

ALCON® INTREPID® AutoSert® IOL Injector Handpiece

DIRECTION FOR USE

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

CAUTIONS:

- A. The ALCON® INTREPID® 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.
 - B. As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.
 - C. U.S. Federal Law restricts this device to sale by or on the order of a physician.
 - D. Not all Cartridge/lenses/OVD combinations are currently approved in all countries. For information on the latest approved combinations in your region, contact your local Alcon surgical sales representative.
 - E. 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) (949) 753-1393 X2091 or contact local Alcon Representative
By Mail: Alcon Technical Services 15800 Alton Parkway Irvine, CA 92618 USA
By E-mail: MedicalSafetyIrvine@AlconLabs.com
- Each IOL Injector Handpiece is identified by a Serial Number which provides traceability and should be given to Technical Service when discussing the IOL Injector Handpiece.
- F. Each time the IOL Injector Handpiece is connected to the driving console, it performs a calibration cycle. If the IOL Injector Handpiece performs improperly and fails the calibration cycle, remove it from the driving console and return it to Alcon for evaluation.
 - G. 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.
 - H. The IOL Injector Handpiece is to be used with only 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.
 - I. 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 any questions, please contact Alcon.
 - J. Be sure the IOL Injector Handpiece connector is dry before connecting it to the console.
 - K. Do not ultrasonically clean the IOL Injector Handpiece connector. Ultrasonic cleaning of IOL Injector Handpiece connector will cause irreparable damage.
 - L. Do not remove the connector from the Driving Console until the IOL Injector Handpiece is fully retracted.
 - M. Extra caution should be used not to bend or impact the plunger when removing the nosecone from the IOL Injector Handpiece, and wiping the plunger to remove OVD. Bending or impacting the plunger could affect the delivery performance of the IOL Injector Handpiece.

WARNINGS:

1. 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.
2. Before each use, the IOL Injector Handpiece and power cord should be inspected for damage (e.g. nicks, crimps, dents, exposed wire). If the IOL Injector Handpiece is damaged, it should be immediately removed from service. Use of a damaged IOL Injector Handpiece may result in serious permanent patient injury.
3. 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.
4. The IOL Injector Handpiece is for the implantation of qualified ALCON® AcrySof® Foldable IOLs. Unqualified lenses shall not be used with the IOL Injector Handpiece Delivery System. See table 1 below for the qualified IOL/cartridge/OVD combination for the IOL Injector Handpiece Delivery System.
5. The IOL Injector Handpiece is non sterile and must be cleaned and sterilized prior to first use, and after each use.
6. The nosecone is not to be detached once the plunger and cartridge are attached to the IOL Injector Handpiece. This could result in a potentially hazardous condition for the patient.
7. Do not immerse the IOL Injector Handpiece in any fluid when the IOL Injector Handpiece is not retracted. This could result in a potentially hazardous condition for the patient.
8. The cartridge/IOL combination listed in Table 1, along with Alcon settings, has been validated per section 5 of EN ISO 11979-3:2006 and at an ambient temperature of 18 °C using the driving console setting (1.7 mm/sec, 3 seconds, and 3.0 mm/sec for initial velocity, pause and final velocity respectively). Using a higher velocity and shorter pause at lower temperatures, especially with high diopter lenses, could induce damage to IOL and/or IOL cartridge, affecting successful IOL implantation. See Lens Delivery section, step 4 and 6, of this document on resolving a trailing haptic situation.
9. Fully retract the plunger before detaching the nosecone from AutoSert® IOL Injector. Otherwise this could expose the non-sterile portion of the shaft and result in a potentially hazardous condition for the patient.
10. For the intended IOL to be implanted the proper Cartridge profile MUST BE SELECTED from the driving console AND the proper plunger MUST BE ATTACHED TO AutoSert® IOL INJECTOR. Failure to do so can result in a potentially hazardous condition for the patient.
11. The metal reusable plunger must be sterilized after each use. The reusable plunger is to be installed onto the handpiece or into the wrench prior to sterilization.

