

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 deliverability¹
- Predictable commissure alignment and quicker deployment.²
- Precise and consistent positioning³

► Maximise Outcomes

- Low PPI rates⁴
- Excellent PVL rates³
- Single-digit gradients⁴

► Optimise Lifetime Patient Management

- Unrestricted coronary access⁵
- Maintained stable hemodynamic function⁴
- Engineered to last⁶



Expanded size matrix allowing for wider treatment range

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

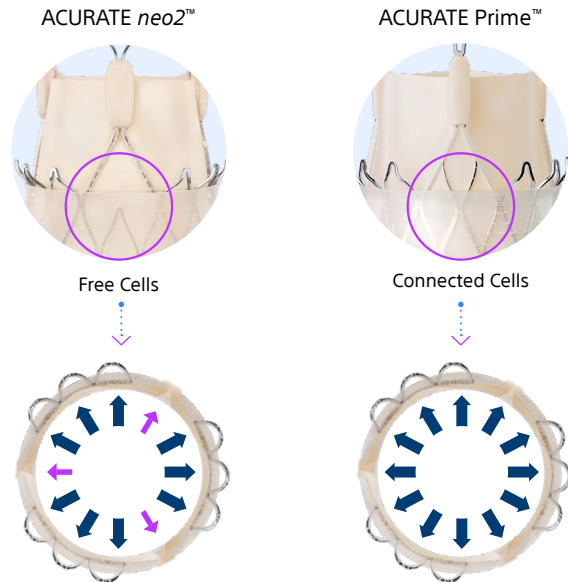
1. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol.* 2021 Dec;110(12):1912-1920.
2. Bieliauskas G, Wong I, Bajoras V, et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural 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

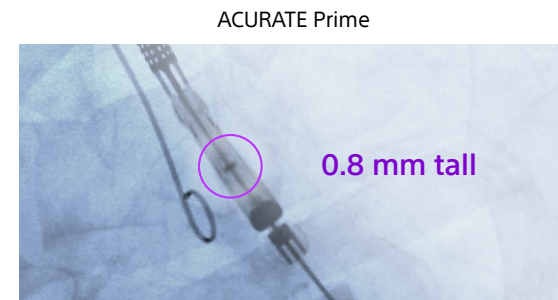
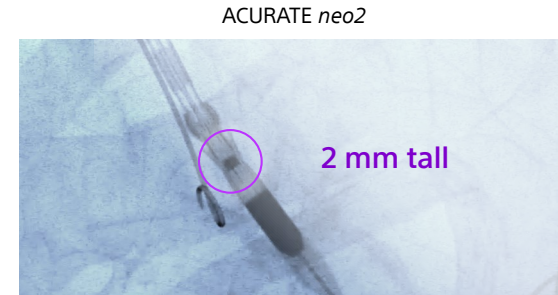
Allows for equally distributed radial force over circumference.¹



