Instructions for Use
Reprocessed VersaCross RF Wire and Connector Cable (including for Connect Watchman and Connect FARADRIVE)

Reprocessed Device for Single Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The VersaCross RF Wire is packaged with a Baylis Single-Use Connector Cable (Connector Cable). The VersaCross RF wire must be used with an approved RFP-100A Radiofrequency (RF) Puncture Generator and the Connector Cable.

The VersaCross RF Wire delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode, which is in compliance with current IEC 60601-2-2 requirements. The Connector Cable connects the compatible Generator to the VersaCross RF Wire. This Connector Cable enables RF power to be delivered from the compatible Generator to the VersaCross RF Wire. Detailed information concerning the compatible Generator is contained in a separate manual that accompanies the equipment. The insulation on the body of the VersaCross RF Wire facilitates smooth advancement of the device and provides electrical insulation. The floppy distal portion of the VersaCross RF Wire has a curve, and the active tip is rounded to be atraumatic to cardiac tissue unless RF energy is applied. A radiopaque and echogenic marker coil is positioned on the distal section for visualization during manipulation. The main body of the VersaCross RF Wire provides a stiff rail for advancing ancillary devices into the left atrium following the creation of an atrial septal defect. The VersaCross RF Wire features visible markers along its length to assist with aligning the wire tip in a compatible transseptal sheath and/or dilator assembly (e.g., the VersaCross Transseptal Sheath kit). The proximal end of the VersaCross RF Wire is bare metal to connect only with the provided Connector Cable and not with electrocautery or electrosurgery devices . The other end of the Connector Cable connects to the compatible Generator.

INDICATIONS FOR USE

The Reprocessed VersaCross RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS FOR USE

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 Generator or any other device.

WARNINGS

- Only physicians with a thorough understanding of angiography, aseptic technique, and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures.
- The VersaCross RF Wire and Connector Cable are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- Do not alter this device in any way.
- Tactile feedback of reprocessed devices may vary during use.
- Note: Please refer to the applicable user manual for recommended settings for the compatible generators.
- 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 use of echocardiography is recommended.
- 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 electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath, dilator, and guidewire advancement should be done under fluoroscopic guidance or echocardiographic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- The Connector Cable must only be used with the compatible 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” (0.89 mm) 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 active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury.
- 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.
- Do not attempt to insert or retract the VersaCross RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury.

PRECAUTIONS

- Do not attempt to use the VersaCross RF Wire and the Connector Cable before thoroughly reading the Instructions for Use.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Do not use the VersaCross RF Wire after the “Use By” date indicated on the label.
- This device is NOT compatible with transseptal needles such as the NRG Transseptal Needle.
- RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage.
- The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised.
- The Reprocessed VersaCross RF Wire is intended for use with only those devices listed in section "Additional Required Items".
- Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements.
- Placement of the dispersive electrode on the thigh could be associated with higher impedance.
- In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application.
- Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the compatible Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the compatible Generator.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications.
- Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip.
- Do not bend the VersaCross RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the VersaCross RF Wire and Connector Cable.
- Careful manipulation of the VersaCross RF Wire must be performed to avoid cardiac damage, tamponade, or vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device.
- VersaCross RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator.
- Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue.
- Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture.
- It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire.
- Never disconnect the Connector Cable from the compatible Generator while RF power is being delivered.
- Never disconnect the Connector Cable from the compatible Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Generator. Twisting the cable may result in damage to the pin connectors.
- The compatible 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.
- Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists.
- 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.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Individual patient anatomy and physician technique may require procedural variations.

