Instructions for Use
Reprocessed Inquiry™ AFocus™ & Inquiry™ AFocus™ II
Steerable Diagnostic Electrophysiology Catheter

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 Inquiry AFocus diagnostic electrophysiology (EP) catheters are steerable flexible insulated catheters constructed of thermoplastic elastomer material and noble metal electrodes. The Inquiry AFocus catheter is offered in two configurations. The Inquiry AFocus configuration includes an adjustable loop. The Inquiry AFocus II includes a deflectable shaft.

INDICATIONS FOR USE

The Reprocessed Inquiry AFocus and AFocus II catheters are used for recording intracardiac signals and cardiac simulation during diagnostic electrophysiologic studies. The Inquiry AFocus catheters are for use in mapping atrial regions of the heart.

CONTRAINDICATIONS FOR USE

- The device 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 intended for use in the ventricles.
- This device is not intended for transcatheter ablation.

WARNINGS

- The device(s) should be used by 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.
- Vascular perforation is an inherent risk of any electrode placement. Do not force the catheter through the vessel.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Removing the handle, by cutting the catheter, will not completely relax the distal tip section.
- Tactile feedback of reprocessed devices may vary during use.

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PRECAUTIONS

- Personnel handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode catheter integrity, do not wipe catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter.
- Standard grounding procedures should be followed if electrosurgical instruments are used.

ADVERSE REACTIONS

None listed.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter and packaging to Innovative Health. **Do not attempt to resterilize**.
- Using proper sterile technique, remove the catheter from its package and place it in a sterile work area.
- Inspect the electrodes and catheter carefully for integrity and overall condition. Do not use the catheter if damage is observed. Return any damaged catheter to Innovative Health.
- Insert the distal tip section of the catheter into the introducer (not provided) using the protective sheath.
- **Note:** Make sure to pull the thumb control downward completely before insertion.
- Slide the protective sheath over the distal loop section of catheter.
- If upon extension from sheath the loop is not perpendicular to shaft, completely retract loop into sheath and re-extend catheter.
- Insert the protective sheath 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 protective sheath out from the hemostasis valve. Re-insert the protective sheath into the hemostasis valve prior to removing the catheter from the introducer.
- The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy and heparinized saline.
- To manipulate the distal end of the catheter, push or pull the thumb control located on the handle. Pushing the thumb control on the Inquiry AFocus catheter will reduce the loop size, while pulling the thumb control restores the loop to its full size. Pushing the thumb control on the Inquiry AFocus II catheter deflects the catheter shaft, while pulling the thumb control straightens the catheter shaft.
- Always use fluoroscopy when manipulating the tip of the catheter.
- To record intracardiac electrograms connect the appropriate cable to the Inquiry AFocus catheter. Refer to the cable instructions for details.
- Observe the polarity of the proximal end connector pins of the patient cable when connecting to an EP monitoring system.
- Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart.
- Always make sure to pull the thumb control downward completely before removing the catheter from the patient.

CONNECTION TO OTHER EQUIPMENT

This device may be connected to a commercially available EP recording system using a connection cable with Redel connector in the pin configuration corresponding to this catheter. EP recording system must be “patient isolated,” or have an isolated patient cable.

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Explanation of Symbols

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight
	Do Not Use if Package is Damaged
	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.

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