



## ENGINEERING INSIGHTS PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

# In Vitro Evaluation Comparing Deliverability of Two Self-expanding TAVI Systems

**Portico™ with FlexNav™ TAVI System is 63% more deliverable than the Evolut<sup>+</sup> PRO valve with EnVeo<sup>+</sup> PRO<sup>1</sup>**

### BACKGROUND

The propensity of a valve and delivery system to glide and negotiate tortuous anatomy can have a significant impact on the force needed and the qualitative feel of the procedure. There are challenges to measuring these factors in the clinical setting that may be overcome through *in vitro* testing.

### OBJECTIVE

To quantify the force required to deliver a valve-loaded delivery system through an anatomically accurate three-dimensional track model including iliac branch, aortic arch and annulus transitions.<sup>1,2</sup>

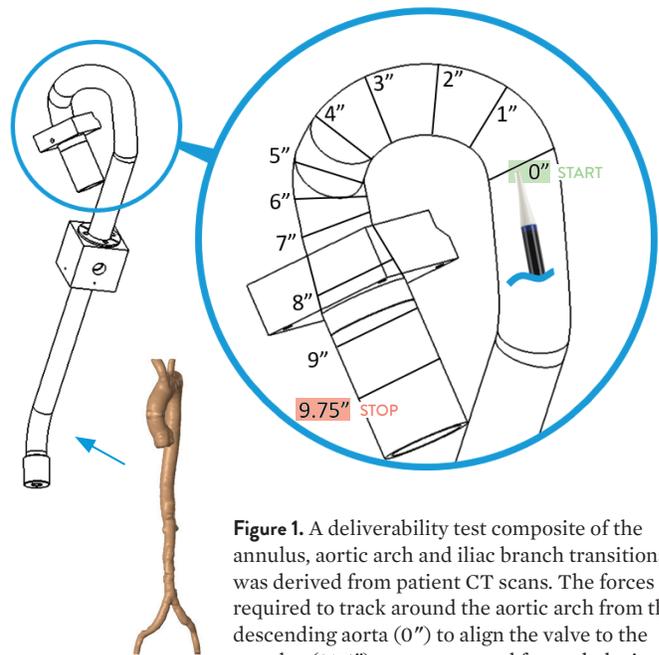
### METHODS

An engineering protocol was developed to direct a series of bench tests on the Portico™ with FlexNav™ TAVI System and the Evolut<sup>+</sup> PRO valve with EnVeo<sup>+</sup> PRO delivery system.<sup>2</sup>

A deliverability test model composite of the aortic arch and annulus was derived from CT scans in previous scientific studies (Figure 1). The iliac branch angle was determined by reviewing CT scans from the Portico™ valve IDE trial, and the maximum angle of 45° was chosen to compensate for simplicities elsewhere in the model. The model closely mirrored anatomic geometry and included the three out-of-plane turns that TAVI systems typically navigate during delivery.<sup>3,4</sup>

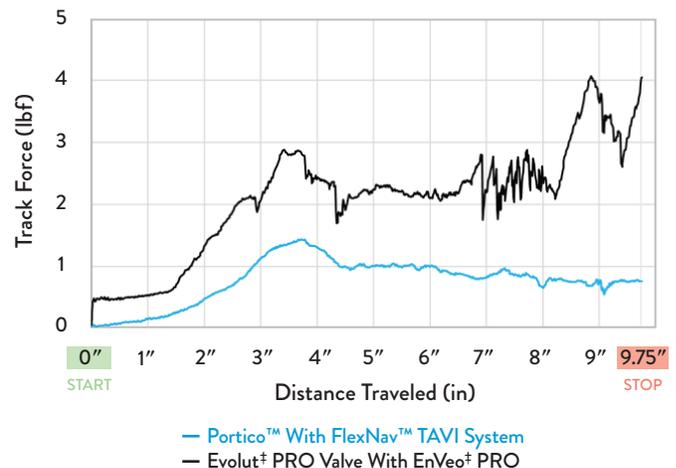
CT = computerized tomography; IDE = investigational device exemption; lbf = pound-force; TAVI = transcatheter aortic valve replacement

See Important Safety Information referenced within.



**Figure 1.** A deliverability test composite of the annulus, aortic arch and iliac branch transitions was derived from patient CT scans. The forces required to track around the aortic arch from the descending aorta (0") to align the valve to the annulus (9.75") were measured for each device, averaged and plotted.

