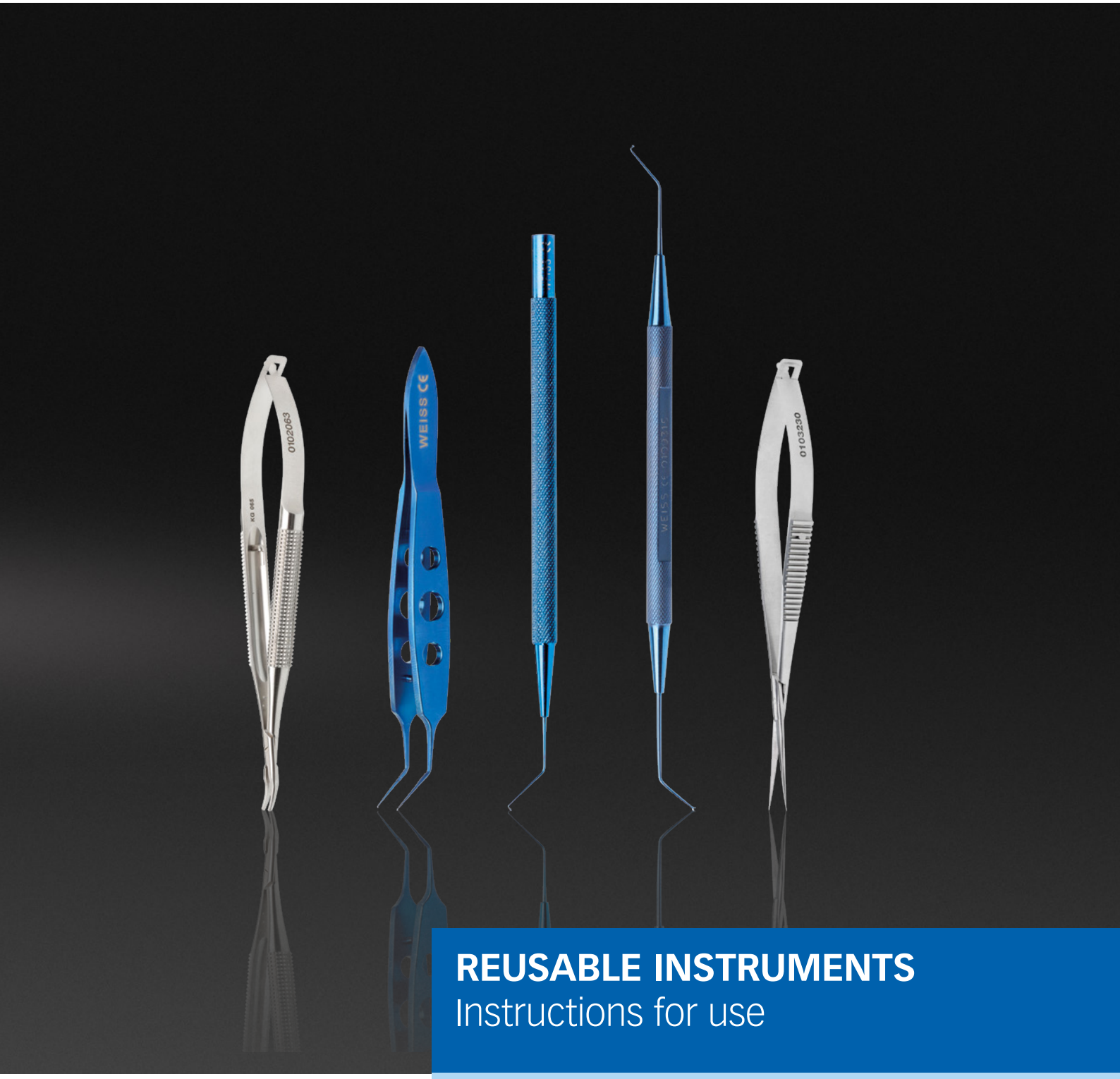

REUSABLE INSTRUMENTS
Instructions for use

HAAG-STREIT
JOHN WEISS

A. Identification

Manufacturer:

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These Instructions For Use (IFU) are for Haag-Streit UK Ltd. reusable instruments with exposed surfaces made from;

- Stainless steel
- Titanium

B. Intended purpose and use including description

Intended purpose

A range of reusable, surgically invasive medical devices and accessories that are intended for transient use in assisting the surgical treatment of patients with medical conditions of the eye or ear, nose or throat (ENT) and which require surgical intervention within a controlled environment by qualified ophthalmic or ENT professional.

Intended use

A range of reusable, surgically invasive medical devices and accessories that are intended for transient use in assisting the surgical treatment of patients with medical conditions of the eye or ear, nose or throat (ENT) and which require surgical intervention within a controlled environment by a qualified ophthalmic or ENT professional.

