ULTRA FLOW™II
I/A Handpiece
DIRECTIONS FOR USE

Refer to the Driving Console Operator's Manual (and Addendums) for Handpiece Compatibility

CAUTION: The ULTRAFLOW™II I/A Handpiece 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.

WARNINGS:

1. If the handpiece is received in a defective condition, do not use and notify Alcon Immediately:
   By Phone: Technical Services
   (In USA) (800) 832-7827
   (International) (949) 753-1393 x2091
   OR contact local Alcon representative.
   By Mail: Alcon
   Technical Services
   15800 Alton Parkway,
   Irvine, CA 92618-3818, USA
   MedicalSafetyIrvine@AlconLabs.com
   Each handpiece is identified with a lot number that provides traceability and should be given to Technical Services when discussing the ULTRAFLOW™II I/A handpiece.
2. Use care in handling the handpiece, particularly in cleaning. Always clean the handpiece over a surface cushioned with a pad or rubber mat.
3. This handpiece is to be used only with approved Alcon® surgical systems. See the particular Operator's Manual of the surgical system for a list of appropriate handpieces for that system.
4. In the event of any differences between this document and the driving console Operator's Manual, please use the information in this Directions For Use. If you have questions, please contact ALCON®.
5. Use of a tool other than the tip wrench supplied in the ALCON® cassette pack may cause damage to the I/A tip and handpiece.
6. Before each use, the handpiece should be inspected for damages (e.g. nicks, crimps, dents). If the handpiece is damaged it should be immediately removed from service. Use of damaged handpiece may result in serious permanent patient injury.
7. The ULTRAFLOW™II handpiece is non sterile and must be cleaned and sterilized prior to first use and after each use.
8. If in the medical opinion of the physician a patient with a prion related disease undergoes a high risk procedure, the instrument should be destroyed or be processed according to local requirements.

DESCRIPTION: Each package contains one ULTRAFLOW™II I/A handpiece (Figure 1) and one tip protector (Figure 2).

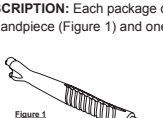


Figure 1

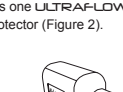


Figure 2

DIRECTIONS FOR USE: The following cleaning and sterilization instructions provide a method for effectively cleaning and sterilizing the ULTRAFLOW™II I/A handpieces per EN ISO 17664.[1] Due to the potential for Toxic Anterior Segment Syndrome (TASS), Alcon does not recommend the use of enzymatic cleaners, detergents or disinfectant solutions. If however, local jurisdictions mandate their use relative to ophthalmic instruments,

the materials of construction are compatible with both, up to a pH of 11.3, when the enzymatic chemicals, detergents or disinfectant solutions are completely rinsed/neutralized immediately after cleaning/processing per the surgical facility's procedure.

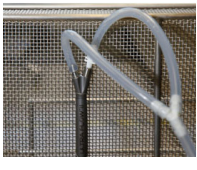
1. Thoroughly clean the handpiece before initial use and IMMEDIATELY after each subsequent use. Do not store or allow the handpiece to dry after use until thoroughly cleaned. Both a manual cleaning process and a cleaning process using an automated washer are presented.
2. **Cleaning Procedure: Manual**
   Perform the following steps to thoroughly clean the handpiece:
   Step One: Remove the irrigation and aspiration tubing from the handpiece.
   Step Two: Remove the infusion sleeve and tip from the handpiece and discard according to surgical facility guidelines.
   Step Three: Wipe any residue from the handpiece with a soft, clean, lint free non-abrasive cloth and rinse the handpiece with room temperature sterile deionized water to remove any remaining debris. If necessary, wash the exterior of the handpiece using a soft bristled cleaning brush.
   Step Four: Submerge the tip end of the handpiece in a container of room temperature sterile deionized water.
   Step Five: Using a syringe, push a minimum of 120cc of room temperature sterile deionized water through both the irrigation and aspiration paths.
   Step Six: Using the same syringe, flush both ports with a minimum of 60cc of air.
   Step Seven: Dry the exterior surfaces of the handpiece body with a soft clean, lint free non-abrasive cloth.
   Step Eight: Visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed.
   Step Nine: Install the ULTRAFLOW™II tip protector by pushing it straight onto the handpiece body.
   Step Ten: Place the cleaned handpiece with tip protector in an autoclavable tray or wrap to prevent damage to handpiece during storage and autoclaving.
3. **Automated Washer Procedure**
   In the event use of an automated process is required, perform all of the following steps to process the handpiece.
   NOTE: a) Due to the potential for the accumulation of particulate and bioburden residues in the washer water reservoirs, it is the surgical facility's responsibility to properly maintain the equipment and their associated filters to ensure the introduction of contaminant- free solutions into the handpieces.
   b) This automated washing procedure provides a method for effectively processing up to three (3) handpieces at a time.
   c) The temperatures and cycle parameters below will not cause damage to the product.
   d) Do not wash the handpieces with non-ophthalmic instruments.
   Step One: Manually clean the handpiece immediately after each surgical procedure per the manual cleaning procedure above before using an automated washer.
   Step Two: Prepare the washer with multi-purpose injector per Operator's Manual. The circulation rate of the automated washer should be at least 106 gallons (401 liters) of water per minute. The use of a typical automated washer and wire basket is depicted below.
   NOTE: Use de-ionized water only.
   Required materials:
   • Detergent with pH range of 8.5 up to 9.5.
   • Organic acid neutralizer with pH range of 3.0-2.6.
   • Adaptors and silicone tubing, e.g. Customized Auto Wash Kit: Alcon **REF** 8065750456.

