

AutoSert™ IOL Injector Handpiece DIRECTIONS FOR USE

Refer to the driving console Operator's Manual and (addendums) for Injector Handpiece compatibility.

CAUTION: The AutoSert™ IOL Injector 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 IOL Injector Handpiece is received in a defective condition, 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

e-mail: MedicalSafetyIrvine@AlconLabs.com

By Mail: Alcon

Technical Services

15800 Alton Parkway

Irvine, CA 92618 USA

Each Injector Handpiece is identified by a Serial Number which provides traceability and should be give to Technical Service when discussing the Injector Handpiece.

2. Each time the IOL Injector Handpiece is connected to the driving console, it performs a calibration cycle. When the IOL Injector Handpiece performs improperly and fails the calibration cycle, remove it from the driving console and return it to Alcon for evaluation.
3. Use care in handling the IOL Injector Handpiece, particularly in cleaning. Always clean the IOL Injector Handpiece over a surface cushioned with a pad or rubber mat.
4. The IOL Injector Handpiece is to be used only with the approved ALCON® surgical systems. See the particular Operator's Manual of the surgical system for a list of the appropriate IOL Injector Handpiece for that system.
5. In the event of any difference between this document and the driving console Operator's Manual, please use the information in this Direction-for-Use. If you have any questions, please contact Alcon.
6. Be sure the IOL Injector Handpiece connector is dry before connecting it to the console
7. Do not ultrasonically clean the IOL Injector Handpiece connector. Ultrasonic cleaning of the IOL Injector Handpiece connector will cause irreparable damage.
8. Never immerse the IOL Injector Handpiece in liquid after autoclaving; allow it to air cool for at least 15 minutes. Quenching could result in a potentially hazardous condition for the patient.
9. The IOL Injector Handpiece delivery system is for the implantation of ALCON® qualified *AcrySoF*® Foldable IOLs. Unqualified lenses shall not be used with the IOL Injector Handpiece Delivery System. See table 1 below for the qualified lens/cartridge combination. Contact Alcon for the most current listing of qualified Injector Handpiece/cartridge combinations.
10. The IOL Injector Handpiece is non sterile and must be cleaned and sterilized prior to first use, and after each use.
11. The nosecone is not to be detached once the plunger and cartridge are attached to the Injector Handpiece. This could result in potentially hazardous condition for the patient.
12. Do not immerse the IOL Injector Handpiece in any fluid when the IOL Injector Handpiece is not retracted. This could result in potentially hazardous condition for the patient.
13. Do not remove the connector from the Driving Console until the plunger is fully retracted.

14. The cartridge/IOL combination listed in Table 1 has been validated per section 5 of BS EN ISO 11797-3:2006. Appropriate use of the IOL Injector Handpiece settings is important for successful IOL Implantation. Inappropriate use of settings may lead to a potentially hazardous condition for the patient.

DESCRIPTION: Each package contains one AutoSert™ IOL Injector Handpiece (Fig. 1), wrench (Fig. 2) and plunger (Fig. 3). **The AutoSert™ IOL Injector Handpiece is intended to implant qualified AcrySof® intraocular lenses into the eye following cataract removal.** The AutoSert™ IOL Injector Handpiece accommodates an Alcon single-use, sterile, cartridge (Fig. 4).

