Navitor™ TAVI System
Navitor™ Vision valve

NOW YOU'VE GOT NAVITOR

STABLE DELIVERY. REMARKABLE PERFORMANCE. FUTURE READY.

STRUCTURAL HEART | TAVI SOLUTIONS

Abbott

EXCELLENT JUST GOT BETTER

Your work demands a safe, intuitive and future ready TAVI system that achieves excellent outcomes, every time. Our Navitor™ TAVI system is intuitive, precise and accurate – with excellent hemodynamics and durability. There are Navitor Vision* valve sizes for a wide range of anatomies. So you and your team can perform at the highest level, even when dealing with challenging cases.

30-DAY OUTCOMES[1]

0%	1.9%	1.9%	4.2%	7.4 mm Hg
MODERATE OR SEVERE PVL	ALL-CAUSE MORTALITY	DISABLING STROKE	MAJOR VASCULAR COMPLICATIONS	MEAN GRADIENT

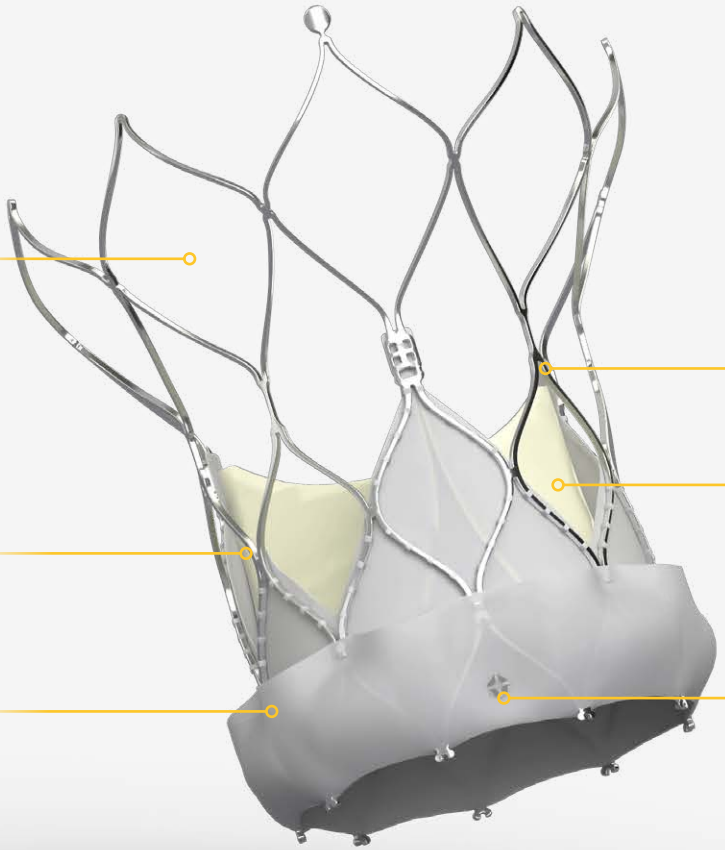
Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Always check the regulatory status of the device in your region.

*Labeled as Navitor and Navitor Titan with Vision Technology.

LARGE CELL DESIGN
Minimizes coronary obstruction and improves coronary access and flow

ANNULUS TREATMENT RANGE
19 mm to 30 mm diameters

ACTIVE SEALING CUFF
Synchronizes to the cardiac cycle to seal and mitigate PVL[2]