They are intended to function through human application by cutting, scratching, scraping, manipulating, clamping, retracting or clipping the skin, mucous membrane, bone or other tissues in or around the eye, ear, nose or throat. They are not intended to be connected to an active device. These devices can be used on patients of any age, gender or ethnicity.

The devices are intended to be washed, disinfected and sterilised by healthcare or decontamination professionals in a clinical or decontamination setting before use. These devices are intended to be used in a sterile condition and handled by users wearing the necessary personal protective equipment, such as medical gloves, as specified by their health care facility's risk assessment.

Indications for use

Indicated for use on patients with medical conditions of the eye or ear, nose or throat which require surgical intervention.

Clinical benefits

Type: These devices provide the user the ability to operate on and treat a patient who has health issues with their eyes, ears, nose or throat. This could mean:

- Eye: the reinstatement of sight, the prevention of or treatment of blindness, and the possibility of preventing the loss of the eye or potential death in the event of life threatening illnesses such as cancer of the eye. This gives the patient the ability to see again and have reduced or no eye pain or even to live longer.
- Ear: Improvement in hearing or in the appearance of ears. Ability to remove obstructions.
- Nose: Improvement in smell, breathing or in the appearance of nose. Ability to remove obstructions.
- Throat: Improvements in breathing. Ability to remove obstructions.
- It can also alleviate or remove pain.

Magnitude and duration: The use of these devices can provide treatment providing relief from the patient's symptoms. The treatment can often allow the patient to resume normal activities fairly quickly in most cases. Preventative treatment can also prevent the potential loss of sight, hearing, smell or life. The treatment can often last the rest of the patient's life.

Benefit factors for healthcare professionals or caregivers: The materials used to make the devices are such that they are economical to manufacture and supply, making them readily available for the intended users. The devices can be reused many times after decontamination, and can be cleaned, washed and sterilised using standard everyday facility decontamination protocols. They comply with industry standard specifications and so are widely recognised and used daily throughout the world, with no unique aspects to them that would require additional training.

Medical necessity: These devices are essential in the prevention and treatment of ophthalmic or ENT complications where medicines are not deemed capable of resolving the issue. They are state-of-the-art devices to the industry standard and used as such.

Patient perspective: The patients will greatly value these devices in that they can improve their eye or ENT conditions or prevent possible death.

⚠ C. General warnings and contraindications

General warnings, cautions and residual risks

- These devices are intended for use by qualified healthcare professionals
- Training in the instructions for use is the responsibility of the clinical institute and the user
- Read these instructions carefully before first use. Failure to comply with these instructions may result in damage to the device and/or pose a risk to the patients and/or users
- These devices are contraindicated on patients deemed unsuitable after a medical assessment such as those with metal allergies, active infection or inflammatory diseases, herpes, low haemoglobin levels, far advanced disease or imminent demise, severe malnutrition, peripheral venous thrombosis, previous severe reactions to anaesthesia, those on medication, pregnant or with special needs including those who may struggle with postoperative care and rehabilitation
- The UKCA mark for these devices does not include veterinary use
- Process devices as soon as practicable after use (see also "Section H" below).
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established
- Use these IFU alongside any additional IFU supplied with the individual device, and those supplied by the detergent and processing machine manufacturer
- The devices are only to be handled and stored as described in these instructions for use by facility approved and trained personnel
- Initial wash temperatures should not exceed 45°C as this can cause protein coagulation and cleaning problems
- Do not use sterilisation trays (e.g. Polymer) or trays with finger matting in the washer-disinfector unless they have been specially designed or UKCA/CE marked for this purpose, these increase the risk of liquids pooling. Solid tray lids and bases restrict the free flow of detergents to and from the devices
- Sterilisation by Ethylene Oxide (EO), gas plasma and dry heat sterilisation has not been validated
- Avoid prolonged soaking of devices as this may cause physical damage to function and structure
- Do not allow biological soils to dry on the devices, decontaminate as soon as practicable after use
- Do not mix chemicals. Some used for reprocessing are inactivated when mixed with other chemicals
- Do not process plated instruments (e.g. Lang Speculum or Jones Dilators) through ultrasonics, as this increases the risk of surface damage
- Do not use wire brushes or other abrasive items to clean the devices
- Do not manually clean instruments under running water as this can produce aerosols that could be inhaled, clean submerged in a designated sink
- Do not overload trays – see "**Positioning devices during processing**" below
- Do not obstruct the spray arms in the washer /disinfector by incorrect loading
- Do not use oil-based lubricants as these cause contaminations and prevent the sterilant access to the surface of the device. Mineral oils also have poor biocompatibility
- Exposure to saline, chlorides, chlorine, bromine, iodine, or iodide increases risk of localised corrosion
- All spaces used for the reprocessing of medical instruments must be equipped with hand hygiene facilities at the entrance and exit points
- To minimise the risk of cross contamination, quality inspections on the devices should be carried out after they have been washed and disinfected
- Devices should only be used for their intended purpose as supplied with the device.
- Unless devices are for non-human use, scissors designed for use with tissues should not be used to cut sutures or wires, and needle holders should not be used as pliers
- Devices such as probes etc should not be bent or otherwise reshaped

