Instructions for Use
Reprocessed Carto Vizigo 8.5F Bi-Directional 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 Carto Vizigo Bi-Directional Guiding Sheath is designed to provide accessibility and maneuverability in the cardiac anatomy. The steerable sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, and fluid infusion. A handle equipped with a rotating collar to deflect the tip clockwise ≤ 180° and counterclockwise ≤ 180°. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to allow fluoroscopic visualization.

The sheath has electrodes on the outer surface to allow interface with compatible Carto 3 EP Navigation Systems. Consult the respective manufacturer for the appropriate interface cables (not provided by Innovative Health with this device). Refer to the appropriate Carto 3 EP Navigation System user manual for details on system settings related to the sheath.

INDICATIONS FOR USE

The Reprocessed Carto Vizigo Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

The sheath curve can be visualized when used with compatible Carto 3 EP Navigation Systems.

CONTRAINDICATIONS

Do not use the device when there are:

- Previous intra-atrial septal patch.
- Known or suspected atrial myxoma.
- Myocardial Infarctions within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA)
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.
- Presence of atrial thrombus.
- Environments with Stereotaxis Systems or Niobe magnets.

WARNINGS

- Do not alter this device in any way.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.

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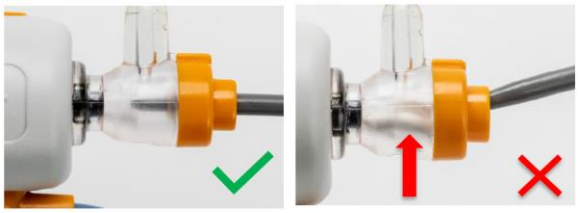
- Do not expose the sheath to organic solvents such as alcohol. Doing so may compromise the structural integrity of the device and/or lead to device failure.
- Do not route pacing to the electrodes of the sheath.
- Each physician must apply the information in these instructions according to professional medical training and experience when using the device for transeptal access.
- Before using the sheath, completely read and understand these Instructions for Use.
- Maintain continuous hemodynamic monitoring throughout the procedure.
- Always observe acceptable hemodynamics prior to advancing the dilator or any other component.
- Always withdraw components and aspirate slowly to minimize the vacuum created during withdrawal.
- From the sideport only, aspirate all air prior to fluid infusion.
- Provide continuous heparinized saline infusion while the sheath remains in the vessel.
- Tactile feedback of reprocessed device may vary during use.

PRECAUTIONS

- **Carefully reading the Instructions before use of this device will help to reduce the potential risks and complications.**
- Do not attempt to insert a catheter having a distal tip or body size larger than 8.5F as indicated on the product label. Doing so may compromise the structural integrity of the sheath or the device being used, and/or lead to the failure of the sheath or device being used.
- The guiding sheath is designed to interlock with the dilator provided. Misuse may result in serious complications.
    - **Always insert a dilator straight into the center of the sheath's valve to prevent damage to the valve. Do not insert a dilator at an angle, as damage to the sheath valve may occur. Please refer to Figure 1:**

a. Correct dilator insertion b. Incorrect dilator insertion

    - Incorrect insertion of the dilator may result in dislodgement of the valve, that can be identified in the clear hub. Please refer to Figure 2:



a. Correct dilator insertion, clear hub b. Incorrect dilator insertion, valve dislodge (arrow) inside clear hub

- Do not attempt to use a guidewire larger than the maximum diameter specified on the package label. Doing so may compromise the structural integrity of the dilator or the guidewire and/or lead to the failure of the sheath or guidewire being used.
- Prior to inserting the device into the patient, pre-assemble the steerable sheath and dilator.
- Use fluoroscopy and/or intracardiac ultrasound to monitor the advancement of the catheter and removal of the catheter and removal of the catheter from the sheath. Move the catheter carefully to avoid cardiac damage, perforation, or tamponade. If resistance is encountered, do not use excessive force to advance or withdraw the catheter through the sheath.

- During insertion, use caution not to create excessive bends which may lead to crimps in this device.
- Use best practices for inserting or retracting any device at the hemostatic valve. Monitor any potential air entrapped and completely aspirate any observed air out of the side port.
- Use best practices for irrigation to minimize the potential for thrombus formation.
- **Do not** remove dilator or catheter rapidly. Damage to the hemostatic valve may occur.
- Indwelling percutaneous sheath should always be supported with a catheter. The sheath is not recommended to dwell in intracardiac space for extended periods without a supporting dilator or cardiac catheter.
- Aspirate slowly, only from the sideport.
- Careful manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement through a guiding sheath should be done using a combination of visual aids available, fluoroscopic guidance and/or intracardiac ultrasound. Intracardiac signals are not recorded from electrodes placed on the sheath. In addition, extra care should be taken while inserting, aspirating, and manipulating the guiding sheath.
- The sheath should not be manipulated in the heart without a device extending from its distal tip.
- Inject or saline flush only from the sideport.
- Certain conditions may require special consideration when using this product. These may be, but are not limited to Enlarged Aortic Root, Small Left Atrium, Marked Right Atrial Enlargement, Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis).
- Store in a cool, dark, dry place. Store away from sunlight.
- Ultrasound images may have visual noise in certain viewing angles when aimed to the sheath.

