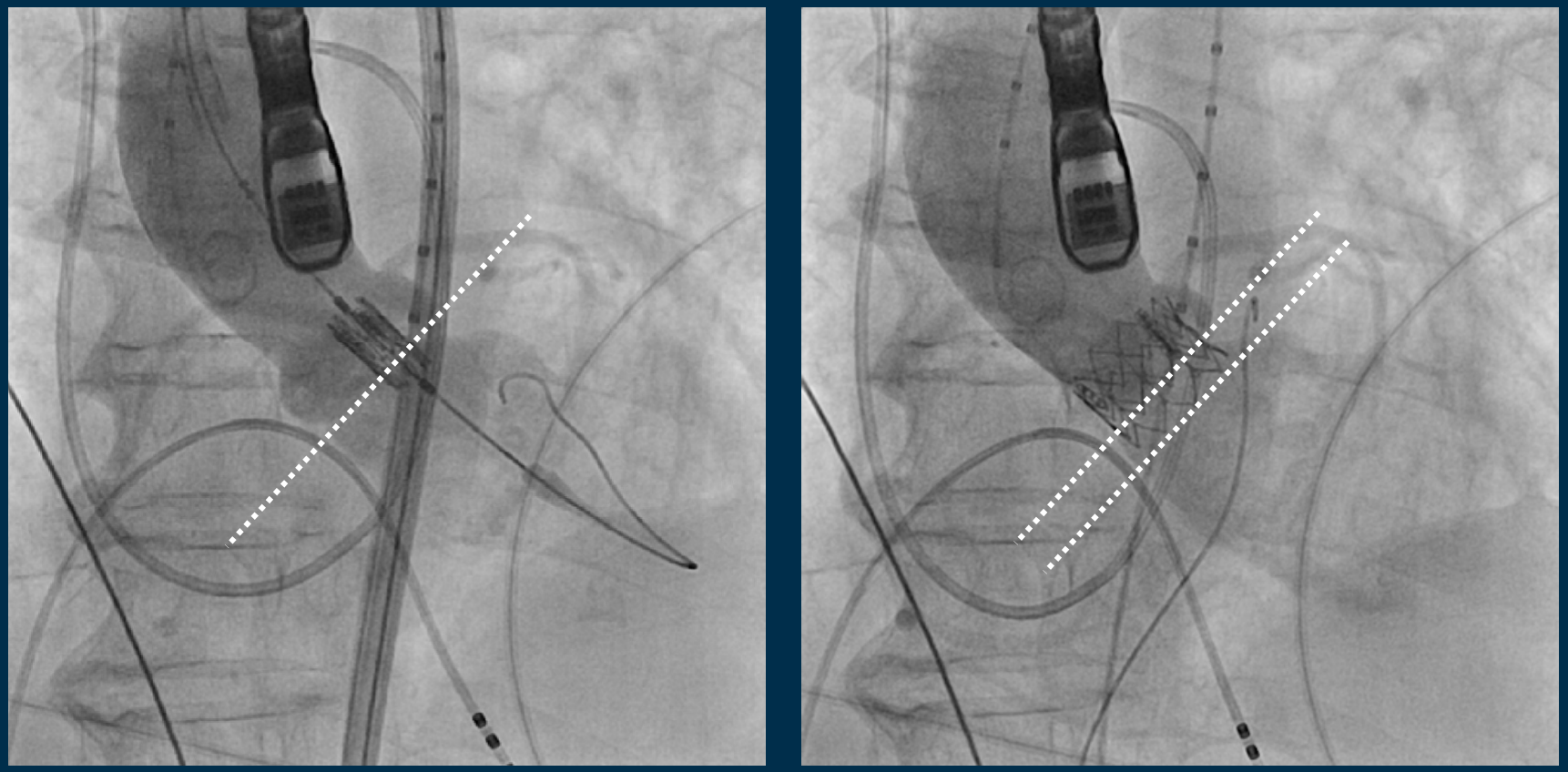
Valve Positioning



Deployment

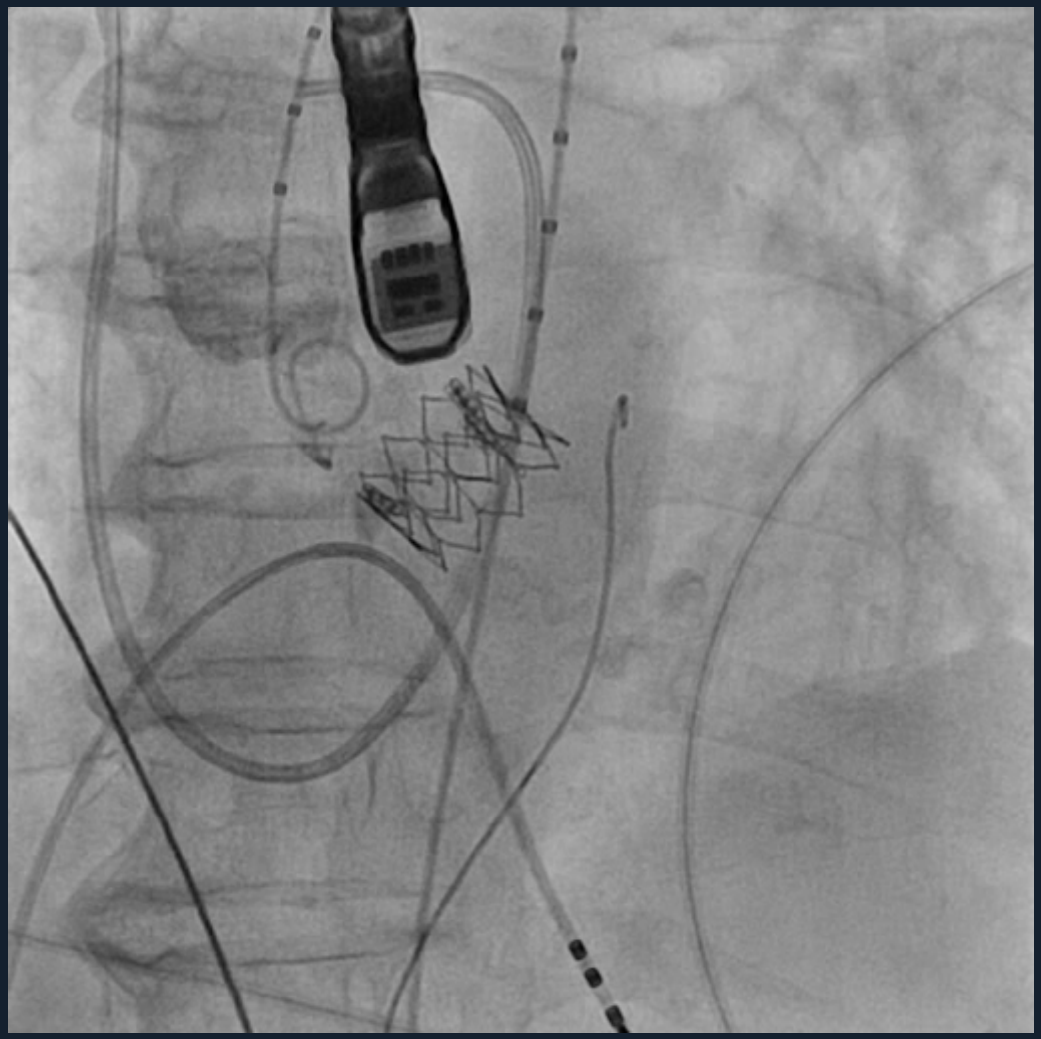


Deployment

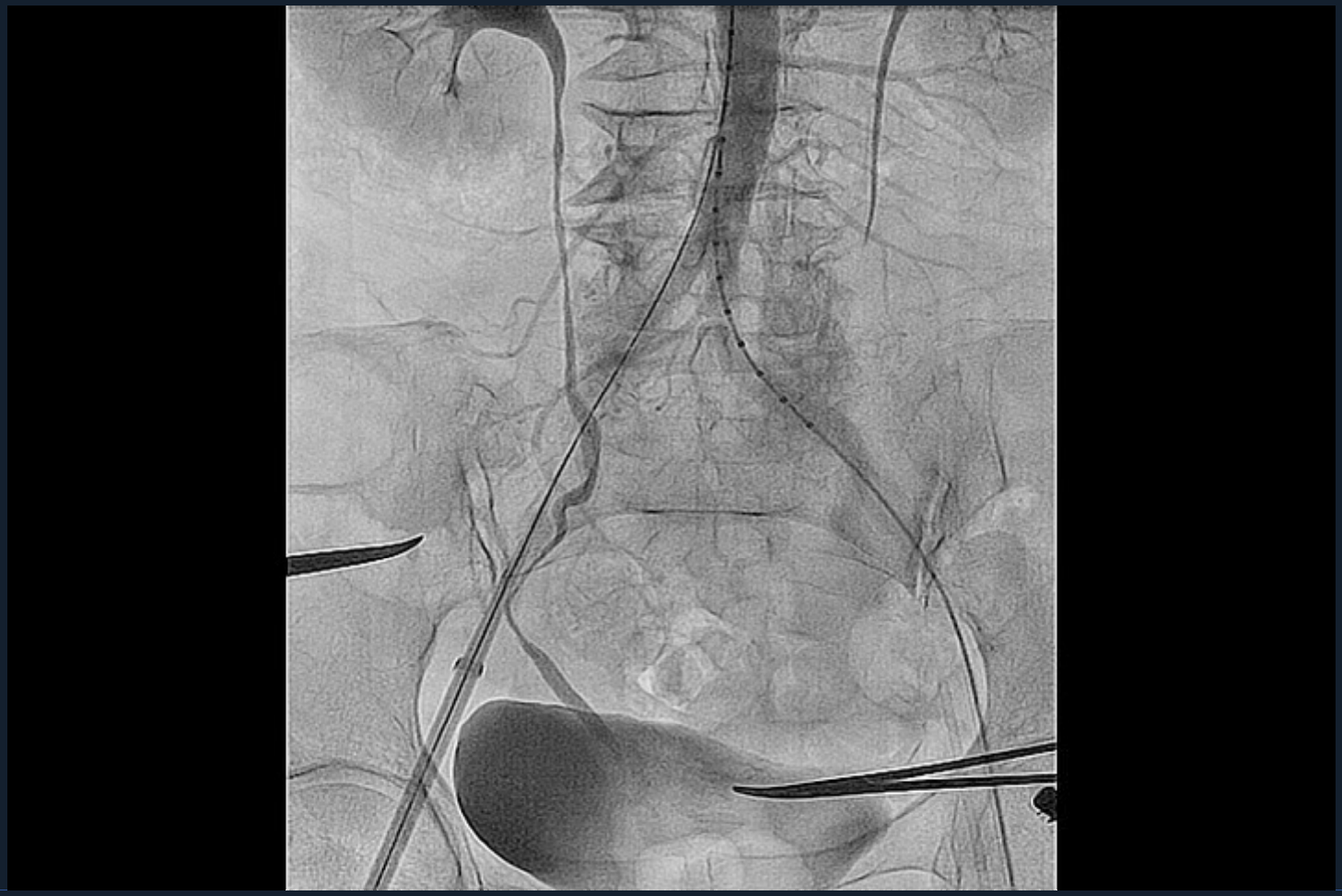


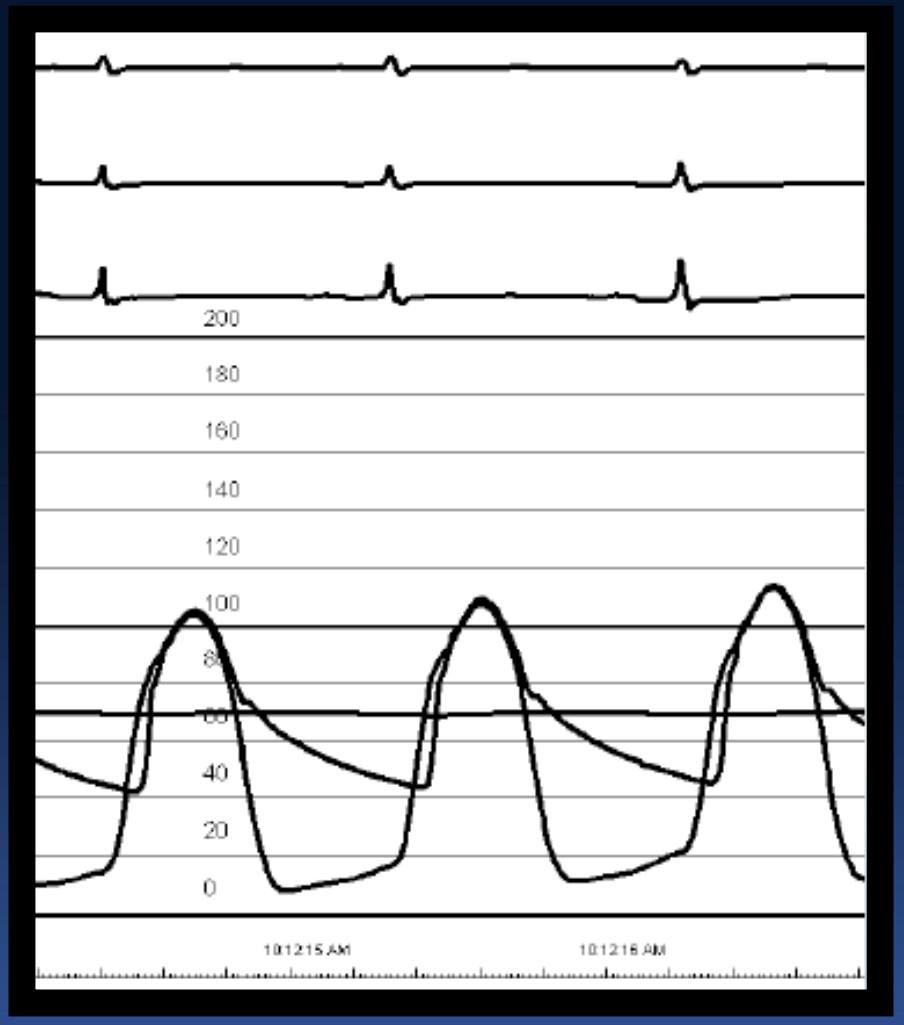
23mm Valve

Post Angiogram



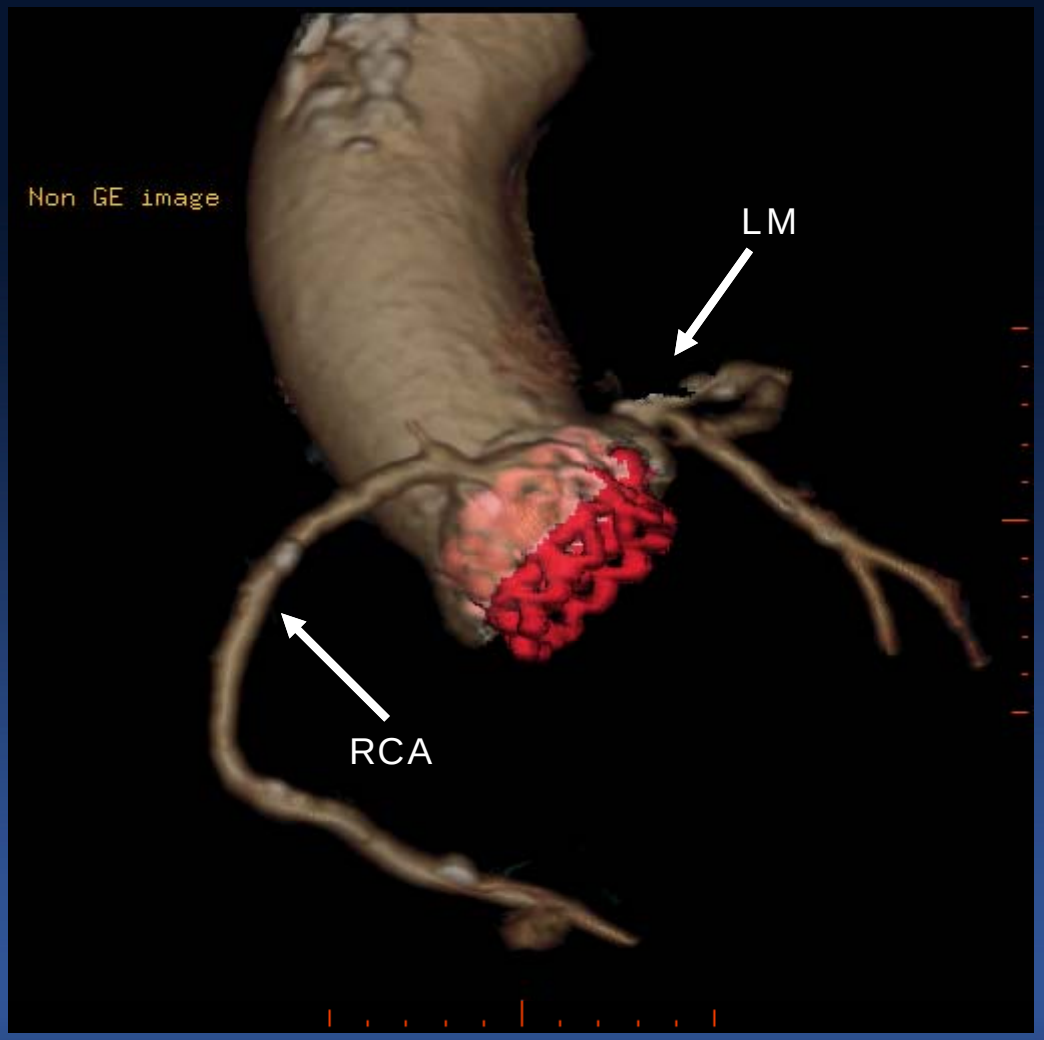
Sheath Removal



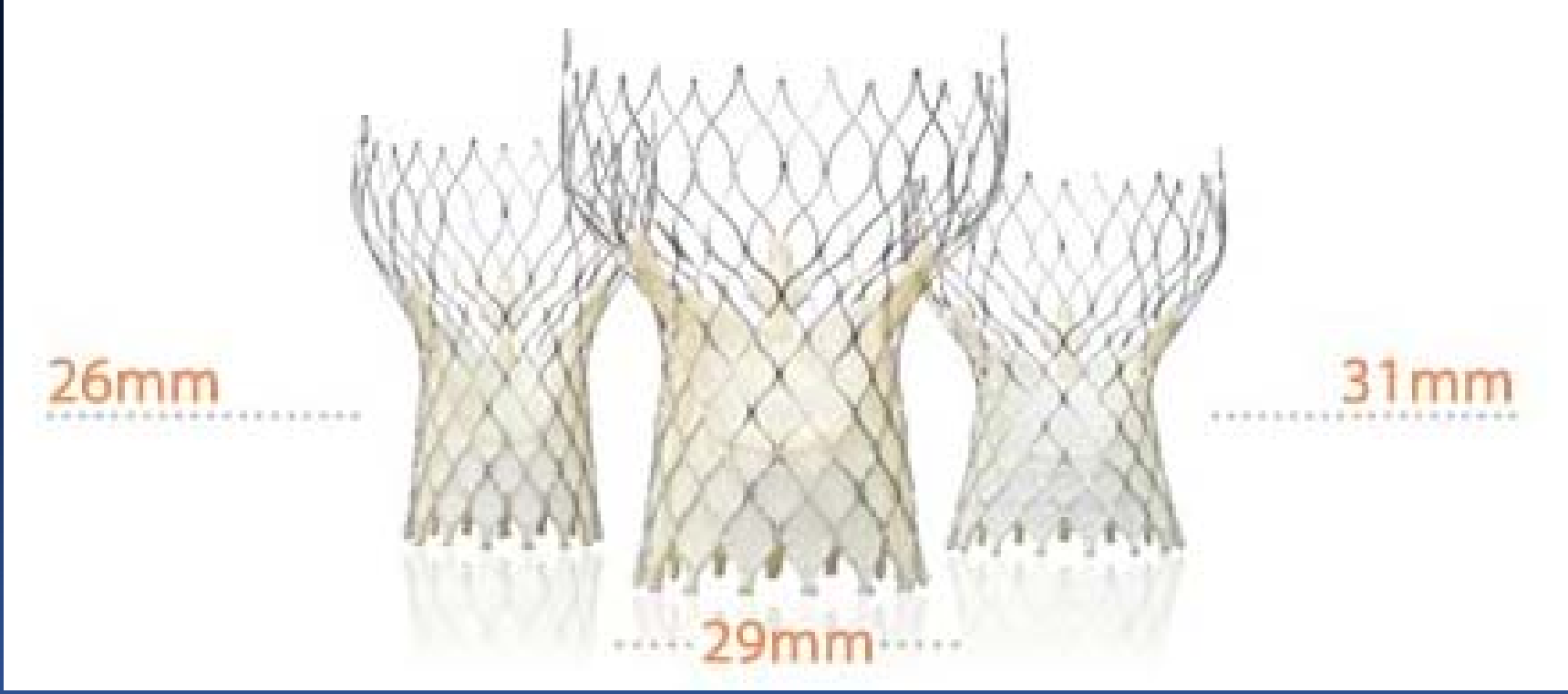


Post procedure gradient = 8 mmHg

Volume Rendered Image

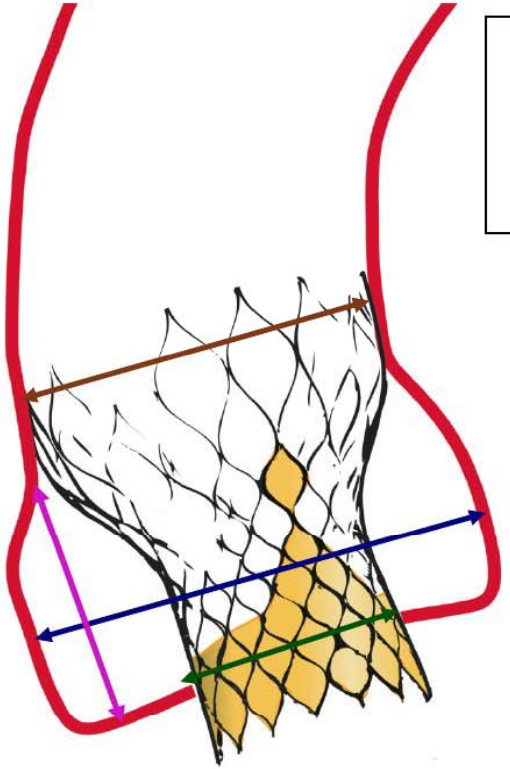


CoreValve Implantation



