

# Instructions for Use

## Reprocessed Orthopedic Trocars and Cannulas

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

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### Reprocessed Orthopedic Trocars and Cannulas

#### Description

Orthopedic trocars and cannulas are designed for general surgical use to establish a port of entry for arthroscopic instruments. The cannula seal reduces escape of bodily fluids while the internal seal assembly holds the cannula in place during the procedure. Cannulas are available in a variety of diameters and lengths. Some trocar and cannula models are supplied separately.

#### Indications for Use

Reprocessed orthopedic trocars and cannulas are indicated for use to establish and maintain a port of entry for arthroscopic instruments in patients requiring diagnostic or surgical arthroscopic procedures.

#### Contraindications for Use

None.

## **Warnings**

- Familiarize yourself with the trocar and cannula model intended for use before beginning the procedure.
- The instructions provided assist in the use of trocar and cannula sets. They are not instructions for trocar insertion.
- Initial trocar insertion requires extreme caution to avoid injury to major vascular structures. Use arthroscopic visualization for subsequent insertions.

## **Precautions**

- Use the trocar before inserting the cannula to avoid punctures to the cannula seal.
- Place the cannula so that it extends through the tissue and fat layers and becomes visible within the joint cavity. If the cannula tip is placed within the soft tissue, fluid extravasation into the tissue is minimized.
- Wetting the instruments before inserting them through the cannula is helpful but not necessary.
- Most models have a spigot with a standard luer connection that can be capped or they are equipped with a sliding valve for closure. Irrigation can be performed with or without an instrument in place in the cannula.
- If the arthroscope's diameter is only slightly above the cannula's diameter, consider removal of the arthroscope's sheath to improve fitting.
- In general, all precautions applicable to arthroscopy apply for trocar and cannula usage. Maintain strict asepsis prevention routines and carefully avoid anatomical hazards.

## **Adverse Reactions**

None.

## **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 packaging before opening. The contents of the package are sterile if the packaging has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument(s) was (were) not used, return the instrument(s) and package to Ascent Healthcare Solutions.
4. Do not attempt to resterilize.
5. Remove the instrument(s) from the package and place it (them) in a sterile work area using aseptic technique. Avoid contact with exposed sharp edges of the trocar.

6. Inspect the instrument(s) for any damage. Do not use the instrument(s) if any damage is noted. Return the instrument(s) and packaging to Ascent Healthcare Solutions if it (they) is (are) not in acceptable condition for surgery.
7. Start the procedure by making a small incision where the trocar will be introduced.
8. First, insert the trocar independently from the cannula. Direct the trocar with careful downward pressure toward the desired position in the joint. Keep the trocar a safe distance from the joint capsule.
9. Proceed according to standard arthroscopic procedure.
10. Verify with arthroscopic visualization that the cannula has fully entered the joint.
11. Follow a suitable surgery protocol.
12. Withdraw the cannula from the joint under direct visualization.

### **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.

**Sterilization:** This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

**Warning:** This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.