

Reprocessed by



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## Sustainability Solutions

### Instructions for Use Reprocessed AGILIS NxT™ Steerable Introducer

#### • STERILE

#### Explanation of Symbols

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	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Date of Processing
	Use by Date
	Catalogue Number
	Do Not Reuse
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight

### Reprocessed Agilis NxT™ Steerable Introducer Description

The reprocessed Agilis NxT™ steerable introducer set consists of a dilator, guidewire, and steerable sheath, which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is filtered 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. A handle equipped with a rotating collar to deflect the tip clockwise  $\geq 180$  degrees and counterclockwise  $\geq 90$  degrees. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

BRK™ Transseptal Needles are used to create a puncture in the interatrial septum to allow the passing of an introducer and/or catheter through the septum from the right side of the heart to access the left side. They are available in a variety of sizes and curves and are designed to be used with our line of fixed and steerable guiding introducers for transseptal access.

**Note: TRANSSEPTAL NEEDLE NOT SUPPLIED BY STRYKER SUSTAINABILITY SOLUTIONS.** Please refer to Original Manufacturer Instructions for Use for additional information on transseptal procedures.

### Indications for Use

The Reprocessed Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

### Contraindications for Use

- Previous intra-atrial septal patch
- Known or suspected atrial myxoma
- Myocardial Infarctions with 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

- This device shall not be altered in any way.
- Introducer should be used by physicians properly trained in transseptal procedures and [St. Jude Medical \(SJM\)](#) catheter delivery systems.
- Contents are sterilized using Ethylene Oxide Gas. Do not use if sterile barrier is damaged. If damage or defects are found call your Stryker Sustainability Solutions representative. Do not attempt to resterilize.
- During the entire procedure, maintain continuous hemodynamic monitoring.
- Prior to advancing the dilator or any other component, always observe acceptable hemodynamics.
- To minimize the vacuum created during withdrawal, always aspirate slowly/withdraw components.
- Prior to fluid infusion, aspirate all air from the sideport only.
- While the introducer remains in the vessel, provide continuous heparinized saline infusion.
- During procedure, fibrin may accumulate on or in the sheath tip. Aspirate when removing catheter or dilator to prevent dislodgement of potential thrombus.
- 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.
- In-vivo time: 7 hours maximum.

### Precautions

- To reduce complications and potential risks associated with the transseptal technique, such as perforation of the aorta and left atrium and/or air emboli, carefully read the instructions before using this device.
- All components shall be carefully inspected before use. If the package or items appear to be damaged or defective, do not use.
- The inner diameter of the introducer sheath is represented by the French size specified.
- Do not attempt to insert a catheter having a body size or distal tip larger than the indicated introducer size.
- The Agilis NxT™ steerable introducer is designed to interlock only with SJM dilators. Misuse may result in serious complications.
- Do not attempt to use guidewire larger than the specified maximum diameter.

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- Pre-assemble the steerable introducer and dilator before inserting the device into the patient.
- Use caution while inserting the device to avoid excessive bends.
- To minimize the potential for thrombus formation, saline flush and aspirate the sheath frequently.
- Do not remove catheter or dilator rapidly as damage to the backbleed valve may occur.
- Do not deflect the device beyond 180° prior to insertion of a 8 mm 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/intracardiac introducer sheaths should always be supported with a catheter or an obturator.
- Aspirate slowly, only from the sideport.
- Inject or saline flush only from the sideport.
- When using this product, special consideration(s) may be required for certain conditions. Such as, but not limited to Marked Right Atrial Enlargement Small Left Atrium, Enlarged Aortic Root, Marked Distortion of the Thorax Configuration (i.e. Kkyphosis or Scoliosis).
- Maintain monitoring of vital signs throughout the procedure.
- 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 manipulate the sheath in the heart without a device extending from its distal tip.
- Once the sheath is inserted into the vasculature and dilator is removed, aspirate until steady blood return is achieved prior to flushing or infusion.

### 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

### Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
3. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the Agilis NxT Steerable Introducer if the sterility has been compromised. If the package is damaged or if it was opened and the introducer not used, return the introducer and the package to Stryker Sustainability Solutions.
4. Do not attempt to resterilize. Stryker Sustainability Solutions will not accept introducers for reprocessing that have been reprocessed and sterilized by other facilities.
5. Remove the Agilis NxT Steerable Introducer from the package and place it in a sterile work area using aseptic technique. **Attention: Tray may have sharp edges after opening. Close tray before disposal.**
6. Inspect the Agilis NxT Steerable Introducer for overall condition and physical integrity. Do not use the Agilis NxT Steerable Introducer if any damage is noted. Return the introducer and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for the procedure.
7. Follow a suitable surgery protocol.
8. Agilis NxT Steerable Introducer is intended for use during single patient procedure.
9. The Agilis NxT Steerable Introducer can be used for transseptal procedures. There are eight 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 sheath over fixed dilator and needle into left atrium.
  8. Remove the dilator and needle from the sheath.

**Note:** Typical variations may occur within these steps depending on available capabilities and operator preference.

**Note:** Please refer to Original Manufacturer Instructions for Use for additional information on transseptal procedures.

### Storage and Handling

- Store in a cool dry place

### Warranty

#### Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

**STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.**

#### Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

#### General Warranty Terms Applicable to All Products

**TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.**

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

**Sterilization:** This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

**Warning:** This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Agilis NxT™ and BRK™ are registered trademarks of St. Jude Medical, Inc.

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