

Reprocessed by









Instructions for Use Reprocessed Phacoemulsification Tips

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

Explanation of Icons

	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
	Ascent Product Code
	Do Not Reuse
	See Instructions For Use

Reprocessed Phacoemulsification Tips

Phacoemulsification Tips Description

Phacoemulsification Tips are used to emulsify and excise cataract tissue in ophthalmic microsurgical procedures.

When connected to the ultrasonic handpiece of a phacoemulsification system and activated, the Phacoemulsification Tip vibrates at an ultrasonic frequency that emulsifies cataract tissue. The extracted tissue is then aspirated away through the hollow tip. Irrigation of the eye with a saline solution compensates for the loss of volume in the eye when the cataract tissue is removed.

Alcon models may be equipped with ABS™ secondary aspiration ports to maintain continuous outflow should the primary port become occluded during the procedure.

Indications for Use

Reprocessed Phacoemulsification Tips are indicated for use to emulsify and excise cataract tissues with simultaneous irrigation and aspiration in patients requiring eye surgery.

Contraindications for Use

Reprocessed Phacoemulsification Tips are contraindicated:

- In any surgical procedure without the proper irrigant.
- When the size or model is inappropriate for the intended surgery.
- When the procedure to be performed is contraindicated for any reason. Please refer to the medical literature.

Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with the surgical procedures employed. For further information about techniques, complications and hazards, consult the medical literature.
- The use of these instruments requires a thorough understanding of the techniques and principles of ophthalmic microsurgery and related procedures.
- Never touch the tip while the phacoemulsification system is activated.
- Always inspect tip, handpiece, microsurgical unit and accessories carefully before use for overall integrity and integrity of the insulation.
- Incorrect positioning of Alcon ABS™ tips may result in obstruction of the bypass hole.
- Mismatching tips and infusion sleeves may create potentially hazardous fluidic imbalances. Use Alcon 0.9mm MicroTip tips exclusively with purple infusion sleeves and Alcon 1.1mm tips exclusively with blue infusion sleeves.
- In order to prevent possible electrical shorts, the needle and handpiece should be dry prior to connection.
- Verify that the test chamber is filled with BSS® (Balanced Salt Solution) before tuning the phaco handpiece. Tuning the handpiece dry will result in premature tip failure and breakage.

Precautions

- Verify compatibility of all parts before use to avoid complications during surgery. Use of incompatible parts may result in improperly balanced fluid levels.
- Become familiar with specific Phacoemulsification Tip model prior to employing it in a microsurgical procedure to avoid damage to patient, to operator or to instrument.
- Never attempt to bend, straighten or alter the shape, as this will produce a broken tip when the instrument is activated. If the tip is bent, it must be discarded.
- Verify surgical settings of the phacoemulsification system prior to attachment and use of the Reprocessed Phacoemulsification Tips.

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 initiating procedure, verify compatibility of all instruments, systems and accessories to be used.
3. Select a Phacoemulsification Tip with the size, tip angle and function most appropriate for the intended procedure.
4. 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 Ascent Healthcare Solutions.

Reprocessed Phacoemulsification Tips

5. Do not attempt to resterilize.
6. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
7. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.
8. Plug in and set up the phacoemulsification system according to the instructions in the manufacturer's operator manual.
9. Thread the Phacoemulsification Tip onto the handpiece and tighten firmly using the wrench. Some tips may require tightening by turning clockwise. Other tips may require tightening by turning counterclockwise.

Applying the Infusion Sleeve

1. Carefully insert the silicone sleeve over the needle and engage its infusion threads.
2. Slowly tighten the infusion threads in a CLOCKWISE rotation until the needle tip is exposed.
3. The angle of the needle should be perpendicular to the infusion ports on the sides of the sleeve.

Connecting the Phacoemulsification System and Peristaltic Tubing

1. Plug the handpiece cable into the console, ensuring that the connector is properly seated.
2. The phaco-system will not operate if the handpiece is not properly connected.
3. Connect the peristaltic tubing.
4. Prior to inserting the needle into the eye, prime the handpiece and verify the aspiration/irrigation functions of the assembled system.

Reprocessed Phacoemulsification Tips

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT 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. ASCENT 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.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT'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. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent 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.

Only Ascent Healthcare Solutions 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.

Alcon[®] and Alcon ABS[™] are registered trademarks or trademarks of Alcon Laboratories, Inc.