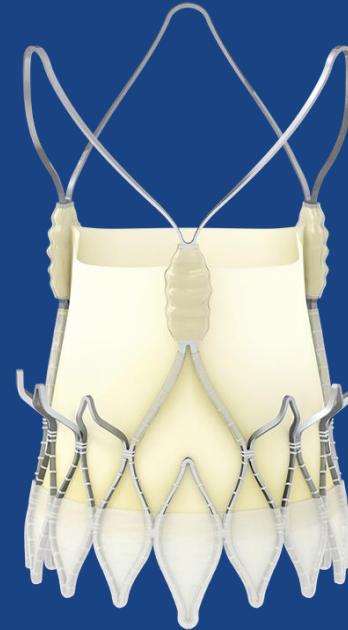


ACURATE *neo*™

Aortic Valve System

IMPLANTATION PROCEDURE



All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. This material is not intended for use or distribution in France, USA and Japan.

- These materials are intended to describe common clinical considerations and procedural steps for the on-label use of ACURATE *neo*[™] and ACURATE TF[™] Delivery System as well as current standards of care for certain conditions.
- As patients and their medical circumstances vary, the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care are solely depend on the physician's professional judgment in light of all available information for the case at hand.
- Prior to use, please review ACURATE *neo*[™] and ACURATE TF[™] Delivery System Directions for Use for full operating instructions.

Overview

Overview of ACURATE *neo*™

Deployment

Introduction and Positioning

Removal and final result

From Start-up to Global Player

> 11000

Valves
implanted

> 2200

Patients included
in clinical trials

> 20

Countries
globally

3

TAVI system in
Europe*

ACURATE neo™
Transfemoral Aortic Valve System



ACURATE neo™
Transapical Aortic Valve System

*Source: BIBA, Q4/2016.

ACURATE *neo*™ Deployment

Boston
Scientific



Advancing TAVI – Intuitive Predictable

- **Intuitive Procedure**

Self-expanding, Nitinol supra annular valve

- **Predictable Release**

Safe two-step, top-down deployment

- **Stable Positioning**

Effective self-alignment and self-sealing

- **Excellent Outcomes**

Very short implantation times combined with very low mortality, complication rates, low gradients and very low new pacemaker rates¹



1. Real-world experience using a 2nd generation self-expanding prosthesis: 1-year outcomes of 1000 patients enrolled in the SAVI-TF registry: Prof. Dr H. Moellmann, presented EuroPCR 2017

Product Highlight

Valve Design: Self-Expanding & Supra-Annular

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STABILIZATION ARCHES

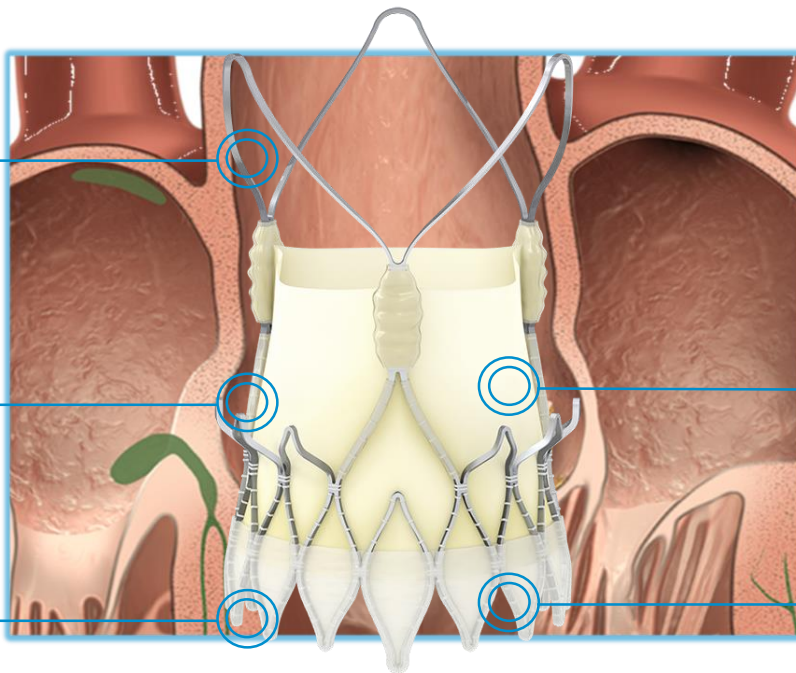
- Axial self-alignment of valve within the native annulus

UPPER CROWN

- Minimal supra-annular anchoring
- Caps native leaflets and provides coronary clearance

LOWER CROWN

- Minimal protrusion into LVOT
- Low risk of conduction system interference.



SUPRA-ANNULAR VALVE

- Low gradients¹
- Porcine pericardium leaflets
- BioFix™ anti-calcification process

ANTI-PVL SKIRT

- Sealing against paravalvular leak

1. Real-world experience using a 2nd generation self-expanding prosthesis: 1-year outcomes of 1000 patients enrolled in the SAVI-TF registry: Prof. Dr H. Moellmann, presented EuroPCR 2017

Valve Measurements



Stent body height:
18 - 19 mm

Landing zone:
≈ 7 mm

Total height:
48 - 51 mm

ACURATE *neo*™

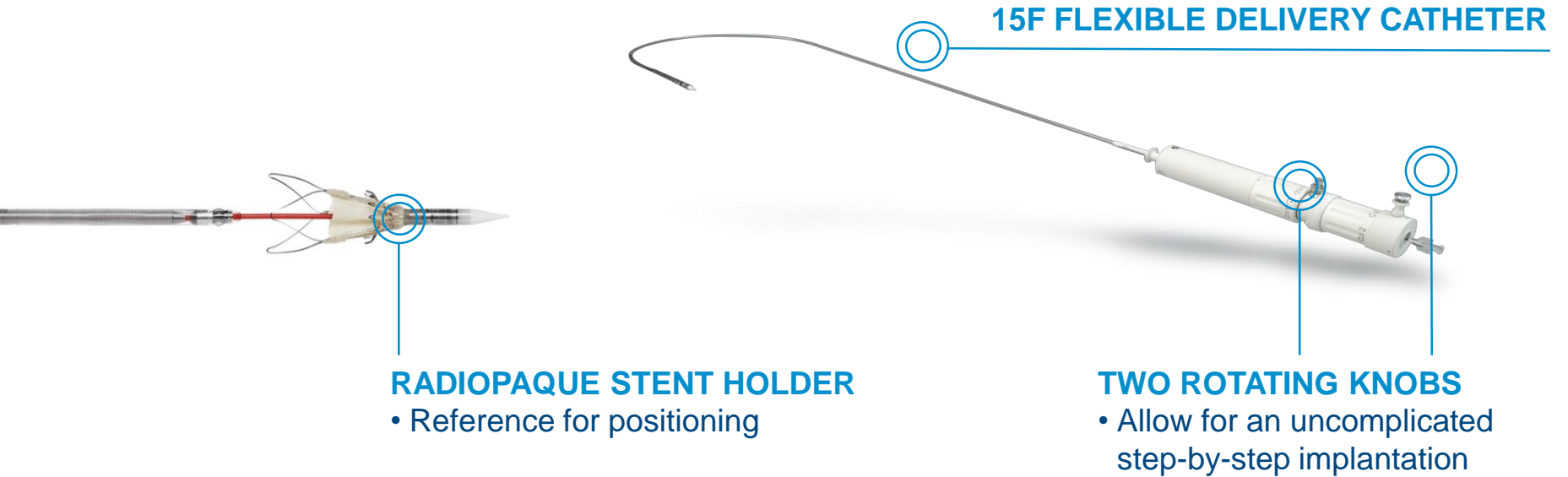
Aortic Valve



Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Order Number	SYM-SV23-002	SYM-SV25-002	SYM-SV27-002
Aortic annulus diameter* (mm)	$21\text{mm} \leq \text{annulus } \varnothing \leq 23 \text{ mm}$	$23\text{mm} < \text{annulus } \varnothing \leq 25 \text{ mm}$	$25\text{mm} < \text{annulus } \varnothing \leq 27 \text{ mm}$
Aortic annulus perimeter (mm)	$66 \text{ mm} \leq \text{annulus } \mathcal{C} \leq 72 \text{ mm}$	$72 \text{ mm} < \text{annulus } \mathcal{C} \leq 79 \text{ mm}$	$79 \text{ mm} < \text{annulus } \mathcal{C} \leq 85 \text{ mm}$

* CT based measurement: Perimeter derived annulus.