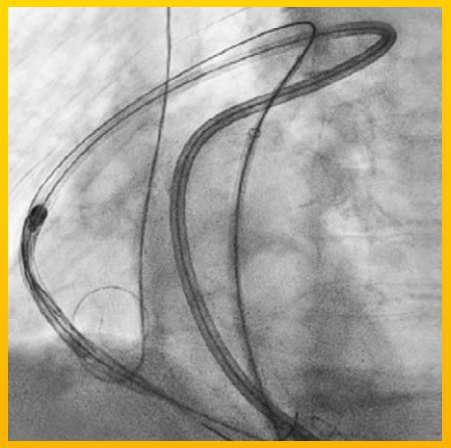


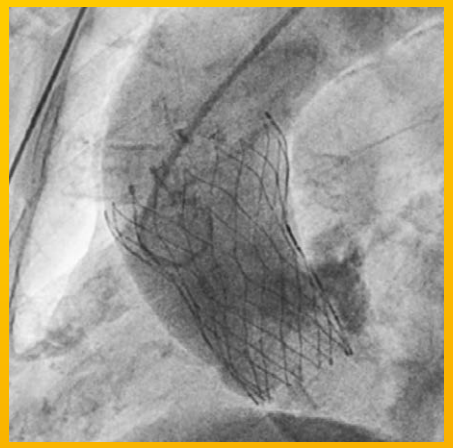
CONSISTENT RADIAL FORCE
Expands, anchors, stabilizes and seals

INTRA-ANNULAR LEAFLETS
Function immediately for continuous hemodynamic stability during deployment

THREE RADIOPAQUE MARKERS
Provide clear visualization of 3 mm implant depth

ATTENTION TO EVERY DETAIL





Images courtesy of Dr. Sumanto Mukhopadhyay, St. Bartholomew's Hospital, UK.

Navitor™ Vision valves are delivered using our highly flexible, ergonomic and hydrophillic FlexNav™ delivery system – that navigates even the most torturous anatomies. The 14 F* integrated sheath and 5.0 mm minimum vessel diameter let you easily handle small access vessels. Our 15 F* integrated sheath delivers our three larger valves, including the new 35 mm valve. At 80% deployment, you can feel and hear the delivery system lock for a final check before pushing the button to complete the procedure.

You're always in control during Navitor Vision valve deployment. The intra-annular leaflets function immediately for continuous hemodynamic stability during deployment.

LOW-PROFILE, HIGHLY FLEXIBLE CATHETER ENABLES EXCELLENT ACCESS AND DELIVERABILITY

THE CONFIDENCE OF CONTROLLED DEPLOYMENT

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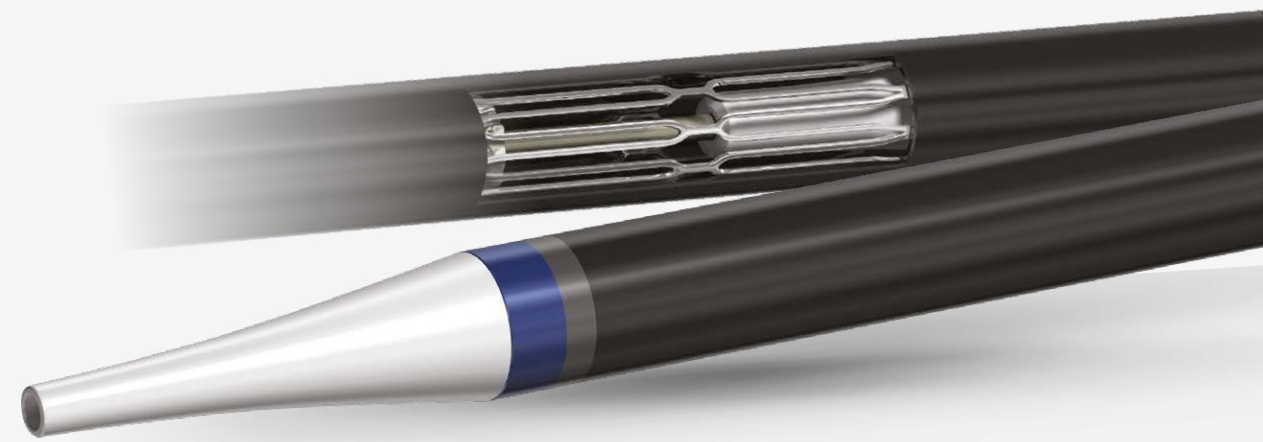
*14 F and 15 F equivalent

LARGEST VALVE, SMALLEST DELIVERY SYSTEM[3]

