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INSTRUCTIONS FOR USE

CLASS I REUSABLE OPHTHALMIC AND MICROSURGICAL DIAMOND KNIVES

CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by or on the order of a physician.

DESCRIPTION AND INTENDED USE

Ophthalmic and microsurgical diamond knives are **manual, non-powered, non-active, hand-held** instruments intended to make precise incisions in or surrounding the tissues during the surgical treatment, mitigation, prevention, and/or diagnosis. Diamond blades are made of natural diamonds.

GENERAL INFORMATION

- These INSTRUCTIONS FOR USE are designated only for persons with the required knowledge and training in a healthcare facility.
- Reusable surgical instruments supplied in a **non-sterile** state and are not to be used without being cleaned, disinfected and sterilized.
- All reprocessing instructions provided are general guidelines and will require validation by the end user at the point of use.
- Cleaning and Disinfection Processing Equipment should be certified and validated.
- Any surgical procedures should be performed by licensed healthcare professional trained and familiar with surgical techniques.

WARNINGS

- **Do not use ultrasonic cleaners as they may cause a damage to a diamond blade.**
- After every use of a diamond knife by the surgeon, the diamond blade should be retracted inside of the handle at all times. No knocking or rubbing of the blade with any metal parts of other instruments or any surgical fabrics (cotton cloth, cotton wool, etc.) during the operation or storage is allowed.
- Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage.
- Do not use acids, ammonia or strong chemicals, they do not affect the diamond blade but can damage the metal holder.
- Do not process diamond knives in an automated washer unless it has a delicate cycle.
- Long narrow cannulations and blind holes require particular attention during cleaning. Automated or manual flushing should be performed thoroughly during cleaning.
- Instruments must be flushed off without delay after surgery to remove tissue, blood, balanced salt solution and viscoelastic. Instruments must be obligatory and properly cleaned prior to sterilization. If not, the blood and residual debris will be baked on the surfaces. So, instruments could become damaged.
- Don't keep on instruments in salt or other aggressive solution for a long time. It could entail deterioration of surface, deformation of fine working parts and, finally, damage to instruments and reduce their lifetime.

- High alkaline solutions (pH>10) can cause damage to certain materials. Avoid using peroxide on titanium instruments or anodized surfaces to prevent discoloration.
- If the instrument was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.

PRECAUTIONS

- Delicate surgical instruments require special handling to prevent damage to the tips. Use caution during cleaning and sterilization.
- The diamond blades must never come into contact with other instruments. Special care must therefore be taken during surgical operations, to ensure that the blades do not come into contact with instruments such as forceps/tweezers or sharp surgical instruments
- Surgical instruments demand a close care and gentle handling. It's forbidden to fling, to drop instruments and to expose them to other mechanical effects.
- Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Saline, cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed 2 hours soaking in any solution.
- Working parts of instruments must be protected with special tips of suitable sizes at the time of storage. It's strongly prescribed to remove tips before sterilization.
- Each instrument is meant for a specific purpose. Improper use entails damage of instrument or reduced its lifetime.
- Do not use high acid (pH 4.0 or lower) or high alkaline (pH 12 or higher) products for disinfection. Neutral pH detergents are preferred.
- Titanium handles are color anodized and may lose their color over time through normal use and reprocessing. This has no any effect on instrument functionality.

LIMITATIONS ON REPROCESSING

Reprocessing according to the instructions provided has minimal effect on the instrument life and functionality. The useful life for metal surgical instruments is normally determined by wear and damage during intended use.

INSTRUCTIONS

Point of use

1. Immediately prior to use, expose the blade from the handle by pushing the proximal end of the handle in the direction of the handle barrel. For safety, retract the blade into the handle immediately after use.
2. Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
3. Ensure that diamond blades are not damaged before use. Damaged diamond scalpels should not be used. The blades can be re-sharpened.
4. The instrument should be immediately cleaned and dried after surgical use.

5. **After every use of a diamond scalpel, care must be taken to ensure that the blade is pulled back into the handle, using the pressure or bayonet mechanism.**

Containment and transport

1. The instruments should be reprocessed as soon as possible.
2. Always keep instruments in a suitable container to protect personnel from contamination during transport to the decontamination area.

Preparation for decontamination and cleaning

Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to Universal Precautions (OSHA) and your institution's policies.

Automated Cleaning

1. Follow the instructions of the washer/disinfector manufacturer using only DELICATE cycle.
2. Use only neutral pH cleaning solutions.
3. If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH cleaning solution may be necessary. To remove protein deposits Enzymatic cleaners should be used following the enzymatic cleaners' instructions. Brush the handle of the knife under running cold tap water with a soft nylon brush until it's visibly clean. The blade has to be retracted into the handle.
4. Rinse the blade under running cold tap water until all visible soil is removed. **Do not touch the blade with another object.**
5. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments. Secure by silicone brackets.
6. Process the instrument according to the conditions indicated below. The cleaning times and conditions may vary based on the amount of soiling present on the instrument.

Phase	Time	Temperature
Pre-Wash	3 min.	30°C (86°F)
Wash	10 min.	40°C (104°F)
Wash	5 min.	55°C (131°F)
Rinse	3 min.	30°C (86°F)
Draining		
Rinse	2 min.	30°C (86°F)
Draining		

7. During the entire automated cleaning process is the blade retracted in the handle.
8. Following processing carefully inspect the instrument for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing it should be reprocessed or manually cleaned.

