

NEW INSTRUMENTS

+ Instruments Handling Manual



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RUMEX HANDLING MANUAL

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WHY MORE THAN 17 000 IN 70 COUNTRIES RUMEX?

By offering multiple material options, we can meet the specific demands of always be confident in terms of our instruments durability and our proactive process. Our technological process allows us to provide surprisingly high prices.

Enjoy The Advantage of Titanium: NO IMPURITIES in RUMEX Titanium

RUMEX titanium purity is higher than 99.9% that allows you to use all the advantages of the material.

UNIQUE STAINLESS STEEL



Hardened & Durable

Maraging stainless steel EP853 alloy is designed especially for space and missile industry. Therefore, RUMEX steel instruments are so durable and last for years.



Extremely Sharp

We use steel to make tools with perfect cutting properties. Unique steel alloy and special sharpening technology make RUMEX steel instruments' dissecting elements stay sharp 40% longer than the tips of other materials.



Matted to Protect You

RUMEX steel instruments are microscope glare protected by additional matting. It protects doctors' eyes and prevents more than 20% errors during the surgery.



Medical Steel

Biocompatible, hypoallergenic, medically approved.



DOCTORS CHOOSE

all our customers. You can approach to the surgery quality at affordable



Excellent Chemical Resistance - NO CORROSION

RUMEX titanium alloys VT6, VT14, VT 16 are produced for aerospace and defence industry. Titanium never rusts, withstands high temperature processing, and doesn't require further drying.

This titanium allows chemical sterilization with any acceptable reagents.



45% Lighter Than Steel

Titanium is a light material. Light weight of an instrument is very important during long surgeries under a microscope demanding the high precision of manipulations.



The Most Durable Material

The strength of titanium reduces the risk of bending. A bullet may shatter a diamond with a medium amount of force applied but does not make a single imprint on titanium.



Medical Titanium

Biocompatible, hypoallergenic, medically approved

SOLID TITANIUM INSTRUMENTS

EASY CLEANING

The detachement of tip from the handle makes cleaning and sterilization easy and convenient



EASY INDENTIFICATION

Unique color code system enables easy identification of tips by fuction and size



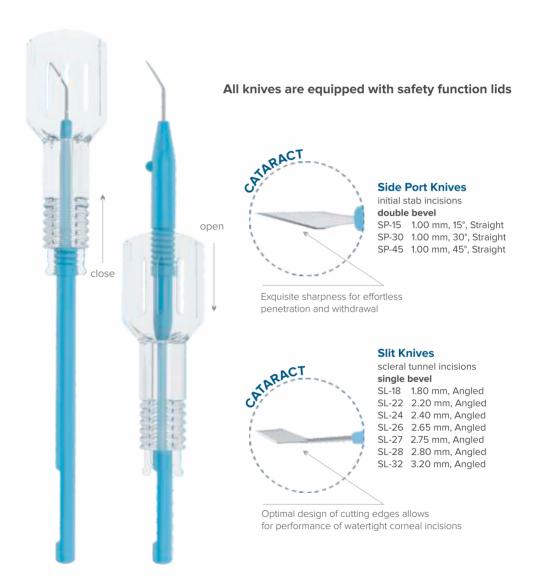
70% LONGER LIFESPAN

of a tool due to the modular system



RUMEX Universal Handles can be used with our interchangeable tips

HIGH PRECISION DISPOSABLE KNIVES WITH SAFETY SYSTEM



DISPOSABLE KNIVES



Clear Corneal Knives

clear cornea incisions
double bevel
CC-22 2.20 mm, Angled
CC-24 2.40 mm, Angled
CC-26 2.65 mm, Angled

CC-27 2.75 mm, Angled CC-30 3.00 mm, Angled

Ultra-thin profile reduces penetration force and contributes to re-epitalization



Clear Corneal Knives with Depth Indicators

tunnel incisions

double bevel

CCD-22 2.20 mm, Angled CCD-24 2.40 mm, Angled CCD-26 2.65 mm, Angled CCD-27 2.75 mm, Angled

