Instructions for Use
Reprocessed Supreme 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 Supreme Diagnostic Electrophysiology Catheters are manufactured in various fixed curves and electrode spacing for electrophysiological mapping for the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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

CONTRAINDICATIONS
- Electrophysiology (EP) 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 technique of angiography electrophysiology and intracardiac recording and stimulation.
- Misuse of this catheter and accessories may result in serious complications.
- The risks of using electrophysiology catheters include those risks related to cardiac catheterization, such as thromboembolism, cardiac 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.
- 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 device with care. Stretching and/or kinking while wiping may result in damage.

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- 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.
- Individual patient anatomy and physician technique may require procedural variations.
- 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 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.
- Remove the catheter from the package and place it in a sterile work area using aseptic technique.
- Most electrophysiology catheters are placed via the femoral vein. Venous access by the Seldinger technique is often used.
- Place electrophysiology catheter.
- Record electrograms.
  Note: Use anticoagulant as training and experience may dictate.

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
	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 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.