**Brief Summary | 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 Directions for Use for more information on indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator Instructions.

**CONTRAINDICATIONS:** When used as a guidewire, this device is contraindicated in the presence of an active implantable cardiac device or under fluoroscopy. Use of RF accessory devices will cause skin burns. Use of RF accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. When used as a transseptal sheath and/or dilator devices, the patient should be allowed to rest in a chair with ground metal surfaces. If using electroanatomical mapping during the procedure, the patient should be instructed to wear metallic clothing. Reuse of accessory devices may result in 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 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:** Proper assembly, installation, and handling of the device are essential. Improper handling of the device may cause skin burns. Use of incompatible accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. Use of RF accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. When used as a transseptal sheath and/or dilator devices, the patient should be allowed to rest in a chair with ground metal surfaces. If using electroanatomical mapping during the procedure, the patient should be instructed to wear metallic clothing. Reuse of accessory devices may result in 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 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.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Sheath include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ RF Wire include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**WARNINGS:** Proper assembly, installation, and handling of the device are essential. Improper handling of the device may cause skin burns. Use of incompatible accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. Use of RF accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. When used as a transseptal sheath and/or dilator devices, the patient should be allowed to rest in a chair with ground metal surfaces. If using electroanatomical mapping during the procedure, the patient should be instructed to wear metallic clothing. Reuse of accessory devices may result in 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 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.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Sheath include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ RF Wire include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**WARNINGS:** Proper assembly, installation, and handling of the device are essential. Improper handling of the device may cause skin burns. Use of incompatible accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. Use of RF accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. When used as a transseptal sheath and/or dilator devices, the patient should be allowed to rest in a chair with ground metal surfaces. If using electroanatomical mapping during the procedure, the patient should be instructed to wear metallic clothing. Reuse of accessory devices may result in 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 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.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Sheath include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ RF Wire include: • Infection • Air embolus • Local nerve damage • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias

**WARNINGS:** Proper assembly, installation, and handling of the device are essential. Improper handling of the device may cause skin burns. Use of incompatible accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. Use of RF accessory devices may damage the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. When used as a transseptal sheath and/or dilator devices, the patient should be allowed to rest in a chair with ground metal surfaces. If using electroanatomical mapping during the procedure, the patient should be instructed to wear metallic clothing. Reuse of accessory devices may result in 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 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.
**VersaCross™**
RF Transseptal Solution

1. Choose your *VersaCross™* RF Wire
   - Pigtail
   - J-Tip
   - Length: 180 cm, 230 cm
   - Diameter: 0.035”

2. Choose your *VersaCross™* Sheath to complete your solution
   - Transseptal sheath
   - Steerable sheath
   - Available with Dilator Curves: D1, D0

**VersaCross™**
Transseptal Sheath:
- Length: 63 cm, 81 cm
- Sheath Curves: 45°, 55°, 90°

**VersaCross™**
Steerable Sheath:
- Length: 72 cm
- Size: S, M, L

1. Insert *VersaCross™* RF Wire and *VersaCross™* Sheath
2. Position on fossa
3. Confirm correct position with OMNiViz™ Technology
4. Transseptal access
5. Retract system to reposition
6. Retract sheath
7. Deliver therapy‡

- † Images provided courtesy of Dr. Gagan Singh
  (UC Davis Medical Center, Sacramento, CA)
- ‡ The therapy referred to here may be one of several left heart procedures that require transseptal access. Additional procedural steps and/or devices may be required to deliver the therapy. Before use, consult Instructions for Use for any devices accordingly.