

ACURATE neo2™

Aortic Valve System

Transfemoral Delivery System Product Overview



iSLEEVE™
Expandable Introducer

Flexible Delivery Catheter

- Minimizes risk of vascular complications
- Compatible with all ACURATE neo2™ valve sizes

Radiopaque Positioning Marker

- Enables high placement accuracy

Atraumatic Tip

- Reliable tracking
- Smooth guidewire transition

Top-down Deployment

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

Two Rotating Knobs

- Intuitive step-by-step implantation

Safety Button

- Prevents premature implantation



ACURATE neo2 Specifications

Access Route	Transfemoral
Deployment Procedure	Phased, Top-Down Deployment
Recommended Guidewire	SAFARI™ Pre-Shaped Guidewire 0.035" (0.89 mm)
Usable Length	113 cm
Valve Compatibility	For use with all ACURATE neo2 Aortic Valves (S, M, L)
Recommended Introducer	14F iSLEEVE™ Expandable Introducer Set
Use	Single Use
Sterilization	Chemically Sterilized
Delivery System and Loading Kit Carton Size	Delivery System: 63.60 cm x 4.75 cm x 2.75 cm Loading Kit: 11.90 cm x 3.25 cm x 14.90 cm
Shelf Life	The ACURATE neo2 Valve Shelf Life = 15 months The ACURATE neo2 Delivery System and Loading Kit Shelf Life = 12 months
Indications for Use	The ACURATE neo2 Aortic Valve, in combination with the ACURATE neo2 Transfemoral Delivery System and the ACURATE neo2 Loading Kit, 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.

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		
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 + 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	
BUN67NEO2SAFSSISM	ACURATE neo2 Aortic Valve System M + ACURATE neo2 Transfemoral Delivery System + 14F iSLEEVE + SAFARI ² Small	
BUN67NEO2SAFSSISL	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 275cm	5
H749 39406S1	SAFARI ² Pre-Shaped Guidewire Small 275cm	5
H749 39406L1	SAFARI ² Pre-Shaped Guidewire Large 275cm	5
H749 39407XS0	SAFARI ² Pre-Shaped Guidewire Extra-Small 275cm	1
H749 39407S0	SAFARI ² Pre-Shaped Guidewire Small 275cm	1
H749 39407L0	SAFARI ² Pre-Shaped Guidewire Large 275cm	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

The SAFARI² Guidewire is manufactured by Lake Region Medical and distributed by Boston Scientific Corporation.

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