Medtronic CoreValve
Self Expanding

Selection of Prosthesis Size

26 mm Inflow Device "Small"		29 mm Inflow Device "Large"
δ 40 mm (Ascending Aorta)		δ 43 mm (Ascending Aorta)
ε 27 mm (Sinus of Valsalva)		ε 29 mm (Sinus of Valsalva)
20-23 mm (AV Annulus)	≥ 15 mm (Sinus of Valsalva)	23-27 mm (AV Annulus)

* Prosthesis not at scale

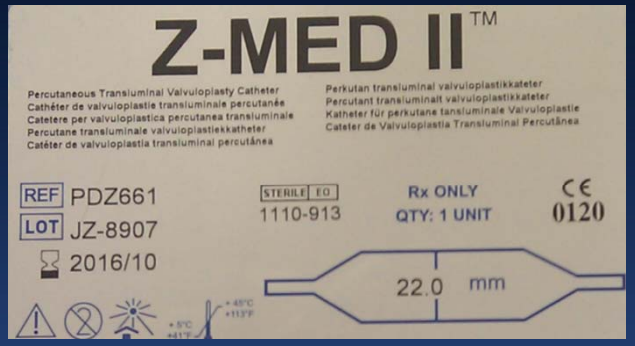
Medtronic CoreValve® System

Delivery Catheter

ULTIMUM EV 18Fr

(St. Jude)

