



Directions for Use with Automated Cleaning and Sterilization Process

Royale Injector (AE-9045)

Caution: In the USA, federal law restricts any sale of this device except by the order of a physician.

Description:

The injector is an autoclavable, reusable handpiece made of titanium; intended to assist in implanting foldable intraocular lenses during normal small incision cataract surgery. It is designed to incorporate cartridges for foldable intraocular lenses. Once the cartridge is loaded into the injector body, the lens will be pushed out of the cartridge and delivered to the desired position, by depressing the piston.

Please follow the manufacturer's instructions for use of the cartridges and the IOL's. IOL's and cartridges are shown below, please check Alcon package insert for current diopter limitations, if any.

Alcon AcrySof[®] lens models which can be used with the injector include: SA30AT, SA60AT, SN60AT, SA60D3, SN60D3 and SN60WF.

1. Monarch[®] II cartridge type B suitable for: SN60AT, SA60AT, SA60D3 and SN60D3
2. Monarch[®] II cartridge type C suitable for: SA30AT, SA60AT (+6 to +27 diopter), SN60AT (+6 to +27 diopter), SN60WF (+6 to +30 diopter), SN60D3 (+10 to +27 diopter) and SA60D3 (+10 to +27 diopter)

Read the operating and maintenance instructions before you use the injector for the first time, and ensure that before the first, as well as with each further use, that the handpiece is undamaged. Do not use the handpiece if it appears damaged. The handpiece SHOULD NOT be disassembled under any circumstances. Doing so may result in malfunctioning of the instrument. ASICO will not be liable for any damage caused in the event the handpiece is disassembled. All warranty on the device will also be voided.

The reusable injector is provided non sterile and has to be sterilized before initial use. For cleaning instructions please refer to 'Handling Before and After Each Use'.

Operating and Maintenance Instructions

Handling Before Initial Use (Sterilization)

The product must be sterilized by the user prior to initial use. The user must adhere to the applicable sterilization regulations. Sterility assurance is the responsibility of the user. Refer to the recommended sterilization procedure provided in this document.

Handling Before and After Each Use:

The injector should be ultrasonically cleaned at least once per surgery day. Immediately after each surgery the injector should be cleaned manually or in an automated system and sterilized.

1. Ultrasonic Cleaning Before Use:

1. Rinse the injector vigorously with de-ionized water.
2. Clean the injector with a mild soap solution and gently scrub it with a soft bristle brush paying particular attention to the inside and the plunger of the instrument.
3. Thoroughly rinse and flush the injector vigorously with de-ionized water for 10 seconds.

4. To reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the ultrasound cleaner after each and every use.
5. The use of ultrasound baths and strong cleaning fluids (alkalis pH > 9 or acids pH < 5) can reduce the life span of products. The manufacturer accepts no liability what so ever in such cases.
6. Ultrasonically clean the injector in a **vertical** position for a minimum of 5 minutes using de-ionized water. Retract the plunger completely to protect the plunger tip during the cleaning. For the use of the ultrasonic cleaning bath follow the instructions provided by the manufacturer.
7. **Always use the protective cap**
8. After ultrasonic cleaning thoroughly rinse and flush the injector under running water and do a final rinsing by using de-ionized water.
9. Dry the injector with a lint-free cloth before returning to storage

2. Automated Cleaning After Use :

Validation: The validation of the cleaning and sterilization procedures has been performed by ASICO with representative instruments according to the following parameters: The parameters applied have to be validated by your hospital.

Procedure:

Prepare: Miele Desinfektor 67735CD per Operator's Manual.

Note: Use de-ionized water only.

