

<https://www.structuralheartsolutions.com/structural-heart-products-solutions/aortic-valve-portico/features/>

## Portico™ Transcatheter Aortic Valve



### PRODUCT HIGHLIGHTS

- Self-expanding stent designed to be fully resheathable\* and repositionable\* at the implant site and retrievable, if needed
- Short valve height allows for sealing without the valve extending deep into the left ventricular outflow tract (LVOT)—to help mitigate conduction system disturbances
- Large stent cells in the annulus section of the stent allow for conformability to help minimize PV leak
- Bovine leaflets and porcine pericardial sealing cuff are treated with Linx™ AC anticalcification treatment\*\*
- Contoured leaflet design allows for optimal leaflet coaptation in round and elliptical annulus configurations
- Rapid pacing is not required to deploy the valve
- Short rinse time of two 10-second rinses (total 20 seconds)

### ORDERING INFORMATION

Contents: Transfemoral / Alternative Access Loading System (1 unit per box)

MODEL/ REORDER NUMBER	VALVE SIZE (mm)	ANNULUS DIAMETER (mm)	VALVE AORTIC DIAMETER (mm)	LEAFLET/ CUFF HEIGHT (mm)	TOTAL HEIGHT (mm)
PRT-23	23	23	39	26	50
PRT-25	25	25	41	28	53
PRT-27	27	27	42	28	49
PRT-29	29	29	44	29	50

\*Until fully deployed.

\*\*There is no clinical data currently available that evaluates the long-term impact of anticalcification tissue treatment in humans.

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# DELIVERABILITY REDEFINED. TAVI REIMAGINED.

PORTICO™ WITH FLEXNAV™  
TAVI SYSTEM

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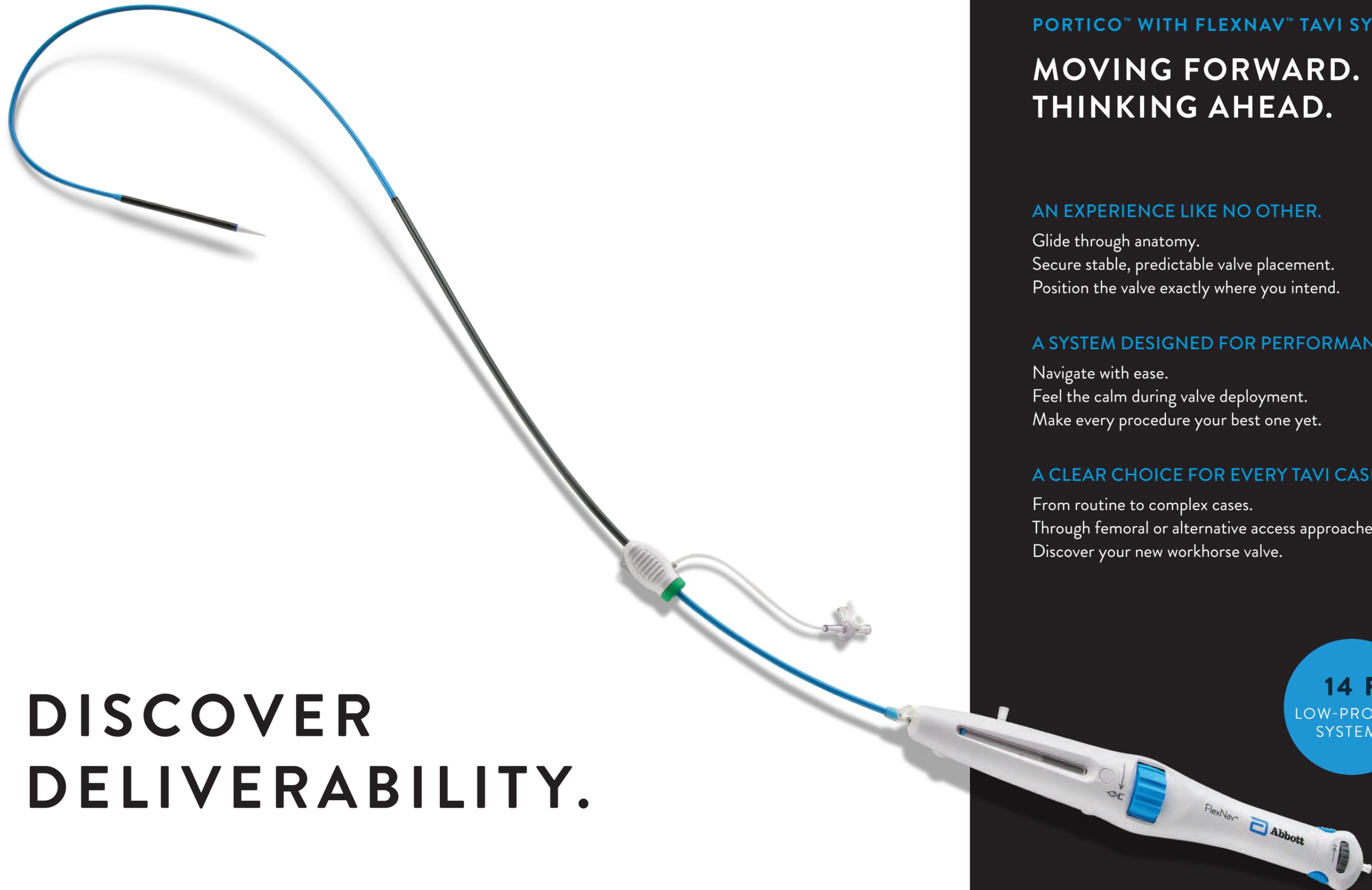