Failure to thoroughly clean a device may:

- Leave foreign materials (e.g. soil and organic materials, including microorganisms and inorganic materials and lubricants) on the device. These can hinder disinfection and/or sterilisation
- Increase the risk pathogens / blood-borne virus transmission (e.g. Human Immunodeficiency Virus (HIV), Hepatitis B and Hepatitis C), in particular highly infectious viral diseases such as Covid and Ebola and the transmission of environmental pathogens, such as Pseudomonas Aeruginosa
- Allow sputum and mucous residues to form with a risk of cross infection of tuberculosis and other bacterial pathogens

- Allow biofilm formation in the lumens, thread of screws and difficult to reach areas. Biofilm protects bacteria by covering them with an impenetrable layer of mucous and deposits (e.g. Pseudomonas Aeruginosa)
- Increase the risk of post-endoscopic infection or pseudo-infection (such as with Pseudomonas species and atypical mycobacteria) due to recontamination during the final rinse
- Can leave hard water, mineral and calcium deposits on the device affecting its performance
- Allow a chemical build-up resulting in loss of integrity of the device or its coating.
- Result in surface dirt and organic matter covering parts of the surface and preventing contact with the disinfectant or sterilant
- Cause the inactivation of some disinfectants by organic matter
- Increase the risk of an allergic reaction in the patient
- Increase the risk of releasing endotoxins and pyrogens
- Shorten the devices life
- Increase the risk of chemical burns from decontamination solution residues if these devices are not processed as specified in these instructions for use
- If devices are not cleaned as soon as possible after use or are not covered in a suitable preparation solution keeping them moist prior to processing, this makes it more difficult to clean the device leading to possible contamination and cross infection
- Incorrect inspection procedures can lead to the use of surgical instruments that contain pitting, corrosion, oxidation, cracks, damaged connectors or pieces of the instrument missing which can cause harm to the patient or cause foreign body contamination in the wound
- Damaged instruments may not function correctly leading to physical harm to the patient, a delay in the procedure or further damage to the instrument
- The use of instrument tape, especially if it is flaking or sticky, may also lead to infection
- Misuse may result in snapping delicate devices leading to possible assembly or functional issues or parts of the device breaking off causing foreign body contamination in the wound
- Incorrect dilution or exposure of cleaning chemical may result in the device not being clean causing infection
- Incorrect dismantling and assembly may result in inadequate cleaning, damage to the device and the device not functioning correctly causing possible physical harm and infection to the patient
- Erroneously using delicate instruments meant for use on tissues on other items (e.g., gauze, tape, tubing, etc.) may result in physical damage to the device and the patient

Side effects

Main operational risks for in or around eyes:

- Pain, headaches, swelling, total or partial loss of sight in the operated eye, blurred or double vision, detached retina, tearing, puffy, difficult to close /numb eyelids, discomfort, irritation or gritty feeling, sensitive eyes, bruising, scarring, asymmetrical eyes, haematoma, injury to eye muscles, ectropion, eyelid retraction, red marks on the conjunctiva, loss of balance, glaucoma, the need for follow up surgery.

Main operational risks for ears:

- Pain, total hearing loss in the operated ear, dizziness, tinnitus and paralysis or weakness of the muscles of the face, disturbance of taste to one side of the tongue. May be either temporary or permanent, the need for follow up surgery.

Main operational risks for nose:

- Pain, bruising, swelling, difficulty breathing through the nose, impaired sense of smell, lumps or bumps, perforated septum (noisy breathing, whistling or drying out of the inside of the nose), damage to the mucosa, corneal abrasions (from inadvertent scratching of the eyes while you are asleep or when waking up from anaesthesia), mild asymmetry, scarring.

Main operation risk for throat:

- Pain, sore throat, scarring, change in voice,

Common operational risks for eye, ear and nose:

- Excessive bleeding
- Blood clot in a vein
- Infection
- Allergic reaction to anaesthetic or nausea from its use
- The need for follow up surgery

Special patients

- Follow local requirements for handling devices which have been exposed to patients with Transmissible Spongiform Encephalopathy (TSE) agents/unconventional slow viruses/prion diseases such as CJD
- If possible use single use devices for these patients
- If necessary identify and segregate reusable devices for use ONLY on these special patients

 Supplied non-sterile

- These devices are supplied clean and non-sterile and require full decontamination, including washing and sterilisation, as outlined in this IFU prior to use
- Contact the Quality Department at Haag-Streit UK Ltd. if in any doubt.

