

## GENERAL INSTRUCTIONS FOR CARE, CLEANING AND STERILIZATION

We at RUMEX guarantee our instruments against manufacturing defects, but the lifespan of reusable instruments lies within proper handling and care. To help your instruments preserve its initial conditions, we strongly recommend you to read the instructions below carefully before use.

A common misconception that "stainless steel" or "titanium" have extreme durability and are indestructible is in need of correction: these metals still might be affected by chemical, mechanical, thermal attacks and etc.

However, if you are aware of metal characteristics and understand how to handle them, the lifespan of the instruments may be enlarged.

A particular care should be taken after microsurgical instruments as they have very delicate working tips.

These instructions being general recommendations, cleaning guidelines of the solutions and equipment manufacturer and your institution, especially those regarding temperature, time of exposure and concentration, should be observed.

### INSPECTION

It is essential that the instrument is inspected before use. Please conduct this inspection under a microscope or magnification lens. If a problem is detected, notify us immediately. Once the instrument is examined and accepted, IT SHOULD BE CLEANED BEFORE PLACING IT IN THE STERILIZATION TRAY.

#### Stage 1: DESINFECTION

##### *Soaking*

1. For effective cleaning of instruments it is recommended to start pre-treatment as soon as possible, no later than 30 minutes after surgery is completed. The cleaning/disinfection should be carried out within the next two hours.

2. Use **distilled/demineralized water** to prepare the working solution.

3. Water temperature should be as specified in the manufacturer's instructions. Water layer above the instruments should be no less than 1 cm (.39 inches).

4. Make sure the disinfectant is free of **aldehydes, glutaraldehydes**. Stainless steel tools must not be exposed for a long time to media which can promote corrosion (for example, chloride or iodine ions). This also applies to the vapors of the substances mentioned.

**Do not immerse stainless steel instruments in an isotonic solution (e.g. physiological saline solution) as stress corrosion cracking and pitting may occur.**

5. Carry out disinfection according to the mode, indicated in the instructions of product manufacturer. Disinfectant solution should not foam.

6. Instruments with hinges and joints must be handled open.

### ***Rinsing***

1. Place the products in a container with distilled/demineralized water and wash off the remaining solution with thorough rinsing of all lumens for 5 minutes.
2. Then rinse with distilled water.

### **Stage 2: PRE-STERILIZATION CLEANING**

Never skip this cleaning stage as residues on instruments such as care agents and the ones of package materials may form stains and depositions in course of sterilization.

### **MANUAL CLEANING**

It is imperative to follow the rules:

1. As much moisture as possible must be eliminated from all instrument's parts since moisture promotes corrosion.
2. Only detergents and cleaners specially designed for use on surgical stainless steel or titanium instruments are acceptable for use in the cleaning process. Cleaning guidelines of the solution manufacturer and your institution should be observed.
3. Thorough cleaning immediately after use is essential for the longevity of the instrument. We recommend that the established surgical instrument cleaning procedures of your institution be followed using these instructions as a guideline.
4. The cleaning/disinfecting solutions should be exchanged daily.

### ***Steps of manual cleaning in solution***

1. Use **distilled/demineralized water** to prepare the working solution. Use chemicals with non-protein-fixing process and with/without anti-microbial effects. Prepare the solution according to the manufacturer's instructions.
2. The detachable products should be disassembled prior to be immersed into the solution. Products with locks should be immersed open with preliminary several working movements done inside the solution for its better penetration into hard-to-reach areas of the instruments. Make sure that there are no air bubbles in the cavities and all the inner surfaces are affected.
3. Soak according to the mode, indicated in the instructions of product manufacturer. **We recommend soaking instruments in a detergent with pH level between 6-9 for 10 min at 40 °C/104 °F. Disinfection agent should be aldehyde-free.**
4. Wash each product with a brush or a cotton-gauze sponge. Use a syringe to wash the lumens of the instruments. Remove all macroscopically visible dirt.

**WARNING! Never use abrasive powders or steel wool to remove stubborn stains – these can damage the superfine finish of an instrument and can actually help cause corrosion of stainless instruments.**

5. Place the products in a container with **distilled/demineralized water** and wash off the remaining solution with thorough rinsing of all lumens for 5 minutes. Repeat the procedure if necessary.
6. Then rinse with distilled water to prevent spotting. Instruments with lumens should be flushed out at least five times at the beginning and at the end of the cleaning (10 ml/0.34 fl.oz) distilled or deionized water to be used each time)).

7. Dry instruments carefully before sterilization with a hot air blower or lint-free cloth. Compressed air is preferred. Sterile compressed air should be used to insufflate cavities of the instruments.
8. The cleaning results must be visually inspected. The instruments must be visibly clean.

