Procedural Steps in TAVI

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Procedural Steps in TAVI

건강보험심사평가원 공고 제2020-85호

「선별급여 지정 및 실시 등에 관한 기준」(보건복지부 고시 제2020-58호, 2020.3.10.)에 따라 '경피적 대동맥판삽입' 실시기관 승인 및 갱신 신청을 아래와 같이 공고합니다.

2020년 3월 31일

건강보험심사평가원장

경피적 대동맥판삽입 실시기관 승인 및 갱신 신청 공고

1. 신청방법

가. 신청 대상

○ 경피적 대동맥판삽입 실시조건*에 따라 시설·인력·장비 등에 대한 요건을 갖춘 요양기관

* 「선별급여 지정 및 실시 등에 관한 기준」[별표 3] 실시조건

○ **2019년 상반기에 승인받은 기관**은 2020.6.30.자로 승인이 만료됨에 따라 **갱신 신청**을 하여야 함

(구비서류)

1. 연간 실적

항목	실적(건수)		분류번호
대동맥판 치환술	개:		자L7820 외공판맥치환술(대동맥판)
			자L78-1나 외공판맥재치환술(대동맥판)
			자L78-2 비분할 대동맥판맥치환술
경피적 혈관내 스텐트-이식 심치술[대동맥] 또는 [대동맥 및 장골동맥]	개:		자6611가 경피적 혈관내 스텐트-이식 심치술[대동맥]
			자6611나 경피적 혈관내 스텐트-이식 심치술[대동맥 및 장골동맥]
경피적 관상동맥 중재적 시술(PCI)	개:		자6555가 경피적 관상동맥확장술-단일혈관
			자6558가 경피적 관상동맥스텐트삽입술-단일혈관
			자6558가 경피적 관상동맥스텐트삽입술-단일혈관 주1. 경피적 관상동맥확장술(PTCA) 및 경피적 관상동맥죽상반절개술과 동시에 시술한 경우
			자6557가 경피적 관상동맥죽상반절개술-단일혈관

주 1. 대상기간은 신청반기 이전 12개월 실적을 기재
(2020년 상반기 신청기관은 2019년 1월 1일부터 2019년 12월 31일까지,
2020년 하반기 신청기관은 2019년 7월 1일부터 2020년 6월 30일까지 실적)
2. 연간 실적은 해당 요양기관의 상근자가 실시한 경우에 한함

2. 상근인력

○ 세부전문의 자격 취득 후 5년 이상의 순환기내과 진료 경험이 있는 순환기내과세부전문의

번호	성명	순환기내과세부전문의			입사일
		자격번호	자격취득일	인정기간	
1					
2					

※ 대표 전문의 2명 기재, 재직증명서, 순환기내과분과전문의 자격증 첨부
※ 순환기내과세부전문의는 순환기내과분과전문의이며, 인정기간은 최근 인정기간을 기재

○ 전문의 자격 취득 후 5년 이상의 심혈관 수술 경험이 있는 흉부외과 전문의

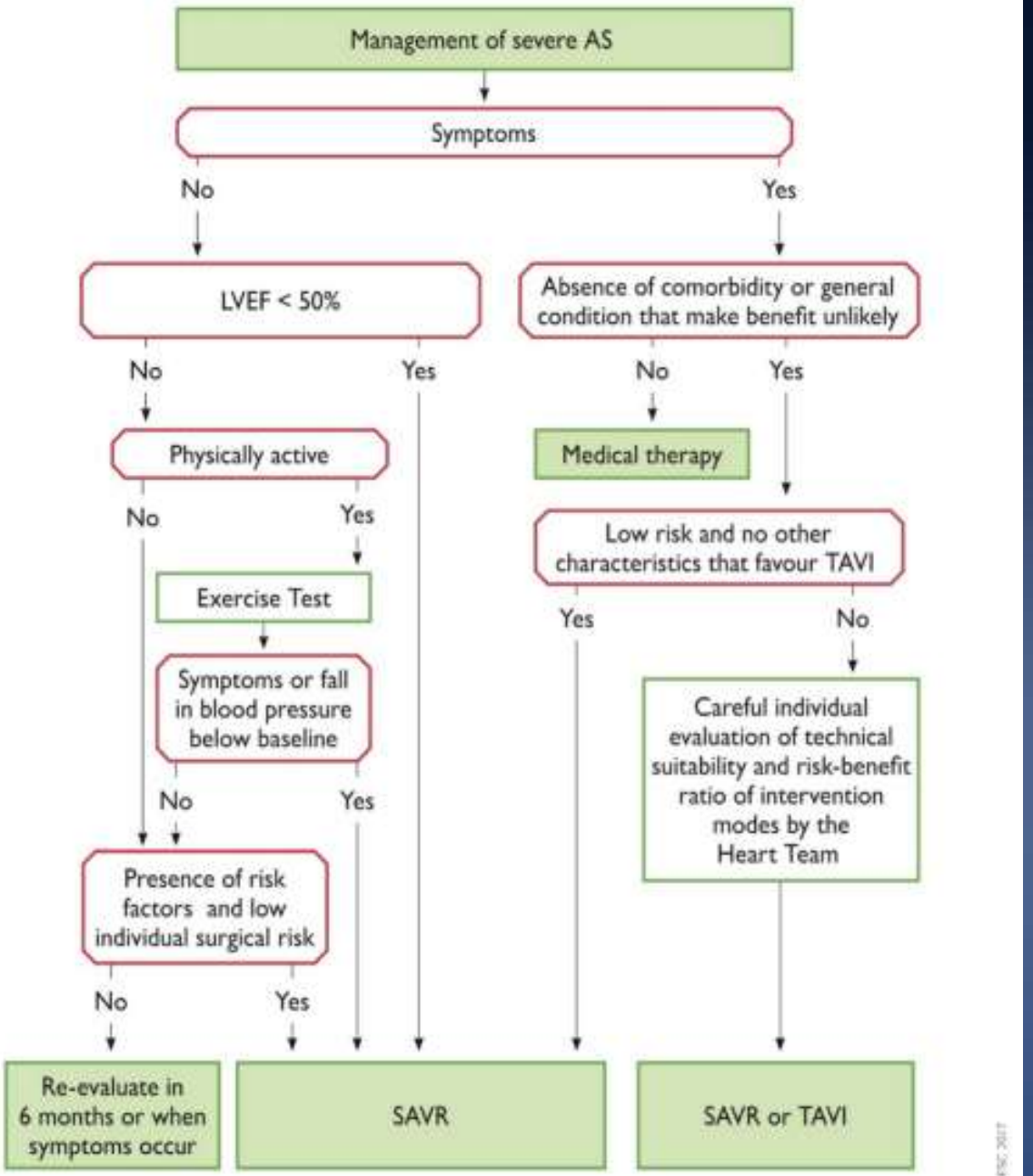
번호	성명	전문의 자격번호	자격취득일	입사일
1				
2				

※ 대표 전문의 2명 기재, 재직증명서, 전문의 자격증 첨부

3. 시술 장소

장소	해당 여부(√)	요건	내용
Hybrid 수술실		실치형 투시장비	식약처 허가번호 : 모 델 명 :
		면적	m^2
심도자실		실치형 투시장비	식약처 허가번호 : 모 델 명 :
		면적	m^2

주 1. 해당 장소의 도면 첨부(시술장소의 면적 확인 가능해야함)
2. 시설 관련 자료(헤파필터, 양압 시설, 공기청정도 검사 결과, 마취용 가스라인 등)가 있는 경우 첨부



Current indication

1. Symptomatic
2. Severe native calcific AS
3. Intermediate or greater risk for SAVR


FDA NEWS RELEASE

FDA expands indication for several transcatheter heart valves to patients at low risk for death or major complications associated with open-heart surgery

For Immediate Release: August 16, 2019

Puncture to closure

1. Puncture, Pre-closure, TPM back up
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5. Valve positioning, Deployment
6. Post balloon, Device Retrieval
7. Femoral artery closure

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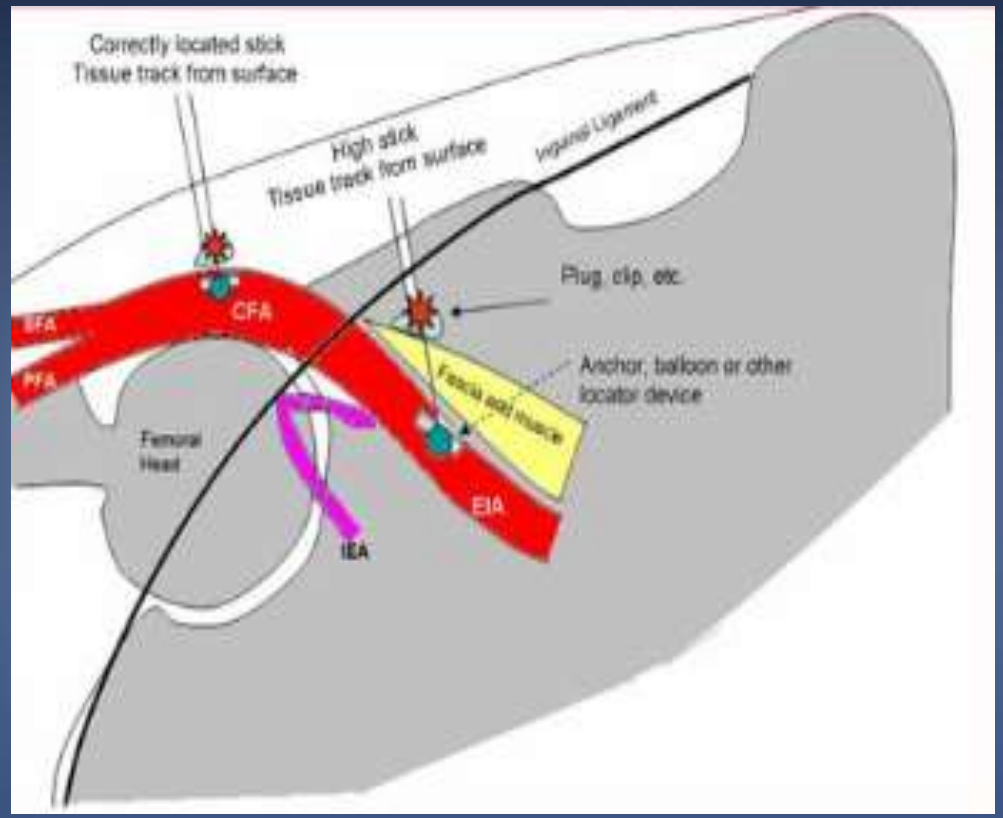
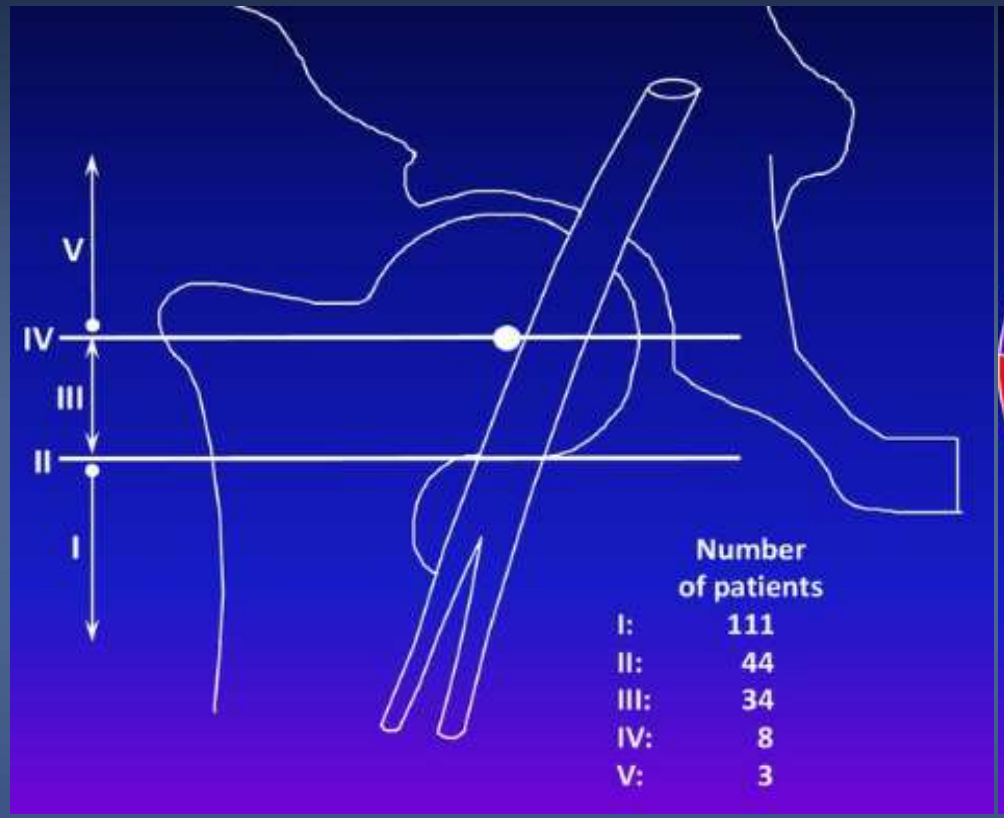
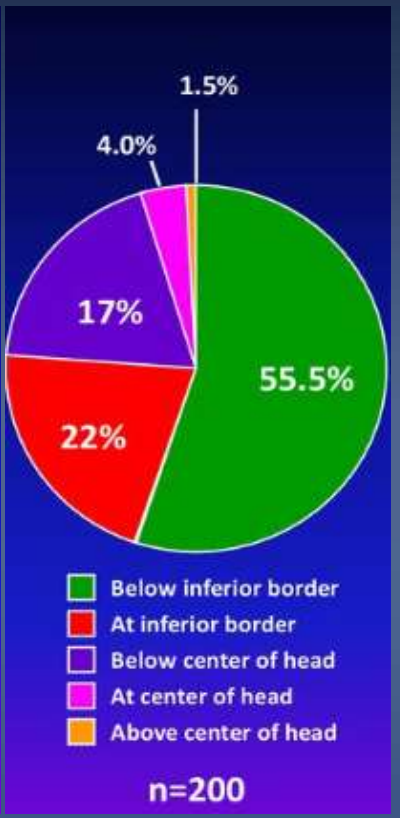
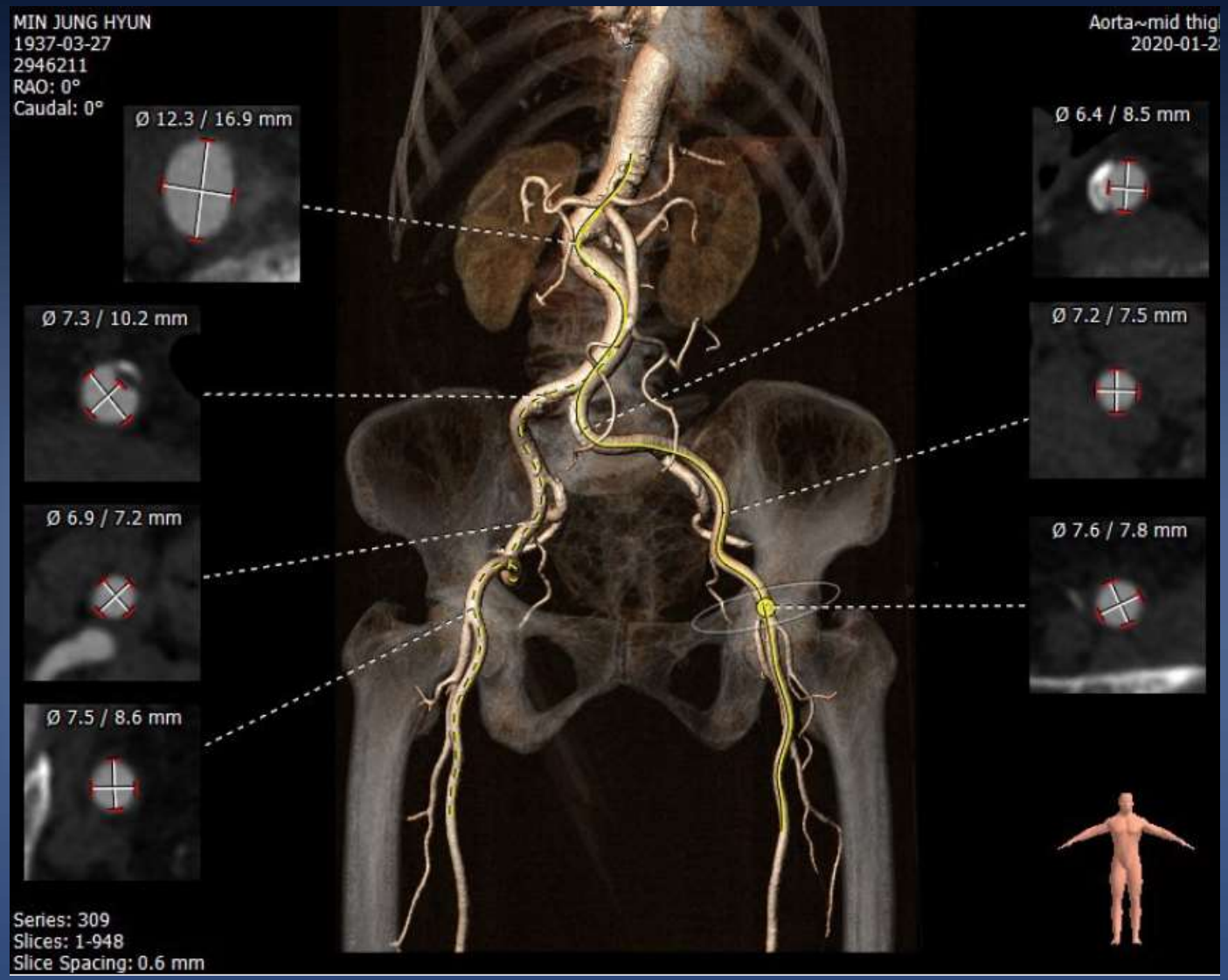
How to decrease Risk of Coplication