Detergents

- Only use detergents that have been UKCA/CE marked or are intended for use on metal medical devices.
- Haag-Streit UK Ltd. recommend the use of a UKCA/CE marked pH neutral endozyme detergent.
- UKCA/CE marked alkaline detergents (<pH12) may also be used if required as long as they are thoroughly neutralised and rinsed off the device. Acidic or alkaline products with >2% available alkalinity are not recommended as they cannot be properly neutralised.
- The detergent should be a liquid, low foaming, free rinsing, non-abrasive and biodegradable. It should not contain artificial colours, optical brighteners, perfumes, halides at a concentration >120mg/L, fatty soaps, glycerine or lanolin or leave a toxic residue.
- Aluminium can be damaged by high alkaline (>pH10) detergents.
- Do not use household washing up liquids or soaps.

Water quality

- Normal tap water contains minerals that can leave stains on the surface of the device, as such the following water is recommended where possible especially for all final rinsing stages, hereafter referred to as PURIFIED WATER: Deionised / reverse osmosis (RO) water, evaluated and treated as necessary to meet the criteria outlined in EN ISO 17665-1:2006 and EN 285 Annex B.
- Note: RO water systems are expensive and waste a lot of water, it also leaves water slightly acidic, as such local protocols may require final rinsing only in RO water which is acceptable.
- Normal tap water can be used for the initial manual cleaning stages and in Tabletop Ultrasonic Cleaners, it is recommended to follow with a final purified water rinse.
    - Where pure water is not an option, for washer-disinfectors and plumbed-in ultrasonic cleaners:
    - Cold tap water pre-wash
    - Hot softened water main wash
    - Hot softened water rinse
    - Thermal disinfection with hot purified soft water rinse.
- Proper steam quality will prolong the life of reprocessed medical devices by reducing adverse effects that water impurities can have on device materials. Lime, rust, chlorine and salt can all be left as deposits on devices if purified water is not used. These compounds can lead to stress corrosion, pitting and discolouration of the device. As such, purified water is recommended for the autoclave.
- Pitting, corrosion and precipitates must be avoided as their formation provides areas where organisms can readily accumulate and be protected from the killing effects of the steam process. This increases the risk of infection transmission due to inadequate sterilisation.

Positioning devices during processing

Ensure:

- The loading pattern has been validated and approved by your facility.
- Loading is in accordance with the processing device manufacturer supplied IFU.
- If a custom-made tray, load accordingly, heavy instruments should be at the bottom of the tray.
- Devices are held in a protective tray and secured with silicone strips, finger matting, etc to prevent unwanted movement. (See also Section F. Instructions).
- As much of the surface of the device is exposed to the processing agent as possible, open hinged or jointed instruments.
- Any lumen, bowls or holes are positioned to drain and that fluids cannot pool.
- The devices do not touch each other in the tray or the sides or bottom of the processing machines.
- Clamps and Forceps designed to have closed jaws (e.g. REF: 0101462, 0101463, 0101464, 0101552, 0101605) should have their jaws manually cleaned and held open if possible during automated washing and sterilisation with retaining pins or similar.

Temperature limitations

To prevent coagulation of proteinaceous substances, initial cleaning or rinsing temperatures should be between 27°C and 45°C. Temperatures should not exceed 140°C.

Personal Protective Equipment (PPE)

During handling and manual cleaning of devices, Personal Protective Equipment (PPE) as specified by your facility, it is recommended that a full face mask, protective gloves and overalls are used.

Follow your facility health and safety procedures and wear and use the PPE, as trained.

Handling

- These devices are fragile. Handle with care, especially with devices with delicate tips to ensure forces are not applied that can bend or snap these tips.
- Do not knock or drop devices and avoid putting them under undue stresses or strains.
- Unless specified elsewhere in this IFU, do not leave devices wet as this may result in staining and promote corrosion.

Training

- These medical devices are very delicate and can also cause a biohazard risk, as such they must be handled with care and only by staff trained in their use and decontamination.

Sharps injury

- Keep sharp tips and edges away from the body, especially the fingers.
- Use caution when handling sharp devices.
- Follow your facility procedures in the event of a sharps injury.

Environment

- All devices should be handled in a suitably controlled environment with controlled access to prevent any unwanted contamination to the devices or persons.
- Cleaned devices should be handled and packaged only in a controlled environment.
- Store sterilised devices away from direct sunlight and keep dry.

Before use

Before using a sterile instrument check to ensure:

STERILE the sterile symbol is on the label

the use by date has not been passed

the packaging has not been damaged and thus the sterility compromised. If the packaging is damaged, soiled or unintentionally opened before use, do not use. If received damaged contact Haag-Streit UK.

