

Not Made
With Natural
Rubber Latex

STERILE EO
Sterilized Using Ethylene Oxide

 Do Not Reuse

COMBO PACK INFORMATION INSERT

Instructions for use:

PMI Combo Pack Includes: Disposable Lap Cholangiography Catheter (PMIXL11) with Percutaneous Introducer Needle (PMIPIN15); for Percutaneous Insertion

INDICATIONS FOR USE: Used for diagnostic evaluation of the bile ducts during percutaneous cholecystectomy procedures.

CONTRAINDICATIONS: These devices are 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 a clip, suture or clamp at the junction of the gallbladder and cystic duct and make a small transverse incision in the cystic duct.
3. Remove needle guard and non-vented white cap from the Percutaneous Introducer Needle (PMIPIN15).
4. Insert Introducer needle sheath assembly into desired location.
5. Remove the needle, leaving the Introducer sheath in position.
CAUTION: DO NOT RE-INSERT NEEDLE WHILE SHEATH IS IN POSITION
6. Prior to insertion, ensure that the PMIXL11 catheter is free of air.
7. Introduce the Laparoscopic Cholangiography Catheter (PMIXL11) percutaneously through the Percutaneous Introducer Needle (PMIPIN15). Align the tip of the metal catheter in the direction of the cystic duct.
8. Insert the catheter into the cystic duct just past the bead on the catheter tip.
9. Secure the catheter in place with a clip, suture or clamp between the bend in the catheter and the bead.
10. Following the cholangiogram, gently remove the clip, suture or clamp and withdraw the catheter from the cystic duct.
11. Remove the introducer sheath. The sheath should withdraw freely from the body. If resistance is encountered, do not force the sheath or its withdrawal. Make procedural corrections and then continue.

General Precautions: Do not attempt to force an instrument having a distal tip or body size larger than the introducer size French 5. Individual patient anatomy and physical techniques may require procedural variations. Do not alter these devices in any way.

Caution: Federal (USA) law restricts this device to use by or on the order of a physician.

Re-Order Catalog No. PMIXLPIN



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