constellation® VISION SYSTEM FRAGMENTATION HANDPIECE

DIRECTIONS FOR USE

Refer to the driving console Operator's Manual (and Addendums) for handpiece compatibility.

CAUTION: The 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 instrument, 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 handpiece.

DIRECTION FOR USE:

The following cleaning and sterilization instructions provide a method for effectively cleaning and sterilizing the **Constellation®** Fragmentation Handpiece 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 standard 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 aspiration tubing from the handpiece.
   Step Two: Unplug the handpiece connector from the console and install the protective cap.
   Step Three: Remove the tip from the handpiece using a tip wrench and discard according to surgical facility guidelines.
   Step Four: 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 brush.
   Step Five: Submerge the Nosecone (front part) of the handpiece in a container of room temperature sterile deionized water.
   Step Six: Using a syringe, draw or push a minimum of 120cc of room temperature sterile deionized water through the aspiration paths.
   Step Seven: Using the same syringe, flush port with a minimum of 60cc of air.
   Step Eight: Dry the exterior surfaces of the handpiece and cable with a soft, clean, lint free non-abrasive cloth.
   Step Nine: Visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed.
   Step Ten: Place the cleaned handpiece and cable in an autoclavable tray to prevent damage to connector and handpiece during storage and autoclaving or wrap to prevent damage in preparation for 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.

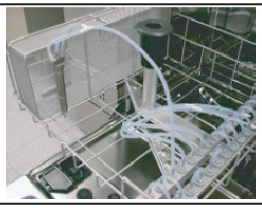
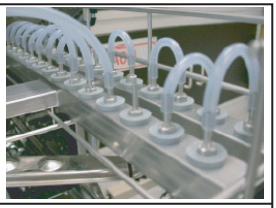
   Step One: Manually clean the handpiece immediately after each surgical procedure per the manual cleaning procedure above before using an automated washer.
   Step Two: Prepare the washer with multi-purpose injector per Operator's Manual. The circulation rate of the automated washer should be at least 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 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 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. Replace the processed handpiece and cable in an autoclavable tray to prevent damage to connector and handpiece during storage and autoclaving or wrap to prevent damage in preparation for 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 **Constellation®** Fragmentation 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, 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 TEMPERATURES AND TIME SETTINGS

STERILIZER TYPE	PULSES	CONFIGURATION	MINIMUM TEMPERATURE	MINIMUM EXPOSURE TIME (MINUTES)
Gravity Displacement	N/A	Wrapped	132° C (270° F)	18
Gravity Displacement	N/A	Unwrapped	132° C (270° F)	8
Pulsing Prevacuum	4	Unwrapped	132° C (270° F)	4
Pulsing Prevacuum	4	Wrapped	134° C (273° F)	5
Pulsing Prevacuum (four negative and four positive pulses)	4	Wrapped	134-137° C (273-279° F)	3

Note: This product has been validated to perform reliably after steam sterilization at 134°C (273°F) for 18 minutes (prevacuum, wrapped).

5. After transport to the driving console for the next use, refer to your driving console Operator's Manual for proper surgical setup.
6. Refer to Alcon's Pack/Tip Directions for use for proper assembly on the tip to the Handpiece.
7. There are no specific limits for the time or conditions of storage.
8. Keep this Direction-for Use for reference when using this handpiece.
9. **References**:
[1]EN ISO 17664: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

PRECAUTIONS AND WARNINGS:

1. If the handpiece is received in a defective condition, please do not use and notify Alcon immediately:
By Phone: Technical Services (In USA) (800) 832-7827 (International) (800) 832-7827 or contact local Alcon representative
By Mail: Alcon Technical Service 15800 Alton Parkway Irvine, CA 92618, USA
Each handpiece is identified by a Serial Number which provides traceability and should be given to Technical Services when discussing the handpiece.
2. Use care in handling the handpiece, particularly when cleaning. Extra attention to protecting the nosecone area should be taken. 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. Each time the Handpiece is connected to the driving console, it performs a check cycle. If the Handpiece performs improperly and fails the check cycle, remove it from the driving console and return it to Alcon for evaluation.
5. Before each use, inspect the Handpiece and power cord for damage (e.g. nick, crimps, dents, exposed wires). If the Handpiece is damaged it should be immediately removed from service. Use of damaged Handpiece may result in serious permanent patient injury.
6. In the event of any difference 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.
7. Be sure the handpiece connector is dry before connecting it to the console.
8. Do not ultrasonically clean the handpiece. Ultrasonic cleaning of this handpiece will cause irreparable damage.
9. Never immerse the handpiece in liquid after autoclaving; allow it to air cool for at least 15 minutes.
10. During any phacoemulsification procedure, metal particles may result from inadvertent touching of the phacoemulsification 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 abrasions of the ultrasonic tip.
11. 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.

DEFINITIONS FOR SYMBOLS APPEARING ON PRODUCT LABELING:

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

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 76134-2009 USA
MADE IN USA

212-2462-001 REV. E