

**ACURATE Prime™**  
Aortic Valve System

Prime  
Performance.  
Today and  
Tomorrow.



# Elevate your TAVI experience.

With a split-level design, precise commissure alignment, and unique top-down deployment, ACURATE Prime™ provides you with the predictable performance you want today, and the outcomes patients need for tomorrow.

- Expanded treatment range
- Enhanced valve frame
- Quicker, controlled deployment
- Streamlined device preparation

## Experience ACURATE Prime™

### ► Implant with Ease

- Streamlined device preparation and smooth deliverability<sup>1</sup>
- Predictable commissure alignment and quicker deployment.<sup>2</sup>
- Precise and consistent positioning<sup>3</sup>

### ► Maximise Outcomes

- Low PPI rates<sup>4</sup>
- Excellent PVL rates<sup>3</sup>
- Single-digit gradients<sup>4</sup>

### ► Optimise Lifetime Patient Management

- Unrestricted coronary access<sup>5</sup>
- Maintained stable hemodynamic function<sup>4</sup>
- Engineered to last<sup>6</sup>



Expanded size matrix allowing for wider treatment range

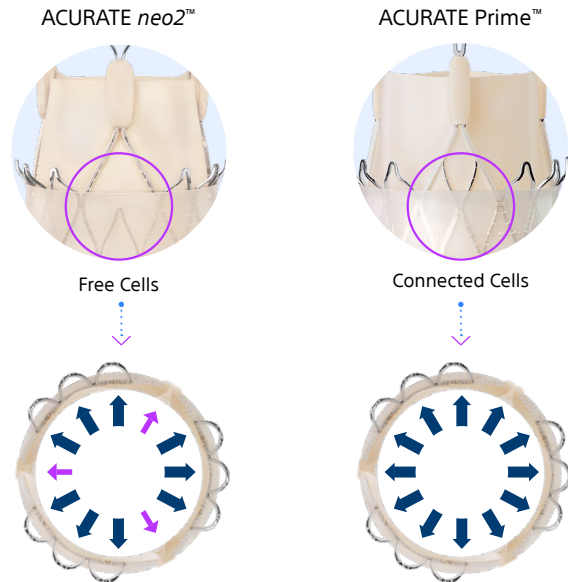
Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

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 Dec;110(12):1912-1920.
2. Bieliauskas G, Wong I, Bajoras V, et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural Alignment With Self-Expanding Transcatheter Aortic Valves. *JACC Cardiovasc Interv.* 2021 October 11;14(19):2097-2108.
3. Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention.* 2023 May 12;19(1):83-92.
4. Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: Transcatheter Aortic Valve Implantation with ACURATE neo2 in a European Population. *J Am Heart Assoc.* 2023 Aug;12(15):e029464.
5. Barbanti M, Costa G, Picci A, et al. Coronary Cannulation After Transcatheter Aortic Valve Replacement: The RE-ACCESS Study. *JACC Cardiovasc Interv.* 2020 Nov 9;13(21):2542-2555.
6. Möllmann H, Noack T, Hilker M, et al. Five-year outcomes of transcatheter aortic valve implantation with the ACURATE neo2 valve system. *EuroIntervention.* 2024 Aug 5;20(15):e951-e953.

# ACURATE Evolves

## Connected cells

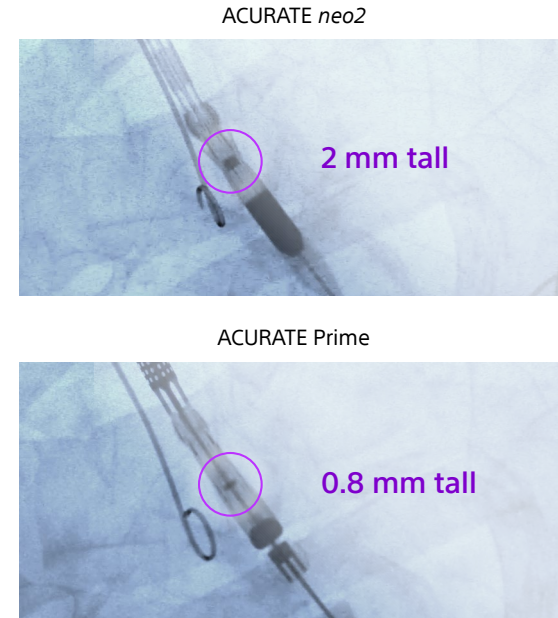
Allows for equally distributed radial force over circumference.<sup>1</sup>



