



Instructions for Use Reprocessed Inquiry™ Optima™ & Inquiry™ Optima™ Plus 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 Optima and Inquiry Optima Plus steerable diagnostic electrophysiology (EP) catheter incorporates both a distal end with a variable loop diameter, which allows selection of diameters within a specific range, and a deflectable shaft steering mechanism. The diameter of the distal loop may be contracted or expanded by turning the rotating knob. The distal shaft may be deflected by pushing and pulling the thumb control.

INDICATIONS FOR USE

The Reprocessed Inquiry Optima and Inquiry Optima Plus Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac simulation during diagnostic electrophysiologic studies. The Inquiry Optima catheters are to be used to map the 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.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Personnel handling the electrophysiology catheter should wear gloves.

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- 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.




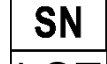









DIRECTIONS

- 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 the catheter to Innovative Health.
- Insert the distal tip section of the Optima, Optima Plus catheter into the introducer using the protective sheath (tip straightener) provided.
- The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy and heparinized saline.
- The catheter has a cable adapter and must be used with the appropriate cable. Refer to the Original Manufacturer cable instructions for details.
- To record intracardiac electrograms, connect a patient cable to the Optima, Optima Plus catheter.
- 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.
- To adjust the distal loop diameter of the catheter, turn the rotating knob clockwise. To deflect the distal shaft of the catheter, push the thumb control located on the handle.
- Always use fluoroscopy when manipulating the tip of the catheter.
- To remove through the introducer sheath make sure to turn the rotating knob counter clockwise fully and pull thumb control downward completely to make the loop larger and to straighten shaft of catheter before removal from introducer.

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.

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
	Catalog Number
	Serial Number
	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 gas (EO). 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.

Inquiry and Optima are trademarks of St. Jude Medical.

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