# SMALL PARTS KITS
# DIRECTIONS FOR USE

**Refer to the driving console Operator's Manual for Small Parts Kit compatibility.**

**CAUTION:** The Small Parts Kit 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 instrument, includes in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the instrument.

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

**CAUTION:** The equipment used in conjunction with the Alcon Small Parts Kit 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 rates.

**DESCRIPTION:** Each Small Parts Kit contains sterile disposable phacoemulsification procedure supplies. The Small Parts Kit contains (1) infusion sleeve with BSI, (1) infusion sleeve, (1) I/A tip wrench, and (1) test chamber

OR

The Small Parts Kit contains (2) infusion sleeves without BSI, (1) I/A tip wrench, (1) test chamber, and may contain (1) phaco tip and wrench.

**DIRECTION FOR USE:** Refer to driving console Operator's Manual and procedural pack Directions for Use for setup instructions. Refer to Table below for recommended infusion sleeve and tip combinations, and incision sizes.

| Infusion Sleeves/Type | Sleeve Color | Recommended Tips | Recommended Incision Size |
|---|---|---|---|
| 1.1 mm High Infusion Sleeve | Light Blue | 1.1 mm and 1.1 mm ***ABS®*** Tip,<br>1.1 mm Flared ***ABS®*** Tip,<br>1.1 mm ***Mackool®*** Flared ***ABS®*** Tip,<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>1.1 mm and 1.1 MI ***AquaLase®*** Tip<br>Standard I/A, Silicone I/A, INTREPID® I/A Tip | 3.2 mm |
| 1.1 mm Sleeve | Dark Blue | 1.1 mm and 1.1 mm ***ABS®*** Tip,<br>1.1 mm Flared ***ABS®*** Tip,<br>1.1 mm ***Mackool®*** Flared ***ABS®*** Tip,<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>1.1 mm and 1.1 MI ***AquaLase®*** Tip<br>Standard I/A, Silicone I/A, INTREPID® I/A Tip | 3.0 mm |
| 1.1 mm Micro Sleeve | Blue/Green | 1.1 mm and 1.1 mm ***ABS®*** Tip,<br>1.1 mm Flared ***ABS®*** Tip,<br>1.1 mm ***Mackool®*** Flared ***ABS®*** Tip,<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>1.1 MI ***AquaLase®*** Tip<br>Standard I/A, Silicone I/A, INTREPID® I/A Tip | 2.75 mm |
| 1.1 mm Ultra Sleeve | Green | 1.1 mm Flared ***ABS®*** Tip,<br>1.1 mm ***Mackool®*** Flared ***ABS®*** Tip,<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>1.1 MI ***AquaLase®*** Tip<br>Silicone I/A, INTREPID® I/A Tip | 2.2 mm |
| 1.1 mm Nano Sleeve | Light Green | 1.1 mm Flared ***ABS®*** Tip,<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>Silicone I/A, INTREPID® I/A Tip | 1.8 mm |
| 0.9 mm High Infusion Sleeve | Light Purple | 0.9 mm and 0.9 mm ***ABS®*** MicroTip,<br>0.9 mm Tapered ***ABS®*** MicroTip,<br>0.9 mm Flared ***ABS®*** MicroTip,<br>0.9 mm ***Mackool®*** Flared ***ABS®*** MicroTip,<br>0.9mm ***ABS®*** Mini and Mini-Flared ***ABS®*** Tip<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>Standard I/A, Silicone I/A, INTREPID® I/A Tip | 3.2 mm |
| 0.9 mm Micro Sleeve | Dark Purple | 0.9 mm and 0.9 mm ***ABS®*** MicroTip,<br>0.9 mm Tapered ***ABS®*** MicroTip,<br>0.9 mm Flared ***ABS®*** MicroTip,<br>0.9 mm ***Mackool®*** Flared ***ABS®*** MicroTip,<br>0.9mm ***ABS®*** Mini and Mini-Flared ***ABS®*** Tip<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>Standard I/A, Silicone I/A, INTREPID® I/A Tip | 2.75 mm |
| 0.9 mm Ultra Sleeve | Red | 0.9 mm Flared ***ABS®*** MicroTip,<br>0.9mm ***ABS®*** Mini and Mini-Flared ***ABS®*** Tip<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>0.9mm ***ABS®*** INTREPID® Balanced Tip<br>Silicone I/A, INTREPID® I/A Tip | 2.2 mm |
| 0.9 mm Nano Sleeve | Orange | 0.9 mm Flared ***ABS®*** MicroTip,<br>0.9mm ***ABS®*** Mini and Mini-Flared ***ABS®*** Tip<br>0.9 mm ***ALCON® UltraChopper®*** Tip<br>0.9mm ***ABS®*** INTREPID® Balanced Tip<br>Silicone I/A, INTREPID® I/A Tip | 1.8 mm |

***WARNINGS!***

1. Improper usage or assembly could result in a potentially hazardous condition for the patient:
   - Mismatch of consumable components and/or use of settings not specially adjusted for a particular combination of consumable components may create potentially hazardous fluidics imbalance.
   - Use of non-approved handpieces may create potentially hazardous fluidics imbalance.
   - Use of incisions that are smaller than recommended can lead to mechanical and/or thermal damage to the eye tissues.

2. If the handpiece test chamber is collapsed after tuning, there is a potential of low irrigation flow through the handpiece and may result in fluidic imbalance. This, in turn, may cause a shallowing or collapsing of the anterior chamber.

3. Use of this product may require setting adjustments especially with the Ultra and Nano Sleeves. It is recommended that the Ultra and Nano Sleeves only be used with the INFINITI® Vision System, LAUREATE® World Phaco System, CONSTELLATION® Vision System, and CENTURION® Vision System as the fluidics performance of other consoles may be insufficient to perform Micro Co-axial cataract procedures. Prior to initial use, contact your Alcon Sales representative for in-service information. (Within the U.S. call 800-TO-ALCON or 817-293-0450. Outside of the U.S., contact your local Alcon Sales Representative.)

4. Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye.

5. If any of the items in the Small Parts Kit 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) 757-9780
   Ask for Medical Safety
   International (817) 293-0450
   Or contact local Alcon Representative

   By Mail: Alcon Research, Ltd
   Attention: Medical Safety (AB2-6)
   6201 South Freeway
   Fort Worth, TX 76134-2099
   USA

   By E-mail: MedicalSafetyHouston@alconlabs.com

   Each Small Parts Kit is identified by a lot number which provides traceability and should be given to Medical Safety Department when discussing the Small Parts Kit.

6. Sterile disposable medical devices should not be re-used. Alcon assumes no responsibility for complications which may arise as a result of reuse or improper usage of any part of the Small Parts Kit.
   - **Potential risk from reuse or reprocessing include: fluid path leaks or obstruction resulting in reduced fluidics performance, and foreign particle introduction into the eye.**

Definitions for symbols that may appear on product labels:

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

EC REP

Alcon Laboratories (U.K.) Ltd.
Frimley Business Park, Frimley, Camberley
Surrey, GU16 7SR, United Kingdom

CE 0123

Alcon®
ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TX 76134-2099 USA
a Novartis company
MADE IN USA

*Mackool is a trademark of
Richard J. Mackool, M. D.



316-2764-001 REV. R