1. BSC data on file. Technical Report 97090122.  
2. BSC data on file. Technical Report 97024304.

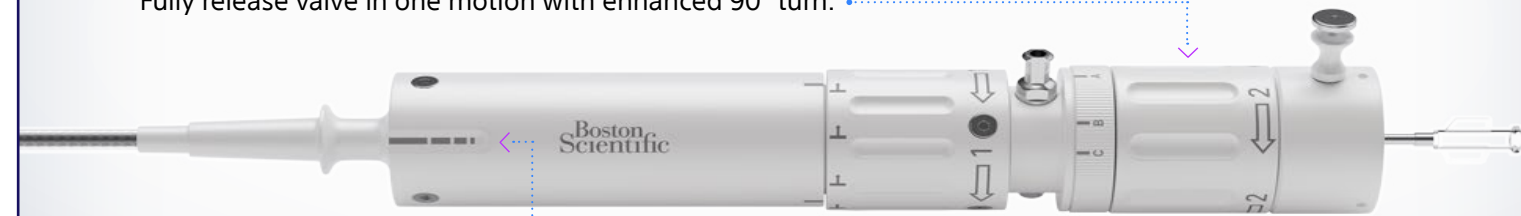
## Radiopaque positioning marker

For more precise placement.<sup>2</sup>



## Enhanced deployment<sup>1</sup>

Fully release valve in one motion with enhanced 90° turn.



## Commissure alignment insertion marker

Enables easy, consistent valve orientation.

## Quicker valve loading

Optimized cath-lab efficiency.

**45%** faster loading compared to ACURATE neo2<sup>2</sup>

## Added size

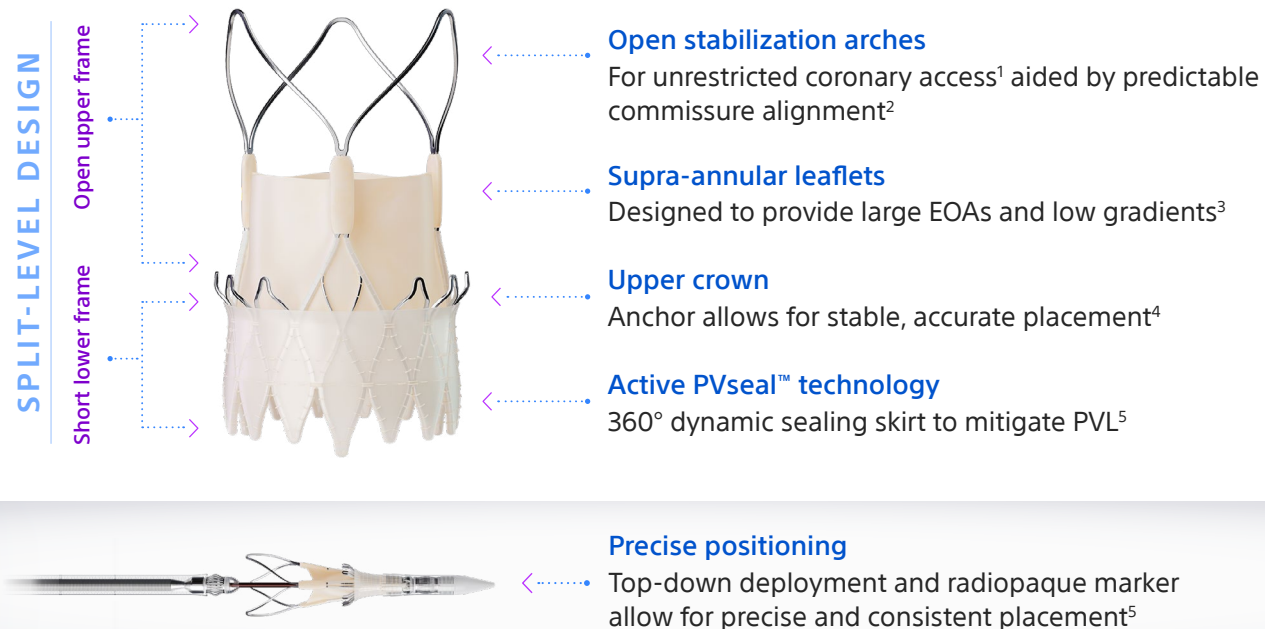
Size matrix expansion to treat annuli measuring up to 29 mm.