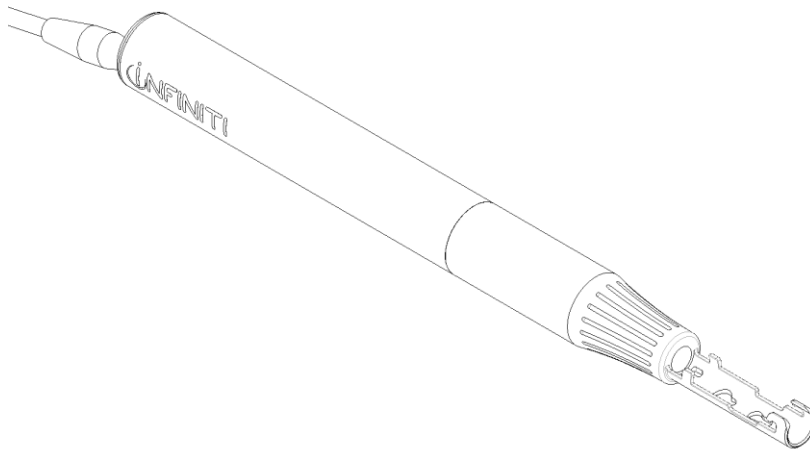


Figure 1

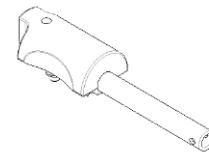


Figure 2

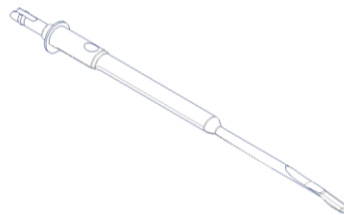


Figure 3

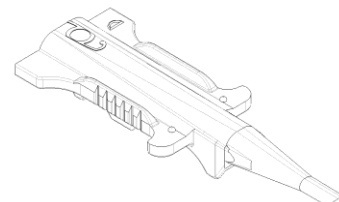


Figure 4

TABLE 1 – QUALIFIED IOL/CARTRIDGE/OVD COMBINATION

Cartridge	Qualified Lens Models	Diopter Range	VISCOAT OVD	Cartridge Product REF
D	SN60WF	+6.0 to +27.0	8065183905 8065183975	8065977763

CLEANING INSTRUCTIONS: The following cleaning instructions provide a method for effectively cleaning the AutoSert™ IOL Injector Handpiece per EN ISO 17664¹. Due to the potential for Toxic Anterior Segment Syndrome (TASS), Alcon does not recommend the use of enzymatic cleaners and detergents. 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. A manual cleaning process is presented.

1. Thoroughly clean the IOL Injector Handpiece before initial use and IMMEDIATELY after each subsequent use. Do not allow the IOL Injector Handpiece to dry after use until thoroughly cleaned.

2. Inspect the IOL Injector Handpiece to ensure that it is not damaged and that the nosecone is installed in the proper orientation before use (Figure 5). Note the nosecone orientation with respect to the cable



Figure 5

3. **PLUNGER INSTALLATION:**

Step One: As shown in figure 6a and 6b, insert the plunger into the wrench

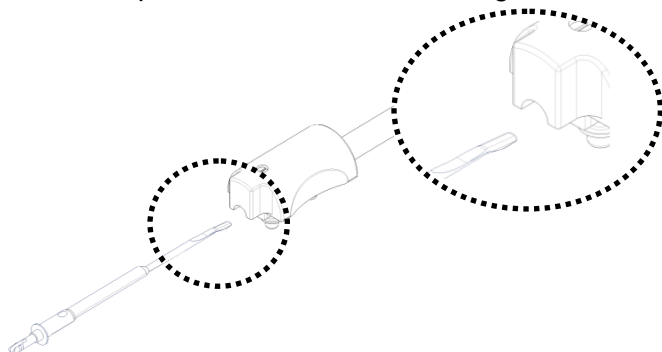


Figure 6a

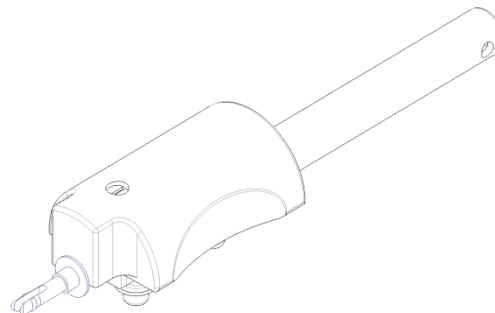


Figure 6b

Step Two: As shown in figure 7a and 7b, install the wrench/plunger onto the IOL Injector Handpiece by aligning the shaft from the wrench into the opening on the nosecone followed by directing the wrench away from the nosecone

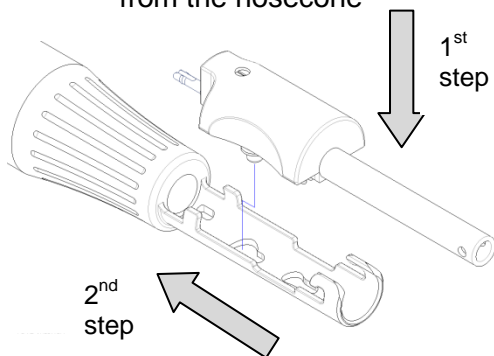


Figure 7a

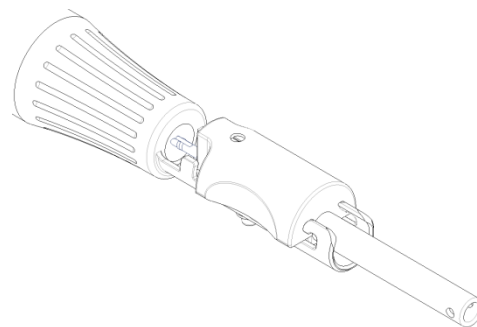


Figure 7b

Step Three: After the Plunger is installed on to the IOL Injector Handpiece, remove the wrench from the IOL Injector Handpiece.

