NAVITOR™ TAVI SYSTEM

SMART SEALING. EXCEPTIONAL STABILITY. UNCOMPROMISED ACCESS.

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

1. Smith, D. One-year clinical trial results with a next-generation aortic transcatheter heart valve. Presented at: EuroPCR conference; May 17-20, 2022.

Information contained herein for **DISTRIBUTION in NZ ONLY**.

Abbott

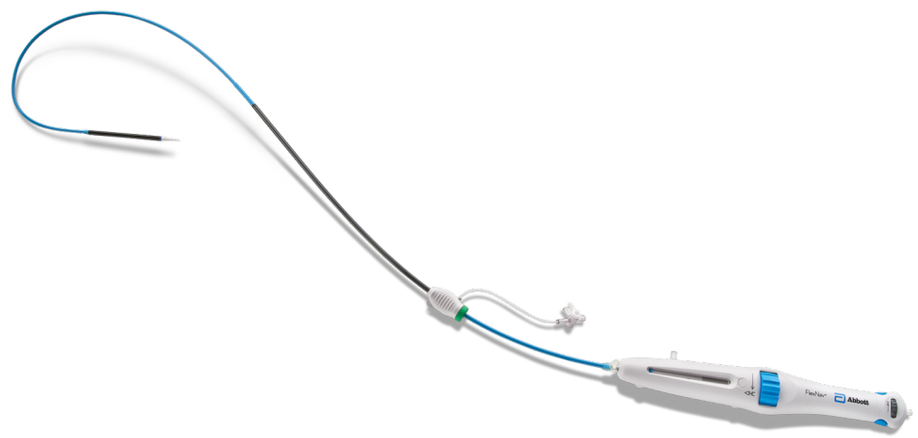
NAVITOR™ VALVE

INTELLIGENT DESIGN.

- Smart PVL-sealing NaviSeal™ Cuff
- Exceptional single-digit gradients[1]
- Uncompromised coronary access

LEARN MORE

FLEXNAV™ DELIVERY SYSTEM



STABILITY AND ACCURACY.

- Low profile 5.0 mm minimum vessel diameter for uncompromised small vessel access
- Enhanced flexibility for excellent deliverability
- Stable deployment and accurate valve placement

LEARN MORE

EXCELLENT OUTCOMES.

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

30-DAY[1]

0%	0%	0.8%	0.8%*	7.4 mmHg
SEVERE TO MODERATE PVL	ALL CAUSE MORTALITY	DISABLING STROKE	MAJOR VASCULAR COMPLICATIONS	MEAN GRADIENT

1. Smith, D. One-year clinical trial results with a next-generation aortic transcatheter heart valve. Presented at: EuroPCR conference; May 17-20, 2022.

* CEC adjudicated as related to procedure but not to device.

NAVITOR™ VALVE

INTELLIGENT DESIGN.

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

1. Smith, D. One-year clinical trial results with a next-generation aortic transcatheter heart valve. Presented at: EuroPCR conference; May 17-20, 2022.

SMART SEALING. REMARKABLE PERFORMANCE.

NaviSeal™ Cuff actively synchronizes to the cardiac cycle, seals, and mitigates PVL[1] by expanding to fill calcification-related gaps between the annulus and the valve.

SMART SEALING MITIGATES PVL

30-DAY ECHO CORE LAB DATA[1]

80%	20%	0%	0%
NONE/TRACE	MILD	MODERATE	SEVERE

SEE THE EVIDENCE
Outperforming TAVI Systems

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NAVITOR™ TAVI SYSTEM

SMART SEALING.

30-DAY | 1-YEAR

PVL 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%

PVL IMPACT.

Moderate or greater PVL increases 1-year mortality and rehospitalization

2.4x-2.7x

following TAVI[5]

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

NOTE: Data not from head-to-head studies. Data provided for informational purposes only.

NOTE: Reference data reflects results from prospective, multicenter clinical studies with contemporary valves in high- and extreme-risk surgical patients conducted in support of CE Mark approval (except Sapien 3 study cohort includes mixed high and intermediate risk patients).

