



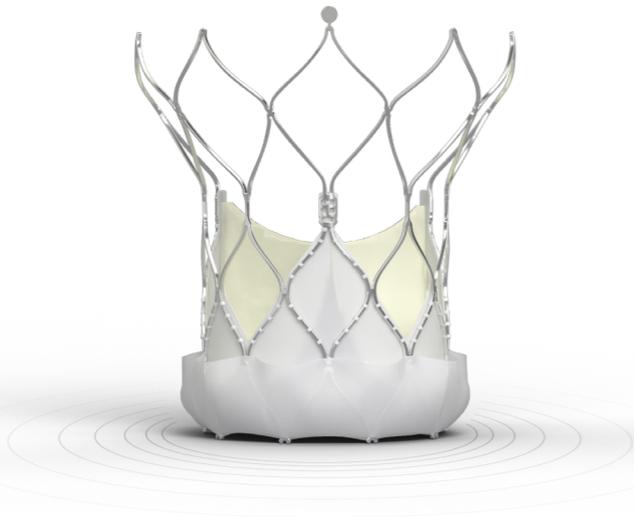
NAVITOR™ TAVI SYSTEM

SMART SEALING. MITIGATES PVL. UNCOMPROMISED ACCESS¹.

Navitor™ TAVI system offers intelligent design advantages, including smart PVL-sealing NaviSeal™ Cuff, stable and accurate placement, desirable single-digit gradients,¹ and uncompromised small vessel access and coronary access to consistently achieve favourable outcomes across a spectrum of routine to challenging anatomies.¹

1. Abbott data on file CL1014440.

NAVITOR™ VALVE

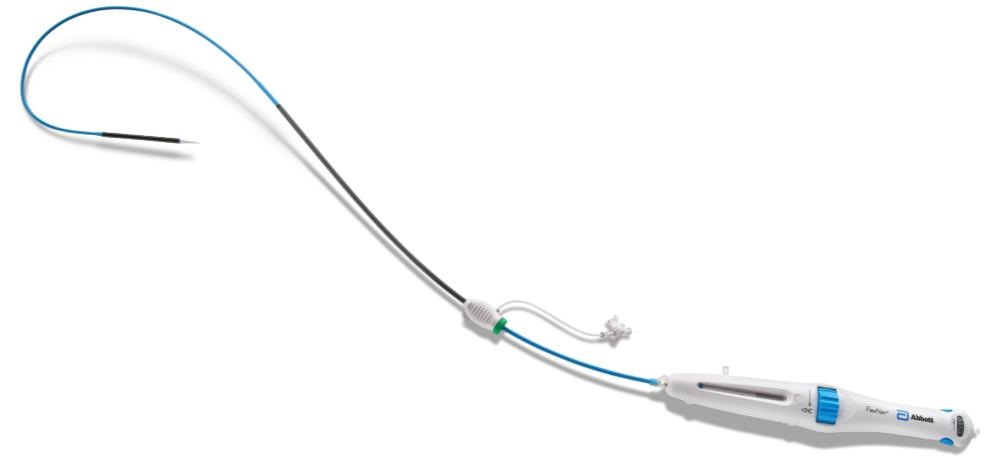


INTELLIGENT DESIGN.

- Smart PVL-sealing NaviSeal™ Cuff
- Desirable single-digit gradients¹
- Uncompromised coronary access¹

LEARN MORE >

FLEXNAV™ DELIVERY SYSTEM



STABILITY AND ACCURACY.

- Low profile 5.0 mm minimum vessel diameter for uncompromised small vessel access
- Designed for flexibility and deliverability²
- Designed for stable deployment and accurate valve placement

LEARN MORE >

FAVOURABLE OUTCOMES.

Clinical results demonstrate favourable outcomes across a spectrum of routine to challenging anatomies.

