Instructions for Use
Reprocessed Agilis NxT Steerable Introducer

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 Agilis NxT Steerable Introducer consists of a dilator, guidewire, and bi-directional steerable introducer, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and exchange. A sideport with a three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The device has a small, medium, or large curl at the distal tip. The introducer handle is equipped with a rotating collar to deflect the tip clockwise ≥ 180° and counterclockwise ≥ 90°. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

INDICATIONS FOR USE
The Reprocessed Agilis NxT Steerable Introducer is indicated for the introduction of various cardiovascular catheters into the heart, including the left side of the heart, during the treatment of cardiac arrhythmias.

Patient Target Group
The Reprocessed Agilis NxT Steerable Introducer is for patients requiring placement of catheters in the cardiac anatomy, including transseptal access, who have a vascular anatomy compatible with introducers that have an outer diameter of 12F.

Clinical Benefit
The intended clinical benefit of the Reprocessed Agilis NxT Steerable Introducer is to facilitate introduction of various cardiovascular devices into the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS
- Previous intra-atrial septal patch.
- Known or suspected atrial myxoma or intracardiac thrombus.
- Presence of any condition that precludes appropriate vascular access.
  Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.
- Patients with an active systemic infection.

WARNINGS
- Do not alter this device in any way.
- Tactile feedback of reprocessed device may vary during use.

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- The Reprocessed Agilis NxT Steerable Introducer is for use by clinicians who are specially trained in percutaneous and transseptal access as well as EP procedures. This device must be used by board-certified electrophysiologists, or EP fellows in training, in a fully equipped and operational EP laboratory. Always aspirate, withdraw components, and exchange catheters slowly to minimize the risk of air emboli.
- Aspirate all air before fluid infusion from the sideport.
  In order to minimize embolic risk, either provide a continuous infusion of heparinized solution or periodically aspirate and flush through the sideport while the introducer is positioned in the vasculature.
- Fibrin may accumulate in or on the introducer tip during the procedure. To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter.
- Before removing the steerable introducer, reinsert the guidewire through the introducer, reintroduce the dilator over the guidewire, straighten the steerable introducer, then remove the dilator, guidewire, and introducer as a unit.
- Read the IFU carefully before using this device to help reduce the potential risks and complications associated with the transseptal technique, such as air emboli and perforation of the aorta and left atrium.
- Aspirate and saline flush the introducer frequently to minimize the potential for thrombus formation.
- Do not use the introducer without a catheter or dilator supporting the lumen. Use of the introducer directly over a wire without a catheter or dilator supporting the lumen may result in complications that can cause death.
- For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant X-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the X-ray beam intensity and duration of the fluoroscopic imaging. Consider the use of this introducer in pregnant women.
- Persons with known history of allergies to any of the materials listed below may suffer an allergic reaction to this device. Before use, counsel the patient on the materials contained in the device and discuss a thorough history of allergies. Per the OM, the device contains:
  - Polyether block amide (Pebax®)
  - Polyetrafluoroethylene
  - ABS
  - Silicone rubber
  - DOW Corning® 360 Medical Fluid
  - HDPE
  - MDX/hexane solution
  - Nylon

PRECAUTIONS

- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- Inspect all components before use. Do not use the device of the package or items in the kit appear to be damaged or defective.
- The French size specified represents the inner diameter of the introducer sheath.
- Do not attempt to insert a catheter having a distal tip or body size larger than the introducer size indicated.
- The Reprocessed Agilis NxT Steerable Introducer is designed to interlock with the dilator provided. Misuse may result in serious complications.
- Do not attempt to use a guidewire larger than the maximum diameter specified on the package label.
- Before inserting the device into the patient, pre-assemble the steerable introducer and the dilator.