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

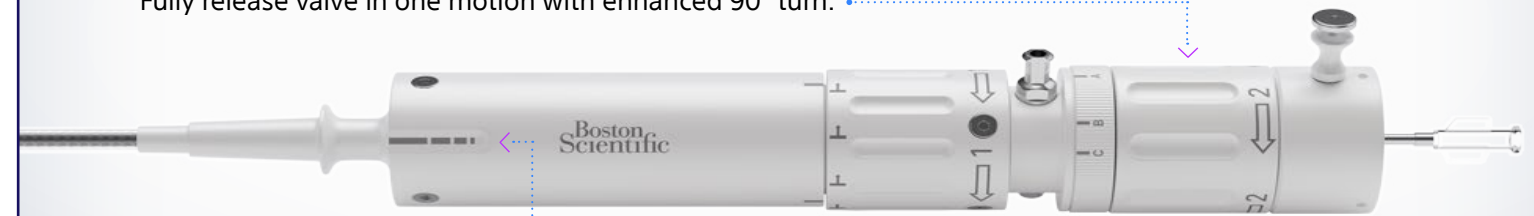
Radiopaque positioning marker

For more precise placement.²



Enhanced deployment¹

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 neo2²

Added size

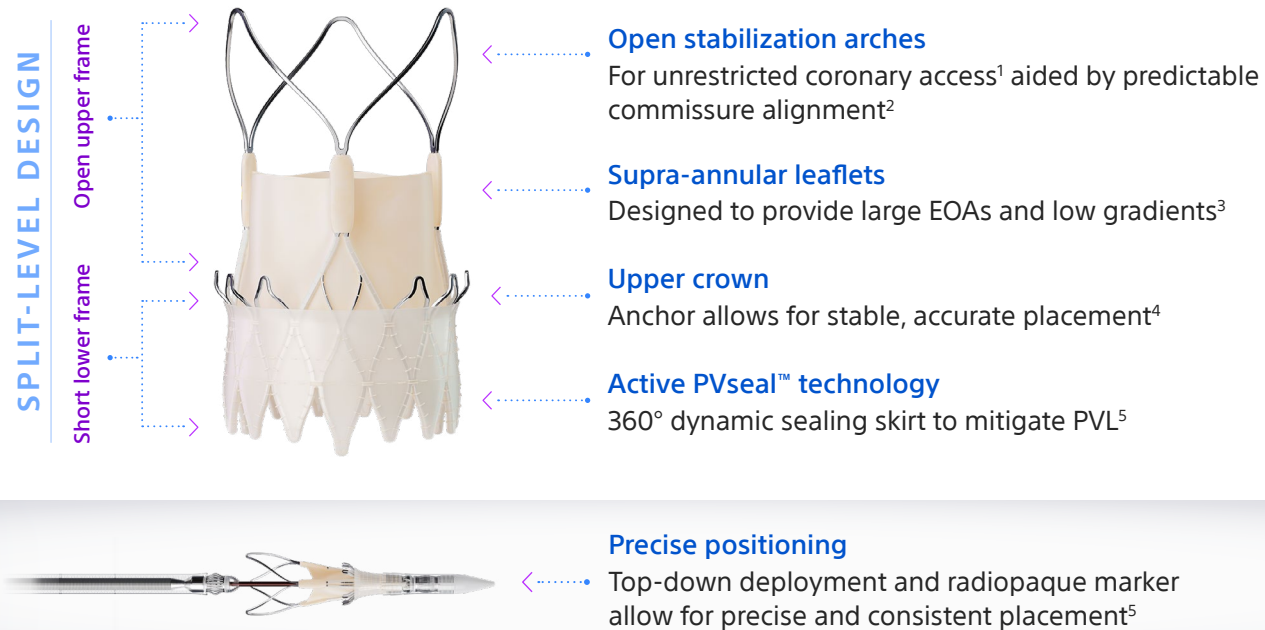
Size matrix expansion to treat annuli measuring up to 29 mm.

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™.

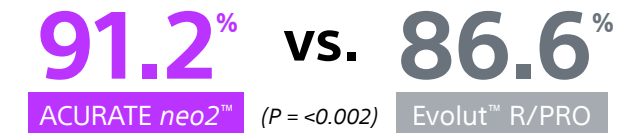
1. Barbanti M, Costa G, Picci A, et al. Coronary Cannulation After Transcatheter Aortic Valve Replacement: The RE-ACCESS Study. *JACC Cardiovasc Interv.* 2020 Nov 9;13(21):2542-2555.
2. Bieliauskas G, Wong I, Bajoras V, et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural Alignment 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 deliverability¹

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 aortas²



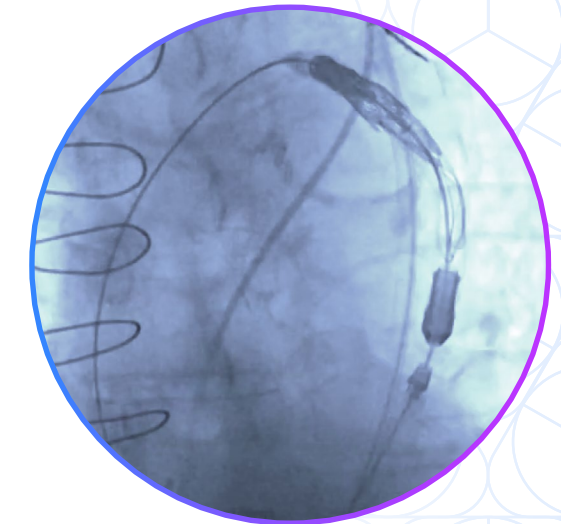
47% of patients in the HORSE Registry had horizontal aortas**

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

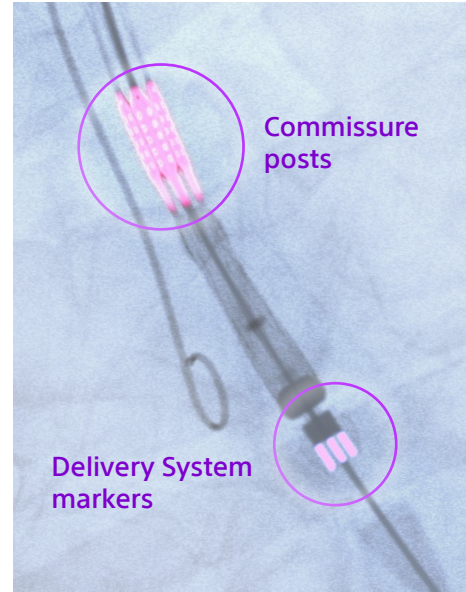
Precise and consistent positioning¹

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



Quicker deployment and predictable commissure alignment⁴

ACURATE™ was the only valve to achieve **100%** successful commissure alignment.*⁴