30-DAY¹

0%

SEVERE TO MODERATE PVL

0%

ALL CAUSE MORTALITY

0.8%

DISABLING STROKE

0.8%

MAJOR VASCULAR COMPLICATIONS

7.4^{mmHg}

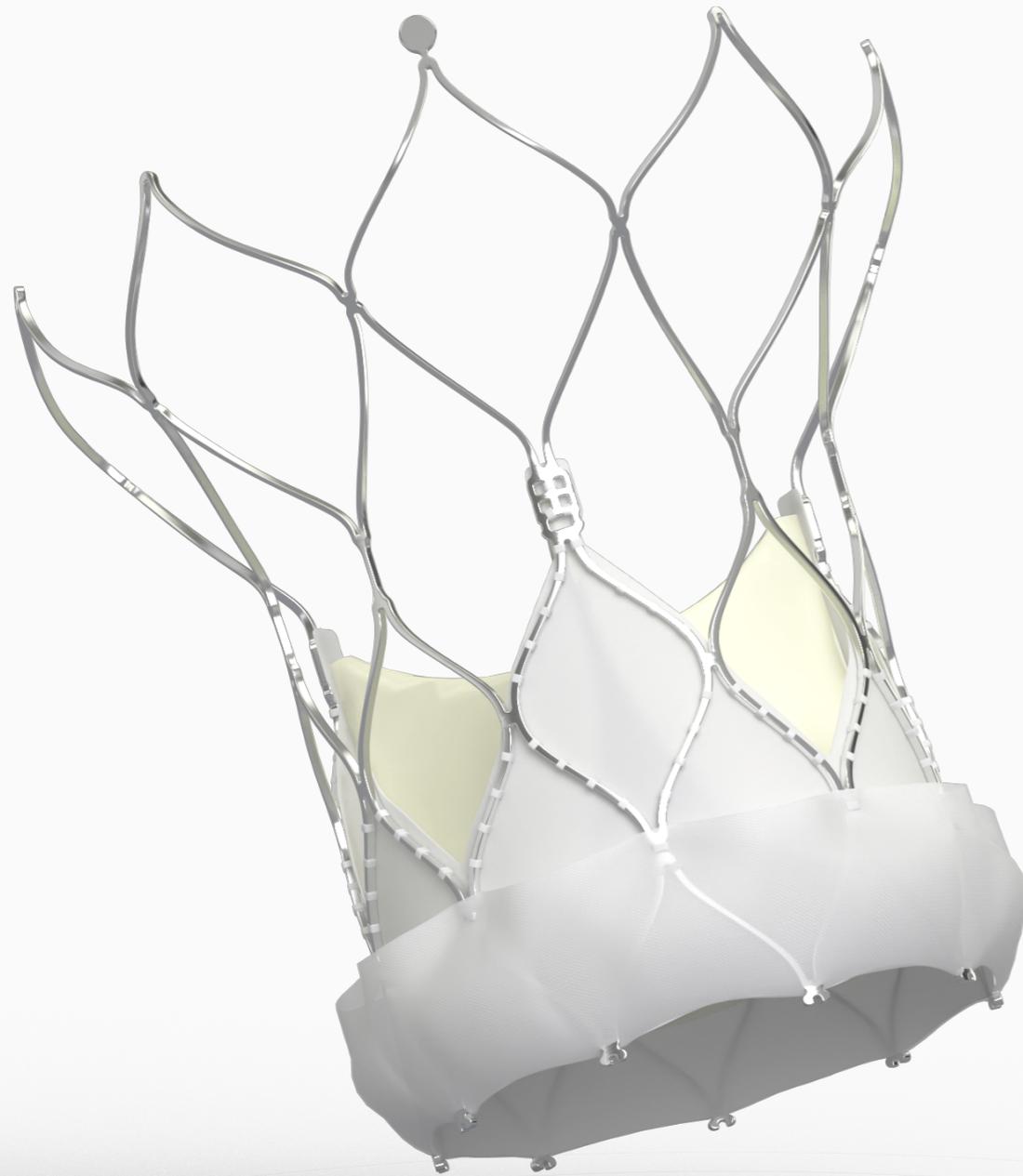
MEAN GRADIENT

1. Abbott data on file CL1014440.
2. Fontana GP, Bedogni F, Groh M, et al. Safety Profile of an Intra-Annular Self-Expanding Transcatheter Aortic Valve and Next-Generation Low-Profile Delivery System. J Am Coll Cardiol Intv 2020;13:2467-78.

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS



NAVITOR™ VALVE

INTELLIGENT DESIGN.

Advancing the forefront of innovative design, the Navitor™ valve brings together smart PVL-sealing technology, favourable single-digit gradients,¹ and uncompromised coronary access to achieve favourable clinical outcomes.¹

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS

SMART SEALING. ACTIVE SYNCHRONIZATION.

NaviSeal™ Cuff actively synchronizes to the cardiac cycle, seals, and mitigates PVL¹ by expanding to fill calcification-related gaps between the annulus and the valve.

SMART SEALING MITIGATES PVL

30-DAY ECHO CORE LAB DATA¹

80%

NONE/TRACE

20%

MILD

0%

MODERATE

0%

SEVERE

SEE THE EVIDENCE
Outperforming TAVI Systems

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS

NAVITOR™ TAVI SYSTEM

SMART SEALING.

