INSTRUCTION FOR USE

EN

INSTRUMENTS – OPHTHALMIC VITREORETINAL AND MICROINCISION SURGERY

Care and Cleaning of Vitreoretinal & Microincision Instruments

INSTRUCTION FOR INITIAL USE

It is essential that the instrument be cleaned and sterilized before initial use following the procedures 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.

CLEANING

1.Unscrew the tip from the handle, then attach flushing adapter

2.Ultrasonically clean both parts, if possible.

3.Flush the tip with distilled or deionized water by connecting syringe filled with water to adapter.

4.Flush the tip with alcohol. This will remove the water and facilitate drying.

5.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.

6.Force special thermoresistant instrument milk through the tip, as in No 3 above.

7.Dry with air as in No 5 above.

8.Handle should be soaked in distilled or deionized water for two minutes.

9.Dry with surgical sponge.

10.Lubricate joints in handle with instrument milk and work the mechanism.

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 the Titan Medical 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 and your institution should be observed.

STORAGE AND STERILIZATION

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 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. 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. TITAN MEDICAL instruments can be sterilized using any of the following methods:

100% ETO cycles

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

Steam Autoclaving
Sterilizer Type: Gravity Displacement Prevacuum
Sample Config.: wrapped wrapped
Temperature: 121°C to 123 C / 132ºC to 135ºC
Exposure time: 15 to 30 minutes / 3 to 4 minutes

'Flash' Autoclaving
Sterilizer Type: Gravity Displacement Prevacuum
Sample Config.: unwrapped unwrapped
Temperature: 132°C-132°C
Exposure time: 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, TITAN MEDICAL 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.

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.

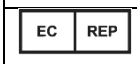
WARRANTY
Warranty period is 2 years from the date of sale. Manufacturer assumes obligation to repair or replace the defective instrument, if defect developed under normal use / storage of the instruments.

CLAIMS
Claims accompanied with this leaflet should be sent to Manufacturer's address:
Technicheskaya str., 120, 420054, Kazan, Russia
Phone/Fax: +7 (843) 277 07 78, +7 (843) 260 17 58

STATEMENT OF COMPLIANCE
This Instrument is in compliance with technical documentation, is ready for the supply, is fit for regular usage.

RECYCLING
Instruments are non-toxic, apyrogenic, recyclable. Before recycling instruments must be disinfected.

Used symbols:

	Manufacturer		Non-sterile
	EU Authorized Representative		Consult instructions for use
	Catalog number		Conformity mark
	Date of manufacture		Batch number
	Keep away from sunlight		Keep dry
	Humidity limitation		Temperature limitation
	Do not use if pack is opened or damaged		

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Date of issue: January 2021