## **ULTRASONIC CLEANING**

An ultrasonic cleaner could also be used in the instrument cleaning process, but not as the sole cleaning method. The instrument should, at the very least, be flushed with distilled water prior to being placed into the equipment. A five to ten minutes cycle in the ultrasonic cleaner should be sufficient.

The following rules should be followed:

1. Fill the bath with room temperature water. **The temperature higher than 45 °C (113 °F) can lead to encrustation due to denaturation of the protein.**
2. Use detergent to soak the instruments. A **distilled/demineralized water** should be used to prepare the working solution. Make it according to the manufacturer's instructions. Newly prepared cleaning solutions require degassing prior to the first use.
3. Place instruments next to each other without stacking them.
4. When carrying out ultrasonic cleaning, all parameters specified by the manufacturer of the cleaning agent, such as exposure time and concentration, must be observed.
5. The use of ultrasonic baths and strong cleaning fluids (alkaline pH > 9 or acid pH < 5) can shorten the lifespan of the products. Make sure the appropriate agents are chosen for performing the procedure.
6. Place the instruments on silicone fingertip mat, previously put into the ultrasonic bath with the solution. When using deionized water or cleaning solution fully submerge the instruments. Change the ultrasonic solution from ultrasound cleaner after each use.

**Instruments with hinges and joints must be handled open to minimize the obscured surface areas. The detachable products should be disassembled prior to be immersed into the solution.**

**Products with locks should be immersed open with preliminary several working movements done inside the solution for its better penetration into hard-to-reach areas of the instruments.**

**Large instruments should be placed vertically in order not to create acoustic shadows.**

**WARNING! Special care should be taken to make certain that the tip of the instrument does not come into contact with the sides of the ultrasonic container, as this could damage the instrument.**

7. Carry out the cleaning procedure. Turn on ultrasonic bath. 3 minutes exposure at frequencies of around 35 kHz would be sufficient. Use soft bristled nylon brush to clean all the parts of the instrument, inside and outside.
8. Place the products in a container with **distilled/demineralized water** and wash off the remaining solution with thorough rinsing of all lumens for 5 minutes. Repeat the procedure if necessary.
9. Then rinse with distilled water to avoid water spots.
10. Dry the instruments before sterilization. A lint free cloth may be used for manual drying. Sterile compressed air should be used to insufflate cavities of the instruments.

**WARNING! DO NOT apply ultrasonic cleaning to diamond knives or instruments with delicate tips (e.g. vitreoretinal and microincisional tips, choppers, hooks, manipulators and etc.)**

## **AUTOMATED CLEANING**

1. Baskets in the form of nets with large holes are recommended to be used in special washing equipment. Be sure to use tool holders in the basket. Place instruments inside them without overloading.
2. Make sure that the large instruments don't obscure other ones and don't create spray shadows.
3. Sort tools by similar metals, avoiding contact between dissimilar ones. This type of contact can cause galvanic corrosion.
4. **Use a solution suitable for washing equipment with low foaming property.**
5. **Use a neutralizer, which not only neutralizes alkali, but also reduces surface tension of the liquid during drying, accelerating it, and minimizing stains.**
6. Set the program for the cleaning step. The chosen program must be suitable for the products and include the appropriate number of rinsing cycles.

For automated cleaning and disinfection thermal and chemo-thermal disinfection options are available. During **thermal processes** disinfection is carried out at temperatures above 65 °C (149°F). A reprocessing program may include the following steps:

1. Pre-wash with cold water to remove dirt and foaming substances.
2. Cleaning is performed with use of suitable pH-neutral or alkaline products added to hot or cold distilled water at temperatures of 40-60 °C (104-140 °F) for at least 5 minutes.
3. Intermediate rinse in hot or cold distilled water with acidic neutralizer added in order to facilitate the removal of remaining alkaline disinfectants.
4. Second intermediate rinse in hot or cold distilled water without additives should follow.
5. Thermal disinfection and final rinse is performed at temperatures of 80-95 °C (176-203 °F).
6. Drying might be carried out in washer/disinfector or in other possible ways. Sterile compressed air should be used to insufflate cavities of the instruments.

**Chemo-thermal disinfection** is suitable for heat-sensitive products. The temperature is limited in all rinsing stages and during the step of drying.