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

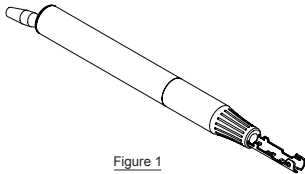


Figure 1

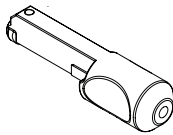


Figure 2

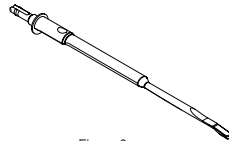


Figure 3

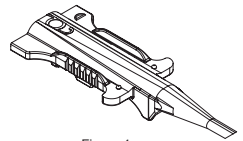


Figure 4

TABLE 1 QUALIFIED IOL/CARTRIDGE/OVD COMBINATION

Cartridge (Product REF)	OVD (Product REF)	Qualified Lens Models	Diopter Range
MONARCH® III D (806597763)	VISCOAT® (8065183905) (8065183975)	SN60WF	+6.0 to +27.0
		SN6AD1	+6.0 to +25.5
		SN6AT3	+6.0 to +23.0
		SN6AT4	
		SN6AT5	
		SN6AT6	
SN6AT7			
MONARCH® II C (806597759)	VISCOAT® (8065183905) (8065183975)	SN6AT3	+6.0 to +27.0
		SN6AT4	
		SN6AT5	
		SN6AT6	
		SN6AT7	
		SN6AT8	

DIRECTION FOR USE

1. SET UP - CARTRIDGE INSTALLATION:

Step One: Refer to the Cartridge DFU on loading the IOL into the cartridge. See Table 1 of this DFU for the approved IOL/Cartridge/OVD 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 Figures 5a and 5b. See Console Operator’s Manual on the PRELOAD LENS function.

Figure 5a

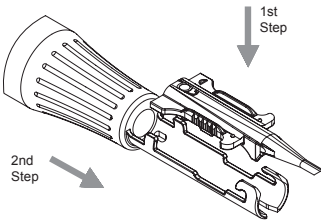
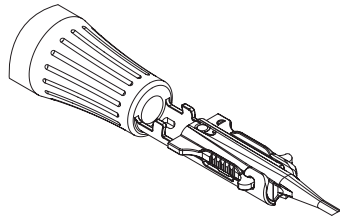


Figure 5b



2. LENS DELIVERY

Step One: During the pre-load function, the plunger should make initial contact with the cartridge at the ramp. In the event the plunger does not contact the cartridge at the ramp, do not use the IOL Injector Handpiece and contact Alcon.
 Step Two: Verify the lens moves forward at the same rate as the plunger.
 Step Three: As the lens moves through the cartridge, verify that the plunger tip is behind the optic and the leading haptic is looped in front of the optic. The leading haptic may become looped back between the folded halves of the optic, which is acceptable.
 Step Four: Visually inspect the lens to ensure proper interface between the lens and plunger. If any sign of over-ride (Figure 6a) or under-ride (Figure 6b) occurs, retract the Plunger and replace it per section 11 (Plunger Installation section of this document). In the event a trailing haptic is detected (Figure 6c) at the pre-load lens position, fully retract the plunger and use another AcrySof® IOL and MONARCH® cartridge.

Figure 6a Plunger Over-ride (viewed from bottom of cartridge and cross-sectional view)

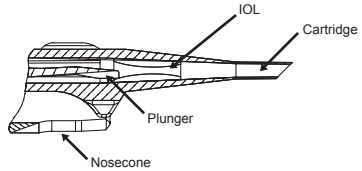
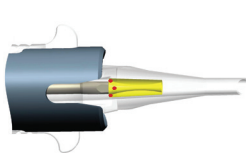


Figure 6b Plunger Under-ride (viewed from bottom of cartridge and cross-sectional view)