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

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

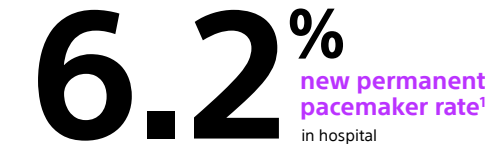
1. Kim WK, Tamburino C, Möllmann H, et al. Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study. *EuroIntervention*. 2023 May 12;19(1):83-92.
2. Pellegrini C, Rheude T, Renker M, et al. ACURATE neo2 versus SAPIEN 3 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 rates¹

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

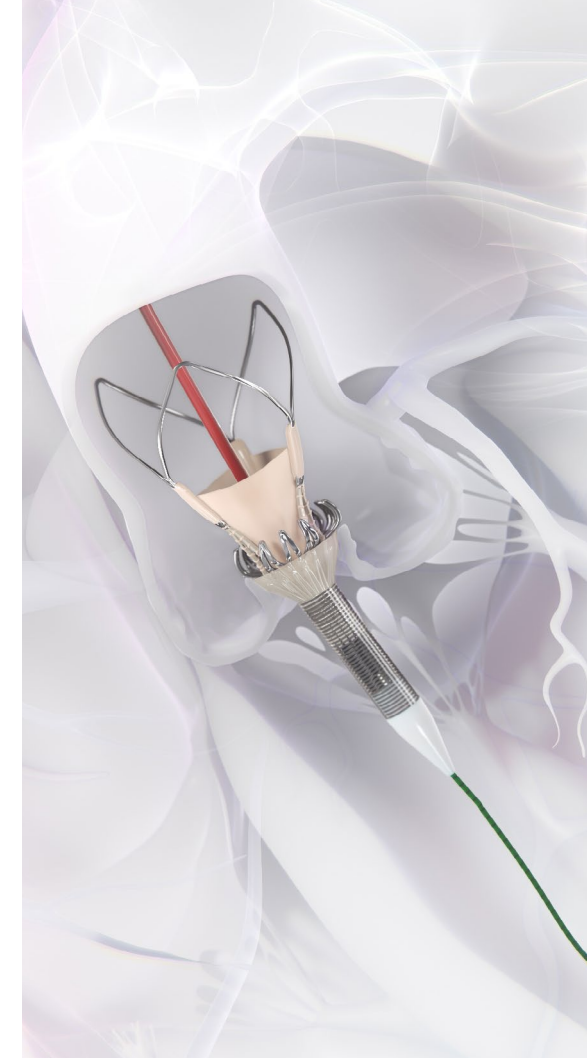
- Lowers your patients' risk of needing a pacemaker¹
- Reduces patient length of stay²



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

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.

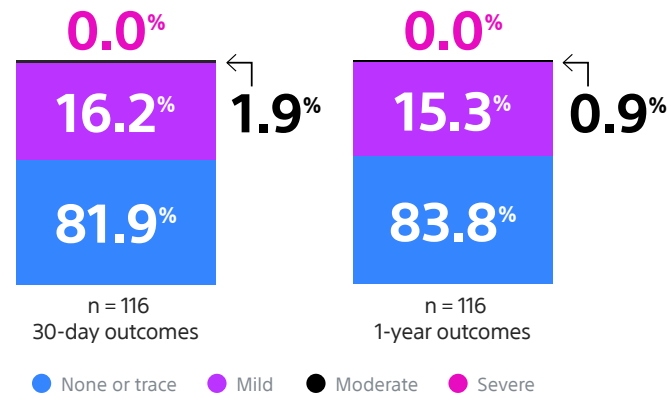


► Maximise Outcomes

Excellent PVL rates¹

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*²



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.