Cleaning is performed normally at < 65 °C (149 °F). A reprocessing program may include the following steps:

1. Pre-wash with cold water to remove dirt and foaming substances.
2. Cleaning is performed with use of suitable pH-neutral or alkaline products added to hot or cold distilled water at temperatures of 40-60 °C (104-140 °F) for at least 5 minutes.
3. Intermediate rinse in hot or cold distilled water followed by chemo-thermal disinfection. Special cleaning agent, compatible with machine-disinfection, is used.
4. Intermediate rinse in hot or cold distilled water without additives.
5. Final rinsing with distilled water at higher temperature.
7. Drying might be carried out in washer/disinfector or in other possible ways. Sterile compressed air should be used to insufflate cavities of the instruments.
8. The cleaning device must be regularly maintained, checked and validated in accordance with internal and manufacturer requirements.

9. When processing the ophthalmic instruments we recommend using the additional intermediate rinsing with water in the washing programs before the final rinse.

**Additional rinsing outside the washing equipment is not required.**

A combination of processing stages 1 and 2 is allowed.

**WARNING! Tools with blind holes, long narrow tips (e.g. tips, cannulas, handpieces and etc), hinges (3-joint instruments) need more attention during cleaning process. The temperature at all stages of the process should not exceed 170 °C (338 °F).**

Aspiration speculums require additional cleaning of silicone tubes prior to be sterilized.

First, soak the instrument in the soap solution at temperature of 50 °C (122 °F) and keep it there for 15 min. After that wash the instrument with brush and cotton/gauze pad. Take the instrument out of soap bath and wash it under streaming water for 3 min. Rinse the instrument with distilled or deionized water. Then attach a syringe filled with warm water into the luer lock and rinse the silicone tubes of the instrument. Finally, blow them with air by forcing one or two syringes full of air through the tubes.

#### **INSTRUMENT DETERGENTS AND/OR CLEANERS**

Only detergents and cleaners specially designed for use on surgical stainless steel or titanium instruments are acceptable for use in the cleaning process. The cleaning guidelines of the solution manufacturer and your institution should be observed.

#### **LUBRICATION**

Moving parts and working mechanisms of the Rumex instruments should be lubricated occasionally with a medical grade instrument lubricant (especially after an ultrasonic bath) to ensure the smooth operation of the working mechanism. The lubricant must be biocompatible, suitable for steam sterilization and vapor-permeable. No silicone oil should be applied. The paraffin/white oil based lubricants are allowed to be used.

After cleaning process let the instruments cool down to room temperature prior to their actuation, as otherwise metal abrasion may develop when the details of the tools rub against each other. This may destroy the instruments' functionality.

The recommended directions of the instrument lubricant manufacturer and your institution should be observed.

#### **Stage 3: STERILIZATION**

Surgical instruments should be stored at room temperature in dry rooms in the sterilizing trays of proper size and lined with soft silicone mats. Instruments should not touch each other. We recommend using protective tips made of soft silicone tubing of the proper size and thickness. Do not use rubber or plastic protective tips, as they can melt during autoclaving and cause damage of instruments.

**WARNING!** Never store the instruments close to the chemicals.

Stainless steel and titanium instruments can be sterilized via steam autoclaving, chemical disinfectants, ethylene oxide gas, or even dry hot air. Gas and dry chemical sterilization are the best methods for stainless steel instruments, but it takes a lengthy time period to accomplish the desired result. The most practical method of sterilization is heat or steam, which require less time, however, these methods can

be damaging to delicate instruments. Please, be sure that you and the members of your staff have read and understood the instructions supplied by the manufacturer of your particular sterilizer.

### STERILIZATION CYCLES

Finally, the instrument should be sterilized prior to the next surgical procedure.

**WARNING! Only clean and disinfected products can be sterilized.**

**For lumen instruments (e.g. tips, cannulas, handpieces) the gravity procedure is not suitable!**

RUMEX instruments can be sterilized using any of the following methods:

<b>100% ETO cycles</b>	
<i>Concentration ETO:</i>	850±50mg/l
<i>Temperature:</i>	37-47 °C (99-117 °F)
<i>Exposure time:</i>	3-4 hours
<i>Humidity:</i>	70% RH minimum
<i>Drying Cycle:</i>	1 hour

**WARNING! ETO method is not recommended for diamond knives sterilization.**

<b>Steam Autoclaving</b>		
<i>Sterilizer Type:</i>	Gravity Displacement	Prevacuum
<i>Sample Configuration:</i>	wrapped	wrapped
<i>Temperature °C :</i>	132 °C	132 °C
<i>Temperature °F:</i>	270 °F	270 °F
<i>Exposure time:</i>	34 minutes	3 minutes
<i>Drying Cycle:</i>	min. 10 minutes	min. 10 minutes

<b>'Flash' Autoclaving</b>		
<i>Sterilizer Type:</i>	Gravity Displacement	Prevacuum
<i>Sample Configuration:</i>	unwrapped	unwrapped
<i>Temperature °C :</i>	132 °C	132 °C
<i>Temperature °F:</i>	270 °F	270 °F
<i>Exposure time:</i>	10 minutes	3 minutes
<i>Drying Cycle:</i>	min. 10 minutes	min. 10 minutes

**WARNING! The sterilization steam must not contain any impurities.**

**Gas plasma sterilization** is not recommended as delicate instruments might be physically damaged when exposed to low pressure.