# TAKE CONTROL.

THE MOMENT IS  
ALL YOURS.

THE FLEXNAV DELIVERY SYSTEM'S EXCEPTIONAL DESIGN WAS PURPOSEFULLY BUILT TO GIVE YOU COMPLETE, INDEPENDENT CONTROL OF VALVE DELIVERY.



# DISCOVER DELIVERABILITY.

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PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

## MOVING FORWARD. THINKING AHEAD.

### AN EXPERIENCE LIKE NO OTHER.

Glide through anatomy.  
Secure stable, predictable valve placement.  
Position the valve exactly where you intend.

### A SYSTEM DESIGNED FOR PERFORMANCE.

Navigate with ease.  
Feel the calm during valve deployment.  
Make every procedure your best one yet.

### A CLEAR CHOICE FOR EVERY TAVI CASE.

From routine to complex cases.  
Through femoral or alternative access approaches.  
Discover your new workhorse valve.

**14 F**  
LOW-PROFILE  
SYSTEM\*1

\*14 F equivalent integrated sheath diameter.

# BIG THINKING, DOWN TO THE SMALLEST DETAIL.

## SEE PROGRESS AS YOU GO

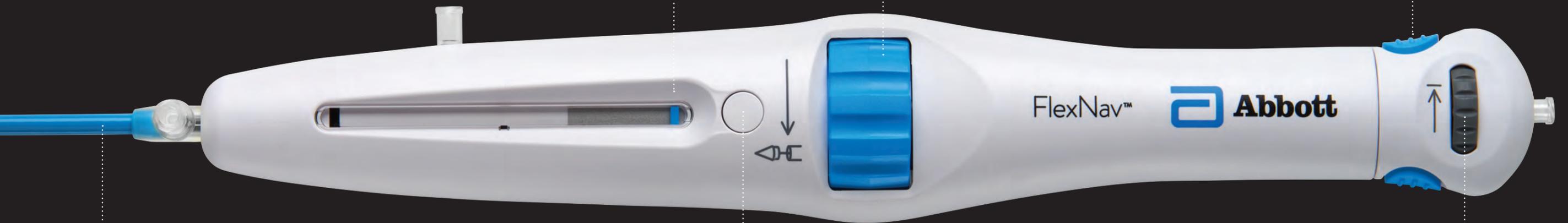
A deployment indicator gives you a clear visualization of the valve's deployment progress.

## FEEL EVERY ADVANCEMENT

The simple deployment wheel provides both audible and tactile feedback as you deploy the valve.