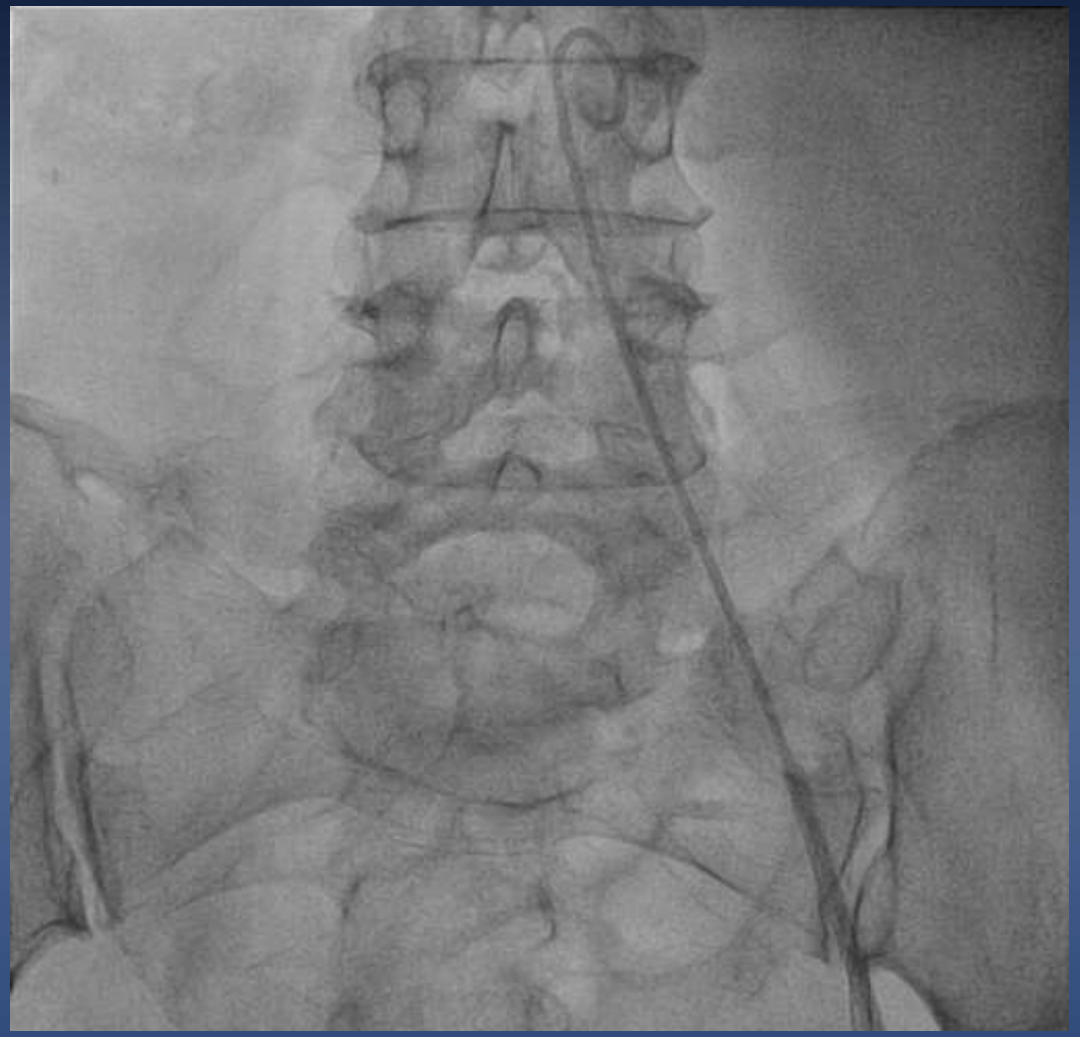


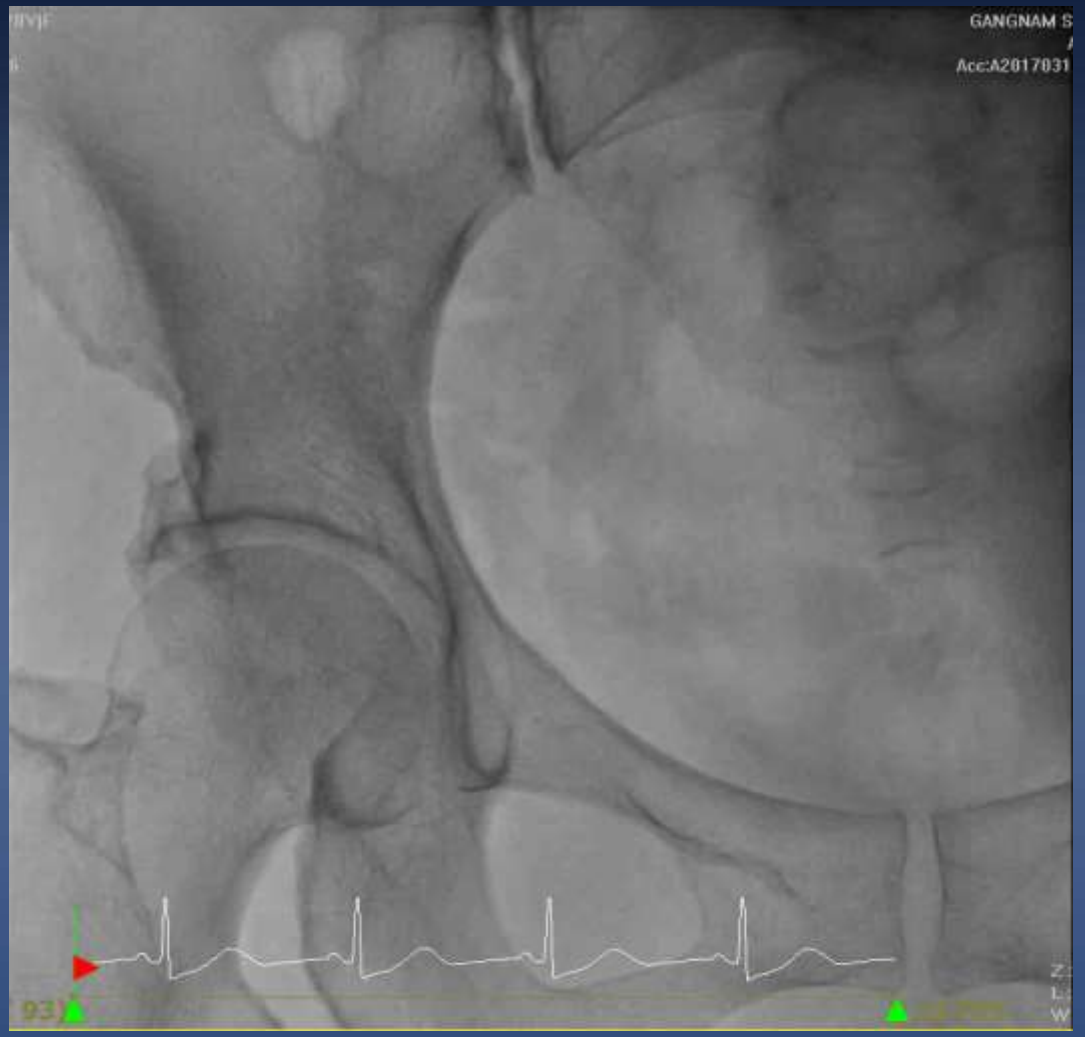


CT guided puncture

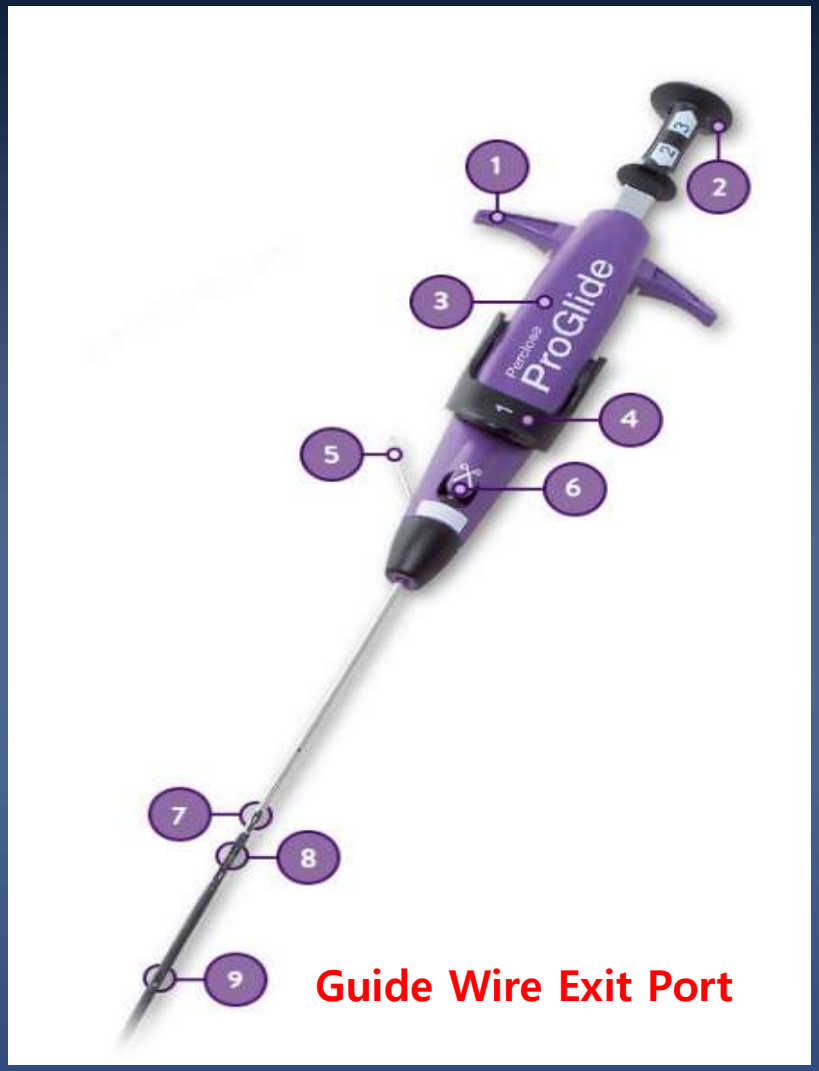


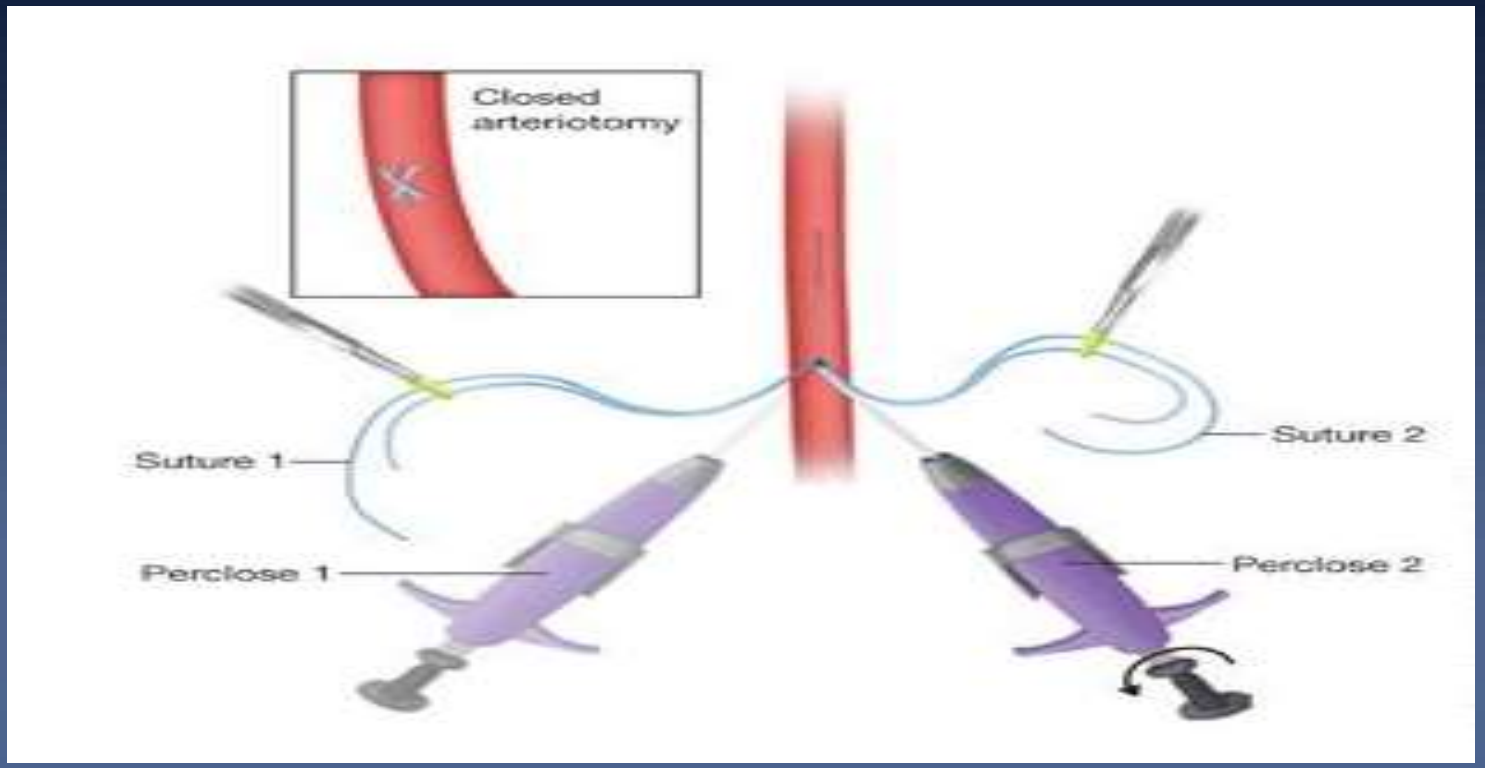
Puncture





Pre-closure Technique





1. 14 = 1 proglide (S3 23mm,26mm)
2. 16Fr,18Fr = 2 proglide (S3 29mm)

Temporary pacemaker

Pacel™ Bipolar Pacing Catheter,
Ventricular Pacing with Right Heart Curve

Torque Control

*Allow up to 3 weeks for delivery.
*Not available in countries requiring CE Mark.

Product referenced is approved for CE Mark.

Cardiology International Catalogue – GMCARD177EN (June, 2010)

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Pacel™ Bipolar Pacing Catheter,
Right Heart Curve

Flow Directed

*Allow up to 3 weeks for delivery.
*Not available in countries requiring CE Mark.

Product referenced is approved for CE Mark.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Cardiology International Catalogue – GMCARD177EN (June, 2010)

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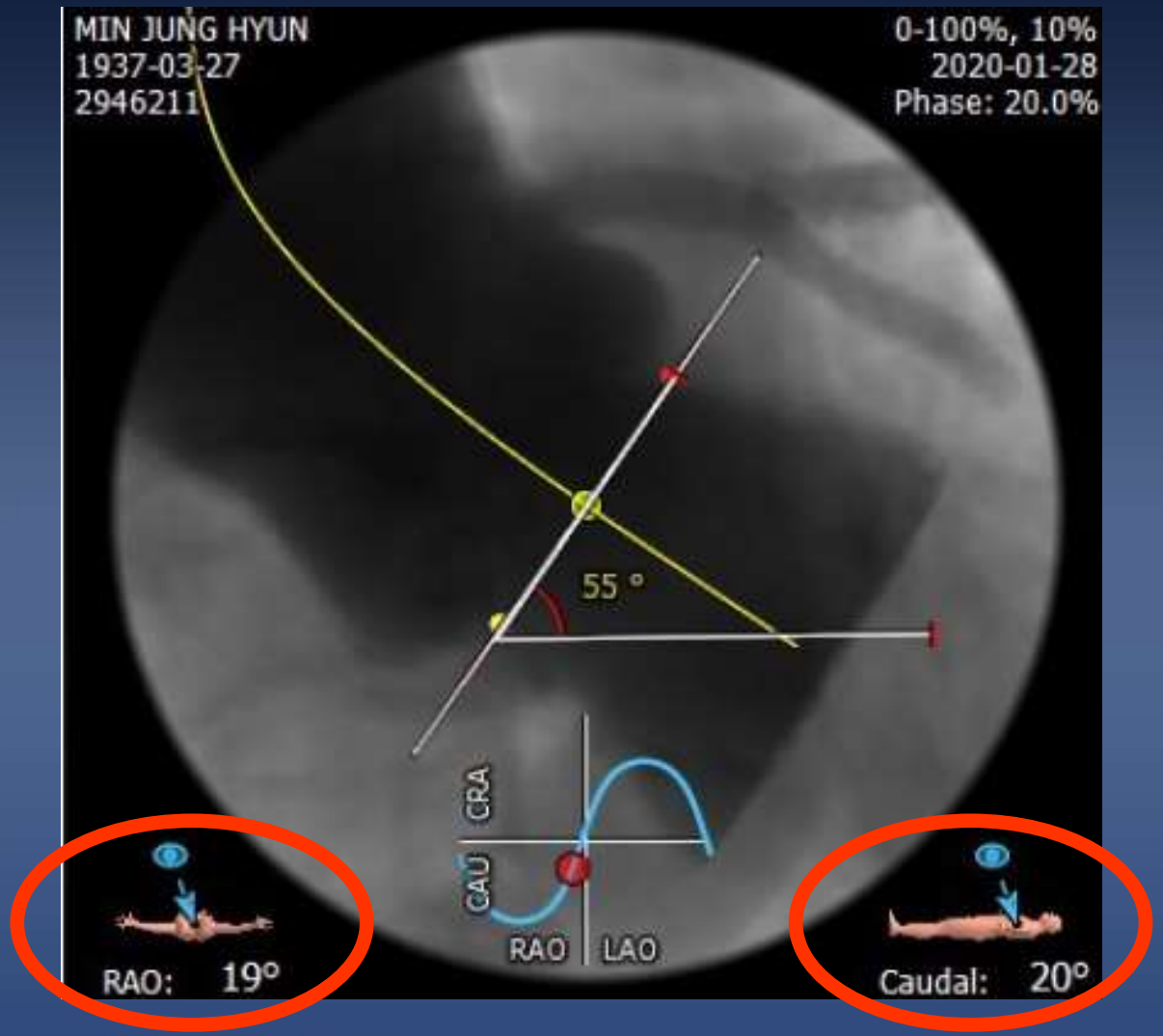
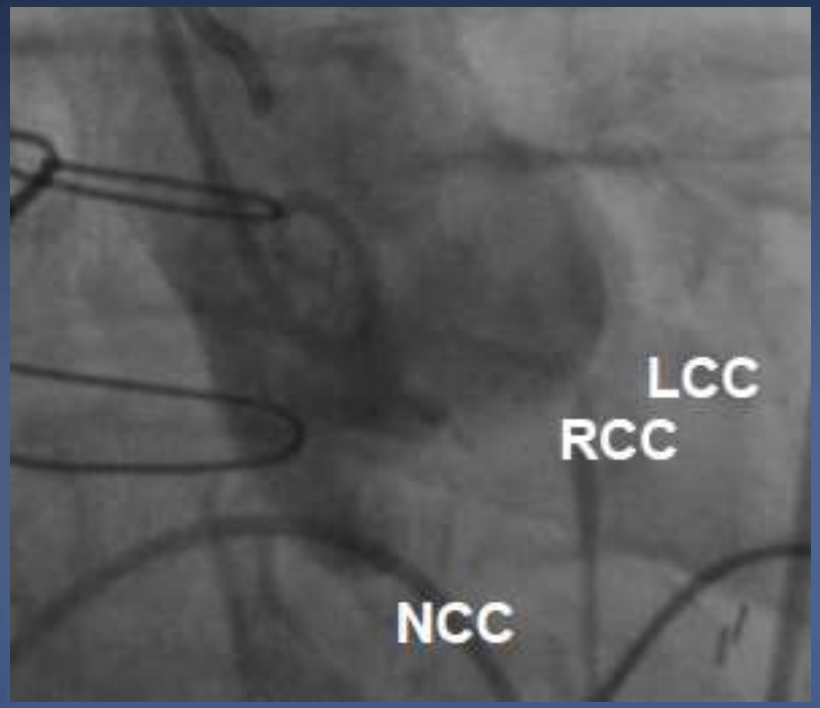
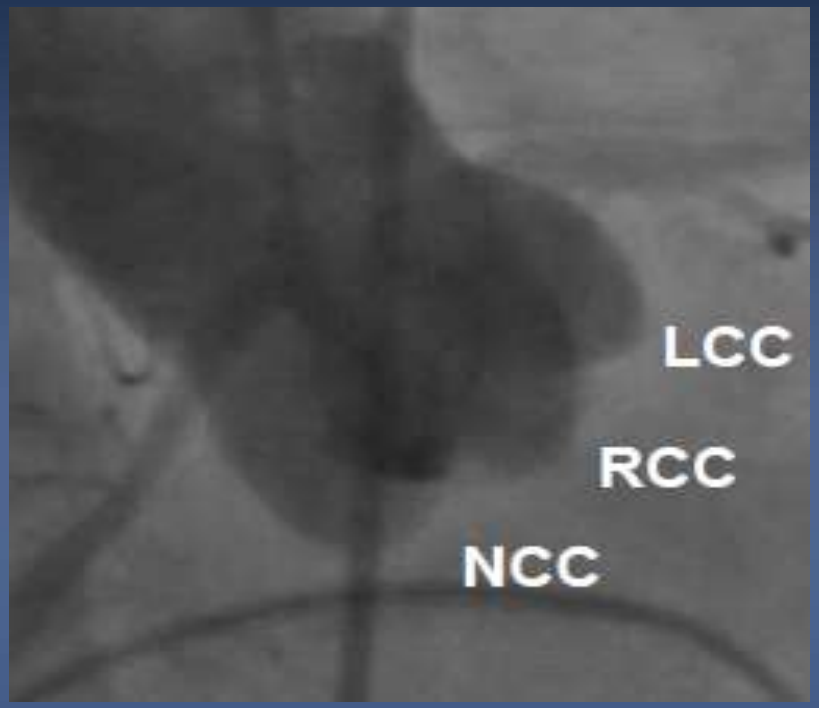
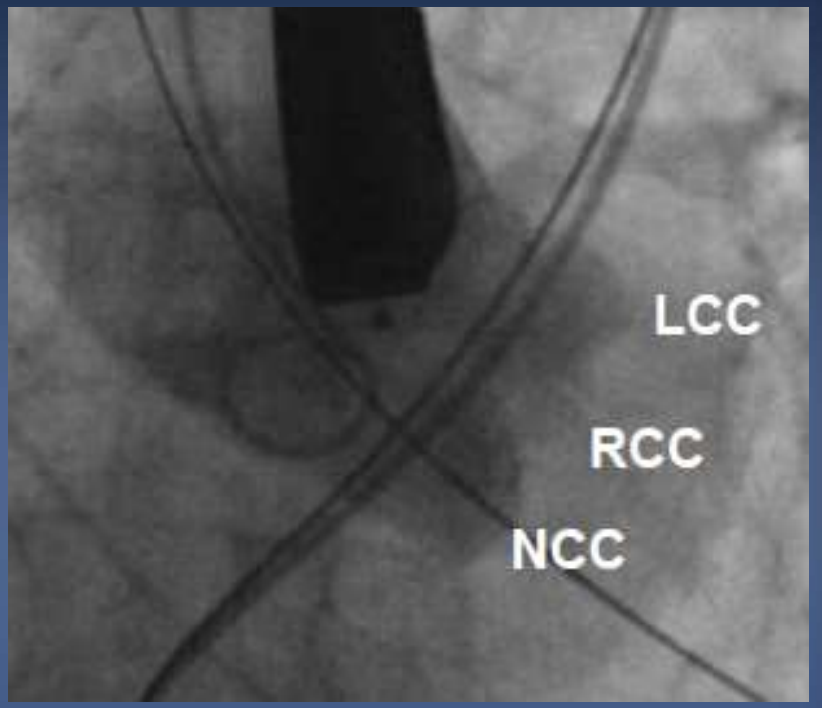
CT pre-evaluation ; coplanar view