Depth indicators of 1.50, 1.75, 2.00 mm for controlled diving



Crescent Knives

lamellar dissections/flap formation single bevel CR-20 2.00 mm, Angled

Facet-free blade for smooth flap formation



MVR Knives

posterior segment penetration/ side port incisions

multifacet

VRS-19 19 Ga, Straight VRS-20 20 Ga, Straight VRS-23 23 Ga, Straight VRA-19 19 Ga, Angled VRA-20 20 Ga, Angled VRA-23 23 Ga, Angled

Promotes safe and easy sclerotomy for vitreoretinal procedures

Other sizes are available upon request



DISPOSABLE INSTRUMENTS

MOST POPULAR INSTRUMENTS FOR CATARACT AND VITREORETINAL SURGERY ARE NOW AVAILABLE FOR A SINGLE USE!



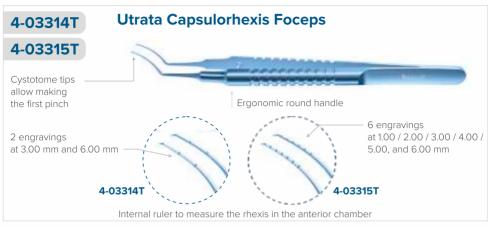
DISPOSABLE INSTRUMENTS

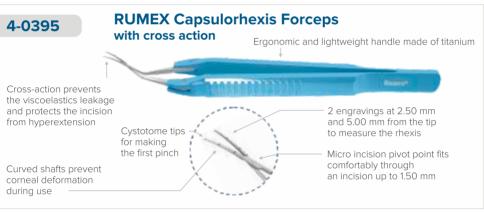


DISPOSABLE INSTRUMENTS



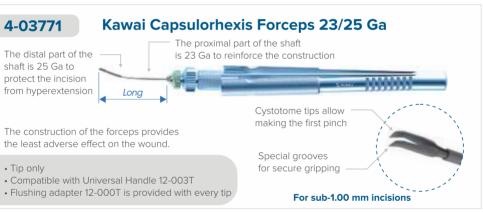














Lesieur Hydrochopper 20 Ga 7-0634/1 This unique design of a tip is efficient for chopping as well as manipulating Nagahara type the nucleus without endangering the chopper

posterior capsule.

Lesieur Hydrochopper is created specifically for Bimanual Microphaco.

> The end opening port provides maximum irrigation



Designed in cooperation with Gilles Lesieur, M.D., France

The dual oval sideports 0.50×0.70 mm provide supplemental irrigation when the front opening is overfilled

For sub-1.00 mm incisions

7-0811 **Stodulka Enhanced Irrigation** Handpiece 21 Ga Recommended for bimanual microphaco and femtosecond cataract surgery Two ports on side 0.50 x 1.00 mm for optimal irrigation Bullet-shaped tip helps to insert the instrument



Designed in cooperation with Pavel Stodulka M.D., Czech Republic

For sub-1.00 mm incisions

7-142

Holz Capsule Custodian

The leading edge and the abrasive bottom surface remove posterior capsular debris

This capsule polisher is designed to simultaneously clean the posterior capsule and anterior capsule after the cortex removal.