## OPEN AND CLOSE WITH EASE

Two macro-slide buttons make it easy for you to open and close the distal end of the delivery system during valve loading and post-deployment.



## TAKE THE TENSION OUT OF TAVI

The stability layer ensures stable, predictable valve deployment to achieve accurate valve placement.

## LOCK IN PLACEMENT ACCURACY

The automatic lock button prevents full valve deployment until you've got the valve right where you want it.

## DIAL IN THE DETAILS

With the unique micro-adjustment wheel, you can close gaps between the valve capsule and the atraumatic nosecone.

# LOOK CLOSER.

## DELIVERABILITY IS IN THE DETAILS.

Portico with FlexNav brings together innovation across every aspect of its design, offering remarkable flexibility and exceptionally smooth tracking.

### 3D FLEXIBILITY. INFINITE POSSIBILITY.

FlexNav offers three-dimensional flexibility at the distal end and throughout its entire working length.



1

ATRAUMATIC NOSECONE AND SMOOTH TRANSITIONS ARE DESIGNED TO REDUCE VASCULAR COMPLICATIONS AND PREVENT CALCIUM DISLODGE<sup>M</sup>ENT.

2

THE LARGE-CELL FRAMEWORK OF THE PORTICO VALVE REDUCES METAL MASS, RESULTING IN A MORE FLEXIBLE CAPSULE.

3

THE CAPSULE IS MORE FLEXIBLE BECAUSE IT DOES NOT REQUIRE BILATERAL METAL RAILS OR EXTRA NITINOL BRAIDING, RESULTING IN ENHANCED FLEXIBILITY.<sup>2</sup>

4

HYDROPHILIC COATING REDUCES FRICTION BY 98%,<sup>3</sup> PROVIDING LUBRICITY TO GUIDE THE SYSTEM THROUGH VASCULATURE.

5

INTEGRATED SHEATH FOR LOW 14 F DELIVERY PROFILE.<sup>1</sup>

<sup>1</sup>14 F equivalent integrated sheath diameter.

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CONTINUOUS  
HEMODYNAMIC  
STABILITY

# STABLE FROM THE START.

EARLY LEAFLET FUNCTIONALITY. NO RAPID PACING.

Intra-annular leaflet position in a self-expanding valve provides early valve function and hemodynamic stability throughout the procedure—for calm and controlled deployment, without compromise.



# THINKING AHEAD

LARGE-CELL GEOMETRY AND **INTRA-ANNULAR VALVE POSITION**  
PRESERVE CORONARY ACCESS.

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# FEEDBACK FROM FLEXNAV USERS\*

## OVERALL DELIVERABILITY

“It was very easy to use. We saved two French sizes of the sheath compared to the previous system. The control of the delivery system was absolutely better. It’s a big advantage in the development of the TAVI procedure with the Portico valve.”

-Interventional Cardiologist  
Italy

## OVERALL FLEXIBILITY

“The system is a major advancement. With release, it didn’t move at all. And this was in a relatively horizontal aorta. We were able to end up being two to three mm in both the non-coronary and the left coronary side. Perfect implant. Very impressed. Big improvement.”

-Interventional Cardiologist  
United States of America

## PLACEMENT ACCURACY

“A key element of this is the stability of the delivery. Having done a lot of cases before, I and the team had a really good understanding of the movements of the valve when it was being released or retracted. But here, with the FlexNav system, it is just stable throughout the whole delivery.”

-Interventional Cardiologist  
Australia

## DELIVERABILITY IN TORTUOUS ANATOMY

“The biggest benefit is the ability for the valve to be advanced even through very tortuous anatomies. The hydrophilic coating of the delivery system allows the valve and the delivery system to swim through arches and accesses without any difficulty at all.”

-Interventional Cardiologist  
United Kingdom

\*Opinions about the treatment discussed can and do vary and are specific to the individual's experience and might not be representative of others.

