

PRODUCT DESCRIPTION

6.5F catheter containing multiple side holes, metal trocar, metal stiffening cannula, suture retention with pull cap and strain relief.

8F, 10F, 12F and 14F catheter containing multiple side holes, metal trocar, metal stiffening cannula, flexible plastic stiffening cannula, suture retention with pull cap and strain relief.

INDICATIONS FOR USE

The catheters are designed for percutaneous drainage of the kidneys.

POTENTIAL ADVERSE EFFECTS

The following adverse reactions have been reported with the use of nephrostomy drainage catheters:

Biocompatibility Reaction
Hemorrhage
Sepsis
Empyema
Skin Infection
Catheter Occlusion
Catheter Dislodgment

WARNINGS

Do NOT use this catheter with alcohol.

Do NOT use this catheter as a delivery system for nutritional supplements.

CAUTION

Federal (USA) law restricts this device to sale by or use under the order of a physician.

This device is sterilized by ethylene oxide. The device is sterile and intended for single patient use. Sterile unless the package is opened or damaged. Do not re-sterilize.

Where long-term use is indicated, it is recommended that indwelling time not exceed 90 days. This catheter should be evaluated by the physician on or before 90 days post-placement.

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US Patent # 7,217,256

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ANGIODYNAMICS®

INCORPORATED

TOTAL ABSCESION®

NEPHROSTOMY DRAINAGE CATHETER

INSTRUCTIONS FOR USE

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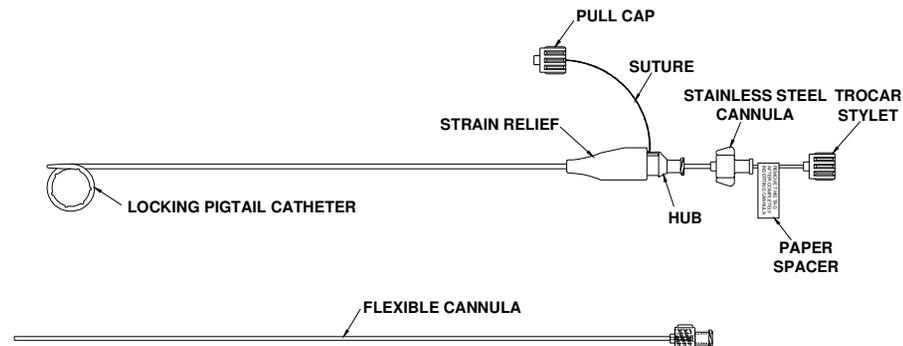
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INSTRUCTIONS FOR USE

Preparation:

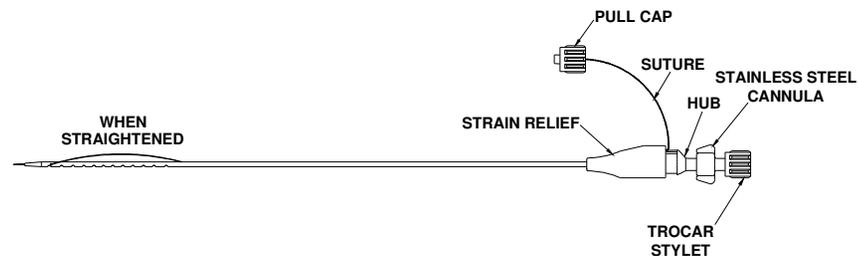
- Remove paper spacer from the trocar stylet. (Fig. 1)

Figure 1 – Drainage Catheter as Furnished



- Advance the stiffening cannula of choice (metal or plastic) into the drainage catheter.
- Engage the luer fittings of the cannula with the catheter hub. (Fig. 2)

Figure 2 – Catheter Assembled for Insertion (shown with stainless steel cannula)



Entry:

For Trocar Entry Technique:

- Advance the trocar inside the metal stiffening cannula.
- Ensure the trocar protrudes past the catheter tip.
- Engage the luer lock fittings.
- Advance the catheter tip into the renal pelvis.
- Remove the trocar.

For Seldinger Entry Technique:

- Optional: A guidewire may be placed through the stiffening cannula to aid in placement of the catheter.
- Advance the catheter tip into the renal pelvis by holding the stiffening cannula while advancing the catheter.

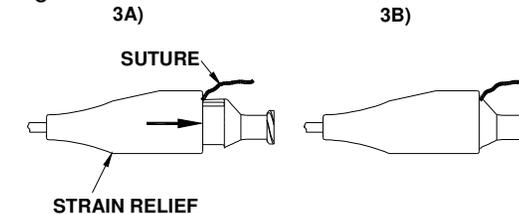
Positioning:

- Under image guidance, form the locking pigtail by slowly removing the guidewire or stiffening cannula and rotating the catheter counterclockwise.
- To tighten the pigtail shape, gently pull the suture until resistance is felt.

Engaging the Lock:

- Move the strain relief and slide to the locked position. (Fig. 3A to 3B) A “click” will be heard when the lock is engaged.

Figures 3A–3B



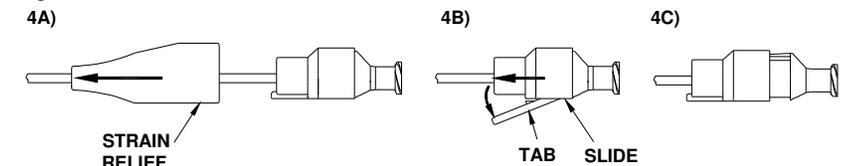
- Remove excess suture material and the pull cap by cutting the suture near the hub.

Removal:

Option 1 – Unlocking the Hub

- Disconnect the drainage bag from the catheter.
- Move the strain relief distally, to expose the slide. (Fig. 4A)
- Lift the tab on the slide (Fig. 4B) and simultaneously move the slide to the unlocked position. (Fig. 4B to 4C)

Figures 4A-4C



- If access is to be maintained, insert the recommended guidewire through the catheter. This may facilitate removal of the catheter while maintaining access.
- Gently withdraw the catheter.

Option 2 – Cutting the Catheter

- Disconnect the drainage bag from the catheter.
- Insert the recommended guidewire past the distal tip of the catheter.
- Carefully cut the catheter just distal to the hub, ensuring that the suture is severed.
- Remove the hub from the guidewire.
- Gently remove the remaining distal portion of the catheter.