Our recently added 35 mm valve completes the range of five Navitor™ Vision valve sizes: 23 mm, 25 mm, 27 mm, 29 mm, 35 mm. With the largest diameter of any valve available to date, it's also the only large-sized valve delivered using a 15 F* delivery system.[3]



ANNULUS TREATMENT RANGE[4] TREATS ANNULUS DIAMETERS OF 19 - 30 mm

Patient Annulus (mm)	19	20	21	22	23	24	25	26	27	30
Valve size (mm)		23		25		27		29		35
Delivery System size		14 F*				15 F*				
Min. vessel diameter		5.0 mm				5.5 mm				

*14 F and 15 F equivalent

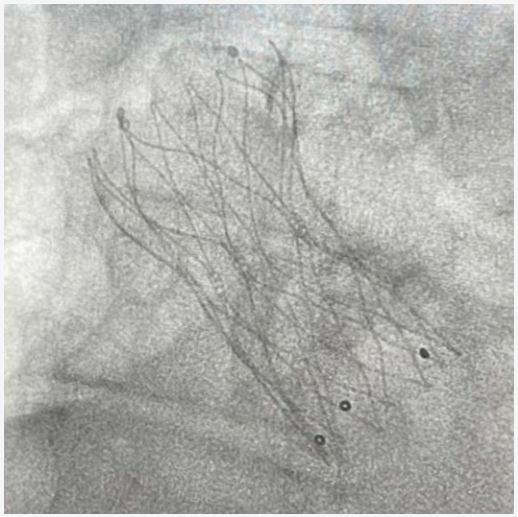
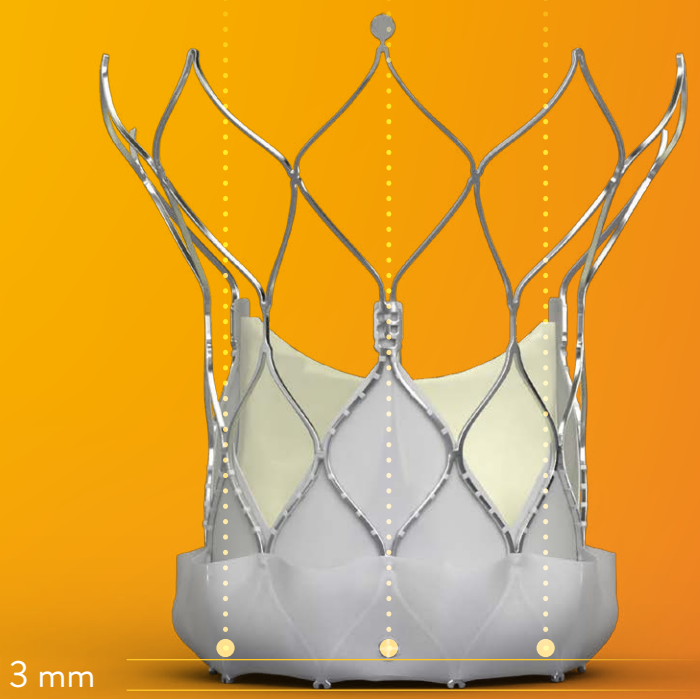


Image courtesy of Dr. Ethan Korngold, Providence St. Vincent Medical Center, USA.

Positioned 3 mm from inflow edge – and directly under valve commissures – our three radiopaque markers are large and highly visible. They shine brightly under fluoroscopy, so you can easily assess implantation depth and valve orientation.

