Instructions for Use
Reprocessed VersaCross Connect Transseptal Dilator

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 Connect Transseptal Dilator is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The dilator provides torque control and is flexible. The dilator features a tapered tip and a shaft that can be reshaped manually. The echogenic shaft and tip and radiopaque tip maximize visualization of the dilator during manipulation in procedures.

The dilator shaft is coated in its entirety with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating.

INDICATIONS FOR USE

The Reprocessed VersaCross Connect Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

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.
- Manual shaping of the dilator distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping.
- Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub.
- Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths.
- Care should be taken when inserting or removing compatible guidewires from the dilator lumen.
- Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury.

- Careful manipulation of the dilator must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. Do not use excessive force to advance or withdraw the device.

PRECAUTIONS

- Do not attempt to use the Reprocessed VersaCross Connect Transseptal Dilator before thoroughly reading the instructions for use.
- The sterile barrier system, and all devices should be visually inspected prior to use. Do not use if the sterile barrier integrity or devices have been compromised or damaged.
- Careful manipulation must be performed to avoid cardiac damage, tamponade or vessel trauma. Dilator advancement should be performed under imaging guidance, such as fluoroscopy or echocardiography.
- If resistance is encountered, do not use excessive force to advance or withdraw the reprocessed VersaCross Connect Transseptal Dilator.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Dilator advancement should be done under imaging guidance.

ADVERSE REACTIONS

A compatible access introducer sheath may be used if desired. Refer to the compatible introducer sheath's Instructions for Use for details regarding Adverse events.

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.
- Dilator may be used with a compatible sheath or as a standalone device to facilitate access to the left atrium via transseptal puncture.
- Thoroughly flush the dilator with heparinized saline solution prior to use.
- Perform a standard vein puncture of the right femoral vein using an access needle (not supplied).
- Care should be taken when inserting or removing the dilator 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.
- The distal curvature of the dilator may be adjusted manually if desired. Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping.
- The dilator can be inserted fully into the compatible access sheath (if sheath is used) and a manual curve may be added to the dilator or the dilator and sheath assembly prior to insertion into the body.
- 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. 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 dilator tip or inside the dilator lumen. Also aspirate when removing the dilator.
- After removal of the dilator, use standard technique to achieve hemostasis.
- Upon use, please return the device per Innovative Health's Instructions.

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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
	Item Number
	Batch 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

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.