PVL 30-DAY ECHO CORE LAB DATA	NAVITOR™ ¹ N=118	EVOLUT [‡] PRO ² N=58	ACURATE NEO2 ^{‡3} N=100	SAPIEN [‡] 3 ⁴ N=113*
None/Trace	79.7%	72.4%	35.0%	74.3%
Mild	20.3%	27.6%	62.0%	22.1%
Moderate	0.0%	0.0%	3.0%	3.5%
Severe	0.0%	0.0%	0.0%	0.0%

Based on number of subjects with data evaluable by the echo core lab.

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

NOTE: Referenced data reflect results from prospective, multicenter clinical studies with contemporary valves in high and extreme risk surgical patients conducted to support CE Mark approval.

* Includes data on subjects implanted via transapical and transaortic access.

1. Abbott data on file CL1014440.

2. Forrest JK, et al. Outcomes with the Evolut PRO repositionable self-expanding transcatheter aortic valve with pericardial wrap. J Am Coll Cardiol Interv. 2018;11:160-168.

3. Möllmann H. Transcatheter aortic valve implantation for severe aortic stenosis with the Acurate neo2 valve system: 30-day safety and performance outcomes. Abstract presented at: PCR London Valves; September 10, 2018; London, UK.

4. Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64:2235-43.

5. Pibarot P, et al. Assessment of paravalvular regurgitation following TAVR: a proposal of unifying grading scheme. JACC Cardiovasc Imaging. 2015;8(3):340-360. doi: 10.1016/j.jcmg.2015.01.008. PMID: 25772838.

PVL IMPACT.

