Reassembly

When all the parts have dried completely the instrument can be reassembled as follows:-

1. Install a new Backflush reservoir by inserting the open end of the reservoir into its fitting at the distal end of the opening within the hand piece (be sure that the reservoir is firmly fixed to the hand piece and the white Teflon washer is in the centre of the bump). After the open end has been secured, the sealed end of the reservoir is inserted into the proximal end of the opening within the hand piece. It is necessary to bend the tubing while inserting. After the Backflush reservoir is in its proper position no bends are allowed in the reservoir tubing.
2. Insert the needle in the distal tip of the hand piece.

Storage

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

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Eye Technology

CARE AND HANDLING INSTRUCTIONS FOR BACKFLUSH INSTRUMENTS

ADVICE FOR USE AND MAINTENANCE

Devices

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

These instructions are only intended to be used by persons with the required specialist knowledge and training.

In all cases the approved Hospital procedures must be followed when handling the devices.

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.

Disassembly

After each surgical procedure the instrument should be disassembled and cleaned before being sterilised. To disassemble: -

b) Unscrew and remove tip. If tip is a disposable product this must be discarded. If re-useable clean and sterilise tip in accordance with manufacturer's instructions.
c) Remove the silicone Backflush reservoir by puling up on the tubing at its centre in the vicinity of the aspiration control port and discard.

Cleaning: Manual

- 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.
- The devices should be cleaned using a Hospital Approved Cleaning Agent that is suitable for use with surgical stainless steel and titanium instruments. **BE CAREFUL** titanium instruments or those with coloured anodised handles cannot be put in acid or alkaline solution.
- Remove residual matter with a delicate brush or surgical sponge moistened with alcohol. Care should be taken to avoid damage to the extreme tip.
- After cleaning, ensure the instruments are rinsed thoroughly with demineralised water to remove all chemical residues.
- Dry using forced air and inspect under magnification to ensure cleanliness and to check for damage.

Cleaning: Ultrasonic

- Ultrasonic cleaning equipment could be used in the cleaning process but not as the sole cleaning method. The instruments should be manually cleaned before being placed in an ultrasonic cleaner.
- Ultrasonic Cleaners should be tested and maintained in accordance with HTM 2030 and it is recommended that devices be cleaned in an Ultrasonic Cleaner with a Hospital Approved Cleaning Agent.
- The instruments should not touch and must be secured on a finger mat during the 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 would damage the instrument.
- Use a cleaning cycle lasting approximately 10 to 15 minutes or as recommended in the Ultrasonic Cleaner Instruction Manual.
- After the ultrasonic cleaning, flush all the instruments fully with demineralised water to remove the remainder of the cleaning solutions.
- Dry immediately.

Cleaning: Automated

- Use only either CE marked or validated washer-disinfector machines that are tested and maintained in accordance with HTM 2030. Use low-foaming, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.
- Load instruments carefully, in accordance with the manufacturers instructions. It is recommended that any box joints and hinges are left open so that any fenestrations in instruments can drain.
- 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.
- Instruments should be washed thoroughly in water purified by de-ionisation or reverse osmosis to prevent residues forming on them. It is recommended to use two cold rinses to prevent coagulation on the instruments.

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 continuous 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	Pre-vacuum
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 minute

Above-mentioned sterilization cycles represent industry standards and should be capable of producing a sterile device. Due to variations in sterilization equipment and device bio-burden in clinical use, we are 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.