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

1. Smith, D. One-year clinical trial results with a next-generation aortic transcatheter heart valve. Presented at: EuroPCR conference; May 17-20, 2022. **2.** Forrest JK. Early outcomes with the Evolut PRO repositionable self-expanding transcatheter aortic valve with pericardial wrap. JACC Cardiovasc Interv. 2018 11(2):160-168. **3.** Möllmann H, 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.** Webb J, Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64(21):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.

NAVITOR™ TAVI SYSTEM

SMART SEALING.

30-DAY | 1-YEAR

PVL ECHO CORE LAB DATA	NAVITOR™[1] N=104	EVOLUT‡ PRO[2] N=46	ACURATE NEO2‡[3] N=81	SAPIEN‡ 3[4] N=100*
None/Trace	**70.2%**	89.1%	60.5%	84.0%
Mild	**28.8%**	10.9%	37.0%	14.0%
Moderate	**1.0%**	0.0%	2.5%	2.0%
Severe	**0.0%**	0.0%	0.0%	0.0%

PVL IMPACT.

Moderate or greater PVL increases 1-year mortality and rehospitalization

2.4x-2.7x

following TAVI[5]

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

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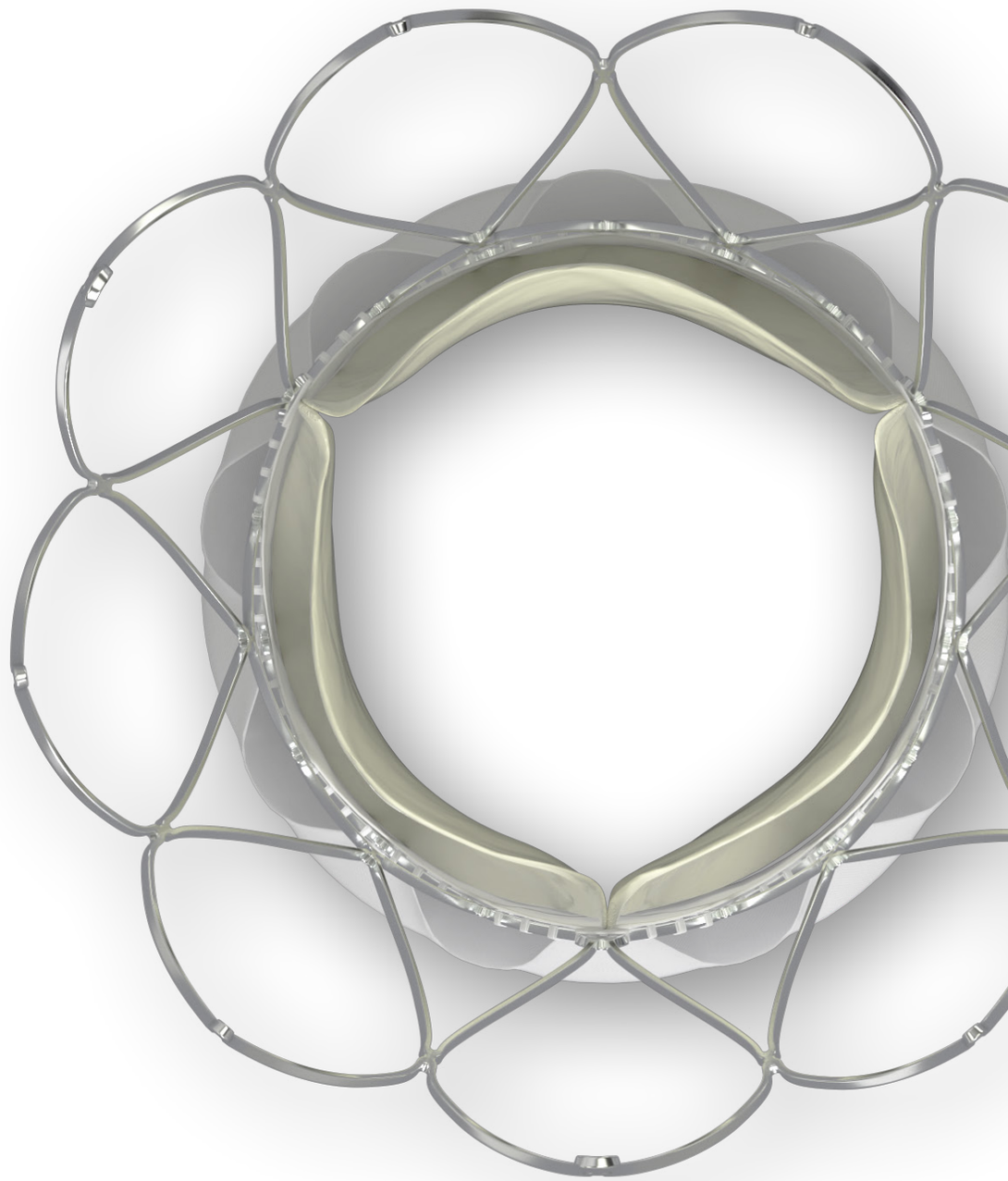
EXCEPTIONAL HEMODYNAMICS.