Introducer Sheath



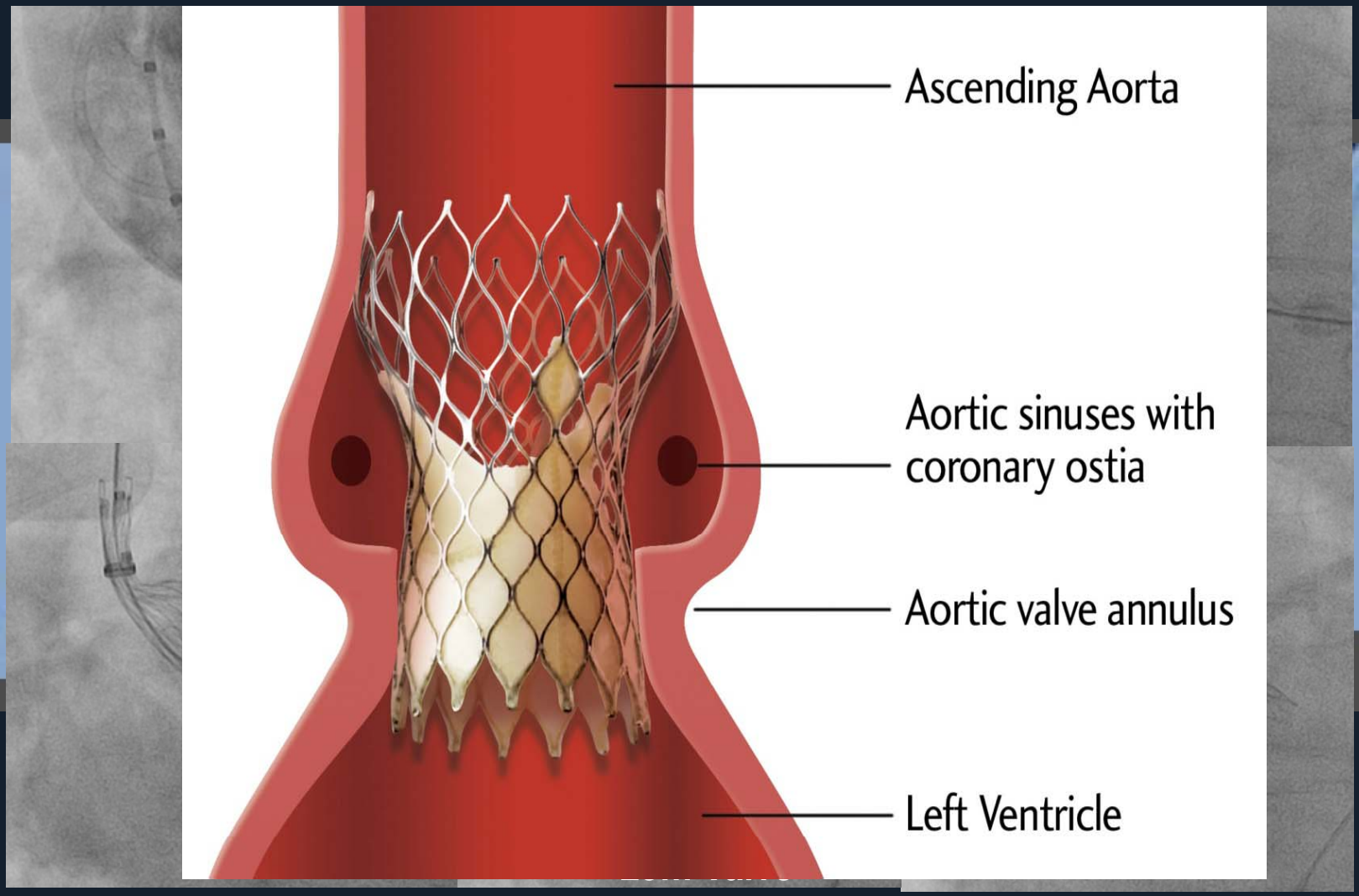
Z- MED II - NuMED

Pre-dilatation Balloon

AMPLATZ GOOSE NECK Snare Kit – ev3

Reposition Device

CoreValve Implantation



TAVI Complication

Procedure-Related Complications

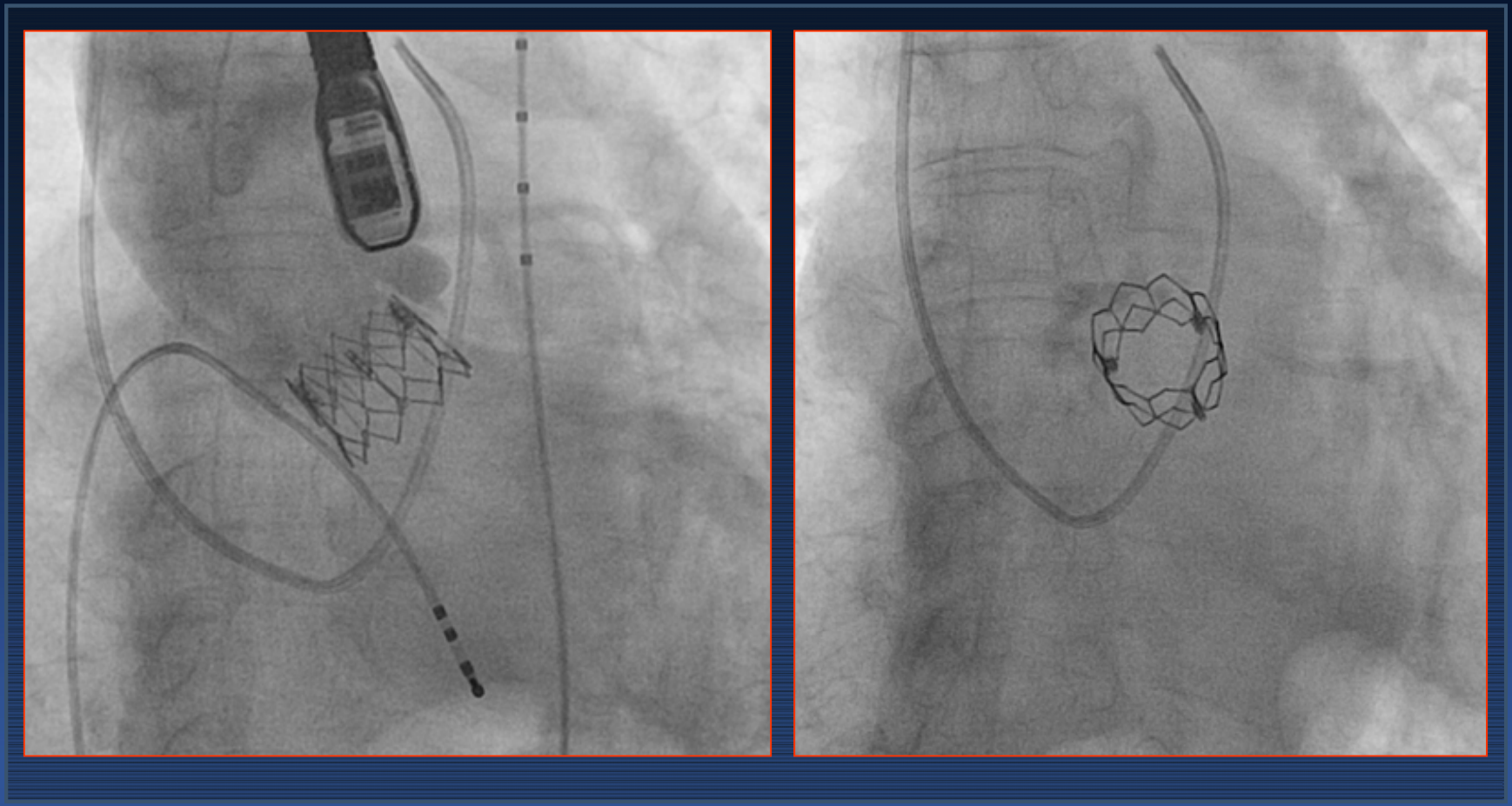
- Valve positioning events
- Peri-valvular aortic regurgitation
- Vascular complications
- Strokes
- Permanent pacemaker implantation
- Coronary obstruction
- VF or ischemia during rapid ventricular pacing
- Cardiac perforation (RV or LV)

Valve Embolization

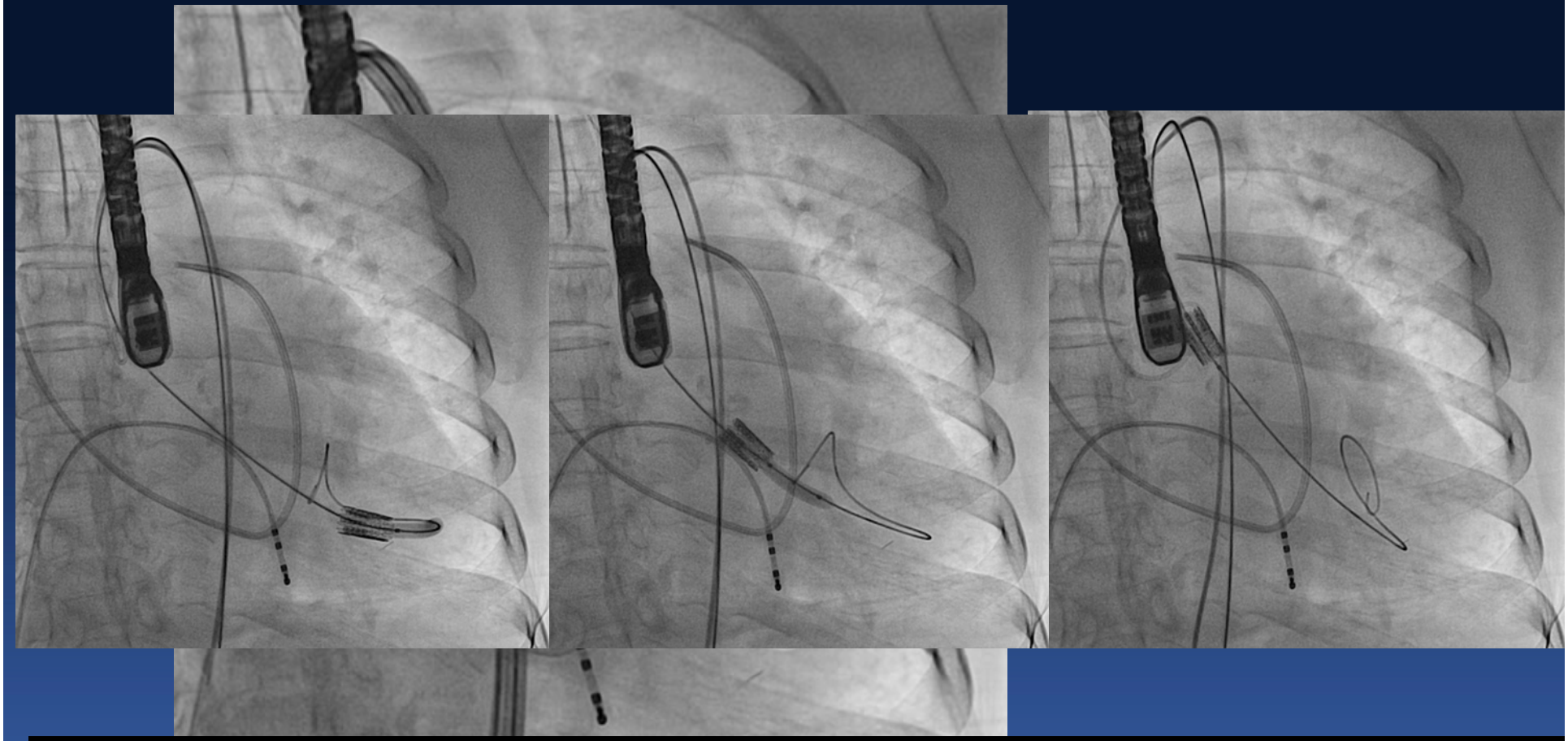
Possible Causes

- Valve positioned too high or too low
- Valve not inflated fully immediately : 3-5 seconds
- Pacing stopped prematurely : stop pacing after complete deflation
- Too aggressive pre-dilation & possible undersizing of valve (annulus too large)

Valve Embolization

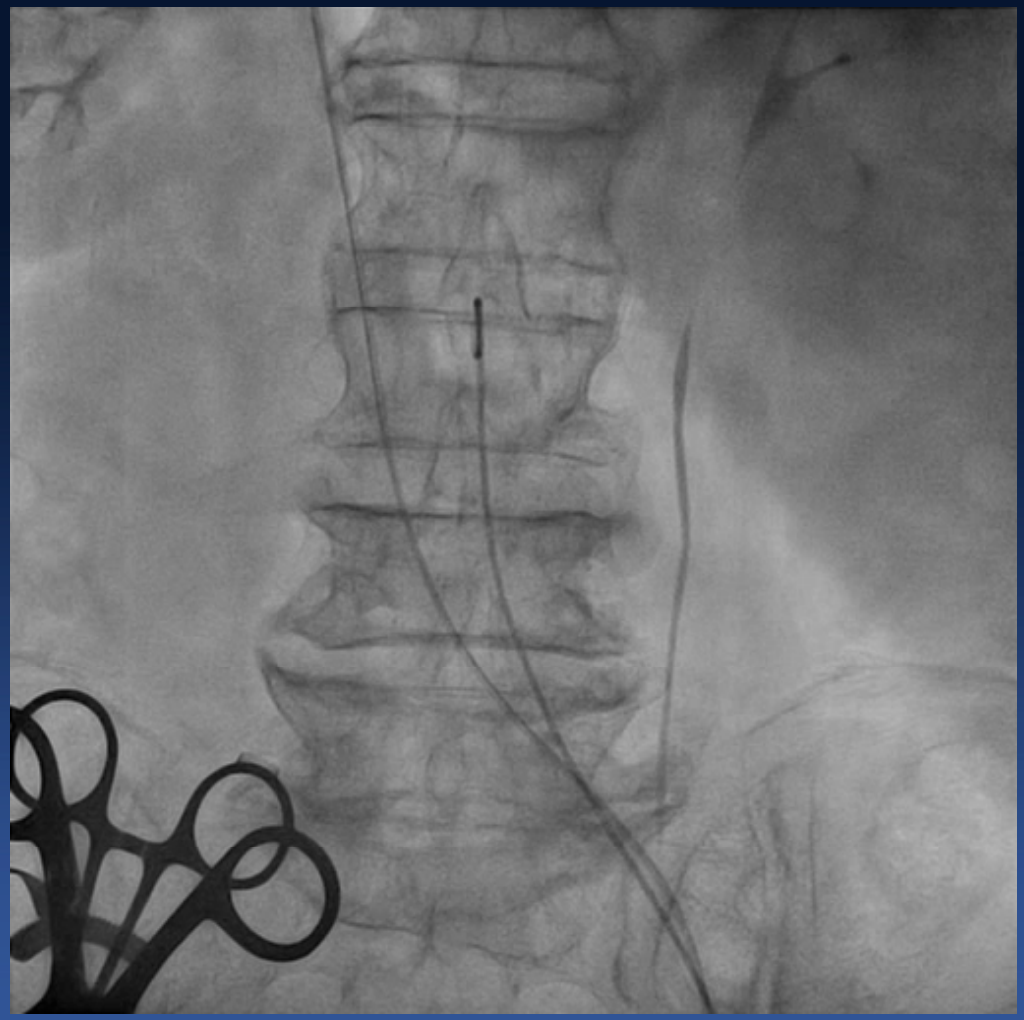


Stent Deployment, but..

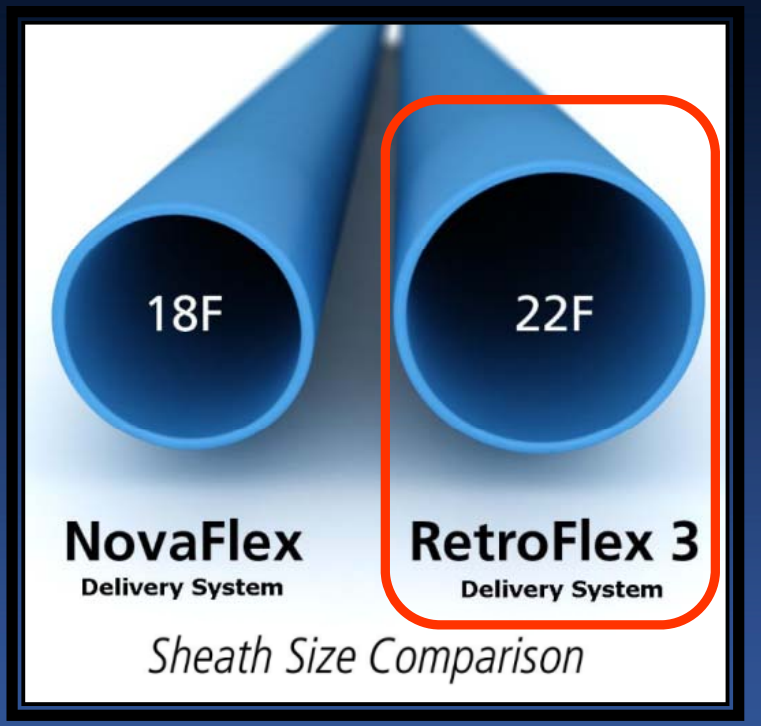


Using 5.0 X 20 mm balloon, the stent was re-positioned in the ascending aorta.

