Instructions for Use
Reprocessed TorFlex Transseptal Guiding 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 TorFlex Transseptal Guiding Sheath consists of three components: a Reprocessed sheath, a Reprocessed dilator, and a J-tipped guidewire.

The Reprocessed TorFlex Transseptal Guiding 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 radiopaque tip maximizes visualization of the sheath during manipulation. The dilator provides support for the sheath and has a tapered tip.

The J-tipped guidewire, hereafter referred to as the “guidewire”, is comprised of a stainless steel core with a flexible, spiral shaped PTFE coated steel coil across the full length of this device. The dilator shaft, sheath shaft and guidewire are in their entirety coated with hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for these coatings.

INDICATIONS FOR USE

The Reprocessed TorFlex Transseptal Guiding 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 devices may vary during use.
- 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 Reprocessed TorFlex Transseptal Guiding Sheath is intended for single patient use only. Do not attempt to resterilize and reuse the Reprocessed TorFlex Transseptal Guiding Sheath.
- The dilator shaft and sheath’s shaft are coated with a lubricious coating. The following warnings must be considered:
    - Use of the sheath with introducer sheaths smaller than 11F may result in a tight fit that affects device performance, including coating integrity.
    - Excessive wiping and/or wiping with a dry gauze may damage the coating.

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- The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered:
    - Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity.
    - Excessive manual bending and/or shaping of the device may affect the coating integrity.
- Do not attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.
- 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 TorFlex Transseptal Guiding Sheath before thoroughly reading the accompanying instructions for use.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath, dilator, and 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 or personnel trained in aseptic techniques should perform aseptic presentation.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- The Reprocessed TorFlex Transseptal Guiding Sheath is compatible with introducer sheaths 11Fr or larger.
- Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.
- Only use compatible tip straighteners with the guidewire.
- Do not attempt to insert the proximal end of the guidewire as the distal end.
- Confirm ancillary devices are compatible with the dilator and guidewire diameters before use.
- Individual patient anatomy and physician technique may require procedural variations.
- Do not attempt to use the guidewire with electrocautery tools.
- Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution, or saline.

ADVERSE REACTIONS

Adverse events that may occur during the use of this device, but are not limited to, the following as there may be other adverse events that are unforeseen at this time:

- Allergic Reaction
- Arrhythmias
- Cardiac Arrest
- Cardiac Trauma
- Catheter Entrapment
- Cerebral Vascular Accident
- Death
- Embolism
- Inflammation/Infection
- Myocardial Infarction
- Nerve Injury
- Pacemaker/Defibrillator Lead Displacement
- Pain
- Pericardial Effusion/Tamponade
- Radiation Exposure
- Respiratory Insufficiency/Failure

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- Fistula
- Heart Failure
- Hematoma
- Hemorrhage
- Thrombosis
- Transient Ischemic Attack
- Vasovagal Reaction
- Vessel Trauma

PRIOR TO USE

Prior to use of the Reprocessed TorFlex Transseptal Guiding 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 (recommended), 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.
- Use aseptic technique when opening the package and handling the product in the sterile field.
- Thoroughly flush the sheath, guidewire, 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 guidewire through the vasculature access point and advance to required depth. If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.
- 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.
- Thread the dilator/sheath assembly over the guidewire using a slight twisting motion into the superior vena cava (SVC) under imaging 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 to 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
	Manufacturer
	Non-pyrogenic

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.