Navitor™ TAVI System



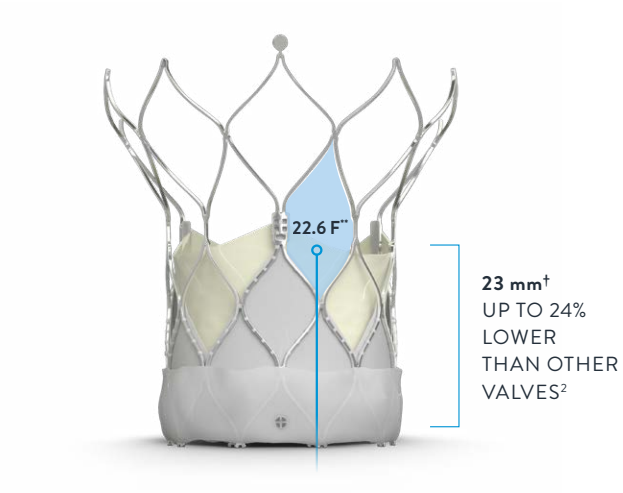
FUTURE READY INDEX TAV

READY FOR FUTURE INTERVENTIONS

UNCOMPROMISED CORONARY ACCESS



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



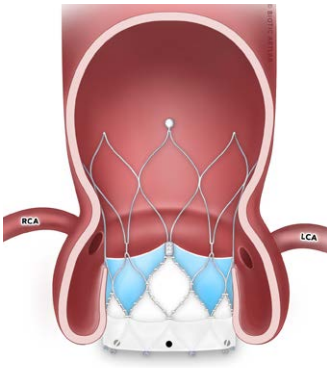
The Navitor™ Vision* valve large cell geometry and intra-annular valve design preserve coronary access for future interventions.

Navitor Vision†***	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

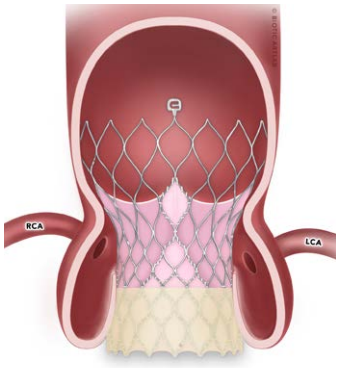
FUTURE READY INDEX VALVE

The intra-annular leaflet position of the Navitor Vision valve allows for TAV-in-TAV procedures with diminished risk of:

SINUS SEQUETRATION

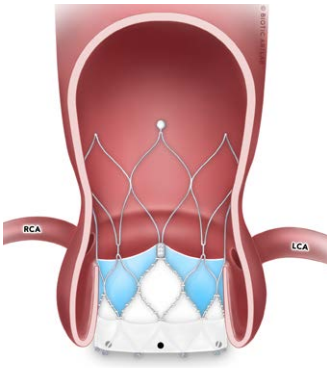


Navitor Vision* valve

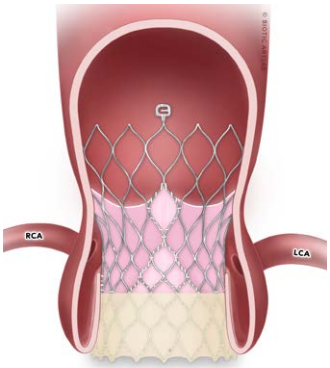


Competitive valve

CORONARY OCCLUSION



Navitor Vision* valve



Competitive valve

For illustrative purposes only, not actual images of diminished risks.

*Labeled as Navitor and Navitor Titan with Vision Technology.
**For 35 mm Navitor Vision Valve.
***Based on Abbott coronary access testing
†For First-Generation Abbott TAVI Valve, size 25 mm. Navitor leaflets are identical in design and construction.

See Important Safety Information referenced within.

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 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.

References
1. Tests performed by and data on file at Abbott, RPT 90664679.

2 Akodad M, Sellers S, Gulsin GS, et al. Leaflet and neoskirt height intranscatheter heart valves: implications for repeat procedures and coronary access. JACC Cardiovasc Interv. 2021;14(20):2298-2300. doi:10.1016/j.jcin.2021.07.034

CAUTION: Product(s) 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 https://www.eifu.abbott/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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