Vascular complications

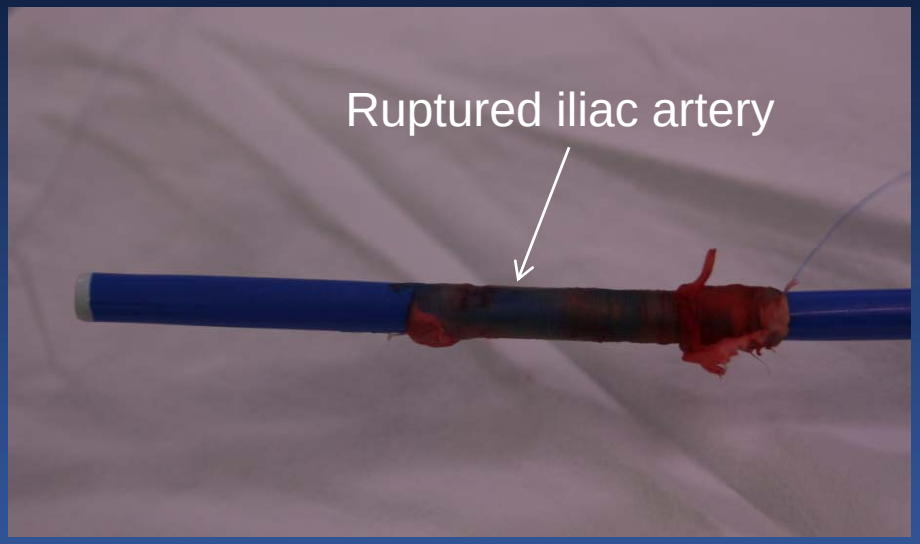


Iliac artery rupture

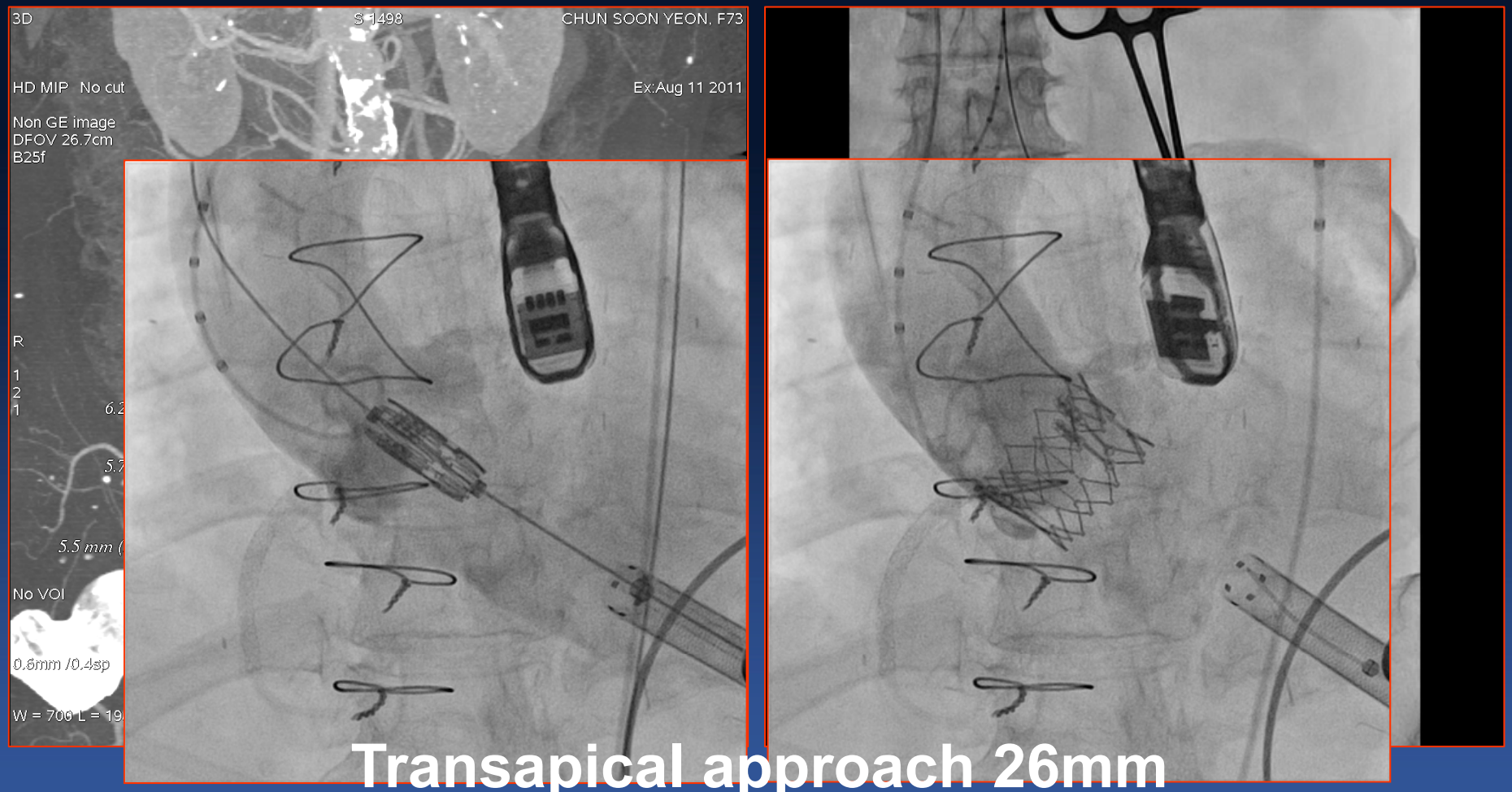


Vascular Operation

Common iliac artery ligation with Femoral-Femoral bypass graft surgery



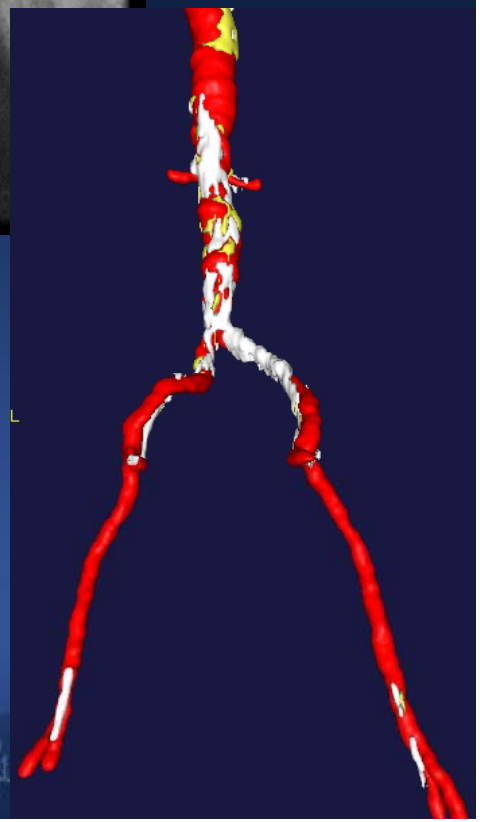
Transfemoral ➡ Transapical



Transapical approach 26mm

Indication of Transapical TAVI

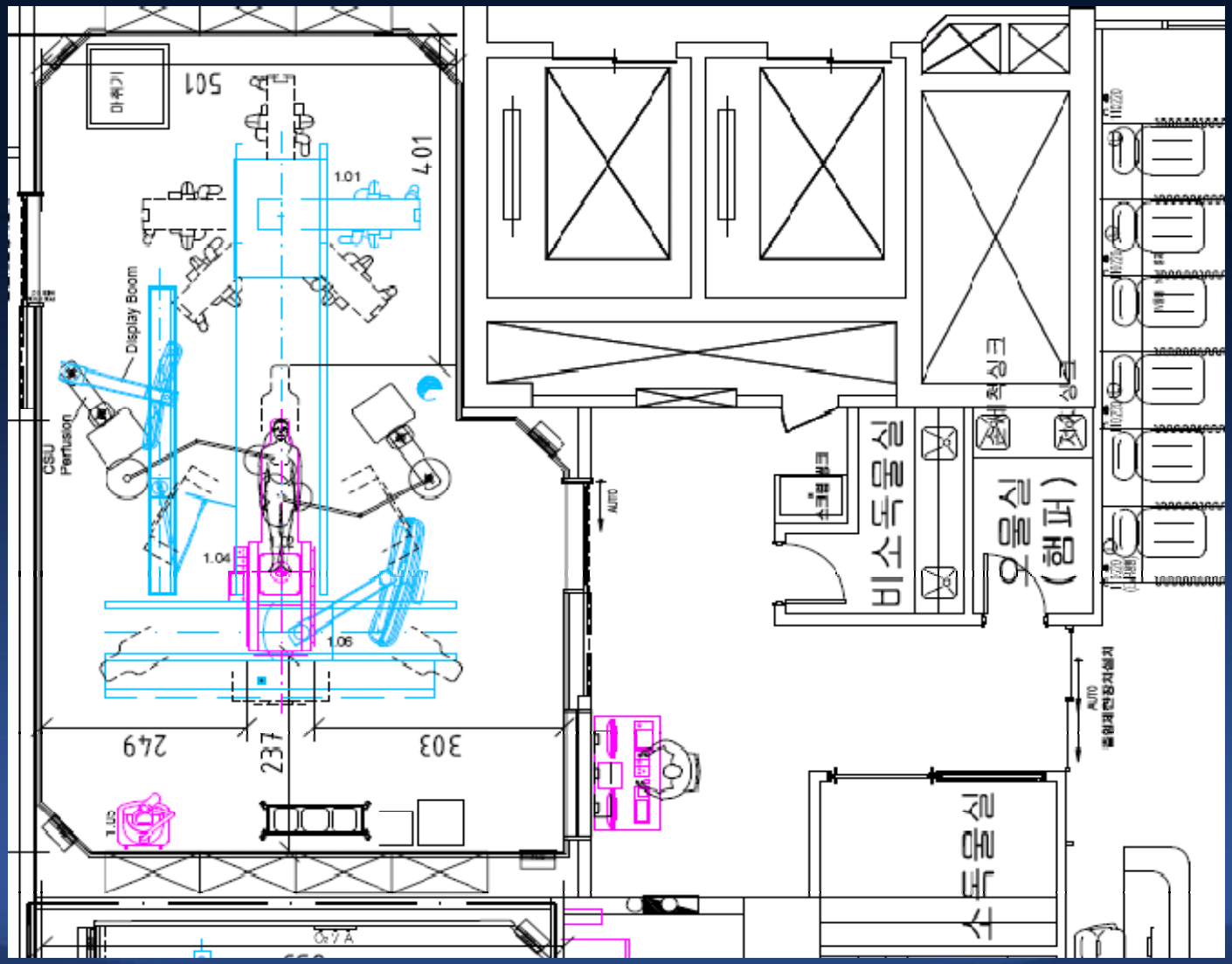
- Poor vascular access
- Aortic arch pathology
  - Bulky Atheroma
  - Porcelain Aorta
- Antegrade AV crossing difficulties
- TA approach currently restricted to patients not a candidate for a TF-TAVR



What we prepare?

Hybrid Room

Hybrid Room - AMC



Multidisciplinary TEAM Approach

Multidisciplinary TEAM

Operator
Interventional Cardiologist

Anaesthesia

The TEAM

Cardiothoracic Surgeon
Vascular Surgeon

Echo Cardiologist (TEE)

Cath lab Team (Nurse & Technician)