Thermal Disinfection is not recommended for Diamond Knives.

Manual Cleaning

1. Inspect the instrument for damage or corrosion.
2. Brush the handle of the knife under running cold tap water with a soft nylon brush until it's visibly clean. **The blade has to be retracted into the handle.**
3. Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to

- flowing water. Depending on the size and extent of soiling of the instrument additional rinsing may be necessary.
- Place the diamond knife (with the blade retracted into the handle) into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution.
 - Gently scrub all surfaces of the instrument using a soft cleaning brush while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
 - If visible soil remains on the instrument, then repeat steps 1-5.
 - Rinse the diamond knife by holding it under cold running deionized water for at least 1 minute, rotating the instrument to expose all surfaces and cavities to flowing water. Depending on the size and extent of soiling of the instrument additional rinsing may be necessary.
 - Do not use ultrasonic cleaners as they may cause a damage to a diamond blade.

Manual disinfection

Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction, TITAN MEDICAL does not recommend the use of enzymatic or liquid chemical disinfectants or sterilant with manually cleaned instruments. See Automated Cleaning above for procedures for thermal disinfection of instruments in an automated washer/disinfectant.

Drying

Dry the instrument with a lint-free surgical wipe or blow the instrument dry with micro-filtered pressurized medical grade air. When blowing dry with pressurized air, ensure a secure grip on the instrument to avoid damage to the instrument from air pressure.

Maintenance, Inspection and Testing

Following cleaning, inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended. Carefully examine each surgical instrument for breaks, cracks or malfunctions before use. Check areas such as blades, points, ends, and stops as well as all moveable parts. A microscope should be used whenever possible. Lubricate all moving parts, lock boxes, joints and catches with a physiologically safe lubricant.

Packaging

The diamond knife should be stored in a sterilization container in the retracted position. Package the diamond knife in a suitable sterilization pouch or instrument tray lined with soft silicone mats. Protective tips made of soft silicone of the proper size and thickness are recommended. Instruments should not be touching each other.

Sterilization

- The diamond knife should be stored in a sterilization container in the retracted position.
- Use the sterilizer manufacturer's instructions for operation and loading of steam sterilizers. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels.
- Unless otherwise indicated in the Instruction for Use provided with the specific instrument, instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods: Pre-vacuum High Temperature Autoclave, Standard Gravity Autoclave, High Speed (Flash) Autoclave (WARNING: Flash sterilization processing should be reserved for

emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/ AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.)

- The tables below represent variations in sterilizer manufactures' recommendations for exposure at different temperatures per ANSI/AAMI ST79:2010 and A1:2010 & A2:2011. Other time and steam temperature cycles may also be used. However, the user must validate any deviation from the recommended time and temperature. Contact the manufacturer of your steam sterilizer to confirm appropriate temperatures and sterilization times.
- The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

Minimum cycle times for gravity-displacement steam sterilization cycles

Instruments:	Wrapped	Unwrapped
Exposure at 121°C (250°F)	30 min	
Exposure at 132°C (270°F)	15 min	3 min
Exposure at 135°C (275°F)	10 min	3 min
Drying	15-30 min	1 min

Minimum cycle times for dynamic-air-removal steam sterilization cycles

Instruments:	Wrapped	Unwrapped
Exposure at 132°C (270°F)	4 min	3 min
Exposure at 135°C (275°F)	3 min	3 min
Drying	16-30 min	N/A

Storage

Following sterilization processing, packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies. The indoor air shouldn't contain foreign substances which could cause corrosion.

Additional Information

For additional information regarding the reprocessing of ophthalmic instruments see:

- ASCRS/ASORN Special Report Recommendations for the cleaning and sterilization of intraocular cataract surgical equipment. J. Cataract Refract Surg. 2007; 33(6):1095-1100.
- ANSI/AAMI ST79:2010 and A1:2010 Comprehensive guide to steam sterilization and sterility assurance.

WARRANTY

All TITAN MEDICAL instruments, except custom ordered or custom etched instruments, are guaranteed to be free from defects in material and workmanship in all mechanical components when used for their intended surgical purpose. Any TITAN MEDICAL instrument that proves defective in workmanship or material will either be repaired or replaced, at TITAN MEDICAL discretion, without any charge.

Warranties are not valid for instruments and products that prove defective as a result of improper care and cleaning or misuse. Instruments or products that are damaged in the fire, flood, or other acts or disasters are also excluded from warranty. TITAN MEDICAL makes no other representations and warranties regarding its instruments or products, either express or implied. In no event will TITAN MEDICAL be liable for any incidental, special or exemplary damages

or loss of profits in connection with the use of TITAN MEDICAL instruments and products.

CLAIMS

Claims accompanied with this leaflet should be sent to Manufacturer's address: Južná trieda 119, 04001 Košice, Slovakia, E.U.
Phone/Fax: +421 55 230 31 74

STATEMENT OF COMPLIANCE

TITAN MEDICAL instruments are in compliance with technical documentation.

RECYCLING

Instruments are non-toxic, pyrogen-free, recyclable. Before recycling, instruments must be disinfected. The country-specific laws and regulations have to be observed for proper disposal.

USED SYMBOLS

	Manufacturer		Non-sterile
	Medical Device		Consult instructions for use
	Catalogue 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		CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.

MANUFACTURER CONTACT



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