LARGE EFFECTIVE ORIFICE AREAS.[1] SINGLE-DIGIT GRADIENTS.[1]

30-DAY ECHO CORE LAB DATA[1]

2.0 cm^2
EOA

7.4 mmHg
MEAN GRADIENT



SEE THE EVIDENCE
Outperforming TAVI Systems

HEMODYNAMIC IMPACT.

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. Smith, D. One-year clinical trial results with a next-generation aortic transcatheter heart valve. Presented at: EuroPCR conference; May 17-20, 2022.

NAVITOR™ TAVI SYSTEM

EXCEPTIONAL HEMODYNAMICS.

30-DAY | 1 -YEAR

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.

NOTE: Data not from head-to-head studies. Data provided for informational purposes only.

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

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NAVITOR™ TAVI SYSTEM

EXCEPTIONAL HEMODYNAMICS.

30-DAY | 1-YEAR

1-YEAR ECHO CORE LAB DATA	NAVITOR™[1]	EVOLUT‡ PRO[2]	ACURATE NEO2‡[3]	SAPIEN‡ 3[4]
Mean Gradient (mmHg)	**7.5 (N=107)**	7.1 (N=44)	7.6 (N=85)	10.9† (N=86)
EOA (cm^2)	**1.9 (N=88)**	2.0 (N=40)	1.7 (N=77)	1.5† (N=64)

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

NOTE: Data not from head-to-head studies. Data provided for informational purposes only.

NOTE: Reference data reflects results from prospective, multicenter clinical studies with contemporary valves in high- and extreme-risk surgical patients conducted in support of CE Mark approval (except Sapien 3 study cohort includes mixed high and intermediate risk patients).

