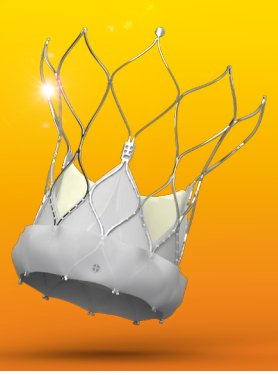
Navitor™ TAVI System

# SINGLE-DIGIT GRADIENTS, LARGE EOAs



## EXCELLENT HEMODYNAMICS

Navitor™ Vision* Valves feature:

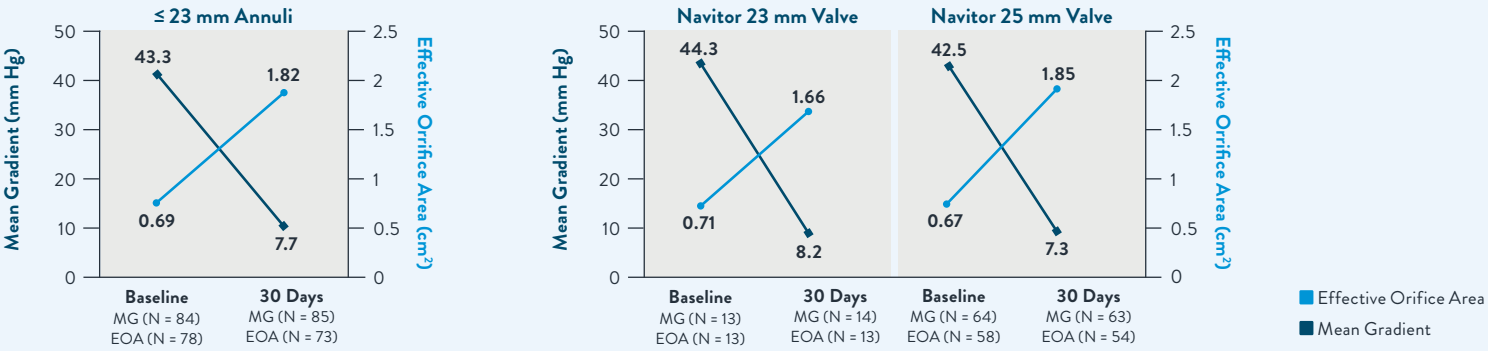
- Intra-annular leaflets that open fully to maximize orifice area and achieve single-digit mean gradients.
- A unique, cylindrical stent.

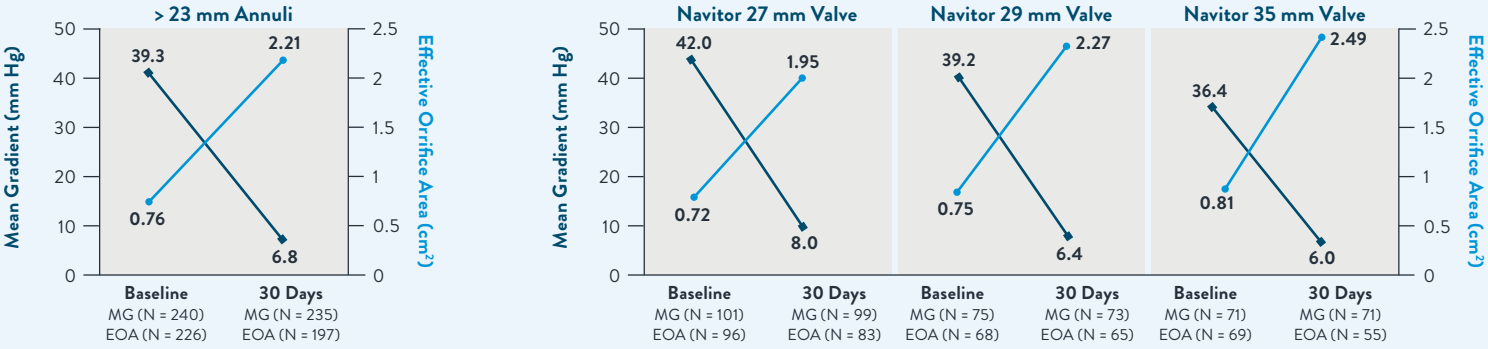
**30-DAY ECHO CORE LAB DATA[1]**

**2.1** $cm^2$ — EOA

**7.1** mm Hg — MEAN GRADIENT

## PROVEN PERFORMANCE — ALSO IN SMALLER SIZES[1]




*Labeled as Navitor and Navitor Titan with Vision Technology.

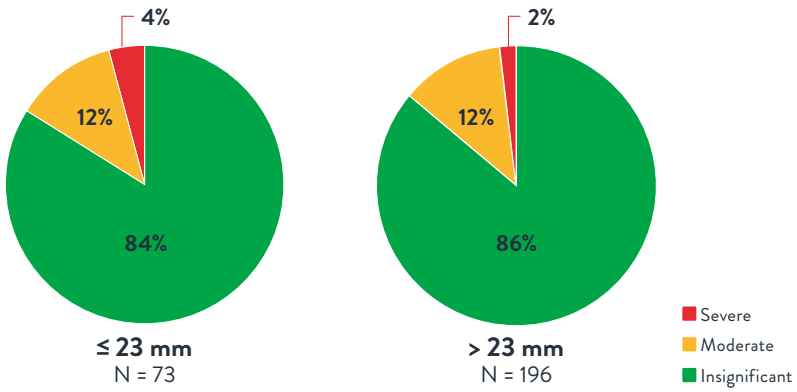
**For U.S. audience, see Important Safety Information referenced within.**
**For audiences outside of the U.S., always check the regulatory status of the device in your region.**

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## LOW INCIDENCE OF SEVERE PROSTHESIS-PATIENT MISMATCH** AT 30 DAYS[1]

### NATIVE ANNULAR DIAMETER

**Prosthesis-patient mismatch classified according to VARC 3 criteria.




**For U.S. audience only**

**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. Data on file at Abbottt, CL1030703.

**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 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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