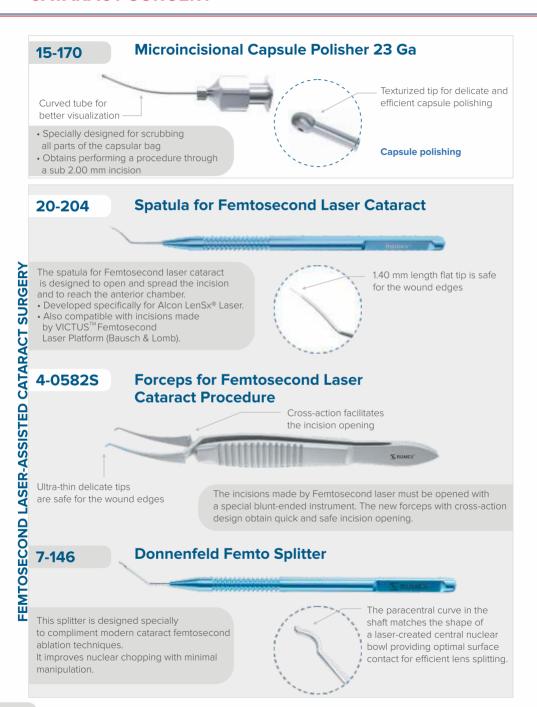




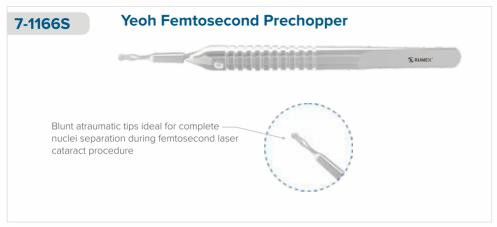
Designed in cooperation with Huck Holz, M.D., USA

The dorsal ridge scrapes cellular remnants from the under surface of the anterior capsule rim

Capsule polishing



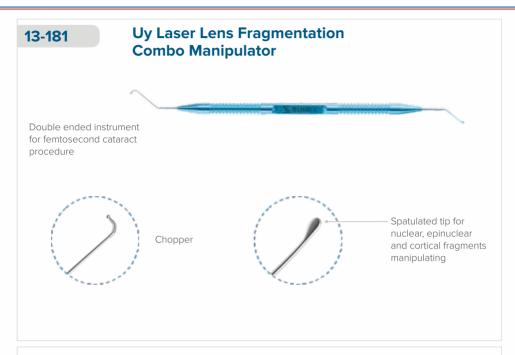
FEMTOSECOND CATARACT SURGERY







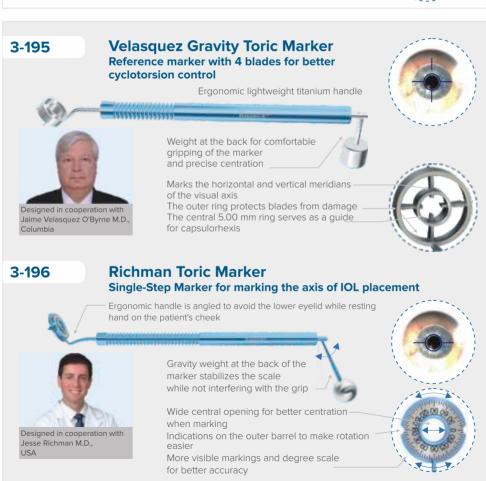
FEMTOSECOND CATARACT SURGERY



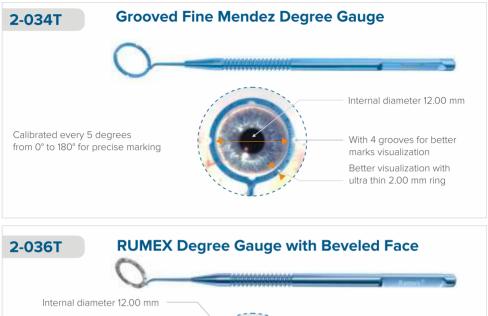
Quick installation and removal thanks to self-locking mechanism Blades are specially curved to accommodate Femtosecond laser docking station

REFRACTIVE SURGERY





MARKERS & GAUGES



- Calibrated every 5 degrees from 0° to 180° for precise marking
- Beveled face minimizes the microscope glare
- Markings are clearly visible providing high accuracy
- External diameter 16.00 mm