† Paired Analysis

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

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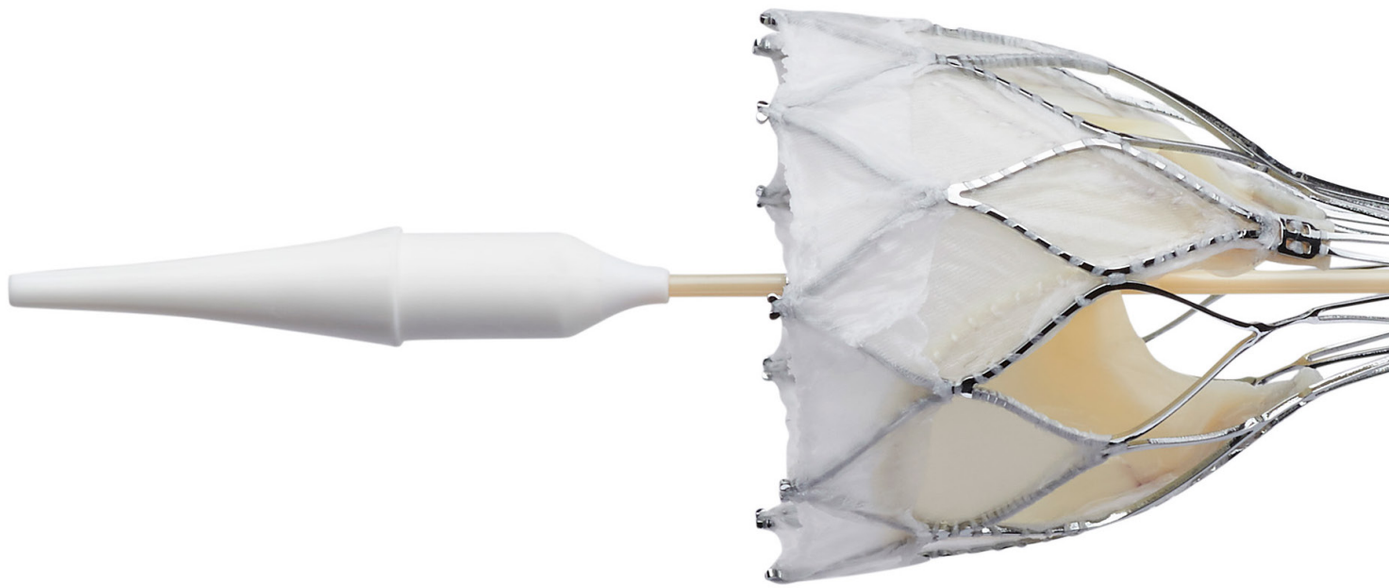
EXCEPTIONAL HEMODYNAMICS.

DESIGNED FOR IMMEDIATE FUNCTIONALITY AND DURABILITY.



CONTINUOUS STABILITY. 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.

