Reprocessed by

Instructions for Use
Reprocessed IBI Diagnostic Electrophysiology Catheters

Reprocessed Device for Single Use

• STERILE

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

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 Diagnostic Electrophysiology Catheters

Catheter Description
Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a handpiece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tips of deflectable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

Specific to the Inquiry™ Optima™, Optima™ Plus steerable electrophysiology catheters:
The catheter incorporates both a deflectable shaft steering mechanism and a distal end with a variable loop diameter, which allows selection of diameters within a specific range. The distal shaft may be deflected by pushing and pulling the thumb control and the distal loop diameter may be expanded or contracted by turning the rotating knob.

Specific to the AFocus™ steerable and the Inquiry™ fixed curve and steerable electrophysiology catheters:
The catheters are flexible and insulated catheters constructed of noble metal electrodes and thermoplastic elastomer material. The control mechanism located in the handle at the proximal end of the catheter manipulates the tip of the steerable catheters. The distal tip on the AFocus™ catheter has been designed to expedite the collection of electrogram recordings of a circumferential area.

Indications for Use
Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation and electrophysiological mapping of cardiac structures. The reprocessed IBI AFocus™ Steerable and the Inquiry™ Optima™ catheters are to be used to map the atrial regions of the heart. The reprocessed Inquiry™ fixed curve and steerable catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.

Contraindications for Use
Reprocessed diagnostic electrophysiology catheters may be contraindicated for:
- Transseptal approach in certain patients (e.g., patients with left atrial thrombus or myxoma and patients with intra-atrial baffle or patch).
- Transcatheter ablation.
- Retrograde transaortic approach in certain patients (e.g., patients with aortic valve replacement).
- The Inquiry™ Optima™, Optima™ Plus, AFocus™ steerable electrophysiology catheters are contraindicated for use in patients with prosthetic valves.
- The Inquiry™ Optima™, Inquiry™ Optima™ Plus steerable electrophysiology catheter are not suggested for use in the heart ventricles.
- Use in patients with current or frequent systemic infection.
- Use in coronary vasculature other than the coronary sinus ostium.
- Patients with acute conditions (including electrolyte abnormality, acute ischemia and drug toxicity) that could make the findings of the electrophysiological study unrepresentative of the patient’s usual state.
- Patients with an underlying cardiac disease (i.e. acute myocardial infarction, unstable angina and hemodynamic instability) that would make induced arrhythmias extremely difficult to terminate and therefore could present a high risk of death.

Warnings
- EP 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 perforation is an inherent risk of any electrode placement. Do not force the catheter through the vessel.
- Do not autoclave catheter.
- Do not use for electrical ablation.
- If electrocardiogram equipment is used for placement of the catheter, the equipment must be front-end isolated or have an isolated patient cable. Current leakage from the electrocardiogram monitor must not exceed 10 microamps.
- Removing the handle by cutting the catheter, will not completely relax the distal tip

Precautions
- Do not attempt to use the reprocessed EP catheter prior to completely reading and understanding the Directions for Use.
Reprocessed Diagnostic Electrophysiology Catheters

- Do not alter this device.
- Inspect the packaging and catheter for damage or defects prior to use.
- Avoid excessive torque, stretching, kinking and/or bending of catheter, as this may interfere with distal tip shaping or cause damage to internal electrode wires.
- Avoid manual pre-bending of distal curve, as this may damage steering mechanism of steerable catheters. Handle catheter with care to avoid improper electrical functioning.
- Standard electrical grounding precautions should be observed when using electrical recording or stimulation equipment.
- Avoid excessive contact of handpiece with fluids, as this could adversely affect the electrical performance of the catheter.

Adverse Reactions
Potential adverse reactions include, but are not limited to, cardiovascular and anesthesia-related complications.

Directions

1. Prior to use, inspect the package. Do not use if the package is damaged or open.
2. Remove the device from its package. Inspect the electrodes and catheter carefully for integrity, continuity of leads and overall condition.
3. Use a standard percutaneous catheter introducer to insert IBI catheter.
   a. To insert the distal tip section of the Optima™, Optima™ Plus catheter into the introducer using the protective sheath:
      Note: Pull the thumb control downward completely and turn the rotating knob counter clockwise fully.
      i. Slide the protective sheath over the distal loop section of the catheter.
      ii. Insert the protective sheath with the catheter distal end into and through the hemostasis valve of the introducer (not included).
      iii. Insert catheter through the hemostasis valve.
      iv. Pull the protective sheath out from the hemostasis valve once the catheter is inside the introducer. Prior to removing the catheter from the introducer, re-insert the protective sheath into the hemostasis valve.
   b. For the AFocus™, make sure to fully pull the thumb control downward before insertion. Carefully advance the distal tip section of the AFocus™ catheter into a sheath equivalent to No. 8F.
4. The catheter should be passed from a peripheral vessel to the desired intracardiac position with the aid of fluoroscopy.
5. The catheters have a built-in cable connector or a cable adapter that must be used with the appropriate interface cable. Refer to the cable instructions for details.
6. Connect the appropriate interface cable to the catheter to record intracardiac electrograms.
7. Observe the polarity of the proximal end connector pins of the interface cable when connecting to an EP recording system or an ECG amplifier.
8. To reduce the chances of developing accidental current pathways to the heart, carefully isolate any unused connector pins.
9. To manipulate the distal end or tip:
   a. For steerable versions of the Inquiry™ and the AFocus™ Catheter: push or pull the thumb control located at the distal end of the handle to manipulate the tip portion of the catheter.
   b. For Bi-directional Catheters: Push the thumb control to deflect the distal section in one direction and pull the thumb control to deflect in the opposite direction.
   c. For Inquiry™ Optima™ Plus Steerable Diagnostic Catheter: adjust the distal loop diameter of the catheter, by turning the rotating knob clockwise. To deflect the distal shaft of the catheter, push the thumb control located on the handle.
10. When manipulating the tip of the catheter, always use fluoroscopy.
11. Before removing the catheter from the patient, always straighten the catheter tip.
   a. To remove the Inquiry™ Optima™ diagnostic catheter through the introducer sheath make sure to turn the rotating knob counter clockwise fully and pull the thumb control downward completely to make the loop larger and to straighten shaft of the catheter before removal from introducer.
   b. For the AFocus™ make sure to completely pull the control downward before removing the catheter.
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.

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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.
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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