Degree marks are close to the cornea

3-091T

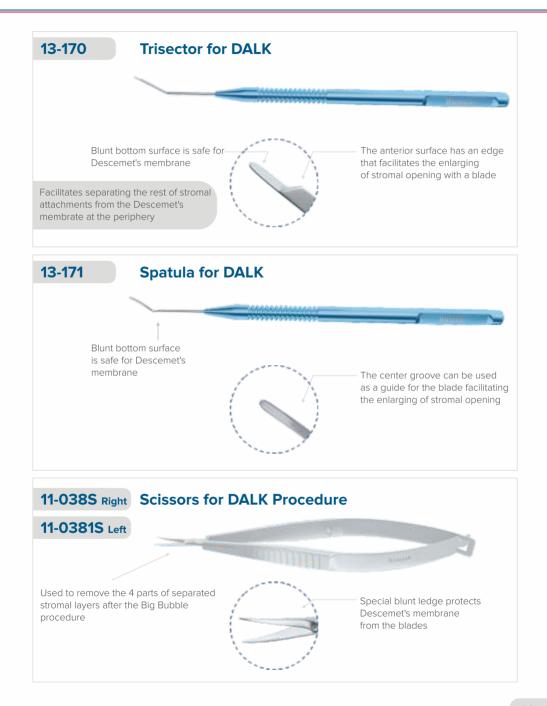
Bores Axis Marker

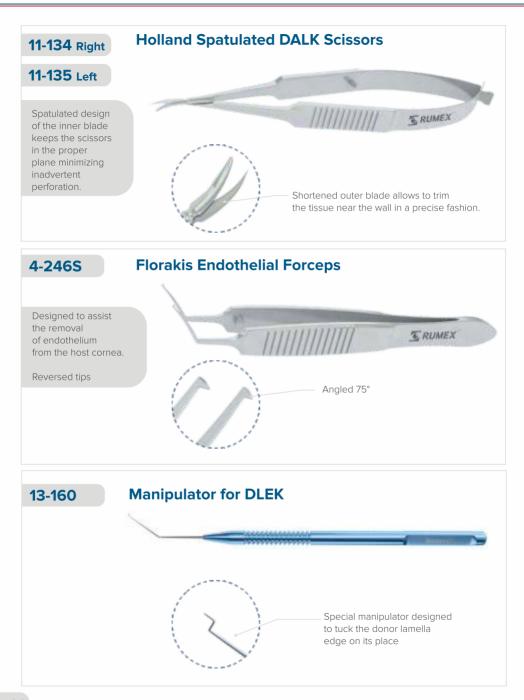


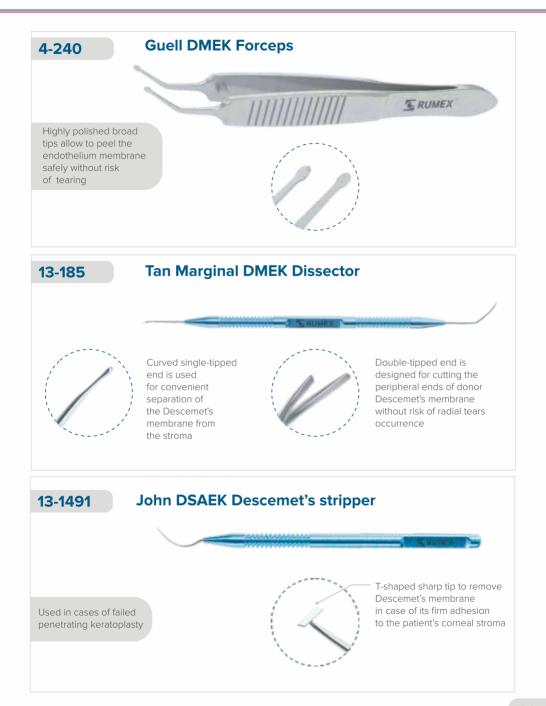
The optimal placement of Toric IOL is essential, because a slight misalignment leads to error of correction, loss of image clarity and it is impossible to resolve the problem without re-operation.

A pair of instruments (degree gauge and Bores axis marker) helps to produce accurate marks of the desired axis for IOL placement.

This instrument is specially designed for 2-034T and 2-036T for precisely marking the axis.









DRY EYE SYNDROME

Physical expression of blocked glands has the goal of removing the obstruction and emptying the inflamed gland





4-1913T

Compressing Lid Forceps



• This instrument obtains quick and delicate meibum expression by equally compressing the eyelid from both the internal and external sides.