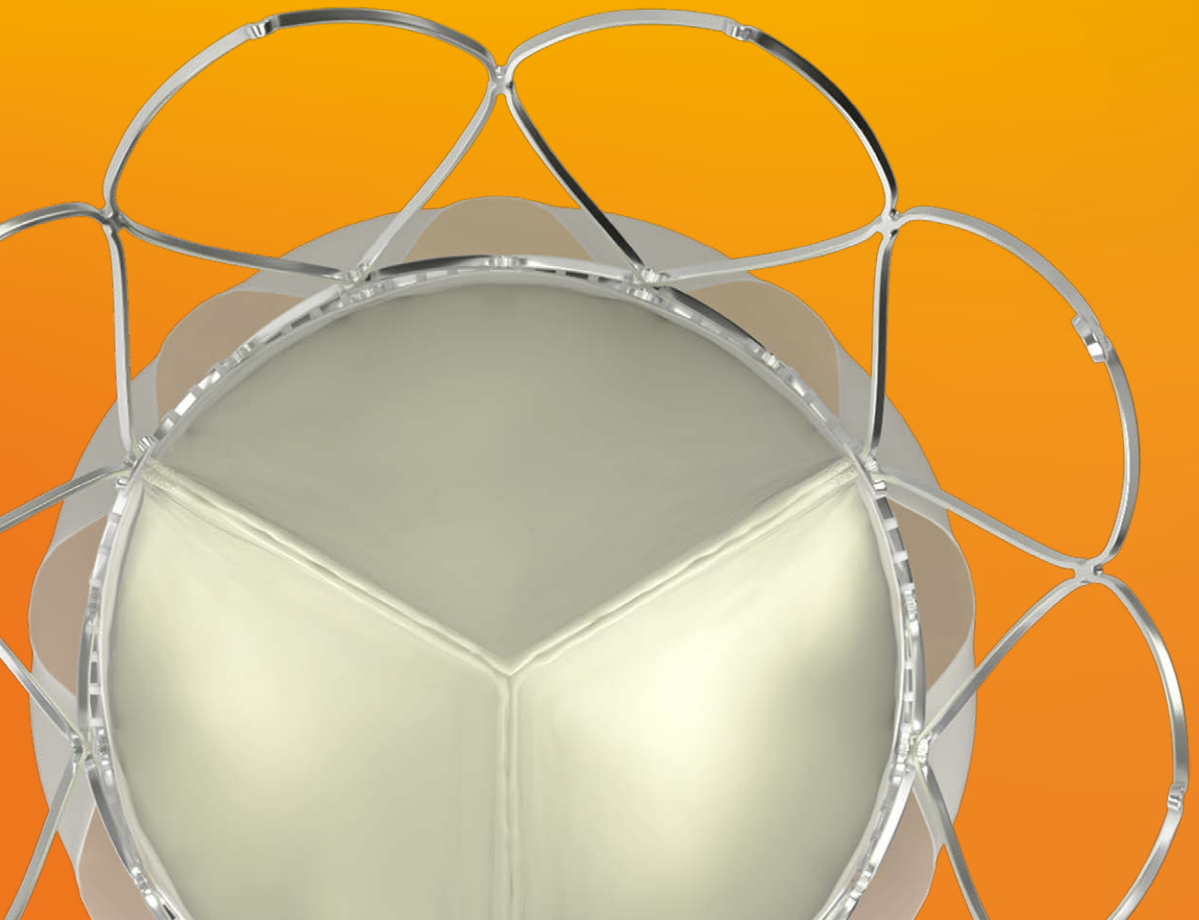
BIGGER.
BRIGHTER.
BETTER.



HIGHLY VISIBLE MARKERS DESIGNED TO ENHANCE RADIOPACITY FOR OPTIMAL PLACEMENT

CONFORMS TO ANATOMY TO ACHIEVE

0% MODERATE OR SEVERE PVL[1]



To prevent leaks, our Navitor™ Vision valves feature a dynamic fabric cuff. It actively synchronizes to the patient's cardiac cycle and seals against even the most challenging anatomies. Data demonstrated 80% of patients treated with the Navitor valve have none/trace PVL at 30 days, with the remaining 20% experiencing mild PVL.[1]

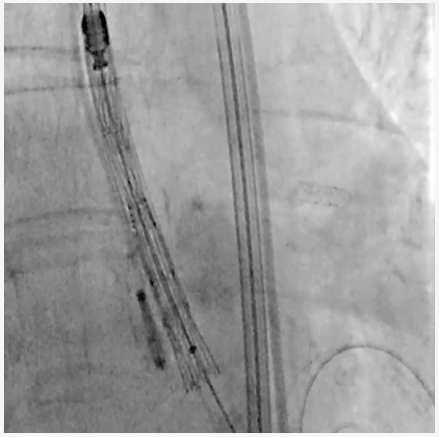
Navitor™ Vision valves feature a unique cylindrical stent and intra-annular leaflets that open fully to maximize orifice area and achieve single-digit mean gradients.

