

## Directions for Use with Cleaning and Sterilization Royale III Spring Injector AE-9036LSP (Spring Injector)

Caution: Federal (U.S.A) law restricts the sale of this device to or by order of a physician in the U.S.A

### Description:

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

**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 product combinations qualified for use with the ASICO Royale III Spring Injector AE-9036LSP (Listed by row)**

IOL Name	IOL Model	Diopter Range	Monarch Cartridge	Viscoelastic
AcrySof UVA Single-Piece	SA60AT	6.0 to 40.0	B	VISCOAT PROVISC DISCOVISC
AcrySof BLF Single-Piece	SN60AT	6.0 to 40.0	B	
AcrySof UVA Single-Piece	SA60AT	6.0 to 27.0	C	
AcrySof BLF Single-Piece	SN60AT	6.0 to 27.0	C	
AcrySof UVA Single-Piece	SA60AT	6.0 to 24.0	D	
AcrySof BLF Single-Piece	SN60AT	6.0 to 24.0	D	
AcrySof PanOptix	TFNT00	6.0 to 27.0	D	VISCOAT PROVISC DISCOVISC HEALON
AcrySof PanOptix	TFNT00	6.0 to 30.0	C	
AcrySof PanOptix	TFNT00	6.0 to 34.0	B	
AcrySof PanOptix Toric	TFNT20	6.0 to 27.0	D	
AcrySof PanOptix Toric	TFNT20	6.0 to 30.0	C	
AcrySof PanOptix Toric	TFNT20	6.0 to 34.0	B	
AcrySof PanOptix Toric	TFNT30-T60	6.0 to 25.0	D	
AcrySof PanOptix Toric	TFNT30-T60	6.0 to 30.0	C	
AcrySof PanOptix Toric	TFNT30-T60	6.0 to 34.0	B	
AcrySof Single-Piece Aspheric	SN60WF	6.0 to 27.0	D	VISCOAT PROVISC DISCOVISC
AcrySof Single-Piece Aspheric	SN60WF	6.0 to 30.0	C	VISCOAT PROVISC DISCOVISC
AcrySof Single-Piece Aspheric	SN60WF	6.0 to 27.0	D	HEALON

 **Please read before use!**

Read the operating and maintenance instructions before you use the injector for the first time. Inspect the injector before each use to ensure it is not damaged.

## **WARNINGS -**

- **INSPECTION & FUNCTIONAL CHECK** - It is very important to carefully examine each instrument for breaks, cracks, or malfunctions before each use. Do not use the handpiece if it appears damaged.
- Instruments shall not be reused after they have been used on patients with or suspected of having Creutzfeldt-Jakob-Disease (CJD), Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) and shall be properly destroyed due to the risk of cross contamination.
- Do not use “Immediate Use” (Flash) steam cycle unless it is for emergency reprocessing,
- Do not use autoclave steam cycle temperature exceeding 137°C (280°F).
- The handpiece **SHOULD NOT** be disassembled under any circumstances. Doing so may result in a malfunctioning instrument. The manufacturer 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 **NONSTERILE** and **MUST** be cleaned and sterilized before initial use.

## **Operating and maintenance instructions (per ISO 17664-1)**

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### **Handling before initial use (Cleaning & Sterilization)**

This **instrument** must be cleaned and sterilized by the user prior to initial use. Refer to the recommended cleaning and sterilization procedures below.

#### **Validation:**

The validation of the cleaning and sterilization procedures in these instructions has been performed with representative instruments according to ISO 17664-1. Any deviation from these instructions at the point of use should be evaluated for risk to process effectiveness. Process effectiveness is dependent upon many factors, and it is only possible to provide common guidance for instrument cleaning and sterilization.

### **Personnel and Personal Protection Equipment (PPE)**

All persons using these instruments should be knowledgeable, trained, and qualified in their use, handling, and care. It is the responsibility of the user facility to ensure instrument reprocessing is performed by trained personnel using equipment, materials, and personal protection equipment (PPE) that will achieve desired results.

### **Reprocessing Limitations**

The limitation of the numbers of reprocessing procedures is determined by the function / wear and handling of the device. **DO NOT USE DAMAGED INSTRUMENTS** – Do not attempt to make repairs. Service and repairs should be performed by qualified persons only. Katena has an instrument repair program, please call for further information. In case of damage, the device should be cleaned & sterilized before sending back to the manufacturer for repair.

## **CLEANING:**

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The following instrument cleaning instructions provide a method for effectively cleaning the Royale Injector handpiece.

### **User Preparation immediately after each use**

Instrument cleaning and rinsing must be done immediately after each use for best results. Failure to clean promptly may result in dried debris that can complicate cleaning and compromise sterilization. To avoid dried debris, instruments should be kept moist until cleaning process can take place. The maximum time between completion of surgery and instrument cleaning process shall be less than 60 minutes. Remove gross soiling by submerging the instrument into cold water (<40°C) immediately after use. Do not use a fixating detergent or hot water (>40°C) as this can cause fixation of residue which may influence the end result of the reprocessing process.

