Alcon® UltraChopper
DIRECTIONS FOR USE

Alcon® UltraChopper is to be used only with Alcon® Ultrasonic Handpieces.
Refer to driving console Operator’s Manual (and Addendums) for tip compatibility.

CAUTION: The Alcon® UltraChopper Directions for Use are not intended to substitute for the necessity of reading and understanding the driving console Operator’s Manual. The Operator’s Manual, which is provided with the console, includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the console.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

DESCRIPTION: Each package contains one sterile single-use Alcon® UltraChopper assembled within a tip holder/wrench to perform one surgical procedure.

DIRECTIONS FOR USE:
1. Open the package and aseptically transfer contents to sterile field.
2. Follow the Cassette Pak Directions-for-use to prime the cassette of the driving console.
3. Connect the handpiece connector to the driving console.
4. After successful completion of the cassette priming/test sequence, thread Alcon® UltraChopper onto handpiece. Tighten firmly using the Tip Holder/Wrench. Remove Tip Holder/Wrench and retain for future tip removal. Thread Infusion Sleeve with BSI onto the handpiece, over the Alcon® UltraChopper. Sleeve end should clear the cutting edge of Alcon® UltraChopper by 1-2 mm. Avoid twisting of the Sleeve. Orient port holes as shown:

ASSEMBLY TO U/S HANDPIECE

![Diagram showing assembly to U/S Handpiece](attachment:image.png)
5. Connect male irrigation line luer and female aspiration line luer to handpiece. To check flow and tune handpiece, follow the driving console Operator’s Manual. Alcon® UltraChopper is intended for breaking lens into pieces only. Another tip is required to complete lens removal procedure.

6. After use of Alcon® UltraChopper is complete, remove it from the handpiece using Tip Holder/Wrench. Push Tip Holder/Wrench over Alcon® UltraChopper, turn it slightly until the flat portions of the Alcon® UltraChopper engage the Tip Holder/Wrench. Then push Tip Holder/Wrench until it is fully seated. Turn counterclockwise until Alcon® UltraChopper is fully removed and dispose tip in the proper hospital disposal container.

PRECAUTIONS AND WARNINGS:
1. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

2. Use of incisions that are smaller than recommended can lead to mechanical and/or thermal damage to eye tissue.

3. If any item in the pak is received in a defective condition, Alcon is to be notified immediately. Do not use any of the contents if the sterile package is damaged or the seal is broken in any way. In these cases, please contact:

   By Phone: (In USA) (800) 445-2389
   Ask for Consumer Affairs or
   (International) (713) 668-9100 or
   contact local Alcon representative

   By Mail: Alcon, Inc.
   Attention: Consumer Affairs Department
   9965 Buffalo Speedway
   Houston, TX 77054-1309 USA

   By E-mail: HoustonConsumerAffairs@AlconLabs.com

   Each pak is identified by a lot number which provides traceability and should be given to Customer Service Department when discussing the pak.

4. The components are intended for one surgical procedure only. Improper usage or assembly could result in a potentially hazardous condition for the patient.
5. The equipment used in conjunction with Alcon® pak disposables constitutes a complete surgical system. Use of disposables other than those of Alcon may affect system performance and create potential hazards, and if it is determined to have contributed to the malfunction of equipment under contract, could result in the voidance of the contract and or invoicing at prevailing hourly rate.

Definitions for symbols that may appear on product label:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>❌</td>
<td>SINGLE USE - DO NOT REUSE</td>
</tr>
<tr>
<td>➔SEX/REF</td>
<td>CATALOG NUMBER</td>
</tr>
<tr>
<td>📜</td>
<td>SEE DIRECTIONS FOR USE</td>
</tr>
<tr>
<td>⌚️</td>
<td>USE BY: YEAR-MONTH</td>
</tr>
<tr>
<td>🌮️</td>
<td>MANUFACTURER</td>
</tr>
<tr>
<td>🧨</td>
<td>DATE OF MANUFACTURE</td>
</tr>
<tr>
<td>⚒️ only</td>
<td>CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN</td>
</tr>
<tr>
<td>✘️</td>
<td>DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER</td>
</tr>
<tr>
<td>🔐</td>
<td>AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY</td>
</tr>
</tbody>
</table>

One of the following sterilization symbols will apply for this package:

- STERILE R: STERILE - STERILIZED BY IRRADIATION
- STERILE EO: STERILE - STERILIZED BY ETHYLENE OXIDE

CE 0123

EC REP

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