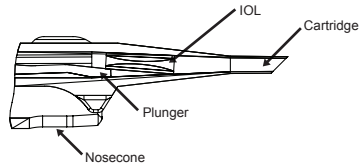
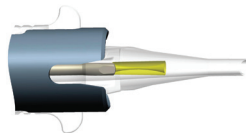
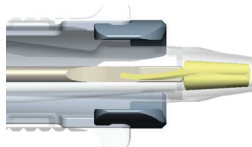


Figure 6c Trailing haptic (viewed from top)



- Step Five: Insert the tip of the cartridge through the incision. Position the tip at the anterior capsule opening. If the leading haptic is looped in front of the optic, rotate the cartridge to be slightly bevel left to facilitate placement of the leading haptic into its normal orientation in the bag.
- Step Six: Advance the lens only until the optic exits the nozzle, rotating the cartridge towards bevel right as needed to place the lens anterior side up. During IOL implantation if the trailing haptic does not exit the cartridge when the plunger is fully extended, retract the plunger to the pre-loaded position then fully extend the plunger to complete the IOL implantation.
- Step Seven: Withdraw the cartridge nozzle.
- Step Eight: Place and center the lens using a suitable positioning instrument.

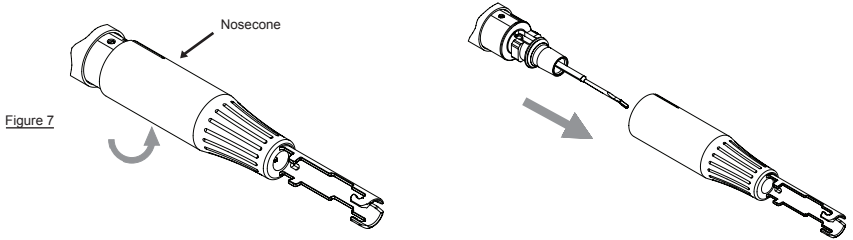
The following cleaning and sterilization instructions provide a method for effectively cleaning the AutoSert® IOL Injector Handpiece per EN ISO 17664¹. Due to the potential for Toxic Anterior Segment Syndrome (TASS), Alcon does not recommend the use of enzymatic cleaners, detergents or disinfectant solutions. 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.

3. Thoroughly clean the IOL Injector Handpiece before initial use and **IMMEDIATELY** after each subsequent use. Do not store or allow the IOL Injector Handpiece to dry after use until thoroughly cleaned.
4. **CLEANING PROCEDURE: MANUAL**

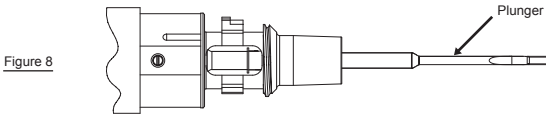
Perform the following steps to manually clean the IOL Injector Handpiece.

Step One: After the plunger has been fully retracted, remove the cartridge from the IOL Injector Handpiece. Discard the cartridge.

Step Two: As shown in Figure 7, detach the nosecone from the IOL Injector Handpiece by rotating the nosecone counter clock-wise first, then carefully slide it away from the IOL Injector Handpiece so it does not deflect the plunger.



Step Three: Wipe any residue from the IOL Injector Handpiece body, Nosecone, and the exposed plunger (Fig. 8) with a soft, lint free non-abrasive cloth.

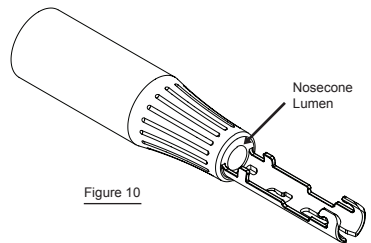
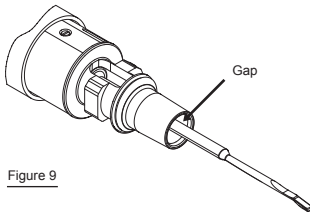


Step Four: Re-attach the nosecone onto the IOL Injector Handpiece by first aligning both index lines shown in Figure 11 then slide the nosecone onto the IOL Injector Handpiece and rotate the nosecone clock-wise until secured.

