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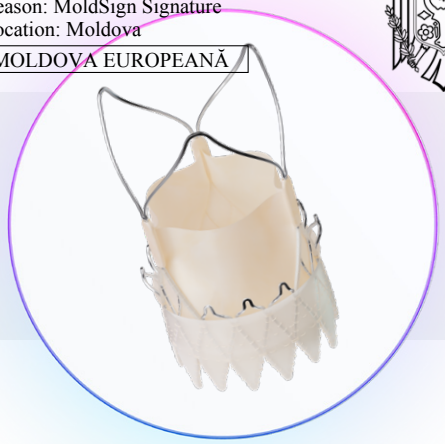


ACURATE Prime™
Aortic Valve System

Product Overview

Open Upper Frame
For unrestricted coronary access[1] aided by predictable commissural alignment

Supra-Annular Leaflets
Designed to provide large EOA's and low gradients[2]

Active PVseal™ Technology
Inner and outer sealing skirt with 360-degree dynamic sealing for PVL[3]

Expanded Size Matrix

Valve Size	23 mm	25 mm	27 mm	29 mm
Aortic annulus diameter †	20.5 mm - 23 mm	22.5 mm - 25 mm	24.5 mm - 27 mm	26.5 mm - 29 mm
Aortic annulus perimeter	64 mm - 72 mm	71 mm - 79 mm	77 mm - 85 mm	83 mm - 91 m

ACURATE Prime™ Valve 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
Sterilisation	Chemically Sterilised
Shelf Life	The ACURATE Prime Valve Shelf Life = 12 months
Indications for Use	The ACURATE Prime Aortic Valve System is intended to improve aortic valve function in symptomatic subjects with severe aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for transcatheter heart valve replacement therapy. See Instructions for Use (IFU) for details.

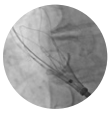
MRI Safety Information

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient field of 4,000 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

ACURATE Prime™ Delivery System

Flexible Delivery Catheter
- Minimizes risk of vascular complications

Top-down Deployment
- Stable and predictable valve release
- Rapid pacing during valve deployment not required



Radiopaque Positioning Marker
- Enables high placement accuracy

Atraumatic Tip
- Reliable tracking
- Smooth guidewire transition

14F iSLEEVE™ Expandable Introducer

Compatible with all ACURATE Prime valve sizes

Commissural Alignment Markers
- Distinct markings to aid in appropriate commissural alignment

Two Rotating Knobs
- Intuitive step-by-step implantation
- 90° turn for enhanced control and stable deployment

Safety Pin
- Prevents premature implantation

ACURATE Prime™ Delivery System Product Specifications

Access Route	Transfemoral
Deployment Procedure	Phased, Top-Down Deployment
Recommended Guidewire	SAFARI²™ Pre-Shaped Guidewire 0.035" (0.89 mm)
Effective Length	115 cm
Valve Compatibility	For use with all ACURATE Prime Aortic Valves (one Delivery System for valve sizes 23-25 mm, one Delivery System for valve sizes 27-29 mm)
Recommended Introducer	14F iSLEEVE™ Expandable Introducer Set
Use	Single Use
Sterilisation	X-Ray Sterilised
Delivery System and Loading Kit Carton Size	Delivery System: 12.07 cm x 6.99 cm x 158.98 cm; Loading Kit: 30.15 cm x 8.20 cm x 37.80 cm
Shelf Life	The ACURATE Prime Delivery System and Loading Kit Shelf Life = 9 months
Indications for Use	The ACURATE Prime Aortic Valve System is intended to improve aortic valve function in symptomatic subjects with severe aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for transcatheter heart valve replacement therapy. See Instructions for Use (IFU) for details.

Ref/Catalog Number	Description	Unit
ACURATE Prime Aortic Valves		
H74939690230	ACURATE Prime Aortic Valve 23 mm	1
H74939690250	ACURATE Prime Aortic Valve 25 mm	1
H74939690270	ACURATE Prime Aortic Valve 27 mm	1
H74939690290	ACURATE Prime Aortic Valve 29 mm	1
ACURATE Prime Delivery System and Loading Kit		
H749396822325	ACURATE Prime Delivery System 23-25 mm	1
H749396822729	ACURATE Prime Delivery System 27-29 mm	1
H749396942325	ACURATE Prime Loading Kit 23-25 mm	1
H749396942729	ACURATE Prime Loading Kit 27-29 mm	1
SAFARI²™ Pre-Shaped Guidewire		
H749 39406XS1	SAFARI² Pre-Shaped Guidewire Extra-Small 275 cm	5
H749 39406S1	SAFARI² Pre-Shaped Guidewire Small 275 cm	5
H749 39406L1	SAFARI² Pre-Shaped Guidewire Large 275 cm	5
H749 39407XS0	SAFARI² Pre-Shaped Guidewire Extra-Small 275 cm	1
H749 39407S0	SAFARI² Pre-Shaped Guidewire Small 275 cm	1
H749 39407L0	SAFARI² 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

* 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. Barbanti M, et al. (RE-ACCESS); NCT04026204) J Am Coll Cardiol Intv 2020. 2. Möllmann, H., Holzhey, D.M., Hilker, M. et al. ACURATE *neo2* for TAVR: 30-day and 1-year outcomes. 3. The Early *neo2* Registry: TAVI with ACURATE *neo2* in a European Population. Rück A, et al. All trademarks are property of their respective owner. 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 use only in countries with applicable health authority product registrations. Information not for use or distribution in France. The SAFARI² Guidewire is manufactured by Lake Region Medical and distributed by Boston Scientific Corporation. SH-1789802-AA

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