Inspect and test the device as described in Section I below or in the IFUs supplied with the device to minimise the risk of using a device that has been damaged during processing or handling.

It is recommended to count the devices before and after use to ensure no devices are missing at the end of the procedure.

After use

After use, the devices will pose a biological risk and must be identified and controlled following facility procedures.

Place used devices in a puncture proof, UKCA/CE marked or equivalent container specially designed for transporting contaminated medical devices.

Ensure devices are held securely in finger matting, silicone strips or similar holders to prevent movement and accidental transit damage. Close and secure the tray and label accordingly.

Ensure devices are not trapped in soiled linen as these will create an injury hazard at the laundry and devices may become damaged beyond repair.

Contraindications

These devices are contraindicated on patients deemed unsuitable after a medical assessment, such as those with metal allergies, active infection or inflammatory diseases, herpes, low haemoglobin levels, far advanced disease or imminent demise, severe malnutrition, peripheral venous thrombosis, previous severe reactions to anaesthesia, those on medication, pregnant or with special needs including those who may struggle with postoperative care and rehabilitation.

D. Symbols library

- Manufacturer
- Consult instructions for use
- Medical device
- Product reference
- Lot reference
- Unique device identifier
- Quantity
- Caution
- Non-Sterile
- Fragile handle with care
- Keep out of direct sunlight
- Keep dry
- Sterile
- Use by date
- Do not use if packaging is damaged
- Biological risk
- Date & country of manufacture
- UK Conformity Assessed (UKCA mark)

E. Limitations on processing

Limitations on processing

- Repeated processing has minimal effect on these instruments.
- End of life is normally determined by wear and damage in use.
- Devices should be inspected after cleaning and prior to sterilisation for functionality and safety by following procedures as described in Section I below.

F. Instructions - top level procedure

Decontamination procedure

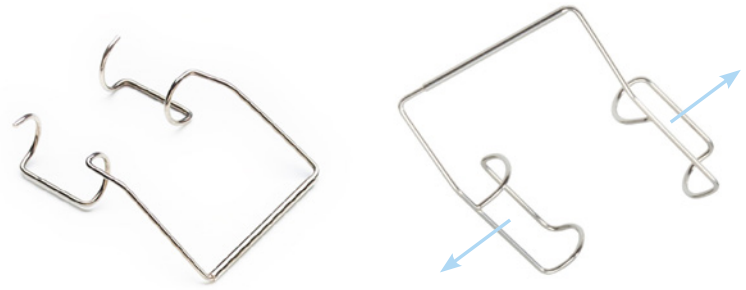
Follow your facilities procedures for identification and traceability throughout the decontamination and inspection and testing process. Only suitably trained staff should handle medical devices.

a) For initial treatment at point of use, remove any gross soil (Step 1.) then send to the decontamination unit (Step 2.).

b) Before processing, remove any protective tips, safety caps or other covers designed for removal.

c) Dismantle the following (see also any separate IFU supplied with the device):

Devices	Dismantling Procedure
Weiss Sphenoidal punch (REF 0101483, 0101484, 0101485, 0101487, 0101488, 0101490, 0101493, 0101494, 0101495)	Unscrew central retaining pin and carefully separate the arms. 
Kelly Punch (REF 0101492)	Pull off protective cap 

Devices	Dismantling Procedure
Kratz-Barraquer sliding speculum (REF 0104085. 0104083)	Separate arms by sliding them apart 

d) Prepare device for cleaning (Step 3.).

e) Manually clean (Step 4.):

- Devices are heavily soiled or stubborn or dried on debris is evident
- If the device has a lumen, complex structure, delicate tips or hidden surfaces
- Any clamps and forceps designed to have closed jaws in their relaxed position (e.g. REF: 0101462, 0101463, 0101464, 0101552, 0101605).

f) Check intended use on IFU and if applicable ultrasonically clean (Step 5.) any:

- Semi-critical devices: those in contact with mucous membranes or non-intact skin.
- Critical devices: those that enter normally sterile parts of the human body
- Devices have complex structures, delicate tips, lumens, hidden surfaces, joints, crevices or other areas that are difficult to clean.

g) If hand drying, dry from the body of the device to the tips, ensure care is taken if wiping so that delicate tips are not damaged. Clean, dry compressed air should be used for removing fluids from cannulated devices. Ensure devices are fully dry (see i) below).

h) Wash and disinfect the device in an automated washer-disinfector (Step 6.) using the validated cycle under the ISO 15883 series of standards.

i) Ensure devices are fully dry by placing them on a sheet of coloured crepe paper on a flat surface and examine for any water discharge or residual dark spots (water stains) on the paper. Lumen should be checked by blowing dry compressed air through the lumen onto a mirror surface. No residual water should be observed from the load or carriage, on the crepe paper or, where relevant, on the mirror surface.

