INFORMATION INSERT Instructions for use:

Not Made With Natural Rubber Latex





PMI Disposable Cholangiograph Catheter 11"; for percutaneous insertion

INDICATIONS FOR USE: To facilitate the introduction of contrast media into the biliary ducts to obtain a cholangiogram during laparoscopic (percutaneously) or 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. Introduce the PMIXL11 percutaneously through a Percutaneous Introducer Needle (Cat. No. PMIPIN15) or a 14G x 5 1/4" angiography catheter with the hub removed. Align tip of metal catheter in direction of the cystic duct.
- 5. Insert the catheter into the cystic duct just past the bead on the catheter tip.
- 6. Secure the catheter in place with a clip, suture or clamp between the bend in the catheter and the bead.
- 7. Following the cholangiogram, gently remove the clip, suture or clamp and withdraw the catheter from the cystic duct.

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

Re-Order Catalog No. PMIXL11

PROGRESSIVE MEDICAL

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Progressive Medical Inc.

997 Horan Drive Fenton, MO 63026 800-969-6331

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