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

DESCRIPTION
The Portico transcatheter heart valve is designed to be implanted in the native aortic heart valve without open heart surgery and without concomitant surgical removal of the failed native valve. The valve is implanted using the Portico transfemoral delivery system. The valve is supplied sterile and non-pyrogenic.

PRODUCT BENEFITS
- Self-expanding stent designed to be fully resheathable,* repositionable, at the implant site and retrievable, if needed
- Low leaflet/cuff within the stent design allows for sealing without the valve extending deep into the LVOT — potentially mitigating heart block
- Large stent cells in the annulus section of the stent allows for tissue to conform around calcific nodules — potentially minimizing PV leak
- Bovine leaflets and porcine cuff are treated with Linx™ Anticalcification treatment**
- Contoured leaflet design allows for optimal leaflet coaptation in round and elliptical annulus configurations
- Rapid pacing not required to deploy the valve
- Short 2 X 10-second rinse time (total 20 seconds)

PACKAGING AND STORAGE
The valve is packaged in a formaldehyde storage solution. The valve is supplied on a disposable holder. 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.

* Until fully deployed.
** There is no clinical data currently available which evaluates the long-term impact of anticalcification tissue treatment in humans.

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MRI SAFETY INFORMATION

The Portico valve components are manufactured using a non-ferromagnetic nickel-titanium alloy, with both elements present in roughly equal atomic percentages. Non-clinical testing has demonstrated that Portico transcatheter heart valves are MR Conditional. Patients can safely be scanned immediately after implantation under the following conditions:

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

PORTICO TRANSCATHETER AORTIC VALVE

- Annulus Diameter (mm): 23
- Valve Aortic Diameter (mm): 39
- Leaflet / Cuff Height (mm): 26
- Total Height (mm): 50

The Portico valve must be implanted using the Portico loading and delivery system.

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Prior to use, appropriate Portico training must be completed by physician.

Product referenced is approved for CE Mark.

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Item GMSH283EN IPN 2609-12