INFINITI MEDICAL

Advanced Technology for Vets and Pets

INSTRUCTIONS FOR USE

Hydrophilic guide wire

CAUTION: U.S federal law restricts this device to sale by or on the order of a veterinarian.
CAUTION: This product is intended for veterinary use only. It is not for human use.

TARGET SPECIES: Canine/Feline

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE: FAILURE TO FOLLOW SPECIFIC INSTRUCTIONS WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS OR ADVERSE EVENTS. AN ASEPTIC TECHNIQUE IS REQUIRED.

DEVICE DESCRIPTION:
Hydrophilic guide wires are constructed from a medical grade steerable, metallic core wire with a polymer coating utilizing a sophisticated construction process. A hydrophilic coating is applied over the radiopaque polymer jacket. Hydrophilic guide wires are supplied sterile, non-pyrogenic, and are intended for single use only. They are available in .018", .025", .035"and .038" diameters in a wide range of lengths, shaft stiffness, and tip configurations. Refer to the product packaging for size and configuration details.

STORAGE
Store in a dry, dark, cool place.

INTENDED USE
Hydrophilic guide wires are used to facilitate the introduction of intravascular devices during diagnostic and interventional Cardiology and Radiology procedures. This product is intended for use by veterinarians appropriately trained and knowledgeable in endovascular procedures. Hydrophilic guide wires are for veterinary use only.

CONTRAINDICATIONS
Hydrophilic guide wires should not be used through access needles or metal cannulas.
Hydrophilic wires should not be used in conjunction with "pushable" embolization coils.

WARNINGS
Care should be taken when manipulating a guide wire inside a vessel during device placement and removal. Guide wires should be manipulated only under fluoroscopy. If resistance occurs and the cause of resistance cannot be determined, remove the guide wire and device as a unit. Never advance the guide wire against resistance without first determining the reason for the resistance under fluoroscopy. Excessive force against resistance may result in damage to the wire and/or to the vessel.

- Inspect wire for damage prior to use, do not use a wire that has been bent, kinked, or damaged. Use of a damaged wire may result in vessel damage or wire fragment release into the vessel.
- Do not reshape the hydrophilic wire by any means. Attempting to reshape the wire may cause damage to the wire.
- Do not manipulate or withdraw the wire through a metal entry needle or a metal dilator, or use this wire with devices which contain metal parts or metal torque devices. This may result in destruction and /or separation of the outer polyurethane coating requiring retrieval.
- A plastic entry needle is recommended when using this wire for initial placement, or a catheter, introducer sheath or vessel dilator should replace the needle as soon as the guide wire has been inserted into the vessel.
- Never advance the guide wire against resistance without first determining the reason for the resistance under fluoroscopy. If resistance occurs and the cause of resistance cannot be determined, remove the guide wire and device as a unit. Excessive force against resistance may result in damage to the wire and/or to the vessel.
- When manipulating, advancing, exchanging, or withdrawing a catheter over the wire, secure and maintain the guide wire in place under fluoroscopy to avoid unexpected guide wire advancement; otherwise damage to the vessel wall by the wire's tip may occur.
- Hydrophilic guide wires should be used only by a veterinarian who is well trained in manipulation and observation of guide wires under fluoroscopy.
- Veterinarians using hydrophilic guide wires should be familiar with the complications of angiography.

POTENTIAL ADVERSE EVENTS

- Thrombus

Infiniti Medical, LLC
240 Twin Dolphin Dr., Suite B
Redwood City, CA 94065
Tel: (650) 327-5000

- Arterial or venous vessel wall damage
- Hematoma at the puncture site
- Vessel perforation
- Hemorrhage
- Emboli
- Plaque dislodgment Infection
- Vessel spasm
- Vascular thrombosis
- Organ injury
- Death or serious injury related to device use or anesthesia required for the procedure

PRECAUTIONS

- The sterile packaging and device should be inspected before use. If sterility or integrity of the device is suspected to be compromised, it should not be used.
- Do not autoclave or resterilize
- Do not expose the delivery system to organic solvents (e.g. alcohol).
- When using a drug or a device concurrently with the wire, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the hydrophilic guide wire.
- Use care when manipulating this guide wire through a tightened Hemostasis valve.
- At least 5 cm of the wire should protrude from the device hub at all times to prevent the wire from sliding entirely in to the device due to the low sliding friction of this wire.
- Hydrophilic guide wires wire must be flushed with saline prior to use and should be maintained in a hydrated state throughout the procedure.

NOTICE

The material contained in this document does not describe the procedure for using this product and is not intended as a reference document for that procedure.

