

INFORMATION INSERT

PMI Insufflation Needle

Sterile: contents sterile unless package is opened, damaged, or expired.

A. INDICATIONS FOR USE

To establish a pneumoperitoneum prior to abdominal endoscopy.

B. CONTRAINDICATIONS

This device is not intended for use except as indicated. In addition, it is not intended for use when endoscopic surgery is contraindicated.

CAUTION: Sterile, disposable product intended for single use. The design of this device may not perform as intended by the manufacturer if it is re-used. 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.

C. DIRECTIONS FOR USE

The PMI Insufflation Needle has specific indications for use as noted above. In that context, the surgeon is best advised to use a method which his/her own practice and discretion dictates to be best for the patient, consistent with the indications and contraindications outlined above. The following instructions are recommended for the proper function of the PMI Insufflation Needle. (This is not a reference for pneumoperitoneum techniques.)

1. Make a small incision to insert the PMI Insufflation Needle. During insertion, inspect the device handle to ensure that the safety band indicator has slid back proximally in the handle toward the stopcock. This action indicates that the blunt inner stylet has retracted into the outer needle, and the needle is ready for penetration. DO NOT attempt to use the needle if the safety band indicator does not slide back.
2. At an angle of insertion, perpendicular to the abdominal wall, insert the PMI Insufflation Needle into the peritoneum, just below the umbilicus, at the mid-line.
3. As the needle passes through the peritoneum the surgeon will feel a "click." The inner cannula is in its full distal position (allowing for insufflation) when the safety band indicator in the hub is seated distally in the handle (away from the stopcock). Once the needle is in place, flush it with saline; then drip 5-10cc of saline into the opening and observe its passage. The column of saline should enter the peritoneal cavity without resistance during the exploratory phase.
4. Purge an insufflation tubing set (not supplied) with CO₂ and attach it to the needle. The peritoneum should be insufflated to 14-18 mmHg. Monitor the pressure during insufflation to insure that the needle remains in place in the intraperitoneal cavity.
5. Once the pneumoperitoneum is established (and the abdomen observed for symmetrical distension and percussion), the needle is withdrawn.

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

Re-Order Catalog No.: PMIIN120/PMIIN150



Distributed by:

Progressive Medical Inc.

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Single Use



EO Sterilization

NOT MADE WITH NATURAL RUBBER LATEX.



Professional Use Only



Consult Instructions For Use

DO NOT USE IF PACKAGE IS DAMAGED