Mounting expert

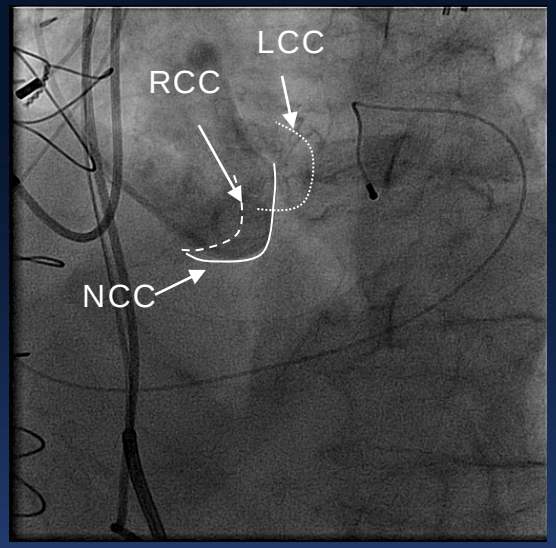
The TEAM

TAVI special assistant

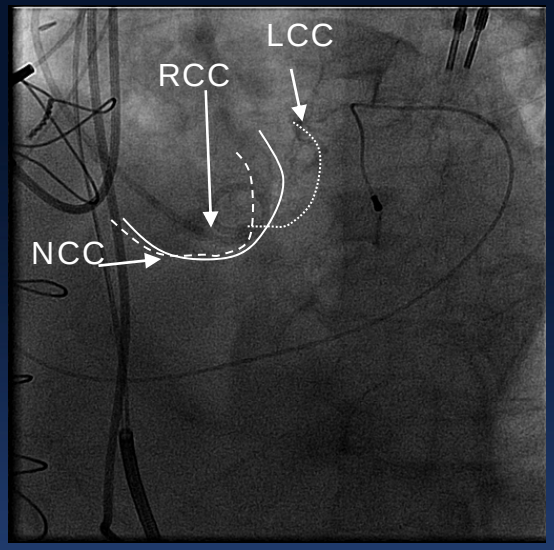
Contrast Injentor & Pacing

Selection of Fluoroscopic Projections

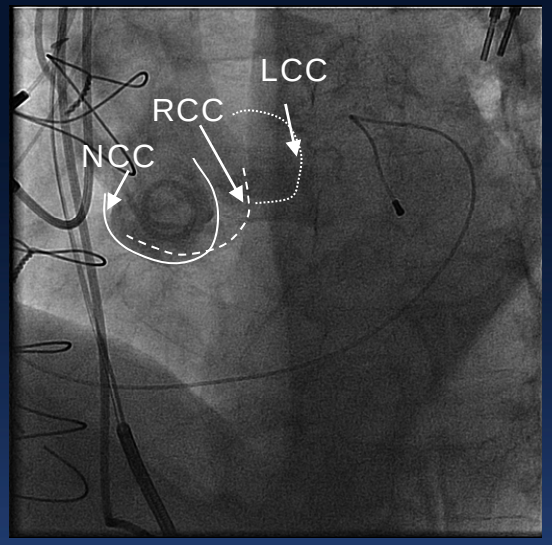
LAO 40 Cr 20

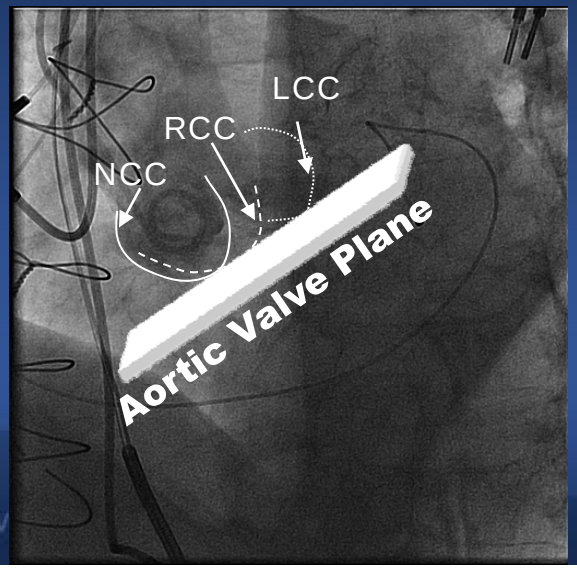


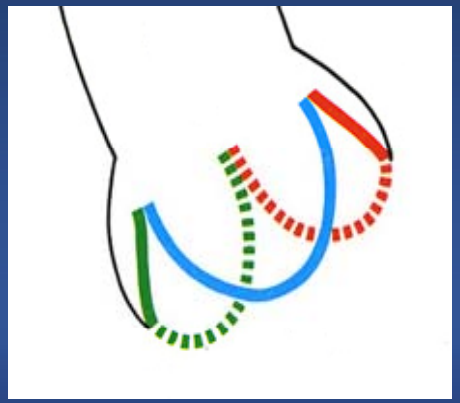
LAO 40 Cr 30

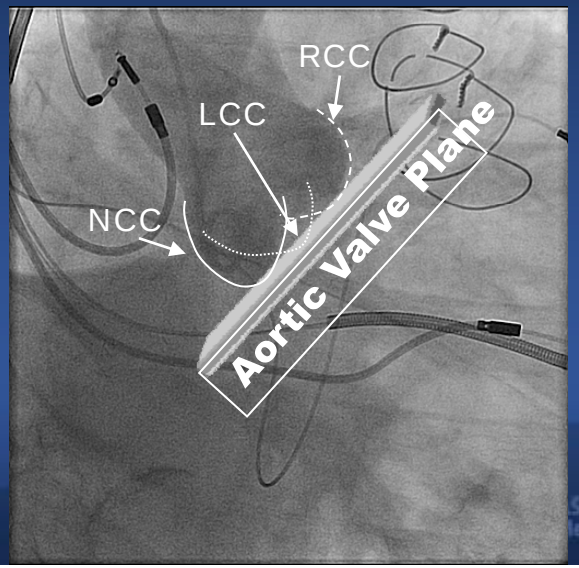


LAO 30 Cr 30

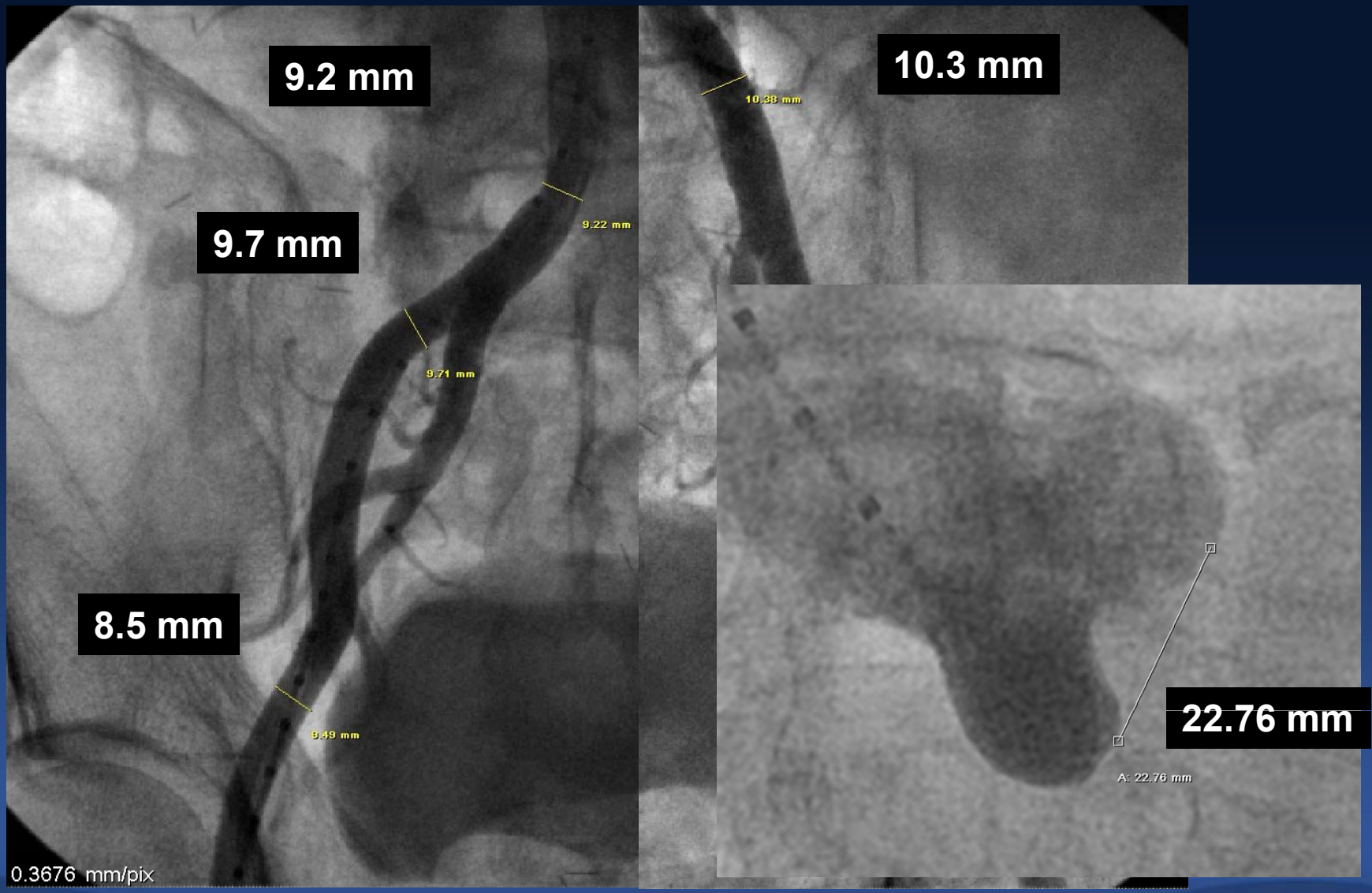




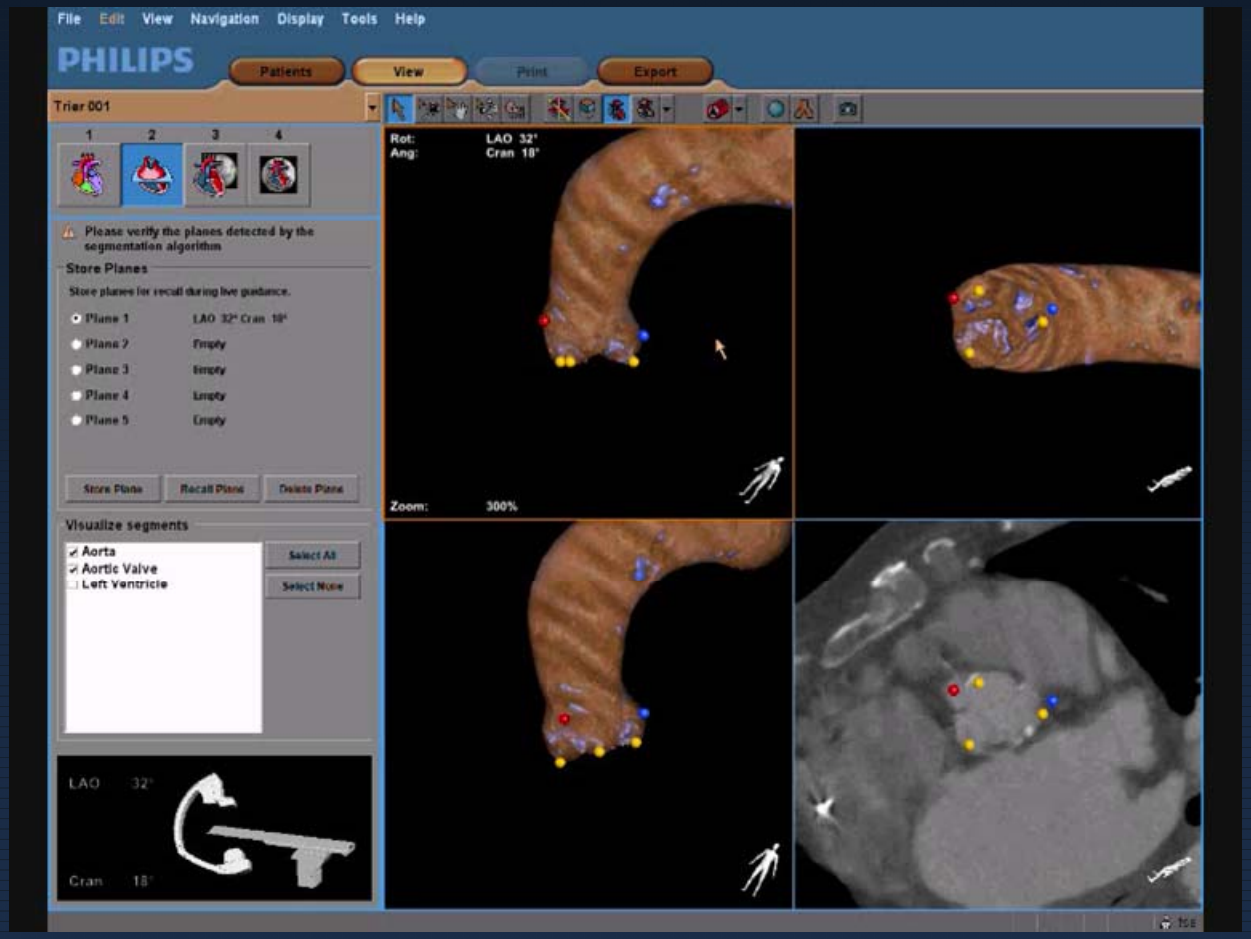




Measurement



Advanced Imaging Modalities



CTA

- ***Philips***
  3D Navigator
- ***Siemens***
  Dyna CT
- ***GE***
  Innova Vision


C-THV
Taieon
Session
Patient Explorer
View
Edit
Help
09/11/2009
11 08
THV
Post DPL Analysis
Patient Anonymous
ID xxxxxxxxx
RAO 10.5
CAUD 15.2
Run 4/4
Frame 130/179
LAO 34 CRAN 14
RAO 11 CAUD 15
RAO 10 CAUD 15
RAO 11 CAUD 15
4. Mark Inner Diameter
* Mark two points on valve's edges
Valve Diameters
Outer 24.1 mm
Minimal 22.8 mm
Inner 23.3 mm
15 fps
CardioVascular Research Found
UNIVERSITY OF ULSAN
COLLEGE MEDICINE
ASAN
Medical Center

Mechanical Tests

- **Excellent in-vitro durability exceeding 5 years**
  - Additional frame fatigue testing up to 15 years
  - Bovine Pericardial Tissue with ThermaFix™ anticalcification treatment
- **Hemodynamics comparable to surgical implanted valves**
  - Uniform leaflet coaptation
  - Large consistent EOA

Optimal function
at 200 million cycles (5 years)

