Device(s):	**Pliers & stainless steel Instruments**

IMPORTANT:

It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

1. Introduction	• These procedures should be followed when cleaning and sterilizing stainless steel reusable instruments. These procedures should be followed in conjunction with any existing Hospital Cleaning and Sterilization procedures. These devices should only be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as ISO 9001 or ISO 13485. Processing systems used must be able to sterilize devices to EN 556. **Follow guidelines in HTM2010 and HTM2030. Use HTM2031 if necessary (see Limitations on Processing).**
2. WARNINGS: *Note: Surgical and Dental medical devices are very delicate and in all instances must be handled treated as fragile*	1. Long narrow cannulations and blind holes require particular attention during cleaning. 2. Do not exceed temperatures of 140°C. Initial rinsing/cleaning temperatures should not exceed 35°C as temperatures above this may cause coagulation of proteinaceous substances and should be avoided. 3. Follow hospital/facility approved Health & Safety procedures at all times. 4. Follow hospital/facility and MHRA Guidance to control the processing of the devices. 5. Follow hospital/facility approved procedures or recommendations in*"Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection"* compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy advisory committee)for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-

	Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc. 6. Carry out procedures in a suitably controlled environment to protect from contamination. 7. Do not process rusty or damaged instruments with good instruments or stainless steel with normal steel or iron instruments. 8. **General note: Do not re-use or reprocess single use devices.** 9. Follow the instructions supplied by the machine and detergent manufacturers. All machines and deteregents used should be CE marked where required. 10. Instruments should not be exposed to Bromine, Iodine, Calcium Chloride, Calcium Hypochlorite, Sodium Hypochlorite or Chlorhexidine. Exposure to Benzyl Ammonium Chloride (BAC) may loosen tungsten carbide inserts. Do not expose Titanium devices Potassium Perchlorate. Any chemicals used should be Tenzide free. Only use CE marked chemicals specifically approved and labelled for use with medical devices.
3. Limitations on reprocessing	• Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use, processing or handling. Exposure to strong acid or alkaline may reduce the working life of instruments
Processing Instructions	
4. Point of use	• Remove excess soil by rinsing in purified water as soon as possible after use. If necessary use a soft bristled brush to remove stubborn contaminants, brush carefully from stock to tips. A Quick rinse Machine may be used to help flush lumen on any cannulated devices. • Care must be taken to ensure fingers are kept away from any sharp surfaces and that any delicate tips are cleaned with the utmost care. Many ophthalmic devices are very fragile and should only be handled by trained staff with special care. • Do not allow contaminants to dry on the device. We *recommend the use of a suitable Enzymatic preparation*

	solution such as Ruhof Prepzyme XF to keep debris moist • Pack the devices in a suitable container, to prevent damage to the instruments during transportation. • Care must be taken to prevent unwanted contamination. • Follow hospital/facility approved procedures for transporting contaminated devices.
5. Preparation for cleaning	1. Disassemble the device when the instructions for use specify this. Only use tools that have been recommended in the specific device's instruction sheet for disassembly. 2. It is recommended to clean devices as soon as is reasonably possible after use. Flush any devices with a lumen using a Quick rinse Machine, syringe or water jet gun where possible. 3. Ensure staff who will be processing the devices are trained in handling the devices
6. Cleaning Equipment and Chemical	1. **Equipment:** Ultrasonic Cleaner and/or Washer /Disinfector as applicable, CE marked and approved by the hospital/facility with a validated cycle. Processing tray *e.g. Microwash* 2. **Detergent:** CE marked pH neutral Endozymatic detergent, *We recommend Ruhof Endozyme AW Triple Plus.*Any chemicals used should be CE marked and be specifically designed and labeled for use with medical devices.
7. Cleaning Ultrasonic Cleaner	1. Ensure the Ultrasonic Machine is clean empty and dry prior to use. 2. Fill fluid reservoir with purified water/detergent to ensure complete immersion of device. Follow the Chemical and Ultrasonic Cleaner Manufacturer's instructions for use. *We recommend using an endozymatic detergent such as Ruhof Endozyme Triple Plus.* 3. Degass the solution by following the machine manufacturer's instructions for use. 4. Flush cannulated devices with the detergent to ensure lumens are clean and free flowing. 5. Protect the dev ices by packing them in Microwash Trays, finger matting or securing blocks to prevent them touching each other or the sides and bottom of the Ultrasonic bath.

	6. Carefully place items into solution, ensure items are fully immersed and that any air contained in the device is displaced. Replace lid and leave for a minimum of 5 minutes or as specified in HTM2030. (We *have validated a 2 minute exposure cycle using Ruhof Endozyme Triple Plus however it is recommended to follow HTM guidance.)* 7. Switch off the cleaner, remove the instruments and drain them. Rinse thoroughly in sterile purified water to remove any residues; NOTE: ensure any lumen are flushed thoroughly. 8. Carefully hand dry using absorbent, non-shedding cloth, industrial hot air dryer or drying cabinet. If hand drying dry from the stock of the device to the tips, ensure care is taken so that delicate items such as tips, probes, hooks, dilators etc. are not damaged. If necessary use medical grade compressed air to dry any cannulated devices.
8. Cleaning **Washer / Disinfector**	1. Place instruments into a suitable container (e.g.. Microwash Tray) to protect devices from handling damage that can occur during processing. 2. Load instruments so that as much contaminated surface area is exposed as possible, e.g.open jaws, hinges and place any devices with holes, lumen or concave surfaces so that they can drain freely. Load the machine so that the load configuration does not impede the cleaning process. Keep heavy objects at the bottom of trays, do not overload baskets and do not let instruments touch each other. Load as described in hospital/facility procedures. 3. Where available use machine attachments to flush the lumen of any cannulated devices. If not available flush lumens with the detergent prior to processing to remove organic matter (e.g. Quickrinse Machine, syringe etc.) Then rinse in purified water to remove any residues. 4. Run a cycle that has been approved and validated by the hospital/facility. The initial rinse should be at or below 35°C, followed by a hot water disinfection rinse where the surface of the device should reach 71°C for a minimum of 3 minutes, 80°C for 1 minute or 90°C for 1 second (HC(91)33 and BS2745). We have validated a cycle with the following

