

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Carpal Tunnel Blades
Manufactured by SterilMed, Inc.
11400 73rd Avenue North
Maple Grove, MN 55369
Toll Free 1-888-541-0078
www.SterilMed.com

Caution: Federal Law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed carpal tunnel blade assemblies from various original equipment manufacturers (OEM). Carpal Tunnel Blade Assemblies are designed for the cutting of the transverse carpal ligament that is not due to any associated or secondary pathology.

The OEM packaged an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

The carpal tunnel blade assembly is one component of the carpal tunnel release system that also includes a handpiece and an endoscope. The release system is attached to a light source and a video system and an initial incision is created in the wrist flexor. The blade assembly is introduced through the endoscope and under extreme visualization of the transverse carpal ligament the blade is extended and cuts the ligament.

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed carpal tunnel blades have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

CONTRAINDICATIONS

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1. Abnormalities of the wrist
2. Congenital anatomical abnormalities

WARNINGS AND PRECAUTIONS

1. The blade assembly must be locked with the blade lock screw after insertion into the handpiece. Failure to do so may result in patient injury.
2. The blade lock screw must not be over tightened. This could lead to the blade not retracting and possible patient injury.
3. It is necessary to have adequate training and a thorough understanding associated with the use and applications of carpal tunnel blades.
4. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training and practical experiences.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

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**Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product 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.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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