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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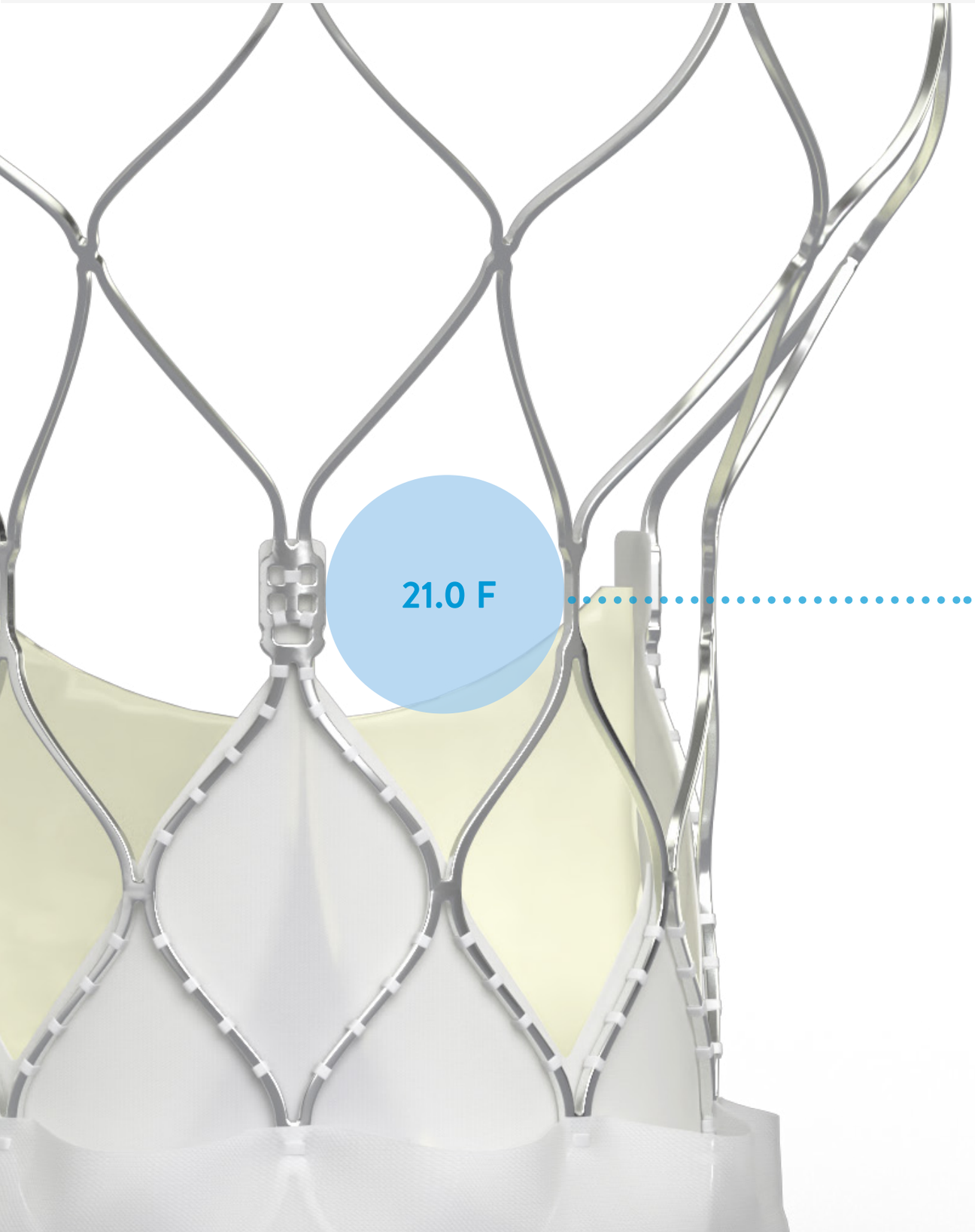
5. Gross J. Calcification of bioprosthetic heart valves and its assessment. J Thorac Cardiovasc Surg. 2003;125:6-8.
6. Edwards website, http://www.webcitation.org/667ClPuMH. This WebCitation captured Edwards' site on 12MAR2012.