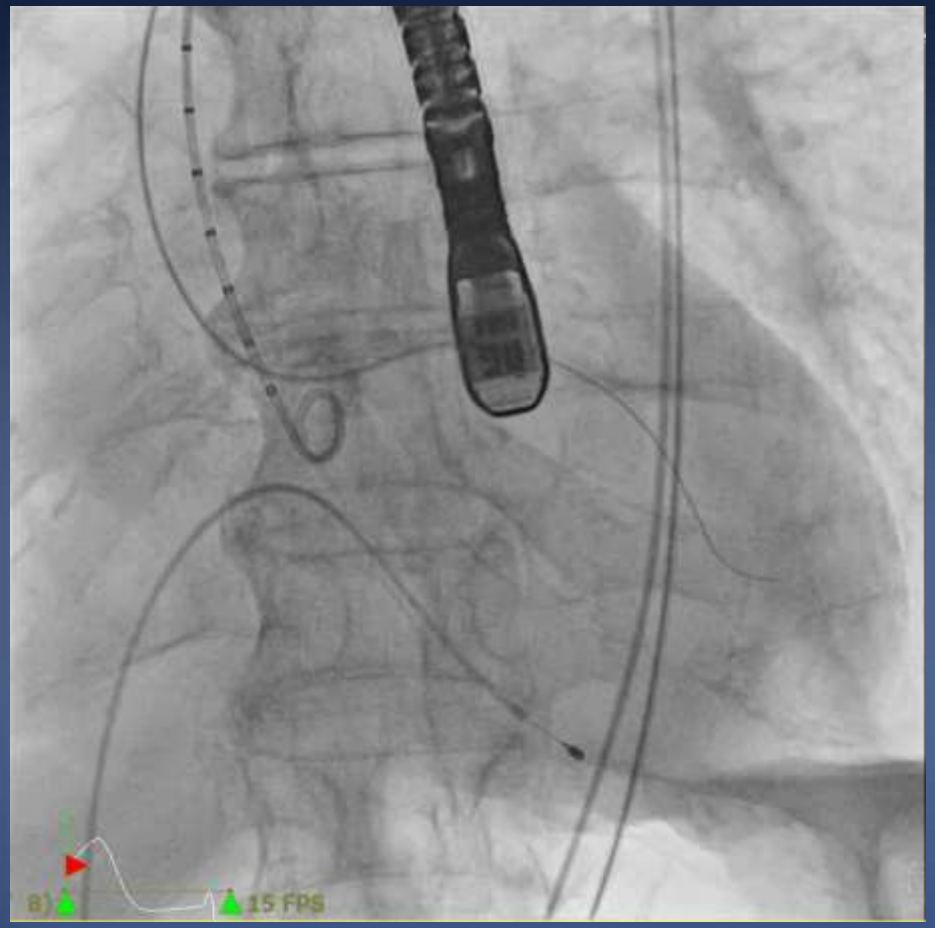
Baseline Aortogram ; coplanar view







LV Wire crossing

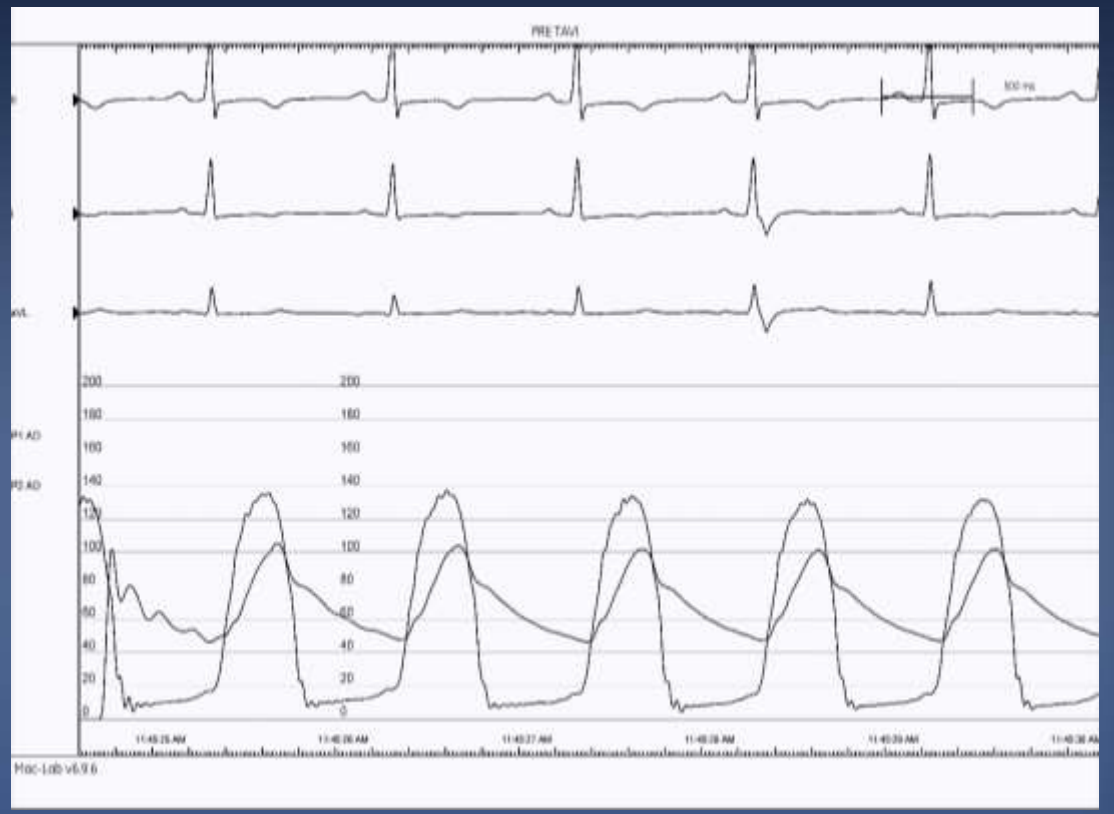


catheter	Wire
AL1	Terumo straight
AL2	Tefron straight
JR,MPA	

Fail?... Guiding + microcaheter

Pressure gradient check

Indicator	Mild	Moderate	Severe
Jet Velocity *(m/s)*	< 3.0	3.0 – 4.0	> 4.0
Mean Gradient *(mmHg)*	< 25	25 – 40	> 40
Valve Area *(cm^2)*	> 1.5	1.0 – 1.5	< 1.0
Valve Area Index *(cm^2/m^2)*	–	–	< 0.6



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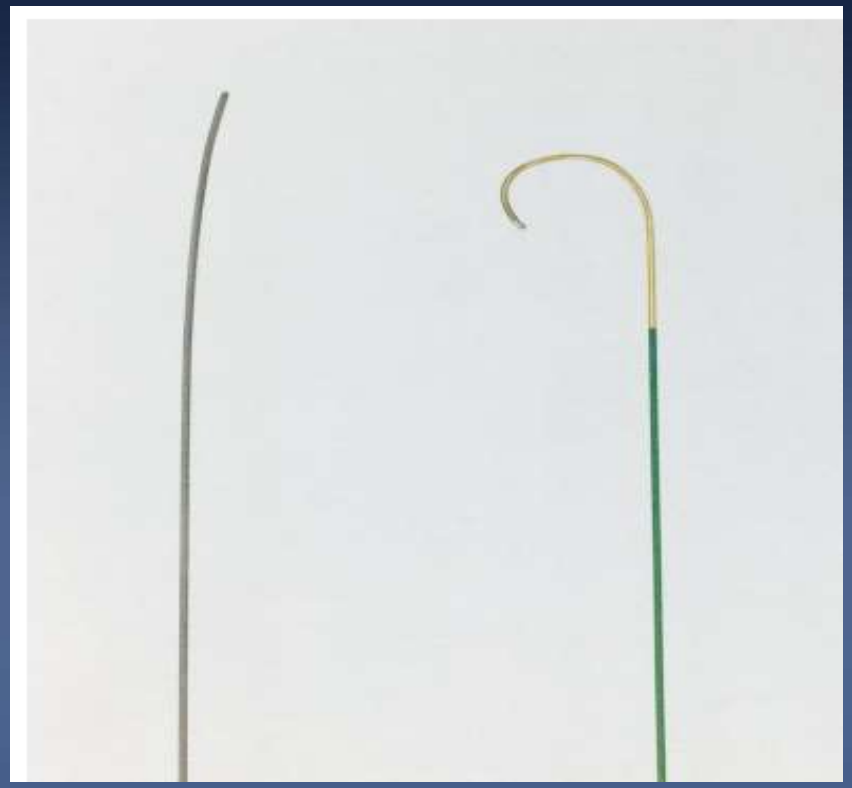
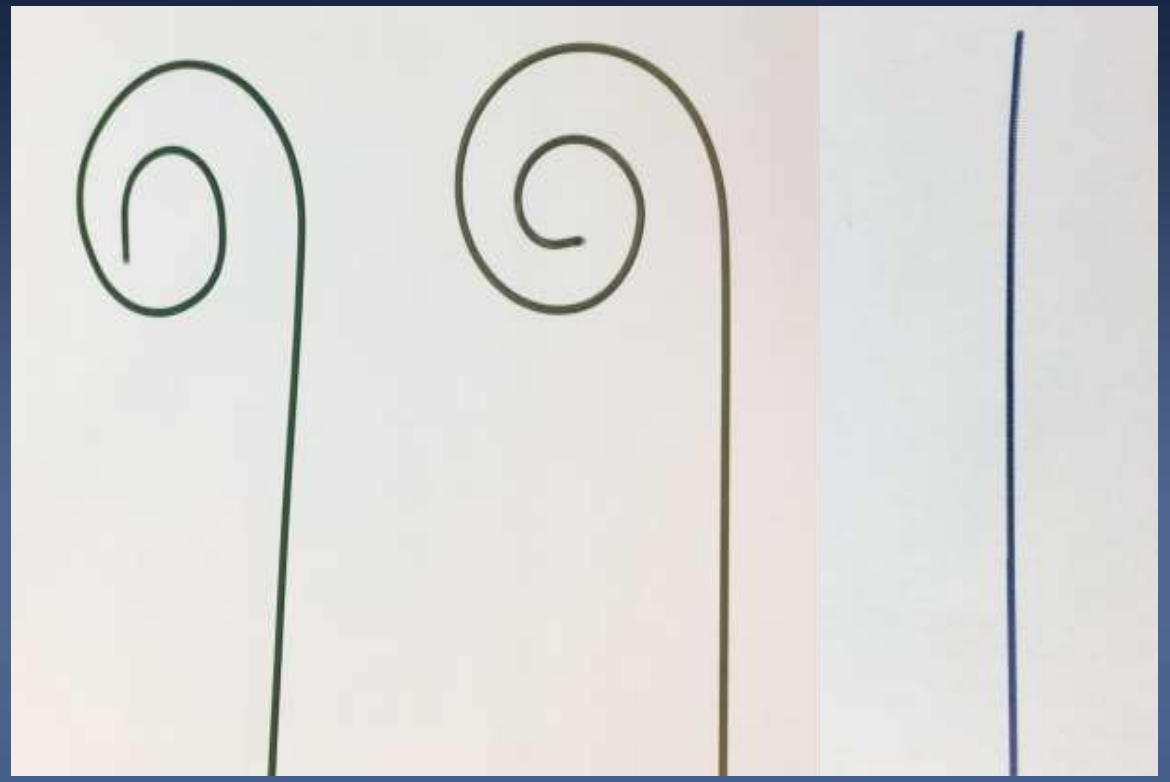
Relative stiffness of wires



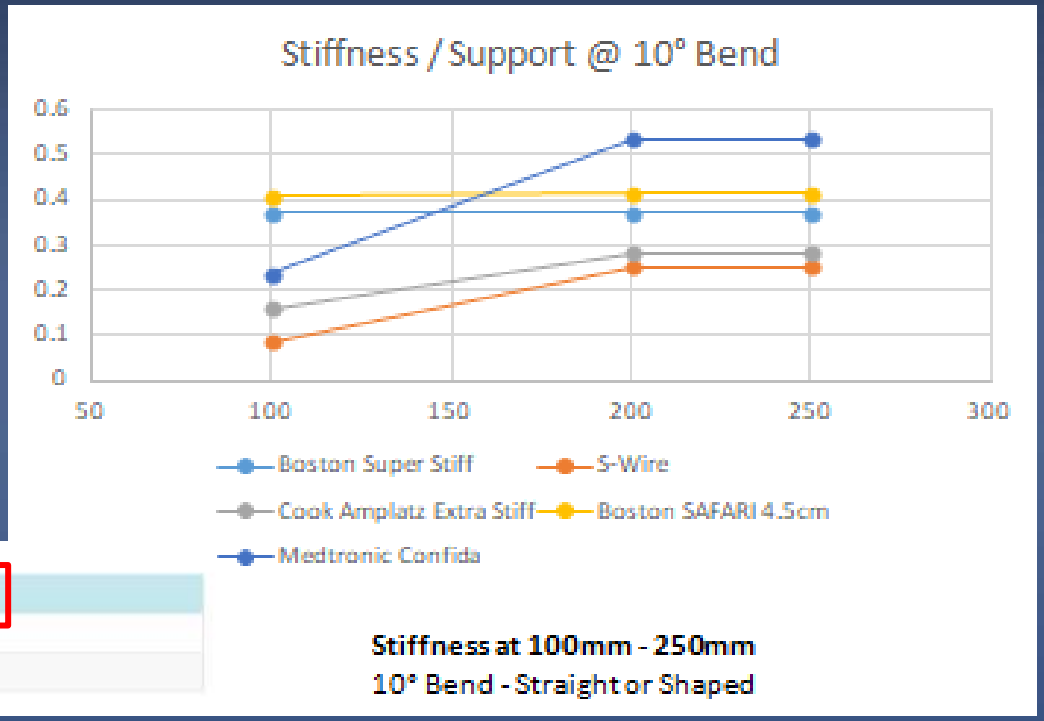


(A) Lunderquist® Extra-Stiff wire (B) Meier guide (C) Confida Brecker (D) Safari2 wire (E)Amplatz Super StiffTM wire

More stiff ← → Less stiff

SAFARI²™ ;
Pre-Shaped TAVI Guidewire

1. Guidewire Specifications Outer Diameter: 0.035” (0.889 mm)
2. Overall Length: 275 cm
3. Core Material: Stainless Steel
4. Coil Material: Stainless Steel
5. Coating: LUBRIGREEN™ PTFE



Curve Dimensions

	Extra Small	Small	Large
Height	3.2 cm	4.2 cm	5.0 cm
Width	2.9 cm	4.2 cm	4.9 cm

6. Unique Product Dimensions by Curve Size

Edwards eSheath Introducer Set

- No color coding for 14F or 16F eSheath introducer set
- Sheath size is labeled on sheath handle

- **14F profile expands the treatable patient population**

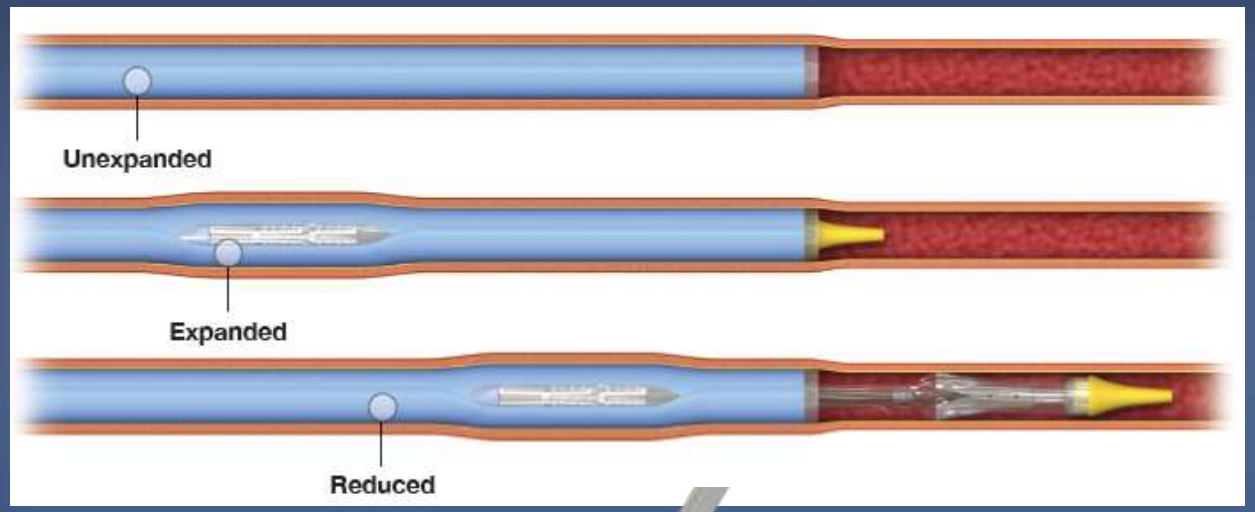
Low profile access demonstrates > 50% reduction in major vascular complications*

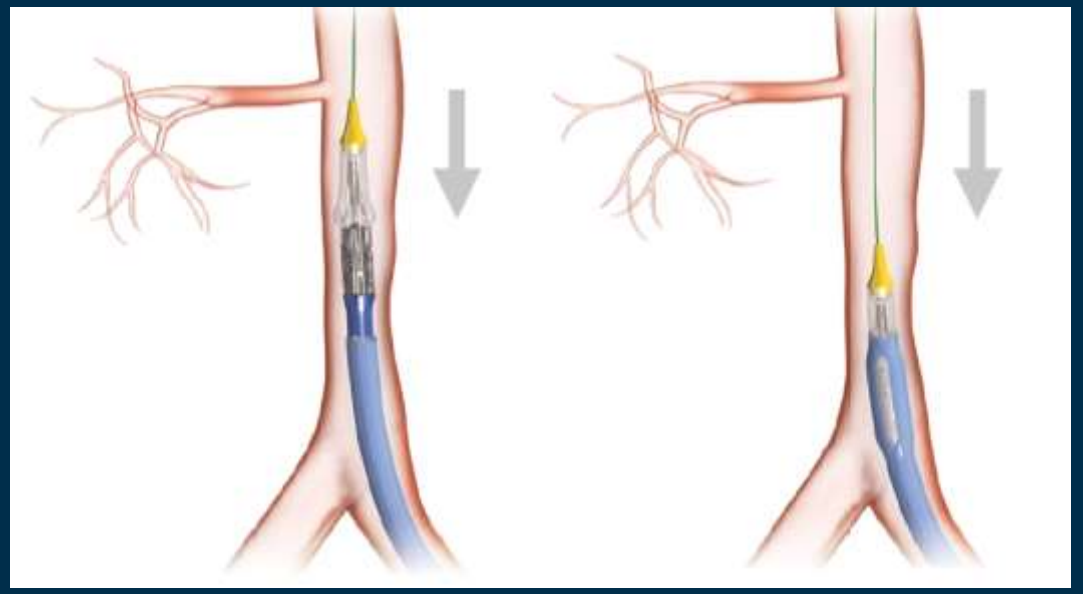
Access Vessel Sizing	20 mm	23 mm	26 mm	29 mm
Edwards eSheath Introducer Set	14F (4.6 mm)	14F (4.6 mm)	14F (4.6 mm)	16F (5.3 mm)
Minimum Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6 mm

Edwards eSheath Introducer Set

Dynamic Expansion Mechanism

- The Dynamic Expansion Mechanism (DEM) is designed for low profile entry and exit





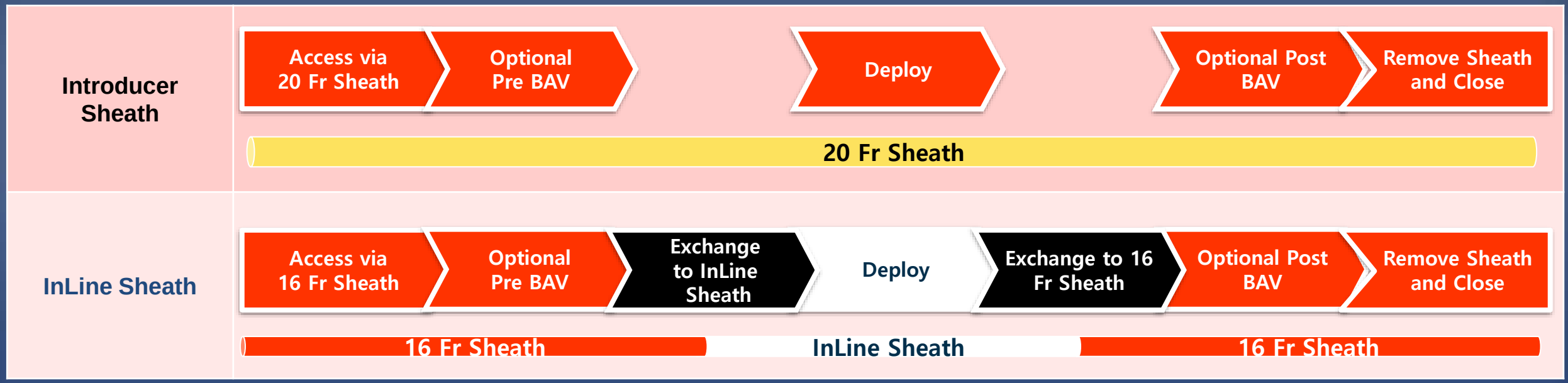
The DEM Feature Allows for Valve Retrievability*

adjustment procedure and
er with valve in the body of the eSheath introducer.

Determine Vascular Access

Determine best vessel to accommodate a large sheath and select access approach based on d elivery system and anatomical considerations:

- **20 Fr Introducer Sheath:** larger delivery profile but doesn't require sheath exchanges
  - Recommended for highly calcified and/or tortuous vessels
- **InLine Sheath:** smaller delivery profile, but requires a 16 Fr sheath for exchanges



LOWEST DELIVERY PROFILE, 14FR-EQUIALENT

SYSTEM WITH INLINE SHEATH ACROSS ALL VALVE SIZES

NOW Indicated for Minimum Transarterial Access Vessel Diameters ≥ 5.0 mm!

CoreValve®	Evolut™ R
with 18Fr Cook Sheath	with 14Fr-Equivalent InLine™ Sheath
18Fr	18Fr
22 Fr (OD)	True 18Fr (OD)

- Sheath to Femoral Artery Ratio (SFAR) great than 1.05 predicted higher rates of VARC major vascular complications. Hayashida K, et al. Transfemoral aortic valve implantation. JACC Intv 2011;4(8):851-8.

