Performance and Durability Derived by Design

TRANSCATHETER HEART VALVE DESIGN: A MATTER OF CHOICES

The design of a Transcatheter Heart Valve (THV) for transcatheter aortic valve implantation (TAVI) must balance requirements related to deliverability, hemodynamic performance, durability, and suitability for reintervention when eventually failing. Each THV reflects a distinct combination of design features optimized to address these demanding and often competing requirements, which differentiates it from other devices. As a result, the overall performance of a THV is not defined by a single design choice—such as self-expanding versus balloon-expandable technology or leaflet position—but by the integrated effect of all design elements working together. Contemporary THVs embody a specific design philosophy, informed by deliberate design choices and incremental refinements aimed at improving and fine-tuning performance characteristics.

NAVITOR™ VISION* VALVE: A DISTINCTIVE APPROACH TO THV DESIGN

The Navitor Vision Valve combines a unique set of design attributes. These attributes are specifically important in view of the trend to increasingly perform TAVI in younger, lower-risk patients†

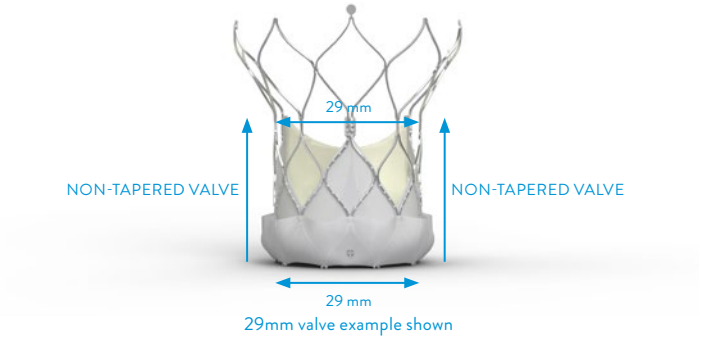
- **Self-expanding THV:** Typically achieving excellent hemodynamic performance (i.e., large effective orifice area and low gradients).

- **Bovine pericardial tissue leaflets in an intra-annular position:**
  - Leaflets that function immediately for continuous hemodynamic stability during deployment.
  - Unrestricted leaflets that open fully to maximize orifice area and achieve single-digit mean gradients.[1,2,3]
  - Reduced risk of coronary obstruction and ease of coronary access.[4,5]
  - Shorter neo-skirt, favorable in case future valve-in-valve (ViV) TAVI is required.[6]

- **Stent design:** Among all components of a THV, the stent is required to address the widest range of design demands, spanning both implantation and in-situ performance. The stent of the Navitor Vision Valve is engineered to deliver the following key characteristics:

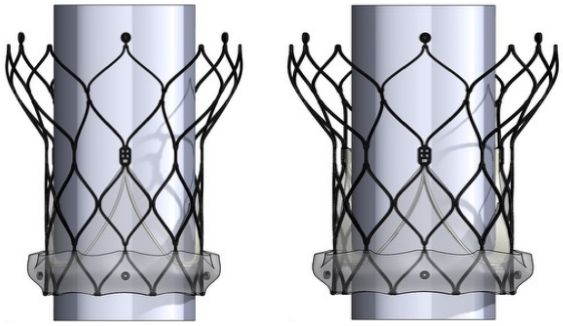
Non-tapered stent and valve leaflets. Provides excellent hemodynamic performance demonstrating low mean gradients and large EOAs. In case of acute PVL, post-dilatation may be required to improve THV expansion. Each Navitor Vision Valve size has a non-tapered stent design with equivalent in- and outflow diameters, never smaller than the use range **(Figure 1)**. This allows complete dilatation consistent with the use range of the specific valve size and optimal stent apposition over the entire stent length without risk of stent over-expansion and potential leaflet injury by overstressing the tissue **(Figure 2)**.

FIGURE 1: NON-TAPERED STENT AND VALVE LEAFLETS ALLOWS 1:1 INFLOW/OUTFLOW DIAMETER RATIO IN ALL SIZES



29mm valve example shown

FIGURE 2: NON-TAPERED STENT AND VALVE LEAFLETS ENABLES COMPLETE DILATATION THROUGHOUT THE USE RANGE OVER THE ENTIRE STENT LENGTH



23mm – 29mm Navitor Vision Valves 35mm Navitor Vision Valve

Large cell geometry. Facilitates coronary access. It also allows the valve tissue to conform around calcific nodules and the remains of the native valve, thereby reducing the risk of paravalvular leak (PVL).

Consistent radial force. As a result, the Navitor Vision Valve offers reproducible, controlled stent deployment, re-sheathing (if required) and stable device anchoring, with consistent behavior across all valve sizes.

- **Active-sealing cuff:** Woven polyethylene cuff designed to synchronize to the patient's cardiac cycle and seals against even the more challenging anatomies. This reduces the risk of PVL and the need for post-dilatation.[1,2,3]

- **Three radiopaque markers:** Improve fluoroscopic visibility and facilitate THV implantation at the appropriate implant depth. This reduces the risk of interference with the conduction system.[7]

*Labeled as Navitor and Navitor Titan with Vision Technology
†Navitor TAVI System low or Intermediate-Risk Indication — OUS Only.

For U.S. audience, see Important Safety Information referenced within.
For audiences outside of the U.S., always check the regulatory status of the device in your region.

