



ACURATE *neo*[™]

Transfemoral Delivery System

Product Overview

Flexible Delivery Catheter

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

Radiopaque Stent Holder

- Reference for positioning

Top-Down Deployment Mechanism

- Stable and predictable valve release

Two Rotating Knobs

- Uncomplicated step-by-step implantation

Safety Button

- Prevents premature implantation

ACURATE *neo* Transfemoral Delivery System Specifications

Access Route	Transfemoral
Deployment Procedure	Phased, Top-Down Deployment
Guidewire Compatibility	0.035" (0.89 mm)
Usable Length	109 cm
Valve Compatibility	For use with all ACURATE <i>neo</i> Aortic Bioprosthesis (S, M, L)
Introducer	14 F (≥ 5.5 mm) with iSLEEVE Expandable Introducer Set
Use	Single Use
Sterilization	Gamma Irradiation Process
Carton Size (Delivery System Only)	1,720 mm × 390 mm × 89 mm
Indications for Use	The ACURATE TF Transfemoral Delivery System with the ACURATE <i>neo</i> Aortic Bioprosthesis 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).*

Ordering Information

ACURATE *neo*™ Transfemoral Delivery System

Ref/Catalog Number	Description	Units
SYM-DS-002	ACURATE™ TF Transfemoral Delivery System	1

ACURATE *neo* Aortic Valves

Ref/Catalog Number	Description	Treatment Range†	Units
SYM-SV23-002	ACURATE <i>neo</i> Aortic Bioprosthesis S	21 mm ≤ annulus diameter ≤ 23 mm 66 mm ≤ annulus perimeter ≤ 72 mm	1
SYM-SV25-002	ACURATE <i>neo</i> Aortic Bioprosthesis M	23 mm < annulus diameter ≤ 25 mm 72 mm < annulus perimeter ≤ 79 mm	1
SYM-SV27-002	ACURATE <i>neo</i> Aortic Bioprosthesis L	25 mm < annulus diameter ≤ 27 mm 79 mm < annulus perimeter ≤ 85 mm	1

ACURATE *neo* Aortic Valves + ACURATE TF Transfemoral Delivery System

Ref/Catalog Number	Description	Units
BUN67ACUNEOTFS	ACURATE <i>neo</i> Aortic Bioprosthesis S + ACURATE TF Transfemoral Delivery System	1
BUN67ACUNEOTFM	ACURATE <i>neo</i> Aortic Bioprosthesis M + ACURATE TF Transfemoral Delivery System	1
BUN67ACUNEOTFL	ACURATE <i>neo</i> Aortic Bioprosthesis L + ACURATE TF Transfemoral Delivery System	1

ACURATE *neo* Aortic Valves + ACURATE TF Transfemoral Delivery System + 14F iSLEEVE™ Expandable Introducer Set

Ref/Catalog Number	Description	Units
BUN67ACURDSTFISL	ACURATE <i>neo</i> Aortic Bioprosthesis + ACURATE TF Transfemoral Delivery System + 14F iSLEEVE™ Expandable Introducer Set Generic Bundle	1
BUN67ACURTFISL14FS**	ACURATE <i>neo</i> Aortic Bioprosthesis S + ACURATE TF Transfemoral Delivery System + 14F iSLEEVE	1
BUN67ACUTFISL14FM**	ACURATE <i>neo</i> Aortic Bioprosthesis M + ACURATE TF Transfemoral Delivery System + 14F iSLEEVE	1
BUN67ACUTFISL14FL**	ACURATE <i>neo</i> Aortic Bioprosthesis L + ACURATE TF Transfemoral Delivery System + 14F iSLEEVE	1

SAFARI²™ Pre-Shaped Guidewire

Ref/Catalog Number	Description	Units
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

14 F iSLEEVE Expandable Introducer Set

Ref/Catalog Number	Description	Units
H749 39349 140	14 F iSLEEVE Expandable Introducer Set	1

SENTINEL™ Cerebral Protection System

Ref/Catalog Number	Description	Units
CMS15-10C	SENTINEL Cerebral Protection System	1

* See Instructions for Use (IFU) for details.

** Only available in the following countries: Germany, Austria, Switzerland and the Netherlands.

† CT based measurement: Perimeter derived annulus.

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

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