## COMBO PACK INFORMATION INSERT





## READ AND BECOME FAMILIAR WITH ALL INSTRUCTIONS AND CAUTIONS BEFORE USING THESE PRODUCTS

**Instructions for Use:** 

PMI Combo Pack Includes: Operative Cholangiogram Catheter (ORC-A-20) with Percutaneous Introducer Needle (PIN-15) for Percutaneous Insertion

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

CONTRAINDICATIONS: These devices are not intended for use except as indicated.

- 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 the needle guard from the Percutaneous Introducer Needle (PIN-15).
- 4. Insert Introducer needle sheath assembly into desired location.
- 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 ORC-A catheter is free of air.
- 7. Introduce the Operative Cholangiogram Catheter (ORC-A) percutaneously through the Percutaneous Introducer Needle (PIN-15).
- 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 on the metal portion behind 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 of 15GA. 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 sale by or on the order of a physician.

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Re-order Catalog No. PMIORCAP20