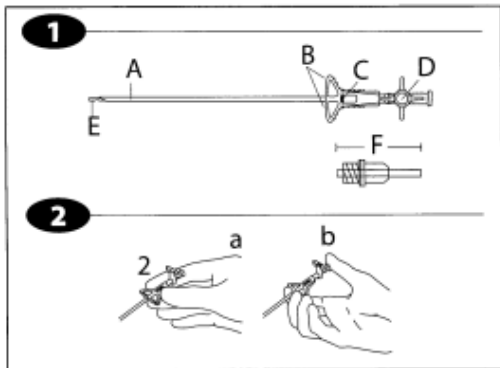


Surgineedle™

Insufflation Needle

1302800



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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques. This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Surgineedle™ pneumoperitoneum needle has a spring-loaded, blunt styler mechanism similar in function to a Veress needle. It is used to establish pneumoperitoneum prior to abdominal endoscopy. The 14 gauge stainless steel needle is attached at its proximal end to a plastic handle. The handle contains flanges for comfortable gripping action, as well as a stopcock and luer lock for inflating the abdominal cavity.

Inside the needle cannula and extending beyond the tip is a spring-loaded, blunt styler. The styler retracts as the needle is pushed through the abdominal wall and automatically advances forward once the peritoneum has been penetrated.

INDICATIONS

The Surgineedle™ needle has application in gynecologic and abdominal endoscopic procedures for establishment of pneumoperitoneum.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

- Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough understanding of the operating principles, risks versus benefits, and the hazards involved in utilizing an endoscopic approach is necessary to avoid possible injury to the user and/or patient.
- Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure.
- Do not attempt to insert the Surgineedle™ needle if the red band in the handle does not slide back toward the stopcock, as this indicates the needle point will not be exposed for insertion.
- The stopcock should be closed during insertion to prevent the abdominal pressure from equilibrating with the ambient pressure, when penetration of the peritoneum occurs.
- After removing the Surgineedle™ needle from the abdominal cavity, always inspect the site for hemostasis.
- This device is provided STERILE and is intended for use in a single procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.

1 SCHEMATIC VIEW

- A) NEEDLE
- B) HANDLE
- C) RED BAND
- D) STOPCOCK
- E) STYLET
- F) LUER LOCK CONNECTOR

NOTE: The luer lock is separately packaged from the needle in the blister. It connects to the stopcock on the Surgineedle™ instrument. The luer lock will connect to almost any standard laparoscopic tubing presently used for insufflation.

2 INSTRUCTIONS FOR USE

NOTE: Stopcock is packaged in the open position.

1. Make a small incision to insert the Surgineedle™ needle. During insertion, inspect the instrument handle to ensure the red band slides proximally toward the stopcock. This action indicates the retraction of the blunt styler and exposure of the sharp needle for penetration.

CAUTION: Do not attempt to use the Surgineedle™ needle if the blunt styler does not retract into the needle cannula.

Once the blunt styler is free of tension from tissue, the red band reseats itself in the distal portion of the handle.

2. The Surgineedle™ needle handle contains no external moving parts and may be securely held several ways, as shown, for precision and control during insertion.

a) Grasp the sides of the Surgineedle™ needle handle between the thumb and forefinger with the finger tips following the contour of the handle.

b) Grasp the Surgineedle™ needle like a spring, placing the index and third finger on either side of the handle and the thumb at the back of the instrument.

3. Test to ensure that the Surgineedle™ needle is in the abdominal cavity, then inflate the abdomen.

4. Following insufflation, remove the Surgineedle™ needle from the abdomen and proceed with the endoscopic procedure.

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.



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STERILE EO

Rx ONLY



Caution, consult accompanying documents



Upper temperature limit



Store at room temperature



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