Moderate or greater PVL increases 1-year mortality and rehospitalization

2.4x-2.7x

following TAVI⁵

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS

HEMODYNAMICS. IMPACT

LARGE EFFECTIVE ORIFICE AREAS! SINGLE-DIGIT GRADIENTS!¹

30-DAY ECHO CORE LAB DATA¹

2.0 cm²
EOA

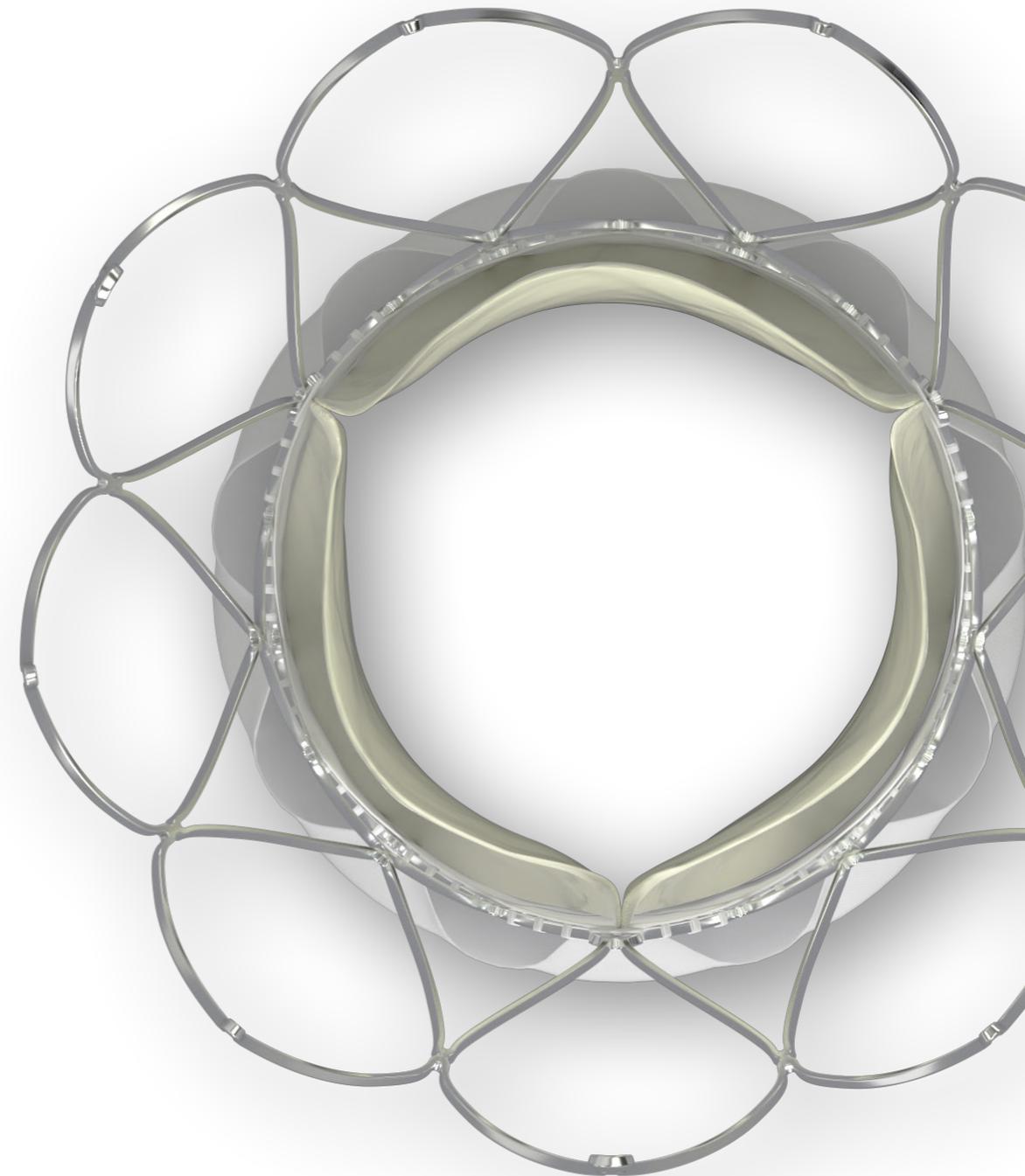
7.4 mmHg
MEAN GRADIENT

SEE THE EVIDENCE
Outperforming TAVI Systems

Non-tapered stent and large EOAs resulting in single-digit gradients are associated with improved cardiac function[^], long-term durability, and minimal prosthesis-patient mismatch.¹

1. Abbott data on file CL1014440. [^]In comparison to the original Portico™ valve.

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SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS

NAVITOR™ TAVI SYSTEM

HEMODYNAMIC IMPACT.

30-DAY ECHO CORE LAB DATA	NAVITOR™ ¹	EVOLUT† PRO ²	ACURATE NEO2† ³	SAPIEN† 3 ⁴
Mean Gradient (mmHg)	7.4 (N=118)	6.4 (N=55)	7.9 (N=104)	10.6 (N=119*)
EOA (cm ²)	2.0 (N=101)	2.0 (N=47)	1.7 (N=99)	1.5 (N=97*)

Based on number of subjects with data evaluable by the echo core lab.

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2. Forrest JK, et al. Early outcomes with the Evolut PRO repositionable self-expanding transcatheter aortic valve with pericardial wrap. J Am Coll Cardiol Interv. 2018;11:160-168.

3. Möllmann H. Transcatheter aortic valve implantation for severe aortic stenosis with the Acurate neo2 valve system: 30-day safety and performance outcomes. Abstract presented at: PCR London Valves; September 10, 2018; London, UK.

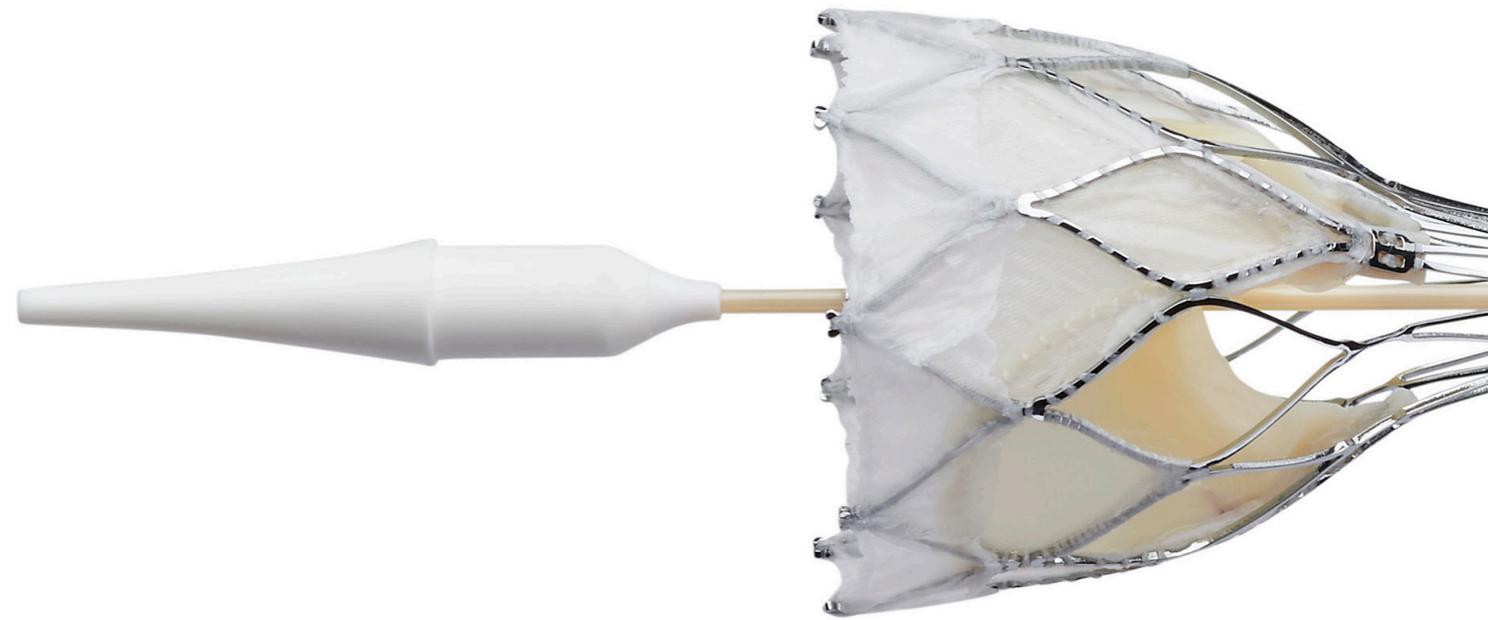
4. Webb J, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64:2235-43.

