

## INSTRUCTIONS FOR USE

### Pigtail Locking Loop Multi Purpose Drainage Catheter

**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

**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® Pigtail Locking Loop Multi Purpose Drainage Catheter* with hydrophilic coating is a percutaneous drainage catheter used for the drainage of fluid collections. The catheter is made from a soft, biocompatible plastic, a material that is radiopaque and therefore visible under X-rays. The distal end of catheter contains a pigtail and drainage holes. A suture is used to lock the distal pigtail in place which helps secure the catheter in place and decrease the risk of displacement.

#### STORAGE

Store in a dry, dark, cool place.

#### INTENDED USE

The catheter is designed for percutaneous drainage of abscess fluid, urine (as a nephrostomy or cystostomy tube), and pleural fluid or collections as a chest tube. The operator can use different drainage sets according to the type of accumulated fluid and place of accumulation. These kits are classified according to the catheter size (5F~16F pertaining to various fluid viscosity) and according to the position of the accumulation. The operator can choose to place the catheter with either a single step technique or by using a two-step Seldinger technique in conjunction with a suitable guide wire. This product is intended for use by veterinarians appropriately trained and knowledgeable in percutaneous drainage procedures. The product is for veterinary use only.

#### AVAILABLE SIZES

Diameter	Effective Length
6 Fr	290 mm
8 Fr	290 mm
10 Fr	290 mm
12 Fr	290 mm
14 Fr	390 mm

#### CONTRAINDICATIONS

*Infiniti Medical® Pigtail Locking Loop Catheters* should not be used in patients with un-corrected coagulopathies or in situations where a safe access route for placement cannot be established. It is contraindicated for intravascular use.

#### WARNINGS

- Do not use catheters for feeding tube/gastrostomy procedures. Exposure to gastric juices may damage the catheter.
- Do not allow alcohol or other solvents to come in contact with the catheter. Exposing the catheter to alcohol or solvents may damage the coating and the catheter.
- Pet owners should be advised that anesthesia carries a risk of serious and irreversible injury including death.

#### POTENTIAL COMPLICATIONS

- Catheter occlusion
- Catheter dislodgement
- Hemorrhage
- Sepsis and urinoma/biloma
- Intestinal perforation
- Peritonitis
- Pneumothorax
- Skin infection
- Organ injury
- Vascular injury
- Death or serious injury related to device placement or anesthesia required for the procedure

## PRECAUTIONS

- Only qualified veterinarians who are familiar with the technique should use the product.
- During insertion avoid contact with bone, cartilage and scar tissue, which may damage the catheter tip.
- U.S federal law restricts this device to sale by or on the order of a veterinarian
- This product is intended for veterinary use only. It is not for human use
- This device is intended for single use only.
- If abnormalities are noted discontinue the use immediately and take appropriate action.
- Do not use continuously for more than 30 days.
- Do not expose to organic solvents, ionizing radiation or ultra violet light.
- Use prior to the sterilization expiration date on package label.
- Handle the product carefully and avoid forceful stretching etc.
- Use this product immediately after opening the package. After use, deposit it in a safe manner.
- 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.

## 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.

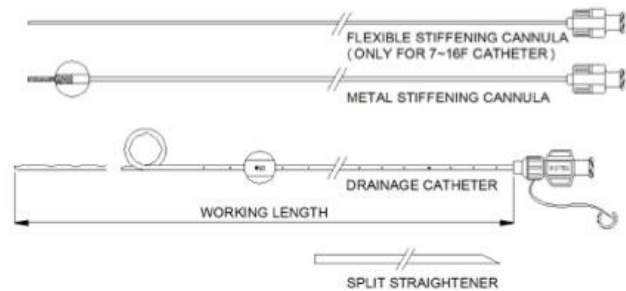
## PRODUCT RECOMMENDATIONS

Use with Infiniti Medical® Rosen wires.