J) Inspect the device for cleanliness and repeat d) to i) as necessary to remove any remaining visible debris. Pay special attention to hidden areas such as lumen.

k) Lubricate only those areas directly that have or contact any moving parts (Step 7.)

l) Reassemble (if applicable) and inspect and test the device for safety and performance as described in Section I below. Dismantle (if applicable) after testing (see c)).

m) Securely pack (Step 8.) to prevent unwanted movement in:

- A UKCA/CE marked medical device peel pouch, preferably double pouch; or
- An instrument tray such as a John Weiss Ophthalmic Tray, which is then sealed within a UKCA/CE marked instrument wrap

n) Ensure identification and traceability is maintained by following your facility procedures.

o) Sterilise the device (Step 8.) using moist heat under the ISO 17665 series of standards.

p) Transport and store in your sterile devices designated storage area (Step 9.)

G. Initial treatment at the point of use

Step 1.
Remove gross soil

As soon as reasonably practical after use:

a) Rinse thoroughly in water, do not use saline in any part of the cleaning process as this can damage the surface of the device.

b) Clean the surface with either a UKCA/CE marked instrument wipe, or single use lint free cloth, or soft bristled (nylon) brush

c) A soft bristled (nylon) brush is recommended for hard to remove surface debris. Brush away from the centre of the device to the tip. Be careful not to damage any delicate tips.

d) Flush any lumen (e.g. using a syringe) and rinse thoroughly in purified water.

Step 2.
Preparation for, and transportation

Containment for safe transportation

a) Send devices for decontamination as soon as practicable after use

b) Pack instruments in a dedicated, leak-proof and puncture-proof container prior to transport

c) Ensure devices are secured through the use of silicone strips, finger matting, brackets etc. so they do not move and become damaged in transit

d) Ensure tray is fully closed prior to despatch.

Prevent organics from drying

a) Keep contaminated soiled instruments open and moist to prevent soil drying

b) Cover surfaces including any lumen with a preparatory solution designed to prevent contaminants from drying on the device, e.g. enzymatic spray. A moist towel can be used with water or foam, spray, or gel specifically intended for this purpose

c) Do not soak in water, chlorine solution or other disinfectants as:

- these may damage the devices and cause a splash hazard
- a disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and formation of biofilm
- this may contribute to the development of antimicrobial resistance to disinfectants.

Safe transportation

a) Protect any delicate tips with guards. Attach any covers or protectors supplied with the devices to protect them during storage or transit

b) Ensure the instrument tray is clearly identified with the contents including it being a biohazard risk

c) Transfer the tray to decontamination department using a specially designed trolley or similar to prevent accidental exposure to soils

d) Do not transport contaminated devices with sterile devices, or through areas designated for the storage of clean or sterile supplies, visitor/patient/resident care areas or high-traffic areas

H. Cleaning

Step 3.
Preparation before cleaning

Disassembly

Unless specified elsewhere in **"Section F. c)"** above or on the labelling supplied with the device, there is no disassembly required.

Gross debris removal

a) Follow **Step 1** above.

b) Ensure any lumen in devices such as enucleation snares, irrigation or aspiration tubing etc have been cleaned and flushed with water.

Step 4.
Manual cleaning

Temperatures

Water and detergent temperatures should be below 45°C.

Step 5.
Ultrasonic cleaning -table top

Safety

Do not put hands in the ultrasonic reservoir!

Temperatures

Water and detergent temperatures should be below 45°C. See detergent and ultrasonic cleaner manufacturer IFU for further details.

Equipment

Validated tabletop ultrasonic cleaner with a heater and timer. Its basket and reservoir should be big enough to fully submerse the device and its processing tray.

Water

- See "Section C. Water quality"
- The volume of water in the Ultrasonic Cleaner should be sufficient to ensure any dilution ratios specified by the detergent manufacturer can be safely achieved, and that the device can be fully immersed.

Process chemicals

- The devices can withstand exposure to a pH neutral endozyme or alkaline detergent that has been UKCA/CE marked for ultrasonic cleaning of medical devices.
- For ultrasonic cleaning, a UKCA/CE marked pH neutral endozyme detergent is recommended.

Exposure time

Exposure times should be as specified by the detergent manufacturer for use in an Ultrasonic Cleaner.

Dilution ratio

The dilution ratios should be as specified by the detergent manufacturer IFUs.

Connectors

If available in the Ultrasonic Cleaner, any devices with a lumen should be connected to the luer connectors of the ultrasonic device spigots.