### 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 mm

\* CT-based measurement: Perimeter-derived annulus.  
1. BSC data on file.  
2. BSC data on file. Technical Report 97265411.

# Split-level design. Unmatched versatility.



Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

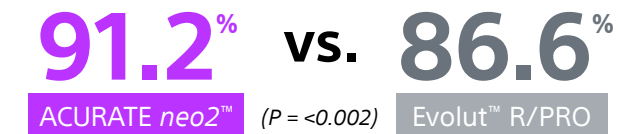
1. Barbanti M, Costa G, Picci A, et al. Coronary Cannulation After Transcatheter Aortic Valve Replacement: The RE-ACCESS Study. *JACC Cardiovasc Interv.* 2020 Nov 9;13(21):2542-2555.
2. Bieliauskas G, Wong I, Bajoras V, et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural Alignment With Self-Expanding Transcatheter Aortic Valves. *JACC Cardiovasc Interv.* 2021 October 11;14(19):2097-2108.
3. 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 Dec;110(12):1912-1920.
4. Okuno T, Lanz J, Pilgrim T. ACURATE neo: How Is This TAVR Valve Doing to Fit into an Increasingly Crowded Field? *Curr Cardiol Rep.* 2020 Aug 8;22(10):107.
5. Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention.* 2023 May 12;19(1):83-92.

## ► Implant with Ease

### Streamlined device preparation and smooth deliverability<sup>1</sup>

ACURATE Prime™ offers streamlined device preparation with fewer components and steps required. Expect uncompromised deliverability, even in small and tortuous anatomies, with the flexible ACURATE Prime delivery system, the low-profile iSLEEVE™ Expandable Introducer Sheath and intuitive, top-down deployment with the ACURATE Prime valve.

### Superior device success among patients with horizontal aortas<sup>2</sup>



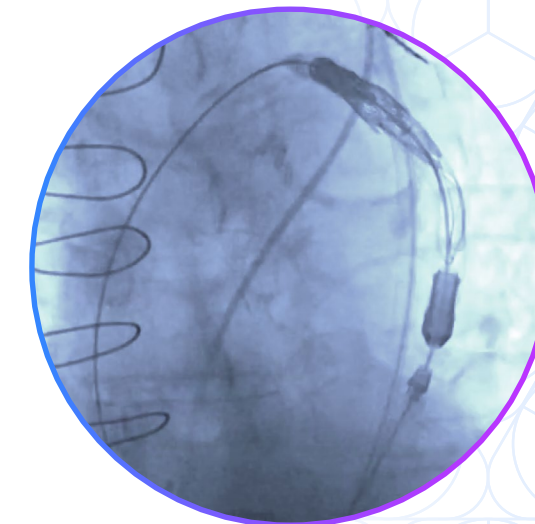
47% of patients in the HORSE Registry had horizontal aortas\*\*

Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

- \* The iSLEEVE Expandable Introducer Sheath is indicated for vessels ≥ 5.5mm. \*\* Horizontal aorta was defined as ≥ 49 degrees.
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 Dec;110(12):1912-1920.
  2. Gallo F, Gallone G, Kim W-K, et al. Horizontal Aorta in Transcatheter Self-Expanding Valves: Insights from the HORSE International Multicentre Registry. *Circ Cardiovasc Interv.* 2021 Sept;14(9):e010641.



