Instructions for Use
Reprocessed Livewire™ 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 Livewire Steerable Diagnostic Electrophysiology Catheter is a flexible electrode catheter constructed of a polyurethane insulation/shaft and incorporates platinum electrodes. The active tip may be manipulated by remote means located at the proximal end of the catheter.

INDICATIONS FOR USE
The Reprocessed Livewire Steerable Diagnostic Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

CONTRAINDICATIONS FOR USE
- This device is contraindicated for use as an ablation catheter.
- Electrophysiology studies are contraindicated when acute factors make the findings unrepresentative of the patient's usual state (i.e. electrolyte abnormality, acute ischemia, and drug toxicity).
- When the patient's underlying cardiac disease makes it likely that induced arrhythmias will be extremely difficult to terminate and carry a high risk of death (i.e. myocardial infarction, unstable angina, hemodynamic instability).

WARNINGS
- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- Misuse of this catheter and accessories may result in serious complications.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of atrial fibrillation, ventricular tachycardia (VT) requiring cardioversion, and VF can be risks associated with electrical stimulation.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheter advancement should be done under fluoroscopic guidance.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS
- Do not attempt to use the reprocessed EP catheter prior to completely reading and understanding the *Directions for use.*
- Do not alter this device.
- Inspect the packaging and catheter for damage or defects prior to use.
- Not recommended for long term pacing.
- Unipolar resistance should not exceed 50 ohms.

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- Use of this device should only extend to those physicians who are skilled in the techniques of transvenous intercardiac studies and temporary pacing.
- Vascular and/or cardiac perforation may occur during use. If resistance is observed, DO NOT FORCE CATHETER. Withdraw catheter, correct difficulty, and reinsert.
- Observe polarity.
- Use patient isolated equipment.
- This device should only be used with equipment that complies with international safety standards.
- Proper electrical functioning of this device requires that you handle the Livewire™ Steerable Electrophysiology Catheter with care. Stretching and/or kinking while wiping may result in damage.
- These instructions are general in nature. The physician may wish to deter from these instructions in light of personal clinical experience.
- Become thoroughly familiar with the operation of the proximally located tip deflection control handle.
- For specific details in the use of electrophysiology catheters and the techniques employed in an electrophysiology study, the physician should be referred to the medical literature and rely on training and practical experience.
- Use only sterile saline or water to wipe the catheter.
- Store in a cool, dark, dry place.

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 package is damaged or if it was opened and the catheter not used, do not use the catheter. Return the catheter and packaging to Innovative Health. Do not attempt to resterilize.
- Remove the catheter from the package and place it in a sterile work are using aseptic technique.
- Use a SJM Fast -Cath™ Introducer to insert the Livewire Steerable Electrophysiology Catheter.
- Always use fluoroscopy when positioning the electrode catheter.
- To record intracardiac electrograms, connect patient cable to catheter. Observe polarity of proximal end connector pins of patient cable when connecting to an ECG amplifier.
- To use this device for temporary pacing, connect patient cable to catheter. Observe polarity of proximal end connector pins of patient cable when connecting to an external pulse generator or pacing systems analyzer.
- Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart.
- To manipulate the tip portion of this catheter, rotate the actuator control located in the handle at the proximal end of the catheter.
- Always use fluoroscopy when manipulating tip of catheter.
- Always straighten catheter tip before removing catheter from patient.

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
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	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 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 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.

Livewire is a trademark of St. Jude Medical, Inc.

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