Tested to full ISO 5840 and FDA Surgical Heart Valve Guidance

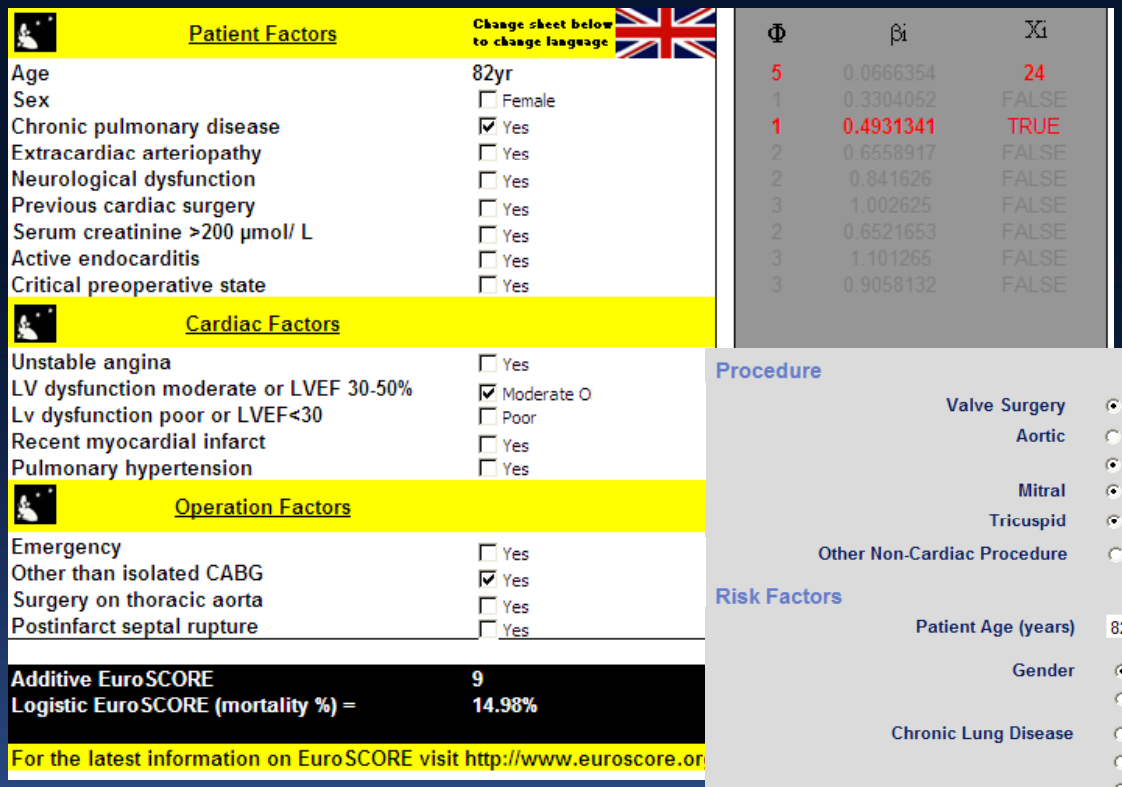
Aortic Valve Replacement

- **Class I**
  - Symptomatic severe AS
  - Severe AS undergoing CABG
  - Severe AS undergoing surgery on the aorta or other valves
  - Severe AS with LV systolic dysfunction (EF < 50%)
- **Class IIa**
  - Moderate AS undergoing CABG or surgery on the aorta or other valves

2006 ACC/AHA guideline; 2008 Focused Update

Bonnow et al, JACC 48 (3) 2006

EuroScore and STS Risk Score



Patient Factors	Change sheet below to change language
Age	82yr
Sex	☐ Female
Chronic pulmonary disease	☑ Yes
Extracardiac arteriopathy	☐ Yes
Neurological dysfunction	☐ Yes
Previous cardiac surgery	☐ Yes
Serum creatinine >200 µmol/ L	☐ Yes
Active endocarditis	☐ Yes
Critical preoperative state	☐ Yes
Cardiac Factors	
Unstable angina	☐ Yes
LV dysfunction moderate or LVEF 30-50%	☑ Moderate O
Lv dysfunction poor or LVEF<30	☐ Poor
Recent myocardial infarct	☐ Yes
Pulmonary hypertension	☐ Yes
Operation Factors	
Emergency	☐ Yes
Other than isolated CABG	☑ Yes
Surgery on thoracic aorta	☐ Yes
Postinfarct septal rupture	☐ Yes
Additive EuroSCORE	**9**
Logistic EuroSCORE (mortality %) =	**14.98%**

For the latest information on EuroSCORE visit http://www.euroscore.or

Φ	βi	Xi
5	0.0666354	24
1	0.3304052	FALSE
1	0.4931341	TRUE
2	0.6558917	FALSE
2	0.841626	FALSE
3	1.002625	FALSE
2	0.6521653	FALSE
3	1.101265	FALSE
3	0.9058132	FALSE

Logistic ES > 20
STS > 10

Procedure

Valve Surgery	◉ Yes ○ No ○ Missing
Aortic	○ No
	◉ Replacement
Mitral	◉ No
Tricuspid	◉ No
Other Non-Cardiac Procedure	○ Yes ◉ No ○ Missing

Risk Factors

Patient Age (years)	82
Gender	◉ Male
	○ Female
Chronic Lung Disease	○ No
	○ Mild
	◉ Moderate
	○ Severe

Previous CV Interventions

Previous Coronary Artery Bypass	○ Yes ◉ No ○ Missing
Previous Valve	○ Yes ◉ No ○ Missing

Preoperative Cardiac Status

Myocardial Infarction	○ Yes
	◉ No
Cardiac Presentation on Admission	○ No Symptoms or Angina
	○ Symptoms Unlikely to be Ischemia
	◉ Stable Angina
	○ Unstable Angina

Calculations

Procedure Name	Isolated AVRepl
Risk of Mortality	15.0%
Morbidity or Mortality	58.8%
Long Length of Stay	35.6%
Short Length of Stay	7.4%
Permanent Stroke	4.9%
Prolonged Ventilation	39.0%
DSW Infection	0.4%
Renal Failure	37.0%
Reoperation	20.8%

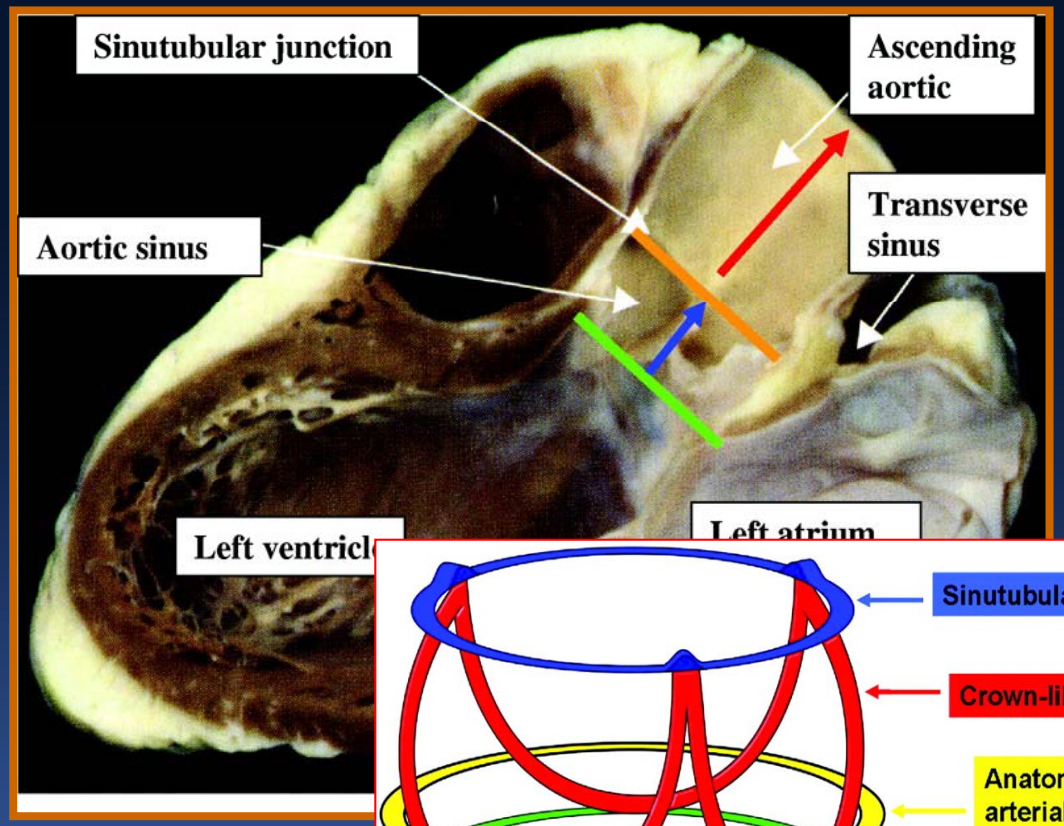
Available at: http://209.220.160.181/STSWebRiskCalc261. (Google: STS Risk Score)

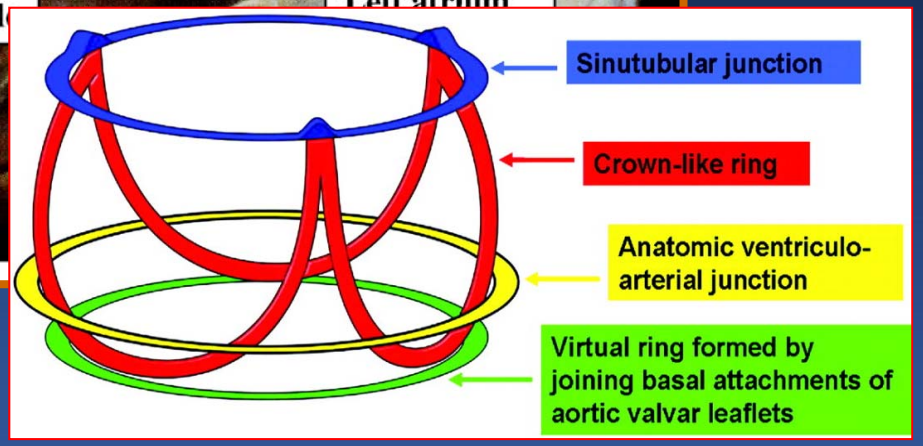
CardioVascular Research Foundation

UNIVERSITY OF ULSAN COLLEGE MEDICINE

ASAN Medical Center

Anatomy of Aortic Valvar Complex





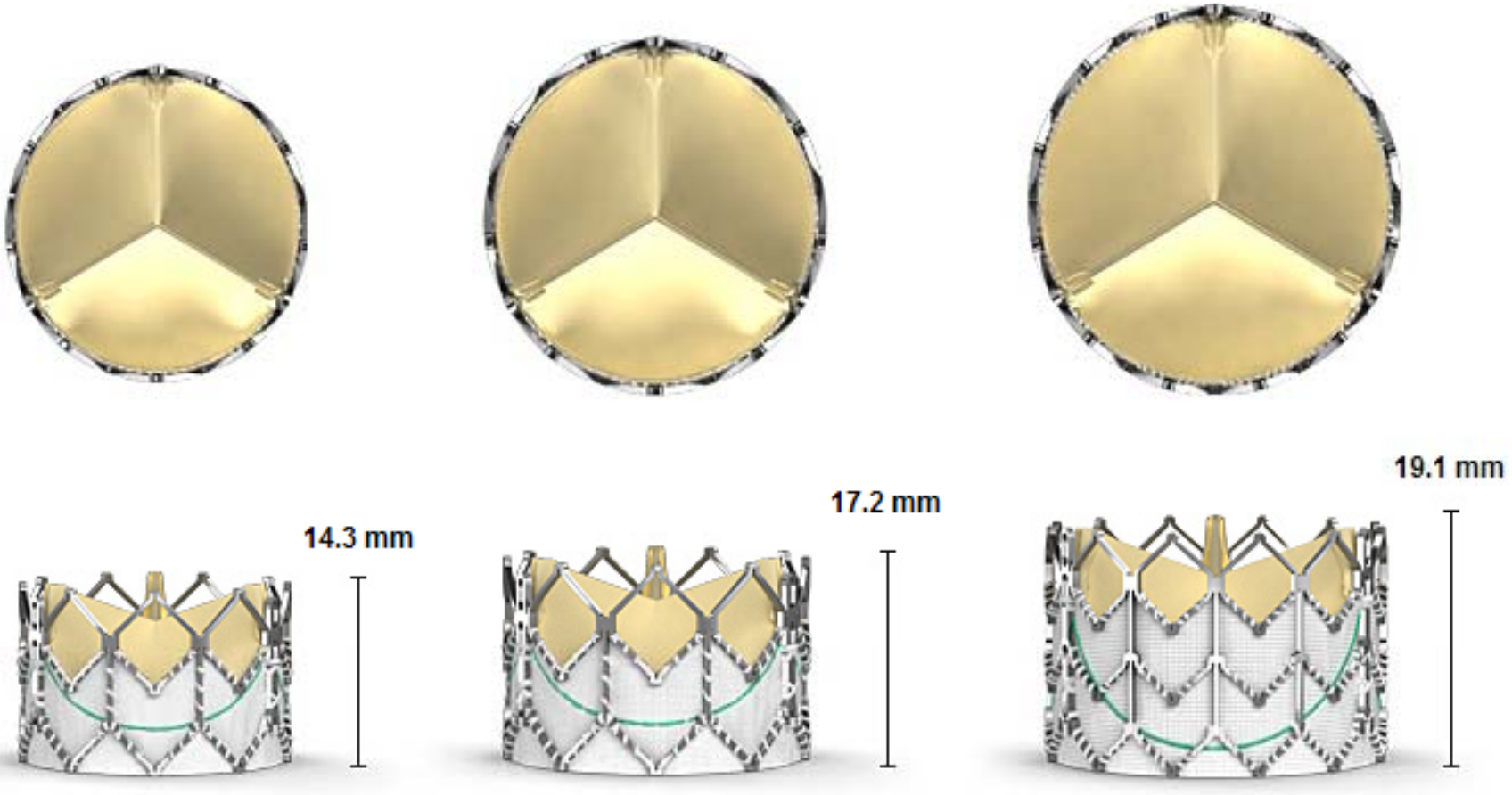
Stability of valve probably determined by the "virtual ring"

Aortic Root thus composed of 3 rings and one crown-like ring

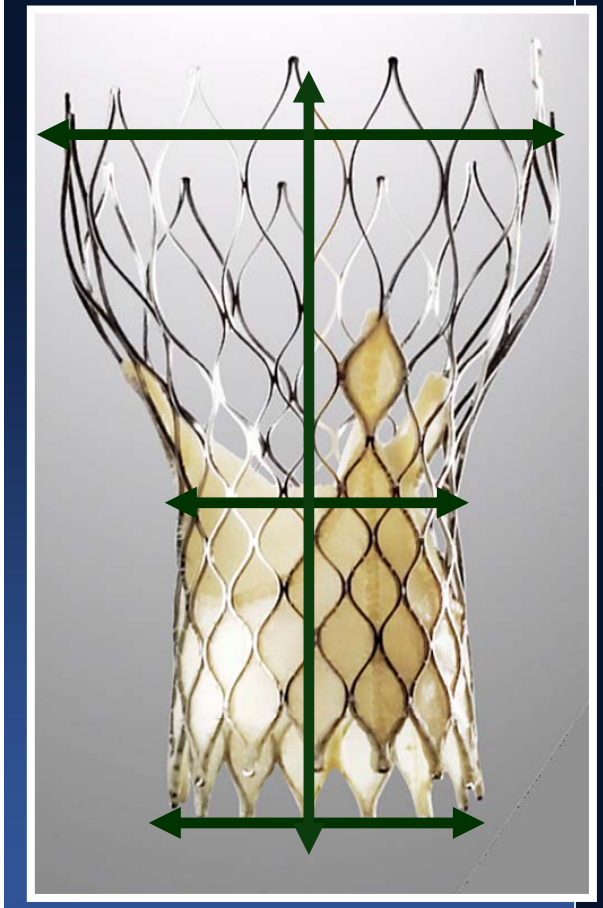
Piazza, N. et al. Circ Cardiovasc Intervent 2008;1:74-81