Compatible with all ACURATE Prime valve sizes



## ► Implant with Ease

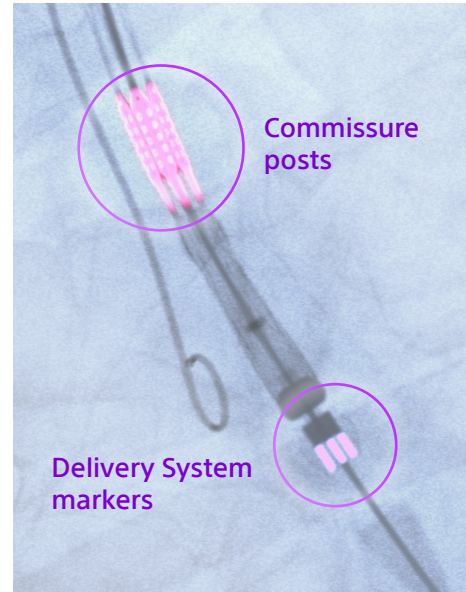
### Precise and consistent positioning<sup>1</sup>

Radiopaque positioning marker is designed for enhanced visualization for short procedures and high success rates.<sup>2</sup>



### Quicker deployment and predictable commissure alignment<sup>4</sup>

ACURATE™ was the only valve to achieve **100%** successful commissure alignment.\*<sup>4</sup>



Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

\* Successful commissural alignment is defined as no moderate or severe commissural misalignment.

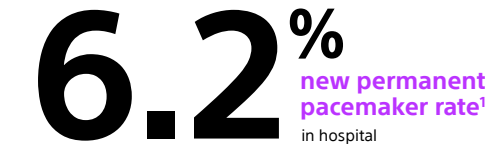
1. Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention*. 2023 May 12;19(1):83-92.
2. Pellegrini C, Rheude T, Renker M, et al. ACURATE neo2 versus SAPIEN 3 Ultra for transcatheter aortic valve implantation. *EuroIntervention*. 2023 Jan 23;18(12):987-995.
3. 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 Dec;110(12):1912-1920.
4. Bieliauskas G, Wong J, Bajoras V, et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural Alignment with Self-Expanding Transcatheter Aortic Valves. *JACC Cardiovasc Interv*. 2021 October 11;14(19):2097-2108.
5. Meduri CU, Rück A, Linder R, et al. Commissural Alignment With ACURATE neo2 Valve in an Unselected Population. *JACC Cardiovasc Interv*. 2023 Mar, 27;16(6):670-677.

## ► Maximise Outcomes

### Low PPI rates<sup>1</sup>

With its unique top-down deployment and minimal interaction in the LVOT, ACURATE Prime™:

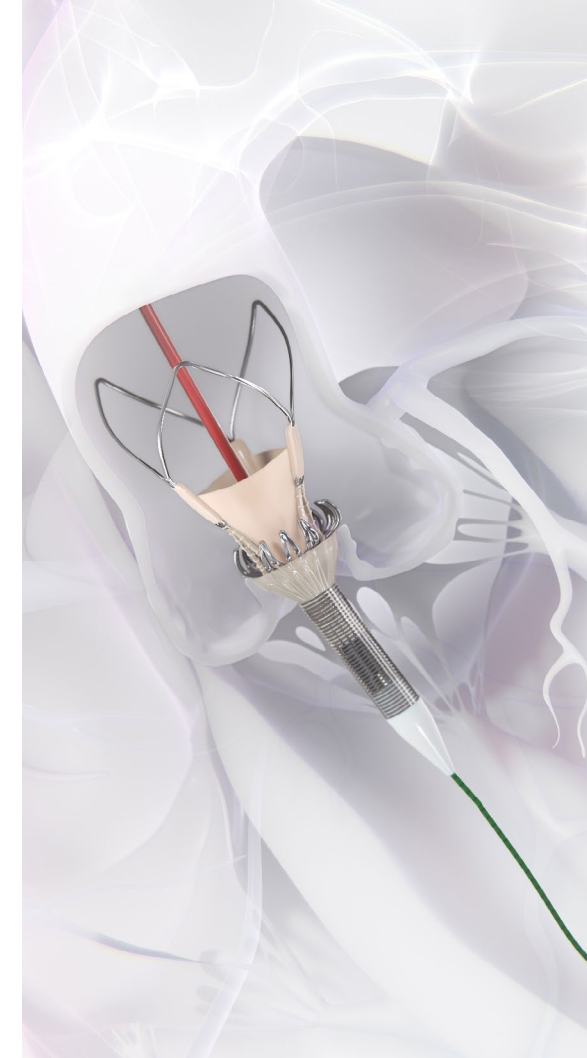
- Lowers your patients' risk of needing a pacemaker<sup>1</sup>
- Reduces patient length of stay<sup>2</sup>



