PORTICO™

Transcatheter Aortic Heart Valve Implantation System

INDICATIONS FOR USE

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

SIZING[1]		23 mm	25 mm	27 mm	29 mm
Annulus Range (mm)		19–21	21–23	23–25	25–27
Area (mm^2)		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		≥ 6.0 mm (18 F)	≥ 6.0 mm (18 F)	≥ 6.5 mm (19 F)	≥ 6.5 mm (19 F)
Cuff Sealing Zone (mm)		9	9	10	10
Landing Zone (mm)		1–9	1–9	1–10	1–10
Implant Target or "Nominal" Depth Below Annulus (mm)		3	3	3	3
VALVE[1]					
Stent Height (mm)		50	50	49	50
Stent Width at Top* (mm)		39	41	42	44
Commissure Attachment Height (mm)		26	28	28	29
Valve Leaflets		Bovine Pericardium			
Inner Cuff Height		9 mm		10 mm	
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[2]			
Storage Solution		Formaldehyde[2]			
Storage Temperature		5°C–25°C (41°F–77°F)[2]			
Shelf Life:	Portico Transcatheter Aortic Heart Valve[3] Portico Delivery System[3] Portico Valve Loading System[3] Ultimum™ EV Introducer[4]	2 years 4 years 2 years 3 years			
DELIVERY SYSTEM[1]					
Guidewire Compatibility		0.035 inch compatible			
Outer Diameter — Distal End		18 F/6.0 mm		19 F/6.33 mm	
Outer Diameter — Proximal End		13 F/4.33 mm			
Vascular Access Diameter (mm)		≥ 6.0		≥ 6.5	
Working Length		110 cm			

*Dimensions at fully expanded and unconstrained stent.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.** Check the regulatory status of the device in areas where CE marking is not the regulation in force.

PACKAGING AND STORAGE[2]

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.

MAGNETIC RESONANCE (MR) SAFETY[2]

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

REFERENCE

1. Abbott. Data on File. 90432050.
2. Portico IFU.
3. Portico Shelf-Life Statement: Valve, Delivery System, and Loading System.
4. Portico Shelf-Life Statement: Ultimum EV Introducer.

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 eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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