Instructions for Use
Reprocessed Inquiry™ Steerable
Diagnostic Electrophysiology (EP) 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 H-Curve Steerable Diagnostic Electrophysiology Catheters are flexible, insulated catheters constructed of thermoplastic elastomer material and noble metal electrodes. The tip of the steerable catheters may be manipulated with the control mechanism located in the handle of the proximal end of the catheter.

INDICATIONS FOR USE

The Reprocessed Inquiry H-Curve Steerable Diagnostic Electrophysiology Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiological studies. The catheters are to be used to map the atrial regions of the heart.

CONTRAINDICATIONS FOR USE

- Patients with prosthetic valves, and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via transseptal approach..
- Via the retrograde transaortic approach in patients with aortic valve replacement.
- Cardioversion.
- Patients with an active systemic infection as this may increase the risk for cardiac infection.

WARNINGS

- The device(s) should be used by board-certified electrophysiologists, or EP fellows in training, in a fully-equipped operational electrophysiology laboratory.
- 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 and pregnant women.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade.
- Do not force the catheter through the vessel.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Catheter advancement should be performed under fluoroscopic guidance to minimize the risk of cardiac damage, perforation, or tamponade. Compatible navigation and real time visualization systems may also be considered.
- Tactile feedback of reprocessed devices may vary during use.

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PRECAUTIONS

- Personal handling the electrophysiology catheter should wear gloves.
- To maintain optimal patient safety and electrode integrity, do not wipe this catheter with alcohol.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual prebending of the distal curve can damage the steering mechanism and may cause patient injury.
- Standard grounding procedures should be followed if electrosurgical instruments are used.
- 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).

ADVERSE REACTIONS

Risks associated with electrical stimulation may include, but are not limited to, the induction of arrythmias, such as atrial fibrillation (AF), bradycardia, ventricular tachycardia (VT), ventricular fibrillation (VF), and the need for cardioversion.

The risks associated with using diagnostic electrophysiology catheters include:

- Hemorrhage/Bleeding
- Hematoma
- Ecchymosis
- Superficial tissue injury
- Cardiac perforation
- Cardiac arrest
- Cardiac tamponade
- Pericardial effusion
- Cardiovascular injury
- Valvular damage
- Great vessel perforation
- Cerebrovascular injury
- Asymptomatic cerebral emboli
- Stroke/cerebrovascular accident
- Transient ischemic attack
- Death
- Electric shock
- Embolism
- Air embolism
- Foreign body embolism
- Pulmonary embolism
- Thromboembolism
- Immunological reaction
- Anesthesia reaction
- Infections
- Anaphylaxis
- Pericarditis
- Endocarditis
- Pneumonia
- Sepsis
- Myocardial ischemia
- Myocardial infarction
- Transient ST elevation
- Angina
- Coronary artery spasm
- Peripheral vascular injury due to vascular access
- Pseudoaneurysm
- Arteriovenous fistula
- Vascular dissection
- Thrombosis/thrombus
- Hypotension
- Radiation injury
- Dislodgement of implantable cardioverter defibrillator or permanent pacing leads
- Pain, groin

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Patient should be connected to an ECG recording system prior to commencing the procedure in order to permit arrhythmia monitoring.
- 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 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, continuity of leads and overall condition.

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- Insert the catheter by using a standard percutaneous catheter introducer with a diameter equal to or greater than its labeled French size.
- The catheter should be passed from a peripheral vessel to the desired intracardiac position with the aid of fluoroscopy.
- The catheter has a built-in cable connector that must be used with the appropriate interface cable for electrogram recording. Refer to the cable instructions for details.
- To record intracardiac electrograms, connect the appropriate interface cable to the catheter.
- Observe the polarity of the proximal end of the connector pins of the interface cable when connecting to an EP recording system.
- Use care to isolate any unused connecter pins. This will reduce the chances of developing accidental current pathways to the heart.

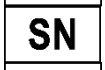
For steerable versions of the Inquiry Catheters

- To manipulate the tip portion of the catheter, push or pull the thumb control located at the distal end of the handle.
- Always use fluoroscopy when manipulating the tip of the catheter.
- Always straighten the catheter tip 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. The use of cables with shrouded pins is recommended and is required in some countries such as the United States. Such equipment 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
	Manufacturer
	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.

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

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