**Figure 2.** Deliverability track force results (average of three trials).<sup>1</sup>



The test model was filled with 37°C water and glycol solution to act as a blood analog.<sup>2</sup>

The valve size selected for testing both the Portico™ valve and Evolut<sup>+</sup> PRO valve was 29 mm because those cover the high-use range.<sup>1</sup>

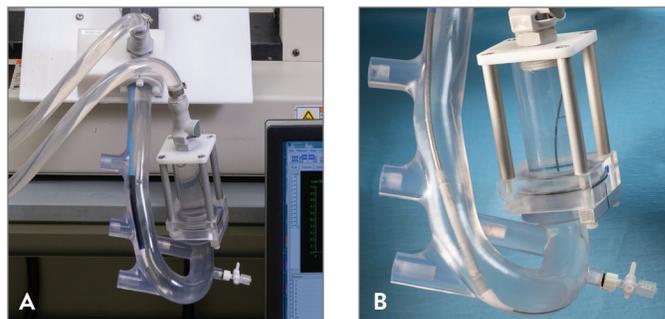
Three tests were performed using the Portico™ with FlexNav™ TAVI System, and three with the Evolut<sup>+</sup> PRO valve with EnVeol<sup>+</sup> PRO. In each, a separate unit was tracked from 0" to 9.75" around the aortic arch from the descending aorta to the annulus site while recording applied force in real time. The resulting data was averaged for each system and can be seen in Figure 2.<sup>1,2</sup>

## RESULTS

The Portico with FlexNav TAVI System demonstrated a 68% reduction in peak track force (1.45 lbf vs. 4.58 lbf) and a 63% reduction in average track force (0.77 lbf vs. 2.08 lbf) when compared to the Evolut<sup>+</sup> PRO valve with EnVeol<sup>+</sup> PRO. Measurements at the annulus showed a 78% lower peak force (1.02 lbf vs. 4.58 lbf) and a 77% lower average force (0.74 lbf vs. 3.17 lbf) for the Portico with FlexNav TAVI System relative to the Evolut<sup>+</sup> PRO valve with EnVeol<sup>+</sup> PRO (Table 1 and Figure 4).<sup>1</sup>

## CONCLUSION

These results quantify delivery forces related to the use of the Portico with FlexNav TAVI System and reinforce physician implanter feedback of its smooth tracking during implantation. Reduced forces and smooth delivery may improve patient safety by reducing complications in tortuous, calcified anatomies.

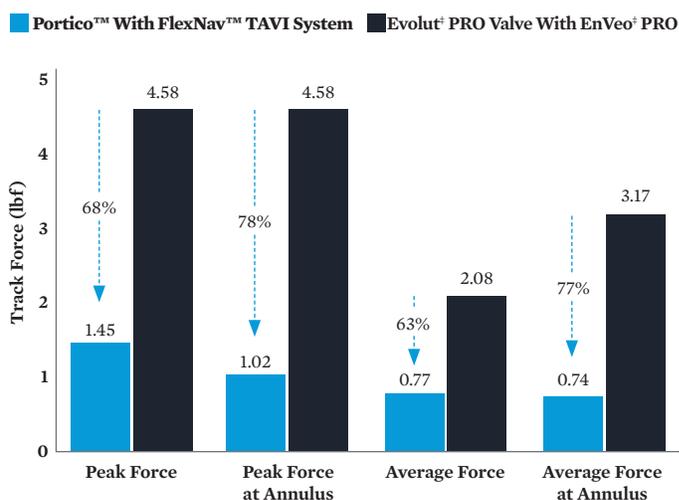


**Figure 3.** A) The three-dimensional track test helped to quantify the importance of flexibility when a TAVI system navigates an anatomically accurate model with three out-of-plane turns during delivery. B) Reduced forces and smooth delivery may improve patient safety by reducing complications in tortuous, calcified anatomies.

**Table 1. Three-dimensional delivery test<sup>1</sup>**

Force (lbf)	Portico™ With FlexNav™ TAVI System	Evolut <sup>+</sup> PRO Valve With EnVeol <sup>+</sup> PRO
Peak	1.45	4.58
Peak at Annulus	1.02	4.58
Average	0.77	2.08
Average at Annulus	0.74	3.17

**Figure 4.** Peak and average track forces for the Portico™ with FlexNav™ TAVI System and Evolut<sup>+</sup> PRO valve with EnVeol<sup>+</sup> PRO delivery system.<sup>1</sup>



## REFERENCES

1. Abbott. Data on file. 90598280.
2. Abbott. Data on file. 90584162.
3. Abbott. Data on file. 90099794.
4. Abbott. Data on file. 90598853.

# PORTICO™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

## IMPORTANT SAFETY INFORMATION

### **Rx ONLY** INDICATIONS

The Portico™ 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  $\geq 8\%$  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.

### WARNINGS

Carefully read all warnings, precautions, and instructions for use for all components of the system before use. Failure to read and follow all instructions or failure to observe all stated warnings could cause serious injury or death to the patient.

- Perform Portico™ valve implantation in a facility where emergency aortic valve surgery is available.
- Verify that the patient's anatomy is consistent with the specifications set forth in the anatomical specifications tables 2 and 3 (found in IFU).
- For single use only. Do not reuse, reprocess, or resterilize the valve, delivery system, or the loading system. Reuse, reprocessing, and/or resterilization creates a risk of contamination of the devices and/or device failure, which could cause patient injury, illness or death.
- Do not manipulate or handle the valve with sharp or pointed objects.
- Rinse the valve as directed before loading the valve onto the delivery system.
- Do not use the valve, the delivery system, or the loading system if the "USE BY" date has elapsed.
- Exercise care to prevent kinking of the delivery system when removing it from the packaging.
- This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/ hypersensitivity to these materials.
- Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, young adults, or patients with altered calcium metabolism.

