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JHC2670298E

**ENDOPATH**

- Pneumoneedle Insufflation Needle
- Aiguille d'insufflation Pneumoneedle
- Standard-Veress-Nadel
- Ago per insufflazione Pneumoneedle
- Agulha de Insuflação Pneumoneedle
- Aguja de insuflación Pneumoneedle
- Pneumoneedle insuflationald
- Pneumoneedle (insuffleringskanyle)
- Pneumoneedle insufflaationeella
- Pneumoneedle Βελάνα Εμφύσηση Pneumoneedle
- Pneumoneedle veressnål
- Igla insuflacyjna Pneumoneedle
- Pneumoneedle insuflaciós tü
- Insufflační jehla Pneumoneedle
- Нафкóвация ihлa Pneumoneedle
- Pneumoneedle 气腹针



**EC REP**

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**Please read all information carefully.**

Failure to properly follow the instructions may lead to serious surgical consequences.

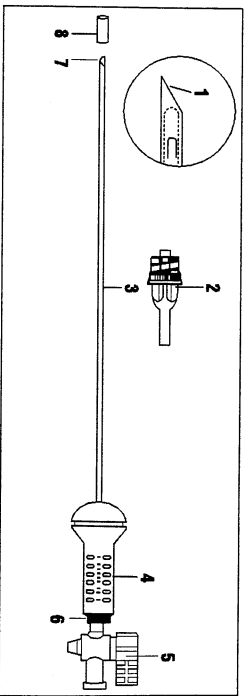
**Important:** This package insert is designed to provide instructions for use of the ENDOPATH • Pneumoneedle Insufflation Needle. It is not a reference to minimally invasive techniques.

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Gebruiksaanwijzing, Bruksvejledning, Ohje, Ostrýček, Brúksanvísing, Instruckia,  
Ulasistások, Návod k použití, Návod, 使用説明



**Indications**  
The ENDOPATH Pneumoneedle Insufflation Needle in the 120 mm and 150 mm sizes has application in gynecologic laparoscopy and other minimally invasive abdominal procedures for establishment of pneumoperitoneum.

**Contraindications**  
The instrument is not intended for use when minimally invasive techniques are contraindicated.

**Device Description**  
The ENDOPATH Pneumoneedle Insufflation Needle has a spring-loaded, blunt stylet safety 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 is cylindrical in shape for comfort in the hand and contains a stopcock and a luer lock connector for insufflating the abdominal cavity.

Inside the needle sleeve and extending beyond the needle tip is a spring-loaded, blunt stylet. The stylet retracts as the needle is pushed through the abdominal tissue and automatically advances forward once the peritoneum is penetrated.

**Illustration and Nomenclature**

1. Needle	5. Stopcock Valve
2. Luer Lock Connector	6. Red Safety Indicator
3. Needle Sleeve	7. Blunt Safety Stylet
4. Handle	8. Red Tip Protector Cap

**Instructions for Use**

**Verify compatibility of all instruments and accessories prior to using the instrument (refer to Warnings and Precautions).**

Prepare the patient in accordance with proper laparoscopic technique prior to insertion of the insufflation needle.

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field. Ensure Red Tip Protector Cap is removed prior to use.
2. Make a small incision to insert the ENDOPATH Pneumoneedle. Hold the ENDOPATH Pneumoneedle handle between the thumb and index finger with the middle finger supporting the rest of the handle. (Illustration 1)
3. During insertion, inspect the instrument handle to ensure that the "red safety indicator" slides proximally in the direction of the stopcock. This action retracts the blunt stylet and exposes the sharp needle tip for penetration. Do not attempt to use the ENDOPATH Pneumoneedle if the blunt stylet does not retract into the needle sleeve. Once the blunt stylet is free of tension from the tissue, the "red safety indicator" resets itself back into the distal portion of the handle.
4. Use appropriate testing to ensure that the ENDOPATH Pneumoneedle is safely in the abdominal cavity. Once testing is completed, insufflate the abdomen.
5. After insufflation to the appropriate pneumoperitoneum pressure, remove the ENDOPATH Pneumoneedle from the abdomen and proceed with the procedure.



- The incorporation of the blunt safety stylet feature in the needle design is intended to minimize the likelihood of penetrating injury to intra-abdominal structures. However, because the needle tip is bluntly unprotected prior to blunt safety stylet advancement, the standard precautionary measures employed in all needle insertions must be observed.
- Do not attempt to insert the ENDOPATH Pneumoneedle if the "red safety indicator" in the handle does not move backward with the stopcock. This indicates that the needle tip will not be exposed for abdominal penetration.
- After removing the ENDOPATH Pneumoneedle, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Use care when using the ENDOPATH Pneumoneedle to avoid damage to major vessels and other anatomic structures (such as bowel or mesentery). To minimize the risk of such injury be sure to:
  - Properly position the patient to help displace organs out of the area of penetration
  - Note important anatomical landmarks
  - Direct the needle tip away from major vessels and structures
  - Do not use excessive force.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

**How Supplied**  
The ENDOPATH Pneumoneedle Inflation Needle is supplied sterile for single patient use. Discard after use.