4-1245

Compressing Lid Forceps with atraumatic rollers



The forceps are designed for mechanical meibum removal from lids

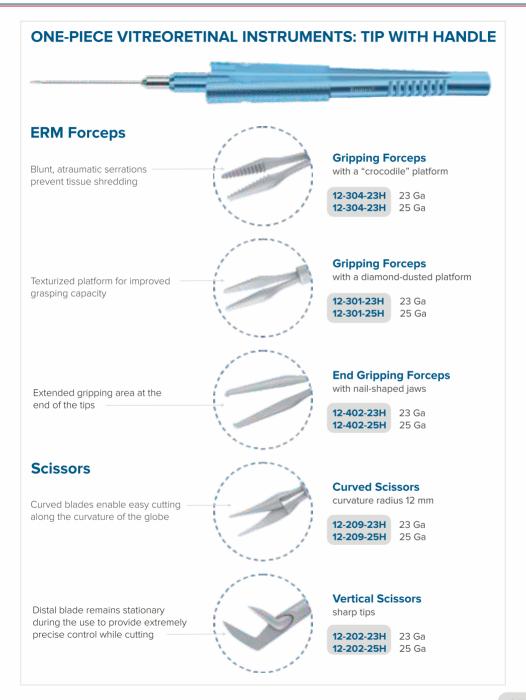


Texturized rollers are safe for the conjuctiva and obtain quick and delicate meibum expression by equally squeezing the eyelid from its base to the margin.

VITREORETINAL INSTRUMENTS



VITREORETINAL INSTRUMENTS



RUMEX HANDLING MANUAL

Handling

All micro surgical instruments, especially their most delicate parts such as tips, blades etc., should be handled very carefully during transportation, cleaning, use, sterilization and storage.

- Instruments should be stored in a dry place at room temperature
- Keep the instruments in the tray they were sterilized in. Do not move them from one tray to another after sterilization if possible.
- Instruments in a tray should not get in contact with each other.
- Use sterilizing trays with fingertip mats to firmly hold the instruments inside the tray to avoid their movement and damage during storage or handling.
- Diamond knives should be sterilized and stored in separate trays.
- Put tip guards on tips of the instruments to protect them during storage. Take care not to damage delicate tips during this procedure. Tip guards are clear for visual control in order to preserve the tips integrity and perforated and thus suit for sterilization. They are designed to enhance sterilization and protection for instruments during the sterilization procedure. The flow-through vents allow full-impact sterilization yet they protect tips and edges from breaking and chipping. We recommend to change tip guards frequently to ensure better protection.

| RUMEX Ref Number | Dimensions (WxH), mm | Dimensions (WxH), inch |
|--|-------------------------|------------------------|
| 21-2011.50, 21-2011.5 | 1.50 × 19.10 | 0.06 x 0.75 |
| 21-2012.50, 21-2012.5 | 2.00 × 19.10 | 0.08 x 0.75 |
| 21-2013.50, 21-2013.5 | 2.80 x 19.10 | 0.11 x 0.75 |
| 21-2014.50, 21-2014.5 | 3.30 x 25.40 | 0.13 × 1.00 |
| 21-2015.50, 21-2015.5 | 4.80 x 25.40 | 0.19 × 1.00 |
| 21-2017.50, 21-2017.5 | 1.50 × 9.70 | 0.06 x 0.38 |
| 21-2018.50, 21-2018.5 | 2.00 x 16.00 | 0.08 x 0.63 |
| 21-2019.50, 21-2019.5 | 3.30 x 25.40 | 0.13 × 1.00 |
| 21-2037.50, 21-2037.5 | 1.50 x 9.70 | 0.06 x 0.38 |
| 21-2011 21-2012 21-2013 21-2014 | 21-2015 21-2017 21-2018 | 21-2019 |

RUMEX recommends using marking tapes for more comfortable instruments handling. We offer precut tapes to make the application easier. Various colors are available. This product is waterproof, detergent resistant and may be sterilized both by washing and by steam. It will help to make your instruments individual, to identify them easily during surgery/sterilization, and to avoid their misuse.

