

Instructions for Use

Reprocessed Endoscopic Trocars

Reprocessed by Northeast Scientific, Inc.


Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.


Device is STERILE unless packaging opened or damaged.

Explanation of Icons

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Do Not Reuse

 See Instructions For Use

Northeast Scientific, Inc. 2007
Waterbury, CT 06704
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Reprocessed Endoscopic Trocars and Cannulas

Endoscopic Trocar and Cannula Description

Trocars and cannulae are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery.

Trocar Cannulae are available with stability sleeve sizes 5mm, 8mm, 11mm, 12mm and 15mm inner diameter and 100mm length and smooth sleeve sizes 5mm and 12mm diameter with 100mm length. Cannulae are equipped with a sealing system for maintenance of pneumoperitoneum during insertion and withdrawal of instruments and with a luer stopcock port for insufflation and desufflation of the operative cavity.

Trocar Obturator is available in bladeless configurations.

Indications for Use

Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Contraindications for Use

Endoscopic Trocars are contraindicated for the following uses:

- Any uses generally contraindicated for thoracoscopic or minimally invasive techniques.
- Certain thoracic trocar sleeves are contra-indicated when insufflation is necessary.
- On individuals with previous abdominal surgery.

Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with minimally invasive techniques. For further information about techniques, complications and hazards, consult the medical literature.
- Prior to use, read and follow the instructions of this insert as well as those of the instruments to be used during the procedure. Damage to the instrument can lead to patient injuries. Always inspect instrument carefully for overall integrity before use.
- Improper use of this product can result in life-threatening injury to internal organs and vasculature. Use extreme caution during trocar insertion.
- Do not attempt secondary trocar punctures until the primary site and recommended pneumoperitoneum (typically 12-18 mmHg) are established.
- Peritoneal pressures exceeding 20 mmHg can pose a risk for increased venous pressure, tachycardia, and hypertension.
- Always keep the trocar straight relative to the cannula when inserting or removing. Introducing or removing the trocar at an angle relative to the cannula can damage the cannula and result in desufflation.
- Although many trocar models are blunt or have safety features, care must be taken when introducing to avoid damage to major vessels and other anatomic structures.
- Keep organs out of reach of trocar penetration by ensuring a suitable positioning of the patient's body.
- Direct the trocar away from major vessels and other anatomic structures.
- Do not use excessive force.
- Special care should be taken during insertion of bladed instruments so as not to damage the cannula valve, resulting in desufflation of the operative cavity.
- Using an instrument with a diameter smaller than the trocar may result in desufflation of the body cavity. A reducer cap or valve should be used to seal the opening into the body cavity and allow access of instruments through the cannula.
- After removing the instruments from the cavity, inspect the surgical site for hemostasis and take appropriate steps to achieve hemostasis as needed.

Precautions

- If using instruments from different manufacturers, verify compatibility of instruments before use to avoid complications during surgery.
- Become familiar with specific model of trocar and cannula prior to employing it in a surgical procedure to avoid damage to patient, to operator or to instrument.
- Careful handling of instruments is necessary to avoid damage or breakage.
- Care should be taken when removing instruments not to prematurely dislodge the cannula.
- All precautions applicable to minimally invasive procedures should be observed at all times.
- Use a trocar that is intended for the procedure and that has all the desired attributes. For example, never use a trocar that is intended to be introduced into an air- or fluid-filled cavity if a pleural space is not present in the body cavity. Never use a trocar that does not ensure a gas seal if a gas seal is needed.