Transfemoral Delivery System: Flexible & Intuitive



ACURATE TF DS

Proximal End

INSERTION AID

- Facilitates insertion DS into introducer

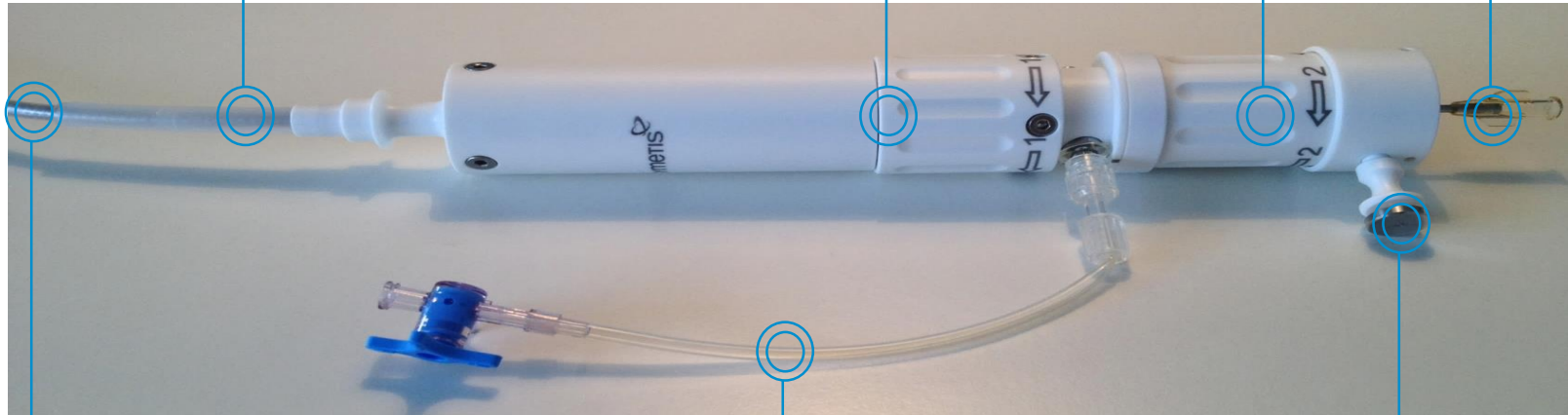
1ST ROTATION KNOB

- Unsheathes upper crown & stabilization arches

2ND ROTATION KNOB

- Unsheathes lower crown

GUIDEWIRE LUMEN



POSITIONING SHEATH

- Controlled valve positioning

EXTENSION LINE

- Flushing of system

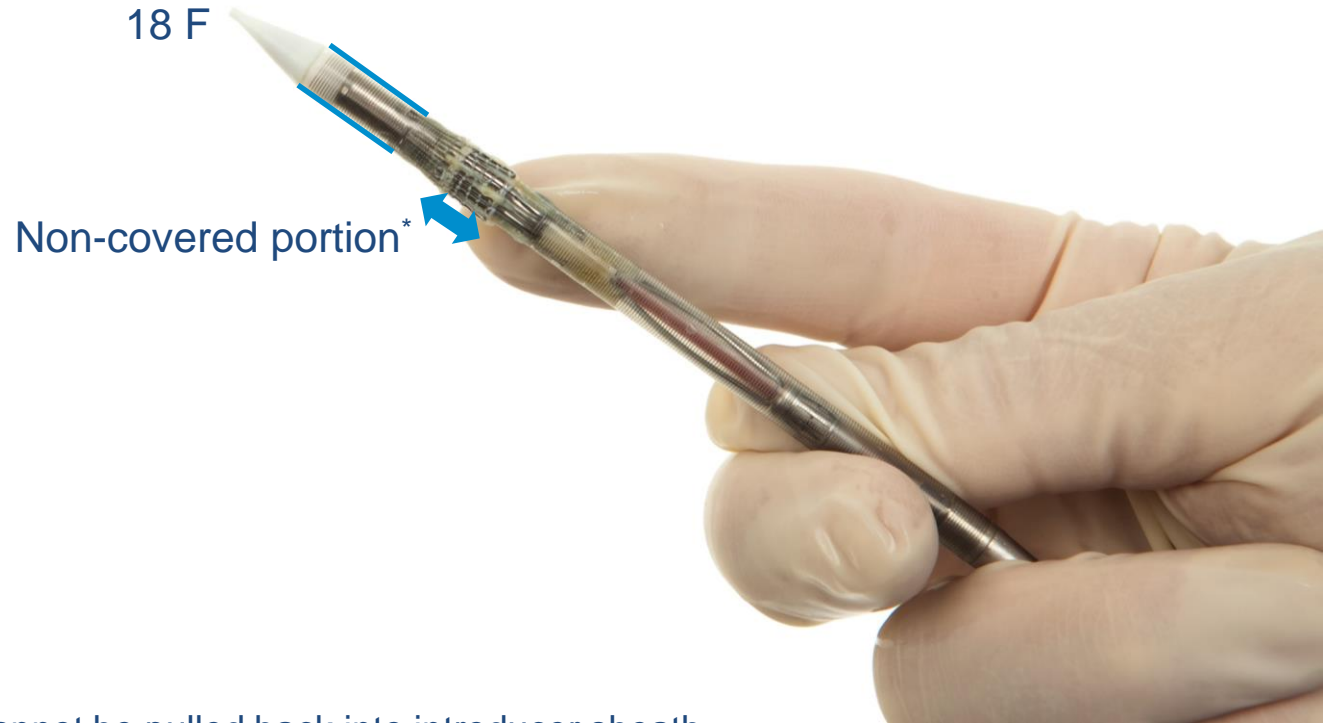
SAFETY BUTTON

- Prevents premature implantation

ACURATE TF Delivery System

Distal End Loaded

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Scientific



*once exiting the sheath cannot be pulled back into introducer sheath

ACURATE TF Delivery System

Distal End

SHUTTLE & SOFT TIP

- Shuttle slides over distal portion of middle member

STENTHOLDER & SELF-EXPANDABLE CAGE

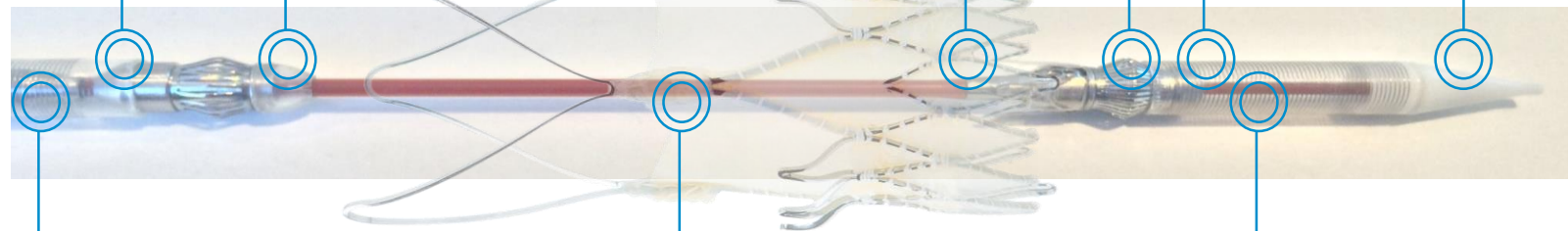
- Stent holder prevents premature deployment
 - Nitinol cage facilitates retrieval of DS after deployment

CAPSULE

- Houses lower crown
- Houses stent body

TIP

- Radiopaque
- Guidewire lumen



OUTER MEMBER

- Radiopaque
- Attached to 1st Rotation Knob
- Houses upper crown, leaflets and stabilization arches
- Positioning sheath is attached to handle
- Insertion aid slides over outer member