ACURATE neo2 permanent pacemaker rate among pacemaker-naïve patients at 30 days in the PMCF study: 6.5%<sup>3</sup>

Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

1. Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: Transcatheter Aortic Valve Implantation with ACURATE neo2 in a European Population. *J Am Heart Assoc*. 2023 Aug;12(15):e029464.
2. Ooms JF, Cornelis K, Wijeyundera HC, et al. Safety and feasibility of early discharge after transcatheter aortic valve implantation with ACURATE Neo - the POLESTAR trial. *Clin Res Cardiol*. 2024 Apr 15.
3. Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention*. 2023 May 12;19(1):83-92.

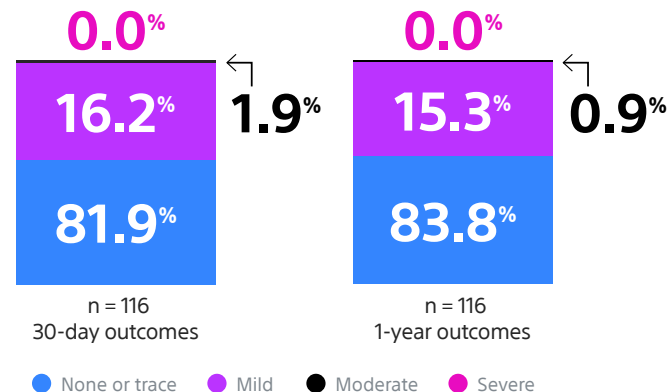


► Maximise Outcomes

### Excellent PVL rates<sup>1</sup>

360° Active PVseal™ extends the full waist of the ACURATE Prime™ valve, designed to maximise sealing efficacy and protect against PVL.

#### ACURATE neo2™ post market clinical follow-up\*<sup>2</sup>



Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

\* Core laboratory- adjudicated echocardiographic and CT imaging analyses.

- Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention*. 2023 May 12;19(1):83-92.
- Kim WK, Möllmann H, Montorfano M, et al. Outcomes and performance of the ACURATE neo2 transcatheter heart valve in clinical practice: one-year results of the ACURATE neo2 PMCF Study. *EuroIntervention*. 2024 Jan 1;20(1):85-94.




► Maximise Outcomes

### Single-digit gradients<sup>1</sup>

Protect your patient's future. Supra-annular leaflets designed to maximise leaflet opening for single-digit gradients and large EOAs.<sup>2</sup>