# ADVANCED OUTCOMES WITH FLEXNAV

THE FLEXNAV DELIVERY SYSTEM COHORT OF  
THE PORTICO IDE STUDY DEMONSTRATED  
THE FOLLOWING OUTCOMES<sup>4</sup>:

**0%**

ALL-CAUSE MORTALITY

**0%**

DISABLING STROKE

**0%**

AKI III

**4%**

LIFE-THREATENING BLEEDING

**7%**

MAJOR VASCULAR COMPLICATIONS



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EVERY ASPECT OF PORTICO WITH FLEXNAV WAS  
DESIGNED TO HELP YOU PLACE THE VALVE  
**ON TARGET, EVERY TIME.**

BUT IN CASE YOU NEED TO MAKE A  
MOVE, REST ASSURED.

**RECAPTURABLE\***  
**REPOSITIONABLE\***  
**RETRIEVABLE\***



## REORDERABLE

### PORTICO™ TRANSCATHETER AORTIC VALVE

Catalog Number	Valve Size (mm)	Annulus Range (mm) <sup>5</sup>	Area Range (mm <sup>2</sup> ) <sup>6</sup>	Perimeter Range (mm) <sup>6</sup>
PRT-23	23	1) 19-21	277-346	3) 60-66
PRT-25	25	21-23	338-415	66-73
PRT-27	27	23-25	405-491	72-79
PRT-29	29	25-27) 2)	479-573	79-85) 4)

### FLEXNAV™ DELIVERY SYSTEM

Catalog Number	Equivalent Integrated Sheath Diameter (F)	Outer Diameter (mm)	Integrated Sheath Working Length (cm)	Delivery System Length (cm)	Minimum Vessel Diameter Requirement (mm)
FNAV-DS-SM	14	6.0	30	107	≥ 5.0
FNAV-DS-LG	15	6.3	30	107	≥ 5.5

### FLEXNAV™ LOADING SYSTEM

Catalog Number	
FNAV-LS-SM	The FlexNav™ loading system facilitates valve preparation/loading onto the FlexNav™ delivery system. The loading system includes a loading funnel, loading base, base insert, loading tube, and leaflet tester.
FNAV-LS-LG	

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# DELIVERABILITY REDEFINED. TAVI REIMAGINED.

## EXPERIENCE REMARKABLE DELIVERABILITY

PORTICO™ WITH FLEXNAV™  
TAVI SYSTEM

**References:** 1. Portico IFU. 2. Abbott Data on File. 90368819. 3. Abbott Data on File. 90346620. 4. Fontana GP. PORTICO: a randomized trial of Portico vs. commercially available transcatheter aortic valves in patients with severe aortic stenosis. Poster presented at: TCT 2019. 5. Abbott Data on File. 90078060. 6. Abbott Data on File. 90066115.

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# PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

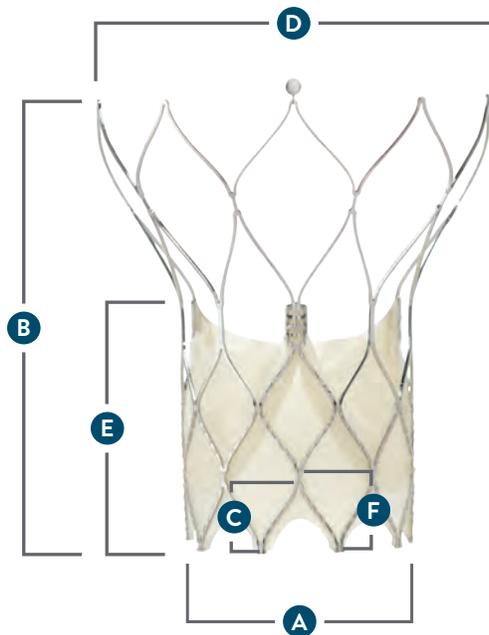
## INDICATIONS FOR USE

The Portico™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.

The FlexNav™ delivery system is indicated for transfemoral or subclavian/axillary delivery of the Portico™ valve. The delivery system is indicated for insertion into the vessel with or without an arterial introducer sheath.

The FlexNav™ loading system is indicated for loading the Portico™ valve in the FlexNav™ delivery system.

