POLARSHEATH™ SINGLE SOLUTION in a VersaCross™ Sheath

**PRODUCT INFORMATION**

**PRODUCT NAME:** POLARSHEATH™ Steerable Sheath

**DESCRIPTION:** A steerable sheath designed for use with the POLARx™ Cryoablation System. It is 68 cm in length and designed to provide a smooth transition between the transseptal needle and the delivery sheath, ensuring zero exchange delivery.

**ACCESSORY:** The VersaCross™ RF Wire is recommended for use with the POLARSHEATH™ Steerable Sheath for optimal performance.

**CONTRAINDICATIONS:**
- Valve damage
- Air embolus
- Vessel trauma
- Pseudoaneurysm
- Atrial septal defect
- Perforation and/or tamponade
- Infection
- Local nerve damage
- Vessel spasm
- AV fistula formation
- Arrhythmias
- Hematoma
- Catheter entrapment

**INDICATIONS FOR USE:**
- Use in procedures where access to the left atrium via the transseptal approach is required.
- Access to the left atrium is necessary for procedures such as ablation or valve repair.

**WARNINGS:**
- Laboratory staff and patients can undergo significant x-ray exposure during RF procedures. Ensure proper imaging guidance is used.
- There are no known contraindications for this device.

**PRECAUTIONS:**
- Ensure proper imaging guidance is used.
- Continuous usage of fluoroscopic imaging can result in acute radiation injury as well as increased risk for somatic genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- The VersaCross™ RF Wire and Connector Cable are not recommended for use with any other Baylis RF Generator or any other device.

**INDICATIONS FOR USE:**
- For use with the POLARx™ Cryoablation System.
- For use in procedures where access to the left atrium is required.
- For use with the POLARx™ Cryoablation System to create an atrial septal defect.

**PRECAUTIONS:**
- In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF procedures.

**WARNINGS:**
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance.
- Do not attempt to use the VersaCross Connect Transseptal Dilator before thoroughly reading the accompanying Instructions for Use.

**CAUTION:**
- Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warning, Precautions, Adverse Events, and Operator’s Instructions. Products shown by INFORMATIOGRAPHICS, Inc. and may not be approved for use in certain countries.

**RAW TEXT END**
Simple, Seamless, Smooth Zero Exchange
POLARSHEATH™ Steerable Sheath Delivery

EXCHANGELESS 3-in-1 RF Wire

1. Start
   easily track up the SVC

2. Access
   with purpose-built RF

3. Deliver
   with confidence

INSTANTLY DEPLOY
0.035” WIRE
To deliver POLARSHEATH™
Steerable Sheath
with confidence

OMNIviz™ Technology
Reliably locate the VersaCross Connect™ solution on fluoroscopy and ultrasound. Positional markers indicate position of RF tip within dilator. Connect to DuoMode™ Cable to track and mark RF tip on mapping system.

Personalize your solution
1. Choose your VersaCross™ RF Wire
   - **Pigtail**
     - Length: 180 cm
     - Diameter: 0.035”
   - **J-Tip**
     - Length: 180 cm
     - Diameter: 0.035”

   **Dilator with TRUform™ technology**
   - Inner diameter: 0.035”
   - Outer diameter: 12F
   - Useable length: 84 cm

2. Connect with VersaCross Connect™
   Transseptal Dilator

DELIVER THERAPY ON TARGET

TRUform™ Shapeable Technology
Precision RF Puncture Technology

Ordering information

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Wire</th>
<th>Wire length</th>
<th>Dilator curve</th>
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