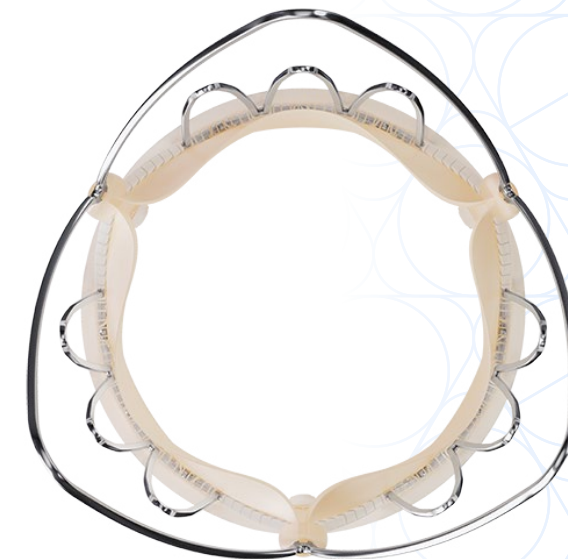
#### See the evidence

 **7.6** mmHg gradients<sup>1</sup>

 **2.2** cm<sup>2</sup> EOAs<sup>1</sup>

Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

- Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: Transcatheter Aortic Valve Implantation with ACURATE neo2 in a European Population. *J Am Heart Assoc*. 2023 Aug;12(15).
- 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 Dec;110(12):1912-1920.



## ► Optimise Lifetime Patient Management

### Unrestricted coronary access<sup>1</sup>

Choose ACURATE Prime™ for a lifetime

ACURATE Prime's open stabilization arches provide the largest accessible stent cell area for easy future coronary reaccess.<sup>2</sup>

**100%**

ACURATE neo™  
Valve platform

successful coronary  
cannulation  
n = 72

**82%**

Evolut™ R/PRO

successful coronary  
cannulation  
n = 123

**99%**

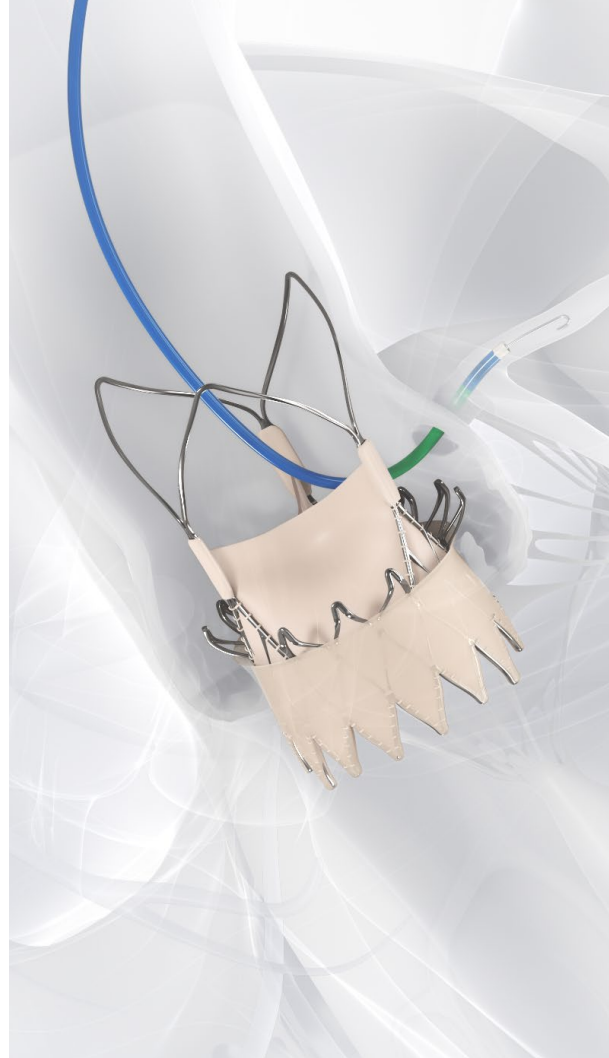
SAPIEN™

successful coronary  
cannulation  
n = 96

Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

1. Barbanti M, Costa G, Picci A, et al. Coronary Cannulation After Transcatheter Aortic Valve Replacement: The RE-ACCESS Study. *JACC Cardiovasc Interv.* 2020 Nov 9;13(21):2542-2555.

2. Meier D, Akodad M, Landes U, et al. Coronary Access Following Redo TAVR. Impact of THV Design, Implant Technique, and Cell Misalignment. *JACC Cardiovasc Interv.* 2022 August 8;15(15):1519-1531.