## INSTRUCTIONS FOR USE

### Prior to Use

The *Infiniti Medical Pigtail Locking Loop Multi Purpose Drainage Catheter* is supplied sterile in a sealed pouch. Prior to use, inspect both the sterile seal and device for any damage. If there is a breach to the seal or if the product is damaged, DO NOT USE! Immediately return defective package/product to Infiniti Medical for replacement.



### Recommended Procedure – Using Direct Access Technique

1. Select the patient for suitability of direct access insertion drainage and make sure there is a safe route for inserting the catheter to the desired location.
2. Using the splittable straightener, straighten the whole catheters out (before advance stiffening cannula and trocar). Advance the stiffening cannula and trocar into the catheter, fully straightening distal tip, and lock cannula in place.
  - (1) Hold the thread stretched, if present, while inserting the stiffening cannula and trocar to avoid tangles.
  - (2) Remove the splittable straightener.
3. Disinfect the entrance site and perform skin incision.
4. Insert the prepared catheter into the entrance site and advance it in the direction towards the accumulated fluid under using fluoroscopy, CT or ultrasound guidance.
5. Once you pass the wall of the cavity, you can unlock trocar stylet from the cannula hub and remove it. Aspirate fluid from accumulated fluid, with a syringe, to determine correct catheter placement. If the catheter is located in the target area, fluid should start flowing out from the catheter (Fig.1).
6. After the catheter is positioned, unlock the cannula from the Catheter. (A guide wire may be inserted at this point to aid in placement, if desired)
7. Holding the cannula stationary, advance the catheter to the desired location ensuring that the pigtail is within the cavity (Fig.2).



Fig. 1

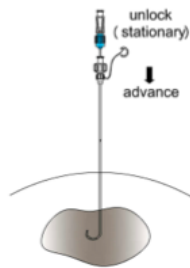


Fig. 2

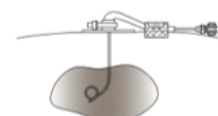


Fig. 3

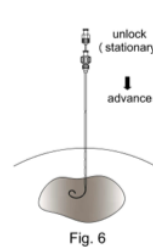
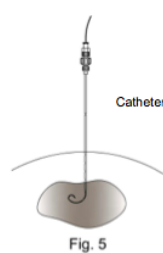
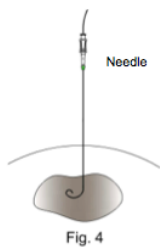
8. To lock the pigtail in its position: (Only for Locking Pigtail)
  - (1) Pull the thread gently.

- (2) Keep thread stretched and attach and **tighten the female/male adapter onto the catheter to activate the valve** in the catheter.
- (3) Wind the thread around the slot and press the clip onto the slot.
9. Connect the catheter to a drainage bag with connecting tube.
10. Check the position of the catheter using fluoroscopy.
11. A flush regimen may be designed for the circumstances of each patient and protocol of the veterinarian.
12. It is essential to fix the catheter securely at the skin so that the entrance site can be easily maintained without disturbing the position of the catheter (Fig. 3).

### Recommended Procedure – Using Seldinger (Guide Wire) Technique

The guide wire method according to Seldinger is suitable for the treatment of deep or poorly accessible localizations.

1. Select the patient for suitability of percutaneous drainage make sure there is a safe route for inserting the catheter to the desired location.
2. Localize the accumulated fluid under CT or ultrasound guidance.
3. Using the splittable straightener, straighten the whole catheters out (before advance stiffening cannula). Advance the stiffening cannula into the catheter, fully straightening distal tip, and lock cannula in place.
  - a. Hold the thread stretched, if present, while inserting the stiffening cannula to avoid tangles.
  - b. Remove the splittable straightener.
4. Disinfect the entrance site and perform local anesthesia.
5. Use a needle to access the intended cavity.
6. Introduce a stiff guide wire (.035" Infiniti Medical® Rosen wire) and coil it in the (Fig.4). Confirm that the wire is in the proper position with ultrasound, CT, or fluoroscopy.
7. Remove the puncture needle back over the guide wire and maintain the wire in the cavity.
8. The puncture site can be gradually expanded with the standard method with the dilators.
9. Advance the catheter, under fluoroscopic control, over the stiff guide wire into the target area. At the point of entry into the cavity, the cannula is unlocked and held stationary, while the catheter is further advanced into the patient over the guide wire. At this time, fluid may start flowing out from the catheter. (Figures 5 and 6)