4. **CARTRIDGE INSTALLATION**

Step One: Refer to the Cartridge DFU on loading the IOL into the cartridge. See table one of this DFU for the qualified IOL/Cartridge combination.

Step Two: Insert the cartridge into the IOL Injector Handpiece (1st step) and fully slide the cartridge forward into the IOL Injector Handpiece slot (2nd step) as shown in figure 9a and 9b.

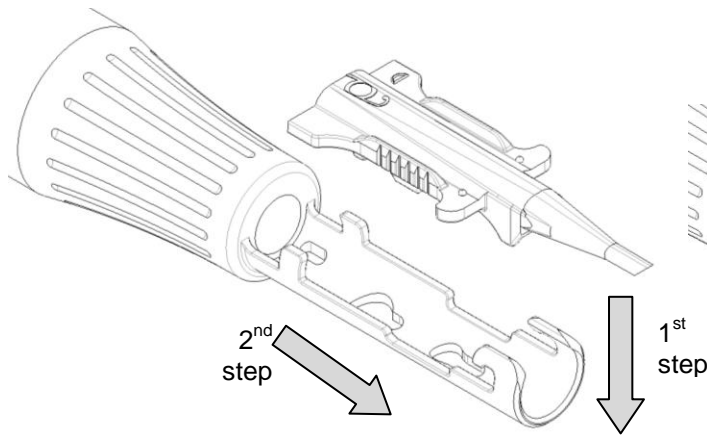


Figure 9a

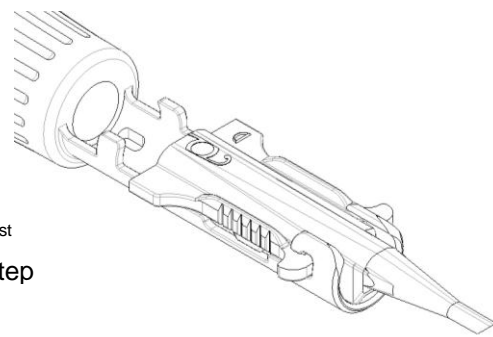


Figure 9b

5. **CLEANING PROCEDURE: MANUAL**

Perform the following steps to manually clean the IOL Injector Handpiece

Step One: Remove the cartridge from the nosecone of the IOL Injector Handpiece.

Step Two: As shown in Figure 10, detach the nosecone from the IOL Injector Handpiece by rotating the nosecone counter clock-wise

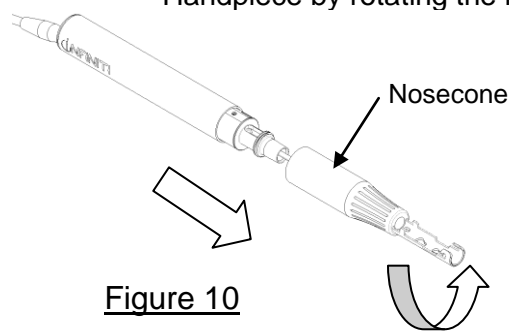


Figure 10

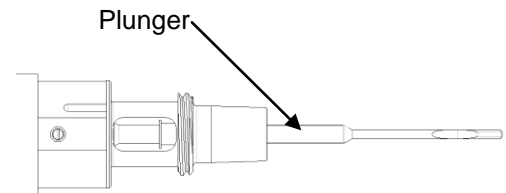


Figure 11

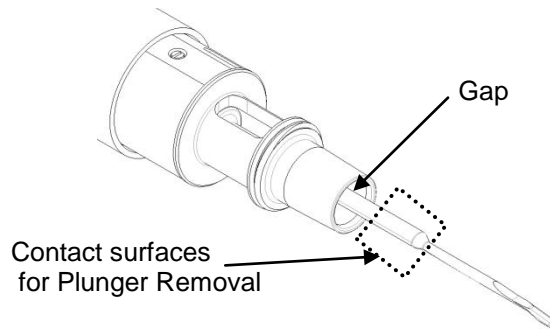


Figure 12

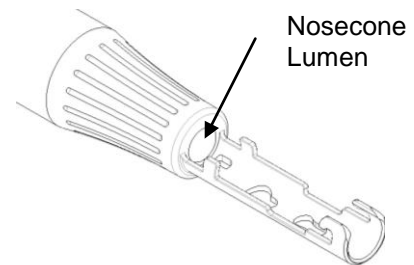


Figure 13

Step Three: Wipe any residue from the IOL Injector Handpiece body, Nosecone and the exposed plunger (fig. 11) with a soft, non-abrasive cloth