MIDDLE MEMBER

- Attached to handle body
- Stent holder & nitinol cage attached here

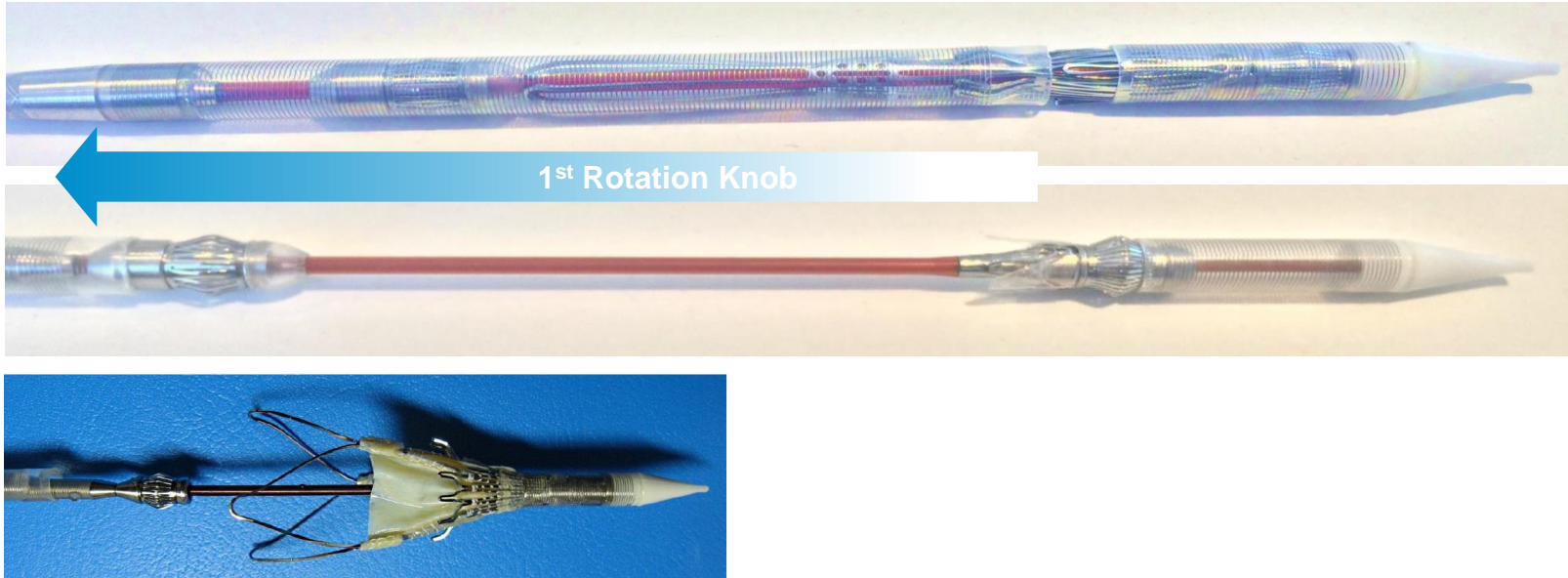
INNER MEMBER

- Attached to 2nd Rotation Knob
- Capsule fixed here

ACURATE TF Delivery System

Mechanisms

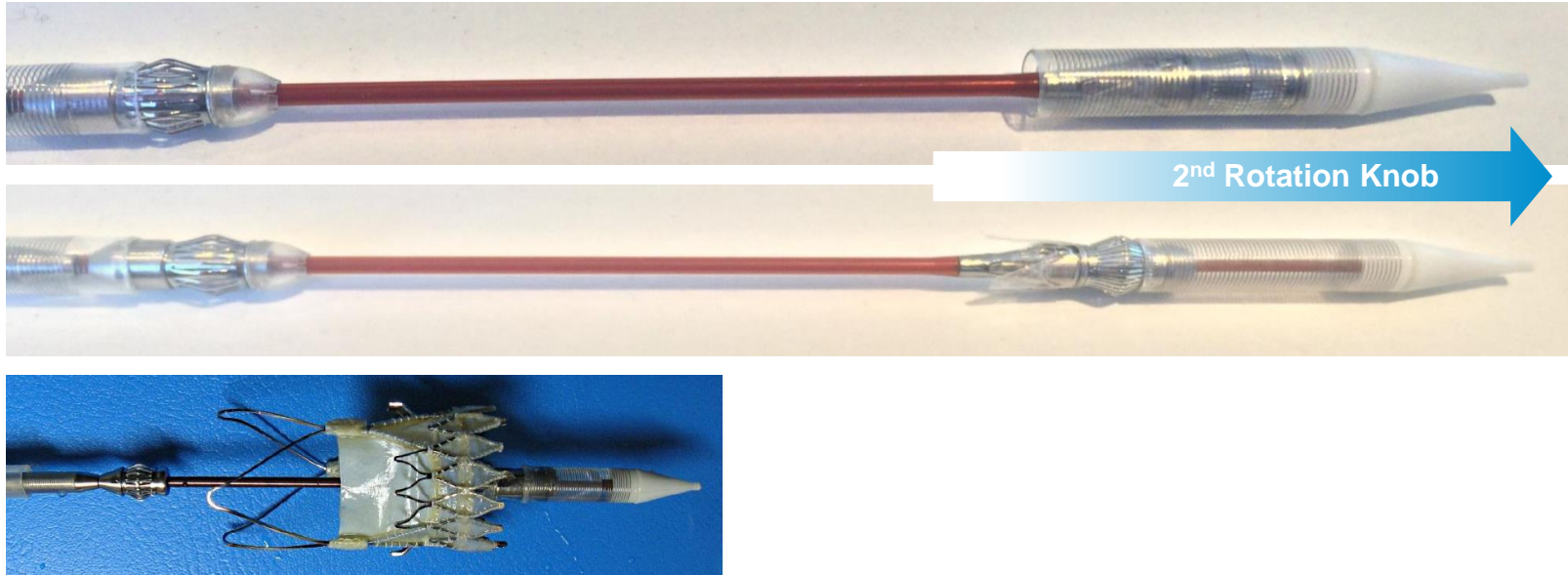
- Retrieve outer-member by turning 1st Rotation Knob counter-clockwise.
- Opens upper crown followed by stabilization arches.



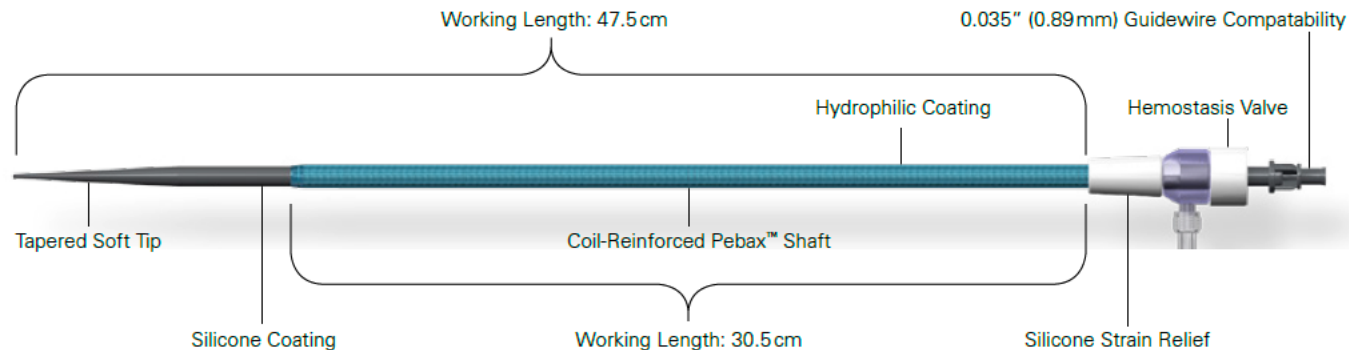
ACURATE TF Delivery System

Mechanisms

- Place capsule inside LV by turning 2nd Rotation Knob counter-clockwise.
- Opens lower crown to release bioprosthesis



LOTUS™ Transfemoral Introducer Sheath - Small



Atraumatic Design

- Tapered soft-tip allows for atraumatic delivery.
- Hydrophilic coating facilitates smooth sheath entry and removal.