### **Pre-cleaning**

Soak instruments in 1% Liquinox (Alconox Inc., pH  $\cong$  8.5)\* detergent for 10 min at 40°C. Scrub the inside and outside of the instruments with a suitable soft bristled nylon brush until all visible soil is removed. Thoroughly flush instrument and all inside channels / lumens. Rinse the injector in a vertical position to allow water to thoroughly rinse inside channels. \*Other near-neutral pH, alkaline cleaning agents may be used; however, users should validate user facility process and materials.

## **Manual Cleaning**

### **Ultrasonic cleaning**

Two separate ultrasonic cleaners (42 kHz, 360W) should be used for cleaning and for rinsing (see table below); this reduces potential of cross contamination. To reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the ultrasound cleaner after each use.

1. Check and retighten any fittings that may have vibrated loose.
2. Place the protective cap onto instrument,
3. Place the instrument into the ultrasonic bath using silicone finger mats to minimize contact and potential damage of delicate instrument tips. Ensure that the instruments are fully immersed in the cleaning solution.
4. Follow the processing stages indicated in the table below:

Phase	Time	Temperature
Pre-Soak in 1% Liquinox without Vibration (Ultrasonic Cleaner Unit 1)	5 minutes	60 °C / 140 °F
Ultrasonic Clean in 1% Liquinox (Ultrasonic Cleaner Unit 1)	10 minutes	60 °C / 140 °F
Warm Tap Water Rinse	2 minutes	47 °C / 117 °F
Ultrasonic Rinse in Distilled Water (Ultrasonic Cleaner Unit 2)	10 minutes	60 °C / 140 °F

5. After the ultrasonic rinse phase, thoroughly flush lumens and all inside channels/lumens with distilled water (with instrument actuated/opened). Rinse the injector in a vertical position to allow water to thoroughly rinse inside channels.
6. After rinsing, dry instruments carefully and completely with lint free surgical wipe or blow dry with filtered compressed air (include inside channels/lumens and inaccessible areas) to prepare for storage and/or sterilization.
7. Inspect instrument to ensure all visible soil has been removed and functionally test instrument for smooth operation.

### **Automated Cleaning:**

Prepare Miele disinfectant G 7735 CD per Operator's Manual.

Place instruments into Miele auto disinfectant tray designed for Ophthalmic instruments

Note: Use de-ionized water only.

### **Vario TD program**

Main wash procedure at 55°C for 5 minutes with 0.5% solution of cleaner (Deconex Power Zyme, Borer) or a cleaning agent with cleaning in alkaline environment preferred

- 2-minute pre-washing with cold water
- Drain
- 5-minute washing at 55°C with 0.5% solution of cleaner (Deconex Power Zyme, Borer); pH value of 1% detergent solution is 7.8 (source; Borer)
- Drain
- 3 minutes Neutralizing with cold water
- Drain
- 2 minutes rinsing with cold water
- Drain

### **Inspection**

Inspect instruments for overall cleanliness and instrument functionally prior to the next step, drying. If necessary, repeat cleaning process until instruments are visibly clean. If instrument, was damaged or found to be not functional please take steps to return instrument to manufacturer, after sterilization, for proper repair.


### **Drying**

After removing instrument from the automated washer thoroughly dry the instrument using a lint-free cloth to manually remove water droplets on all surfaces of the injector and its protective cap. Blow dry the injector cavities and the protective cap by using sterile compressed air for at least 5 mins to flush out completely any remaining fluids. Replace the protection cap to the injector tip for storage, transport and/or sterilization.

## Sterilization

 **WARNING:** The injector must be sterilized prior to each use and before initial use.

Steam Cycle	Preparation	Temperature	Exposure Time (Minimum Time in Minutes)	Drying Time (Minimum Time in Minutes)
Gravity Displacement	Wrapped	132 °C / 270 °F	15	30
Dynamic Air Removal **	Wrapped	132 °C / 270 °F	4	20
Dynamic Air Removal	Wrapped	134 °C / 273 °F	3	20
Immediate-Use (Flash) (Gravity or Dynamic Air Removal)	Unwrapped	132 °C / 270 °F	3	N/A

 **WARNING - Do not use** “Immediate Use” (Flash) steam cycle unless it is for emergency reprocessing, \*\* Pre-Vacuum or Steam Flush Pressure Pulse (SFPP) is classified as Dynamic Air Removal Steam Cycle by AAMI. The above parameters/cycles have been validated in accordance with ISO 17664 Sterilization of medical devices and ISO 14937 Sterilization of health care products standards. If other methods, times and temperatures are used; the user should validate these methods.