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS

HEMODYNAMIC IMPACT DESIGNED FOR IMMEDIATE FUNCTIONALITY AND DURABILITY.



DESIGNED FOR CONTINUOUS STABILITY AND NO RAPID PACING.

The only self-expanding valve with intra-annular leaflets* that immediately function and a non-tapered stent, providing hemodynamic stability for a calm and controlled deployment.

DESIGNED FOR DURABILITY.

Exclusive Linx™ anticalcification (AC) technology resists calcification in four distinct ways to improve long-term valve performance.¹⁻⁴

SEE THE EVIDENCE
Outperforming TAVI Systems

1. Frater RWM, et al. Advances in anticalcific and antidegenerative treatment of heart valve bioprostheses. *Silent Partners Inc.* 1997;8:105-13.
 2. Kelly SJ, et al. Biocompatibility and calcification of bioprosthetic heart valves. *Society for biomaterials. Sixth World Biomaterials Congress Transaction.* 2000;13534.
 3. Vyavahare N, et al. Prevention of bioprosthetic heart valve calcification by ethanol preincubation: efficacy and mechanisms. *Circulation.* 1997;95(2):479-88.
 4. Vyavahare N, et al. Prevention of calcification of glutaraldehyde-crosslinked porcine aortic cusps by ethanol preincubation: mechanistic studies of protein structure and water-biomaterial relationships. *J Biomed Mater Res.* 1998;40(4):577-85.
 5. *Current as of 25 June 2021

NAVITOR™ TAVI SYSTEM

DESIGNED FOR DURABILITY.

	ABBOTT LINX™ AC*1-4	MEDTRONIC AOA†*5	BOSTON SCIENTIFIC BIOFIX†*	EDWARDS THERMAFIX†*6
PRODUCTS	NAVITOR™	EVOLUT† PRO	ACURATE NEO2†	SAPIEN† 3
Reduces free aldehydes ^{1,2}	✓	✓	Not Publicly Available	✓
Extracts lipids ³	✓		Not Publicly Available	✓
Minimizes uptake of cholesterol ⁴	✓		Not Publicly Available	
Stabilizes leaflet collagen ⁴	✓		Not Publicly Available	

* There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

1. Frater RWM, et al. Advances in anticalcific and antidegenerative treatment of heart valve bioprostheses. Silent Partners Inc. 1997;8:105-13.

2. Kelly SJ, et al. Biocompatibility and calcification of bioprosthetic heart valves. Society for biomaterials. Sixth World Biomaterials Congress Transaction. 2000;13534.

