

## INSTRUCTIONS FOR USE

### Infiniti Medical Guide Wires

**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 PROCEDURE COMPLICATIONS. AN ASEPTIC TECHNIQUE IS REQUIRED.**

#### DEVICE DESCRIPTION

Infiniti Medical guide wires are fabricated from medical grade stainless steel utilizing a sophisticated construction process and are available with a PTFE coating. Guide wires are supplied sterile and are intended for single use only. Infiniti Medical guide wires are packaged in a plastic hoop, which is fitted with a luer hub. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire be flushed with saline prior to use. Infiniti Medical guide wires are available in the configurations list in the table below.

Wire type	Length	Tip configuration
.035" Rosen	180 cm	1.5 mm J tip
.035 " Bassett	180 cm, 260 cm	15 cm distal floppy straight

#### STORAGE

Store in a dry, dark, cool place.

#### INTENDED USE

Infiniti Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures. This product is intended for use by veterinarians appropriately trained and knowledgeable in interventional radiology or cardiology procedures. Infiniti Medical guide wires are for veterinary use only.

#### CONTRAINDICATIONS

There are no known contraindications.

#### WARNINGS

Angiography should be undertaken only by a veterinarian familiar with proper technique. Pet owners should be advised that anesthesia carries a risk of serious and irreversible injury including death.

#### PRECAUTIONS

- Single use only. Guide wires will collect blood and other foreign material in their lumens; neither autoclaving nor ultrasonic cleaning will completely remove foreign material, therefore guide wires are recommended for one time use.
- Inspect all guide wires prior to use. Do not use any unit if the package is open or damaged or if integrity of the device is suspected to be compromised.
- Employ an aseptic technique during removal from the package and during use.
- All guide wires are secured in the hoop dispenser by the locking J-tip straightener. To avoid damaging the guide wire during removal from the flush hoop, grasp the J-tip straightener near the base and slide it forward approximately 5mm or until the J-tip straightener is no longer attached to the flush hoop adaptor. Holding both the guide wire and J-tip straightener, continue to dispense guide wire from the hoop.
- Do not use excessive force to advance the moveable core while the guide wire is in a vessel. Advancement with excessive force may cause coil penetration and vessel damage.
- Avoid withdrawing PTFE coated guide wires back through a metal needle. The sharp edge of the needle may scrape the coating. It is suggested that a catheter or PTFE vessel dilator replace the needle as soon as the guide wire has reached the appropriate position.
- During advancement of the catheter and guide wire within the aorta, it is recommended that the guide wire be removed at the appropriate level of the aorta.
- Care should be taken when manipulating a catheter during placement and withdrawal to prevent possible intravascular tissue damage. If resistance is felt when removing a guide wire from a catheter, the guide wire and catheter should be removed as a unit to prevent potential damage to the vessel wall.
- A guide wire is a delicate instrument and remains the most fallible instrument used in a percutaneous procedure. Any time that a guide wire is used there is a possibility of thrombus formation/emboli, vessel wall damage, and plaque dislodgement, which could result in myocardial infarction, cardiac arrhythmia, stroke or death. The veterinarian should be familiar with the use of angiography products and the complications of angiography.
- Do not autoclave.

#### POTENTIAL ADVERSE EVENTS

- Thrombus
- 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

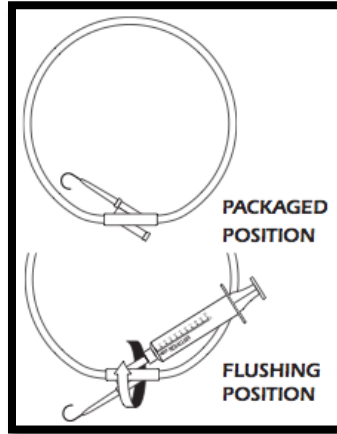
**PRODUCT RECOMMENDATIONS**

Infiniti Medical guide wires are intended to be use with Infiniti Medical Cobra, Berenstein, Reverse Curve and Marker catheters.

**INSTRUCTIONS FOR USE**

**Flush Hoop Instruction Guide:**

1. Attach flush filled syringe to flush port luer
2. Rotate syringe clockwise (as pictured)
3. Inject saline into hoop
4. Detach syringe from hoop
5. Dispense guide wire



In order to reduce the potential of clot formation, it is recommended that the guide wire be flushed with saline prior to use. Attach a filled syringe to the luer hub located at the end of the plastic hoop, flush several times. After flushing, remove guide wire from hoop and use as described above.

The following schematic shows a typical procedure for percutaneous entry utilizing the Seldinger technique. Variations in individual patient anatomy may preclude the utilization of this technique.



**1. Vessel puncture with a two part needle**



**2. When using a two part needle remove stylet leaving cannula in place, insert flexible (distal) end of guide wire through cannula into vessel**



**3. "J" guide wires are shipped with "J" straightener to aid in the insertion of the wire into the puncture needle. Advance the straightener until 2-3 mm of the tip extends from the tip. Insert wire into hub and through needle. Remove "J" straightener proximally and discard.**



**4. Remove needle cannula leaving the guide wire within the lumen of the vessel.**



**5. Pass dilator or catheter over the guide wire directly into vessel.**



**6. Carefully remove the guide wire leaving the catheter in place.**

**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.

**HOW SUPPLIED**

Supplied sterilized by ethylene oxide gas in peel-open packages. Infiniti Medical guide wires are individually packaged with 5 per box. 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.

**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.

All material copyright © 2019 Infiniti Medical. All rights are reserved. No part of any material on this page may be reproduced, or stored in a database or retrieval system, distributed, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of Infiniti Medical.