

Instructions for Use

Reprocessed Carpal Tunnel Release Blade Assembly

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 Carpal Tunnel Release Blade Assembly

Assembly Description

The carpal tunnel release blade assembly is a component of the carpal tunnel release system that also includes a handpiece and an endoscope. To perform surgery, the release system is attached to a light source and video system, an initial incision is created in the wrist flexor and the blade assembly is introduced through the endoscope. Under close visualization of the transverse carpal ligament, the blade is extended from the blade assembly to cut the ligament.

Indications for Use

Reprocessed carpal tunnel release blade assemblies are indicated for use in patients requiring release of the flexor retinaculum (transverse carpal ligament) for carpal tunnel syndrome that is not due to any associated or secondary pathology (i.e., "idiopathic" carpal tunnel syndrome).

Contraindications for Use

Reprocessed carpal tunnel release blade assemblies are contraindicated for:

- Use in patients with known abnormalities of the wrist, including distal radial deformities, rheumatoid and other diseases of the synovium.
- Use in patients with congenital anatomical abnormalities, especially abnormalities of the hook of the hamate.

Warnings

- Take great care to lock the blade assembly with the blade lock screw after inserting it into the hand piece. A loosened blade assembly may separate from the hand piece and could injure the patient or cause instrument damage.
- Do not over tighten the blade lock screw. An over tightened blade lock screw could lead to the blade not retracting and create a risk of injury to the patient.

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 attempt to use the reprocessed carpal tunnel release blade assembly in surgery before completely reading the *Directions for Use*.
- To avoid fogging and impaired visualization, the reprocessed carpal tunnel release blade assembly must be used without introduction of fluid or gas.
- Refrain from the following when handling the endoscope:
 - Do not use clamps or forceps.
 - Do not handle the endoscope at distal end.
 - Do not place anything on top of the endoscope.
- Handle the blade assembly with care to avoid accidental injuries to patient and/or operator.

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 carpal tunnel release blade assembly 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.

Inserting the blade assembly:

- Unlock the blade lock screw on the handpiece by turning it counterclockwise, pull it out and hold onto it for later use.
 - Align the carpal tunnel release blade assembly with the shuttle inside the handpiece.
 - Push the blade assembly into the handpiece as far as it will go.
 - Put the blade lock screw back on the handpiece by turning it clockwise. Avoid overtightening.
 - Push blade trigger to check for proper function of blade extension and retraction.
6. Assemble the endoscope and handpiece.
 7. Follow a suitable surgery protocol.
 8. To disassemble the blade assembly from the handpiece, loosen the blade lock screw and pull out the blade assembly.

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.