INSTRUCTIONS FOR USE

1. Before attempting to remove the guide wire from its' dispenser, inject sterile saline solution into the luer lock hub end of the dispenser to fill the dispenser coil. This will completely cover the guide wire surface, activate the hydrophilic coating, and will make the guide wire very lubricious. Failure to hydrate the dispenser prior to guide wire removal may result in damage to the guide wire or make it difficult to remove.
2. After hydrating the guide wire, gently grasp the straightener device and pull from the dispenser. Once the straightener is separated from the dispenser, continue to remove the wire from the hoop.
3. If guide wire is not properly hydrated, it will be difficult to remove from the dispenser. Inject additional saline solution into dispenser and repeat step # 2.
4. Fill intended device with saline solution before and during use to ensure smooth movement of the hydrophilic guide wire within the device.
5. Insert the guide wire into the device and advance to the desired position. If movement of the wire within the device becomes diminished, remove the guide wire and reactivate the hydrophilic coating by wetting its surface with saline.
6. Wipe the guide wire with 4x4 gauze moistened with saline solution to remove excess blood from the guide wire surface. Do not use dry gauze as this may damage the guide wire surface resulting in increased resistance when the wire is reinserted in to the device.
7. Rehydrate the guide wire prior to re-insertion into any device or placement into a patient.
8. Use of alcohol, antiseptic solutions or other solvents must be avoided as this may adversely affect the surface of the guide wire.
9. After cleaning the wire, place into the saline filled hoop, proximal end first. The wire may also be placed in a guide wire basin and completely covered with heparinized saline solution.

Infiniti Medical does not recommend a particular technique for the use of this guide wire. The steps contained in the proceeding instructions are for informational purposes only. Each veterinarian should evaluate the appropriateness according to individual patient condition and his or her training and experience. If the guide wire does not move with ease upon re-insertion, withdraw and completely rehydrate the wire. If upon re-insertion, the wire does not move with ease, exchange for a new hydrophilic guide wire.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. The product is intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred. Hydrophilic guide wires are packaged in a plastic hoop fitted with a luer hub. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire must be flushed with saline prior to use (See instructions for use).

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

LIMITED WARRANTY

Infiniti Medical warrants to Buyer that products supplied by Infiniti Medical that are sold to Buyer will be free from defects in material and workmanship for six (6)

months after delivery to Buyer. Buyer must inspect and notify Infiniti Medical of any such defects within this six (6) month period. Further, notice of a defective product must be given to Infiniti Medical in writing within ten (10) days following the discovery of such defect prior to the expiration of the warranty period in order to recover under the warranty. All returns are subject to the prior authorization of INFINITI, in its discretion.

The warranty does not cover and Infiniti Medical will have no warranty obligation whatsoever with respect to any damage to a product caused by or associated with: (i) usage not in accordance with product instructions or usage for a purpose not indicated on the labeling; (ii) abuse, misuse, neglect, improper maintenance or storage, accident, vandalism, or the negligence of any party other than Infiniti Medical; (iii) external causes, including (but not limited to) natural disasters, acts of God, power failure, cosmetic damage or damage to product packaging; or (iv) use of unauthorized consumables and/or accessories with the product. Infiniti Medical's sole liability under this warranty will be, at Infiniti Medical's sole option, to a) replace; b) repair; or c) refund the purchase price of the defective product(s). This will be Buyer's exclusive remedy for a covered defect. Any oral or written statement concerning the products inconsistent with the limited warranty set forth herein will be of no force or effect.

INFINITI EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS ANY WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE, AND INFINITI MEDICAL DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET BUYER'S REQUIREMENTS.

RETURNS

Buyer must notify Infiniti Medical within seven (7) calendar days of delivery regarding any products delivered to Buyer that were shipped in error, were damaged in shipping, or were in a shipping package that was damaged in shipping and such damage to the shipping package may have affected the quality of the products inside the shipping package.

Any products which Buyer wishes to return due to a) being shipped in error or damaged in shipping or b) a defect subject to the warranty provisions will be subject to receiving a Return Material Authorization (RMA) from Infiniti Medical. All returns are subject to the prior authorization of Infiniti Medical in its discretion. Only items appearing on an approved RMA are acceptable for return. Product returns will only be accepted from the original Buyer. Product returns will not be accepted from any third parties. Unauthorized returns will be destroyed and no credit issued. All authorized returned products must be shipped freight prepaid to the Infiniti Medical location indicated on the RMA, except Infiniti Medical will pay freight costs for product shipped-in-error or damaged in shipping.

LIMITATIONS OF LIABILITY

In no event shall Infiniti Medical be liable to Buyer for any unforeseen, indirect, incidental, special, punitive or consequential damages (including any loss of use, loss of revenue or damage for lost or anticipated profits), or otherwise arising out of or in connection with furnishing of products or service hereunder, or the performance, use of, or inability to use any products or service, or otherwise, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory. Infiniti Medical's total liability for any claim or action, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory shall not exceed the purchase price of the product or products out of which such claim or action arose, or Ten Thousand Dollars ($10,000.00), whichever is less.

Infiniti Medical, LLC
240 Twin Dolphin Dr., Suite B
Redwood City, CA 94065
Tel: (650) 327-5000