Impressive trackability¹ and exceptional kink resistance²

- Coil reinforced Pebax™ shaft and silicone strain relief provides resistance to kinking while maximizing trackability.

Enhanced Control

- Hydrophilic coating enhances tracking through challenging anatomy.
- Coating on dilator minimizes resistance during dilator insertion.

SAFARI²™ Pre-Shaped Guidewire

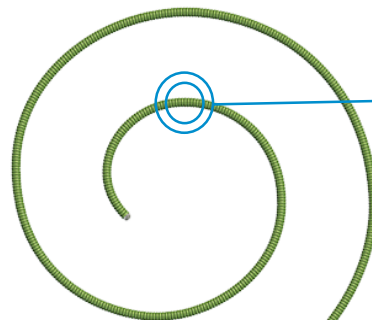
Boston
Scientific

ENHANCED WIRE PREDICTABILITY

- With superior shape retention

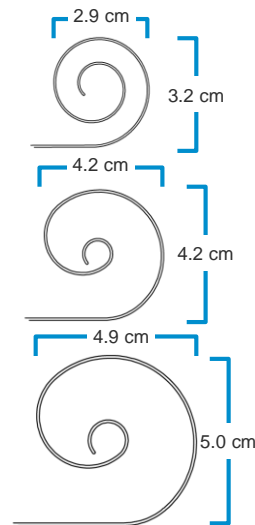
STREAMLINED DEVICE DELIVERY

- Through optimized rail support



WIDEST GUIDEWIRE CHOICE

- With three curve sizes



Specifications

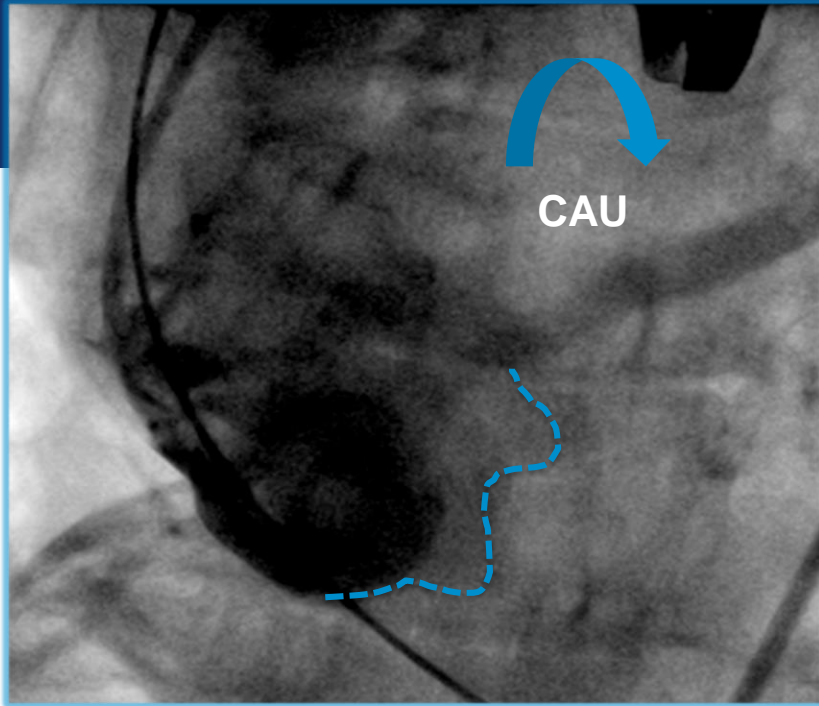
- Outer Diameter: 0.035" (0.889mm)
- Overall Length: 275 cm
- Core Material: Stainless Steel
- Coil Material: Stainless Steel
- Coating: LUBRIGREEN™ PTFE
- Unique Product Dimensions by Curve Size

IMPLANTATION STEPS

Preparation for ACURATE *neo*™

Orthogonal alignment (3 cusp view)

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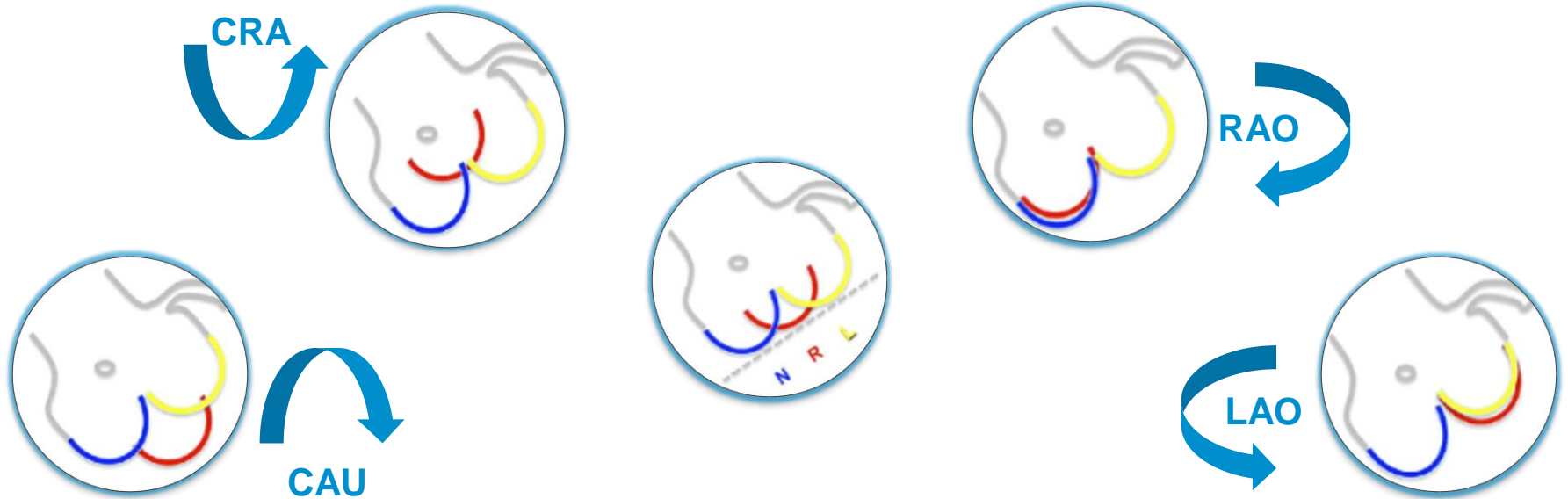


Preparation for ACURATE *neo*™

Orthogonal alignment (3 cusp view)

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- Follow the **right cusp**.

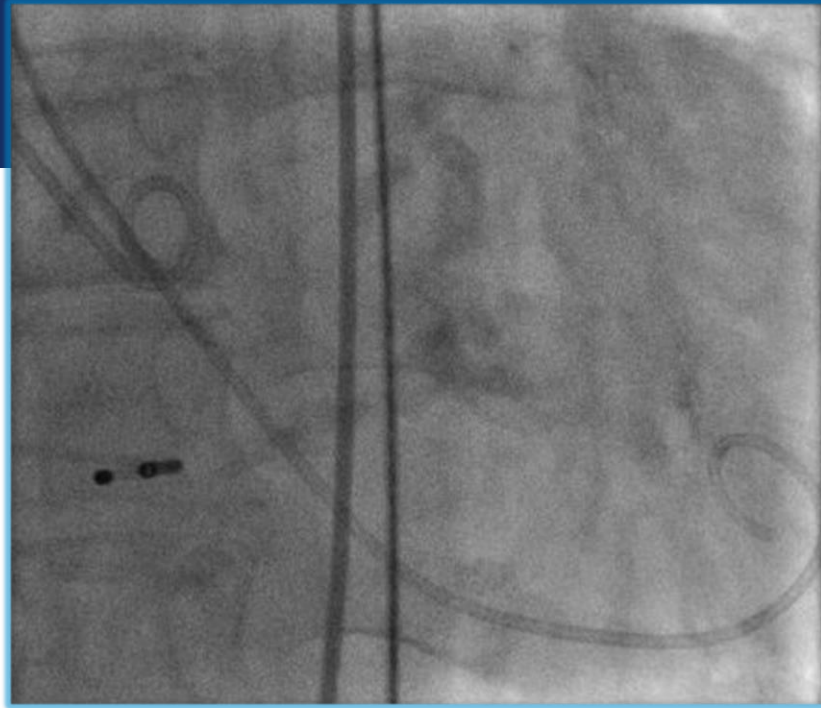


Adapted from Kasel et al, JACC Cardiovasc Imag 2013.