### Note

1. The catheter must be introduced far enough such that all the side holes of the catheter are located inside the cavity. In order to form the pigtail tip, slowly remove the guide wire while rotating the catheter counter-clockwise. This movement observed with fluoroscopy will cause the catheter to reform the pigtail tip in the cavity.
2. After verifying the proper positioning of the catheter inside the cavity, remove the guide wire and wash/drain off the secretion. The proper positioning of the catheter can be verified after administration of the contrast medium through the catheter itself. The position can be corrected with the repeated introduction of the guide wire or reinforcement cannula.
3. Once the catheter has been placed successfully (all side perforations of the catheter are located inside the cavity), remove the reinforcement cannula from the catheter.
4. To lock the pigtail in its position: (Only for Locking Pigtail)
  - (1) Pull the thread gently.
  - (2) Keep thread stretched and attach and **tighten the female/male adapter onto the catheter to activate the valve** in the catheter.
  - (3) Wind the thread around the slot and press the clip onto the slot.
5. Connect the catheter to a drainage bag with connecting tube.
6. Check the position of the catheter using fluoroscopy.
7. A flush regimen may be designed for the circumstances of each patient and protocol of the physician.
8. It is essential to fix the catheter securely at the skin so that the entrance site can be easily maintained without disturbing the position of the catheter.

### Recommended Exchanging the Catheter Procedure

To replace a catheter in case of clogging:

1. Using the splittable straightener, straighten the whole catheters out (before advance stiffening cannula). Advance the stiffening cannula into the catheter, fully straightening distal tip, and lock cannula in place.
2. Hold the thread stretched while inserting the stiffening cannula to avoid tangles. Remove the splittable straightener.
3. To unlock the pigtail in its position:
  - a. Remove the clip and unwind the suture if any.
  - b. Loosen the female/male adaptor from the standard luer hub at the catheter to deactivate the valve. Check that both threads are loose and cut one thread in order to loosen the pigtail.
4. Insert the 0.035" guide wire through the catheter introduced into the patient to the relevant cavity.
5. Remove the catheter carefully from the puncture drain over the guide wire.
6. Introduce the replacement catheter into the relevant cavity over this guide wire.

7. Once the catheter has been placed successfully (all side holes of the catheter are located inside the cavity), remove the reinforcement cannula from the catheter and then the guide wire.
8. To lock the pigtail in its position: (Only for Locking Pigtail)
  - a. Pull the thread gently.
  - b. Keep thread stretched and attach and **tighten the female/male adaptor onto the catheter to activate the valve** in the catheter.
  - c. Wind the thread around the slot and press the clip onto the slot.
9. Connect the catheter to a drainage bag with connecting tube.
10. Check the position of the catheter using fluoroscopy.
11. A flush regimen may be designed for the circumstances of each patient and protocol of the veterinarian.
12. It is essential to fix the catheter securely at the skin so that the entrance site can be easily maintained without disturbing the position of the catheter

#### **Recommended Removal of Catheter Procedure**

1. Disconnect the drainage bag connecting tube from catheter.
2. To unlock the pigtail in its position: (Only for Locking Pigtail)
  - (1) Remove the clip and unwind the suture if any.
  - (2) Loosen the female/male adaptor from the standard luer hub at the catheter to deactivate the valve.
  - (3) Check that both threads are loose and cut one thread in order to loosen the pigtail.
3. Pull the catheter out gently. If access is to be maintained, a straight floppy tip guide wire passed through the catheter will facilitate removal while maintaining access.

#### **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.

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.

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