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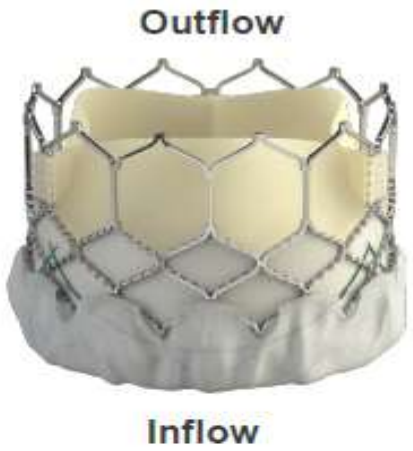
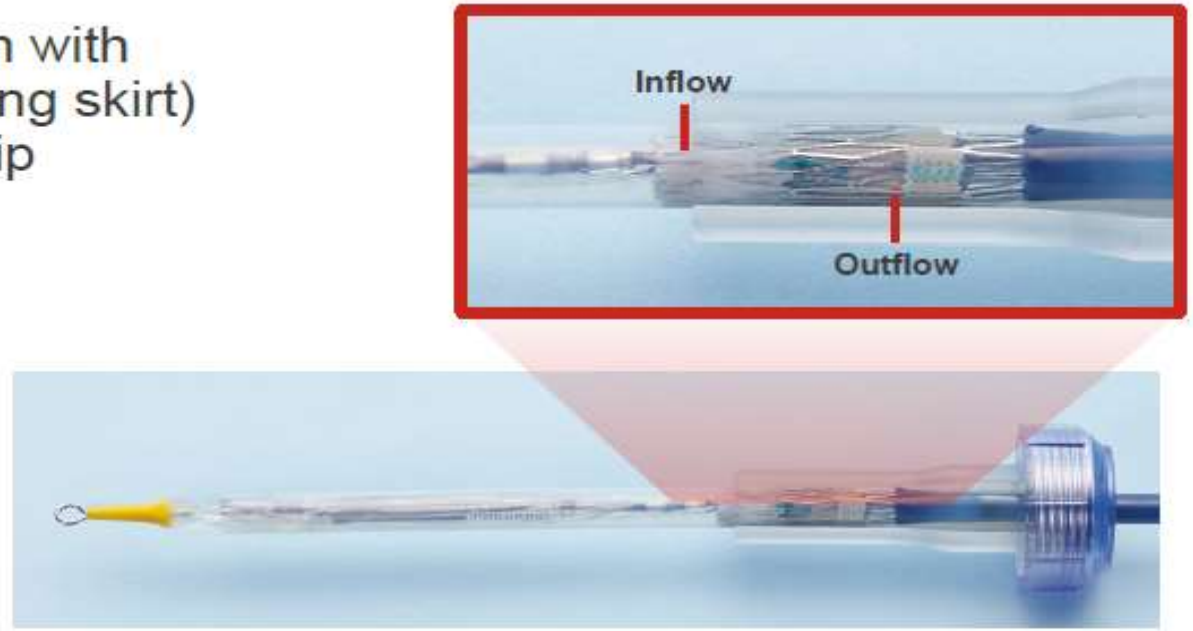
Verify THV Orientation and Correct Volume

- Verify THV orientation with the inflow (outer sealing skirt) towards the tapered tip





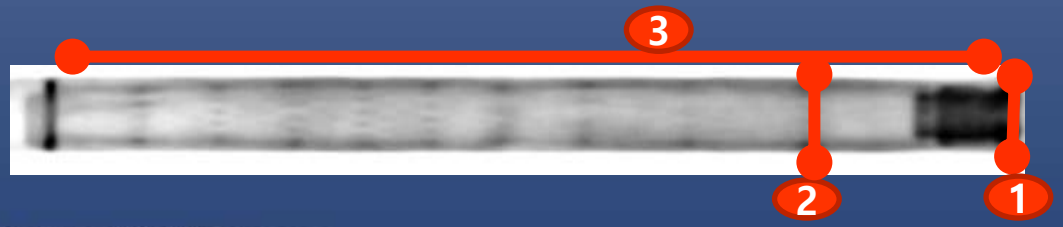
CAUTION:
To prevent possible leaflet damage, the THV should not remain fully crimped and/or in the loader for over 15 minutes

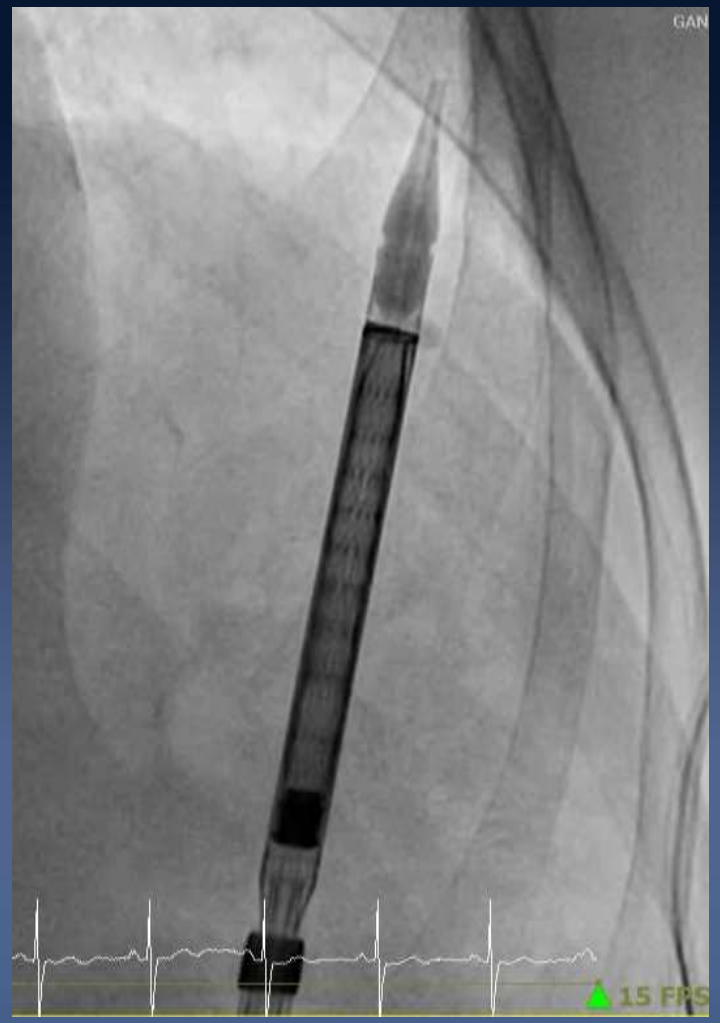
NOTE:
The proximal end of the loader may be brown in color

FLUORO ROAD INSPECTION

Inspect the loaded delivery system under fluoroscopy to ens ure proper loading

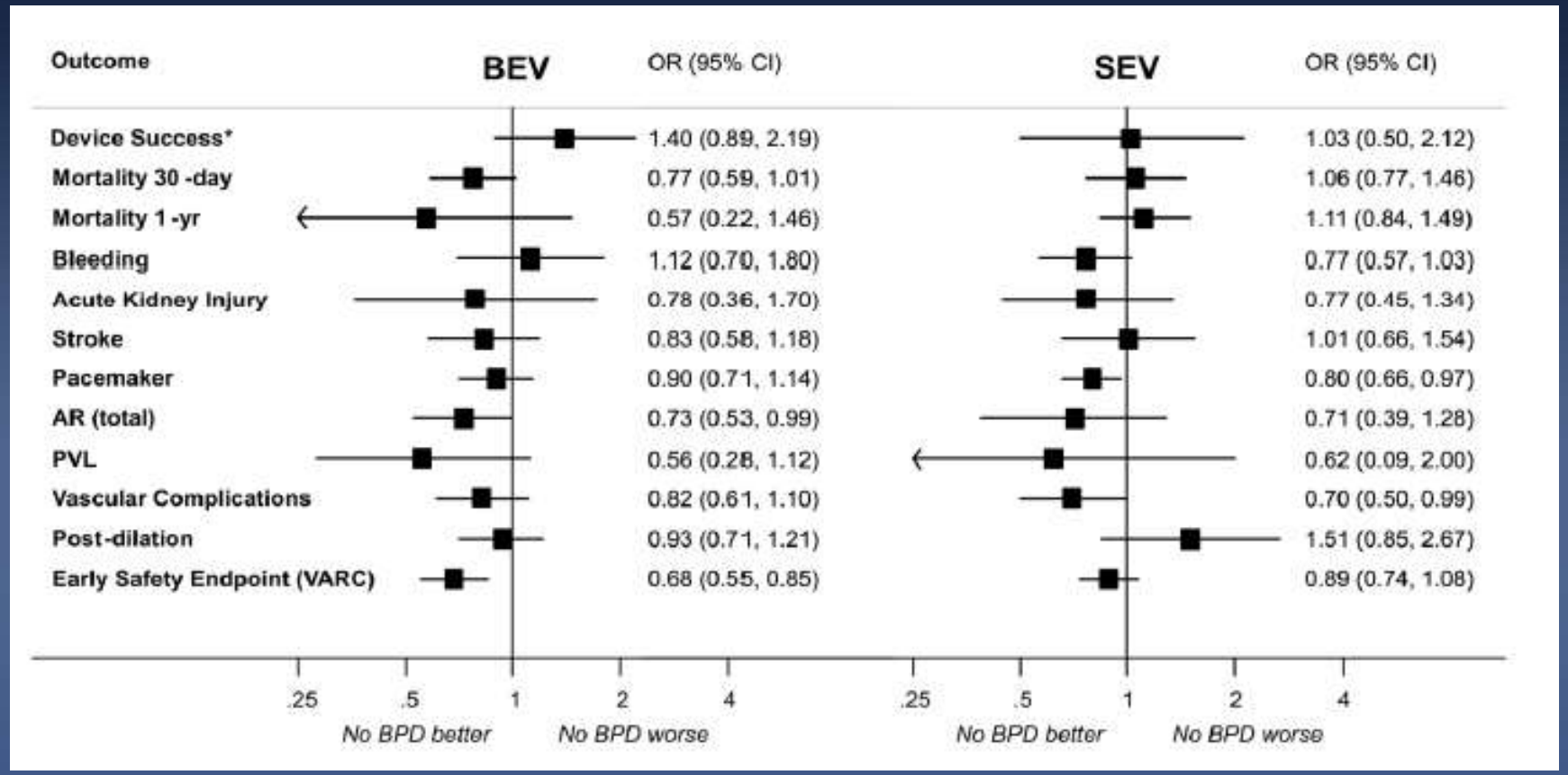
- Imaging Guidance:
  - **AP imaging projection performed at high resolution cin e and magnification**
  - **Rest capsule on patient or table for stability**
  - **Hold flush ports to the side and rotate slightly in either direction until both paddles are visible**
- Focus inspection on three critical areas
  - **1. Paddle attachment area**
  - **2. Outflow crown alignment**
  - **3. Length of capsule**





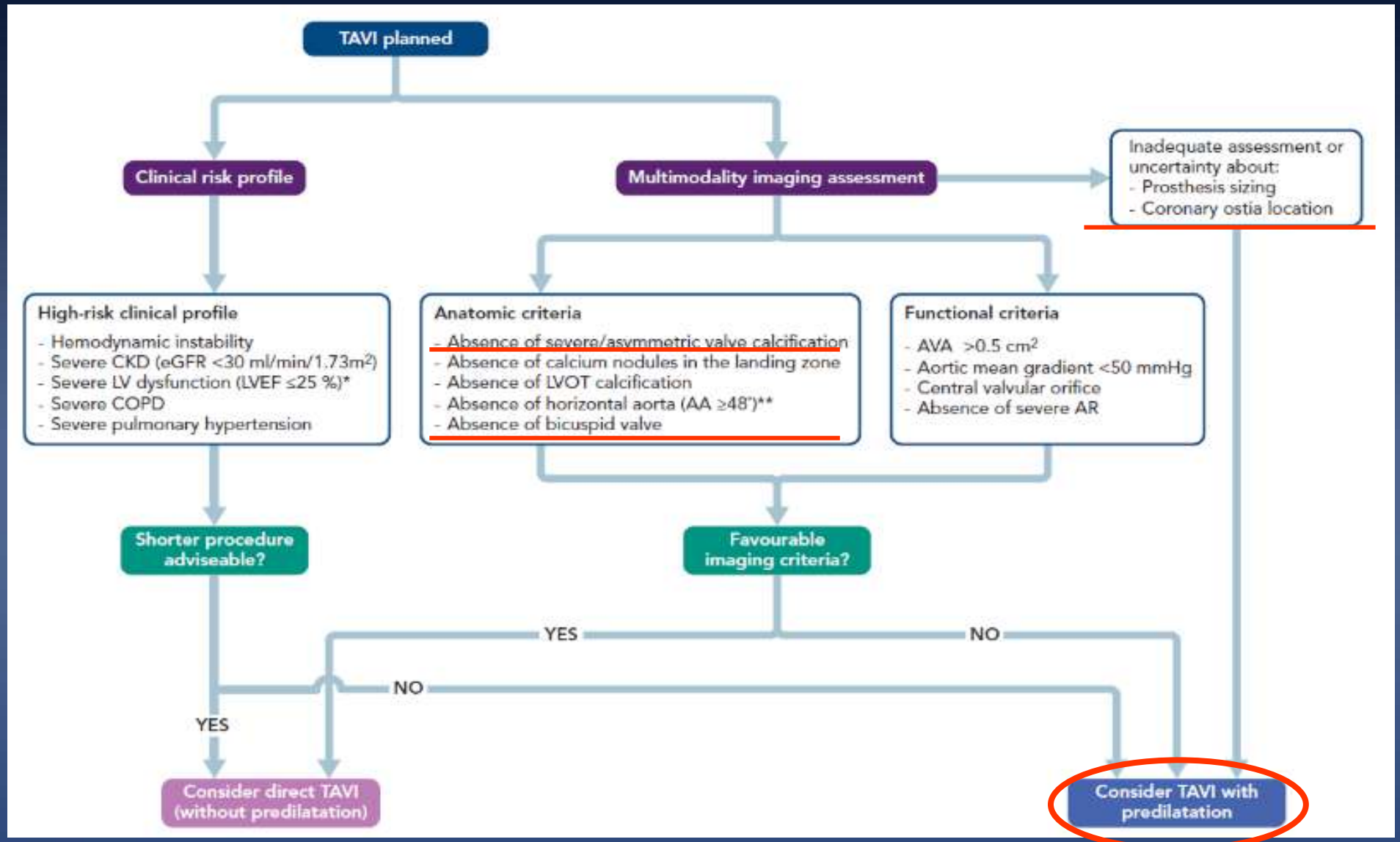
Note distance between capsule and nosecone as a visual reference to ensure tip is not over/under captured before retrieving delivery system after deployment.

Meta-analysis of the Impact of Avoiding Balloon Predilation in Transcatheter Aortic Valve Implantation



TAVI without BPD is safe and effective. NoBPD is associated with fewer vascular complications, less aortic regurgitation, and fewer pacemaker requirements and composite early safety end points.

Proposed Decision-Making Algorithm For The Selection Of Patients Who Can Be Considered For Direct TAVI (Without Predilatation)



Balloon Aortic Valvuloplasty

Verify Correct Inflation Volume in Inflation Device

Position Balloon

Verify Inflation Device Unlocked

Initiate Rapid Ventricular Pacing (RVP)

Fully and Rapidly Inflate Balloon

Rapidly Deflate Balloon and Stop RVP

THV Size	Edwards Balloon Catheter	Inflation Volume	Nominal Pressure	Rated Burst Pressure
23 mm	20 mm x 4 cm x 130 cm	16 mL	4 atm	6 atm
26 mm	23 mm x 4 cm x 130 cm	21 mL	4 atm	6 atm
29 mm	25 mm x 4 cm x 130 cm	26 mL	4 atm	6 atm

NOTE:
Always maintain control of the plunger of the inflation device when releasing it

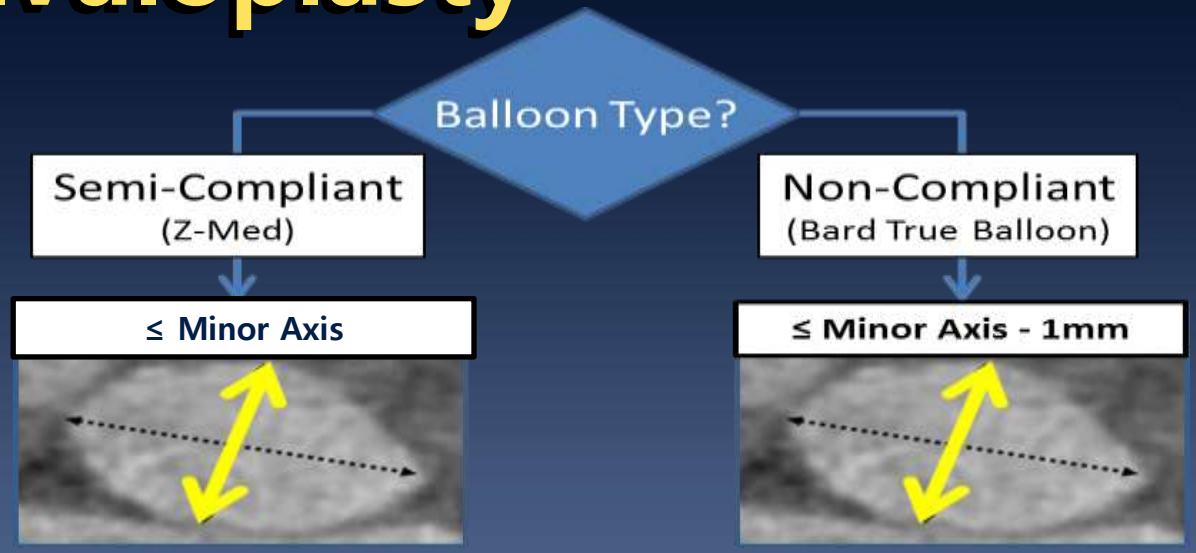
NOTE:
Never lock the inflation device during inflation/deflation

EVOLUT R/PRO

Balloon valvuloplasty

Balloon Valvuloplasty Procedure

- This is an optional step according to IFU for the EvolutR implant procedure.*
- Balloon selection and sizing guidance:
  - Chose balloon based on the minor axis from CT annul us measurement.
  - **Recommended balloon should be short** (4 – 5 cm), straight and non-compliant or semi-compliant.
- Perform a rapid pacing test.
  - Pacing is set at 170-200 bpm.
  - Successful test is defined as 1-to-1 pacing capture wit h an immediate drop in pressure and elimination of th e systolic-diastolic waveform.
- IFU for CE Mark countries requires a pre- BAV, although some physicians choose to skip this step.