Preparation for ACURATE *neo*™

Handling of the guidewire

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Preparation for ACURATE *neo*™

Pre-dilatation BAV

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Recommendations for balloon size:

- One mm smaller than **effective annulus diameter** (If annulus is 23.4mm use a 22 mm balloon)



Effective and complete pre-dilatation is important for good annular apposition.

Overview

Overview of ACURATE *neo*™

Introduction and Positioning

Deployment

Removal and final result

Introduction and Positioning

Insertion

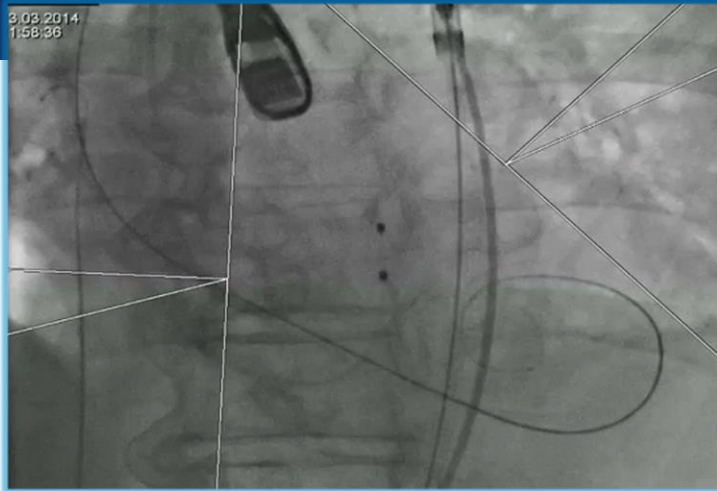
- Insertion of **Loader** into **Sheath**
- Advance delivery system 10cm and pull back insertion aid, parking it in the handle



Introduction and Positioning

Insertion

- Guidewire **management** during **Delivery System advancement**
 - **Hold** guidewire at a **fixed point** while:
 - inserting DS into introducer
 - crossing vasculature



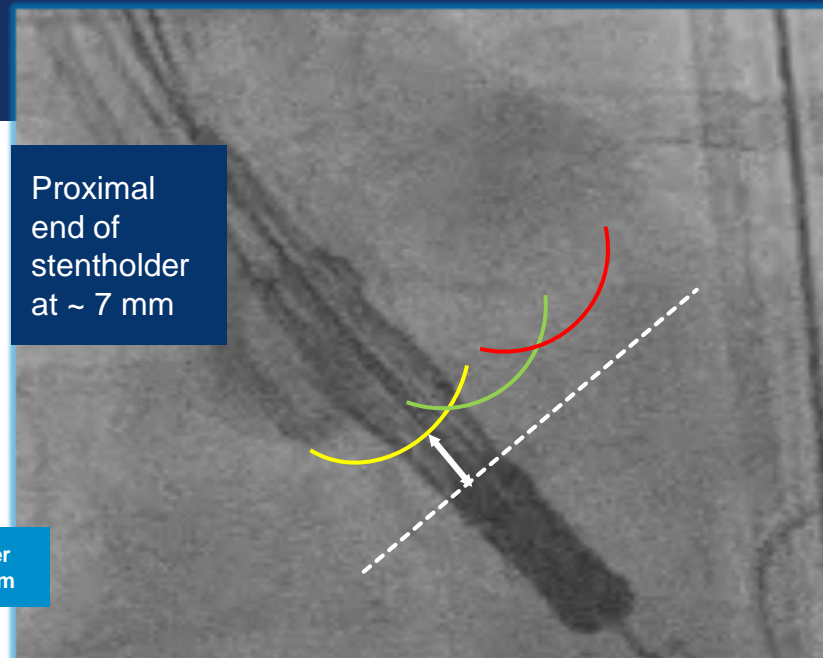
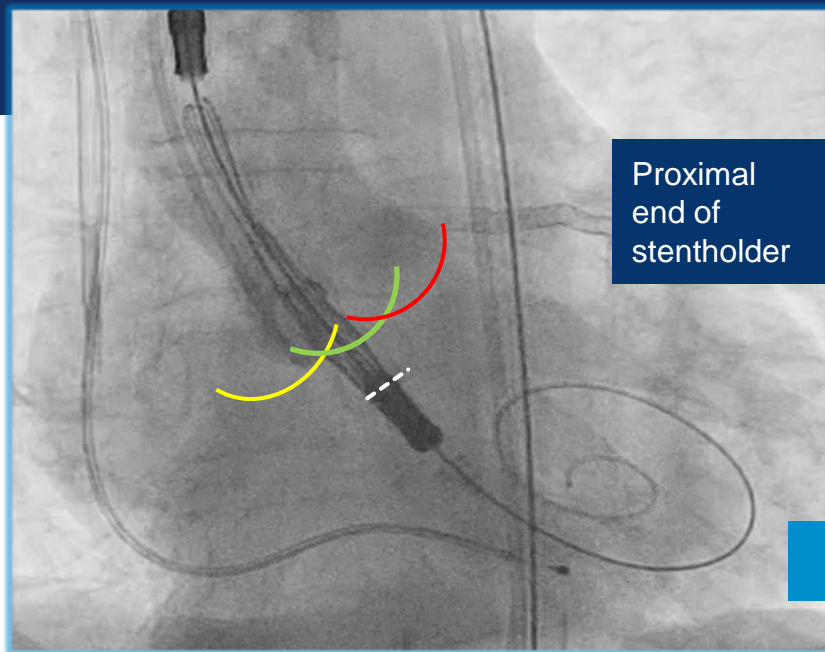
- Ensure guidewire is not moving inside LV while advancing DS.
- Reposition guidewire if needed after initial positioning.

INITIAL POSITION IS KEY TO SUCCESS

Positioning

Initial positioning

- **Initial positioning** is the **key** for a **successful** implantation!



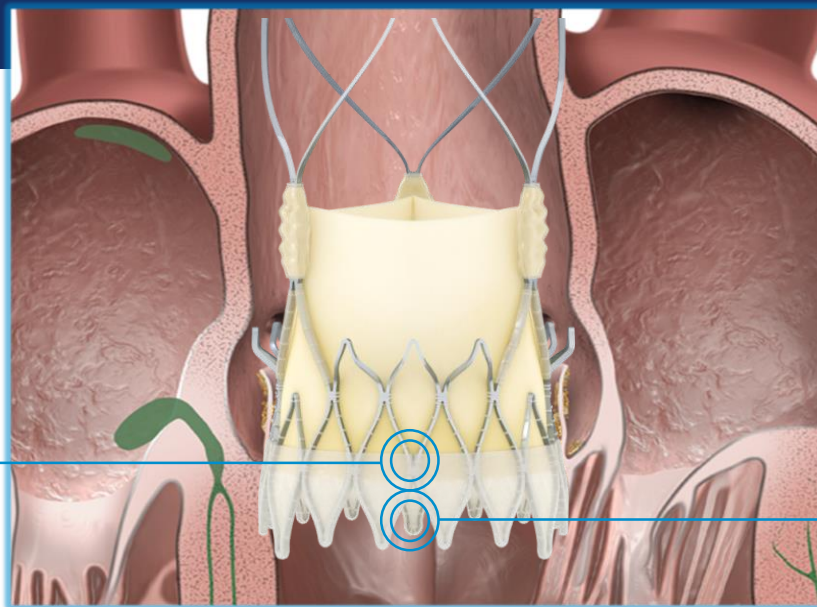
Deployment

Final goal

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- The final implant position has the **proximal end** of stentholder **~7 mm** below the annulus approximately.