LONGER-TERM CLINICAL OUTCOMES

Clinical events rates from the Navitor IDE study at 5 years demonstrate 37.1% all-cause mortality and 12.2% stroke.[3] For the first generation Abbott TAVI valve pooled analysis study, the all-cause mortality at 5 years was 49.4% and stroke rate at 5 years was 12.3%.[8] Tables 1 and 2 show the valve durability results and excellent hemodynamic performance from these studies characterized by absence of severe hemodynamic structural valve deterioration and low reintervention rates. Surgical reintervention was required only once (4%) in the 1464 patient analysis of the first-generation Abbott TAVI Valve, suggesting a design suitable for transcatheter reintervention **(Figure 3)**.

TABLE 1: DURABILITY THROUGH 5 YEARS

NAVITOR IDE STUDY[3] (N=120)			
Bioprosthetic Valve Dysfunction (BVD)			
5.9%			
Moderate HSVD	NSVD	Infective endocarditis	Valve thrombosis
0.0%	1.7%*	4.2%	0.0%
Bioprosthetic Valve Failure (BVF)			
0.0%			
Severe HSVD	Reintervention	Valve-related death	
0.0%	0.0%	0.0%	
FIRST GEN. ABBOTT TAVI VALVE POOLED ANALYSIS STUDY[8] (N=1464)			
Bioprosthetic Valve Dysfunction (BVD)			
nr			
Moderate HSVD	NSVD	Infective endocarditis	Valve thrombosis
0.9%	nr	1.3%	0.7%
Bioprosthetic Valve Failure (BVF)			
2.7%			
Severe HSVD	Reintervention	Valve-related death	
0.0%	2.0%**	0.7%	

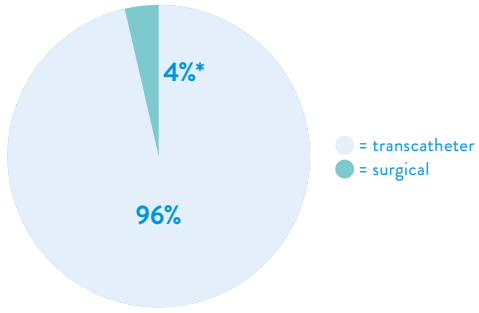
* All related to prosthesis-patient mismatch** All interventions within 30 days due to NSVD. Most frequent cause through 5 years was PVL.
HSVD, hemodynamic structural valve deterioration; NSVD, non-structural valve deterioration

TABLE 2: HEMODYNAMIC PERFORMANCE THROUGH 5 YEARS

NAVITOR IDE STUDY[3] (N=120)							
	Baseline	30 d	1 yr	2 yr	3 yr*	4 yr	5 yr
Mean gradient (mmHg)	42.7	7.4	7.5	7.5	nr	5.9	6.9
EOA (cm2)	0.71	2.03	1.92	1.90	nr	1.98	2.00
≥moderate PVL (%)	n/a	0	1	0	nr	0	0
FIRST GEN. ABBOTT TAVI VALVE POOLED ANALYSIS STUDY[8] (N=1464)							
	Baseline	30 d	1 yr[8]	2 yr	3 yr	4 yr	5 yr
Mean gradient (mmHg)	47.2	8.1	8.0	7.4	7.1	6.9	6.2
EOA (cm2)	0.71	1.81	1.78	1.83	1.79	1.81	1.83
≥moderate PVL (%)**	n/a	3.7	ns	ns	ns	ns	1.9

*3 year echocardiographic assessments not reported per study protocol.
** paired analysis, n/a = not applicable, ns = not stated

FIGURE 3: TYPE OF REINTERVENTION (5 YR)[8]



*1 patient, infective endocarditis

KEY TAKEAWAYS

- The Navitor™ Vision Valve transcatheter heart valve design reflects a series of deliberate engineering decisions aimed at balancing multiple, often competing requirements. Through these choices, the Navitor design emerges as a distinctive solution to the transcatheter heart valve design challenge, exhibiting unique design features and performance characteristics that differentiate it from other THVs.

- Longer-term clinical data shows that the Abbott transcatheter heart valve platform achieves the required clinical performance, demonstrated by excellent hemodynamic performance and low PVL and reintervention rates.

Rx Only
Important Safety Information (For U.S. audience only)

NAVITOR™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

INDICATIONS
The Navitor™ Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

CONTRAINDICATIONS
The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant therapy or nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

POTENTIAL ADVERSE EVENTS
Adverse events potentially associated with the use of transcatheter bioprosthetic heart valves include but are not limited to: access site complications (e.g., pain, bleeding, infection, hematoma, pseudoaneurysm, etc.); acute coronary obstruction; acute myocardial infarction; allergic reaction to antiplatelet agents, contrast medium, or valve components; aortic rupture; ascending aorta trauma; atrio-ventricular node block; cardiac arrhythmias; conduction system injury; conversion to open surgical procedure; death; dissection; embolism; emergent balloon valvuloplasty; emergent percutaneous coronary intervention (PCI); emergent surgery (i.e., coronary artery bypass, heart valve replacement); endocarditis; explantation; heart failure; hemodynamic compromise; hemolysis; hemolytic anemia; hemorrhage; hypotension or hypertension; infection; myocardial ischemia; mitral valve insufficiency; multi-organ failure; non-structural dysfunction (i.e., entrapment by pannus, paravalvular leak, inappropriate sizing or positioning); pannus; pericardial effusion; perforation of the myocardium, ventricle, or a blood vessel; permanent disability; permanent pacemaker; regurgitation; renal insufficiency or renal failure; reoperation; respiratory failure; sepsis; stroke; structural deterioration (i.e., calcification, leaflet tear); thrombosis; tamponade; transfusion; valve embolization or migration; vessel dissection or spasm.

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