ANNULUS

Diameter (mm)	21.3	x	26.9	,	24.1
	Min		Max		Mean
Perimeter (mm)	74.9			,	23.9
					Derived Diameter

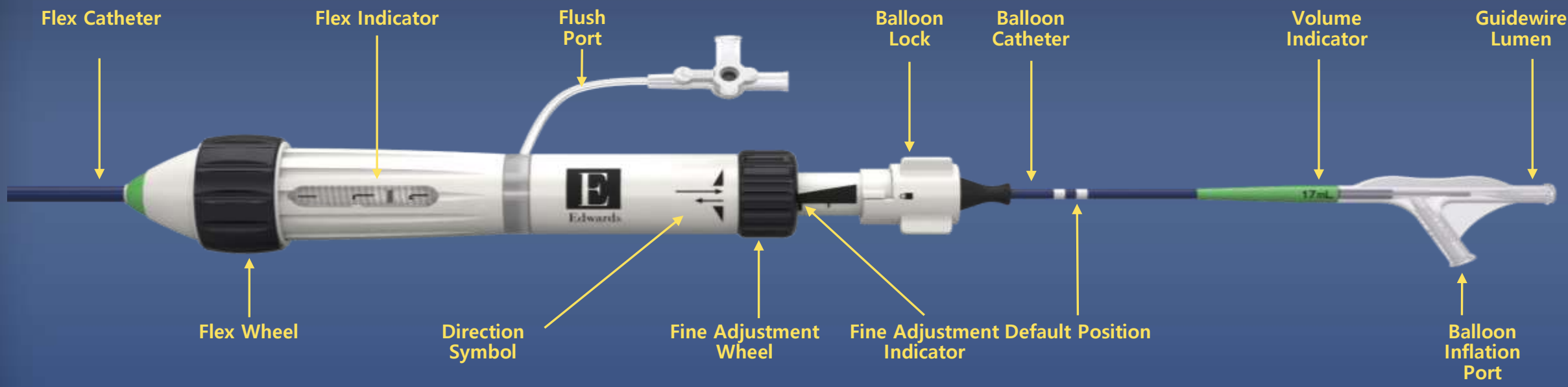
Puncture to closure

1. Puncture, Pre-closure, TPM back up
2. Aortogram, LV Wire crossing, Pressure gradient check
3. LV support wire exchange, sheath insertion
4. TAVR valve check, Pre balloon
5. Valve positioning, Deployment
6. Post balloon, Device Retrieval
7. Femoral artery closure

Edwards Commander Delivery System

Edwards Commander Proximal End

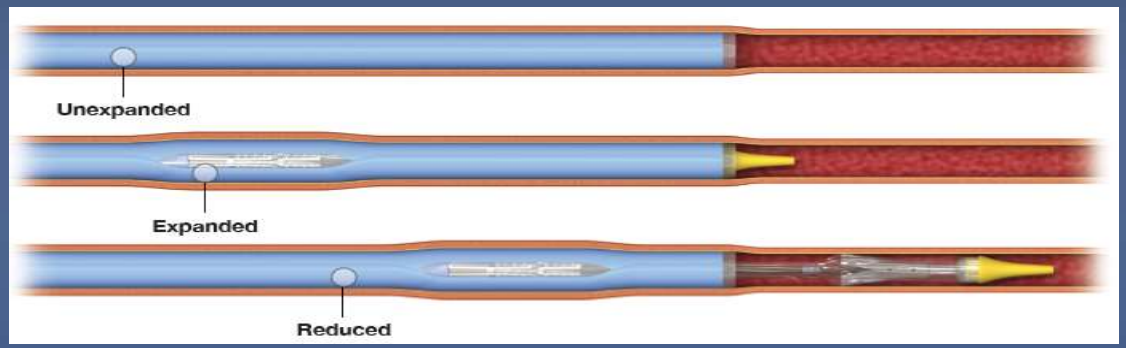
- New indicators and symbols
- Balloon lock allows user to manually lock / unlock balloon catheter

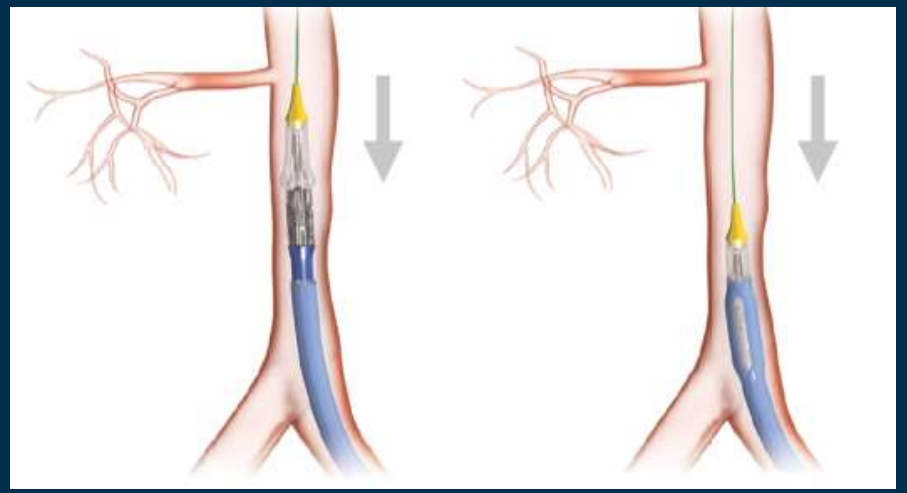


Edwards eSheath Introducer Set

Dynamic Expansion Mechanism

- The Dynamic Expansion Mechanism (DEM) is designed for low profile entry and exit





The DEM Feature Allows for Valve Retrievability*

*The Edwards SAPI[illegible] and fine adjustment procedure and prior to valve deploym[illegible] emoved together with valve in the body of the eSheath introducer.

Valve Alignment

- Slowly rotate the Fine Adjustment Wheel towards you to center the THV exactly between the Valve Alignment Markers with **no gap or overlap**
- Fine Adjustment Indicator shows how much fine adjustment is left

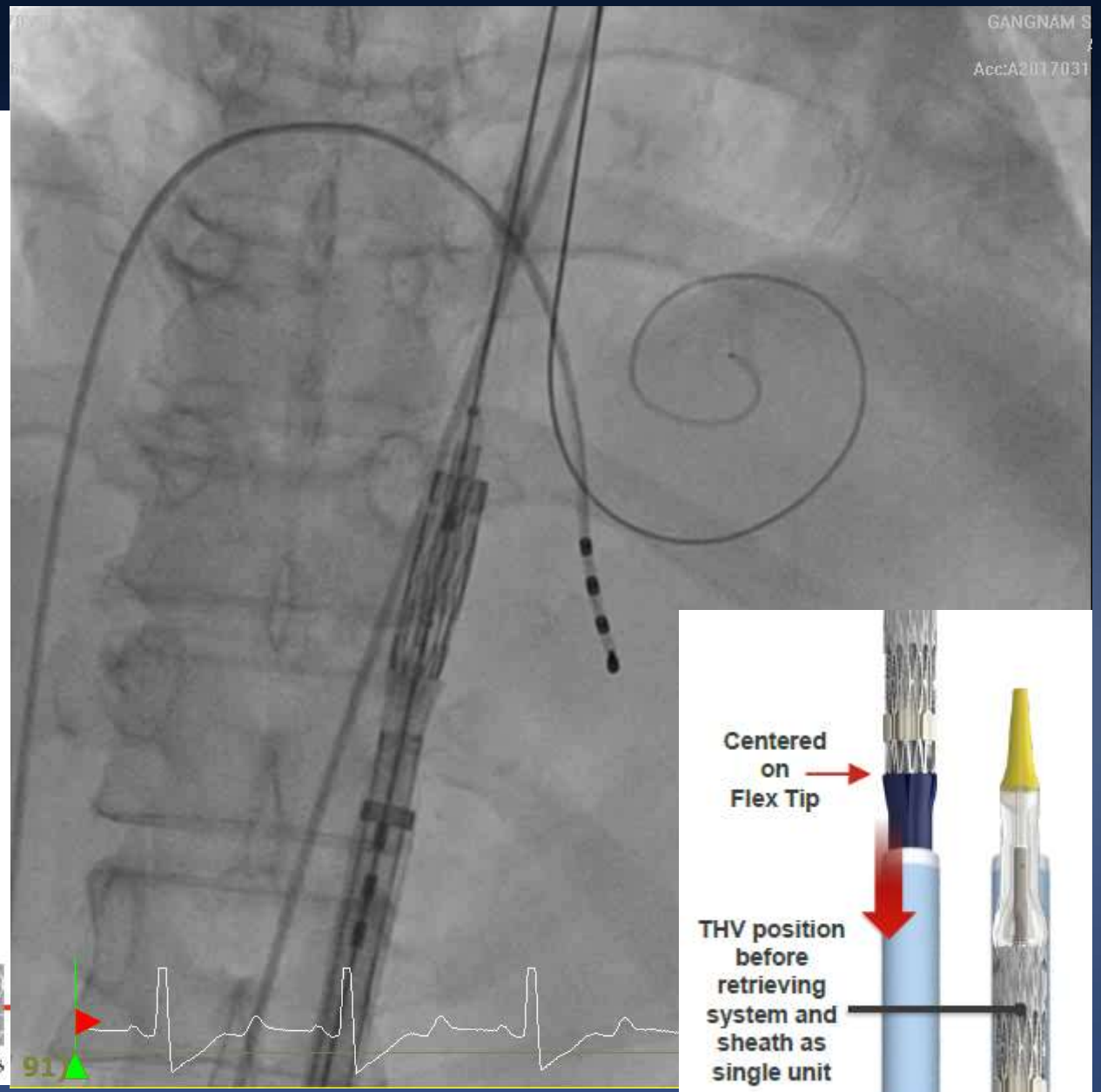
- If additional fine adjustment is needed, unlock and rotate the Fine Adjustment Wheel away from you until part of the Warning Marker is visible and relock

NOTE:
A gap between the THV and distal Valve Alignment Marker may result in difficulty crossing. An overlap cannot be reversed and may prevent proper THV deployment.

NOTE:
Fine Adjustment Wheel functions only when the Balloon Lock is locked

NOTE:
Do not bend or apply torque to the proximal end of the balloon catheter throughout the procedure

WARNING:
Do not position the THV past the distal Valve Alignment Marker. This will prevent proper THV deployment.

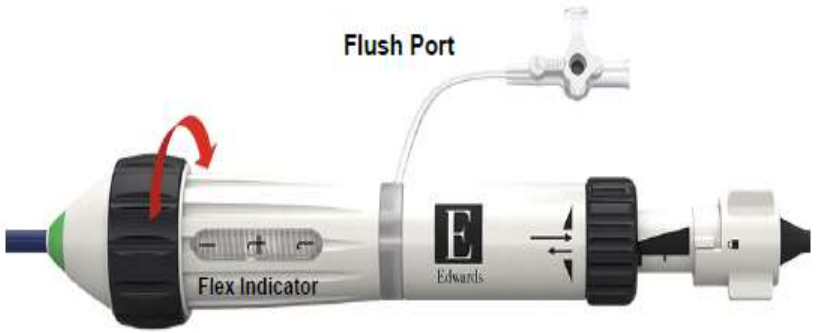


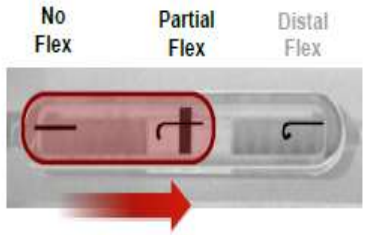
Tracking Over Aortic Arch

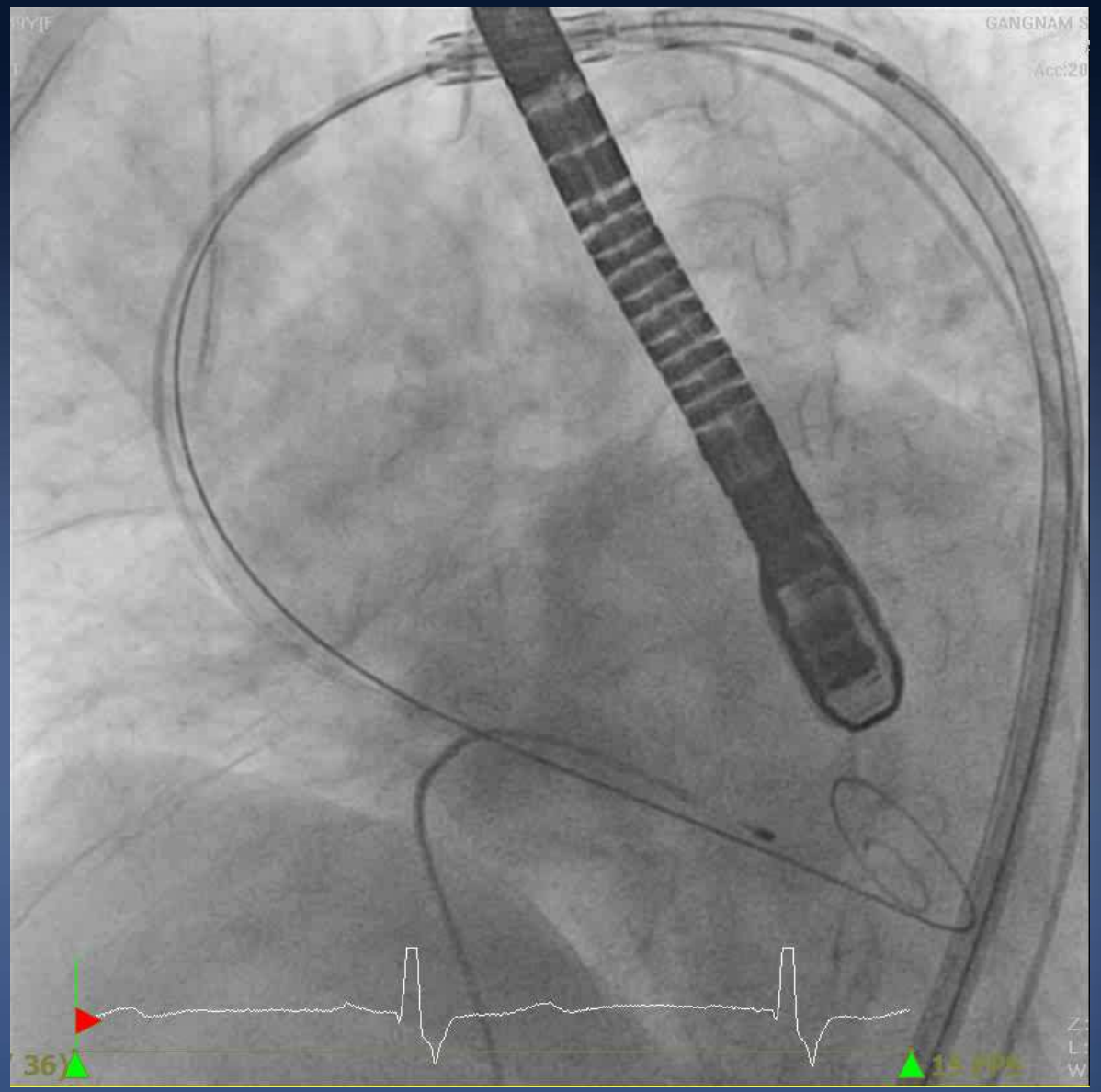
Additional Considerations

- **Do not overflex** while tracking over aortic arch
- To prevent kinking of the delivery system, do not torque the handle while rotating the flex wheel
- Ensure the **Edwards logo faces upward** throughout flexing and tracking

NOTE:
The Flex Indicator may be used as a reference to assess degree of articulation in the delivery system throughout the procedure







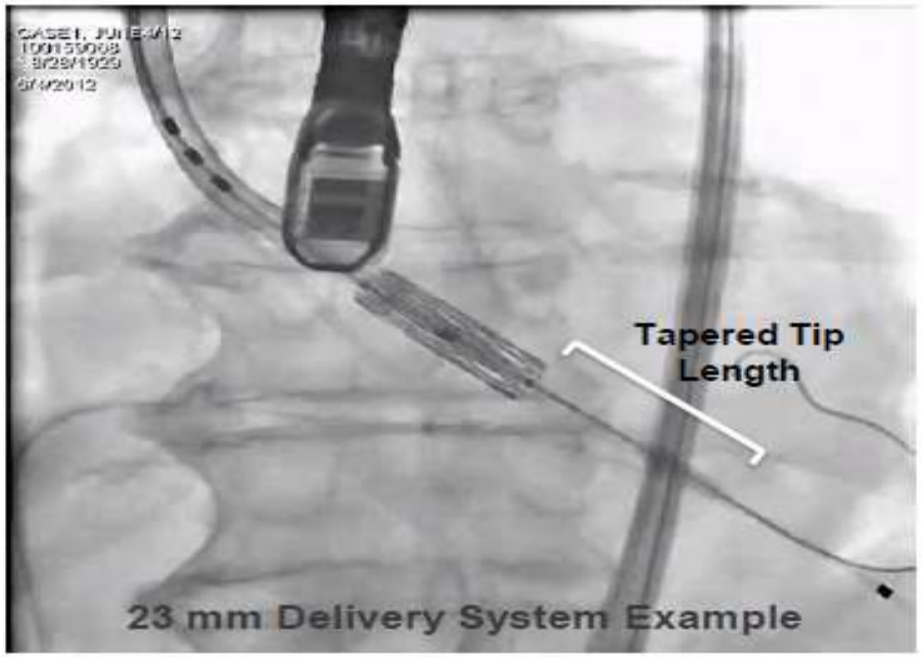
Crossing Native Valve

- Ensure the flex catheter tip is flush with the THV for support during crossing
- Be patient! **Do not force the THV.**
- Use **short movements** to prevent "jumping" of the THV into the ventricle
- Use RAO or AP projection to ensure wire position is maintained in the ventricle

NOTE:
The wire must extend beyond the distal end of the delivery system and the stiff portion of the guidewire should be incorporated in the curved section of the wire at all times

Tapered Tip Length Comparison

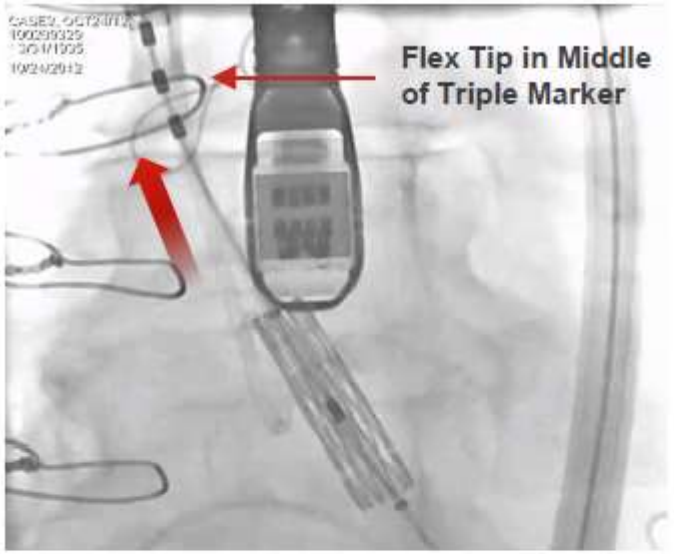
	23 mm	26 mm	29 mm
Edwards NovaFlex+	36 mm	37 mm	44 mm
Edwards Commander	32 mm	32 mm	36 mm



Pull Back Flex Catheter

Additional Considerations

- Placing Flex Tip on the middle of the Triple Marker will enable fine adjustment in either direction during THV positioning
- Positioning Flex Tip on the Triple Marker prior to THV deployment will help maintain stability while ensuring unobstructed inflation during deployment
- Partially unflexing may help when pulling back the Flex Catheter



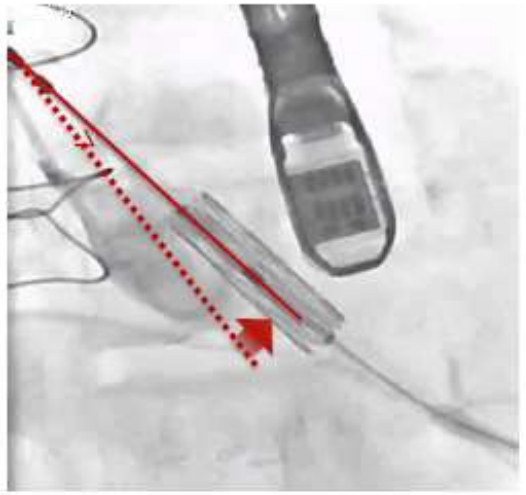
NOTE:
Re-lock the device after unlocking every time

SAPIEN 3 Valve Positioning

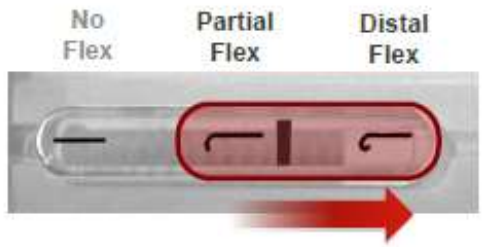
Use the Distal Flex to Position the THV Coaxial

- Slowly rotate the Flex Wheel away from you to help adjust the **THV coaxial** within the native valve
- Wire manipulation or slight rotation of the delivery system may help

NOTE:
Using multiple angiographic views may help in coaxial positioning



NOTE:
The Flex Indicator may be used as a reference to assess articulation in the delivery system throughout the procedure



