

Advancing science for life[™]



OPTIMIZING TAVI

TRANSFEMORAL



With iSLEEVE[™] Expandable Introducer Set

UNIQUE Self-Expanding Supra-Annular VALVE TECHNOLOGY

for Transfemoral TAVI







PREDICTABLE DEPLOYMENT





ACURATE *neo*[™] Aortic Valve System

INTUITIVE Design

AORTIC VALVE

The unique valve design of ACURATE *neo*[™] provides very high survival rates with excellent hemodynamics and low pacemaker rates.^{1,2}

UPPER CROWN

- Supra-annular anchoring
- Caps native leaflets and provides coronary clearance

LOWER CROWN

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

*No clinical data are available which evaluate the long-term impact of the BioFix™ tissue treatment in patients

STABILIZATION ARCHES

• Axial self-alignment of valve within the native annulus

SUPRA-ANNULAR VALVE

- Large effective orifice areas and low gradients^{1,2}
- Porcine pericardium leaflets with BioFix[™] anti-calcification process^{*}

ANTI-PVL SKIRT

• Sealing against paravalvular leak

TRANSFEMORAL DELIVERY SYSTEM

With intuitive valve delivery and positioning, ACURATE *neo* minimizes complications and improves procedural efficiency.

FLEXIBLE DELIVERY CATHETER

- Reduced risk of vascular complications
- Full range of ACURATE *neo* valve sizes



With iSLEEVE[™] Expandable Introducer Set

TWO ROTATING KNOBS

Allow for an uncomplicated step-by-step implantation

SAFETY BUTTON

0

symens

NUMBER

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• Prevents premature implantation

RADIOPAQUE STENT HOLDER

Reference for positioning

PREDICTABLE Deployment

The predictable top-down deployment of ACURATE *neo*[™] delivers the hemodynamic stability and precise placement needed for high procedural success and low rates of complications.^{1,2}

Valve positioning

• Flexible delivery system Precise positioning

- Top-down deployment
- Co-axial self-alignment Hemodynamic stability

Valve release

 Controlled release Predictable positioning

STRONG Clinical Outcomes

From early studies establishing safety and efficacy to head-to-head studies that show performance against other valves, ACURATE *neo*[™] continues to undergo rigorous testing and demonstrate outstanding clinical outcomes.

FEATURED CLINICAL STUDIES

SAVI-TF Post-Market Registry^{1,2}

MORENA Multicenter Comparison Study: ACURATE neo vs. SAPIEN 3³

HIGH PROCEDURAL EFFICIENCY¹

98.7 [%]	PROCEDURAL/DEVICE SUCCESS
6:34 ^{mins}	AVERAGE DEVICE USAGE TIME
0.0%	CORONARY OBSTRUCTION REQUIRING REINTERVENTION*
8.3%	NEW PACEMAKER IMPLANTATION*
1.4%	ALL-CAUSE MORTALITY*

*Results at 30 days

STRONG Clinical Outcomes

SAVI-TF Post-Market Registry^{1,2}

REAL-WORLD EXPERIENCE 1,000 PATIENTS

- **CONFIRMED SAFETY AND PERFORMANCE**
- Strong safety and effectiveness data
- Very low complication and pacemaker rates
- Low mortality and excellent hemodynamic performance





MORENA Multicenter Comparison Study

1:2 PROPENSITY-MATCHED MULTICENTER REGISTRY: ACURATE neo[™] vs. SAPIEN 3^{™ 3}

ACURATE *neo* demonstrated:

- Comparable VARC-2 procedural, performance and safety outcomes
- Lower acute/30-day new permanent pacemaker rates
- Superior hemodynamic performance

PACEMAKER RATE & HEMODYNAMIC PERFORMANCE

ACURATE *neo* (N = 311) SAPIEN 3 (N = 622)



* PVL more than mild was observed only in moderately and severely calcified annuli † at discharge/7 days



% of patients/mmHg

COMMITTED to TAVI

As part of our commitment to the structural heart community, Boston Scientific focuses on providing innovative solutions that advance safety in TAVI procedures, help optimize patient outcomes and improve procedural efficiency. Our differentiated portfolio of TAVI devices – including valves, accessories and a proven cerebral embolic protection device – delivers enhanced control and precision backed by strong clinical evidence and program support.



1. Möllmann H, Hengstenberg C, et al. Real-world experience using the ACURATE *neo* prosthesis: 30-day outcomes of 1,000 patients enrolled in the SAVI-TF registry. *EuroIntervention*. 2018;13:e1764-e1770.

- Kim W, MD, et al. 1-year outcomes of the European post-market registry using the ACURATE neo transcatheter heart valve under real-world conditions in 1,000 patients. JACC: Cardiovasc Interv. Vol. 11, no. 14, 2018; July 23, 2018: 1368–74.
- Husser O, et al. Multicenter Comparison of Novel Self-Expanding versus Balloon-Expandable Transcatheter Heart Valves. JACC: Cardiovasc Interv. 10. 2078-2087. 10.1016/j.jcin.2017.06.026.

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