## ► Optimise Lifetime Patient Management

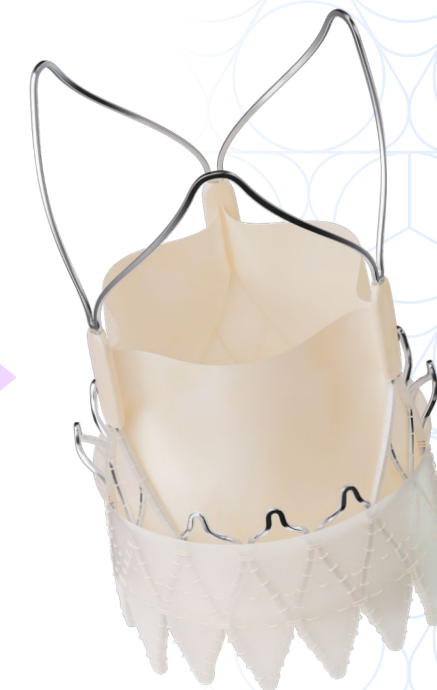
### Maintained stable hemodynamic function<sup>1</sup>

Reduce the risk of valve deterioration and improve long-term cardiac function with a self-expanding, supra-annular design.<sup>2</sup>

### Engineered to last<sup>3</sup>

Supra-annular leaflets treated with BioFix™ anti-calcification process are designed with your patient's lifetime in mind.<sup>4</sup>

Accelerated wear testing equivalent to 25 years demonstrated robust wear resistance and excellent hydrodynamic performance<sup>5</sup>



Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

1. Rück A, Kim WK, Abdel-Wahab M, et al. The Early neo2 Registry: Transcatheter Aortic Valve Implantation with ACURATE neo2 in a European Population. *J Am Heart Assoc.* 2023 Aug;12(15):e029464.

2. Flameng W, Herregods MC, Vercauteren M, et al. Prosthesis-patient mismatch predicts structural valve degeneration in bioprosthetic heart valves. *Circulation.* 2010 May 18;121(19):2123-2129.

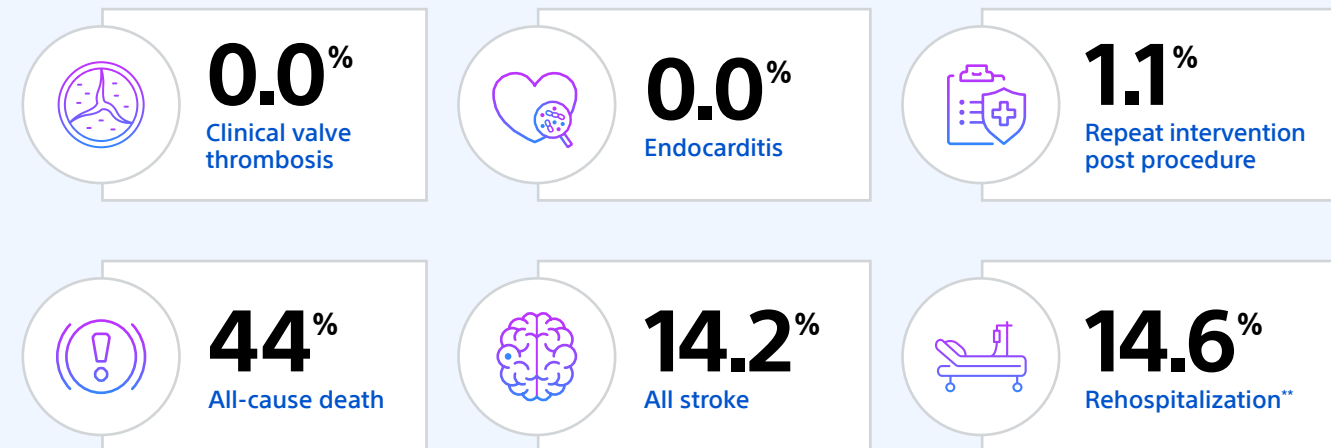
3. Möllmann H, Noack T, Hilker M, et al. Five-year outcomes of transcatheter aortic valve implantation with the ACURATE neo2 valve system. *EuroIntervention.* 2024 Aug 5;20(15):e951-e953.

