Instructions for Use
Reprocessed VersaCross Transseptal Sheath

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 Reprocessed VersaCross Transseptal Sheath consists of two components: a reprocessed sheath and a reprocessed dilator.

The Reprocessed VersaCross Transseptal Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The sheath device shaft and dilator shaft in their entirety are coated with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating. The dilator provides support for the sheath, features a tapered tip and a shaft that can be reshaped manually. Radiopaque markers maximize visualization of the sheath and dilator during manipulation.

INDICATIONS FOR USE

The Reprocessed VersaCross Transseptal Sheath is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

- Tactile feedback of reprocessed device may vary during use.
- 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.
- Laboratory staff and patients can undergo significant x-ray exposure during interventional 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 Transseptal Sheath is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Transseptal Sheath.
- The sheath's shaft and dilator shaft are coated with a lubricious coating. The following warnings must be considered:
    - Use of the sheath with introducer sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity.

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  - Excessive wiping and/or wiping with a dry gauze may damage the coating.
  - Manual shaping of the sheath distal curve shall be done with smooth motions along the curve without applying excessive pressure. Excessive manual bending and/or shaping of the device may affect the coating integrity.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port.
- Care should be taken when inserting or removing the dilator and catheters from the sheath.
- Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

PRECAUTIONS

- Do not attempt to use the Reprocessed VersaCross Transseptal Sheath/dilator before thoroughly reading the instructions for use.
- Carefully manipulation must be performed to avoid cardiac damage or tamponade. Sheath, dilator and compatible guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, do not use excessive force to advance or withdraw the device.
- The sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Only physicians or personnel trained in aseptic techniques should perform aseptic presentation.
- The Reprocessed VersaCross Transseptal Sheath is compatible with introducer sheaths 11Fr or larger.
- The Reprocessed VersaCross Transseptal Sheath and Dilator are compatible with 0.035 in (0.89 mm) maximum guidewire outer diameter and transseptal devices or smaller.
- The Reprocessed VersaCross Transseptal Sheath is NOT compatible with transseptal needles such as the “NRG Transseptal Needle”.
- Confirm ancillary devices are compatible with the dilator diameter before use.
- Individual patient anatomy and physician technique may require procedural variations.

ADVERSE REACTIONS

Adverse events that may occur while using the Reprocessed VersaCross Transseptal Sheath include, but are not limited to, the following as there may be other potential adverse events that are unforeseen at this time:

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

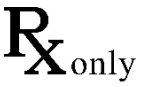
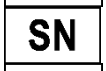
PRIOR TO USE
Prior to use of the Reprocessed VersaCross Transseptal Sheath, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the device.

EQUIPMENT REQUIRED
Intracardiac puncture procedures should be performed in a sterile environment in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, echocardiographic imaging, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the device and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the device is damaged or if the package is compromised, do not use the device. Return the device and packaging to Innovative Health. Do not attempt to resterilize.
- Carefully read all instructions prior to use. Failure to do so may result in complications.
- Carefully read the applicable compatible guidewire instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications.
- Thoroughly flush the sheath, compatible guidewire (not provided), and dilator with heparinized saline solution prior to use.
- Perform a standard vein puncture of the right femoral vein using an access needle (not supplied).
- Introduce the compatible guidewire through the vascular access point and advance to required depth.
- Enlarge the cutaneous puncture site as necessary.
- Note: a compatible access introducer sheath may be used at the venous cutaneous puncture site if desired. Refer to the compatible introducer sheath's Instructions for Use for details and directions.
- Assemble the dilator and sheath until the dilator hub locks into the sheath hub. The sideport of the sheath and curve indicator of the dilator should be in the same orientation.
- The distal curvature of the dilator may be adjusted manually if desired. Do not use excessive force when reshaping.
- Thread the dilator/sheath assembly over the compatible guidewire using a slight twisting motion into the superior vena cava (SVC) under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the dilator/sheath assembly over the guidewire. Determine the cause of resistance before proceeding.
- Use standard technique to position the sheath/dilator assembly into the desired heart chamber.
- If transseptal puncture is required, refer to the Instructions for Use of the transseptal puncture device. Echocardiographic guidance is also recommended.
- Ensure the sheath is clear of air. To aspirate blood, use the sheath side port.
- Monitor the location of the radiopaque tip of the sheath and dilator frequently under fluoroscopy. Echocardiographic guidance is also recommended.
- Deliver a continuous heparinized solution infusion or aspirate periodically. This may help reduce the risk of thromboembolic complications due to thrombus formation, as there may be a possibility of thrombus development at the distal sheath tip or inside the sheath lumen. Also aspirate when removing the transseptal device or dilator.
- After removal of the sheath, use standard technique to achieve hemostasis.
- Upon use, please return the device per Innovative Health's Instructions.

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
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	Non-pyrogenic
	Manufacturer
Max Guidewire O.D.	Maximum guidewire outside diameter that can be used with this device (not provided).

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.