Procedure

Cautions:

- The surface of plated instruments may be affected if processed through an Ultrasonic Cleaner.
- Ensure the Ultrasonic Cleaner has been validated through facility procedures or by visual inspection, foil tests and commercial tests at least once a year.
- **Follow the Detergent and Ultrasonic Cleaner Manufacturer supplied IFU if different from below.**

  a) Ensure the Ultrasonic Cleaner is clean, empty, dry and has been approved by the facility for use

  b) Fill the fluid reservoir with the cleaning solution using the dilution ratio specified by the detergent manufacturer

  c) Heat to the required temperature and de-gas the solution as specified by the detergent manufacturer IFU

  d) Load the device into the Instrument Tray as described in **"Section C. Warnings & Contraindications", "Positioning devices during processing"** above.

  e) Place Instrument Tray into the ultrasonic cleaner tray then immerse in the reservoir solution. Ensure any air contained in the device is displaced.

  f) Replace the lid to prevent aerosol production, and ultrasonically clean for the exposure time specified by the detergent manufacturer.

  g) When the cycle has been completed carefully remove the device and rinse thoroughly in purified water following the detergent manufacturer IFUs. If not provided, immerse, rotate and agitate in water. A water jet or water filled syringe can be used. Ensure detergent is fully rinsed from lumen and any complex structures, cavities etc.

  h) Dry the device using a hot air dryer, drying cabinet or HEPA filtered air gun. If not available use the instrument wipe or a non-linting cloth. Position the device during drying so that any liquids can drain freely.

  i) Ensure the device is completely dry before removing from the drying process, (see **"Section F. i)"**).

  j) Inspect the device for cleanliness and manually (Step 4.) and ultrasonically (**Step 5**) clean again if necessary.

Step 6.
Automated cleaning and disinfection

Temperatures

- Prewash water temperature should be below 43°C.
- See the ultrasonic cleaner and detergent manufacturer IFU for further details on temperatures for other stages.

Process chemicals

- See "Section C. Detergents" above.
- The selection of the detergent to be used should take into account the hardness of the water supply. See detergent manufacturer IFU.

Water

See **"Section C. Water quality"**

Connectors

If available, any devices with a lumen should be connected to the luer connectors on the washer-disinfector spigots.

Load configuration

See **"Section C. Positioning devices during processing"** for the correct methods of loading the instrument tray for use in the washer-disinfector

Disinfection

Thermal disinfection recommended at between 90°C to 95°C for a minimum 1 minute.

Cycle parameters

Process using a washer-disinfector under the validated cycle requirements of the ISO 15883 series of standards. The following cycle was validated however these may vary depending upon the load:

- Pre-wash time and temperature: 18°C and 4 minutes
- Wash time and temperature: 64°C and 12 minutes
- Rinse time and temperature: 48°C and 4 minutes
- Drying time and temperature: 67°C and 29 minutes

Temperature

- The temperature of the water and aqueous solutions in contact with the devices shall be controlled within limits stated by the washer-disinfector manufacturer, and the detergent temperature limits specified by the detergent manufacturer.
- The devices should not be exposed to temperatures over 140°C.

Drying

- Use hot dry compressed air (preferable HEPA filtered) that does not impair the cleanliness of, nor introduce microbial contamination to, the devices.
- Drying time will be dependent upon load and your validated drying cycle. Use the approved drying cycle in your washer-disinfector as in **"ISO 15883-1"**, or dry at 100°C for 15 minutes.
- Ensure the devices and tray are completely dry after removal from the washer-disinfector see **"Section F. i)"** above.

Step 7.
Lubrication and assembly

Lubricant

- Only use water soluble lubricants that have been specially designed for use on medical devices.
- Do not use oil-based lubricants unless specifically designed and UKCA/CE marked for use on reusable medical devices.
- Incompatible lubricants can inhibit sterilisation, create harmful by-products, and damage the device or the steriliser.
- Devices shall be decontaminated and free of visible soil and rust before they are lubricated.
- Make up the lubricant according to the manufacturer's guidelines, as applicable.
- Avoid contaminating the lubricant and the reuse of containers for storing them.
- Dispose of lubricants past their use by date or if they are soiled.

Manual application

Apply only to the moving parts on the reusable devices, such as joints, hinges, screw threads, scissor blades, moving arms etc. Contact Haag-Streit UK Ltd, if in any doubt.

Assembly

Reassemble any of the dismantled devices (see **"Section F. c)"** above) and inspect for safety and performance as in "**Section I"** below. If the device passes the inspection and testing, lubricate as required then dismantle again (see **"Section F. c)"** above) and pass for sterilisation.

Step 8.
Sterilisation

Packaging

- Only trained staff should pack devices using validated pouch sealing equipment and wrapping techniques.
- All devices must be packed securely in a sterilisation tray (such as a John Weiss Ophthalmic Tray) placed in wrap and sealed with autoclave tape, or in a peel pouch heat sealed to prevent movement and minimize handling damage.
- Devices should not be in contact with each other when packed.
- Ensure devices have any protective tips attached.
- Peel pouches or sterilisation wraps should meet the requirements of the applicable ISO 11607-1 series of standards.
- Ensure identification and traceability is maintained, e.g., labelling.

