



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 steerable sheath, dilator, and guidewire 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/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The handle is equipped with a rotating collar to deflect the tip clockwise $\geq 180^\circ$ and counterclockwise $\geq 90^\circ$. 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 when introducing various cardiovascular catheters 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.
- 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.

WARNINGS

- Do not alter this device in any way.
- The user of the device should have adequate training and a thorough understanding of the use and applications of the steerable introducer.
- Maintain continuous hemodynamic monitoring throughout the procedure.
- Always observe acceptable hemodynamics prior to advancing the dilator or any other component.
- Always withdraw components/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 introducer remains in the vessel.

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- Fibrin may accumulate in or on the sheath tip during the procedure. To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter.
- Prior to 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.
- Maximum in-vivo time: 7 hours

PRECAUTIONS

- **Carefully reading the Instructions before use of this device will help to reduce the potential risks and complications associated with the transseptal technique such as air emboli and/or perforation of the aorta and left atrium.**
- 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 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.
- Prior to inserting the device into the patient, pre-assemble the steerable introducer and dilator.
- During insertion, use caution not to create excessive bends in this device.
- Frequently aspirate and heparinized saline flush the sheath to minimize the potential for thrombus formation.
- Do not remove dilator or catheter rapidly. Damage to the backbleed valve may occur.
- Do not deflect the device beyond 180° prior to insertion of a 8mm tip electrode catheter.
- If resistance is met when advancing or withdrawing guidewire or introducer, determine cause and correct before continuing with this procedure.
- Indwelling percutaneous introducer sheaths should always be supported with a catheter.
- Aspirate slowly, only from the sideport.
- 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.

ADVERSE REACTIONS

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

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

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

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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 transeptal technique such as air emboli or perforation of the aorta or left atrium. Fluoroscopy should be used to confirm positioning throughout the procedure.

Lab capabilities should include, but are not limited to:

- Intracardiac pressure monitoring capabilities;
 - Systemic pressure monitoring;
 - Contrast media injection, and management of untoward reactions to contrast media;
 - Pericardiocentesis;
 - Surgical backup;
 - Anticoagulation therapy and monitoring
- Maintain monitoring of vital signs throughout the procedure.
 - Inspect all components before use.
 - Use only a BRK™ type curved needle with stylet (**not supplied by Innovative Health**).
 - 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.
 - During insertion, 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 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.
 - Thrombus may accumulate in or on the sheath tip during the procedure. Aspirate when removing dilator or catheter.
 - In order to minimize embolic risk, either provide a continuous infusion of heparinized solution or periodically aspirate and flush through the sideport while the sheath is positioned in the vasculature.
 - Do not remove dilator or catheter rapidly. Damage to the valve may occur, potentially compromising hemostasis.
 - If resistance is met when advancing or withdrawing guidewire or introducer, determine the cause and correct before continuing with this procedure.

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- Indwelling Intracardiac introducer sheaths should always be supported with a catheter or an obturator.
- Do not manipulate the sheath in the heart without a device extending from its distal tip.

Suggested Transseptal Procedure

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

1. Prepare and assemble equipment.
2. Advance sheath/dilator assembly into superior vena cava.
3. Position BRK needle inside assembly.
4. Drag assembly and engage fossa ovalis.
5. Puncture the fossa ovalis with the BRK needle.
6. Advance sheath/dilator assembly over fixed needle.
7. Advance the sheath over fixed dilator and needle into left atrium.
8. Remove the dilator and needle from the sheath.

Note: TRANSSEPTAL NEEDLE IS NOT SUPPLIED BY INNOVATIVE HEALTH.

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.

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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



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

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.

SJM, Agilis and BRK are trademarks of or licensed to St. Jude Medical or one of its subsidiaries.

Please refer to www.innovative-health.com for product warranty.