

# Instructions for Use

## Reprocessed Orthopedic Cutting Tools: Knives, Blades, Probes, Hooks and Curettes

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 Cutting Tools

#### Description

Orthopedic cutting tools include knives (e.g. cartilage knives), blades, probes, hooks and curettes. They are hand-held surgical instruments and/or components of ligament release systems.

Cartilage Knives are available with triangular, push or hook tips in several widths. Stand-alone versions are ready to use, whereas models designed for attachment to a handpiece need to be pre-assembled. The respective ligament release system in use provides the appropriate blade handles and other needed accessories.

#### Indications for Use

*Reprocessed cartilage knives and blades* are indicated for use in patients requiring release of the carpal ligament, the plantar fascia or the extra-articular lateral ligament to relieve pain or to aid in stabilizing the surrounding area.

*Reprocessed general use knives, blades, probes, hooks and curettes* are surgical instruments designed to cut, scrape, or manipulate tissue according to the specific needs of the surgeon.

### **Contraindications for Use**

None.

### **Warnings**

None.

### **Precautions**

- These instruments are only intended for use by individuals with adequate training and familiarity with the applicable techniques. For further information about techniques, complications and hazards, consult the medical literature.
- Do not apply excessive force. Excessive force could alter the instrument's performance and lead to instrument failure.
- Other precautions:
  - Any precautions applicable to any surgical procedure.
  - Employ proper aseptic techniques throughout surgery.
  - Avoid anatomical hazards. Always verify the instrument's position.

### **Adverse Reactions**

None.

### **Directions for Use**

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect packaging before opening. The contents of the package are sterile if the package 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 not used, return the instrument and package to Northeast Scientific.
3. Do not attempt to resterilize.
4. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
5. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. If such problems exist, return the instrument and packaging to Northeast Scientific.
6. If applicable, assemble the instrument according to the operation and maintenance manual of the system in use.
7. Follow a suitable surgery protocol.
8. If applicable, disassemble the instrument according to the operation and maintenance manual of the system in use.

## **Storage and Handling**

- Store in a cool, dry place away from direct sunlight.
- Protect the package from water contamination, damage and tampering.

## **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.