INFINITI MEDICAL
Advanced Technology for Vets and Pets

INSTRUCTIONS FOR USE
Infiniti Medical® Renal Access Kit

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
The *Infiniti Medical® Renal Access Kit* utilizes an over the wire tear-away sheath for the placement of 2.5 Fr pigtail catheter into the renal pelvis. The kit consists of a .018" double ended gold tip/stainless steel tip nitinol mandrel, 3 Fr x 5cm tear-away introducer, and a 21 G x 15 cm trocar needle. The 2.5 Fr pigtail catheter is packaged separately.

STORAGE
Store in a dry, dark, cool place.

INTENDED USE
The *Infiniti Medical® Renal Access Kit* is intended to introduce up to a 2.5 Fr catheter into the renal pelvis utilizing an image guided percutaneous approach. This product is intended for use by veterinarians appropriately trained and knowledgeable in percutaneous renal interventions. It is for veterinary use only.

CONTRAINDICATIONS
Use of the introducer is contraindicated in patients with known or suspected coagulopathy and in patients with anatomy not suitable for the percutaneous placement of a catheter into the renal pelvis.

WARNINGS
This device is intended to be used by veterinarians trained in interventional procedures. Withdrawal, pull back, or manipulation of the guide wire distal tip through the needle tip may result in breakage or embolization. Do not advance the guide wire if resistance is met. Pet owners should be advised that anesthesia carries a risk of serious and irreversible injury including death.

POTENTIAL ADVERSE EVENTS
Potential complications include risks normally associated with percutaneous interventional procedures. Other complications include, but are not limited to:

- Infection
- Hematoma
- Bleeding
- Renal injury
- Vascular injury
- Inadvertent injury to organs/structures adjacent to the kidney
- Death or serious injury related to device use or anesthesia required for the procedure.

PRECAUTIONS
- Store in a dry, dark, cool place. Inspect all components prior to use. 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**.**
- If resistance is met when advancing or withdrawing the guide wire or the introducer, determine the cause by fluoroscopy and correct before continuing with the procedure.
- Because of the delicate and fragile nature of guidewires, extra care in handling must be taken.
- Do not attempt to use a guide wire or catheter larger than the maximum diameter specified on the package label.
- Individual patient anatomy and veterinarian technique may require procedural variations.

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

- Do not use alcohol, acetone or solutions containing these agents. These solutions may affect the properties of the plastic components resulting in degradation of the device.
- Do not reuse this device.
- Do not withdraw guide wire through metal needles; guide wire may shear or unravel.

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

Use sterile technique

1. Peel open package and place contents on sterile field.
2. Prep skin and drape in area of anticipated needle puncture as desired.
3. Insert 21-gauge introducer needle into the renal pelvis along the least vascular plane with the assistance of ultrasound and or fluoroscopic guidance. Remove inner cannula. The needle position should be verified with imaging and by the ability to aspirate urine. Note that infected urine or urine contaminated with debris may be difficult or impossible to aspirate through the needle.
4. Remove the syringe and insert soft tip of the .018 in. outside diameter guide wire through the introducer needle into the renal pelvis. Advance guide wire to required depth so that the tip is securely in the renal pelvis. Leave an appropriate amount of guide wire exposed. At no time should the guide wire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding.
5. Hold the guide wire in place and remove introducer needle. Do not withdraw the guide wire back into the cannula as this may result in separation of the guide wire. **Caution:** If the guide wire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guide wire.
6. Thread the Peel Away assembly over the guide wire.
7. Advance the Peel Away assembly over the guide wire and into the renal pelvis. Fluoroscopic observation may be advisable.
8. Remove the inner dilator leaving the outer catheter of the Peel Away Sheath and guide wire in place.
9. Thread the drainage catheter over the guide wire and advance the catheter through the Peel Away Sheath until the leading loop is in the renal pelvis.
10. Slowly withdraw and remove the guide wire allowing the pigtail to form in the renal pelvis.
11. Remove the Peel Away sheath by splitting the catheter and removing carefully.
12. Secure the drain in place with suture and attach to drainage bag.

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.

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.

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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.