| RUMEX Ref Number | Туре | COLOR |
|----------------------|--------------|-------|
| 21-4005.5, 21-4005.1 | Purple | |
| 21-4008.5, 21-4008.1 | Yellow | |
| 21-4009.5, 21-4009.1 | Orange | |
| 21-4010.5, 21-4010.1 | Red | |
| 21-4012.5, 21-4012.1 | Green | |
| 21-4017.5, 21-4017.1 | Zebra Yellow | |
| 21-4019.5, 21-4019.1 | Zebra Red | |
| 21-4021.5, 21-4021.1 | Zebra Green | |
| 21-4023.5, 21-4023.1 | Zebra Brown | |
| 21-4025.5, 21-4025.1 | Zebra Purple | |

RUMEX HANDLING MANUAL. STERILIZATION

Sterilization

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

| 100 % ETO cycles | | | |
|-------------------|----------------|--|--|
| Concentration ETO | 850±50mg/l | | |
| Temperature | 37 °C − 47 °C | | |
| Exposure time | 3–4 hours | | |
| Humidity | 70% RH minimum | | |



| Steam Autoclaving | | | "Flash" Autoclaving | |
|-------------------|------------------------------------|------------------------------------|----------------------|------------------|
| Sterilizer Type | Gravity Displacement | Prevacuum | Gravity Displacement | Prevacuum |
| Sample Config. | wrapped | wrapped | unwrapped | unwrapped |
| Temperature | 121 °C – 123 °C 250 °F – 253 °F | 132 °C – 135 °C 270 °F – 275 °F | 132 °C 270 °F | 132 °C 270 °F |
| Exposure time | 15 to 30 minutes | 3 to 4 minutes | 3 minutes | 3 minutes |

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. Do not use sterilization as a sole method of instruments reprocessing. Make sure to complete all previous steps thoroughly described above. Keep in mind that flash sterilization is meant for immediate-use of instrument and should not substitute the standard reprocessing routine. Make weekly check of steam autoclave error-free performance and carry out regular maintenance of sterilizer according to manufacturer instructions.

Repairs

Since most RUMEX instruments are delicate and precise and are handmade by a qualified and specially trained technician, never try to make repairs yourself. Repair of fine and delicate instruments used for eye surgery requires special skills and knowledge otherwise it can end up with damage to the instrument. To be sure that repair of your instruments is in hands of professionals, follow RUMEX Repair Program. Contact us for further details.

RUMEX HANDLING MANUAL. VITREO & MICS

Care & cleaning of vitreoretinal and microincisional instruments

RUMEX Instruments (ophthalmic scissors and forceps for vitreoretinal and microincisional surgery) are designed for various applications in ophthalmic surgery.

It is essential that the instrument is cleaned and sterilized before initial use and after each surgery, following as outlined in this instruction brochure.

Care and handling

The intraocular tips have a delicate precision mechanism inside. Intraocular fluids will enter this mechanism during surgery. If these fluids are not promptly and properly cleaned out, it will lead to corrosion or clogs and the possibility of instrument malfunction. Proteins may also accumulate inside of the mechanism. Ensure the cleaning procedure is implemented after each surgery — warranty shall not extend to instruments that have been improperly handled.

Cleaning



- 1. Unscrew the tip from the handle, then attach flushing adapter 12-000T.
- 2. Flush the tip with distilled or deionized water by connecting a syringe filled with water to adapter.
- 3. Flush the tip with alcohol. This will remove the water and facilitate drying.
- 4. Dry the tip by forcing one or two syringes full of air through tip. Pressurized air is recommended, as it flushes out debris and fluid more efficiently than syringe forced air. Thoroughly dry handle, tip and cup.
- 5. Force special thermoresistant instrument milk through the tip, as in No 2 above.
- 6. Dry with air as in No 4 above.
- 7. Handle should be soaked in distilled or deionized water for two minutes.
- 8. Dry with surgical sponge.
- 9. Lubricate joints in handle with instrument milk and work the mechanism by pressing the key.