Required materials:

- Detergent: neodisher * mediclean forte
*neodisher is a registered trademark of Chemische Fabrik Dr. Weigert GmbH&Co
- Neutralizer: neodisher Z 0,1% to 0,2%
- Tray: Regular Miele rack
- Ophthalmologic rack: Regular Miele ophthalmic rack
- Water jet pistol: Selecta

2.1. Manually pre-cleaning:

- Rinse for 10 seconds with a water jet pistol. Use cold tap water (<30°C).
- Brush intensively with a toothbrush or another available brush in a water bath with cold tap water (<30°C) by moving the pin in the guiding tube for 10 seconds in cold tap water (<30°C).
- Rinse again for 10 seconds with a water jet pistol using cold tap water (<30°C).

2.2. Reprocessing in a washer disinfector (without disinfection step):

The injectors should be positioned in a tray with the open side of the injector facing up. The tray should be positioned in the middle level of the ophthalmologic rack.

Set detergent dispenser to 0,5% ml/liter (Reference Miele Desinfektor 67735CD Operator's Manual)

Set neutralizer dispenser to 0,1 – 0,2 % ml/liter(Reference Miele Desinfektor 67735CD Operator's Manual)
(it also depends about the filling quantity of the machine and the available water quality)

Program Labwasher to have the following cleaning cycle

Vario TD program

- a. 4 min pre-washing with cold water (<30° C)
- b. Emptying
- c. 6 min washing with 0.5 % neodisher Mediclean forte at 55°C
- d. Emptying
- e. 3 min neutralisation with warm water (>40°C) or use neodisher-Z 0.1% to 0.2 %
- f. Emptying
- g. 2 min intermediate rinsing with warm water (>40°C)
- h. Emptying
- i. Dry at >100°C

After emptying add the protective cap to the injector tip and remove the injector to prepare for sterilization.

Please note this process will be invalid if enzymatic cleaning solutions are used. Improper rinsing and removal of enzymatics and detergents from Ophthalmic Surgical Instrumentation have been linked to Toxic Anterior Segment Syndrome.

3. Alternative: Manual cleaning after use:

The following cleaning instructions provide a method for effectively cleaning the Royale handpiece. Although not recommended, the materials of construction of the Royale handpiece are compatible with enzymatic cleaners and detergents. However, improper rinsing and removal of enzymatics and detergents from Ophthalmic Surgical Instrumentation have been linked to Toxic Anterior Segment Syndrome.

1. Clean the handpiece immediately before first use and after each subsequent use, immediately after every surgery rinse the injector with de-ionized water.
2. After each use, advance the plunger and wipe clean. Hold the instrument vertically to allow water to drain after cleaning.
3. Soak the handpiece for at least 5 minutes in water. Do not allow viscoelastics or debris from surgery to dry on the instrumentation prior to cleaning.
4. **Flush the hand piece with water forced through a syringe for at least 5 seconds. Then use a small, soft brush and brush the handpiece for at least 5 seconds to remove Viscoelastic and cellular debris on the injector. The use of hydrogen peroxide may cause discoloration of the hand piece.**
5. Clean the injector with a mild soap solution and gently scrub it with a soft bristle brush paying particular attention to the inside and the plunger of the instrument. Touch the plunger very softly otherwise it may bend.
6. **Add the protective cap to the Injector tip and ultrasonically clean for at least 5 minutes in water. Retract the plunger completely to protect the plunger tip during the cleaning.**
7. **Remove the Protective cap from the tip and perform a final, thorough rinsing of the handpiece with de-ionized water for at least 15 seconds. Hold the handpiece vertically to allow water to drain, and dry with a sterile, lint-free instrument wipe.**
8. Add the protection cap to the Injector tip.
9. Start the sterilization process for the injector.

4. Sterilization

1. The injector must be sterilized prior to initial use and prior to each use.

Method of Sterilization	Sterilizer Type	Sample Configuration	Temperature	Exposure Time (Minutes)
Steam	Gravity Displacement	Wrapped	134°C (270°F)	15.0
Flash	Gravity Displacement	Unwrapped	134°C (270°F)	15.0
Steam	Prevacuum	Wrapped	134°C (270°F)	4.0
Flash	Prevacuum	Unwrapped	134°C (270°F)	4.0

NOTE: Due to the variation found in steam autoclaves and the variable bioburden on instruments in clinical use, it is not possible for ASICO to provide specific parameters to ensure an adequate sterility assurance level. The appropriate parameters to be used and the sterility assurance level achieved with these parameters must be validated by each hospital. Please refer to current ANSI/AAMI standards or your hospital's standard procedures for the most appropriate specifications.