	parameters: 5 minute pre-wash at 20°C followed by an Endozyme wash at 50°C for 5 minutes, a 1 minute rinse at 60°C and a thermal disinfection cycle of 90°C for 6 minutes; however it is recommended to follow HTM Guidance where applicable 5. When unloading check devices, including cannulations and holes etc. for complete removal of visible soil. Ensure instruments are dry. If necessary test lumen flows rates using a Quick rinse Machine or syringe. If necessary repeat cycle or carry out manual cleaning.
9. Cleaning Manual	1. Use a double sink system dedicated only for cleaning instruments - DO NOT use a hand wash basin. Ensure water is warm but does not exceed 35°C. Use a hospital/facility approved and CE marked detergent diluted as necessary to the manufacturer's guidelines in the first sink. We recommend an Endozymatic detergent such as Ruhof Endozyme Triple Plus. 2. Fill second sink with purified water or ensure a water jet gun is available at the sink. Carefully immerse item in the solution and displace any trapped air. Ensure solution reaches all areas of the device, flush any lumened surfaces with the detergent. 3. Keeping the device fully immersed in the solution, brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge any visible dirt. Do not use steel wool, abrasive powders or hard bristled brushes. Pay particular attention to joints, lock serrations, or areas where debris may collect. Remove from the solution and drain over the detergent filled sink. 4. Transfer item to second sink. Rinse device thoroughly with sterile distilled water, ensure device is fully immersed and any residues are removed. Flush any cannulated devices with sterile purified water. Remove from the rinse water and drain. 5. Carefully hand dry using absorbent, non-shedding cloth, an industrial hot air dryer or drying cabinet. If necessary use medical grade compressed air to dry any cannulated devices.

10. Special note:	• Any reusable brushes used should be cleaned after use and disinfected, ideally in a washer disinfector. Reusable brushes used should be stored dry.
11. Inspection/ maintenance	1. Visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of any debris such as organic matter and any chemical residues. If devices are not visibly clean, reprocess using manual cleaning or automated cleaning as necessary. If unsure about the integrity of cannulated device flush with sterile purified water and check the flow rate. 2. Reassemble any devices where necessary, see instructions supplied with the device. 3. Inspect each device as follows using a microscope where necessary: **Alignment -** All jaws, teeth, arms etc. correctly aligned and interlock where appropriate. **Finish -** Device should be clean with no staining, debris or residues, any markings should be clear and easily visible. Staining may be removed by using a specially designed cleaning agent company recommend Ruhof Surgi-Stain, follow manufacturer's instructions for use then clean the device using an automated or manual process as available. **Structure -** No scratches, nicks, bends, distortions, cracks, flaking, pitting or other signs of physical or handling damage. **Movement** - Smooth without grating, scratching, jerking or excessive play unless designed to be otherwise. **Locking Mechanisms** - Should open and closed easily, check also for any cracks in box locks and hinges **Tips -** Check the integrity of any delicate parts on probes, hooks, dilators etc. **Assemblies** - All interlocking and detachable parts should fit easily and correctly without the need to apply any excessive force **Cutting edges -** Should give a clean cut along the length of the blade. Test by cutting damp tissue paper: ensure cut is clean, along full length of blade and does not pull at tissue

	fibres. **Lubrication** - When necessary instruments should be lubricated on all moving parts after cleaning. Follow the Lubricant Manufacturers instructions. Any lubricants used must be specifically designed, CE marked and labeled for use with medical devices, we recommend the Ruhof Premix-Slip lubricant.
12. Packaging	1. Use hospital/facility approved and validated protocols and packing material, e.g. pouches or wraps. Protect devices from handling damage (e.g. Microwash Tray) during processing. 2. Ensure packing is large enough to prevent pressure on the seals. We recommend products to BS 868. Ensure traceability with LOT number and shelf life with use by date. 3. Pack devices so jaws, lock boxes, ratchets etc are open and exposed to sterilization process.
13. Sterilization:	1. Use a hospital/facility approved and validated protocol and sterilize to EN556. Ensure all equipment and systems are controlled, maintained and calibrated, e.g. HTM2010 HTM2030. Ensure all devices are suitably packed in a protective barrier (e.g. pouch, wrap) to maintain sterility after removal from the sterilizer. We recommend using materials to EN868. 2. The preferred sterilization cycle and one that has been validated by us is a standard Autoclave cycle operating between 134°C and 137°C with a 3 minute holding time. These conditions may vary; see also Table 5 in HTM2010 for suitable variations if required.
14. Storage	1. Stores should ensure optimum quality conditions are maintained. Devices should be kept away from floors, walls, and ceilings. Store in a clean, dry well ventilated environment. 2. Sterile devices should be clearly identified with use by dates and be segregated from non-sterile devices where appropriate. Keep sterile products out of direct sunlight at normal room temperature and humidity. Ensure all devices are dry before storage. Reject any device(s) in wet or

	damaged packing. **NEVER STORE INSTRUMENTS WHEN WET.**
15. Damaged devices	1. If a device fails inspection protocols it should be rejected. If in any doubt as to the integrity of a device after processing , send to the company Repairs Department for evaluation along with a signed Decontamination Certificate. If the device is beyond repair then it should be decontaminated and wrapped to protect handlers from sharp edges. It should then be disposed of by following hospital/facility approved procedures.