# Instructions for Use
# Reprocessed Viking and Viking Soft Tip 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 Viking and Viking Soft Tip (hereinafter Viking) Diagnostic Electrophysiology Catheters are manufactured in various fixed curves and electrode spacing. The catheter has an insulated polymer shaft with platinum electrodes located along the distal section of the shaft.

## INDICATIONS FOR USE
The Reprocessed Viking Diagnostic Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

## CONTRAINDICATIONS
- 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.
- If using an open lumen catheter remove any guidewire / stylette prior to electrical stimulation.
- Tactile feedback of reprocessed device may vary during use.

## PRECAUTIONS
- Do not attempt to use the reprocessed electrophysiology 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.
- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.
- Use only sterile saline or water to wipe this catheter.
- Store in a cool, dark, dry place.

## ADVERSE REACTIONS
None listed.



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**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. If the catheter is packaged with a curve retainer, remove the retainer.
- Inspect the catheter. If the catheter is damaged, do not use it.
- If using an open-lumen catheter, flush the catheter with a heparinized solution.
- Remove any stylette or guidewire prior to insertion.
- Insert the catheter by using standard percutaneous catheter introducers. The electrode catheter should be maneuvered under fluoroscopic guidance.
- If the catheter ends in a connector, attach the catheter to the appropriate cable. (See the cable instructions for further details.) If the catheter ends in tails, this step is not necessary.
- For stimulation and recording electrograms, connect the lead pins to an amplifier. For temporary pacing, connect the lead pins to an external pulse generator.

**EXPLANATION OF SYMBOLS**

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| 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.**