

PRODUCT DESCRIPTION

Catheter with multiple side holes, metal stiffening cannula, plastic stiffening cannula, suture retention with pull cap, strain relief, injection cap and needle-less injection port.

INDICATIONS FOR USE

The catheters are intended for percutaneous transhepatic biliary drainage.

POTENTIAL ADVERSE EFFECTS

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

Hemorrhage
Sepsis
Pneumothorax
Skin Infection
Catheter Occlusion
Catheter Dislodgment
Biloma
Bile Peritonitis
Perforation of the bile ducts, liver and/or duodenum

WARNINGS

Do NOT use this catheter with alcohol.

Placing a 10 French or larger catheter as the primary drain before formation of a tract may be difficult in some patients. In these patients, the initial biliary drainage should be started with a smaller (8 French) catheter until a suitable tract allows placement of a larger catheter.

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 ABSCSSION®

BILIARY DRAINAGE CATHETER
With Radiopaque Marker Band

INSTRUCTIONS FOR USE

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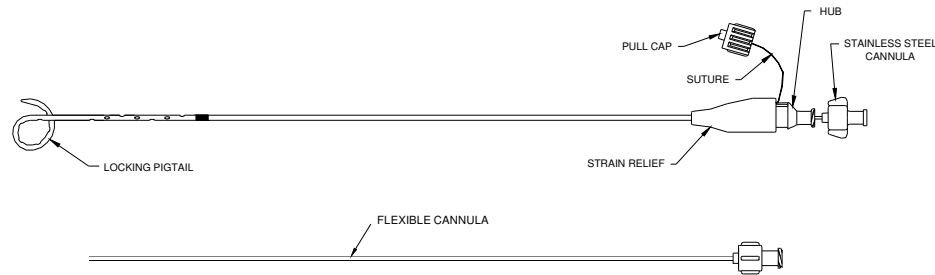
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INSTRUCTIONS FOR USE

Preparation:

- Perform standard radiographic studies.
- Advance a 0.038" guidewire percutaneously through the biliary tree, common bile duct into in the duodenum.
- Dilate the tract with fascial dilators, if necessary.

Figure 1 – Drainage Catheter as Furnished



- Straighten the pigtail.
- 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:

- Advance the catheter over the guidewire and into the biliary tree using fluoroscopic guidance.
- At the entry point to the biliary tree, unlock the stiffening cannula and hold it stationary.
- Advance the catheter into the biliary tree until the distal tip is past the ampulla and directed down stream into the duodenum.
- Remove the stiffening cannula.

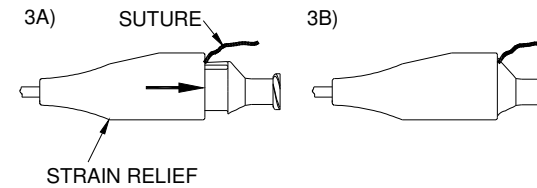
Positioning:

- Under fluoroscopic guidance, form the locking pigtail by slowly removing the guidewire 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 to the locked position. (Fig. 3A to 3B)

Figures 3A–3B



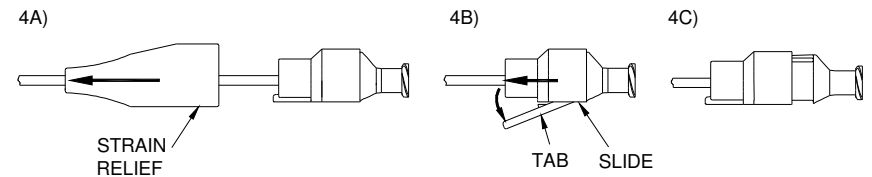
- Remove excess suture material and the pull cap by cutting the suture near the hub.
- Connect the hub of the catheter to the drainage bag for external drainage.
- Attach one of the injection ports to the hub for internal drainage.

Removal:

Option 1 – Unlocking the Hub

- Disconnect the drainage bag from the catheter.
- Move the strain relief distally, to expose the slide. (Fig. 4A)

Figures 4A-4C



- Lift the tab on the slide (Fig. 4B) and simultaneously move the slide to the unlocked position. (Fig. 4B to 4C)
- If access is to be maintained, insert a floppy tipped 0.038" 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 a floppy tipped 0.038" 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

