

Product Overview



Stabilization Arches

- Axial self-alignment of valve within the native annulus
- Extra-large open cells to facilitate coronary access

Upper Crown

- Supra-annular anchoring
- Caps native leaflets and provides coronary clearance¹

Lower Crown

- Minimal protrusion into LVOT
- Low risk of conduction system interferences²

Top-Down Deployment

- Stable and predictable valve release²
- No requirement for rapid pacing during deployment

Supra-Annular Valve

- Large effective orifice areas and low gradients²
- Porcine pericardium leaflets with BioFix™ anti-calcification process*

Active PVseal™ Technology¹

- Conforms to the native aortic annulus
- Actively seals to prevent potential paravalvular leak



Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Aortic annulus diameter [†]	21 mm ≤ annulus ≤ 23 mm	23 mm < annulus ≤ 25 mm	25 mm < annulus ≤ 27 mm
Aortic annulus perimeter	66 mm ≤ annulus ≤ 72 mm	72 mm < annulus ≤ 79 mm	79 mm < annulus ≤ 85 mm

ACURATE neo2™ Specifications

Access Route	Transfemoral
Deployment Procedure	Phased, Top-Down Deployment
Expansion Mechanism	Self-Expanding
Valve Sealing Technology	Active PVseal
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
Indications for Use	The ACURATE neo2 Aortic Valve, in combination with the ACURATE neo2 Transfemoral Delivery System, is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy. See Instructions for Use (IFU) for details.

MRI Safety Information

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient field of 720 Gauss/cm or less
- Maximum MR system reported, whole body averaged Specific Absorption Rate (SAR) of < 2.0 W/kg for 15 min of scanning (i.e., per pulse sequence)
- Normal operating mode of operation for the MR system

Ordering Information

Ref/Catalog Number	Description	Units
ACURATE neo2 Aortic Valves		
SYM-SV23-004	ACURATE neo2 Aortic Valve S	1
SYM-SV25-004	ACURATE neo2 Aortic Valve M	1
SYM-SV27-004	ACURATE neo2 Aortic Valve L	1
ACURATE neo2 Transfemoral Delivery System and Loading Kit		
SYM-DS-010	ACURATE neo2 Transfemoral Delivery System	1
SYM-AC-010	ACURATE neo2 Loading Kit	1
ACURATE neo2 Bundles		
ACURATE neo2 Aortic Valve + ACURATE neo2 Transfemoral Delivery System		
BUN67NEO2TFDSS	ACURATE neo2 Aortic Valve System S + ACURATE neo2 Transfemoral Delivery System	
BUN67NEO2TFDSM	ACURATE neo2 Aortic Valve System M + ACURATE neo2 Transfemoral Delivery System	
BUN67NEO2TFDSL	ACURATE neo2 Aortic Valve System L + ACURATE neo2 Transfemoral Delivery System	
ACURATE neo2 Aortic Valve + ACURATE neo2 Transfemoral Delivery System + iSLEEVE™ Expandable Introducer Set		
BUN67NEO2TFDSISLS	ACURATE neo2 Aortic Valve System S + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE	
BUN67NEO2TFDSISLM	ACURATE neo2 Aortic Valve System M + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE	
BUN67NEO2TFDSISLL	ACURATE neo2 Aortic Valve System L + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE	
ACURATE neo2 Aortic Valve + ACURATE neo2 Transfemoral Delivery System + iSLEEVE™ Expandable Introducer Set + SAFARI²™		
BUN67NEO2SAFXISLS	ACURATE neo2 Aortic Valve System S + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Extra-Small	
BUN67NEO2SAFXISLM	ACURATE neo2 Aortic Valve System M + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Extra-Small	
BUN67NEO2SAFXISLL	ACURATE neo2 Aortic Valve System L + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Extra-Small	
BUN67NEO2SAFSSIS	ACURATE neo2 Aortic Valve System S + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Small	
BUN67NEO2SAFSISM	ACURATE neo2 Aortic Valve System M + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Small	
BUN67NEO2SAFSISL	ACURATE neo2 Aortic Valve System L + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Small	
ACURATE neo2 Aortic Valve Generic Bundle Codes		
BUN67NEO2DSTF	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System	
BUN67NEO2DSTFIS14	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + 14F iSLEEVE	
BUN67NEO2DSTFLIS	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + LIS	
BUN67NEO2IS14SAF	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + 14F iSLEEVE + SAFARI ²	
BUN67NEO2ISSAFSEN	Generic Bundle ACURATE neo2 Aortic Valve + Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² + SENTINEL	
SAFARI²™ Pre-Shaped Guidewire		
H749 39406XS1	SAFARI ² Pre-Shaped Guidewire Extra-Small 275 cm	5
H749 39406S1	SAFARI ² Pre-Shaped Guidewire Small 275 cm	5
H749 39406L1	SAFARI ² Pre-Shaped Guidewire Large 275 cm	5
H749 39407XS0	SAFARI ² Pre-Shaped Guidewire Extra-Small 275 cm	1
H749 39407S0	SAFARI ² Pre-Shaped Guidewire Small 275 cm	1
H749 39407L0	SAFARI ² Pre-Shaped Guidewire Large 275 cm	1
14F iSLEEVE™ Expandable Introducer Set		
H749 39349 140	14F iSLEEVE Expandable Introducer Set	1
SENTINEL™ Cerebral Protection System		
CMS15-10C	SENTINEL Cerebral Protection System	1

Visit and learn more:

www.bostonscientific.com/en-EU/products/transcatheter-heart-valve/acurateneo2-tavi-valve-system

* Significant reduction in calcification demonstrated in animal models. Data on file with Boston Scientific. No clinical data are available which evaluate the long-term impact of the BioFix tissue treatment in patients.

† CT-based measurement: Perimeter-derived annulus.

1. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol.* 2021;110:1912-1920.

2. 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.

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