UNCOMPROMISED CORONARY ACCESS.

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

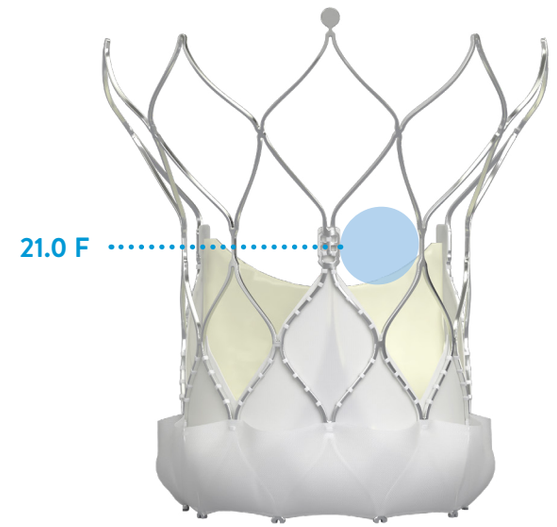
SEE THE EVIDENCE
Outperforming TAVI Systems

NAVITOR™ TAVI SYSTEM

UNCOMPROMISED CORONARY ACCESS.

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

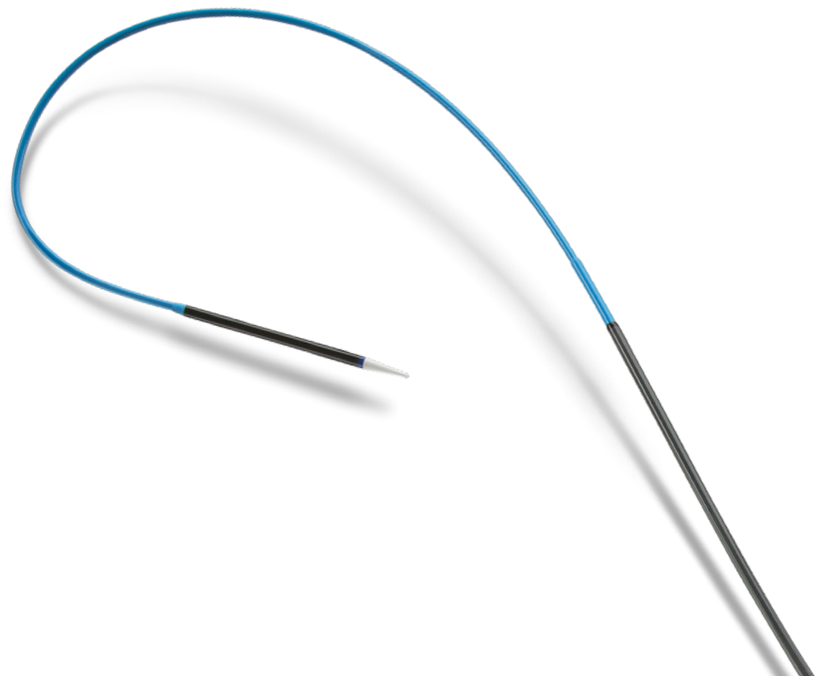
29 mm EVOLUT‡ PRO VALVE*1

135 CELLS TOTAL

15 CELLS IN THE ANNULUS SECTION OF THE STENT

* Based on Abbott coronary access testing.

1. Abbott data on file 90664679.



FLEXNAV™ DELIVERY SYSTEM

STABILITY AND ACCURACY.