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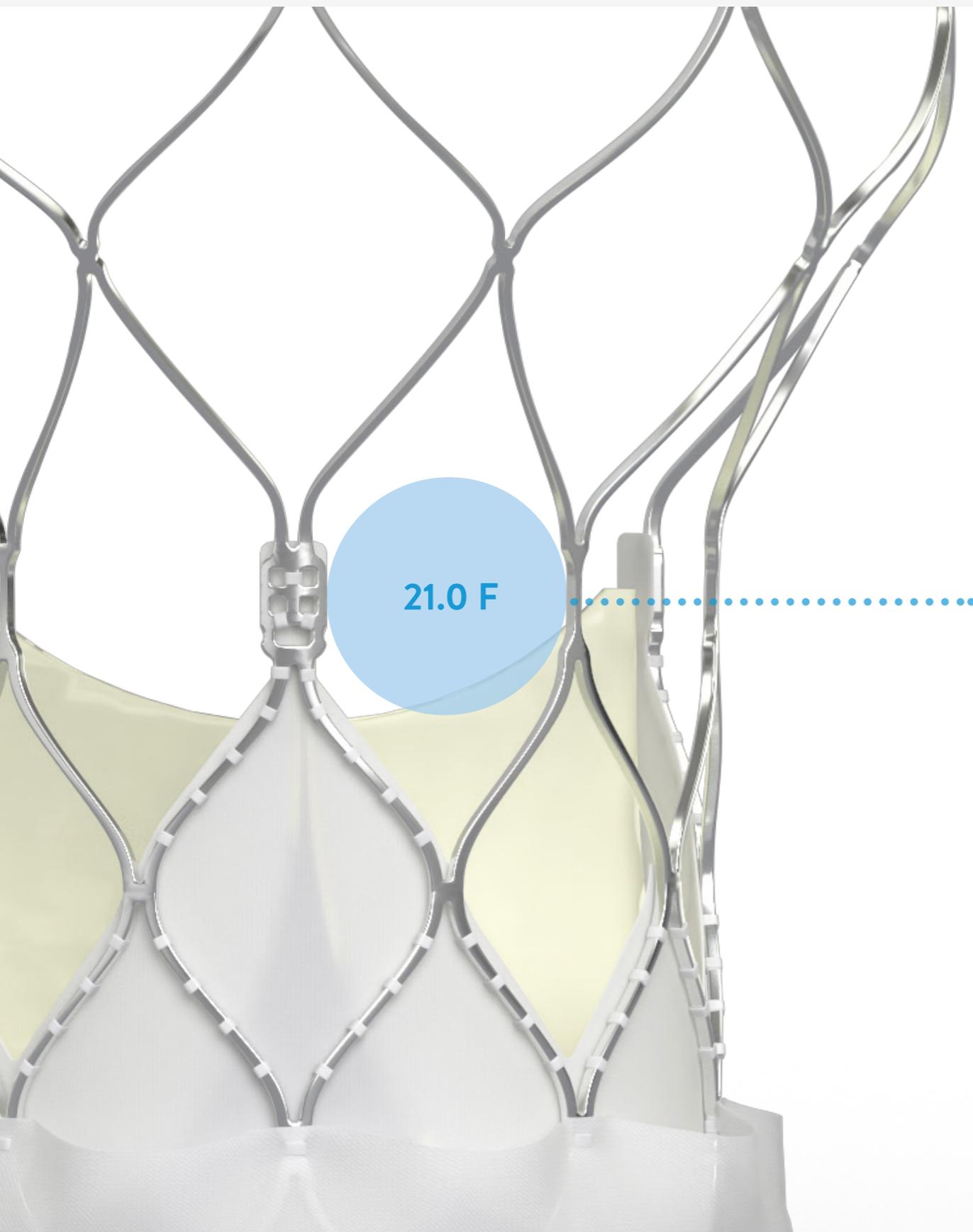
5. Gross J. Calcification of bioprosthetic heart valves and its assessment. J Thorac Cardiovasc Surg. 2003;125:6-8.

6. Edwards website, <http://www.webcitation.org/667CIPuMH>. This WebCitation captured Edwards' site on 12MAR2012.

SMART SEALING

HEMODYNAMIC IMPACT

UNCOMPROMISED CORONARY ACCESS



UNCOMPROMISED CORONARY ACCESS.¹

Large-cell geometry and intra-annular valve design preserve coronary access for future intervention.