Step Five: Submerge the IOL Injector Handpiece, wrench and nosecone excluding the connector, in a container of room temperature sterile deionized 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 Six: Remove the nosecone and flush the length of the plunger, shown in Figure 8, and nosecone with room temperature sterile deionized water for a minimum of 5 seconds.

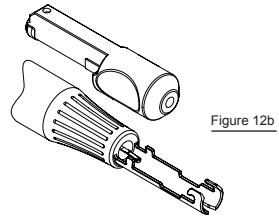
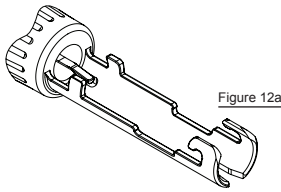
Step Seven: Using a soft bristle brush, brush the gap between the plunger/IOL Injector Handpiece (Fig. 9) and nosecone lumen (Fig. 10) under room temperature sterile deionized water for a minimum of 5 seconds.



Step Eight: Re-attach the nosecone onto the IOL Injector Handpiece by first aligning the index lines (Figure 11) then insert the nosecone onto the IOL Injector Handpiece then lock the nosecone by rotating the nosecone clockwise.



Step Nine: Ultrasonically clean the IOL Injector Handpiece with the nosecone/plunger attached (Figure 12a) and wrench separated from the IOL Injector Handpiece (Figure 12b) in room temperature sterile deionized water for a minimum of 5 minutes.



Step Ten: Thoroughly rinse the nosecone lumen with room temperature sterile deionized water for a minimum of 15 seconds.
 Step Eleven: Shake off excess fluids and dry the surfaces of IOL Injector Handpiece and wrench with a soft, clean, lint free non abrasive cloth.
 Step Twelve: Visually inspect to ensure the IOL Injector Handpiece is clean. Repeat the process as needed.

5. **STERILIZATION**

Sterilize (after Cleaning step is completed) AutoSert® IOL Injector in one of the configurations below using a steam sterilization cycle.

Configuration 1	Configuration 2
<ul style="list-style-type: none"> Plunger and nosecone attached to the IOL Injector Wrench detached from the IOL Injector 	<ul style="list-style-type: none"> Nosecone attached to the IOL Injector Wrench detached from the IOL Injector with the plunger inserted into wrench (Figure 14b)

The sterilization installation instruction 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 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, such as AAMI Standards or to your facility's standard procedures.

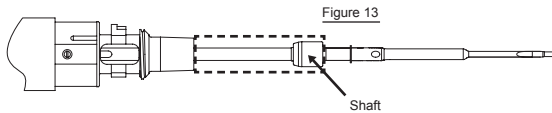
Note: Due to the potential for the accumulation of particulate and bio-burden residues in their sterilizer water reservoirs, it is the surgical facility's responsibility to properly maintain the equipment and their associated filters to ensure the introduction of steam into the IOL Injector Handpiece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

Table 2 - STERILIZATION TEMPERATURE AND TIME SETTINGS

STERILIZER TYPE	CONFIGURATION	MINIMUM TEMPERATURE	MINIMUM EXPOSURE TIME (MINUTES)	MINIMUM DRYING TIME (MINUTES)
Gravity Displacement	Wrapped	132° C (270° F)	15	15
Gravity Displacement	Unwrapped	132° C (270° F)	10	N/A
Pre-vacuum	Unwrapped	132° C (270° F)	4	N/A
Pre-vacuum	Wrapped	135° C (275° F)	3	16

6. **References:**

- 'ISO 17664: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- After sterilization, allow the components to cool and re-tighten the nosecone to the IOL Injector Handpiece.
- There are no specific limits for the time or conditions of storage.
- After transport to the driving console for the next use, refer to your driving console Operator's Manual for proper surgical setup.
- At the end of the last surgery of the day, while the IOL Injector is connected to the console, fully extend the IOL Injector Handpiece shaft (shown in Fig. 13). Remove the nosecone and wipe the exterior IOL Injector Handpiece shaft enclosed by the dotted line with a soft, clean, lint free non-abrasive cloth. After wiping, reinstall the nosecone then fully retract the IOL Injector Handpiece.