**RADIOPAQUE
INTERSECTION LINE AT
THE LEVEL OF ANNULUS**

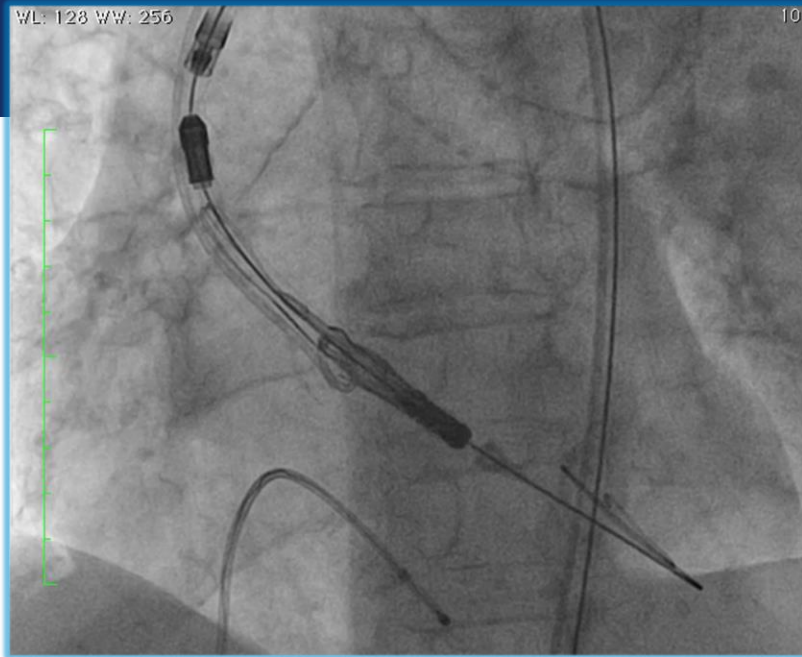


**PROXIMAL END OF
STENTHOLDER IN LVOT
(≈ 7 mm).**

Positioning

Initial positioning

- **Initial positioning** is the **key** for a **successful** implantation!

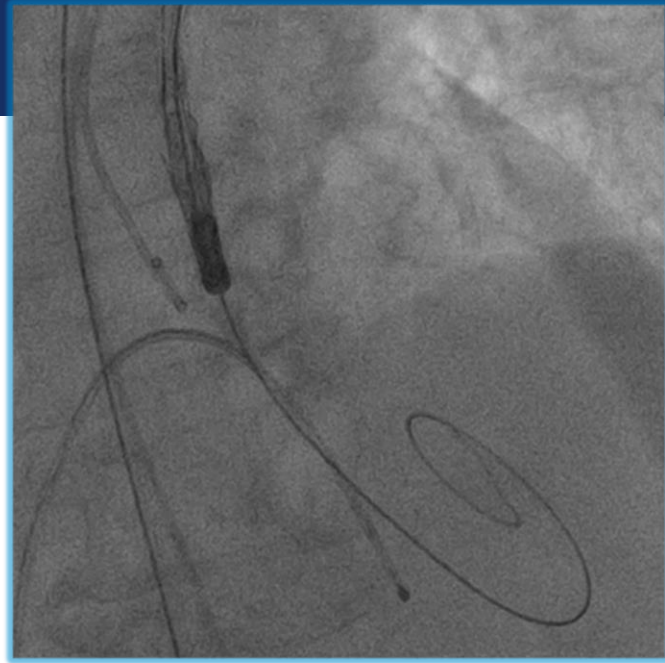
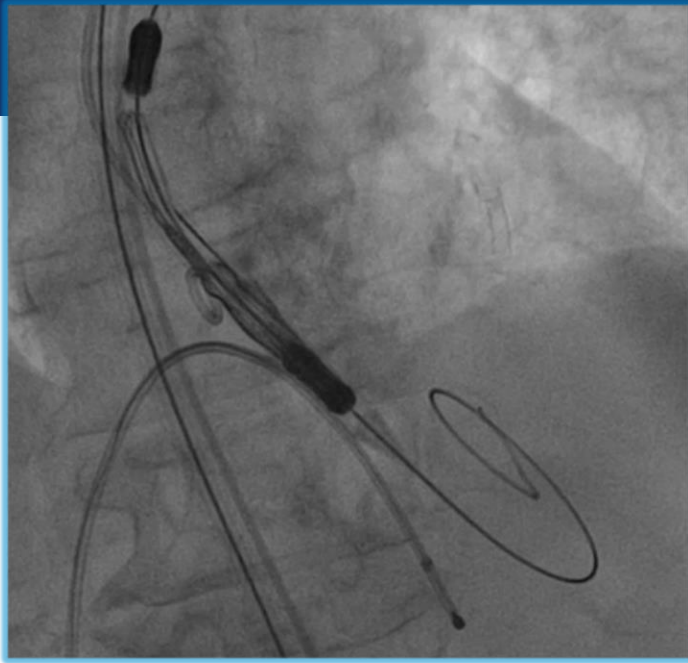


Positioning of the valve **MUST** be during **forward** movement to guarantee a stable position of the DS on the outer curvature of the aorta

Positioning

Example of positioning

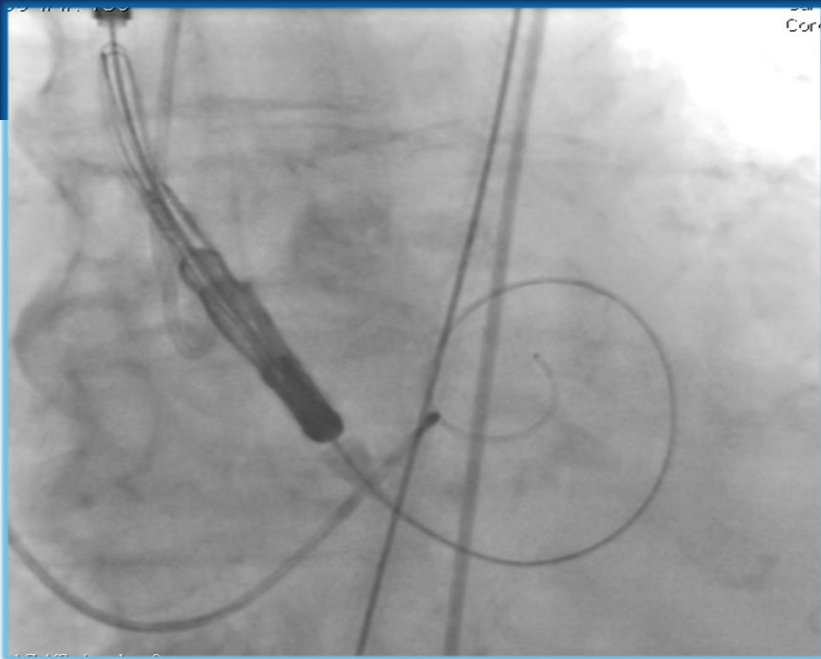
- Too deep – **Pull** tip to annulus level and **small steps** forward into position.



Positioning

Example of positioning

- Too high – **Small steps** forward by first operator. Advancing valve into starting position.



DO NOT RELEASE HANDS.
HOLD SYSTEM IN PLACE.