ADVERSE REACTIONS

For VersaCross RF Wire and Connector Cable Only:
Adverse events that may occur while using the device include but are not limited to:

- Arrythmia
- Perforation of Myocardium
- Sepsis/infection
- Hemorrhage
- Hematoma
- Vessel Spasm
- Vascular Vessel Trauma
- Vessel Perforation
- AV Fistula Formation
- Pericardial/Pleural Effusion
- Embolic Events
- Air Embolus
- Thromboembolic Episodes
- Vascular Thrombosis
- Foreign body/wire fracture
- Tissue burns
- Perforation and/or Tamponade
- Sustained Arrhythmias
- Tachycardia
- Atrial Fibrillation
- Wire entrapment/entanglement
- Local Nerve Damage
- Pseudoaneurysm
- Valve Damage
- Catheter Entrapment
- Atrial Septal Defect
- Pain and Tenderness
- Allergic reaction
- Myocardial infarction
- Additional surgical procedure
- Atrial Flutter

For VersaCross RF Wire and Cable for Connect Watchman and Connect FARADRIVE Only:
Adverse events that may occur while using the device include but are not limited to:

- Allergic Reaction
- Arrythmias
- Burn
- Cardiac Arrest
- Cardiac Tamponade
- Cardia Trauma
- Cerebral Vascular Accident
- Death
- Electric Shock
- Embolism
- Fistula
- Heart Failure
- Hematoma
- Hemorrhage
- Hypotension
- Infection
- Myocardial Infarction
- Nerve Injury
- Pain
- Pericardiac Effusion
- Pneumothorax
- Respiratory Insufficiency/Failure
- Thrombosis
- Transient Ischemic Attack
- Vasovagal Response
- Vessel Trauma

INSPECTION PRIOR TO USE

Prior to use of the device, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure including the compatible Generator. Do not use defective equipment.

ADDITIONAL REQUIRED ITEMS (Not Supplied by Innovative Health)

RF transseptal procedures should be performed in a sterile environment in a specialized clinical setting equipped with appropriate imaging equipment and compatible examination table, echocardiography imaging, physiologic recorder, emergency equipment and instrumentation for gaining vascular access. Ancillary materials required to perform this procedure include:

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- RFP-100A RF Puncture Generator
- 0.035 in (0.89 mm) compatible sheath (optional) and dilator devices
- DIP electrode, meeting or exceeding IEC 60601-2-2 requirements for electrosurgical electrodes
- DuoMode Cable for use with electroanatomic mapping systems
- For VersaCross RF and Connector Cable for Connect FARADRIVE Only: Introducer sheath 13 F or larger (optional)
- For VersaCross RF and Connector Cable for Connect Watchman Only: Introducer sheath 12.5F or larger (optional)

Please refer to applicable user manual to verify compatibility details for equipment above.

DIRECTIONS

Preparation

- The package label is detachable and may be affixed to the medical record of the patient.
- All instructions for additional materials required should be carefully read, understood, and followed. Failure to do so may result in complications.
- If using a separate guidewire, carefully read the applicable compatible guidewire instructions (not supplied) prior to use. Observe all warnings and precautions noted in these directions. Failure to do so may result in patient complications.
- Use of the device is expected to reduce the number of exchanges in the procedure resulting in a more efficient transseptal puncture. This should be taken into account when estimating the timing for heparin administration to ensure appropriate ACT levels after transseptal puncture.
- Inspect the wire and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the wire is damaged (i.e. kinks and/or breaks) or if the package is compromised, do not use the wire. Return the wire to Innovative Health. **Do not attempt to resterilize**.
- Using proper aseptic sterile technique, remove the wire from its package and place it in a sterile work area.
- Connect the generator connector end of the Connector Cable to the isolated patient connector port on the compatible Generator as per the Generator Instructions for Use. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket. Any attempt to connect the cable otherwise will damage the pins on the connector.
- Do not use excessive force in connecting the Connector Cable to the compatible Generator. Use of excessive force may result in damage to the connector pins.
- Thoroughly flush the sheath, guidewire and dilator (not supplied) with heparinized saline solution prior to use.