ADVERSE REACTIONS

The following adverse reactions may occur during the use of this device, but are not limited to:

- Air embolism
- Infection
- Intimal tear
- Hematoma
- Perforation
- Thrombus formation
- Bleeding

Please consult the respective manufacturer’s labeling for adverse events associated with the use of other devices.

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.
- Remove the device from the package and place it in a sterile work area using aseptic technique.

Procedural Considerations

Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the transseptal technique such as air emboli or perforation of the aorta or left atrium. Only those physicians who are specially trained in transseptal procedures should use this device for transseptal use.

- Fluoroscopy and/or intracardiac ultrasound should be used to confirm positioning throughout the procedure. Transseptal procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures. Maintain monitoring of vital signs throughout the procedure.
- Inspect all components before use.
- Use only with compatible transseptal needle. Refer to the original manufacturer for a list of compatible transseptal needles. (Not provided by Innovative Health)
- Prior to inserting the device into the patient, pre-assemble sheath, dilator, and stylet on the table. Advance the needle through the dilator to check for excessive resistance as the tip of the needle advances through the curvature of the sheath/dilator assembly.
- Before inserting the sheath into the patient, flush the sheath and dilator with heparinized normal saline to remove air bubbles and any potential particulate. After the sheath is in the left atrium of the patient, maintain a constant flow of heparinized normal saline to the sheath to minimize the risk of air emboli.
- Flush and maintain continuous saline.
- Connect the sheath to the Carto navigation system with the appropriate interface cables. Use only Biosense Webster interface cables.
- During insertion over the guidewire, use caution not to create excessive bends in this device. This may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly.
- During insertion, always use the stylet to facilitate needle passage through the dilator/sheath assembly. (Failure to use the stylet for transseptal needle may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly or skiving of material from the inner surface of the dilator).
- To minimize the potential for creating a vacuum in the sheath, remove components and make catheter exchanges slowly.
- Once the sheath is inserted into the vasculature and the dilator is removed, aspirate until steady blood return is achieved prior to flushing or infusion.
- All fluid infusion should be through the sideport.
- In order to minimize the risk of air embolism provide a continuous infusion of heparinized saline solution once the sheath is inserted into the patient.
- Slowly remove or insert the dilator or other devices.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine the cause and correct before continuing with this procedure.

- Following completion of the procedure, proper precautions should be taken prior to and during removal of the sheath, including but not limited to careful monitoring of clotting time and baseline vital signs. Apply clinical guidelines to minimize the risk of bleeding from the puncture site following removal of the sheath.
- Upon use, please return the device per Innovative Health's Instructions

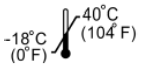
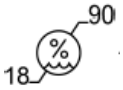
Suggested Transseptal Procedure: Remove from packaging and inspect all components before use

1. Flush all components before use.
2. Prepare and assemble equipment and ensure compatibility of all devices.
3. Connect the sheath to the Carto 3 EP Navigational system using appropriate cables.
4. Insert guidewire.
5. Advance sheath/dilator assembly into superior vena cava and pull back into the right atrium.
6. Drag assembly along septal wall and engage fossa ovalis.
7. Remove guidewire and insert transseptal needle as indicated above.
8. Puncture the fossa ovalis with the transseptal needle.
9. Advance sheath/dilator assembly over transseptal needle.
10. Advance the sheath over fixed dilator and needle into left atrium.
11. Remove the dilator and needle from the sheath.
12. Insert a sensor based catheter to create a Carto 3 EP Navigational system visualization matrix (fast anatomical map optional) in the chamber; this will allow for visualization of the sheath curve. Refer to the Carto 3 EP Navigational system user guide.

Note: TRANSSEPTAL NEEDLE IS NOT SUPPLIED BY INNOVATIVE HEALTH WITH THIS DEVICE.

Note: Typical variations may occur within these steps, depending on available capabilities and operator preference. Please refer to the Original Manufacturer's Instructions for Use for additional information regarding transseptal procedures.

EXPLANATION OF SYMBOLS

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	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
	Temperature limit
	Humidity limitation

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.