For steam sterilization, refer to ANSI/AAMI Standards and Recommended Practices Volume 1: Sterilization, Designation ST46-1993, Section 5.8.

For flash sterilization, refer to ANSI/AAMI Standard for Good Hospital Practice: Flash Sterilization – Steam Sterilization of Patient Care Items for Immediate Use. Designation ST37-1996, Section 5.4

The recommended method shall be a wrapped injector exposed to 270°F (134°C) in either a gravity displacement steam autoclave for eighteen (18) minutes or in a prevacuum steam autoclave for eighteen (18) minutes.

General Care Items:

- A new injector is provided non sterile and must be ultrasonically cleaned and sterilized prior to initial use.
- Ultrasonically clean the injector at least once per day.
- Do not allow blood, tissue or saline to dry on the injector.
- Do not use saline (balanced salt solution) for rinsing the instrument.
- Always use de-ionized water for final rinsing **and clean the injector always in a vertical position.**
- Do not use metal brushes or abrasive powders to clean the injector.
- **Always use the protection cap.**
- Store instrument in a protective tray.
- If any of the parts of the injector are lost, broken or damaged, send the instrument to ASICO LLC with 'Attention: Repairs' on the package.

Caution

- The tip of the injector should be protected with a protective cap immediately upon use. The injector should be cleaned as per DFU. Test the injector prior to surgery – if any problems occur please refer to page 7 for problems of functionality. **If the problem is not resolved do not use the product in surgery.**
- Direction of the injector tip in the eye, pressure applied to the plunger of the injector and the speed at which the plunger is moved are all at the discretion and control of the surgeon. **It is the responsibility of the surgeon to verify the proper condition of the injector prior to each use.**
- **The handpiece SHOULD NOT be disassembled under any circumstances. Doing so may result in malfunctioning of the instrument. ASICO will not be liable for any damage caused in the event the handpiece is disassembled. All warranty on the device will also be voided.**

Prior to Each Use:

Ensure the proper working of the injector:

The product must never be dismantled for cleaning and/or preparation for use.

Handling After Use

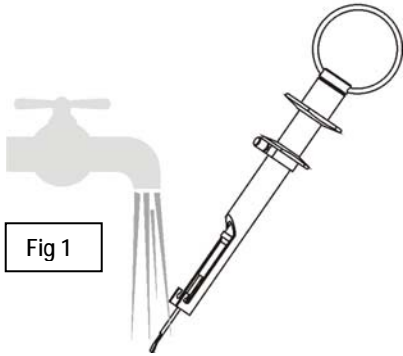


Fig 1

After each operation, the tip of the injector must be washed in cold water (**Fig 1**) and cleaned upright using ultrasound apparatus with the protective cap on. **Fig 2**



Fig 2

The injector should be positioned upright to dry. Then, position the protective casing according to the sketch, so that the tip is protected. **Fig 3**

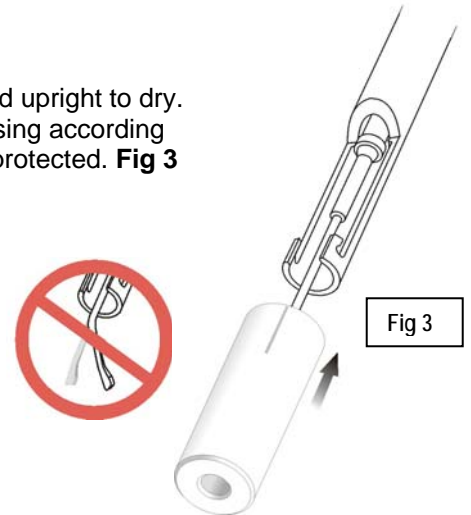


Fig 3

Replacing the rings

Carefully pull the rings apart and remove them (**Fig 4**)
Carefully pull the new rings apart and place both ends in the corresponding slots.

