

Reprocessed by



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## Sustainability Solutions

### Instructions for Use Reprocessed Ultrasound Catheters

#### Reprocessed Device for Single Use

- **STERILE**


#### Explanation of Symbols

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**ROnly** Federal Law in the USA restricts this device to sale by or on the order of a physician

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 Sterilized by Ethylene Oxide Gas


 Date of Reprocessing


 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

 Non-Pyrogenic

# Reprocessed Ultrasound Catheters

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## Catheter Description

Ultrasound Catheters are specially designed catheters that provide two-dimensional imaging using an ultrasound transducer. The ultrasound transducer is at the distal tip of the catheter and can be positioned for ultrasound imaging by a steering mechanism that rotates the catheter tip and variable deflection. Ultrasound Catheters incorporate a handpiece, a flexible shaft and a distal tip section containing an ultrasound transducer. The Ultrasound Catheter is 10 French with a 90 cm insertion length or 8 French with 110 cm insertion length.

## Indications for Use

Reprocessed Ultrasound Catheters are indicated for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Note: The original manufacturer indications for use includes usage for pediatric population. The Stryker Sustainability Solutions indications for use does not specifically include usage for pediatric population but also does not contraindicate for pediatric population usage. The use of the device should be based on clinical judgment.

## Contraindications for Use

Reprocessed Ultrasound Catheters are contraindicated for:

- Presence of conditions that create unacceptable risk during cardiac catheterization.
- Inadequate vascular access.
- Sepsis
- Major coagulation abnormalities
- Presence of any right-heart intracardiac thrombus
- Deep vein thrombosis
- Significant peripheral vascular disease
- Use in coronary vessels
- Insertion into the arterial system
- Fetal use

## Warnings

- Ultrasound catheters should be used only by or under the supervision of an appropriately trained physician using proper procedures and techniques.
- Do not exert excessive pressure during placement of catheter if unknown resistance is encountered.
- Vascular damage, including perforation, is a small but inherent risk.
- Carefully manipulate the catheter in order to avoid cardiac damage, perforation or tamponade.
- If encountering strong resistance during catheter articulation, discontinue the procedure and determine the cause of the resistance before proceeding.

## Precautions

- Do not attempt to use the Reprocessed Ultrasound Catheter prior to completely reading and understanding the *Directions for Use*.
- Inspect the packaging and catheter for damage or defects prior to use.
- Avoid excessive kinking or bending of catheter, as this may interfere with distal tip shaping.
- Ensure that the two articulation knobs are in the neutral position and the brake is released before advancing or withdrawing the ultrasound catheter.
- For proper care and handling of the ultrasound catheter, always hold the ultrasound catheter by the handle and support the catheter shaft. Avoid touching the ultrasound catheter interconnect tab.

## Adverse Reactions

The following are known potential adverse reactions:

- Pulmonary embolism
- Stroke
- Death
- Thrombosis
- AV fistula
- Air embolism
- Pneumothorax
- Valve or structural cardiac damage
- Myocardial infarction
- Tamponade
- Femoral artery or vein injury
- Pseudoaneurysm
- Cardiac perforation
- Hemothorax

## Reprocessed Ultrasound Catheters

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### Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Turn the ultrasound system on. Verify incoming main voltage is 120 V AC.
3. Inspect the catheter and package before opening. The contents of the package are sterile unless the package is opened or damaged. If the package is damaged or if it was opened and the catheter not used, do not use the catheter. Return the catheter and packaging to Stryker Sustainability Solutions for resterilization by ethylene oxide (EtO) gas.
4. Do not attempt to resterilize.
5. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
6. Inspect the catheter for overall condition and physical integrity. Do not use the catheter if any damage is noted. If such problems exist, return the catheter and packaging to Stryker Sustainability Solutions.
7. Rotate the steering control knobs. The function should be smooth and the catheter tip should flex in a corresponding direction up to 160°. The tension control knob is completely released by rotating fully counter clockwise.
8. Position the control knobs in the neutral position by aligning the marks on the knobs to the marks on the housing.
9. Slip the sterile sheath over the interconnect tab until it is fully seated on to the handle.
10. Lift the lever on the connector, slipping it onto the catheter interconnect tab until fully mated with the steering handle. Push the lever down, locking it into place.
11. Carefully slip the sterile sheath over the catheter connector, covering a sufficient length so that it is out of the sterile field.
12. Connect the other end of the catheter connector to the ultrasound system. Ensure that the imaging screen appears.
13. Create a vascular access with a catheter introducer sheath (hemostatic) large enough to accommodate the catheter with heparinized saline.
14. Advance the catheter into the vasculature through the catheter introducer sheath. Fluoroscopy may aid in advancing the catheter into the heart.
15. Once inside the heart, use the steering knobs to direct the ultrasound transducer to visualize the desired cardiac anatomy.
16. Prior to device withdrawal, release the tension control knob and return the steering knobs to the neutral position.
17. Remove the catheter at the end of the evaluation.

### Compatibility

- Ultrasound catheters are connected to standard ultrasound equipment using appropriate connectors.

### Storage and Handling

- Store Reprocessed Ultrasound Catheters in a cool, dry place.
- Air freight only in pressurized cargo.
- Relative humidity: Up to 90% non-condensing.
- Temperature: Maximum 50°C (122°F), Minimum 10°C (14°F)

## Reprocessed Ultrasound Catheters

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### 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.

## Reprocessed Ultrasound Catheters

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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.