Water

See **"Section C. Water quality"**

Pre-vacuum steam sterilisation parameters:

- Load the autoclave as described in the autoclave manufacturer's instructions for use, do not overload.
- Use a facility approved steriliser, e.g., a steriliser meeting EN 285, validated according to EN 554 and under the ISO 17665 series of standards.
- Validated exposure times and temperatures to achieve 10^{-6} sterility assurance.
- If the door is open before the cycle has finished, this may result in product becoming wet. If the product or packaging is wet after completion, the devices should be reprocessed and the autoclave checked for suitability.
- If no local requirements for sterilising TSE contaminated devices are available and devices need to be sterilised, follow the below cycle 6 times or increase the holding time to 18 minutes as recommended by the ACDPSE.

Parameter	Value
Temperature	134–137°C
Exposure time	3 minutes minimum to 3 ½ minutes maximum holding time
Pressure	2.2 bar

Step 9.
Storage

After sterilisation

After removal from the steriliser, move to an area where the devices are allowed to cool. When cool, place in a sterile store until delivery to the point of use. The storage area needs to be a restricted area and away from any windows or traffic. The sterilised devices should be handled as little as possible. Identification and traceability must be maintained.

Transport

It is recommended to transport sterile devices between the decontamination unit and the point of use/storage, in a specially designated clean trolley, or similar by, trained staff.

At point of use

Sterile devices should be stored in a clean, dry and well-ventilated area with open racks for air circulation and moderate temperatures and humidity. Avoid storing in closed cupboards or on the floor. They should be stored away from direct sunlight and contamination with dust, moisture or gases, e.g., exhaust fumes. They should be placed securely away from traffic to prevent accidental physical damage. Identification and traceability must be maintained along with a "first-in first-out" policy. Expiry dates should be checked regularly.

I. Inspection and testing

Inspection and testing

Device structure

- No physical damage such as scratches, chips, cracks, rust, flaking, grinding marks, pitting etc.
- Ensure device has not been bent (e.g., bent tip) or is otherwise distorted and that any locking mechanisms function properly.
- No sharp edges unless they are designed in, e.g., blades.
- Check box locks and hinges for any physical damage including excessive wear.

Alignment

- Ensure all jaws, serrations, teeth, arms etc. align correctly in both open and closed position, and that they interlock without clicking, grating or sticking.
- Ensure any locking mechanism functions correctly, that it holds the device in the required position when both locked and unlocked.
- Any detachable or interlocking parts should connect easily without the need for excessive force.
- DCR sphenoidal punch arms (e.g. 0101483 etc.) should move smoothly and the jaws close fully without any tip damage.
- The ball should fit snugly in the socket of the Towel Clamp 0101583.

Movement

- Unless designed intentionally to do so, the devices should:
- Move easily without clicking, grating, jerking or sticking.
- Have no excessive play.
- Have jaws that can easily open and close with finger pressure where applicable.

Moveable fixation rings such as REF 1501094 should move easily with the finger or otherwise remain stationary.

Mini clamps (e.g. 0101462, 0101463, 0101464) and needleholders in the locked close position, should apply sufficient pressure to securely hold a suture.

Tips and teeth

Ensure any delicate tips and teeth are functional and have not been physically damaged. They should be appropriately sharp and equally shaped where designed and move freely when reopening. Any tips that are held closed in the normal position should interlock correctly and move freely when opened and closed when operated under finger pressure.

Scissors

Scissors should give a clean cut from the tip down to at least two-thirds of the length of the blade. Test by cutting moist tissue paper in one continuous movement, keep the jaws closed and retract the blades. Lateral pressure should not be applied during the cut. While the blades are closed check to make sure there are no tissue fibres trapped between them. The cut in the tissue should be clean with no pulled fibres or tears from when the closed blades were retracted.

Contaminants

If there are any visible contaminants on the device or it is wet after coming from the washer-disinfector or autoclave repeat manual and automated cleaning.

Failures

Any devices that fail these tests should be segregated, identified accordingly, decontaminated and sent for repair with a signed De-contamination Certificate. If damage is beyond repair, devices should be safely disposed of in a purpose made and controlled sharps bin or by following local protocols.

J. Repairs

Repair Process

Haag-Streit UK Ltd offers a repair service on Haag-Streit instruments that have failed inspection and testing. Contact customer services on info@haag-streit-uk.com for further information. All devices must be returned with a signed decontamination certificate.

K. Disposal

Disposal instructions

To ensure safe disposal, these reusable instruments must be disposed of in a purpose made and controlled sharps bin or by following local protocols. Do not dispose in general waste.

IMPORTANT

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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