Adverse Reactions

- Superficial lesions
- Injury to internal vessels
- Bleeding
- Hematoma
- Injury to the abdominal wall
- Infection
- Peritonitis

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
3. Inspect the instrument and package before opening. The contents of the package are sterile if the packaging has not been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and packaging to Northeast Scientific, Inc. for resterilization by ethylene oxide (EtO) gas.
4. Do not attempt to resterilize.
5. Remove the instrument from the package and place it in a sterile work area using aseptic technique. Avoid contact with exposed sharp edges of the trocar.
6. Inspect the instruments for any damage. Do not use the instrument if any damage is noted. Return the instrument *and packaging* to Northeast Scientific, Inc. if it is not in acceptable condition for surgery.
7. Select and follow a suitable endoscopic and/or thoracoscopic protocol.
8. The trocar is packaged with the stopcock in its open position. To prevent desufflation during insertion, close the valve prior to use.
9. If a stability anchor is used, lock it into position near the cannula proximal end.
10. Establish the primary puncture site and insufflate the operative cavity using recommended procedures.
11. Make a small incision where the instrument will be introduced. A larger, deeper incision may be necessary for blunt trocar models.
12. Create a secondary incision of adequate size to accommodate the trocar sleeve. Note: Greater trocar insertion force will be required if the incision is too small.
13. Insert the trocar and cannula assembly through the incision by applying continuous downward pressure until the body cavity has been completely penetrated.
14. Position the cannula as desired and, if used, slide the stability anchor down the sleeve into the incision. Lock the anchor in place and secure the sutures from the skin flaps around the anchor posts to ensure the seal.
15. To insufflate, attach a gas line to the trocar port and open its valve.
16. Remove the obturator and insert appropriately sized instruments. Apply an appropriately sized reducer cap as needed for smaller diameter instruments.
17. When retrieving a tissue sample through a cannula with a reducer cap, detach the cap and slide up the instrument shaft until the specimen has been removed.
18. At the end of the procedure, leave the laparoscope in place during desufflation and removal of the trocar cannula. Exteriorization of the cavity contents can occur if the laparoscope is first pulled from the cannula.
19. Detach the stability anchor (if used), remove the cannula, and suture the incision site.

Storage and Handling

Store in controlled environment, not exceeding 100°F, away from chemical fumes.

Decontamination

Recommended Decontamination for Customers

1. **Segregation of Devices** - At the completion of each procedure, single-use devices to be reprocessed by Northeast Scientific, Inc. should be physically segregated from other devices. All devices to be reprocessed should be transported from the operating room suite to an adequate decontamination area.
2. **Presoak** - Presoaking with an enzymatic solution (the recommended enzymatic solution is Endzol® Enzymatic Cleaner) is generally recommended. When presoaking instruments, personnel should refer to the solution manufacturer's instructions for the correct dilution, temperature, and soak time. Instruments should be thoroughly rinsed after presoaking.
3. **Clean and Rinse** - Lukewarm water/detergent solutions (at temperatures below 43°C (110°F)) will prevent coagulation and will thus assist in the removal of protein substances. The detergent manufacturer's instructions should be consulted. The water used for the final rinse of the devices should be endotoxin-free. Brushes and other cleaning instruments may be used to assist in the physical removal of soil. Brushes and other cleaning instruments should be disinfected daily.
4. **Dry** - Devices should be air or manually dried after the final rinse.
5. **Collection and Staging** - After drying, devices to be reprocessed should be placed in the appropriate collection container system and staged for pick-up.

The user facility is responsible for providing personal protective equipment (PPE) for all service personnel. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant clothing, face shields, and surgical face masks. PPE should be worn whenever an individual is performing collection and initial decontamination procedures.

Additionally, personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, the user facility should offer hepatitis B vaccinations to their service staff. Any questions regarding these instructions should be forwarded to the Northeast Scientific, Inc. corporate office at:

Northeast Scientific, Inc.
29 South Commons Road
Waterbury, CT 06704
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Warranty

Northeast Scientific, Inc. (NES) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations for medical devices.

NES warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. NES warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

NES shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY shall become legally obligated to

pay as damages caused by bodily injury to patients as a result of NES's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. NES shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of NES and NES makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

NES does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.
This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

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Only Northeast Scientific, Inc. bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.