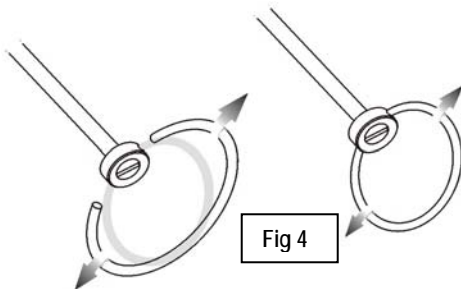


Fig 4

Loading and Implanting the Lens:

	<p>1. Fill the entrance of the cartridge with Viscoelasticum*. Use room temperature (20 to 23 °C, 68 to 73 °F) viscoelastic (Alcon® VISCOAT® Ophthalmic Viscosurgical Device or other qualified viscoelastic).</p> <p>* For the validation of this process ASICO used VISCOAT (Alcon®) as a Viscoelasticum</p>
	<p>2. Use the Forceps to horizontally, pick up the lens out of the container. Pushing the leading Haptic against the cartridge, bend it over the optic. Use holding forceps to grasp the lens by the optic and place the lens anterior side up into the back of the cartridge as shown.</p>
	<p>3. The lens should be inserted until it is approximately half way into the back of the cartridge.</p>
	<p>4. Lift the trailing haptic over the optic and place it on the anterior surface of the optic.</p>
	<p>5. Load the cartridge as shown, 1) insert the cartridge into the handpiece and 2) fully slide the cartridge forward into the handpiece slot.</p>
	<p>6. Advance the plunger to position the leading edge of the lens optic at the parting line of the cone and nozzle tip (dwell position). Delivery into the capsular bag is performed by advancing the plunger in one continuous motion, advancing the lens from the dwell position fully through the cartridge lumen and into the capsular bag. The delivery should be performed in approximately six seconds.</p>

Problems of functionality

Injector plunger does not move smoothly	Clean the injector as per DFU
Injector plunger moves rapidly	Send the injector for service to ASICO office
The tip is damaged	Send the injector for service to ASICO office

Please send the reports immediately to ASICO. In case you are in Europe please send the reports to mdi Europa with a copy to ASICO. We will investigate the complaint and respond to you.

<p>Address : ASICO LLC 26 Plaza Drive Westmont, IL 60506 USA Tel: 630 986 8032 Fax: 630 986 0065</p>	<p>mdi Europa GmbH Langenhagener Str. 71 30855 Hannover-Langenhagen Germany Tel: +49 - 511 -3908 9530 Fax: +49 - 511 -3908 9539</p>
--	---

Caution: In the USA, federal law restricts any sale of this device except by the order of a physician.

Ordering Information

Contact the ASICO head office by phone 1-630-986-8032, fax 1-630-986-0065, or email sales@asico.com.

Customer service

The manufacturer guarantees a repair service and/or a replacement/repair of the original products.

Identification

All products are identified by an article and batch number. All expedited products are registered by the supplier, and all repair or inspection work that is carried out by the manufacturer is documented in writing. This system ensures traceability of all repairs or inspections completed on the products dating back to initial delivery.

Traceability

All products that are expedited by ASICO LLC, can be comprehensively traced at any time.

Manufactured by:

ASICO LLC
26 Plaza Drive
Westmont, IL 60559
U.S.A
Tel.: 630-986-8032
Fax: 630-986-0065

Produced by:

SDI
Mattenstrasse 11
CH-255 Brugg
Switzerland
Tel.: +41 32 374 77 00
Fax: +41-32 331 52 57

Authorized EU Representative:

mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany
Tel: +49 - 511 -3908 9530
Fax: +49 -511 -3908 9539