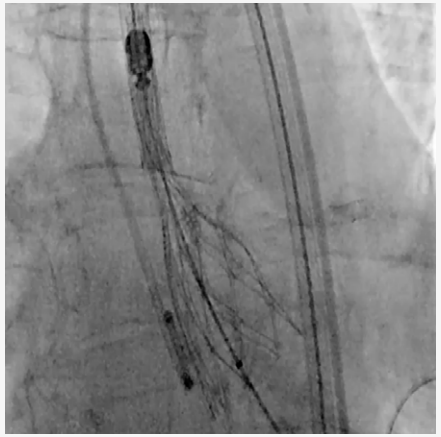
30-DAY ECHO CORE LAB DATA[1]

2.0 cm^2
EOA

7.4 mm Hg
MEAN GRADIENT

EXCELLENT HEMODYNAMICS





Images courtesy of Prof. Lars Søndergaard, Rigshospitalet, Denmark.

The controlled deployment made possible with the stability layer used on our FlexNav™ delivery system also gives you the opportunity to achieve single-digit pacemaker rates.

SINGLE-DIGIT PACEMAKER RATES

FROM INITIAL IDE STUDY TO REAL-WORLD EXPERIENCE

IDE STUDY[1]

19%

PPI AT 30 DAYS
(N=232)

RAO VS. LAO VIEW STUDY[5]

8.2%

PPI AT 30 DAYS
(N=183)

OPTECH STUDY[6*]

6.3%

PPI AT 30 DAYS
(N=49)

DUAL-CENTER STUDY REAL-WORLD EXPERIENCE[7]

2.9%

PPI AT 30 DAYS
(N=39)

*OPTECH is a sub-study of the first-generation Abbott TAVI Valve Adjudicated Registry.

DURABLE TAVI PLATFORM

The Abbott TAVI platform is an excellent choice as a patient's first valve. Once safely deployed, the platform has demonstrated freedom from SVD at 5 years of >99%.[8,9] Exclusive Linx™ technology prevents further calcification.* And the large open-cell design makes future coronary access easy.

FREEDOM FROM SVD: >99% AT 5 YEARS[8,9**]

One valve platform. Two adjudicated trials. Over 1,300 patients.

FIRST-GENERATION TAVI VALVE	FREEDOM FROM SVD
Adjudicated Registry (N=941)[8]	**100%**
Randomized Controlled Trial (N=375)[9]	**99%**

*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.
**First-generation Abbott TAVI Valve Adjudicated Registry (NCT01802788; N=941) and first-generation Abbott TAVI Valve RCT (NCT02000115; N=375).

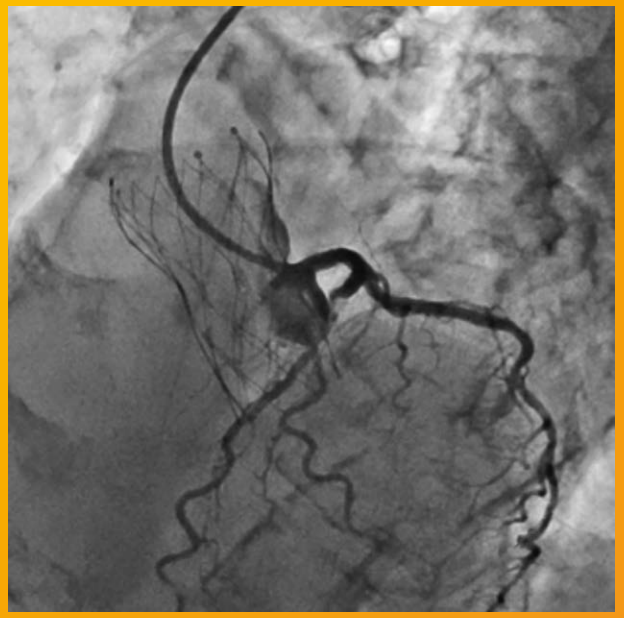


Image courtesy of Dr. Norio Tada, Sendai Kousei Hospital, Japan

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

UNCOMPROMISED CORONARY ACCESS

Navitor™ Vision[10**]	23 mm	25 mm	27 mm	29 mm	35 mm
Cell size	14.6 F	16.3 F	18.7 F	21.0 F	22.6 F

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*For 35 mm Navitor Vision Valve. **Based on Abbott coronary access testing.