Active PVseal conforms to native valve annulus


► Maximise Outcomes

Single-digit gradients¹

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

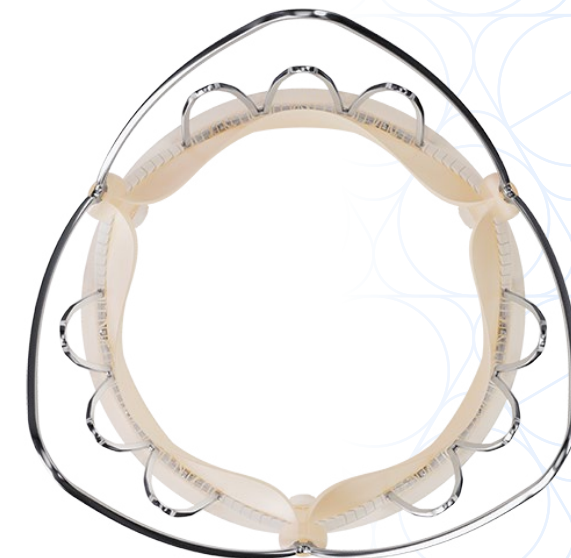
See the evidence

 **7.6** mmHg gradients¹

 **2.2** cm² EOAs¹

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 access¹

Choose ACURATE Prime™ for a lifetime

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

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

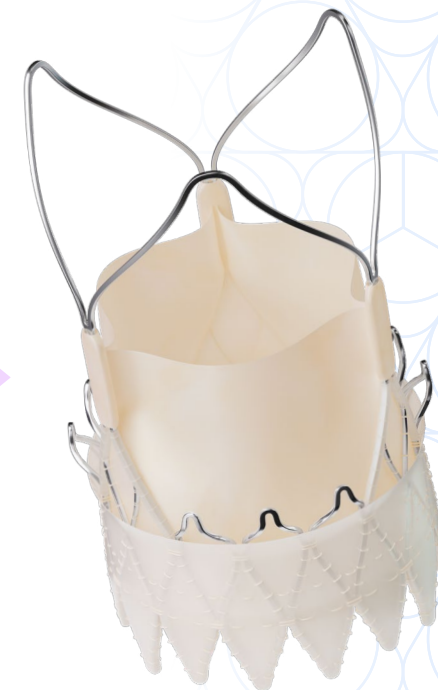
Maintained stable hemodynamic function¹

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

Engineered to last³

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

Accelerated wear testing equivalent to 25 years demonstrated robust wear resistance and excellent hydrodynamic performance⁵



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.

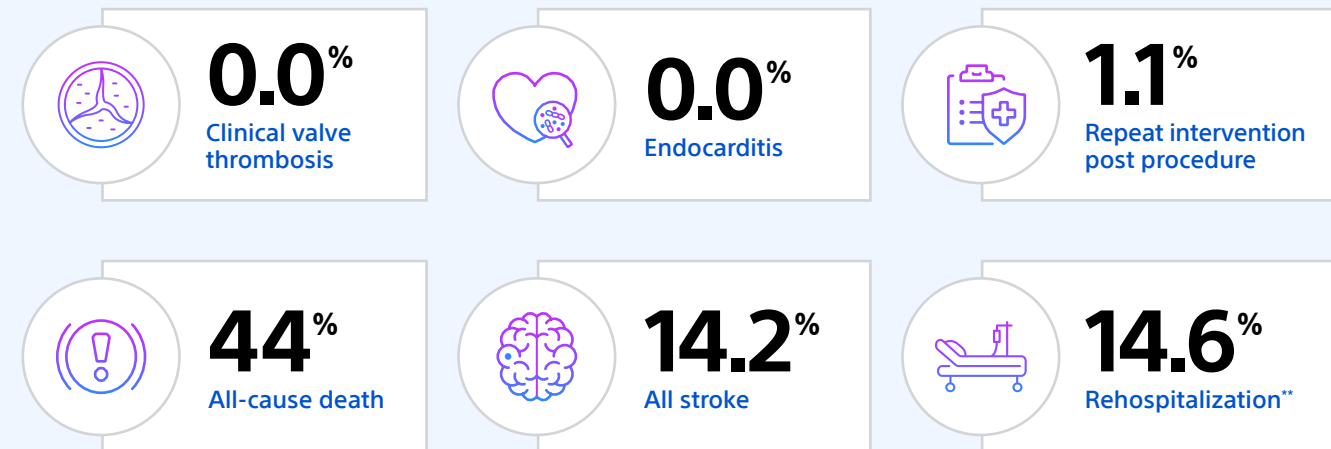
3. Möllmann H, Noack T, Hilker M, et al. Five-year outcomes of transcatheter aortic valve implantation with the ACURATE neo2 valve system. *EuroIntervention.* 2024 Aug 5;20(15):e951-e953.

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*¹



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 |
|--|--|------|
| 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 |
| ACURATE Prime™ Customizable Bundle Kits - Contact your BSC representative for details | | |
| 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 |
| SAFARI™ Pre-Shaped Guidewire | | |
| 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 |
| 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 |

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

CE 0344

**Boston
Scientific**
Advancing science for life™

© 2024 Boston Scientific Corporation or its affiliates. All rights reserved.