Step Three: Set detergent and neutralizer dispensers as recommended by detergent and washer manufacturer.

Step Four: Program washer to have the following automated cycle:

- Main wash at a minimum of 55° C for at least 10 minutes (dispense detergent as recommended by detergent and washer manufacturer).
- Neutralize for a minimum of 1.5 minutes (dispense neutralizer as recommended by detergent and washer manufacturer).
- Rinse for a minimum of 5 minutes at 22 - 27° C then drain.
- Repeat rinse for a minimum of 5 minutes at 22 - 27° C then drain.
- Final Rinse at a minimum of 70° C for at least 1.5 minutes then drain.
- Dry at a minimum of 100° C for at least 5 minutes.

NOTE: Additional rinsing steps will not alter the effectiveness of the validated cycle.

	**Step Five:** Using the Auto Wash Kit, secure the handpiece to the wire mesh basket using the small gauge wire and connect the handpiece with the "Y" adapter assembly as shown.
	**Step Six:** Place wire basket with handpiece in multi-purpose injector rack and connect the "Y" adapter assembly to the 4 mm diameter injector nozzle as shown.
	**Step Seven:** Plug off any unused injector nozzles with silicone tubing. **Pictured:** Miele** Labwasher, Model G7735 with injector Model #0-177.

Step Eight: Start the wash program. When the wash program is completed, visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed. Then replace the processed handpiece with tip protector in an autoclavable tray or wrap to prevent damage to handpiece during storage and autoclaving.

4. **Sterilization**

Sterilize the handpiece using a steam sterilization cycle. The sterilization instructions provided in Table 1 below have been validated by Alcon Laboratories, Inc. as being CAPABLE of sterilizing the ULTRA-LOW™II I/A handpiece for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility achieve the desired result. This requires verification and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for

effectiveness and potential adverse consequences. Please refer to nationally recognized standards[2], such as AAMI Standards or to your facility's standard procedures.

NOTE: Due to the potential for the accumulation of particulate and bioburden residues in the sterilizer water reservoirs, it is the surgical facility's responsibility to properly maintain the equipment and their associated filters to ensure the introduction of steam into the Handpiece is contaminant free at levels acceptable per the surgical facility's requirements.

Table 1 **- STERILIZATION TEMPERATURE AND TIME SETTINGS**

CYCLE TYPE	PULSES	CONFIGU-RATION	MINIMUM TEMPER-ATURE	MINIMUM EXPOSURE TIME (MINUTES)	MINIMUM DRYING TIME (MINUTES)
Gravity	N/A	Wrapped	132° C (270° F)	15	15
Gravity	N/A	Unwrapped	132° C (270° F)	10	N/A
Pulsing Prevacuum	4	Unwrapped	132° C (270° F)	4	N/A
Pulsing Prevacuum	4	Wrapped	135° C (275° F)	3	16

5. After sterilization, transport the handpiece to the driving console for the next use, and refer to your driving console Operator's Manual for proper surgical setup.
6 There is no specific limits for the time or conditions of storage.
7. **References:**

[1]EN ISO 17664: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

[2]EN ISO 17665: Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the development, validation and routine control of sterilization process for medical devices.

Definitions for symbols that may appear on product labels:

	SEE DIRECTIONS FOR USE		MANUFACTURER
LOT	BATCH CODE	REF	CATALOG NUMBER
	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER		
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
℞ only	CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		

CE 0123

EC REP

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