Navitor™ Vision* Valve: PVL sealing by unique design

KEY POINTS

- The design of the Navitor Vision Valve incorporates the concept of active PVL reduction by means of a unique, active -sealing cuff, providing confident sealing in various annulus geometries and under challenging anatomical conditions.
- The Navitor IDE study has demonstrated excellent sealing at 30 days, with extremely low rates of moderate, and no occurrence of severe paravalvular leak out to 2 years.

THE CHALLENGE BY ANATOMY

Paravalvular leak (PVL) is the result of incomplete sealing between a transcatheter heart valve (THV) and the native annulus. Moderate or severe PVL potentially impacts short- and mid-term outcomes.[1] PVL may be the result of inappropriate device sizing (an undersized valve leaves space between the native annuls and the device) or ineffective/absence of balloon dilatation. However, even with an appropriately sized device, calcium nodules and the remains of the (often calcified) native valve leaflets may result in an uneven surface for sealing, eventually causing PVL.

THE PASSIVE APPROACH

To reduce the risk of PVL by design, the THV should provide complete sealing between the valve and the native annulus, even when challenged by complex anatomical conditions such as severe calcification of the native annulus and valve leaflets. The design of a self-expanding THV typically incorporates a cuff or wrap made of pliable material (e.g., polyethylene terephthalate or pericardium) fixed to the outer frame of the THV. During implantation of the valve, this material is intended to provide passive PVL reduction by filling open spaces between the device and the landing zone at the native annulus.

Unlike this passive approach, the design of the Navitor Vision THV implements the concept of active PVL reduction. This is established by an active-sealing cuff (Figure 1), made of woven polyethylene fibers. With an oversized design, it provides sealing along the entire valve landing zone in various geometries of the aortic annulus. Most importantly, the cuff is fixed at the nitinol struts but free in between the struts. This facilitates the creation of a parachute or windsock effect that allows these areas to fill during diastole, preventing blood from passing by or leaking, and mold to any remaining gaps between the device and the native annulus until the healing process is complete and the cuff heals in. In vivo testing of the the active-sealing cuff demonstrated optimal healing and no adverse calcification or thrombus altering cusp motion.[2]

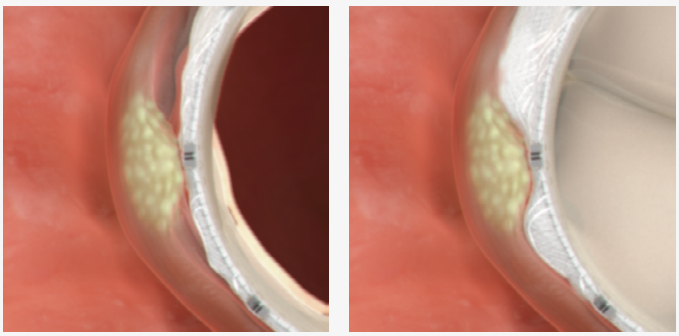

Figure 1 : Navitor Active-sealing cuff

NAVITOR™ ACTIVE SEALING CUFF IS FIXED AT THE STRUTS BUT FREE IN BETWEEN

Facilitating a parachute effect to fill during diastole molding around gaps.

***Labeled as Navitor and Navitor Titan with Vision Technology.**
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.

THE CLINICAL RESULTS

The results of the Navitor IDE study demonstrate the clinical performance of the active sealing cuff. For this study, 260 patients were enrolled at 26 clinical sites in the US, Europe and Australia (mean age: 83.4 ± 5.4 years, 57.3% female).

Per assessment by an independent echocardiographic core laboratory at 30 days after valve implantation, 79.8% of the patients showed none or trace PVL, while 20.2% had mild PVL.[3] Moderate or greater PVL was not observed at 30 days.

The rate of moderate or greater PVL remained extremely low through 2 years after valve implantation[4] (Figure 2). Extended follow-up is scheduled until 5 years.

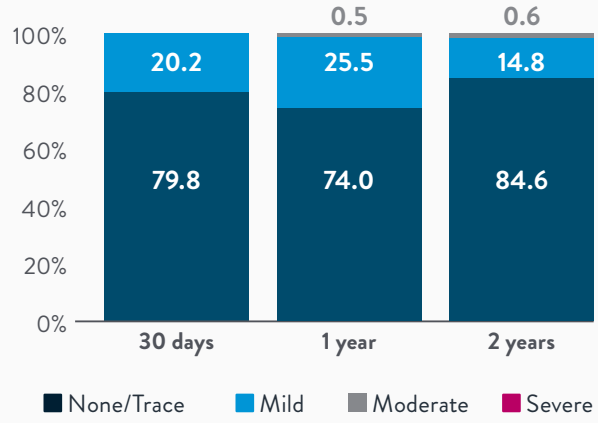

Figure 2 : PVL at various follow-up visits in the Navitor IDE study.

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Rx Only
Important Safety Information

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; 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, ventrcle, or a blood vessel; permanent disability; permanent pacemaker; regurgitation; renal insufficiency or rena failure; reoperation; respiratory failure; sepsis; stroke; structural deterioration (i.e., calcification, leaflet tear); thrombosis; tamponade; transfusion; valve embolization or migration; vessel dissection or spasm.

References

1. Takagi H, Umemoto T. Impact of paravalvular aortic regurgitation after transcatheter aortic valve implantation on survival. Int J Cardiol. 2016;221:46-51.
2. Manahoran G. Design principles and case study of a next generation self-expanding TAVI valve. Presented at 2021 EuroPCR in Paris, France..
3. Reardon MJ, Chehab B, Smith D, et al. 30-Day Clinical Outcomes of a Self-Expanding Transcatheter Aortic Valve: The International PORTICO NG Study. JACC Cardiovasc Interv. 2023;16(6):681-689.
4. Waksman R. Two-Year Outcomes in the Navitor IDE Study. TCT 2024; Washington DC.

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