Step Four: Submerge the IOL Injector Handpiece, excluding the connector, and Nosecone in a container of sterile or distilled water for a minimum of 5 minutes. Do not allow viscoelastics or debris from the surgery to dry on the instrument prior to cleaning

Step Five: Flush the plunger shown in figure 11 and the Nosecone with sterile or distilled water for a minimum of 5 seconds

Step Six: Using a soft bristle brush, brush the gap between the plunger/IOL Injector Handpiece (fig. 12) and Nosecone lumen (fig. 13) under sterile or distilled water for a minimum of 5 seconds

- Step Seven: Remove the plunger from the IOL Injector Handpiece
- Step Eight: Ultrasonically clean the IOL Injector Handpiece, Plunger and Wrench in distilled water for a minimum of 5 minutes
- Step Nine: Rinse the plunger with sterile or distilled water for a minimum of 15 seconds
- Step Ten: Dry the surfaces of IOL Injector Handpiece, Plunger and Wrench with a soft, non abrasive cloth.

6. **STERILIZATION**

Sterilize (after Cleaning step is completed) with the Plunger, Nosecone and Wrench detached from the IOL Injector Handpiece. Sterilize the IOL Injector Handpiece, plunger, nosecone, and wrench using a steam sterilization cycle. The sterilization instructions provided in Table 2 below have been validated by Alcon Laboratories, Inc. as being capable of sterilizing the IOL Injector 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 achieves 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 standards², such as AAMI Standards or to your facility's standard procedures.

Note: Due to the potential for the accumulation of particulates and bio-burden 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 contaminate-free steam into the IOL Injector Handpiece.

TABLE 2 - STERILIZATION TEMPERATURES AND TIME SETTINGS*

CYCLE TYPE	PULSES	SAMPLE CONFIGURATION	TEMPERATURE	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 Pre-vacuum	4	Unwrapped	132°C (270°F)	4	N/A
Pulsing Pre-vacuum	4	Wrapped	135°C (275°F)**	3	16

Notes:

*This product has been validated to perform reliably after steam sterilization at 134°C (273 °F) for 18 minutes (pre-vacuum, wrapped)

**Validated at 134°C to accommodate European Community/HTM2010 requirements for a 134°C cycle of 3 minute duration.

7. **References:**

¹ISO 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 a sterilization process for medical devices.

8. After sterilization, allow the components to cool and re-attach the nosecone on to the IOL Injector Handpiece by first aligning both index lines shown in figure 14, then slide the nosecone onto the IOL Injector Handpiece and rotate the nosecone clock-wise until tightened. After installation, verify the orientation of the nosecone with respect to the cable (see figure 5).

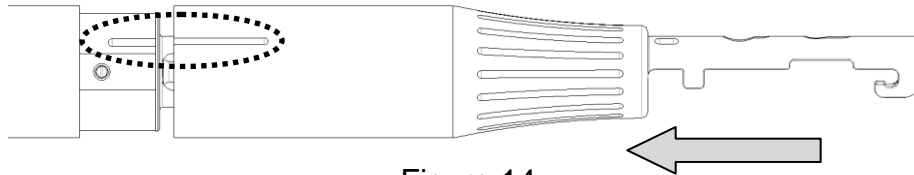


Figure 14

9. After transport to the driving console for the next use, refer to your driving console Operator's Manual for proper surgical setup.
10. At the end of the day, fully extend the IOL Injector Handpiece shaft (shown in fig. 15). Remove the nosecone and wipe the exterior IOL Injector Handpiece shaft enclosed by the dotted line with a soft, non-abrasive cloth. After wiping, reinstall the nosecone, then fully retract the IOL Injector Handpiece shaft and verify orientation of the nosecone with respect to the cable (figure 5).

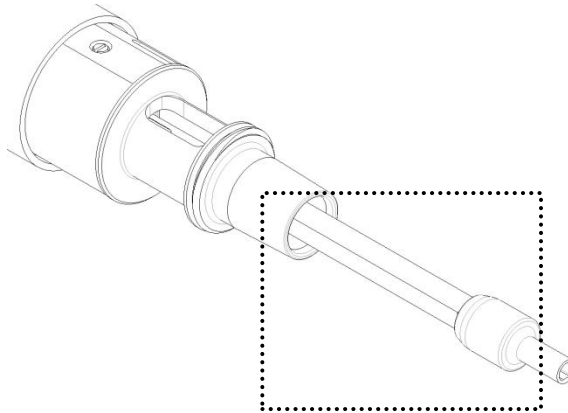






Figure 15

Definitions for symbols that may appear on product labels:

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

EC **REP**

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