Edwards SAPIEN XT THV

23mm **26mm** **29mm (Trans-apical)**

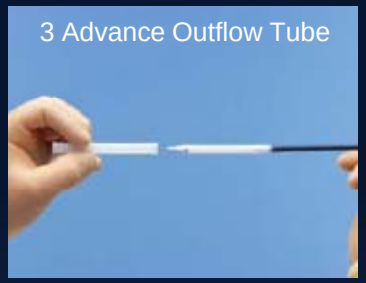


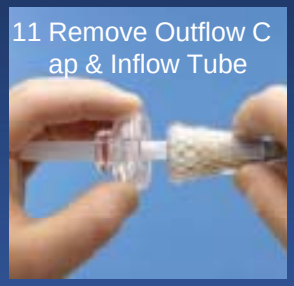
CoreValve Bioprosthesis: From July 2011
3 sizes: 26mm, 29mm and 31mm

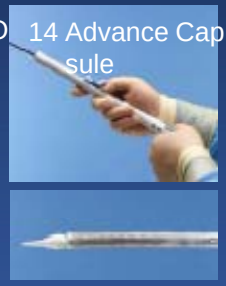


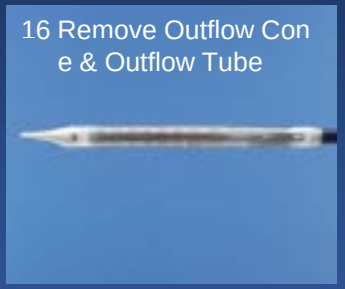
	"Smaller" 20-23mm	"Larger" 23-27mm	"X-Large" 26-29mm
Height	55 mm	53 mm	52mm
Outflow	40 mm	43 mm	43mm
Constrained	22 mm	24 mm	24mm
Inflow	26 mm	29mm	31mm
Access	18 F	18F	18F

Loading Procedure



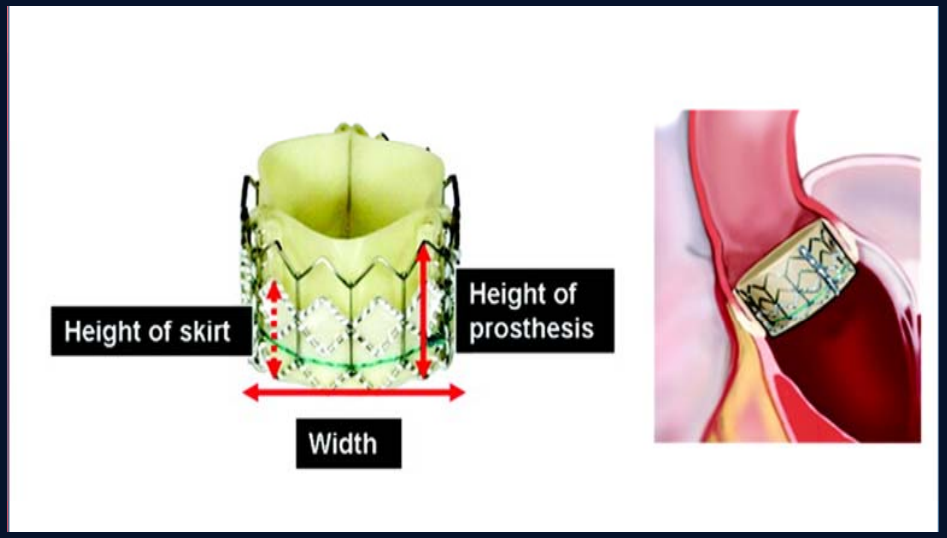


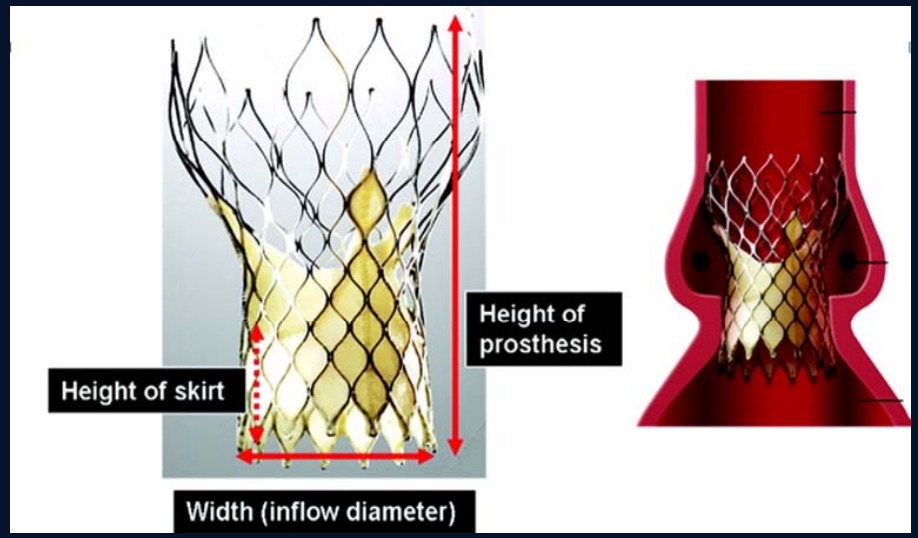




Dimension of the Prostheses

	Width	Hight	For annulus diameter	Height of skirt
Edward SAPIEN XT™	23mm	14.3mm	18-22mm	10.1/7.74mm
	26mm	17.2mm	21-25mm	11.4/8.67mm
CoreValve Revalving™	26mm	55mm	20-23mm	12mm
	29mm	53mm	23-27mm	12mm





Edwards Sapien Indications

EDWARDS SAPIEN Valve

- AVA < 0.8cm^2
- Logistic Euroscore > 20%
  STS > 10%

EDWARDS SAPIEN XT Valve

- AVA < 1.0cm^2
- Estimate operative/procedural mortality risk ≥ 15% (predicted by Cardiologist and surgeon)

ANNULUS BY TEE

18 to 22mm -> 23mm SAPIEN

21 to 25mm -> 26mm SAPIEN

FEMORO-ILIAC AXES

(without calcification/tortuosity)

Min 6.0mm -> 23mm SAPIEN

Min 6.5mm -> 26mm SAPIEN

Edwards Sapien Contraindications

- Other than calcified degenerative AS
- Intracardiac mass, thrombus or vegetation
- Untreated clinically significant CAD
- Ejection fraction < 20%
- Unstable angina during index procedure
- AMI within 1 month
- Cerebrovascular accident
- Unable to tolerate anticoagulation therapy
- HOCM with or without obstruction
- Mitral bioprosthesis
- Recent pulmonary emboli
- Severe chest deformities
- Bilateral iliofemoral bypasses

CoreValve Indications (CE)

Morphological Criteria (Mandatory)	**Native Aortic Valve Disease** **Severe AS: AVAI ≤ 0.6 cm^2/m^2** **27mm ≥ AV annulus diameter ≥ 20mm** **Sino-tubular Junction ≤ 43mm**
Clinical Criteria	**Logistic EuroSCORE ≥15% (18F)** **Or Age ≥ 75 y (18F)** **Or Age ≥65 y plus 1+ of the following:** **- Liver cirrhosis (Child A or B)** **- Cachexia** **- Pulmonary disease: FEV1<1L** **- Previous cardiac surgery** **- Recurrent P.E's** **- PHT (PAP>60mmHg)** **- RV failure** **- Hostile thorax (radiation, burns,etc)** **- Severe connective tissue disease**

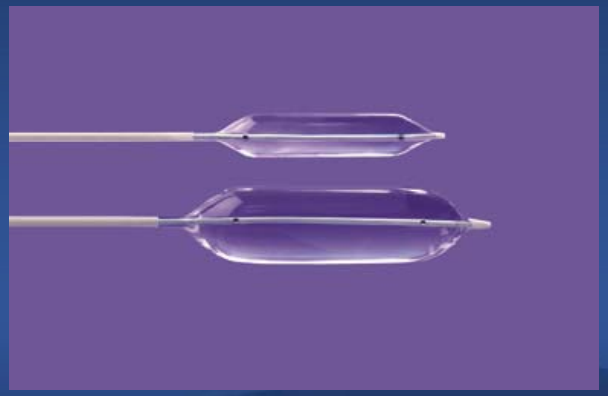
Vascular Access: Recommended Equipment

- 9 Fr hemostatic vessel introducer sheath
- Standard 0.035” x 260 cm guidewire (j-tip)
- Prostar® XL 10 Percutaneous Vascular Surgical (PVS) System
- Amplatz Super Stiff™ 0.035” x 260 cm (6 cm tip) guidewire (shaped with a pigtail loop)
- Ultimum™ EV 18 Fr (x 30cm) hemostatic vessel introducer sheath (St Jude Medical reference # 407689)
- Cook 18 Fr Introducer Sheath

Balloon Valvuloplasty

- Balloon catheter selection
  - 5 to 6 cm length
  - 20, 22, 25 mm balloon diameters
- Proctor choice -
  - Nucleus (Dog-bone feature - helps stablize position)
  - Other options: Z-med II, Tyshak II (low atmoshere balloon)
- Rapid pacing of right ventricle ~ 150 – 200 beats per minute
  (systolic pressure < 60 mmHg)