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.

Ultrasonic cleaning equipment

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 in the ultrasonic cleaner. A five to ten minutes cycle in the ultrasonic cleaner should be sufficient. The instrument must be secured on a silicone finger mat during the ultrasonic cleaning procedure. 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.

Lubrication

Moving parts and working mechanisms of RUMEX instruments should be lubricated occasionally with a medical grade instrument lubricant (especially after an ultrasonic bath) to ensure smooth operation of the working mechanism. The recommended directions of the instrument lubricant manufacturer should be observed.

Storage

Surgical instruments should be stored in the sterilizing trays of proper size lined with soft silicone mats. Instruments should not touch each other. We recommend using safety protectors made of PTFE, which is autoclavable. RUMEX International Co. designed two models of safety protectors. The photos below illustrate the

way to fix a tip in a protector.

RUMEX HANDLING MANUAL. VITREO &MICS

Please insert the tips into PTFE protectors as shown in the picture:



- 1. Match the nut indicating the gauge with the hub, press the tip gently Make sure the branches do not touch the protector
- 2. The tips in their final position safely fixed by the protector.

Note: the tips should be sterilized in the protector to avoid any contact with other instruments.

Sterilization

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

| 100 % ETO cycles | | | |
|-------------------|----------------|--|--|
| Concentration ETO | 850±50mg/l | | |
| Temperature | 37 °C – 47 °C | | |
| Exposure time | 3–4 hours | | |
| Humidity | 70% RH minimum | | |

| | Steam Autoclaving | | "Flash" Autoclaving | |
|-----------------|------------------------------------|------------------------------------|----------------------|------------------|
| Sterilizer Type | Gravity Displacement | Prevacuum | Gravity Displacement | Prevacuum |
| Sample Config. | wrapped | wrapped | unwrapped | unwrapped |
| Temperature | 121 °C – 123 °C 250 °F – 253 °F | 132 °C – 135 °C 270 °F – 275 °F | 132 °C 270 °F | 132 °C 270 °F |
| Exposure time | 15 to 30 minutes | 3 to 4 minutes | 3 minutes | 3 minutes |

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 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 RUMEX products.

Inspection

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.

RUMEX HANDLING MANUAL, DIAMOND KNIVES

Application

Ophthalmic microsurgical knives with diamond blades are used for cutting and dissection of tissues during ophthalmic, microvascular, neurosurgical and plastic surgery.

Characteristics



The blades are made from natural diamonds and the handles are manufactured from titanium alloy. Blade size: The thickness of the diamond blade cutting edge should not exceed 0.2 μm .

The blade points must be edged with no visible chips (visible at 100x power magnification).

Device

The diamond knife consists of a titanium handle and a diamond blade. The handle is fit with a mechanism providing blade installation and its safe fixation in an operative and non-operative position. The construction of the knife can be changed in order to improve its usability.



Completed units

Each complete set must contain:

- diamond knife 1 unit
- sterilization tray 1 unit
- a label 1 unit
- care and cleaning instructions 1 unit

Usage instructions

- 1. The diamond blade is very fragile, therefore, each knife must to be handled, cleaned and stored delicately. Avoid blows or vibrations. Any contact of the blade with other instruments or materials should be avoided.
- 2. Before using a knife, make sure there are no chips on the cutting edge. A microscope with at least 100x power magnification should be used for the inspection.
- 3. When transporting diamond knives, the blades must be fully retracted into the handles (non-operative position). We recommend the knives to be kept and carried in sterilizing cases or with a teflon shipping clamp to avoid self-movement. When a knife is not in-use, its blade must be retracted into the handle and protected from mechanical damage.
- 4. Please rotate the movable part of the handle clockwise and fix the blade to set the knife in its operative position. The blade is to be set in the operative position for the surgical operation just prior to usage.
- 5. After usage, slightly pull the movable part of the handle downwards and rotate counter clockwise to return the blade into its non-operative position. To avoid accidental movements of the spring, please make sure the handle is fixed tightly. When a handle is fixed, a slight click will occur.
- 6. To install the knife with a micrometer, pull the protective cap down and rotate the bottom part of the handle (with a scale) downwards; the blade will appear. Customize the depth of the blade by screwing the handle; the scale marks will indicate the chosen depth. The scale increment is 0.5 mm. Rotate the handle upwards then put on the protective cap to set the knife in the initial non-operative position. The service life of the knife varies due to usage and handling. The blade must never be dropped or be in contact with foreign objects. The blade and the spring mechanism need to be handled with care and caution. Never disassemble the parts of a knife.

