INDICATIONS:
The ReSolve Biliary Drainage Catheter with locking pigtail and hydrophilic coating is used for drainage of bile within the biliary system.

CONTRAINDICATIONS:
The ReSolve Biliary Drainage Catheter is contraindicated for use where percutaneous biliary drainage catheterization is unacceptable.

The ReSolve Biliary Drainage Catheter is contraindicated for intravascular use.

MRI INFORMATION

MR CONDITIONAL
The ReSolve Biliary Drainage Catheter is MR Conditional

Non-clinical testing has demonstrated that the ReSolve Biliary Drainage Catheter is MR Conditional. This device can be scanned safely in a patient, immediately after placement under the following conditions:
- Static Magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled Operating Mode of operation for the MR system

MRI-RELATED HEATING
Under the scan conditions defined above, the ReSolve Biliary Locking Drainage Catheter is expected to produce a maximum temperature rise of 2.3°C after 15 minutes of continuous scanning.

ARTIFACT INFORMATION
The maximum artifact size as seen on the gradient echo pulse sequence at 3-Tesla extends approximately 2-mm relative to the size of the shape of the ReSolve Biliary Drainage Catheter.

The safety of the initial placement system including the metal stiffening cannula has not been evaluated in the MR environment, and therefore, these components should not be used within the MR environment.

CAUTIONS: 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.

To maximize the advantages of the hydrophilic coating on the surface of the distal portion of the catheter, wet the catheter prior to use with sterile water or saline. Keep catheter wet during placement.

WARNINGS:
- **B Only** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Contents of unopened, undamaged package are sterile and non-pyrogenic
- This device is intended for single use only
- DO NOT wipe catheter with dry gauze or any solvents because it may damage the catheter coating
- DO NOT over tighten the connection between the drainage catheter and drainage tubing or dead end cap
- If using alcohol to clean the catheter hub, allow sufficient time for alcohol to dry before connecting the drainage tubing or dead end cap
- Do not modify the catheter as modification may damage the catheter

REUSE PRECAUTION STATEMENT
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocesing or reprocessing 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, reprocesing or reprocessing may also create a risk of contamination of the device and/or cause patient infection or crossinfection, 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.

POTENTIAL COMPLICATIONS:
- Hemobilia
- Cholangitis
- Pancreatitis
- Pneumothorax
- Hemorrhage
- Biloma
- Fever
- Catheter leak
- Catheter occlusion
- Catheter dislodgement
- Bile peritonitis
- Skin Infection
- Perforation of the bile ducts, liver and/or duodenum

INSTRUCTIONS FOR USE:

Seldinger Entry Technique or Guide Wire Exchange

1. Remove the stiffening cannula from catheter.
2. Ensure that the distal portion of the catheter is wet prior to placement. See Cautions, Page 1.
3. Flush catheter prior to use.
4. Ensure suture locking mechanism is in the proximal position.
5. Slide pigtail straightener along distal portion of catheter to straighten curve prior to placing stiffening cannula into the catheter. Place the stiffening cannula into the catheter and tighten the luer lock fittings. See Figure 1.
6. Remove pigtail straightener from catheter prior to insertion.
7. Place catheter/cannula assembly over appropriate guide wire and advance into the biliary system. Disconnect stiffening cannula from catheter and continue to advance catheter over guide wire into desired position. The catheter accommodates a 0.038” (0.97 mm) wire. See Figure 2. Placement should be confirmed with diagnostic imaging.
CAUTION: Failure to follow could cause stiffening cannula to lodge in catheter.

8. After placement is confirmed, remove cannula and guide wire.

ENGAGING THE SUTURE LOCKING MECHANISM

9. Pull the suture until desired pigtail is formed. Do not overly tighten the pigtail as over tightening may damage the catheter. Rotate the suture locking mechanism distally to hold the suture in place. See Figure 3.

Note: If the catheter needs to be repositioned, unlock the suture locking mechanism by rotating the arm proximally to the point of resistance. Do not rotate the suture locking mechanism beyond the point of resistance.

10. Once placement is confirmed, and the suture locking mechanism has been rotated to the most distal position, press the suture locking mechanism into the hub to secure it. The suture locking mechanism is now locked into position. See Figure 4.

11. The catheter is now ready to be connected to appropriate drainage bag or tubing.

12. A flush regimen should be designed for the circumstances of each patient and the protocol of the physician.

CATHETER EXCHANGE, REPOSITIONING OR REMOVAL

1. Disconnect catheter from drainage bag or tubing.

2. To release the pigtail loop choose one of the following options:

OPTION 1: Using the Repositioning Tool, align the opening of the round section of the Repositioning Tool in line with the handle of the suture locking mechanism which will release the suture and allow the pigtail to straighten upon removal.

OPTION 2: For exchange or removal only, cut the hub off the drainage catheter and sever suture. This will release the suture and the pigtail loop.

CAUTION: The suture will no longer be secured to the catheter. Take care to remove both the suture and catheter.

3. For catheter exchange or if access is to be maintained, advance appropriate guide wire through catheter; use diagnostic imaging to confirm wire placement. Guide wire will maintain access to drainage site. To ease guide wire placement, the flexible stiffening cannula may be used.

4. Carefully remove the catheter. Proceed with either catheter exchange or skin closure.

ATTENTION ATTENDING PHYSICIAN: IF PATIENT WILL NOT BE FOLLOWED UP BY YOU, IT IS RECOMMENDED THAT THE “INSTRUCTIONS FOR USE” OR THE SECTION ON HOW TO REMOVE THE CATHETER BE ATTACHED TO THE PATIENT’S CHART.