Reprocessed by

stryker®

Sustainability Solutions

# Instructions for Use
# Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled

## Reprocessed Device for Single Use

℞ Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

### Explanation of Symbols

| | |
|---|---|
| STERILE EO | Sterilized using ethylene oxide |
| | Date of reprocessing |
| | Use-by date |
| REF | Catalog number |
| LOT | Lot number |
| SN | Serial number |
| | Consult instructions for use |


Keep dry


Keep away from sunlight


Do not re-use

Do not resterilize


Do not use if package is damaged


Non-pyrogenic


Temperature limit


Humidity limitation

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### Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ Description

Reprocessed Advisor™ FL Circular Mapping Catheters, Sensor Enabled™ are steerable, flexible, insulated electrophysiology catheters constructed of thermoplastic elastomer material and noble metal electrodes. For the bi-directional catheters, the shaft curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The distal loop is oriented counter-clockwise as viewed from the handle. See label for outer diameter and specific loop configuration.

### Indications for Use

The Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is a sensor-enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart.
The catheter is used with the EnSite Precision™ System to combine and display magnetic processed patient positioning and navigation mapping information.

The catheter is not compatible with the MediGuide System, as it has not been tested for compatibility.

### Contraindications for Use

- The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach.
- This device should not be used via retrograde approach.
- This device is not recommended for use in the ventricles.
- The device is not intended for transcatheter ablation.
- This device should not be used with patients with active systemic infections.

### Warnings

- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of transvenous electrophysiology studies.
- 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, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must therefore be given for the use of this catheter in pregnant women.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid thromboembolism, cardiac damage, perforation, or tamponade. The induction of atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF) can be risks associated with electrical stimulation.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.

### Caution
- United States law restricts this device to sale by or on order of a physician.
- Read directions prior to use.

### Precautions
- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- Use care to isolate any unused connector pins of the electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
- Always straighten the catheter before insertion or withdrawal.
- Catheter advancement must be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade. Compatible navigation and visualization systems may be used in conjunction with fluoroscopy.
- Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve.
- Handling of the device may be different from the OEM device due to reprocessing.

### Directions for Use
1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ if the sterility has been compromised. If the package is damaged or if it was opened and the catheter is not used, return catheter and the package to Stryker.
3. Do not attempt to resterilize. Stryker will not accept Reprocessed Advisor™ FL Circular Mapping Catheters, Sensor Enabled™ for reprocessing that have been reprocessed and sterilized by other facilities.
4. Remove the catheter from the package and place it in a sterile work area using aseptic technique.
5. Inspect the catheter for overall condition and physical integrity. Do not use the catheter if any damage is noted. Return the catheter and packaging to Stryker if it is not in acceptable condition for the procedure.
6. The catheter is intended for use during single patient procedure.
7. Remove the catheter from its packaging.
   - Completely remove the tray from the pouch.
   - Remove the handle retainer from the tray before removing the catheter. See Figure 1 in the Packaging and Shelf-Life section.
   - To prevent potential damage to the loop, lift the catheter up and out of the tray.
8. Inspect the electrodes and catheter carefully for integrity and overall condition.
9. Insert the distal tip section of catheter into an 8F minimum introducer (not included) using the loop straightener:
   - Prior to insertion, deflect catheter shaft to straight position.
   - Slide the loop straightener over the distal loop section of catheter.
   - Insert the loop straightener with the catheter distal end into and through the hemostasis valve of the introducer (not included).
   - Insert catheter through the hemostasis valve.
   - After the catheter is inside the introducer, pull the loop straightener out from the hemostasis valve.
10. Never manipulate the loop or deflectable section of the shaft while within the introducer.
11. Connect to compatible systems using the appropriate cable. Refer to the cable's instructions for use.

12. If the loop is not perpendicular to the shaft when extended from the sheath, completely retract the loop into the sheath and re-extend catheter.
13. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy. Compatible navigation and visualization systems may be used in conjunction with fluoroscopy.
14. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction.
    NOTE: The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.
15. Prior to withdrawal, deflect catheter shaft to straight position. Re-insert the loop straightener into the hemostasis valve prior to removing the catheter from the introducer.
16. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

**Connection to Other Equipment**

The catheter may be connected to a commercially available EP recording system and navigation and visualization system using the connection cable. All systems must be patient isolated. For instructions regarding the use of these systems with the catheter, refer to the system's instructions for use.

**Packaging and Shelf-Life**

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. The expiration date is marked on the outside of the package. The product should be stored in a cool, dry location. To remove the catheter from its tray, remove the handle retainer from the tray then lift the catheter up and out of the tray. See Figure 1.

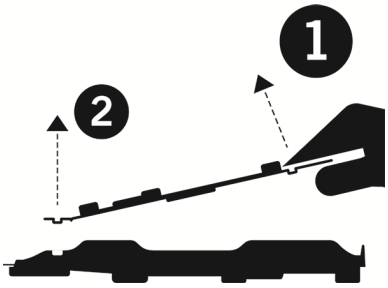


**Figure 1**

**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.

**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.

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.



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