Eye Technology

CARE & HANDLING INSTRUCTIONS FOR MICRO FORCEPS & SCISSORS

ADVICE FOR USE AND MAINTAINANCE

Devices

These instruments are not delivered sterile; and consequently it is necessary to clean and sterilise them properly before use.

These instructions are intended for use only by persons with the required specialist knowledge and training.

Warnings

- Instruments must be used for their specified purpose and incorrect use could damage the instrument.
- Our instruments are designed for use by ophthalmic surgeons, who have a good knowledge of their features and how they should be used. Any other use can compromise the safety of the user and the patient. It is the responsibility of the surgeon to choose the most suitable instrument for the surgical technique being performed, based on his experience and expertise.
- Before using, examine the instruments with special lenses. Do not use instruments that show problems or defects.
- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 140°C.
- Some sensitive materials (e.g. Aluminium) are damaged by high alkaline solutions (pH>10).
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.
- Do not use hydrogen peroxide on titanium instruments or on anodised surfaces in order to avoid decolourisation.

Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.

Limitations on Reprocessing

- Repeated processing has minimal effect on these instruments.
- End of life is normally determined by wear and damage in use.

Instructions

- Wherever possible, do not allow blood, debris or bodily fluids to dry on the instruments. For best results and to prolong the life of the medical device reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.
- Instruments should be flushed clean of all residues, dried and inspected after each use.
- It is imperative that as much moisture as possible is eliminated from all of the instrument crevices, since moisture promotes corrosion of the instrument.
- Flushing, drying and inspecting the instrument under magnification helps to ensure that the instrument is kept in optimum condition for the next surgical procedure.

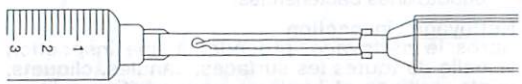
We recommend that you strictly follow the instructions given below in order to guarantee the longevity of your instruments. The life of an instrument depends on the care given to it whilst it is being used, cleaned and maintained.

Cleaning : Manual

The minimal cleaning routine recommended is as follows and should be done post procedure without delay.

Instruments should be both flushed and dried using the specially designed cleaning syringe in seven separate steps.

1) Fill the syringe with the appropriate substance (i.e. distilled water, alcohol or air), for maximum results Eye Technology recommends that Maximum Recovery Diluents is used. Insert the distal tip of the instrument into the silicone tubing at the distal tip of the syringe and flush the appropriate substance through the instrument by gently pressing the piston of the syringe (some pressure will be required to enter the mechanism). Repeat this process five times. Do not flush the instrument with any fluid that might leave residue, such as tap water or saline.



2) The instrument should be flushed thoroughly with distilled water.
3) Remove the distilled water by flushing the instrument through with 70% alcohol.
4) Blow one or two syringes of air through the instrument to remove most of the alcohol.
5) Clean the exterior of the instrument handle and shaft carefully with a moist surgical sponge (moist with Isopropyl alcohol). Avoid direct contact with the delicate tip of the instrument.
6) Wipe the exterior of the instrument dry.
7) After cleaning, the instrument should be carefully inspected under magnification for any possible wear or damage prior to sterilisation.

Cleaning : Automated

- Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.
- Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain.
- Protection caps are provided with the instruments to protect the delicate tips. These should remain on the instruments during automated cleaning, but ensure that the protection cap never obstructs the handle from remaining in its correct open position.
- Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets, and ensure instruments are not touching each other.
- Place instruments with concave surfaces facing down to prevent pooling of water.
- Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.
- Ensure that soft, high purity water controlled for bacterial endotoxins is used in the final rinse stage.

Cleaning : Inspection

After cleaning, visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

Maintenance

Apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions.

Inspection and Function Testing

- Visually inspect and check all instruments for damage and wear; cutting edges are free of nicks and present a continous edge; jaws and teeth align correctly; all articulated instruments have smooth movement without excess play; locking mechanisms fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.
- **Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.**

Note: If an instrument is returned to the manufacturer / supplier, the instrument **must** be decontaminated and sterilised and be accompanied with the relevant documented evidence.

Packaging

All instruments to be packed following local protocol in accordance with BS standards.

Sterilisation

Instruments can be sterilised using 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

Stream autoclaving

Sterilizer type | Gravity displacement | Prevacuum
Sample config.: wrapped | wrapped
Temperature: 121°C to 123°C | 132°C to 135°C
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

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

⚠ Special notes for Silicone Oil: Silicone oil is extremely difficult to completely remove from the silicone accessories. Therefore, if silicone oil is used in the surgical procedure, all silicone parts that come in contact with the silicone oil, should be replaced.

Storage

Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

Additional Information

Other forms of cleaning (i.e. ultrasonic) are available. However, always follow the instructions for use as issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.

NOTE: It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment; materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

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