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ACURATE *neo*™
Aortic Valve System

Product Overview

Stabilization Arches
- Axial self-alignment of valve within the native annulus

Upper Crown
- 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
- Large effective orifice areas and low gradients*
- Porcine pericardium leaflets with BioFix™ anti-calcification process†

Anti-PVL Skirt
- Seals against paravalvular leak

ACURATE *neo* Specifications

Access Route	Transfemoral and Transapical
Deployment Procedure	Phased, Top-Down Deployment
Expansion Mechanism	Self-Expanding
Valve Leaflet Position	Supra-Annular
Valve Frame Material	Nitinol
Valve Leaflet Material	Porcine Pericardium
Valve Leaflet Treatment	BioFix Anti-Calcification Process†
Use	Single Use
Sterilization	Chemically Sterilized
Carton Size (Valve Only)	114 mm × 172 mm × 114 mm
Indications for Use	The ACURATE *neo* Aortic Bioprosthesis and its Delivery Systems are indicated to improve valve function for symptomatic patients with severe calcific aortic stenosis (mean aortic gradient > 40 mmHg or peak jet velocity > 4.0 m/s or aortic valve area < 1.0 cm^2) with high risk for conventional surgical aortic valve replacement (sAVR).‡

MRI Conditional

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient field of 720 Gauss/cm or less
- Maximum whole body averaged Specific Absorption Rate (SAR) of 2.0 W/kg for 15 min of scanning‡

ACURATE *neo*™ Valve Sizing			
Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Aortic Annulus Diameter§	21 mm ≤ annulus diameter ≤ 23 mm	23 mm < annulus diameter ≤ 25 mm	25 mm < annulus diameter ≤ 27 mm
Aortic Annulus Perimeter	66 mm ≤ annulus perimeter ≤ 72 mm	72 mm < annulus perimeter ≤ 79 mm	79 mm < annulus perimeter ≤ 85 mm

Ordering Information

ACURATE *neo* Aortic Valves			
Order Number (GTIN)	Ref/Catalog Number	Description	Units
07640168110062	SYM-SV23-002	ACURATE *neo* Aortic Bioprosthesis S	1
07640168110079	SYM-SV25-002	ACURATE *neo* Aortic Bioprosthesis M	1
07640168110086	SYM-SV27-002	ACURATE *neo* Aortic Bioprosthesis L	1

ACURATE *neo* Delivery Systems			
Order Number (GTIN)	Ref/Catalog Number	Description	Units
07640168110055	SYM-DS-002	ACURATE™ TF Transfemoral Delivery System	1
07640168110093	SYM-DS-004	ACURATE *neo* TA Transapical Delivery System	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.

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

‡ See Instructions for Use (IFU) for details.

§ CT-based measurement: Perimeter-derived annulus.

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