Note: Corevalve prosthesis should be loaded and ready for implant at time of BAV



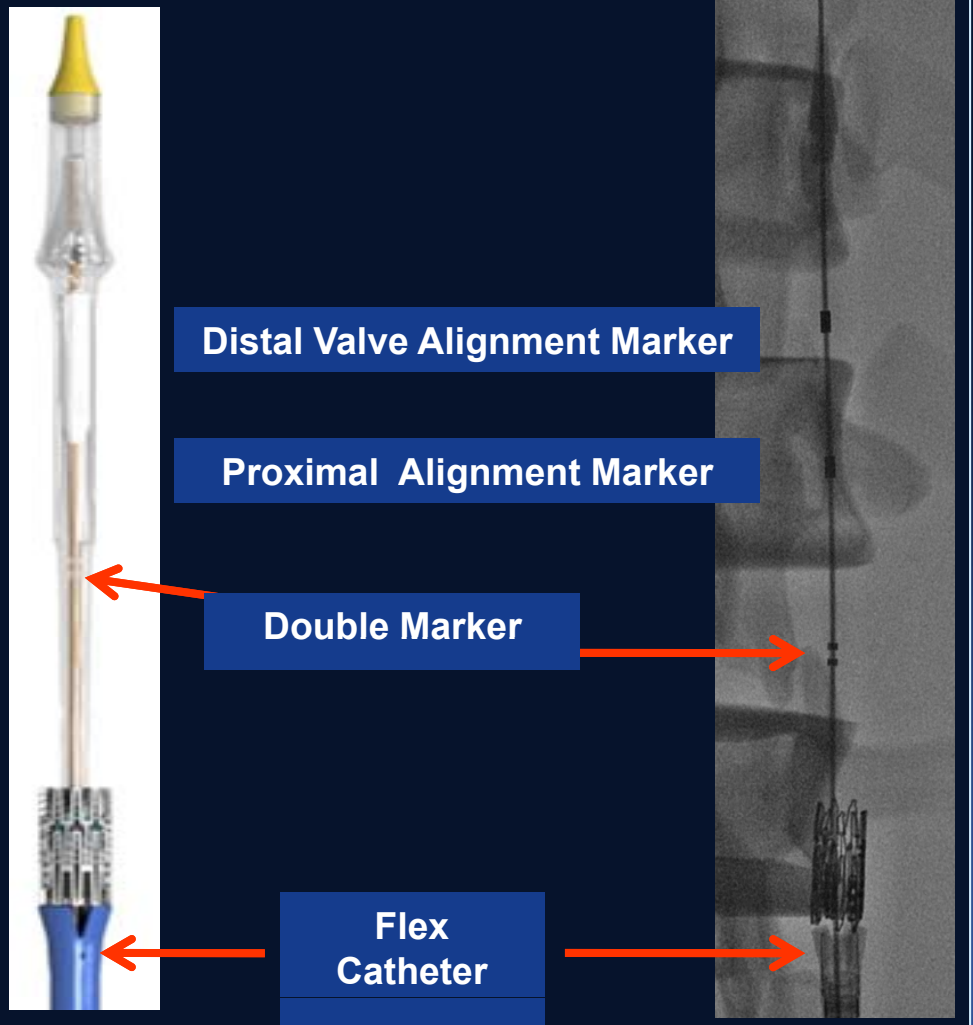
Recommended Equipment

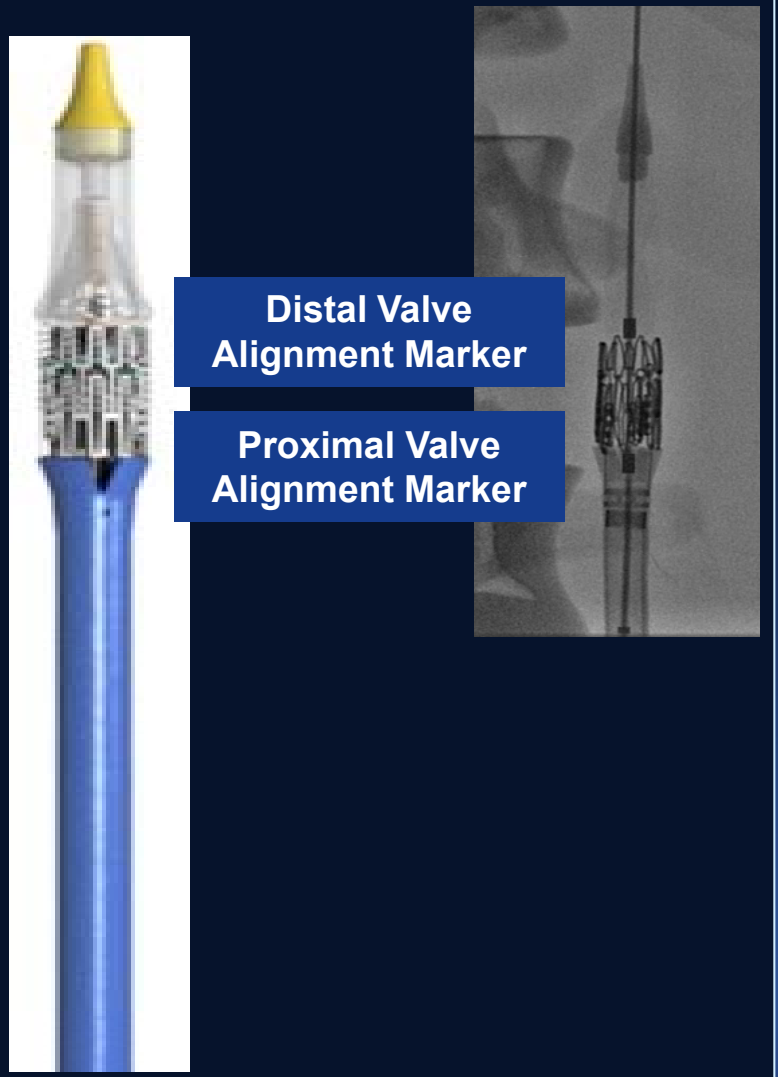
- Balloon valvuloplasty catheters (4 cm x 20, 22, and 25 mm diameters):
  - NuMED NuCLEUS™ (Cat #PVN231, or PVN232)
  - Inflation device or syringe and diluted contrast media

Standby

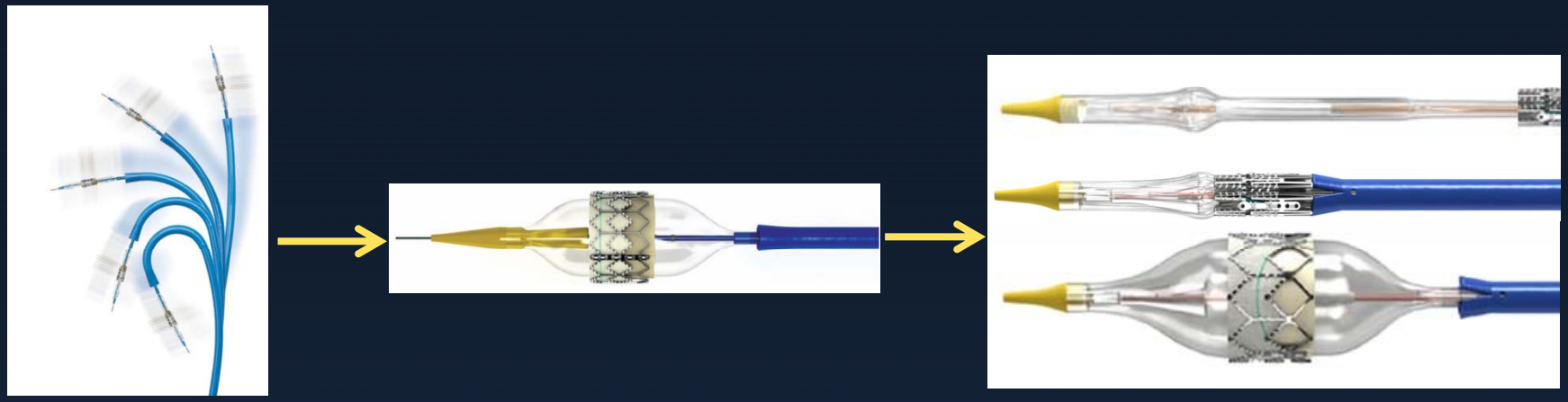
- Balloon valvuloplasty catheters (long-length and 23, 25, or 28 mm diameters):
  - NuMED Z-Med (Cat #SOØ47, PDZ339 and PDZ387)

NovaFlex : Fluroscopic Markers





Evolution of the Edwards Transfemoral Delivery System



RetroFlex System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter

RetroFlex 3 System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- Accurate valve deployment

RetroFlex 4 System

- low-profile SAPIEN XT

NovaFlex System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- Accurate valve deployment

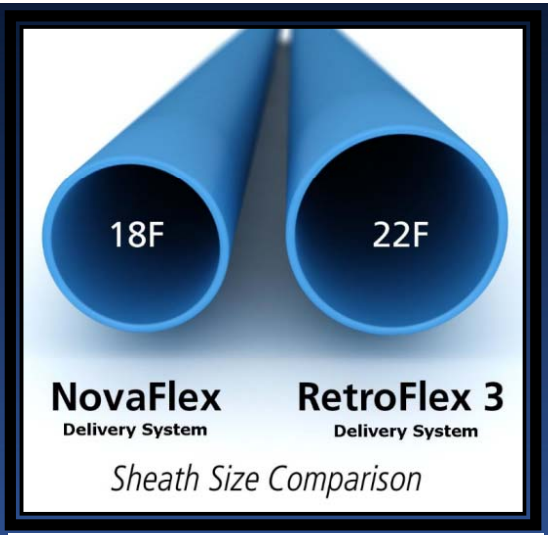
Product Design Updates

- **18F Profile**
- **Enhanced distal end**
- **Designed for Valve Alignment**

Innovative Catheter Tip Design

New shorter
softer tip

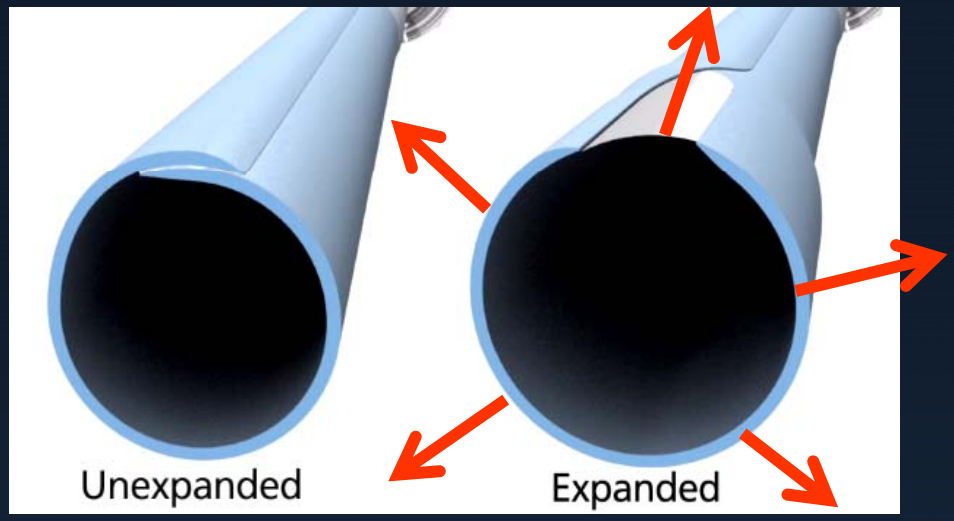
New balloon
Processing for
Smooth transition
To valve



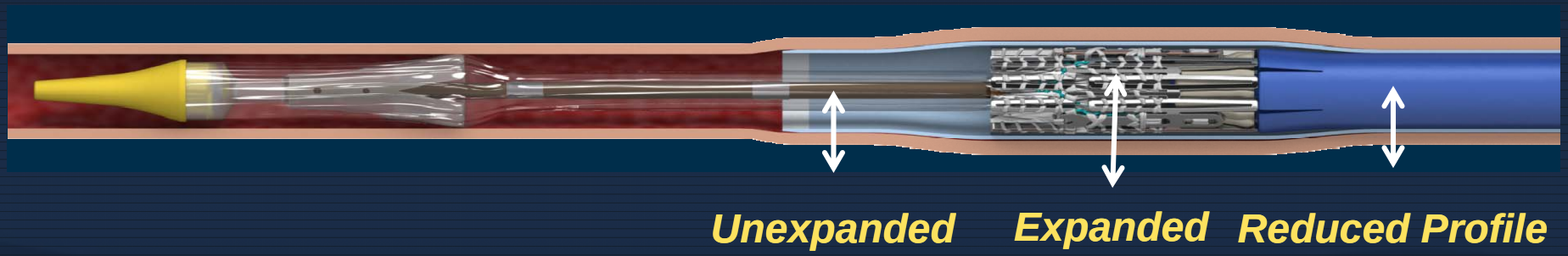
NovaFlex System

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

The New Edwards eSheath

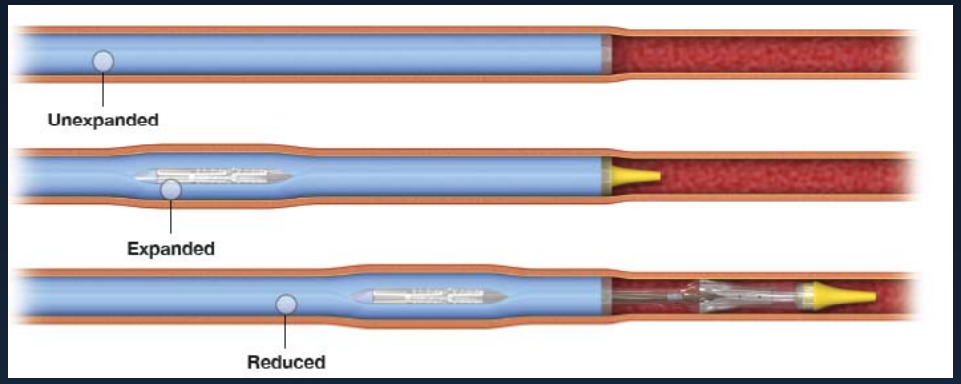


The eSheath expands from 16F to 18F which facilitates smooth delivery system passage, then returns to a reduced profile once the valve has passed through the sheath

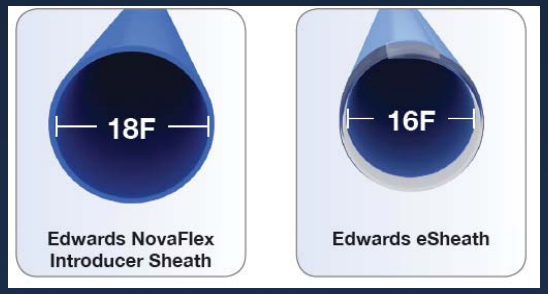


The New Edwards eSheath

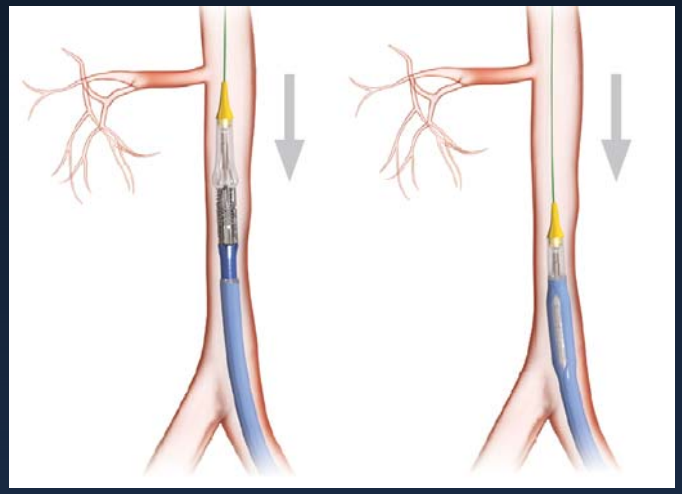
Reduced profile and transient sheath expansion reduces vascular trauma



Smaller (16F) entry and exit profile



The expandable sheath alloows valve retrievability



-40%

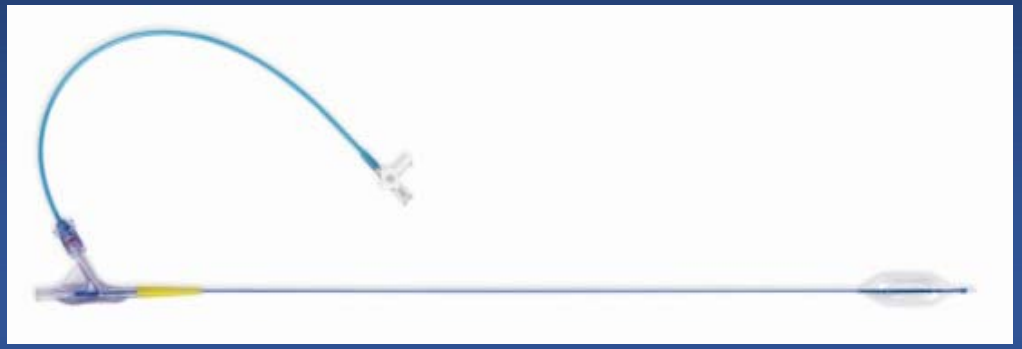
Up to 40% reduced push force during device insertion

Transapical System Refinement

Ascendra 2 Delivery System

Ascendra 2 Delivery System

Ascendra 2 Introducer Sheath Set



Ascendra Balloon Aortic Valvuloplasty Catheter

Proglide ® Abbott Vascular Devices