SEE THE EVIDENCE
Outperforming TAVI Systems



SMART SEALING

HEMODYNAMIC IMPACT

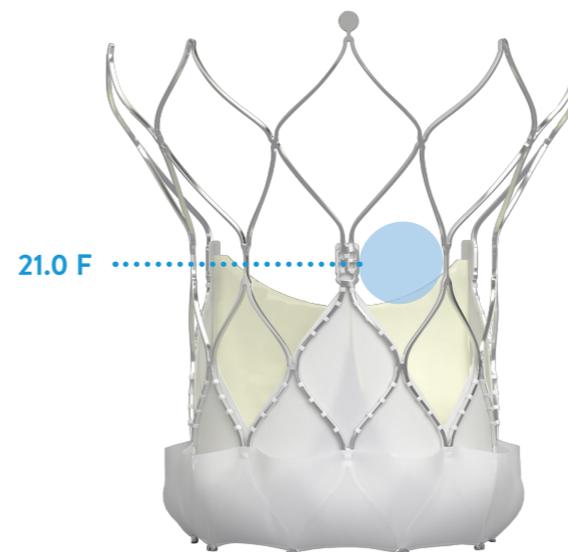
UNCOMPROMISED CORONARY ACCESS

NAVITOR™ TAVI SYSTEM

UNCOMPROMISED CORONARY ACCESS.¹

VALVE SIZE	NAVITOR™*1	EVOLUT‡ PRO*1
23 mm	14.6 F	12.1 F
25 mm	16.3 F	n/a
26 mm	n/a	11.8 F
27 mm	18.7 F	n/a
29 mm	21.0 F	11.9 F

29 mm NAVITOR™ VALVE*1



36 CELLS TOTAL

9 CELLS IN THE ANNULUS SECTION OF THE STENT

29 mm EVOLUT‡ PRO VALVE*1



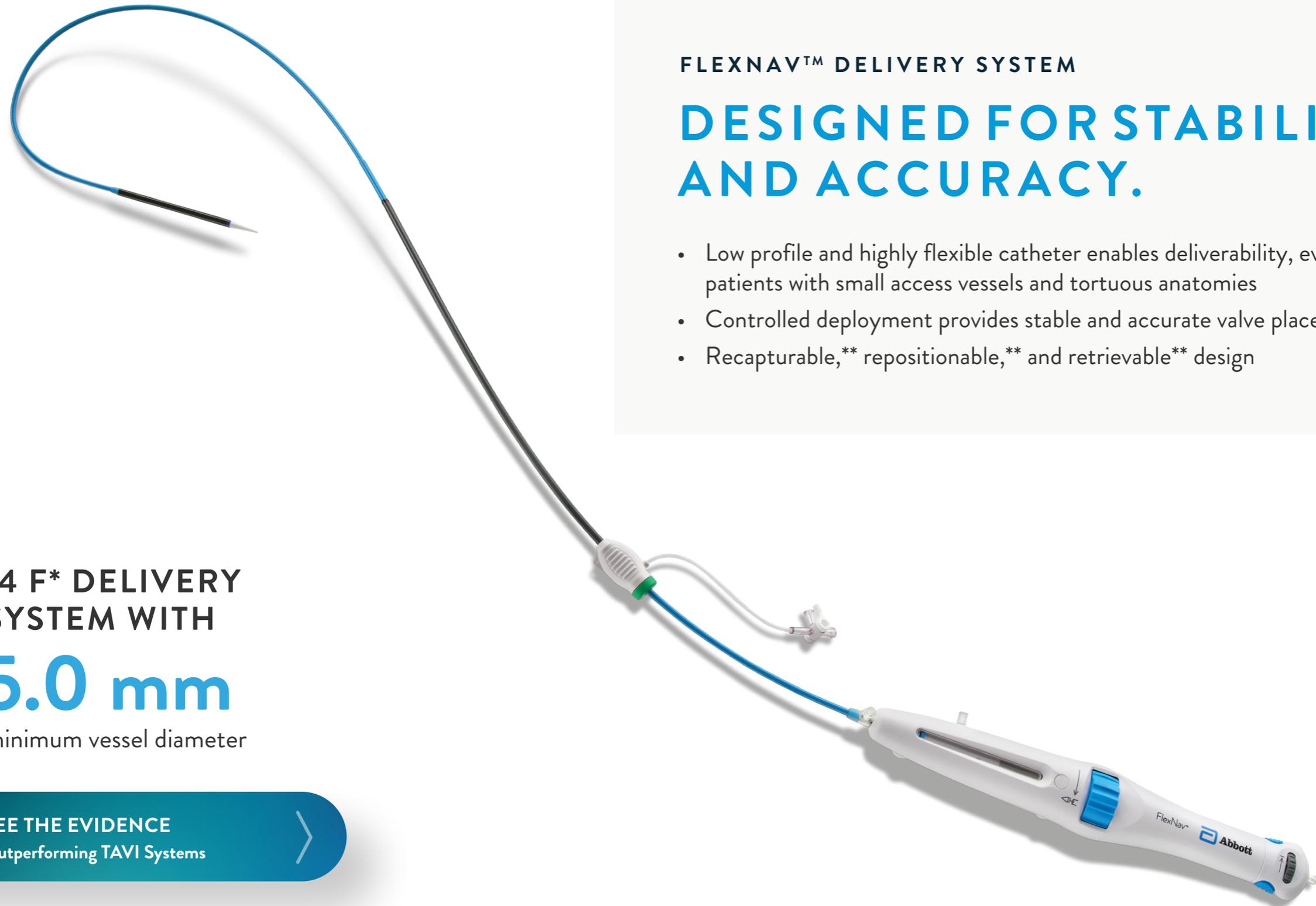
135 CELLS TOTAL

15 CELLS IN THE ANNULUS SECTION OF THE STENT

* Based on Abbott coronary access testing.