In this example:

- The valve needs to be **advanced** 7 mm into perfect starting position.
- The **pigtail** should also be **advanced** to the deepest part of the NCC to serve as a positioning tool.
- Advance **wire** deeper into ventricle

Overview

Overview of ACURATE *neo*™

Introduction and Positioning

Deployment

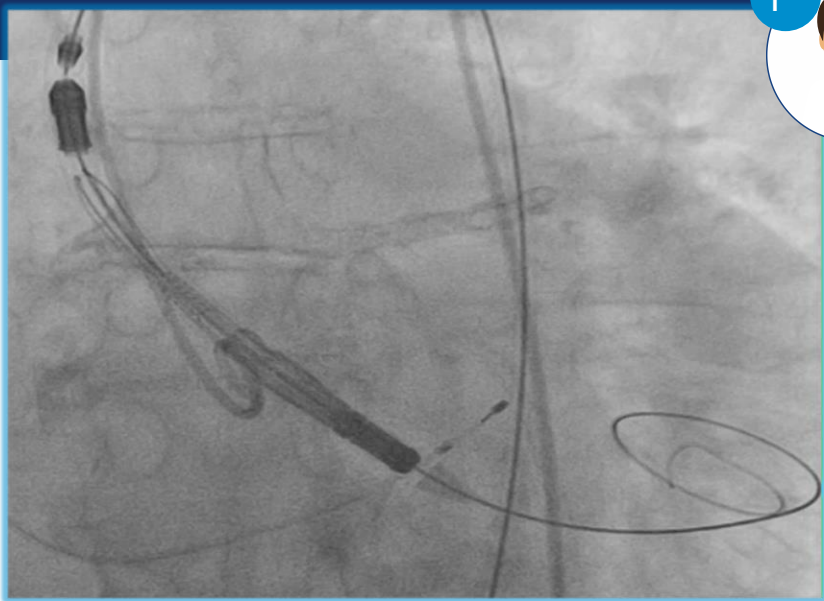
Removal and final result

Deployment

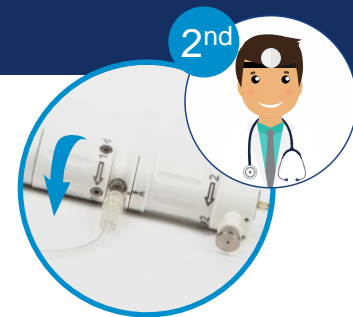
Step 1a – Unsheath Upper Crown

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1st operator: Maintain position of delivery system on outer curvature to inhibit movement of bioprosthesis.



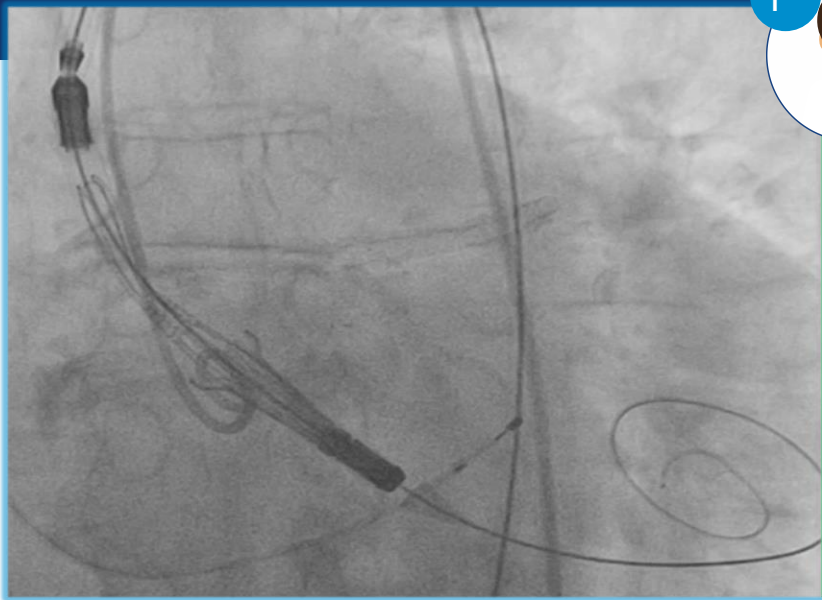
2nd operator: Rotate Knob 1 until upper crown is released



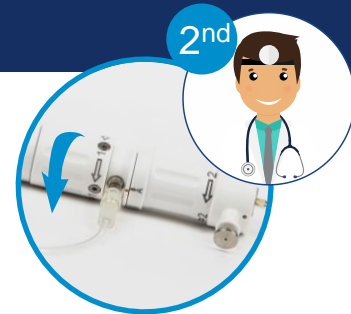
Deployment

Step 1b – Unsheath Stabilization Arches & Confirm Position

1st operator: Continue to maintain position.
If necessary, make any adjustments



2nd operator: Continue to turn Knob 1 to release **stabilization arches**. **Confirm position** by injecting small amount of contrast



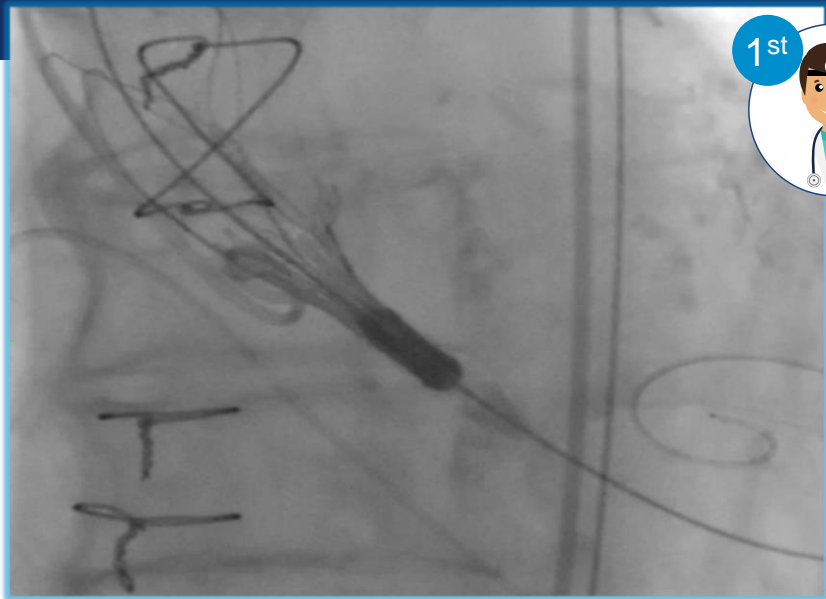
- To ensure the stentholder releases properly, the last movement on the DS must be forward

Deployment

Step 1 – Confirm Final Position

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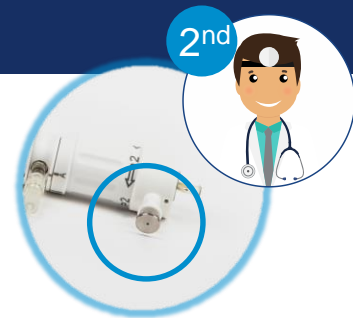
1st operator: Continue to maintain position.
If necessary, make any adjustments



1st



2nd operator: Pull **Safety Button**.
Small injection of contrast to **confirm position**.
Pull Pigtail.



2nd

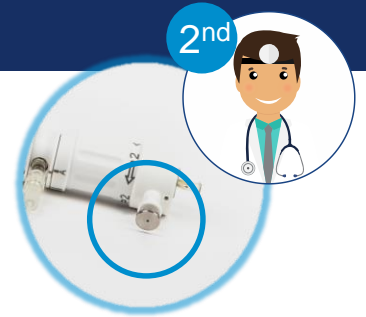
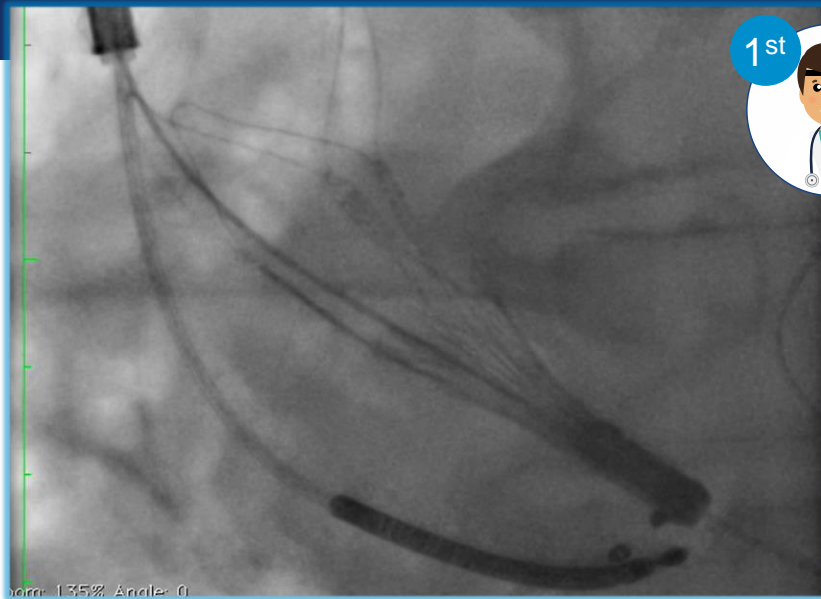


Deployment

Step 1 – Confirm Final Position

1st operator: Continue to maintain position.

