INFORMATION INSERT



Instructions for use of this Cholangiography Catheter (FOR TRADITIONAL OPEN PROCEDURE)

INDICATIONS FOR USE: To facilitate the introduction of contrast media into the biliary ducts to obtain a cholangiogram during open cholecystectomy.

CONTRAINDICATIONS: This device is not intended for use except as indicated.

CAUTION: Sterile, disposable product intended for single use. The design of this device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device. After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

- 1. Expose and skeletonize the cystic duct as usual in preparation for cholangiography. It is suggested that the junction of the cystic duct and common bile duct be exposed and identified.
- 2. Apply clip, suture or clamp at the junction of the gallbladder and cystic duct and make a small transverse incision in the cystic duct.
- 3. Prior to insertion of the catheter, ensure that the system is free of air.
- 4. Insert the catheter into the cystic duct just past the bead on the catheter.
- 5. Secure the catheter in place with a clip, suture or clamp just below the proximal end of the bead.
- 6. Take the cholangiogram, gently remove the clip, suture or clamp and then remove the catheter.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. DO NOT alter this device.

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