Procedure

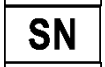
- Perform a standard vein puncture at the desired access site using an access needle (not supplied).
- Care should be taken when inserting or removing the dilator (not supplied) from the venous cutaneous puncture site, note that a compatible access introducer sheath may be used if desired. Refer to the compatible introducer sheath's instructions for use for details and directions.
- Introduce a compatible guidewire through the vascular access point and advance to required depth. The VersaCross RF Wire may be used for this purpose.
- Enlarge the cutaneous puncture site as necessary.
- A transseptal sheath and/or dilator are usually inserted through the access site and are then advanced over a guidewire to be positioned into the Superior Vena Cava (SVC) under image guidance such as fluoroscopy or echocardiography.
- If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of the resistance before proceeding.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Use standard technique to position the dilator/guidewire assembly or the sheath/dilator/guidewire assembly (if sheath is used) into the desired heart chamber.
- If the VersaCross RF Wire was not used to advance the sheath to the SVC, remove the guidewire and exchange for the VersaCross RF Wire with the provided tip straightener.
- Advance the VersaCross RF Wire through the transseptal sheath and/or dilator assembly until the wire tip is just within the dilator tip. The visible markers on the wire body can be used to assist with the positioning of the wire tip with the distal end of the dilator.
- Firmly grasp the catheter connector end of the Connector Cable in one hand. Using your thumb, depress the red button on the top of the connector. Slowly insert the proximal end of the VersaCross RF Wire into the opening of the catheter connector. Once the exposed portion of the proximal end of the device is no longer visible, release the red button on the connector. Gently tug on the device to ensure that you have a secure connection.
- Position the tip of the transseptal assembly (RF wire, sheath and/or dilator assembly) in the right atrium against the fossa ovalis under appropriate imaging guidance including but not limited to fluoroscopic, echocardiographic and/or electroanatomic mapping guidance using standard technique.
- **NOTE: If using electro anatomical mapping guidance, it is recommended to confirm tip placement and septal tenting with echocardiographic imaging or another imaging modality.**
- Apply pressure to the dilator to tent the septum at the fossa ovalis.
- Advance the VersaCross RF Wire so that the active tip is engaging the septum at the fossa ovalis but still within the dilator.
- Once appropriate positioning has been achieved, deliver RF power via the compatible Generator to the active tip. This results in puncture of the targeted cardiac tissue. Please refer to the compatible Generator Instructions For Use for the correct operation of the generator.
- Apply firm pressure to the VersaCross RF Wire during the application of RF energy to successfully advance the VersaCross RF Wire through the tissue.
- **NOTE: Use the lowest appropriate RF settings to achieve the desired puncture.**
- For RFP-100A: An initial RF setting between one (1) second on “PULSE” mode to two (2) seconds on “CONSTANT” mode has been shown to be sufficient for successful puncture.
- RF power delivery can be terminated by pressing the RF ON/OFF button on the compatible Generator if the timer has not expired.
- Entry into the left atrium can be confirmed by monitoring the VersaCross RF Wire under appropriate imaging guidance. Echocardiographic guidance is also recommended.
- If septal puncture is not successful after five (5) RF power applications, it is advised that the user utilize an alternate method for the procedure.
- Once the puncture is successfully completed, the VersaCross RF Wire should be mechanically advanced without any RF power. Positioning in the left atrium is sufficient when the full distal curve and floppy section have crossed the septum and are observed in the left atrium. Echocardiographic guidance is also recommended.
- The dilator can then be advanced over the VersaCross RF Wire to enlarge the puncture.
- To disconnect the VersaCross RF Wire from the Connector Cable, depress the red button on the catheter connector and gently remove the proximal end of the VersaCross RF Wire from the Connector Cable.
- To disconnect the Connector Cable from the compatible Generator, grasp the connector firmly and gently pull it straight out of the socket.
- Retract the VersaCross RF Wire slowly through the transseptal sheath and/or dilator assembly.
- Ensure the dilator is clear of air. To aspirate blood, use the dilator hub.
- Monitor the location of the radiopaque tip frequently under imaging guidance, such as fluoroscopy or echocardiography.
- Deliver a continuous heparinized solution infusion or aspirate periodically. Use best practices for irrigation to minimize the potential for thrombus formation. Aspirate when removing the transseptal device or dilator.
- After removal of the dilator, use standard technique to achieve hemostasis.
- Upon use, please return the device per Innovative Health’s instructions.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

Explanation of Symbols

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight
	Do Not Use if Package is Damaged
	Non-pyrogenic (The RF Wire supplied is non-pyrogenic unless package is opened or damaged)
	Manufacturer

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Please refer to www.innovative-health.com for product warranty.