The above-mentioned sterilization cycles represent the industry standards and should be capable of producing a sterile device. Due to variations in sterilization equipment and device bioburden in clinical use, RUMEX International Co. is not able to provide specific cycle parameters. It is the responsibility of each user to perform the validation and verification of the sterilization cycle to ensure an adequate sterility assurance level for our products.

**WARNING!** Follow the guidelines of the processing times. The rapid sterilization process should be reserved for emergency processing only and should not be used for routine instrument sterilization. Longer sterilization period and higher temperatures can lead to premature aging of instruments.

## RECOMMENDED PRODUCTS FOR CARE AND CLEANING

Product name, Manufacturer	Description	Composition	Processing stage	Compatibility
<b>SEKUSEPT Activ</b> , Ecolab Deutschland GmbH	<b>Disinfectant</b> for automatic and manual processing of tools	≥ 30% oxygen-based bleaching agents; <5% non-ionic surfactants, phosphonates; 50% sodium perborate monohydrate; 25% tetraacetythylenediamine; active antimicrobial components, nonionic surfactants, corrosion inhibitor; <b>pH of 2% solution: 7.4-8.4</b>	Disinfection; Pre-sterilization cleaning; Sterilization	Compatible. Discoloration of metal, residual detergent or water film formation may occur.
<b>Neodisher MediClean Forte</b> , Dr. Weigert GmbH & Co.	<b>Detergent</b> for automatic and manual cleaning of surgical instruments. Prevents reprecipitation of protein residues.	< 5% non-ionic and anionic surfactants; enzymes; <b>pH: 10.4-10.8</b>	Pre-sterilization cleaning	Compatible. Discoloration of metal, residual detergent or water film formation may occur.
<b>Neodisher MediKlar</b> , Dr. Weigert GmbH & Co.	<b>Rinser</b> for automatic and manual cleaning of surgical instruments. Recommended for use with MediClean forte. Prevents reprecipitation of protein residues.	< 5% anionic surfactants, polycarboxylates; 5 - 15% non-ionic surfactants also preservatives; 2-octyl-2H-isothiazol-3-one, a mixture of: 5-Chloro-2-methyl-2h-isothiazol-3-one [EC-no. 247-500-7] and 2-Methyl-2H-isothiazol-3-one; <b>pH: 5.9-6.9</b>	Pre-sterilization cleaning	Compatible
<b>ERIZYME</b> , KiiltoClean FARMOS Oy	<b>Detergent</b> for hand treatment, washer disinfectors and ultrasonic treatment	non-ionic surfactants (< 5%); amphoteric surfactants (< 5%); complexing agent (5-15%); monopropylene glycol (15-30%); anti-foaming agent; enzymes; <b>pH: 7.5</b>	Pre-sterilization cleaning	Compatible

<b>ERISAN OXY+</b> , KiiltoClean FARMOS Oy	<b>Disinfectant</b> in disposable sachets	sodium percarbonate 30 - <50%; citric acid 15 - <30%; tartaric acid 5 - <15%; <b>pH: 5.9-6.9</b>	Disinfection; Pre- sterilization cleaning; Sterilization	Compatible
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**Fully demineralized water for rinsing and correct loading must be used to prevent staining!**

The color of titanium instruments may change due to development of different properties of oxide layers. Such discoloration does not bring a safety risk, as well as water stains on the surface of the instruments. They don't affect the biocompatibility, functionality, and lifetime of the instruments. However, discoloration may affect the visual inspection of the tools (e.g. determining residual dirt). To prevent the color change of titanium instruments, use only neutral or mild alkaline cleaning agents. While using them, do not exceed a temperature of 70 °C (158 °F).

**AT THE END OF THE SURGICAL DAY**

Instruments should be washed clean of all residues, dried and inspected after each use. Be sure to inspect every microsurgical instrument at the end of your surgical day. Please conduct this inspection under a microscope or magnification lens. If a damaged instrument is detected, repair or replace it. Washing, drying and inspecting the instrument under magnification helps to ensure that the instrument is kept in proper condition for the next surgical procedure.