1. Abbott data on file 90664679.

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FLEXNAV™ DELIVERY SYSTEM

**DESIGNED FOR STABILITY
AND ACCURACY.**

- Low profile and highly flexible catheter enables deliverability, even in patients with small access vessels and tortuous anatomies
- Controlled deployment provides stable and accurate valve placement¹
- Recapturable, ** repositionable, ** and retrievable** design

14 F* DELIVERY
SYSTEM WITH

5.0 mm

minimum vessel diameter

SEE THE EVIDENCE
Outperforming TAVI Systems



* 14 F equivalent integrated sheath diameter.

** Until fully deployed.

1. Abbott data on file CL1014440.

NAVITOR™ TAVI SYSTEM

UNCOMPROMISED SMALL VESSEL ACCESS.¹

	NAVITOR™ WITH FLEXNAV™¹	EVOLUT[‡] PRO WITH ENVEO[‡] PRO²	ACURATE NEO2[‡] WITH iSLEEVE^{‡3,4}	SAPIEN[‡] 3 WITH eSHEATH^{‡5,6}
Delivery System Profile (Outer Diameter)	6.0 mm 6.3 mm	6.7 mm	6.0 mm	7.6 mm 8.2 mm
Minimum Vessel Diameter	5.0 mm 5.5 mm	5.5 mm	5.5 mm	5.5 mm 6.0 mm

1. Navitor™ TAVI System IFU.

2. Medtronic CoreValve Evolut[‡] PRO IFU.3. Boston Scientific Acurate neo2[‡] IFU.4. Boston Scientific iSleeve[‡] IFU.5. Edwards Sapien 3[‡] IFU.6. Koehler Sapien 3[‡] eSheath OD BMRI 2015.

NAVITOR™ TAVI SYSTEM

FAVOURABLE OUTCOMES.

30-DAY¹

0%

SEVERE TO
MODERATE PVL

0%

ALL CAUSE
MORTALITY

0.8%

DISABLING
STROKE

0.8%

MAJOR VASCULAR
COMPLICATIONS

7.4^{mmHg}

MEAN
GRADIENT

SEE THE EVIDENCE
Outperforming TAVI Systems



1. Abbott data on file CL1014440.

NAVITOR™ TAVI SYSTEM

FAVOURABLE OUTCOMES.

30-DAY	NAVITOR™ ¹ N=120	EVOLUT‡ PRO ² N=60	ACURATE NEO2‡ ³ N=120	SAPIEN‡ 3 ⁴ N=96*
All-Cause Mortality	0.0%	1.7%	3.3%	2.1%
Disabling Stroke	0.8%	1.7%	1.7%	0.0%
Life-Threatening Bleeding	2.5%	11.7%	5.0%	3.1%
Acute Kidney Injury Stage 2/3	1.7%	1.7%	0.8%	1.0%
Major Vascular Complications	0.8% ^{††}	10.0%	3.3%	4.2%
New Permanent Pacemaker Implantation	15.0%	11.8%	16.1%	14.5%

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

NOTE: Referenced data reflect results from prospective, multicenter clinical studies with contemporary valves in high and extreme risk surgical patients conducted to support CE Mark approval.

* Transfemoral access cohort.

†† 0% TAVI delivery system access site-related, 0.8% non-TAVI delivery system access site-related, and 0% non-access site-related.

1. Abbott data on file CL1014440.

2. Forrest JK, et al. Early outcomes with the Evolut PRO repositionable self-expanding transcatheter aortic valve with pericardial wrap. J Am Coll Cardiol Interv. 2018;11:160-168.

3. Möllmann H. Transcatheter aortic valve implantation for severe aortic stenosis with the Acurate neo2 valve system: 30-day safety and performance outcomes. Abstract presented at: PCR London Valves; September 10, 2018; London, UK.

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**SMART SEALING.
MITIGATES PVL.
UNCOMPROMISED ACCESS¹.**

**EXPERIENCE FAVOURABLE OUTCOMES WITH
THE NAVITOR™ TAVI SYSTEM.**

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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