<b>A SIZING<sup>1</sup></b>	<b>23 mm</b>	<b>25 mm</b>	<b>27 mm</b>	<b>29 mm</b>
Annulus Range (mm)	19–21	21–23	23–25	25–27
Area (mm <sup>2</sup> )	277–346	338–415	405–491	479–573
Perimeter (mm)	60–66	66–73	72–79	79–85
Ascending Aorta Diameter (mm)	26–36	28–38	30–40	32–42
Minimum Vessel Diameter	≥ 5.0 mm	≥ 5.0 mm	≥ 5.5 mm	≥ 5.5 mm
Cuff Sealing Zone (mm)	9	9	10	10
Implant Depth (mm)	3–5	3–5	3–5	3–5
Implant Target or “Nominal” Depth Below Annulus (mm)	3	3	3	3
<b>VALVE<sup>1</sup></b>				
<b>B</b> Stent Height (mm)	50	53	49	50
<b>C</b> Ventricular Half-cell Section (mm)	7	7	8	8
<b>D</b> Aortic Stent Section Width* (mm)	39	41	42	44
<b>E</b> Commissure Attachment Height (mm)	26	28	28	29
<b>F</b> Inner Cuff Height (mm)	9	9	10	10



## MATERIALS, PREPARATION, STORAGE & SHELF LIFE<sup>1</sup>

**Valve Leaflet Material:** Bovine Pericardium

**Inner Cuff Material:** Porcine Pericardium

**Stent:** Self-expanding Nitinol

**Tissue Anticalcification:** Linx™ Anticalcification Treatment

**Valve Preparation:** Simple two short 10-second rinses in sterile isotonic saline at room temperature<sup>2</sup>

**Storage Solution:** Formaldehyde<sup>2</sup>

**Storage Temperature:** 5°C–25°C (41°F–77°F)<sup>2</sup>

**Shelf Life:** Portico Valve<sup>3,5</sup> – 2 Years  
 FlexNav Delivery System<sup>3,5</sup> – 2 Years  
 FlexNav Loading System<sup>3,5</sup> – 2 Years  
 Ultim™ EV Introducer<sup>4-5</sup> – 3 Years

<sup>1</sup>Dimensions at fully expanded and unconstrained stent.

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DELIVERY SYSTEM <sup>1</sup>	23 mm	25 mm	27 mm	29 mm
Guidewire Compatibility	0.035 inch compatible			
Outer Diameter — Distal End (mm)	SM 6.0		LG 6.3	
Vascular Access Diameter (mm)	≥ 5.0		≥ 5.5	
Working Length (cm)	107			
Hydrophilic Coating Length (mm) Capsule, Integrated Sheath, Nosecone	354			

### VALVE PACKAGING AND STORAGE<sup>2</sup>

The valve is supplied in a jar containing formaldehyde storage solution. The jar has a screw cap closure and tamper-evident seal. The valve is supplied on a disposable holder. The contents of the jar are sterile and must be handled aseptically to prevent contamination. Store the valve in the upright position.

**CAUTION:** Do not use the valve without thoroughly rinsing as directed.

**CAUTION:** 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.

### DELIVERY SYSTEM/LOADING SYSTEM PACKAGING AND STORAGE<sup>2</sup>

The delivery system and loading system are sterilized with ethylene oxide gas. The delivery system is supplied in a tray within an outer pouch.

The loading system is supplied in a double-barrier tray. The inner delivery system/loading system trays are supplied sterile provided the outer pouch/tray packaging is not opened or damaged.



### MAGNETIC RESONANCE (MR) SAFETY<sup>2</sup>

Non-clinical testing has demonstrated Portico™ transcatheter aortic heart valves are MR Conditional. Patients can safely be scanned immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5 T) or 3.0 Tesla (3.0 T)
- Maximum spatial gradient magnetic field of less than or equal to 3,000 gauss/cm (30 T/m)
- Normal Operating Mode: Maximum whole-body specific absorption rate of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

### REFERENCES

1. Abbott. Data on File. 90432050/90465559.
2. Portico IFU.
3. Shelf-Life Statement: Valve, Delivery System, and Loading System.
4. Shelf-Life Statement: Ultimium EV Introducer.
5. Abbott. Data on File. 90434228/90434239

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