2nd operator: Fully turn **Knob 2** quickly.



Visualize stentholder moving forward & fully releasing valve.

Overview

Overview of ACURATE *neo*™

Introduction and Positioning

Deployment

Removal and final result

Removal and final result

Withdrawal of the delivery system

Withdrawal of delivery system (DS) through the bioprosthesis



1st

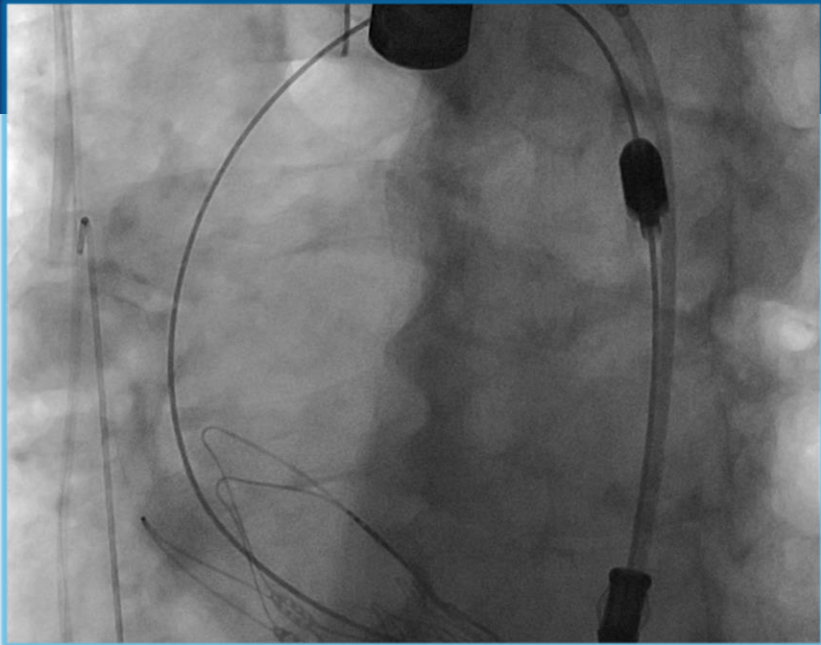


- Wait a few cardiac cycles to allow nitinol to continue to expand.
- Pull on guidewire so DS is not lying on internal surface of bioprosthesis, continue to **pull on guidewire** to center the tip of the DS.
- Gently retrieve DS ensuring no contact with bioprosthesis.
- If contact is felt, do not pull further on DS.

Removal and final result

Closure of the delivery system

Closure of the Delivery System

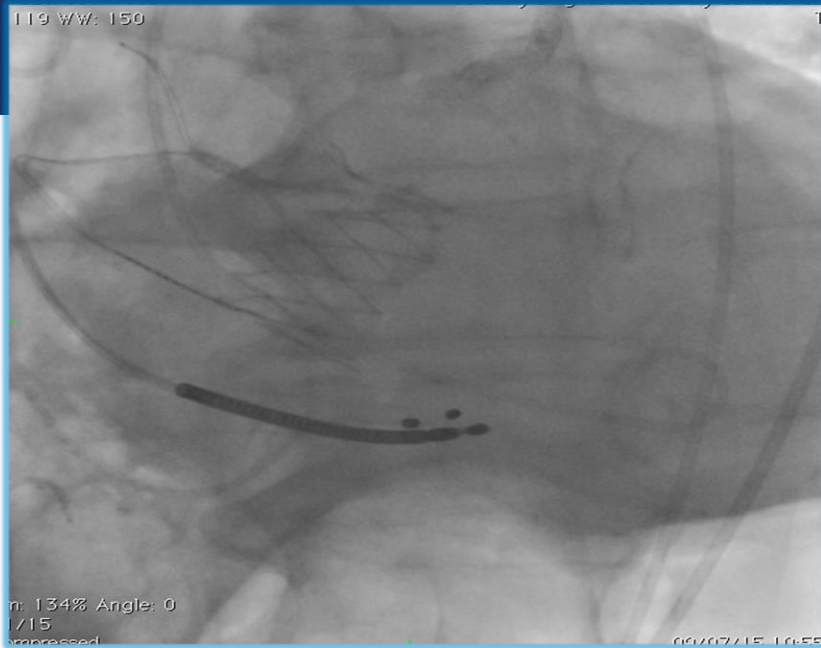


- Full closure of DS is recommended before its removal through introducer.
- Rotate Knob 2 clockwise until the stop.
- Rotate Knob 1 clockwise until there is visual contact of shuttle & stentholder (radiopaque portions of the DS).
- Gently remove DS through introducer.
- **Do not over close system.**

Removal and final result

Final evaluation

Final evaluation



- Replace wire with pigtail.
- Place pigtail above commissural posts to avoid direct injection through leaflets.
- Injection recommendations:
 - S & M valves: 20 cc @ 20 cc/sec
 - L valves: 25 cc @ 20 cc/sec

2 important factors to consider

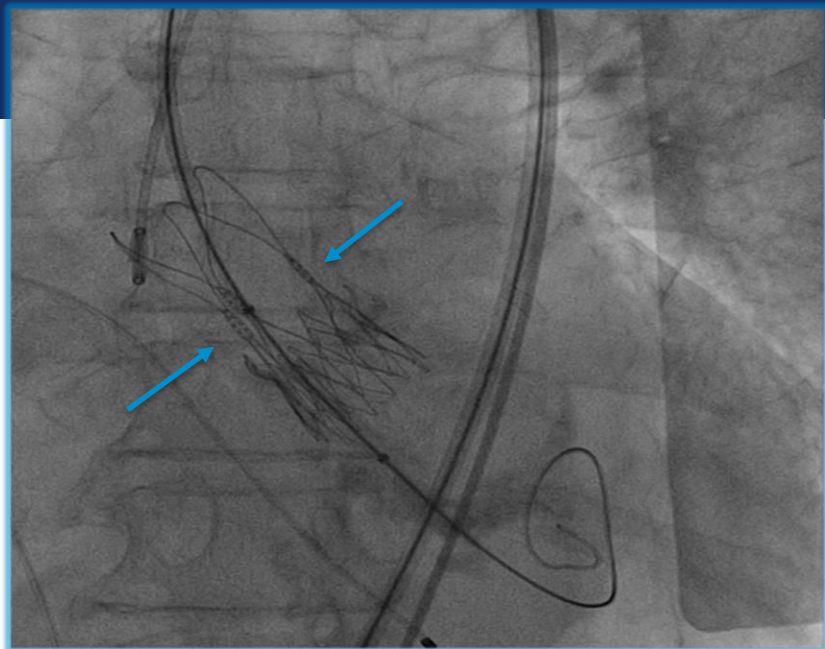
Patients Anatomy

- Post Dilatation Balloon should never be bigger than the patients anatomy.
- **Take into consideration the annulus size**
Typically choosing the same size of balloon as the annulus is acceptable.
- **Calcification**
If calcium is present in the LVOT or STJ ensure the balloon is not too big to over stretch & potentially cause a rupture.

Valve Size

- Maximum Post Dilatation Balloon size for each size valve (including tolerance)
 - Small: 22 mm
 - Medium: 24 mm
 - Large: 26 mm
- **When using a compliant balloon**
 - A smaller balloon size should be chosen for each valve due to the unpredictable growth.
 - Positioning more ventricular is also recommended when using a compliant balloon (to avoid the balloon growing up by the leaflets & potentially rupturing a leaflet).

Post Dilatation Technique



- Top marker of the balloon should be mid-commissural post
 - Prevents excessive pressure on leaflets.
- Careful size selection.
- Use progressive expansion.

