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 patients with an active systemic infection as this may increase the risk for cardiac infection.
- The catheter is contraindicated for patients with prosthetic valves and patients with left atrial thrombus or myxoma, or interatrial baffle or patch via the transseptal approach.
- The catheters is contraindicated for the retrograde trans-aortic approach in patients who had aortic valve replacement.
- Presence of any condition that precludes appropriate vascular access.

WARNINGS
- This device should be used only by board-certified electrophysiologist or under the supervision of physicians thoroughly trained in the techniques of cardiac catheterization and electrophysiology studies in a fully equipped and operational cardiac catheterization facility.
- Misuse of this catheter and accessories may result in serious complications.
- Adverse effects of using nonsterile components may include, but are not limited to:
    - Local and/or systemic infection
    - Mechanical damage
    - Inaccurate functionality
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade.
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures. If resistance is encountered, do not force catheter. To unentangle the catheter, straighten the catheter shaft gently to avoid detachment from the handle; then rotate the handle clockwise.
- Individual patient anatomy and physician technique may require procedural variations.
- For both patients and laboratory staff, cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for

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somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging.
- During use of the catheter in the left side of the heart, therapeutic anticoagulation needs to be achieved. Anticoagulation treatment should adhere to the ESC/AHA/ACC or any other consensus guidelines to avoid thromboembolism.
- 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. Inspect the catheter for any damage, kink, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter is damaged, kinked, or does not hold its curve. Do not use if the package is open or damaged.
- Not recommended for long term pacing. This device should not be used for life sustaining pacing.
- Observe labeling of the proximal and distal ends. If the connectors are forcefully connected, the pins in the connector can be bent or broken and the cable is no longer useable.
- Connected equipment must be patient isolated.
- This device should only be used with equipment that complies with international safety standards.
- Before using the catheter, check proper handle assembly setting, deflection functionality, and visually inspect and evaluate the performance of the actuator control knobs. The catheter should also deflect or return when handle is actuated. Do not use if the catheter does not perform each of these test functions as described.
- 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.
- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- For catheters equipped with a cable connector, use with the appropriate Abbott cable.
- Prior to use, inspect the catheter carefully for tip integrity, continuity of leads and overall catheter condition. Ensure there are no kinks. After the procedure, inspect the catheter carefully for any damage which may have occurred during use.
- Always straighten the catheter before insertion or withdrawal. Do not deflect shaft while distal tip portion is in vascular introducer.
- Use correct sized catheter for the introducer. The physician should consider anatomical size restrictions if considering use of the Reprocessed Livewire Steerable EP Catheter.
- Slowly remove the catheter to prevent hemostasis valve leak.
- Use care to isolate any unused connector pins. This will reduce the chances of developing accidental current pathways to the heart.
- Proper electrical functioning of this device requires that you handle the Livewire Steerable Electrophysiology Catheter with care. Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can result in inadequate shaft performance and damage the steering mechanism. .
- Unipolar resistance should not exceed 50 ohms.
- Use of this device should only extend to those physicians who are skilled in the techniques of transvenous intercardiac studies and temporary pacing.

- Do not use excessive force to advance or withdraw the catheter. Using excessive force can result in patient injury or death. Ensure that the two steering knobs are in the neutral position and the tension control knob is released before advancing or withdrawing the catheter. If you encounter strong resistance during catheter articulation, discontinue the procedure. Identify and address the cause of the resistance before resuming the procedure. Withdraw and redirect the catheter as needed.
- Observe polarity.
- 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.

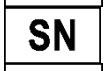
ADVERSE REACTIONS

Potential Adverse Event Category	Potential Adverse Event Subcategory
Bleeding	Hemorrhage/bleeding Hematoma
Superficial tissue injury	N/A
Cardiac perforation	Cardiac tamponade Pericardial effusion
Cardiovascular injury	Valvular damage Great vessel perforation
Cerebrovascular injury	Asymptomatic cerebral emboli Stroke/cerebrovascular accident Transient ischemic attack
Electric shock	N/A
Embolism	Air embolism Foreign body embolism Pulmonary embolism Thromboembolism Thrombosis/thrombus
Immunological reaction (allergic reaction, hyper-sensitivity or toxic reaction to anesthesia, device material, a drug reaction to anticoagulant)	Anaphylaxis
Infection	Pericarditis Endocarditis Sepsis
Myocardial ischemia	Myocardial infarction Transient ST elevation Angina Coronary artery spasm
Organ injury	Organ perforation
Peripheral vascular injury due to vascular access	Pneumothorax
Hypotension	Pseudoaneurysm Arteriovenous fistula Vascular dissection
Radiation injury	N/A
Dislodgement of implantable cardioverter defibrillator or permanent pacing leads	N/A
Heart failure decompensation	N/A
Peripheral nerve injury	N/A

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 area using aseptic technique.
- Use a SJM Fast -Cath™ Introducer to insert the Livewire Steerable Electrophysiology Catheter.
- Always use a navigation system, fluoroscopy, or intracardiac echocardiography (ICE) when positioning the electrode catheter.
- To record intracardiac electrograms, connect the patient cable to the catheter. Observe the polarity of the proximal end connector pins of the patient cable when connecting to an ECG amplifier.
- To use this device for temporary pacing, connect the patient cable to the catheter. Observe the polarity of the proximal end of the connector pins of the patient cable when connecting to an external pulse generator or pacing systems analyzer.
- 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 a navigation system, fluoroscopy, or intracardiac echocardiology (ICE) when manipulating the tip of the catheter.
- Always straighten the catheter tip before removing 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
	Manufacturer
	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.