Instructions for Use
Reprocessed Orbiter™ ST 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 Orbiter ST Steerable Diagnostic Electrophysiology (EP) Catheter is a radiopaque, flexible, insulated catheter with a polymer shaft and a 2mm distal tip. The catheter handle has a slider mechanism which, when moved forward or back from the neutral position, results in curvature of the distal tip.

INDICATIONS FOR USE
The Reprocessed Orbiter ST Steerable Diagnostic EP Catheter is intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

CONTRAINDICATIONS FOR USE
- The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

WARNINGS
- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.
- 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.*
- Inspect the packaging and catheter for damage or defects prior to use.
- Use only sterile saline or water to wipe the catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate cable.
- Excessive bending, torqueing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.

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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 to Innovative Health. **Do not attempt to resterilize**.
- Remove the catheter from its package using appropriate sterile technique and place it in a sterile work area.
- Inspect the electrodes and catheter for integrity, continuity of leads and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health.
- Insert the catheter by using a standard percutaneous catheter introducer.
- The catheter should be passed from a peripheral vessel to the desired intracardiac position under fluoroscopic guidance.
- The catheter tip can be deflected by advancing or retracting the slider mechanism, on the handle from the neutral position. When the slider mechanism is in the neutral position, the tip is approximately straight.

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
STERILIZE	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Type CF Applied Part
45°C (113°F)	Upper Limit of Temperature
	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.