INDICATIONS FOR USE

The Portico transfemoral delivery system is intended for the delivery and placement of the Portico transcatheter aortic heart valve. The system may be used to deploy, reposition* and retrieve* the valve from the patient if necessary.

PRODUCT BENEFITS

- Delivery system enables self-expanding stent to be fully resheathed* — allowing for repositioning of the valve (proximally or distally) at the implant site, or retrieving* the valve if needed
- Facilitates gradual, controlled deployment — providing time to accurately assess final placement of the valve
- Annulus-first deployment allows optimal placement for overall valve performance
- Designed for enhanced flexibility and trackability

TECHNICAL SPECIFICATIONS

- Over-the-wire, 0.035"-compatible
- 18 F outer diameter at the distal end
- 13 F outer diameter at the proximal end
- Designed for use with vessel diameters ≥ 6 mm
- Working length: 110 cm

SYSTEM COMPONENTS

VALVE LOADING SYSTEM

The Portico valve loading system facilitates valve preparation/loading onto the Portico delivery system. The loading system includes a loading base, loading funnel, loading tube, base insert and leaflet testers (Figure 1).

Figure 1

- Loading Funnel
- Base Insert
- Loading Base
- Loading Tube
- Leaflet Testers (2)

* Until fully deployed
DELIVERY SYSTEM: CONTROL HANDLE

A control handle is located on the proximal end of the delivery system. The handle includes the following features (Figure 2):

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sliding Mechanism Buttons</td>
<td>Facilitates rapid travel of the protective sheath. The sliding mechanism is used to open the delivery system for valve loading, and to resheath the delivery system prior to withdrawal from the descending aorta.</td>
</tr>
<tr>
<td>Deployment/Resheath Wheel</td>
<td>Used to adjust the position of the protective sheath during valve loading and deployment.</td>
</tr>
<tr>
<td>Locking Buttons</td>
<td>Controls movement of the sliding mechanism.</td>
</tr>
<tr>
<td>80% Release Lever</td>
<td>Limits full deployment of the valve. When the valve position is optimized, slide the lever in the direction of the arrow for full valve deployment.</td>
</tr>
<tr>
<td>Lumen Flush Port</td>
<td>Facilitates de-airing of the delivery system lumen.</td>
</tr>
<tr>
<td>Sheath Flush Port</td>
<td>Facilitates de-airing of the delivery system sheath.</td>
</tr>
</tbody>
</table>

Figure 2

DEPLOYMENT SYSTEM: DISTAL END

The valve is deployed annulus end first, from the distal end of the delivery system. The distal end of the delivery system includes the following features (Figure 3):

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atraumatic Radiopaque Tip</td>
<td>Used to guide the delivery system and facilitate visualization.</td>
</tr>
<tr>
<td>Protective Sheath</td>
<td>Covers and maintains the valve in the collapsed position.</td>
</tr>
<tr>
<td>Protective Sheath Marker Band</td>
<td>Provides a reference point used to determine the extent of the valve deployment. The protective sheath may be advanced or retracted to facilitate valve loading and deployment. When the protective sheath is retracted the inner shaft is exposed.</td>
</tr>
<tr>
<td>Inner Shaft</td>
<td>The valve is loaded onto the inner shaft. Retainer tabs on the valve lock into a retainer receptacle that is mounted on the inner shaft. The inner shaft also features a radiopaque inner shaft marker band that provides a reference point used to align the valve in the native annulus.</td>
</tr>
</tbody>
</table>

Figure 3

ORDERING INFORMATION

Model Number | Description
-------------|-------------------------------------------------|
PRT-DS-TF-18F | Portico Transfemoral Delivery System - 18F |
PRT-LS-TF/ALT-18F | Portico Transfemoral / Alternative Access Loading System - 18F |
C407698 | Ultimum™ EV Hemostasis Introducer - 18 F |

Valve Ordering Information

PRT-23 | Portico Transcatheter Aortic Valve - 23 mm |
PRT-25 | Portico Transcatheter Aortic Valve - 25mm |

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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

Product referenced is approved for CE Mark.

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