VITREORETINAL / MICROINCISIONAL INSTRUMENTS / INSTRUCTION FOR USE

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 should be cleaned and sterilized before initial use and after each surgery following as outlined in this instruction brochure.

CARE AND HANDLING

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.

Make sure the cleaning procedure is implemented after each surgery - warranty shall not extend to instruments that have not been handled in the proper way.

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 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 thermostable 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. Rumex International Co suggests that each tip should be inserted into a safety protector and then placed into the cleaner.
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 the 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 teflon, which is autoclavable. Rumex International Co designed two models of safety protectors. The schemes below illustrate the way to fix a tip in a protector.

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 stainless steel 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: 37ºC - 47ºC
- Exposure time: 3-4 hours
- Humidity: 70% RH minimum

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<tr>
<th>Sterilizer Type</th>
<th>Gravity Displacement</th>
<th>Prevacuum</th>
<th>Gravity Displacement</th>
<th>Prevacuum</th>
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</thead>
<tbody>
<tr>
<td>Sample Configuration</td>
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<td>wrapped</td>
<td>unwrapped</td>
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<tr>
<td>Temperature</td>
<td>121ºC to 123ºC</td>
<td>132ºC to 135ºC</td>
<td>132ºC</td>
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<tr>
<td>Exposure time</td>
<td>15 to 30 minutes</td>
<td>3 to 4 minutes</td>
<td>3 minutes</td>
<td>3 minutes</td>
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Steam Autoclaving: 'Flash' Autoclaving:

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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.