### PRECAUTIONS

#### Pre-Implantation Precautions

- The safety, effectiveness, and durability of a Portico™ valve implanted within a surgical or transcatheter bioprosthesis have not been demonstrated.
- Long-term durability has not been established for the Portico valve. Regular medical follow-up is advised to evaluate valve performance.
- For transaortic access, ensure the access site and trajectory are free of internal patent right internal mammary artery (RIMA) or pre-existing patent RIMA graft.
- For subclavian/axillary access, use caution in patients with mammary artery grafts.
- Balloon aortic valvuloplasty (BAV) of the native aortic valve is recommended prior to delivery system insertion. The balloon size chosen should be appropriate, not exceeding the minimum diameter of the native aortic annulus as assessed by CT imaging to minimize risk of annular rupture and not undersized to minimize risk of stent under-expansion which could lead to paravalvular leak (PVL) or device migration.
- Do not use the valve if the shipping temperature indicator on the product package has turned red, or if the valve has been improperly stored in temperature conditions outside of the 5°C–25°C (41°F–77°F) range.
- Do not use the valve if the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging.
- Do not advance the delivery system without the guidewire extending from the tip.

- Do not use the valve without thoroughly rinsing as directed.
- Do not use the delivery system without thoroughly flushing as described in the "Directions for Use" section.
- The safety and effectiveness of the Portico™ valve and FlexNav™ delivery system have not been evaluated in the following patient populations:
  - Congenital unicuspid or bicuspid valve, or any leaflet configuration other than tricuspid
  - Severe ventricular dysfunction with left ventricular ejection fraction  $<20\%$
  - Non-calcific aortic annulus
  - Echocardiographic evidence of intracardiac mass, thrombus or vegetation
  - Patients at low or intermediate surgical risk
  - Patients who are pregnant or breastfeeding
  - Pediatric patients (less than 21 years of age)
  - Patients with a pre-existing prosthetic heart valve or prosthetic ring in any position
  - Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation  $>3+$ )
  - Patients with severe circumferential mitral annular calcification (MAC) which is continuous with calcium in the LVOT, severe (greater than 3+) mitral insufficiency, or severe mitral stenosis with pulmonary compromise
  - Blood dyscrasias as defined: leukopenia (WBC  $<3000 \text{ mm}^3$ ), acute anemia (Hb  $<9 \text{ g/dL}$ ), thrombocytopenia (platelet count  $<50,000 \text{ cells/mm}^3$ )
  - Patients with untreated clinically significant coronary artery disease requiring revascularization
  - Patients with bulky calcified aortic valve leaflets in close proximity to coronary ostia
  - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
  - Renal insufficiency (creatinine  $>3.0 \text{ mg/dL}$ ) and/or end stage renal disease requiring chronic dialysis
  - Hemodynamic instability requiring inotropic support or mechanical heart assistance
  - Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick  $>5 \text{ mm}$ ), protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta
  - Patients with known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media which cannot be adequately premedicated
  - Patients with access characteristics that would preclude safe placement of the introducer sheath, when necessary, such as severe obstructive calcification, or severe tortuosity

#### Implantation Precautions

- To minimize risk of guidewire perforations in the left ventricle, a manufacturer pre-shaped guidewire should be used during the procedure and during valve deployment.
- Do not deploy the valve if excessive resistance to deployment is encountered. If the valve does not deploy easily, re-sheath the valve, remove it from the patient, and use a different valve and delivery system.
- Follow the procedure in "Implanting the Valve" to reposition the valve or to remove the valve from the patient.
- Do not attempt to reposition the valve by advancing it distally unless the valve has been fully re-sheathed within the delivery system.
- Do not re-sheath the valve more than two times prior to final valve release. Additional re-sheath attempts may compromise product performance.
- To minimize likelihood of permanent pacemaker implantation (PPI): a) maintain implant depth of 3mm, and b) limit manipulations across the LVOT.

#### Post-Implantation Precautions

- In the event that a post-implant balloon dilatation is performed to address paravalvular leak (PVL), valve size, patient anatomy, and implant depth must be considered when selecting the size

of the balloon for dilatation. The balloon size chosen should not exceed the mean diameter of the native aortic annulus. Moderate or Severe PVL should be addressed at the time of the TAVI procedure.

- Exercise care when removing the delivery system from the patient.
- Exercise care when crossing the valve with adjunctive devices.
- Once the valve is fully deployed, repositioning and retrieval of the valve is not possible. Attempted retrieval (e.g., use of a guidewire, snare, or forceps) may cause aortic root, coronary artery, and/or myocardial damage.
- Valve recipients should be maintained on antiplatelet and/or anticoagulant therapy post procedure, per institutional standards and established guidelines, except when contraindicated, using individualized treatment as determined by their physician.
- Post-implant monitoring and/or possible electrophysiology evaluation may be considered in patients with transient high degree or complete AV block or other conduction disturbances during or following implantation of the valve. This may include continuous ECG monitoring after hospital discharge.

### 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

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 [efu.abbottvascular.com](http://efu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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