4. Anderson-Cunanan C, Thomas K, Hou D. Calcification Assessment of the BSC-Symetis Valve Leaflet Material Treated with the Biofix™ Process. *JACC Cardio Interv.* 2019 Feb 18;12(4):S35-S36.

5. Sathanathan J, Landes U, Flaction L, et al. Long-Term Durability of the Next-Generation Acurate neo2 Transcatheter Heart Valve: Insights From Bench Testing to 25 Years. *JACC Cardiovasc Interv.* 2021 Mar 8;14(5):586-588.

## ► Optimise Lifetime Patient Management

### Positive clinical outcomes at five years\*<sup>1</sup>



Data from clinical trials with ACURATE neo™ or ACURATE neo2™.

\* Outcomes consistent with corresponding high-risk trials.\*\* >30 days for valve-related symptoms or worsening congestive heart failure.

1. Möllmann H, Noack T, Hilker M, et al. Five-year outcomes of transcatheter aortic valve implantation with the ACURATE neo2 valve system. *EuroIntervention*. 2024 Aug 5;20(15):e951-e953.

## ► Ordering Information

Ref/Catalog #	Description	Unit
<b>ACURATE Prime™ Aortic Valves</b>		
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
<b>ACURATE Prime™ Delivery System and Loading Kit</b>		
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
<b>ACURATE Prime™ Customizable Bundle Kits - Contact your BSC representative for details</b>		
BUN67PRIME	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System and ACURATE Prime Loading Kit	1
BUN67PRMISL	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit and 14F iSLEEVE™ Expandable Introducer Set	1
BUN67PRMISLS2	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit, 14F iSLEEVE Expandable Introducer Set and SAFARI™ Pre-Shaped Guidewire	1
BUN67PRMISLS2SN	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit, 14F iSLEEVE Expandable Introducer Set, SAFARI™ Pre-Shaped Guidewire and SENTINEL Cerebral Protection System	1
BUN67PRMISLSN	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit, 14F iSLEEVE Expandable Introducer Set and SENTINEL™ Cerebral Protection System	1
BUN67PRMS2	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit and SAFARI™ Pre-Shaped Guidewire	1
BUN67PRMS2SN	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit, SAFARI™ Pre-Shaped Guidewire and SENTINEL Cerebral Protection System	1
BUN67PRMSN	ACURATE Prime Aortic Valve, ACURATE Prime Delivery System, ACURATE Prime Loading Kit and SENTINEL Cerebral Protection System	1
<b>SAFARI™ Pre-Shaped Guidewire</b>		
H749 39406XS1	SAFARI™ Pre-Shaped Guidewire Extra-Small 275 cm	5
H749 39406S1	SAFARI™ Pre-Shaped Guidewire Small 275 cm	5
H749 39406L1	SAFARI™ Pre-Shaped Guidewire Large 275 cm	5
H749 39407XS0	SAFARI™ Pre-Shaped Guidewire Extra-Small 275 cm	1
H749 39407S0	SAFARI™ Pre-Shaped Guidewire Small 275 cm	1
H749 39407L0	SAFARI™ Pre-Shaped Guidewire Large 275 cm	1
<b>14F iSLEEVE™ Expandable Introducer Set</b>		
H749 39349 140	14F iSLEEVE Expandable Introducer Set	1
<b>SENTINEL™ Cerebral Protection System</b>		
CMS15-10C	SENTINEL Cerebral Protection System	1



# ACURATE Prime™

Aortic Valve System

Prime  
Performance.  
Today and  
Tomorrow.



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. Illustrations for information purposes – not indicative of actual size or clinical outcome. All photographs taken by Boston Scientific. SH-1895404-AA

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