ACURATE neo™
Aortic Valve System

IMPLANTATION PROCEDURE

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Important Information

• 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 of ACURATE neo™

- Introduction and Positioning
- Deployment
- Removal and final result
# ACURATE™ TAVI Platforms

## Key Achievements

### From Start-up to Global Player

<table>
<thead>
<tr>
<th>&gt; 11000</th>
<th>&gt; 2200</th>
<th>&gt; 20</th>
<th># 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valves implanted</td>
<td>Patients included in clinical trials</td>
<td>Countries globally</td>
<td>TAVI system in Europe*</td>
</tr>
</tbody>
</table>


**ACURATE neo™**
- Transfemoral Aortic Valve System
- Transapical Aortic Valve System
ACURATE neo™ Deployment
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 rates\(^1\)

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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

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

Upper crown diameter: waist + 5 mm

Lower crown diameter: waist + 3 mm

Landing zone: ≈ 7 mm

Total height: 48 - 51 mm
<table>
<thead>
<tr>
<th>Valve Size</th>
<th>S – 23 mm</th>
<th>M – 25 mm</th>
<th>L – 27 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic annulus diameter* (mm)</td>
<td>21mm ≤ annulus Ø ≤ 23 mm</td>
<td>23mm &lt; annulus Ø ≤ 25 mm</td>
<td>25mm &lt; annulus Ø ≤ 27 mm</td>
</tr>
<tr>
<td>Aortic annulus perimeter (mm)</td>
<td>66 mm ≤ annulus Ø ≤ 72 mm</td>
<td>72 mm &lt; annulus Ø ≤ 79 mm</td>
<td>79 mm &lt; annulus Ø ≤ 85 mm</td>
</tr>
</tbody>
</table>

* CT based measurement: Perimeter derived annulus.
Transfemoral Delivery System: Flexible & Intuitive

15F FLEXIBLE DELIVERY CATHETER

- RADIOPAQUE STENT HOLDER
  - Reference for positioning

- TWO ROTATING KNOBS
  - Allow for an uncomplicated step-by-step implantation
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

18 F

Non-covered portion*

*once exiting the sheath cannot be pulled back into introducer sheath
ACURATE TF Delivery System
Distal End

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

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
• Retrieve outer-member by turning 1<sup>st</sup> 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

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)
Follow the **right cusp**.

Adapted from Kasel et al, JACC Cardiovasc Imag 2013.
Preparation for ACURATE neo™
Handling of the guidewire
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 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
• **Initial positioning** is the key for a **successful** implantation!

- **Proximal end of stentholder** at ~ 7 mm
- **Stentholder Width**: 5 mm
Deployment
Final goal

• The final implant position has the **proximal end** of stentholder ~7 mm below the annulus approximately.
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 of ACURATE neo™

Introduction and Positioning

Deployment

Removal and final result
Deployment
Step 1a – Unsheath Upper Crown

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

2\textsuperscript{nd} 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

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

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 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

- 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.
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
# Post Dilatation

## 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

Post Dilatation Technique

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