A full spectrum of solutions for any transseptal procedure

ENABLING LEFT HEART THERAPIES

VersaCross™
RF Wire-Based Platform

NRG™
RF Needle-Based Platform
PROVEN RF TRANSSEPTAL FOR ALL NEEDS

Transseptal Reimagined
The only exchangeless* solution for access-to-delivery of left heart therapy devices

The Standard in Transseptal Access
Interchangeable solutions that easily integrate with your current workflow

PERSONALIZE YOUR SOLUTION
INTERCHANGEABLE DEVICES

VersaCross™
RF Wire (J-Tip)

VersaCross™
Transseptal Sheath

VersaCross™
Steerable Sheath

VersaCross™
Large Access Transseptal Dilator

VersaCross™
Transseptal Dilator

NRG™
Transseptal Needle

TorFlex™
Transseptal Guiding Sheath

SureFlex™
Steerable Guiding Sheath

ProTrack™
Pigtail Wire

* VersaCross™ RF Wire can be used, without exchanges, as a guidewire, as a transseptal puncture device or as an exchange rail for delivering therapy sheaths.

**TRANSEPTAL SOLUTIONS FEATURE:**

**Benchmark Technology:**

- **Proven RF Puncture Technology**
  - Precise RF puncture technology to optimize transseptal location for any anatomy

- **OMNiviz™ Technology:**
  - **Radiopaque**
    - Visualize your tip on fluoroscopy
  - **Echogenic**
    - Reliably locate your active tip on ultrasound for precise puncture
  - **Mapping**
    - Track and mark RF tip position on your mapping system

**VersaCross™ RF Wire**

**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, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**INDICATIONS FOR USE:** The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

**CONTRAINDICATIONS:** The VersaCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device.

**WARNINGS:**
- Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The VersaCross™ RF Wire and Connector Cable are intended for single-patient use only. Do not attempt to sterilize and reuse these devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. The VersaCross™ RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. Do not use the VersaCross™ RF Wire with electrosurgery generators, connector cables, or accessories as attempted use can result in patient and/or operator injury. The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. The VersaCross™ RF Wire must be used with 0.035” compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross™ RF Wire or accessory devices and may cause patient injury. The VersaCross™ RF Wire has only been validated for transseptal puncture use through VersaCross™ dilators which have been demonstrated to provide the required support for optimal function. The VersaCross™ RF Wire is not intended for use with neonatal patients (i.e., less than one month of age). Do not attempt to treat neonatal patients with the VersaCross™ RF Wire.

**PRECAUTIONS:**
- In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. Careful manipulation of the VersaCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross™ RF Wire on any sheath and/or dilator assembly. Excessive force may lead to breaking or kinking of the device leading to advancement and extraction of sheaths and/or dilator devices. The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.

**ADVERSE EVENTS:** Adverse events that may occur while creating an atrial septal defect include: Tamponade • Septal Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Myocardial Arrest • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular Trauma • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment • entanglement • Foreign body/wire fracture

**NRG™ Transseptal Needle**

**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, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

**INDICATIONS FOR USE:** The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

**CONTRAINDICATIONS:** The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

**WARNINGS:**
- Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The NRG™ Transseptal Needle is intended for single-patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. The NRG™ Transseptal Needle must be used with the BMX Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

**PRECAUTIONS:**
- Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered DO NOT use excessive force to advance or withdraw the needle. During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. Forcing electroanatomical mapping guidance if it is recommended to confirm tip placement on the fossa ovalis and septal fenestration before RF puncture with graphic imaging or another imaging modality.

**ADVERSE EVENTS:** Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: Tamponade • Septal Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular Trauma • Pericardial effusion • Tachycardia • Myocardial reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Anterograde fistula • Retrograde Erosion

**All trademarks are property of their respective owners. Patents pending and/or issued. CAUTION: Federal law (USA) restricts these devices 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, warnings, precautions, adverse events, and operator’s instructions.**

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**Barlow Scientific**

Advancing science for life™

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