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

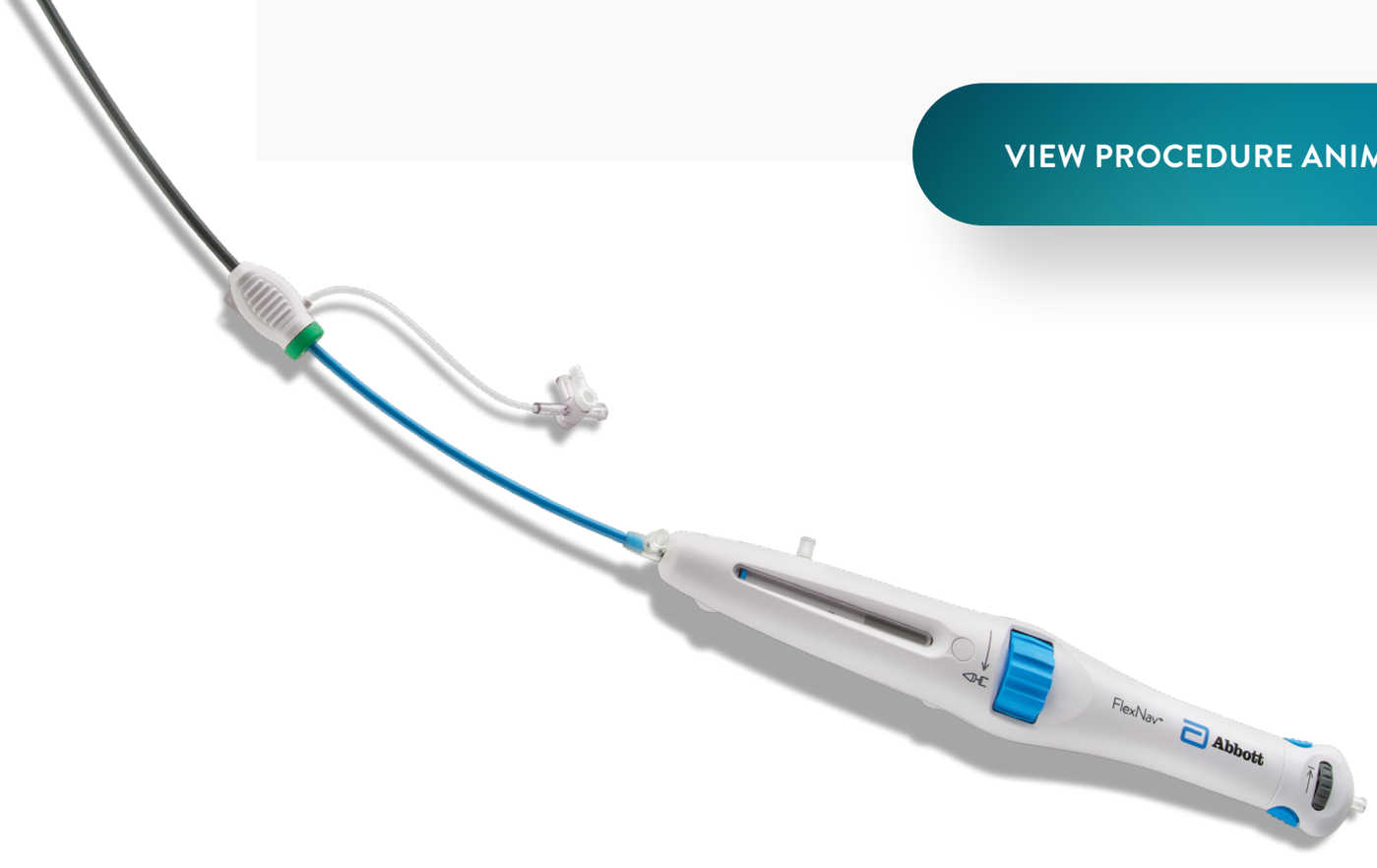
VIEW PROCEDURE ANIMATION

14 F* DELIVERY SYSTEM WITH

5.0mm

minimum vessel diameter

SEE THE EVIDENCE
Outperforming TAVI Systems



* 14 F equivalent integrated sheath diameter for patients requiring 23mm or 25mm valve

** Until fully deployed.

NAVITOR™ TAVI SYSTEM

UNCOMPROMISED SMALL VESSEL ACCESS.

	NAVITOR™ WITH FLEXNAV™[1]	EVOLUT‡ PRO WITH ENVEO‡ PRO[2]	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

EXCELLENT OUTCOMES.

30-DAY[1] | 1-YEAR[1]

0%	0%	0.8%	0.8%*	7.4 mmHg
MODERATE OR SEVERE PVL	ALL CAUSE MORTALITY	DISABLING STROKE	MAJOR VASCULAR COMPLICATIONS	MEAN GRADIENT

SEE THE EVIDENCE
Outperforming TAVI Systems

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NAVITOR™ TAVI SYSTEM

EXCELLENT OUTCOMES.

30-DAY[1]	1-YEAR[1]
1.0%	4.2%
MODERATE PVL (0% SEVERE PVL)	ALL CAUSE MORTALITY
0.8%	0.8%
DISABLING STROKE	MAJOR VASCULAR COMPLICATIONS
7.5 mmHg	
MEAN GRADIENT	

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NAVITOR™ TAVI SYSTEM

EXCELLENT OUTCOMES.

30-DAY | 1-YEAR

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%
Naïve Pacemaker Implantation	**15.0%**	11.8%	16.1%	14.5%

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* Transfemoral access cohort.

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NAVITOR™ TAVI SYSTEM

EXCELLENT OUTCOMES.

30-DAY | 1-YEAR

1-YEAR	NAVITOR™[1] N=120	EVOLUT‡ PRO[2] N=60	ACURATE NEO2‡[3] N=120	SAPIEN‡ 3[4] N=96*
All-Cause Mortality	4.2%	11.8%	11.9%	8.4%
Disabling Stroke	0.8%	1.7%	1.7%	1.1%
Life-Threatening Bleeding	5.0%	NR	8.5%	NR
Acute Kidney Injury Stage 2/3	1.7%	NR	0.8%	NR
Major Vascular Complications	0.8%	NR	3.3%	NR
Naïve Pacemaker Implantation	16.8%**	15.9%	18.8%	15.7%

NOTE: Data not from head-to-head studies. Data provided for informational purposes only.

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* Transfemoral access cohort.

** Of the 18 subjects who required new PPI through 1 year, 13 had pre-existing conduction abnormalities.

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SMART SEALING. EXCEPTIONAL STABILITY. UNCOMPROMISED ACCESS.

EXPERIENCE EXCELLENT 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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