11. **PLUNGER REMOVAL/INSTALLATION:**

In the event the plunger is dislodged from the IOL Injector Handpiece, perform the following steps to attach the plunger into the IOL Injector Handpiece.

Step One: To remove the plunger, fully extend the Injector as shown in Figure 13a, then detach the plunger from the shaft by grasping the plunger, where indicated, and pull it away from the Injector. Fully retract the Injector.

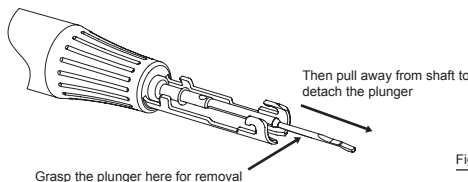
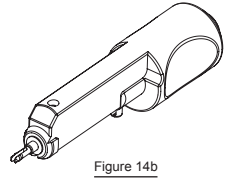
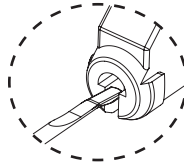
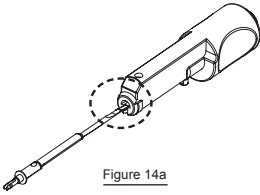
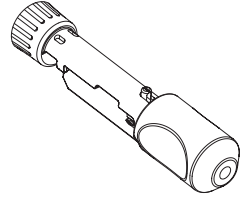
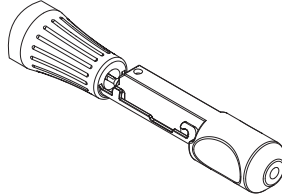
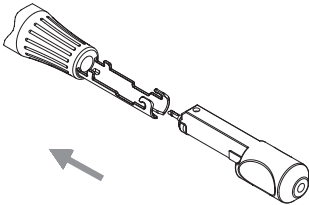


Figure 13a

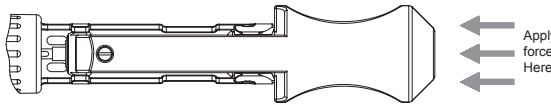
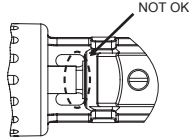
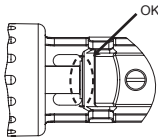
Step Two: As shown in Figures 14a and 14b, insert the plunger into the wrench.



Step Three: As shown in Figure 15a to 15c, install the wrench/plunger into the IOL Injector Handpiece nosecone. See driving console Operator's Manual on the LOAD PLUNGER function.



Step Four: Observe the plunger during the installation. A gap should not exist between shaft and plunger after installation (Figure 16a). If a gap exists between the plunger and shaft (Figure 16b), remove the plunger from the shaft and repeat plunger installation step and apply adequate force, using fingers, shown in Figure 16c during the load plunger process.



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

12. **PLUNGER REPLACEMENT DURING SURGERY:**

Perform the following step to replace the plunger during surgery.

Step One: If necessary, fully retract the Injector and remove the cartridge

Step Two: With the Injector fully extended and nosecone attached, detach the plunger from the shaft by grasping any portion of the plunger extending beyond the nosecone then pull it away from the Injector. Fully retract the Injector.

Step Three: Load the new plunger per instruction in step two to five in section 11 of this document.

Definitions for symbols that may appear on product labels:

	CONSULT INSTRUCTIONS FOR USE		SERIAL NUMBER		CATALOG NUMBER
	MANUFACTURER		DATE OF MANUFACTURE		
	DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

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

0123

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FORT WORTH, TX 76134-2099 USA
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