## General Care Items:

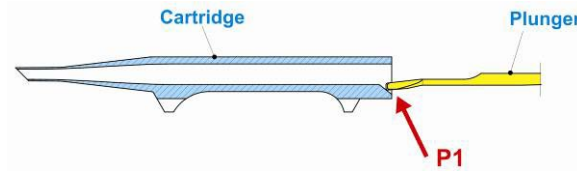
- A new injector is provided nonsterile and must be cleaned and sterilized prior to initial use.
- Ultrasonically clean the injector after every use.
- Do not allow surgical debris (blood, tissue, etc.) or saline to dry on the injector.
- Do not use saline (balanced salt solution) for rinsing the instrument
- Always use de-ionized water for final rinsing and always clean the injector in a vertical position to allow water to thoroughly rinse inside channels.
- Do not use metal brushes or abrasive powders to clean the injector
- Always use the protective cap when storing the injector.
- Delicate microsurgical instruments must be handled with great care when being transported, cleaned, treated, sterilized, and stored. Store the instruments in instrument trays with silicone finger mats that are specifically designed for storage and transport.
- There are no specific requirements for storage temperature and humidity.
- If any of the parts of the injector are lost, broken or damaged, send the instrument to Katena by obtaining an RMA number from Katena. Send to Attention: Repairs with RMA number on the package.

## **Caution**

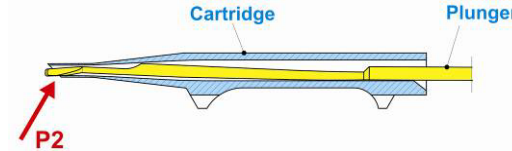
- The tip of the injector should be protected with a protective cap immediately after use.
- Test the injector for smooth and full range of plunger motion after cleaning and prior to surgery – if any problems occur, please refer to “Problems of Functionality” below. **If the problem is not resolved do 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. The manufacturer will not be liable for any damage caused in the event the handpiece is disassembled. All warranty on the device will also be voided.**

## Plunger Operation

When the plunger is advanced, the contact of the ramp on the cartridge will be felt by the surgeon as an initial resistance (P1)



When the plunger exits the cartridge after implanting the IOL- the surgeon will feel the same (P2).



This resistance does not impact the implanting process  
The delivery should be performed in approximately six seconds

## Thumb Ring Position

To prevent any impediment to smooth implantation, please ensure that the thumb is secured within the thumb ring as seen in Figure 1 below. Please make sure the thumb ring is not pointing downwards as seen in Figure 2 as it will prevent a smooth implantation.

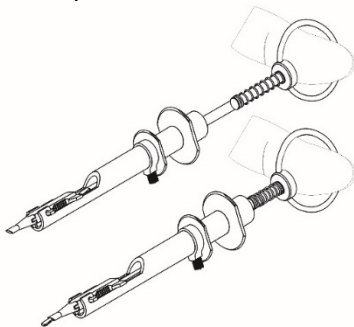


Figure 1

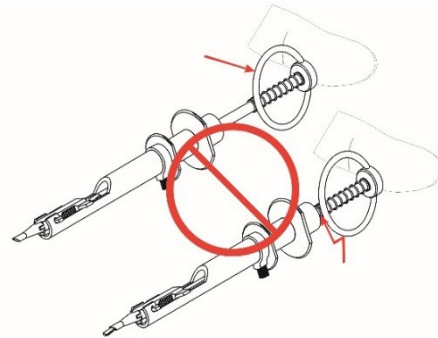


Figure 2

## Prior to each use:

Ensure smooth and full range of injector plunger motion prior to each surgery.  
The product must never be dismantled for cleaning and/or preparation for use.  
Note: Exception - thumb ring can be removed from the plunger for cleaning (see below, Figure 6):


## Handling after use

After each surgery, the tip of the injector must be thoroughly rinsed in cold water (Figure 3) to prevent surgical debris from drying on the instrument. Rinse the injector in a vertical position to allow water to thoroughly rinse inside channels. The maximum time between completion of surgery and the instrument cleaning process shall be less than 60 mins.



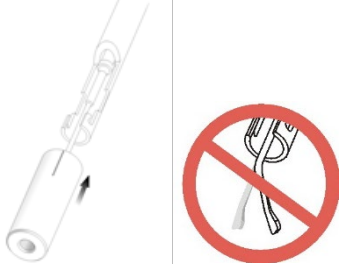
Figure 3

Always use the protective cap apparatus so that the tip is protected. (Figure 4)



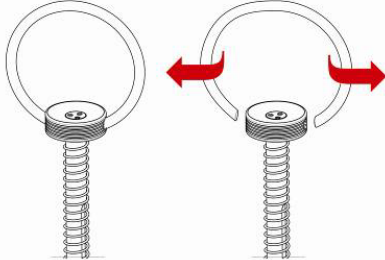
**Figure 4**

The injector should be positioned upright to dry. Then, position the protective casing according to the sketch (Figure 5)



**Figure 5**

Removal and Re-assembling of the thumb ring  
Carefully pull the old rings apart and remove them (Figure 6)  
Carefully pull the new rings apart and place both ends in the corresponding slots.



**Figure 6**

## **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 Katena
The tip is damaged	Send the injector for service to Katena

## **Disposal**

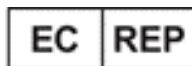
Follow country-specific laws and regulations for proper disposal, including procedures for disposal of sharps and/or biohazardous material.

## **Regulatory Information**

Any serious incident that occurs in relation to this product should be reported to the manufacturer, and to the healthcare authority of the country in which the incident occurred.



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