Flex Wheel

SAPIEN 3 Valve Positioning

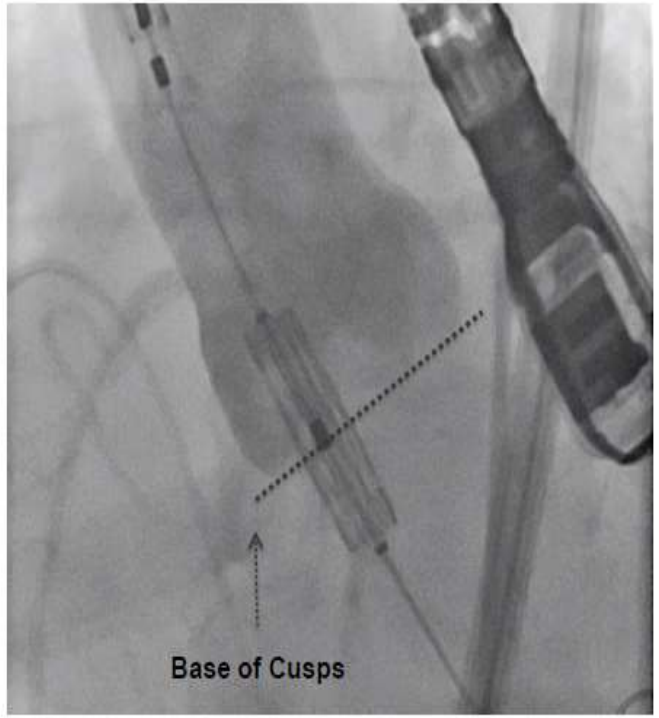
SAPIEN 3 Valve Positioning

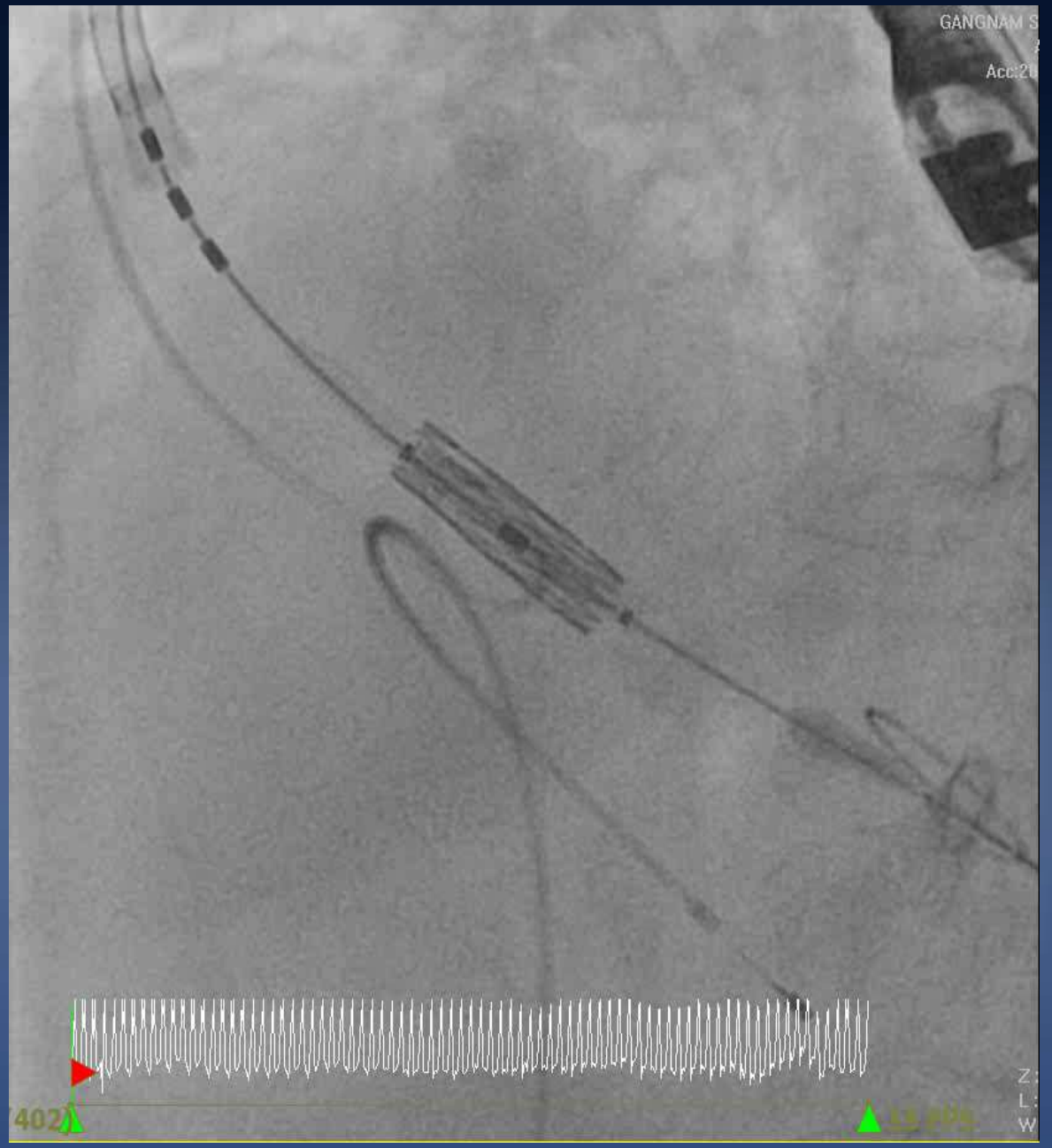
Position THV with Bottom of Center Marker at Base of Cusps

- The inflow of the SAPIEN 3 valve will **be further in the ventricle** when positioned (compared to SAPIEN XT valve) prior to THV deployment

- Use the Center Marker to help aid in THV positioning, **but not as a reference during THV deployment** (Center Marker on delivery system not THV)

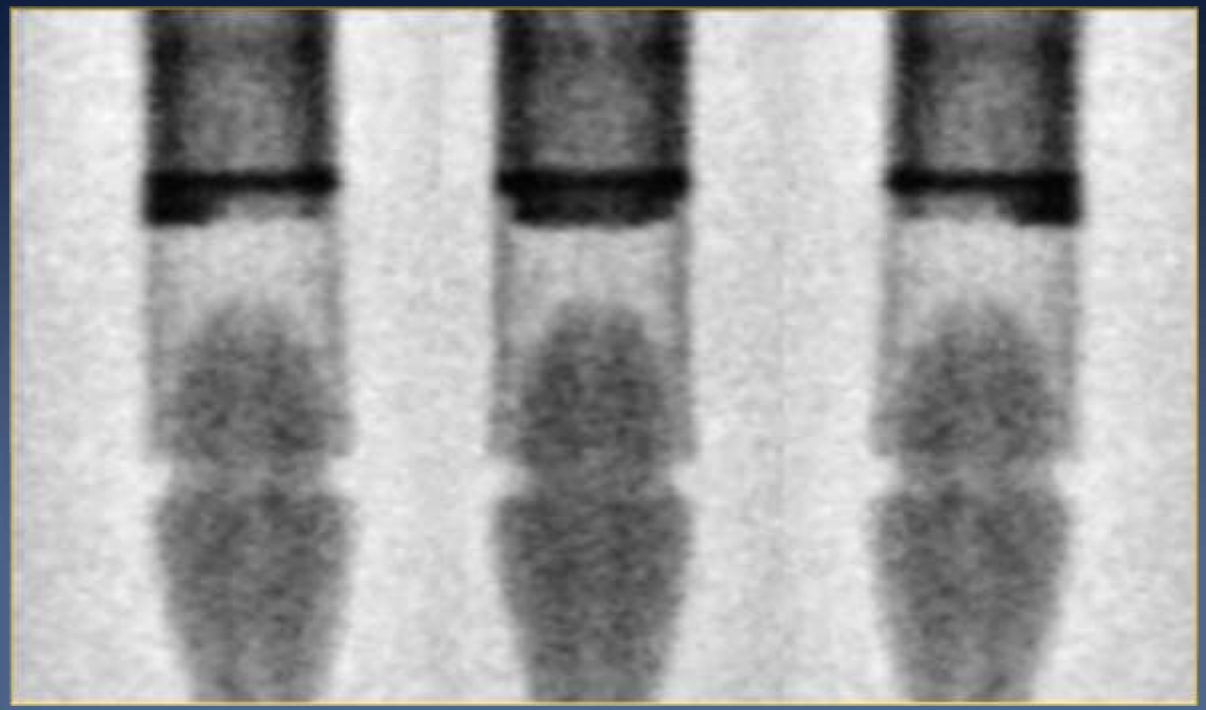
NOTE:
A Center Marker has been added to help aid in the initial positioning of the THV

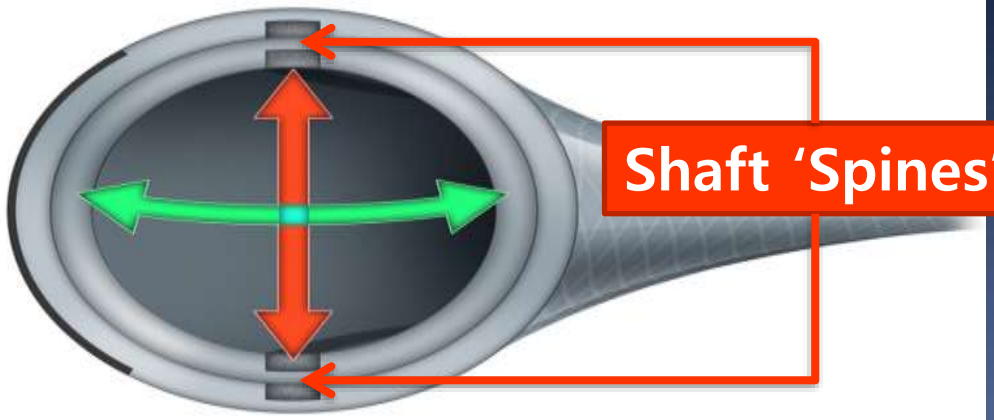




Addressing navigation challenges

HAT MARKER ORIENTATION & PREFERRED NAVIGATION PLANE





Cross section of catheter shaft
(excluding the stability layer)

- The hat marker is a wide band that runs approximately 1/3 the circumference of the radiopaque marker band
- The hat marker position can be used to interpret the system’s preferred navigation plane due to it’s relation to the shaft spines

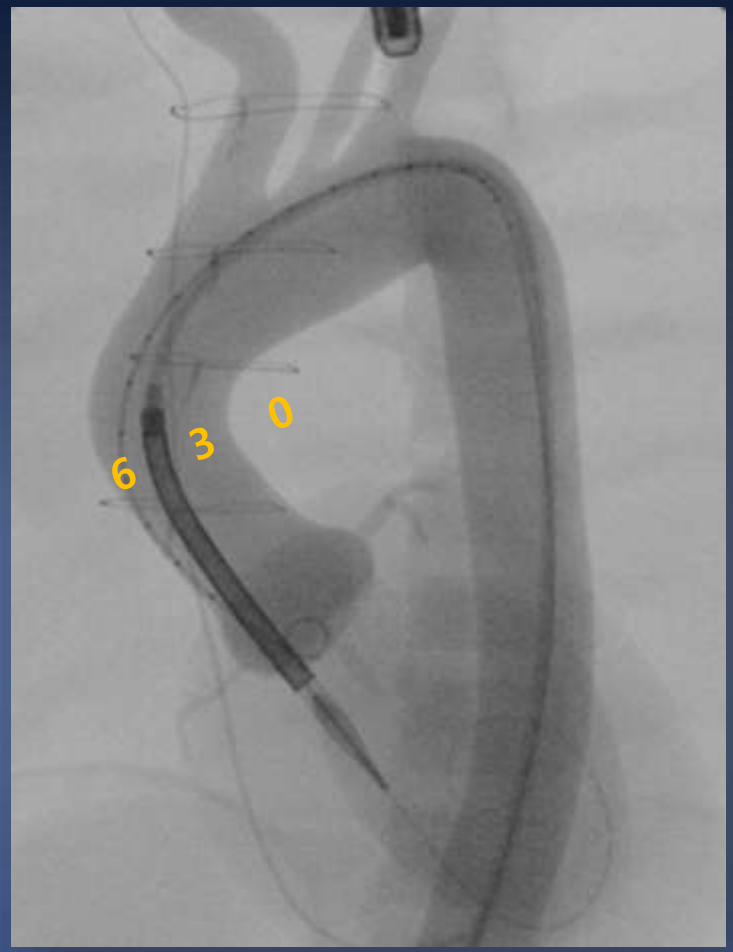
Capsule Position and Initial Deployment Depth

- Initial depth adjustments based on capsule position within t he ascending aorta may facilitate implant at target depth on first deployment.

Steps:

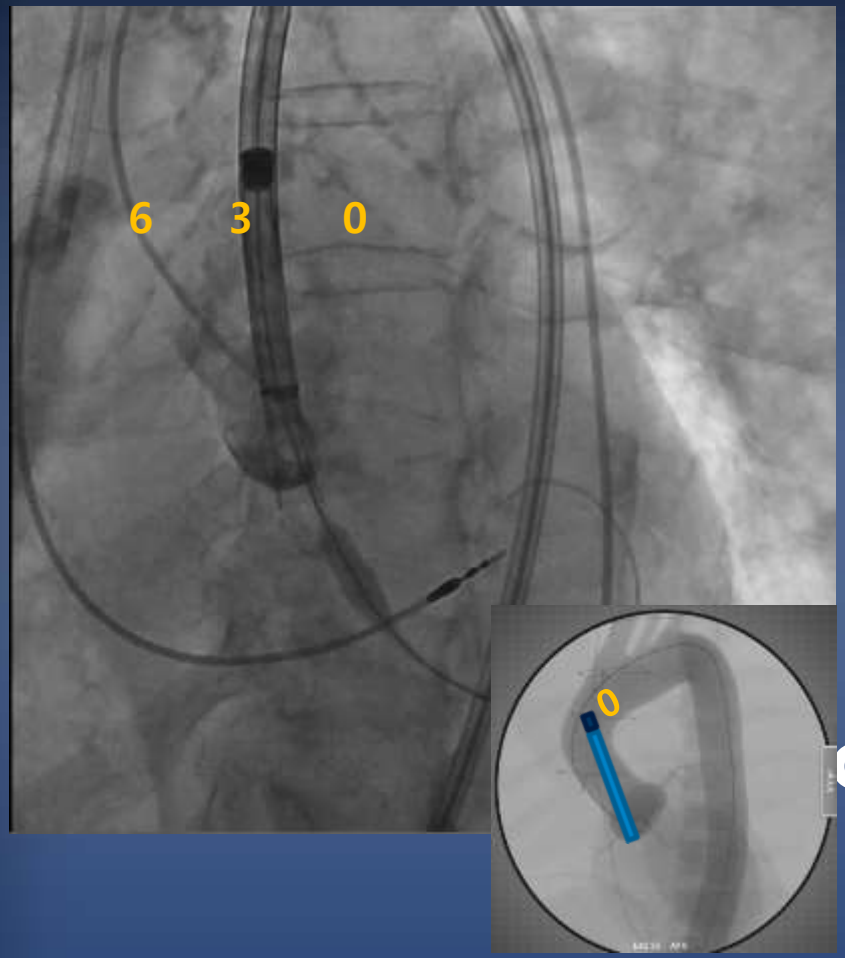
- Assess position of capsule in ascending aorta at the level of paddle attachment.
- Adjust to an initial starting depth of 0, 3, or 6 mm, accordin g to the following:

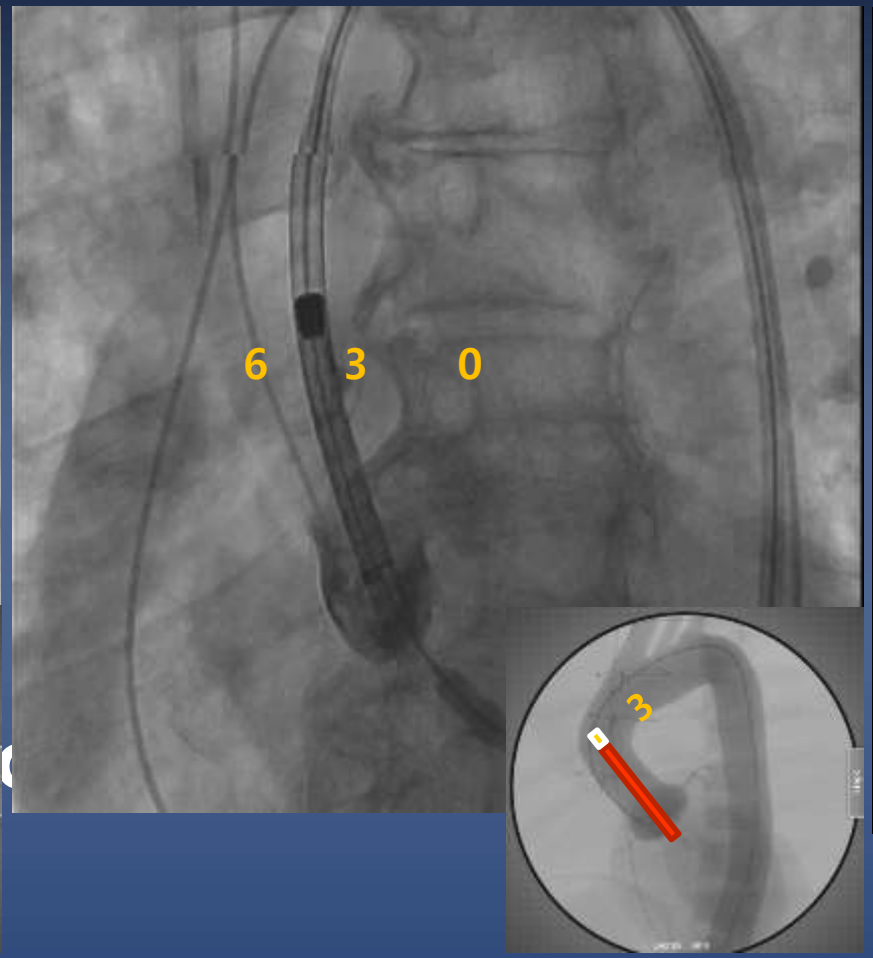
Capsule Position in Ascen ding Aorta	Initial Depth
Lesser Curve	0 mm
Central	3 mm
Greater Curve	6 mm

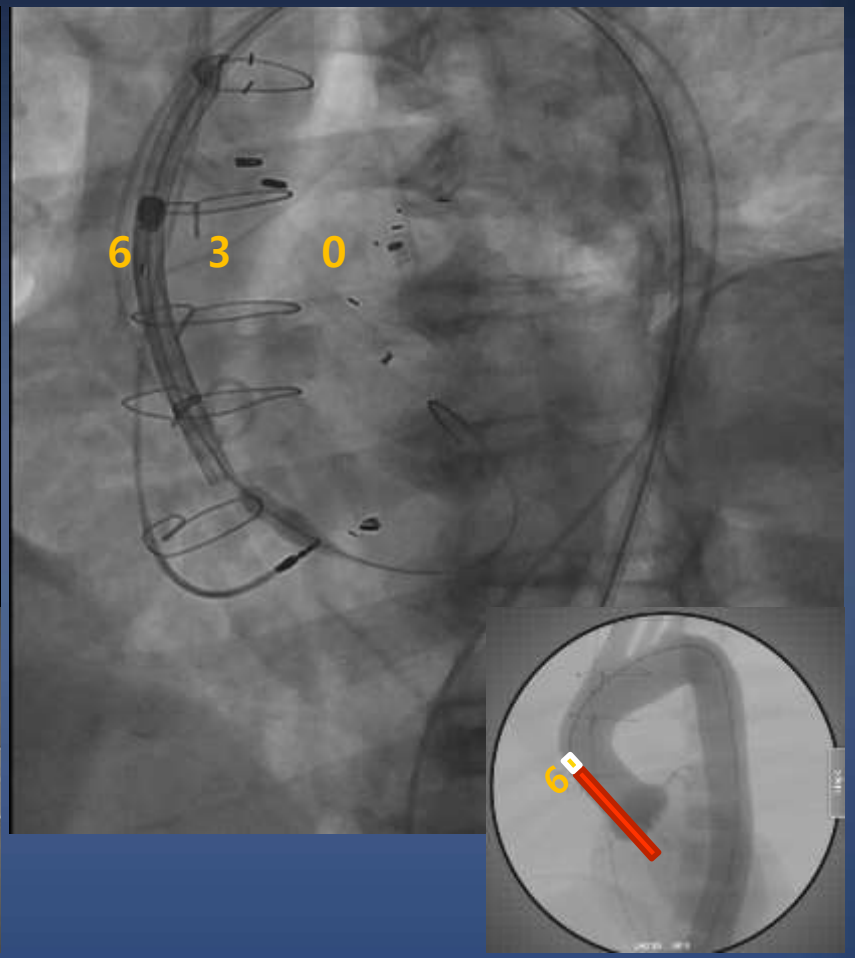


Initial Deployment depth Determination

CASE EXAMPLES



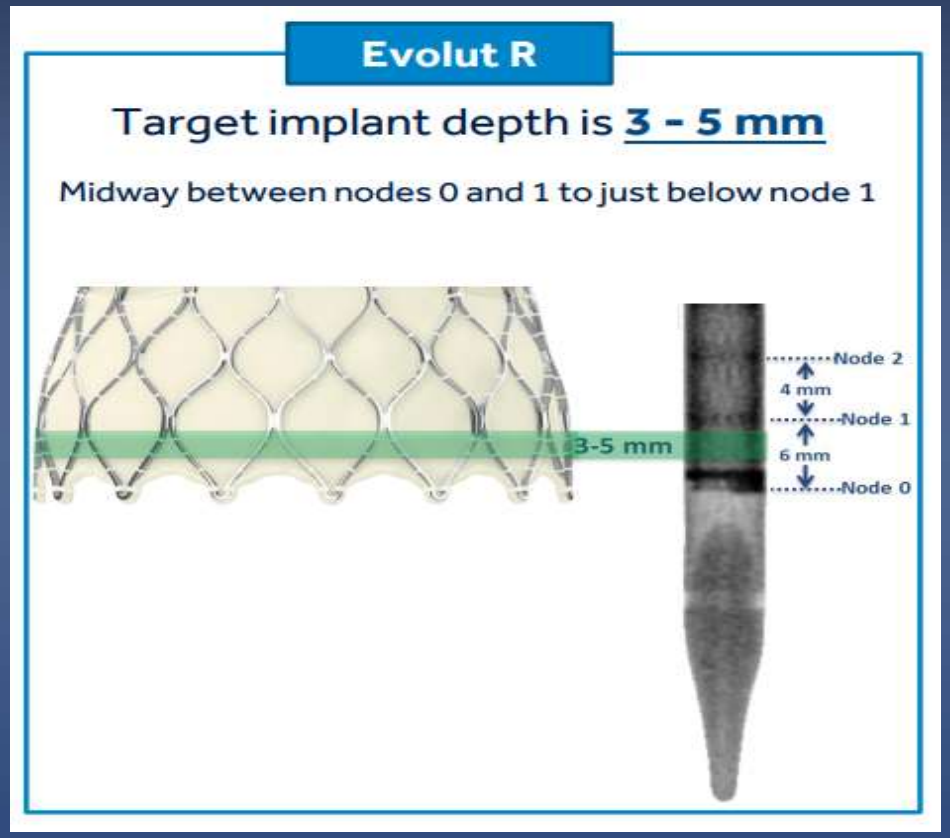


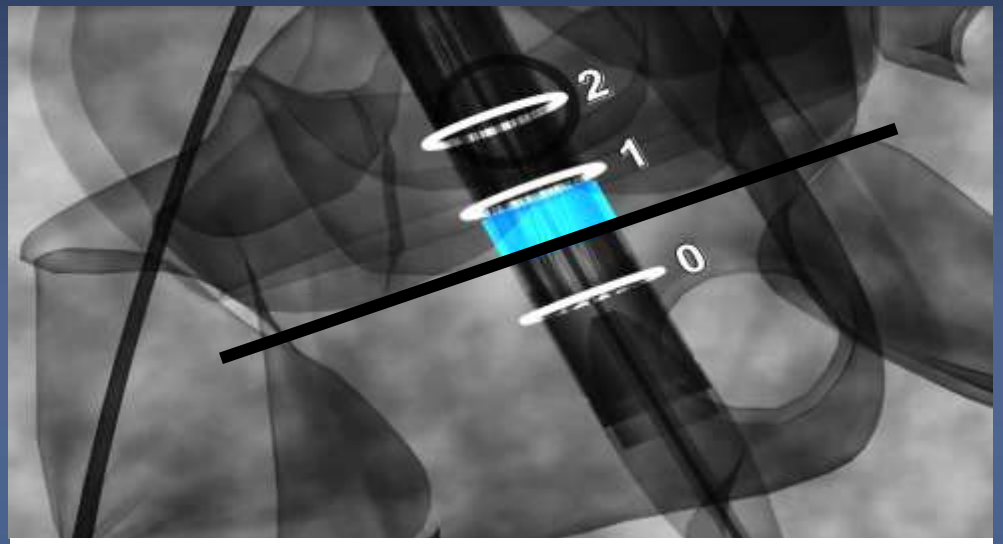


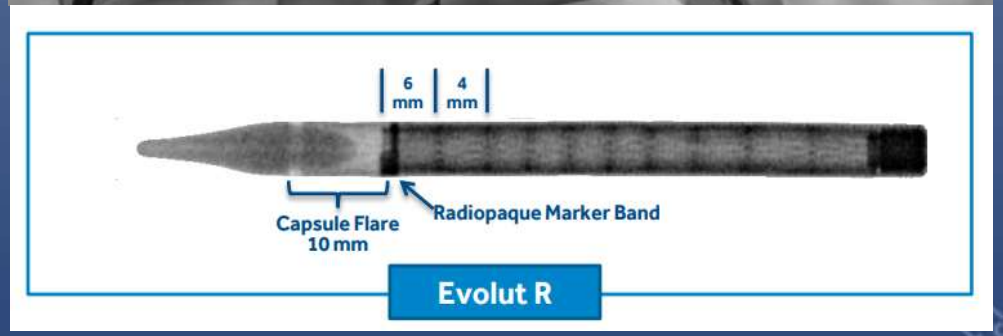
Start deployment at target implant depth

