INFORMATION INSERT

Instructions for use of this PMIPIN15 Percutaneous Introducer Needle (5 French)



INDICATIONS FOR USE: Introducer for Endoscopic/Laparoscopic procedures. 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.

CAUTION: The sheath should withdraw freely from the body. If resistance is encountered, do not force sheath or its withdrawal. Make procedural corrections and then continue.

SUGGESTED DIRECTIONS FOR USE: The French size specified (5 French) represents the inner diameter of the introducer sheath.

DO NOT ATTEMPT TO FORCE AN INSTRUMENT HAVING A DISTAL TIP OR BODY SIZE LARGER THAN THE INTRODUCER SIZE INDICATED. Individual patient anatomy and physical techniques may require procedural variations.

- 1. Remove Introducer unit from sterile packaging.
- 2. Remove outer protective sheath from unit and follow normal accepted aseptic practice.
- 3. Insert Introducer needle sheath assembly into desired location and remove the needle, leaving the Introducer sheath in position.

CAUTION: DO NOT REINSERT NEEDLE WHILE SHEATH IS IN POSITION.

- 4. Insert desired instrument.
- 5. Upon procedural completion, carefully remove sheath.

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

PROGRESSIVE MEDICAL

Re-Order Catalog No. PMIPIN15

Distributed by:

Progressive Medical Inc.

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

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