

# 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.

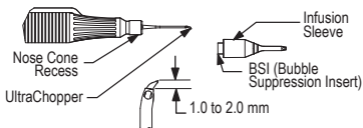
**CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

**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



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](mailto: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**<sup>®</sup> 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:

	SINGLE USE - DO NOT REUSE		SEE DIRECTIONS FOR USE
<b>REF</b> / <b>REF</b>	CATALOG NUMBER		USE BY : YEAR-MONTH
<b>LOT</b>	BATCH CODE		MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED		DATE OF MANUFACTURE
R <sub>x</sub> only	CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		
	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER		
<b>EC</b>   <b>REP</b>	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
One of the following sterilization symbols will apply for this package:			
<b>STERILE</b>   <b>R</b> STERILE - STERILIZED BY IRRADIATION			
<b>STERILE</b>   <b>EO</b> STERILE - STERILIZED BY ETHYLENE OXIDE			

**CE** 0123

**EC** | **REP**

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