Target implant depth is 3 - 5 mm

- Midway between node 0 (inflow edge of frame) and node 1 to just below node 1
- Note: due to minor valve frame length differences, ensure to assess valve position from frame inflo w (node 0) and not the edge of the marker band:



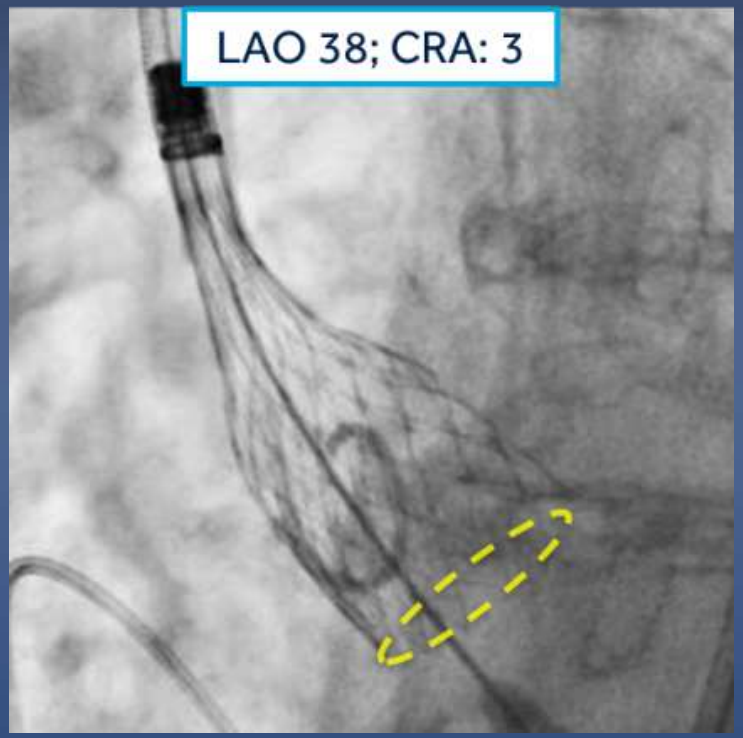


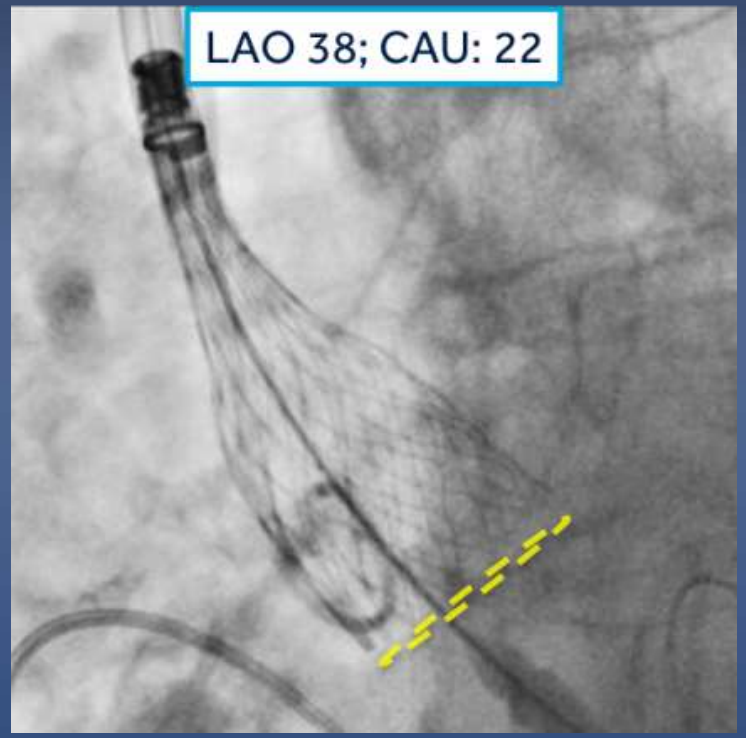


Deploy to Point of No Recapture

Just before the point of no recapture, evaluate valve position and performance

- Adjust projection to remove parallax in inflow to precisely determine implant depth
- Assess position and performance using angio and echo to determine to deploy or r ecapture

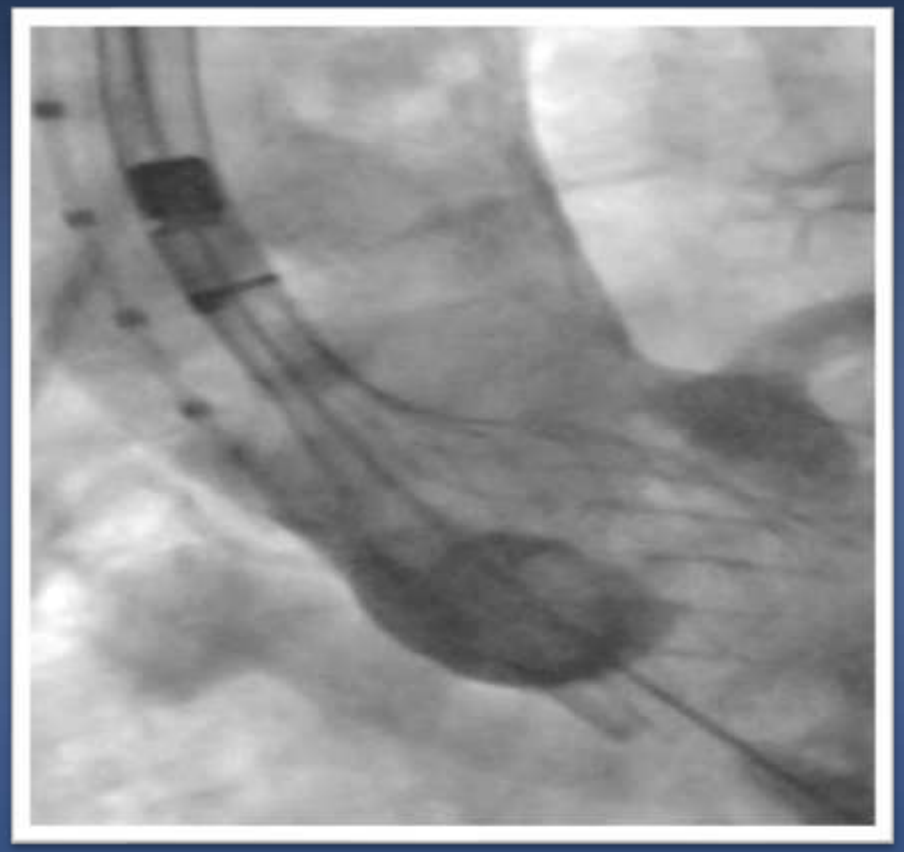




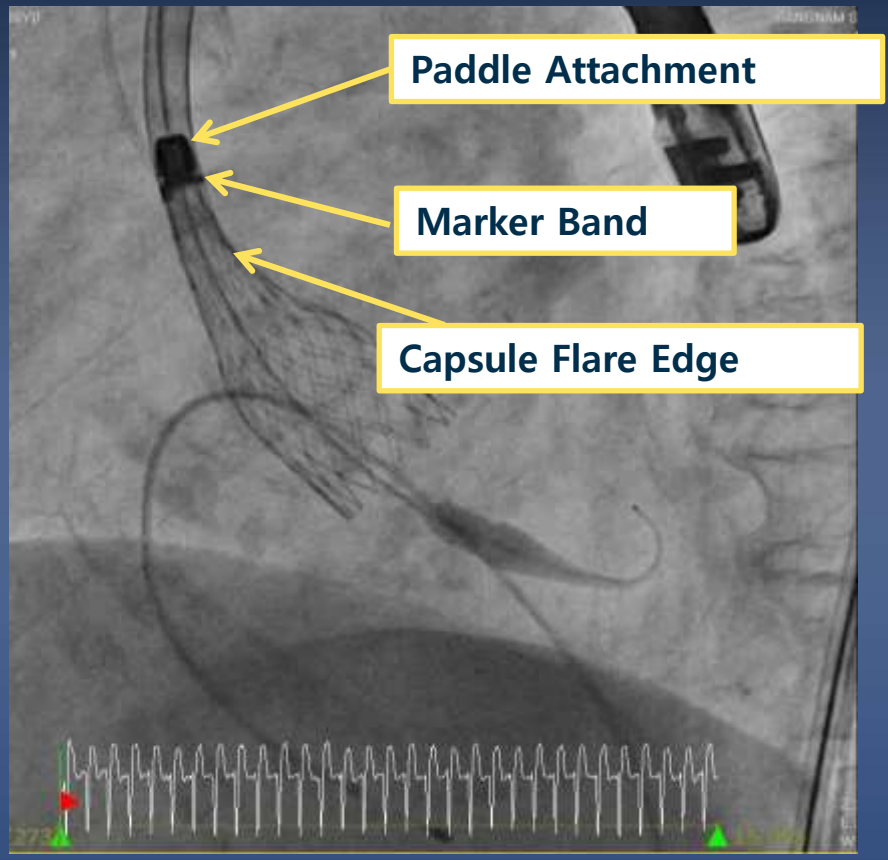
Control During Deployment

ABILITY TO RECAPTURE AND REPOSITION

The Evolut PRO DCS provides the option to **recapture and reposition** up to three times before reaching the 'Point of No Recapture'



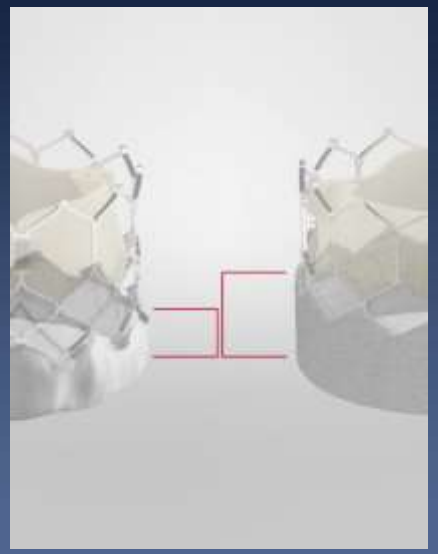
Tactile Indicator
~ 2/3 Deployment



Point of No Recapture
~ 80% Deployment

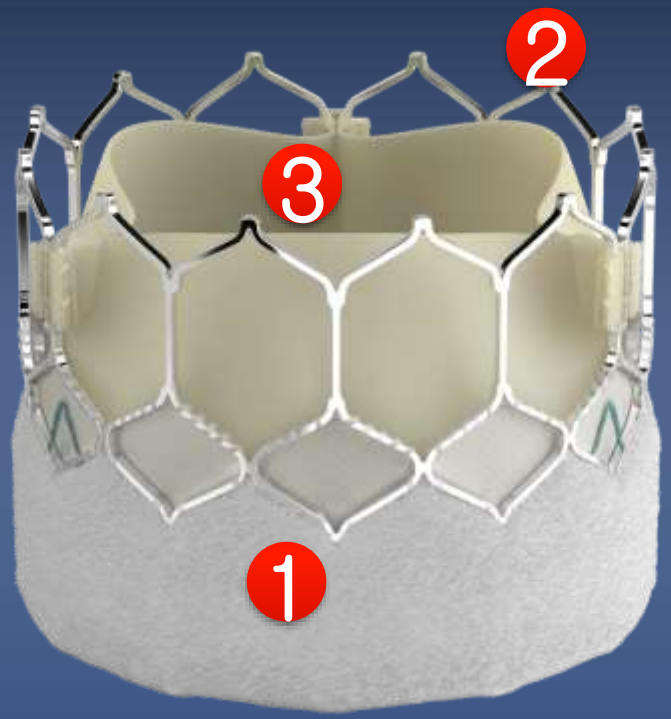
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

featuring a taller, textured PET outer skirt



Increased outer skirt height

- Approximately 40% taller outer skirt*
- Same inner skirt height*



Taller, Textured PET Outer Skirt 1

- Approximately 40% increased outer skirt height*
- Same inner skirt height*
- Textured PET material
- Similar biocompatible material as the SAPIEN 3 valve

Frame Design 2

- Frame geometry designed for an ultra-low delivery profile with high radial strength for circularity and optimal haemodynamics

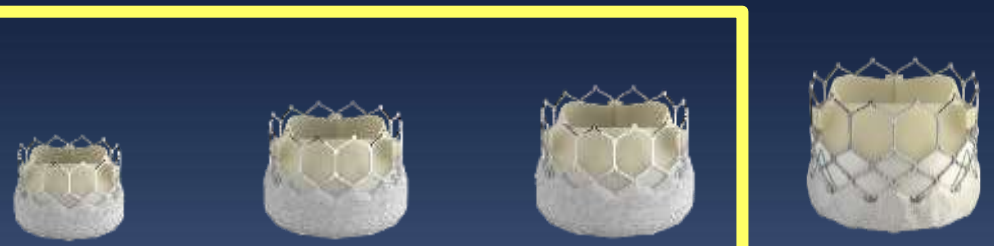
Bovine Pericardial Tissue 3

- Utilises the same bovine pericardial tissue and processes as Edwards surgical valves