Presterilization treatment and sterilization

Presterilization treatment includes a number of procedures. Please remember to clean the blade and the handle, remove blood, tissue debris and viscoelastic directly after the operation.

Manual cleaning:

- use a syringe with distilled water to flush the instrument;
- dip the knife (blade retracted) into weak alkaline cleaning solution and keep for 60 minutes at a temperature of $+22^{\circ}\text{C}$ (+72°F);

RUMEX HANDLING MANUAL. DIAMOND KNIVES

- the handle of a knife can be cleaned with a soft brush;
- flush the instrument with flowing water for 30 seconds, then sluice with distilled water for other 30 seconds; the blade should be pointed down for flushing.



We recommend to use a diamond knife cleaning pack (21-602-1) for gentle cleaning of the blade. The pack contains three solutions that eliminate residual debris off the blade and prepare it for sterilization.

Diamond knives can be cleaned in an automatic washer designed for micro-surgical instruments. Please follow the manufacturer's instruction.

Ultrasonic cleaning:

- The cleaning machine should be filled with warm distilled water +70°C (+152°F).
- Immerse the knife with the retracted blade into the water. The sterilizing case with finger mats will reduce vibration and protect the blade.
- 2 to 3 min washing cycle should be enough to clean knife.
- Rinse the instrument with distilled water before steam sterilization.

Sterilization:

The knives should be sterilized before each surgical case by one of these methods:

| Sterilization Method | Type of Sterilization | Item | Temperature | Exposure Time |
|----------------------|-----------------------|-----------|-----------------|----------------------|
| Steam | Gravity Displacement | wrapped | +132°C (+270°F) | 30 min |
| Flash Process | Gravity Displacement | unwrapped | +132°C (+270°F) | 4 min |
| Steam | Prevacuum | wrapped | +132°C (+270°F) | 4 min |
| Flash Process | Prevacuum | unwrapped | +132°C (+270°F) | 4 min |

Make sure the blade is in its non-operative position (retracted) before sterilization; self-movement must be avoided. We recommend sterilizing the knives in trays specially designed for diamond knives as the silicone holders will help stabilize them. 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 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 and observe the instruction provided by the manufacturer of sterilization and cleaning units.

Storage



Diamond knives must be kept at a temperature from $\pm 10^{\circ}$ C to $\pm 35^{\circ}$ C ($\pm 50^{\circ}$ F to $\pm 95^{\circ}$ F) and relative air humidity at most 98%. Indoor air must not contain corrosive additive agents. The blade must be fully retracted into the handle (non-operative position). Self-movement must be avoided and blows or vibrations should be avoided.

Manufacturer's warranty

Manufacturer guarantees knives to be in accordance with the documentation when service and storage instructions are followed by the consumer. We provide a 2 year guarantee for the spring mechanism and titanium parts. The diamond blade can be re-sharpened or exchanged according to the after-sale service program.

Reception inspection

Incoming inspection is obligatory. It includes:

- visual examination of the package obtained (no mechanical damages are permitted);
- visual inspection of the knife (no mechanical damages such as cracks, chips, oxide scales etc. are permitted; all parts of the knife must be joined smoothly);
- blade must be set into the operating/non-operating position without jamming; it must be fixed easily. The knives you purchase are not sterile and should be sterilized before the first surgery. Please examine the blade before each operation and never use a knife in the event any defect is noticed. Damaged knives should be sent for resharpening or blade replacement.

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