FUTURE READY
INDEX VALVE

In addition to the large cell design, the Navitor™ Vision valve intra-annular leaflet position allows for TAV-in-TAV procedures with diminished risk of coronary occlusion or sinus sequestration. This combination, along with excellent durability, makes the Navitor Vision valve an ideal choice for a patient's first TAV.

TRUSTED PARTNERSHIP, LEADING TECHNOLOGY

Abbott Structural Heart is not only dedicated to thoroughly researching, developing, and clinically evaluating innovative cardiac technologies. We understand the importance of listening closely to your needs and your patients' desires. We value our partnership with you, providing comprehensive training, proctoring, and support to ensure optimal patient care.

This collaboration is fundamental to leveraging the full potential of our innovative heart therapies, from initial training to ongoing clinical support. We share a mutual and heartfelt goal: improving patient outcomes so people of all ages can live their lives to the fullest.

REFERENCES

1. Reardon, M, Chehab, B, Smith, D. et al. 30-Day Clinical Outcomes of a Self-Expanding Transcatheter Aortic Valve: The International PORTICO NG Study. J Am Coll Cardiol Intv. 2023 Mar, 16 (6) 681–689. https://doi.org/10.1016/j.jcin.2023.02.002.
2. Sondergaard, L. 30-day outcomes from a next generation TAVI device with an active sealing cuff. Presented at: EuroPCR conference; May 18-20, 2021; Paris, France.
3. Data on file at Abbott, REF-14562.
4. Navitor™ TAVI System Instructions for Use.
5. Wang X, Wong I, Bajoras V, et al. Impact of implantation technique on conduction disturbances for TAVR with the self-expanding portico/navitor valve. Catheter Cardiovasc Interv. 2022 Dec 21. doi: 10.1002/ccd.30517.
6. Taramasso M. , Maisano F, Worthley S, et al. Optimal sizing and implant depth of the Portico™ Valve: OpTech results, a substudy of the Portico I trial. E-Poster: PCR London Valves Conference; November 19-21, 2020.
7. Corcione N, Berni A, Ferraro P, et al. Transcatheter aortic valve implantation with the novel-generation Navitor device: Procedural and early outcomes. Catheter Cardiovasc Interv. 2022 Jul;100(1):114-119. doi: 10.1002/ccd.30179.
8. Sondergaard L. Five-year outcomes for TAVI with an intra-annular, self-expandable bioprosthesis. Presented at: EuroPCR conference; May 16-19, 2023; Paris, France.
9. Makkar R. PORTICO IDE Trial: Five-year Outcomes of Portico vs. Commercially Available Valves. Presented at: EuroPCR conference; May 16-19, 2023; Paris, France.
10. Tests performed by and data on file at Abbott, RPT 90664679.
11. Data on file at Abbott, RPT 90447579, 90465559.

NAVITOR™ VISION VALVE SIZING[11]

	23 mm	25 mm	27 mm	29 mm	35 mm
Annulus Use Range Diameter (mm)	19-21	21-23	23-25	25-27	27-30
Annulus Area (mm^2)	277-346	338-415	405-491	479-573	559-707
Annulus Perimeter (mm)	60-66	66-73	72-79	79-85	85-95
Ascending Aorta Diameter (mm)	26-36	28-38	30-40	32-42	27-44
Minimum Vessel Diameter (mm)	≥ 5.0	≥ 5.0	≥ 5.5	≥ 5.5	≥ 5.5
Implant Target Depth Below Annulus (mm)	3	3	3	3	3

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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