

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Phacoemulsification Needles (Phaco Tips)
Manufactured by SterilMed, Inc.
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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 phacoemulsification needles (commonly referred to as phaco tips) from various original equipment manufacturers (OEM.) Phaco tips are accessories to a phacoemulsification hand piece, which is intended for the use in the phacoemulsification of a natural crystalline lens (or cataract removal.)

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

DEVICE DESCRIPTION

Phaco tips are hollow metal tipped needles that are cylinder shaped. Irrigation fluid flows between the external surface of the needle and the internal surface of an irrigation sleeve, or bypass port, to provide continuous outflow throughout the nucleus emulsification. Phacofragmentation of the cataractous lens is accomplished by the oscillation of the phaco tip.

Phaco tips are manufactured using titanium alloy and are available in a wide range of gauges, axis lengths, and tip angles.

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 phaco tips 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.

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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

1. These instruments are not intended for use when phacoemulsification techniques are contraindicated.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use applications of phaco tips.
2. Inspect the packaging, needle tip, and tip holder/wrench prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Use of incisions that are smaller than recommended can lead to mechanical and/or thermal damage to the eye tissue.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with the use of the Phaco Tip. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Corneal/ocular burns
2. Infection

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

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

**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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