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- During insertion, do not create excessive bends in the device. This may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/introducer assembly.
- Do not remove dilator or catheter rapidly. Damage to the hemostasis valve may occur.
- Do not deflect the device beyond 180° before insertion of a catheter.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine and correct the cause before continuing with this procedure.
- Do not torque or rotate the handle if the distal tip/shaft is constrained.
- If the shaft is unable to rotate freely, only manipulate the introducer via the articulation knob.
- Only aspirate (slowly) from the sideport.
- Only inject or saline flush from the sideport.
- Conditions requiring consideration when using this product may be, but are not limited to, Small Left Atrium, Marked Right Atrial Enlargement, and Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis).
- If pericardial or aortic entry occurs, do not advance the dilator over the needle. If the needle has penetrated the pericardium or aorta, it must be withdrawn. Monitor vital signs closely.
- There is a risk of air infiltration when withdrawing objects from the hemostasis valve of the introducer. To prevent vacuum buildup in the introducer, withdraw objects slowly. Monitor the introducer fluoroscopically for the presence of air during device insertion.
- Only use this device with equipment that complies with international safety standards.
- Advance the introducer under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade. Compatible navigation and real time visualization systems may also be considered.
- Before advancing the dilator or any other component, verify that the hemodynamics are acceptable. Monitor the hemodynamics throughout the procedure.
- Only use a curved needle with a stylet, such as the BRK Transseptal Needle.
- During insertion, check for excessive resistance as the tip of the needle advances through the curvature of the introducer/dilator assembly. If there is any resistance to needle advancement, retract the needle and inspect the components.
- During insertion, always use the stylet to facilitate needle passage through the dilator/introducer assembly. Failure to use the stylet may inhibit advancement of the needle and result in inadvertent puncture of the dilator/introducer assembly or skiving of material from the inner surface of the dilator.
- After the introducer is inserted into the vasculature and the dilator is removed, aspirate until steady blood return is observed before flushing or infusion.
- Do not manipulate the introducer in the heart without a device extending from its distal tip.
- During preparation and assembly of equipment, close the introducer stopcock immediately after flushing the dilator and introducer to prevent air from being introduced into the system.
- To prevent cardiovascular injury, ensure the needle and stylet remain inside the dilator until ready to puncture the atrial septum.
- To remove any air from the needle, remove the stylet from the needle, flush the needle with heparinized saline, and reinsert the stylet.
- During equipment assembly and introducer advancement, insert the dilator fully into the introducer to prevent an air embolism.
- Upon guidewire removal, aspirate air and confirm backflow of blood before flushing with heparinized saline.
- Identify anatomic landmarks correctly to avoid cardiac injury. Individual patient anatomy and physician technique may require procedural variations.
- Prevent any movement of the assembly parts relative to each other. It is critical to maintain previous orientation of the pointer flange while dragging the assembly.

- Confirm the correct location of the needle on the fossa ovalis and then advance the needle carefully.
- Do not attempt to recross the septum without using the needle when access is lost. Only withdraw the needle and introducer/dilator after confirming insertion in the left atrium.
- Introducer materials are incompatible with magnetic resonance imaging (MRI).
- Upon use, please return the device per Innovative Health's Instructions.
- Store in a cool, dark, dry place.

ADVERSE REACTIONS

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

- Arrythmia
- Major Bleeding requiring surgery or transfusion
- Hematoma
- Anemia
- Cardiac Tamponade
- Pericardial Effusion
- Hemopericardium
- Pneumopericardium
- Atrial/Ventricular trauma
- Great vessel perforation
- Valvular damage
- Asymptomatic cerebral emboli (ACE)
- Stroke/cerebrovascular accident
- Transient ischemic attack (TIA)
- Coronary artery injury
- Air embolism
- Foreign body embolism
- Pulmonary embolism
- Thromboembolism
- Thrombosis/Thrombus
- Vasovagal reaction
- Anaphylaxis
- Endocarditis
- Pneumonia
- Sepsis/shock
- Esophageal injury
- Pleural effusion
- Groin pain
- Pericarditis
- Arteriovenous fistula
- Dissection
- Pseudoaneurysm
- Femoral aneurysm
- Superficial tissue injury.

Please consult the respective manufacturer's labeling for adverse events associated with the use of either cardiovascular catheters or endomyocardial biopsy devices.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the packaging before opening. The contents of the package are sterile unless the package is opened or damaged. 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. **Attention: To avoid potential damage to the device, during removal of the device from the packaging, ensure that the tabs on the tray covering the hemostasis tubing are all fully unfastened before removing.**
- Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device and packaging to Innovative Health if it is not in acceptable condition for the procedure.
- Maintain monitoring of vital signs throughout the procedure.
- Inspect all components before use.
- Prior to inserting the device into the patient, pre-assemble sheath and dilator, 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.
- To minimize the potential for creating a vacuum in the sheath, remove components and make catheter exchanges slowly.
- Indwelling Intracardiac introducer sheaths should always be supported with a catheter or an obturator.

Suggested Transseptal Procedure

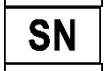
There are eight (8) major steps in the transseptal technique:

1. Prepare and assemble equipment.
2. Advance introducer/dilator assembly into superior vena cava.
3. Position transseptal needle and stylet assembly inside introducer/dilator assembly.
4. Engage fossa ovalis.
5. Puncture the fossa ovalis with the BRK needle.
6. Advance introducer/dilator assembly.
7. Advance introducer over fixed dilator and needle into left atrium.
8. Withdraw the needle and dilator.

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

	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

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.