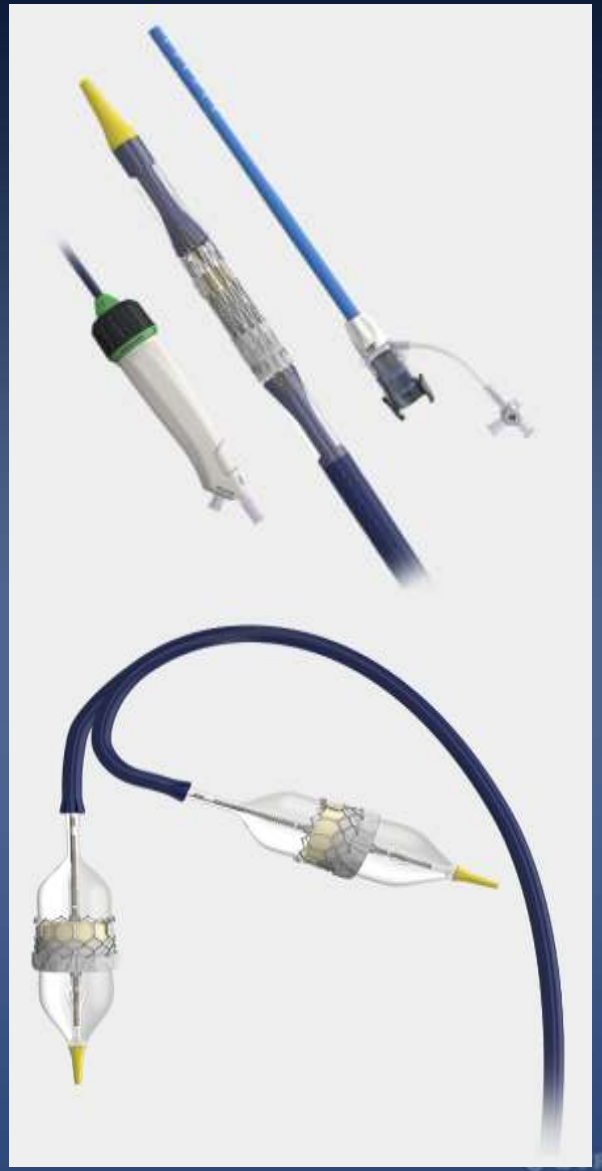
** Compared to the SAPIEN 3 valve*

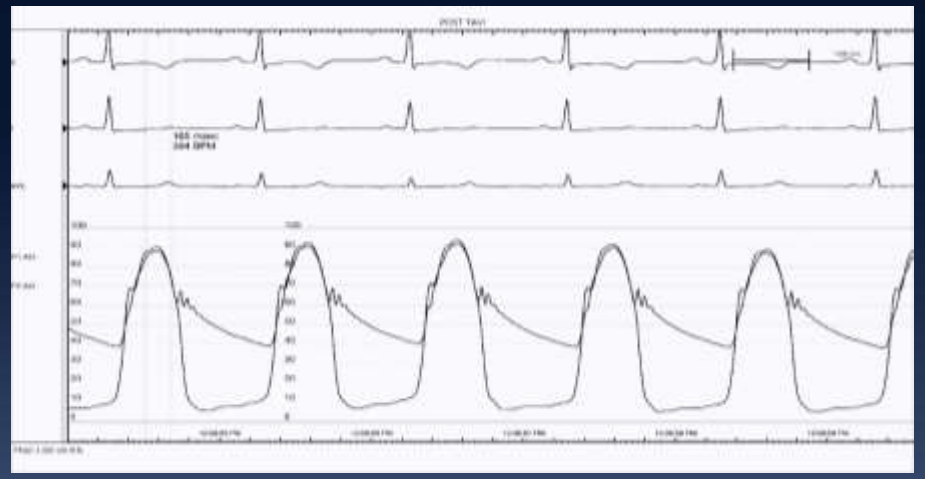
Edwards SAPIEN 3 Ultra System

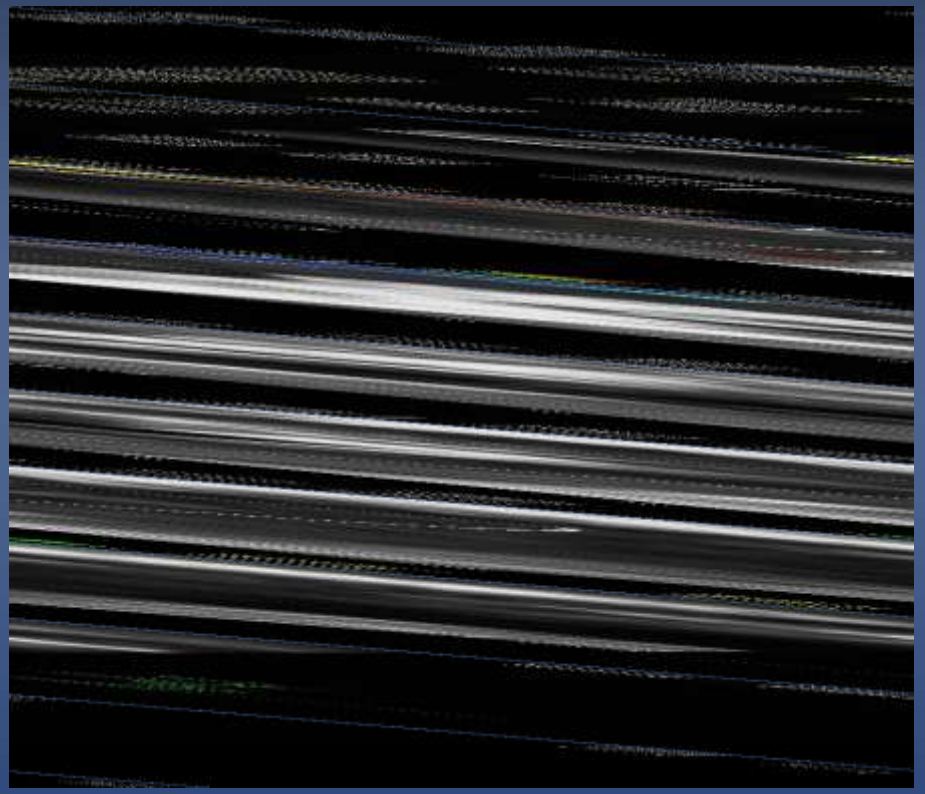
Complete range of valve sizes

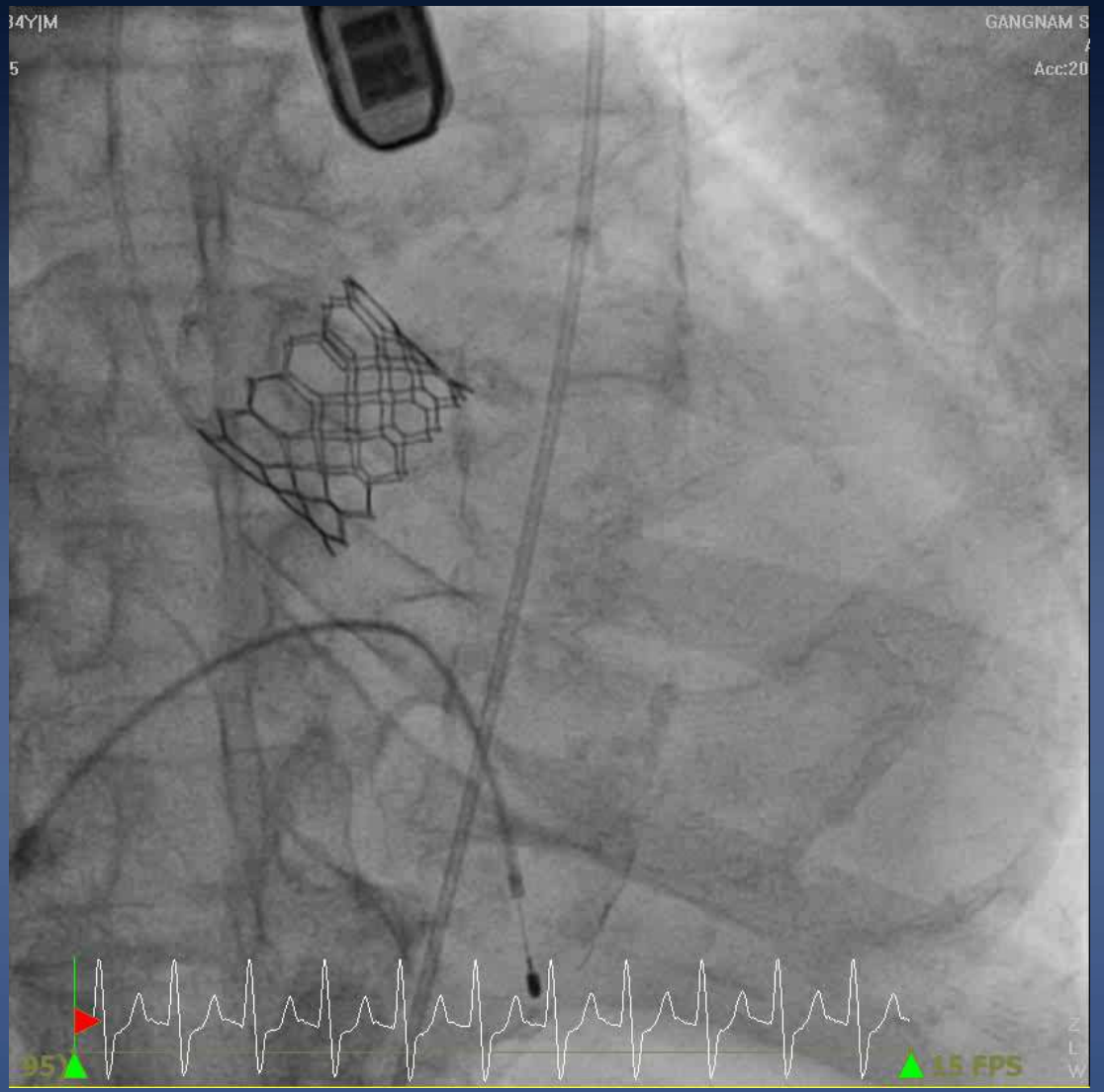


Valve size	20 mm	23 mm	26 mm	29 mm
Valve	SAPIEN 3 Ultra	SAPIEN 3 Ultra	SAPIEN 3 Ultra	SAPIEN 3
Native Annulus Size by TEE*	16 – 19 mm	18 – 22 mm	21 – 25 mm	24 – 28 mm
Native Annulus Area (CT)*	273 – 345 mm^2	338 – 430 mm^2	430 – 546 mm^2	540 – 683 mm^2
Area-derived Diameter (CT)*	18.6 – 21 mm	20.7 – 23.4 mm	23.4 – 26.4 mm	26.2 – 29.5 mm





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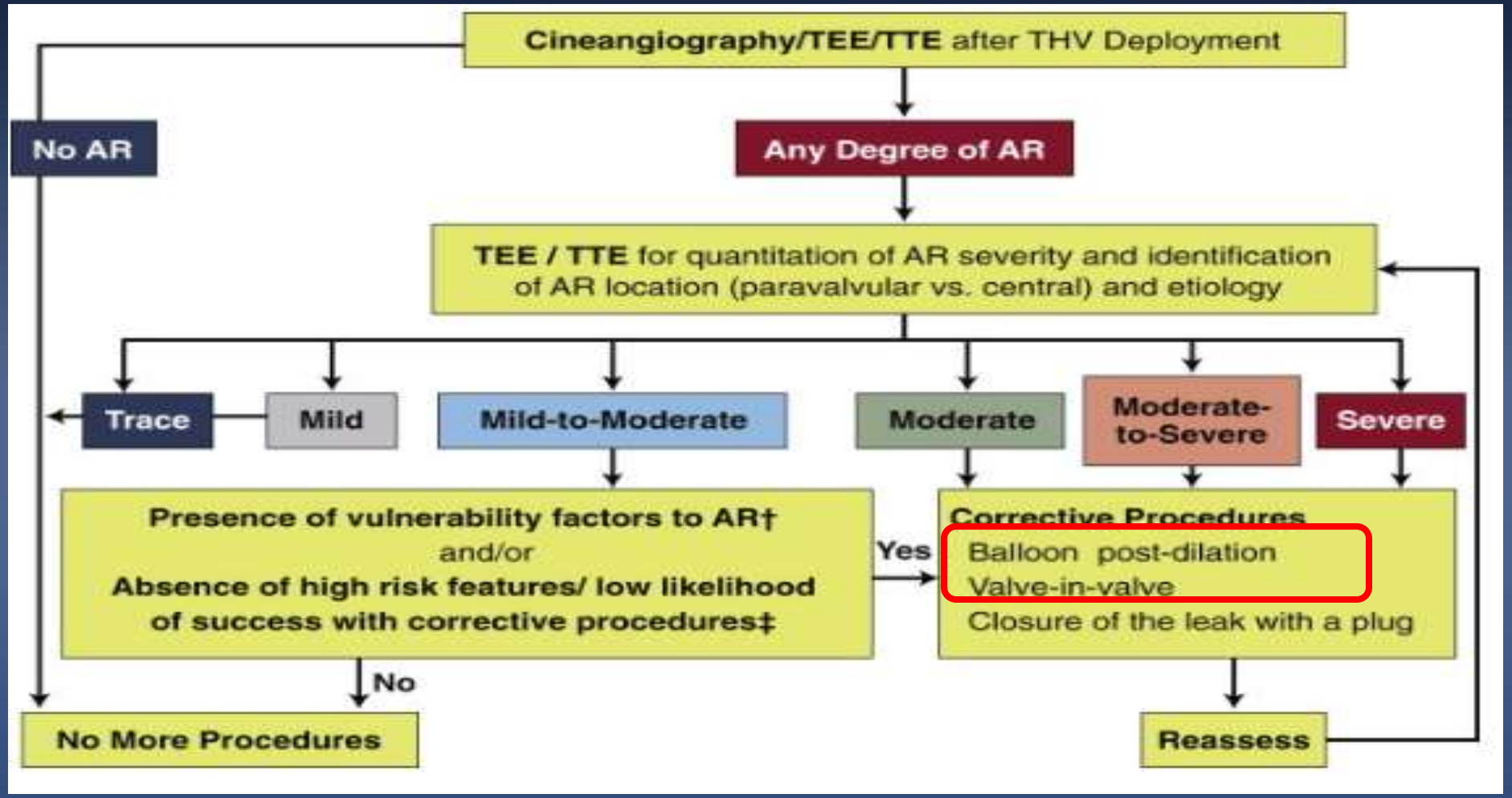
Puncture to closure

1. Puncture, Pre-closure, TPM back up
2. Aortogram, LV Wire crossing, Pressure gradient check
3. LV support wire exchange, sheath insertion
4. TAVR valve check, Pre balloon
5. Valve positioning, Deployment
6. Post balloon, Device Retrieval
7. Femoral artery closure

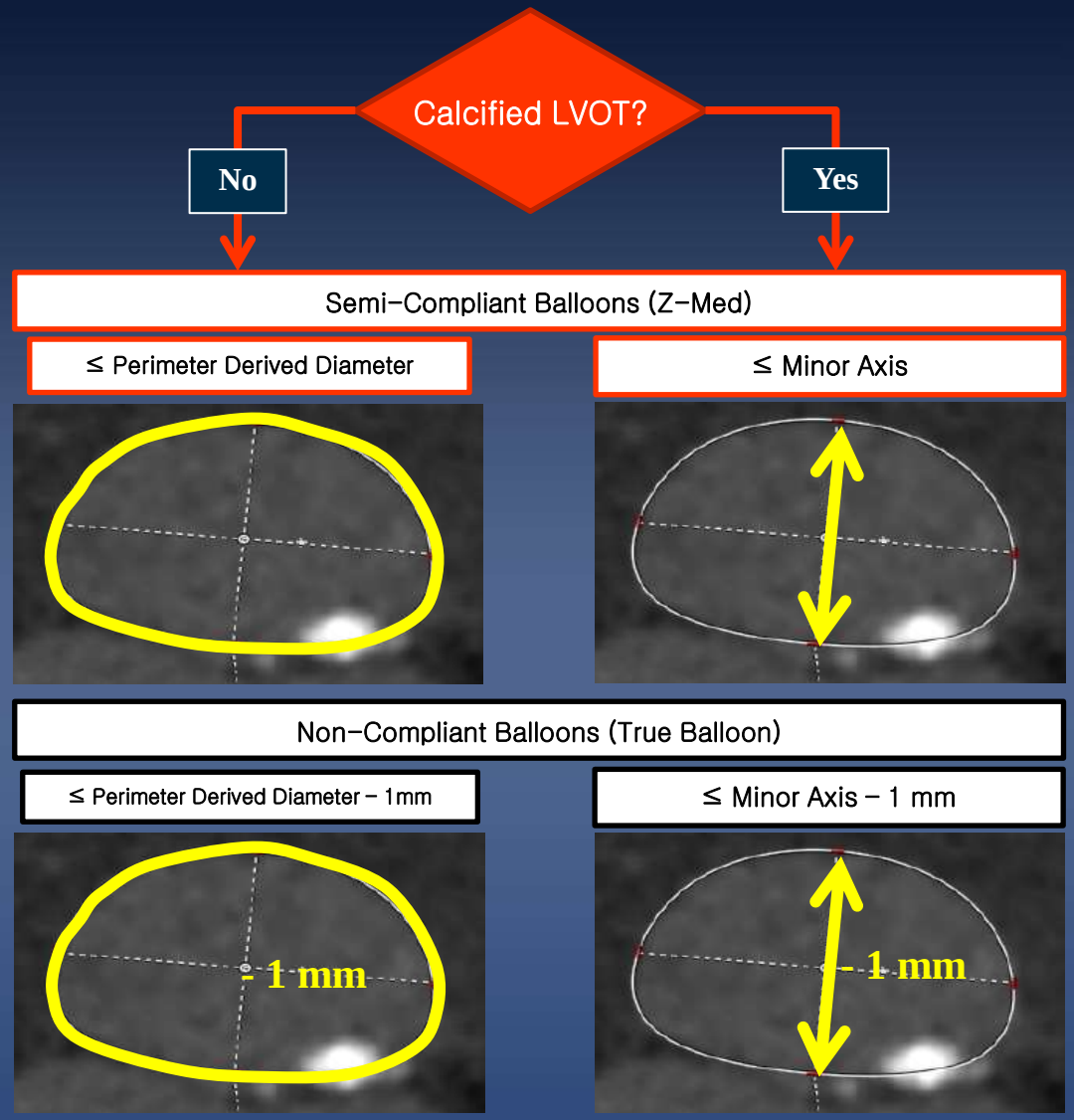
Algorithm for the Intraprocedural Management of PVR



Bicuspid Procedural Considerations

POST-BAV GUIDANCE

- **PVL > mild, high gradient, and frame infolding can be addressed with post-BAV**
  - If there is calcium in the LVOT, the maximum balloo n size should be no greater than the minor axis dia meter of the annulus
  - If there is no calcium in the LVOT, the balloon size c an be sized up to the perimeter derived diameter of the annulus
- **As with pre-BAV, exercise caution when sizing the ball oon to prevent annular rupture during post BAV – esp ecially in cases with dense focal calcium**
  - NOTE: As with pre-BAV, the fused leaflets typically w on't yield during balloon inflation, causing the ballo on to expand towards the non-fused sinus



Sheath Removal

Appearance of the Sheath Upon Removal

- Some curvature of the sheath may be present
- Ripples along the seam are normal
- An open tip and seam are to be expected. It is important to remember through the procedure to

– Initially insert the introducer sheath with the Edwards logo facing up

– Suture the sheath in place

– Once completed, remove the sheath completely with the Edwards logo facing up

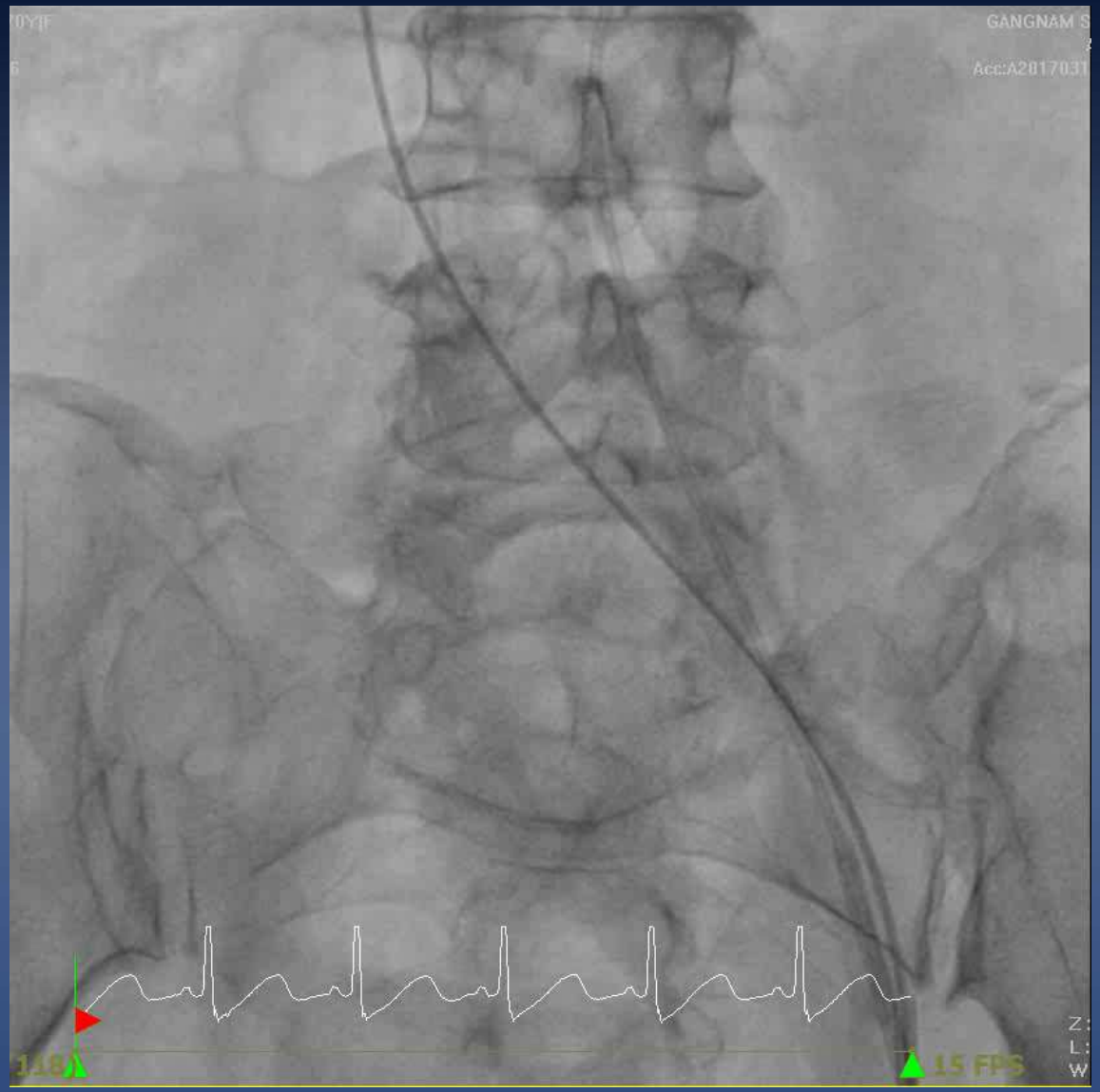
– Remove the sheath without torquing

– Do not reinsert the sheath at any time

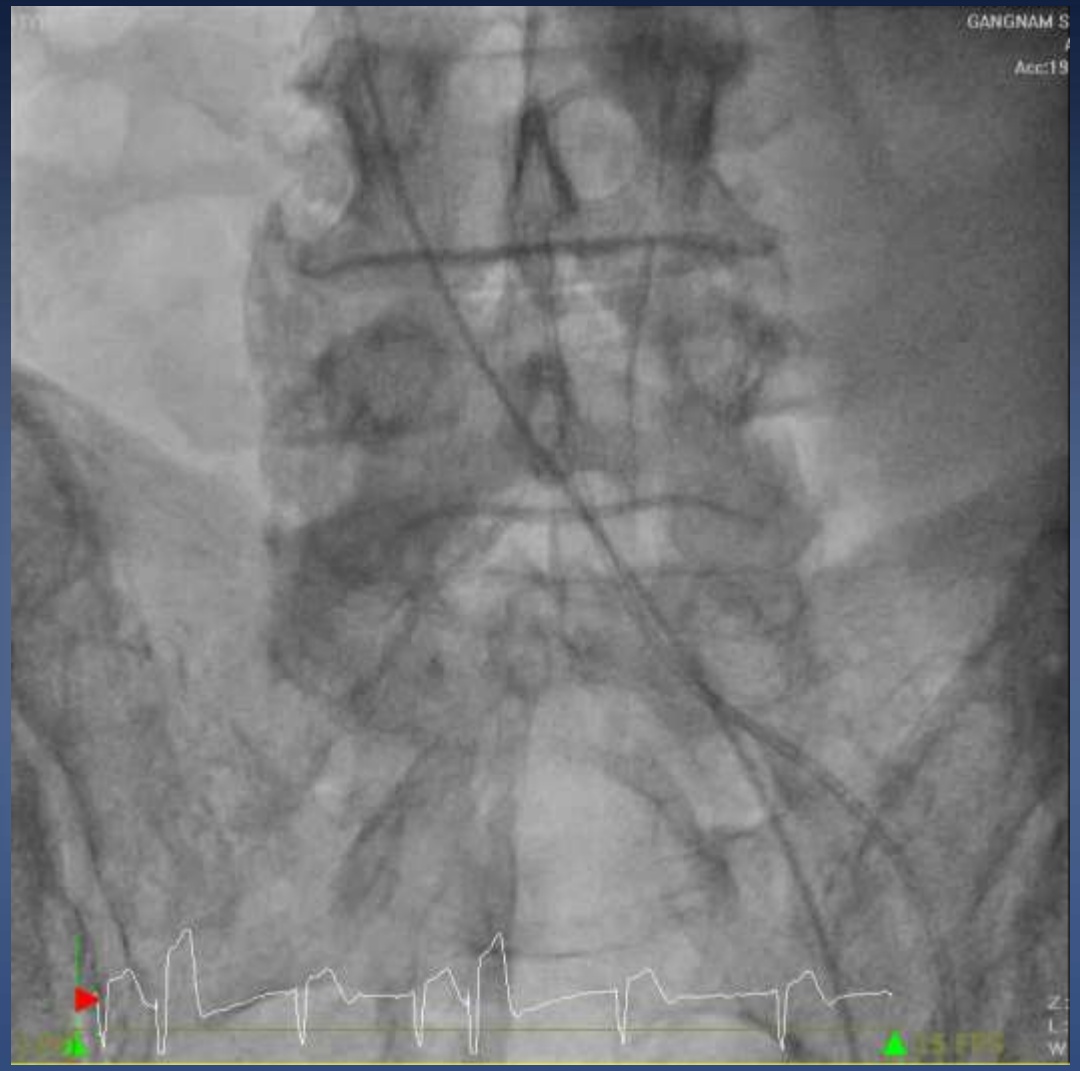
Puncture to closure

1. Puncture, Pre-closure, TPM back up
2. Aortogram, LV Wire crossing, Pressure gradient check
3. LV support wire exchange, sheath insertion
4. TAVR valve check, Pre balloon
5. Valve positioning, Deployment
6. Post balloon, Device Retrieval
7. Femoral artery closure

Post Procedure peripheral angio



Post Procedure complication



Two TAVR Options