


SECTION 2

INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

MEDICAL DEVICES DIRECTIVE 93/42/EEC

Document change record:				
<u>Issue No.</u>	<u>Date of change</u>	<u>Section ref. changed</u>	<u>Nature of latest change(s)</u>	<u>Authorised By</u>
1	29/7/21	2.5	First issue as a separate document. Was part of Section 2.0 issue 1. Removed and issued as a standalone section. No change to wording or content.	

2.5 INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE (IFU) - UK

Device name Re-usable ophthalmic surgical instruments

Item specifics For use in ophthalmic surgery.


Intended use For use in the human eye.

For use by Only for use by a suitably trained medical professionals.




The following are guidelines for reprocessing all reusable medical devices supplied by Surgitrac Instruments UK Limited, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training. Additional information will be supplied with certain products regarding dismantling or interaction with other products. Such information will be enclosed with the specific products and are supplemental to these instructions.

The following instructions have been validated by Surgitrac as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing performed, using equipment, materials and personnel in the facility, achieve the desired results. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilisation processes require validation at the point of use. Their effectiveness will depend on many factors and it is only possible to provide general guidance on proper device cleaning, disinfection and sterilisation.

Category	Guidelines
Warnings	<p>Products supplied by Surgitrac are non-sterile. Never use reusable instruments that have not been cleaned, disinfected and sterilised first. Used surgical instruments are contaminated. Disease may occur from injury. Dispose of in a puncture resistant container. Refer to local regulatory guidelines .</p> <p>Risks, contradictions, precautions and side effects - Incorrect use may cause blindness.</p> <p>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. Surgitrac reusable devices are precision surgical devices. The utmost care must be taken at all times when handling these devices to avoid damage. Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. No part of the process shall exceed 170°C</p> <p>DO NOT apply an ultra-sonic cycle to devices with fine delicate tips, such as hooks and probes.</p> <p>Note: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.</p>

<p>Medical Device Status</p> 	<p>These devices are currently placed on the market. Provided non-sterile. Refer to reprocessing guidelines.</p>
<p>Limitations on reprocessing:</p>	<p>Repeated processing has minimal effect on these devices. End of life is normally determined by wear and damage due to use. Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. For best results, and to prolong the life of the device, reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying, removing excess soil with disposable cloth/paper wipe. If supplied, ensure protective caps and guards are fitted to devices. The warranty provided on reusable devices is 2 years.</p>
<p>Preparation for cleaning</p>	<p>Reprocess all devices as soon as it is reasonably practical following use. Using a bristled brush so soft not to damage delicate tips, remove all blood, debris or bodily fluids.</p>
<p>Cleaning: Ultrasonic</p>	<p>We recommend a non-ionic detergent is used in the ultrasonic bath and that a 5-minute ultrasound cycle is used. Avoid any acid based products when cleaning Surgitrac's instruments and always follow the guidelines set by the detergent manufacturer and mechanical cleaner manufacturer. Care must be taken, as not all the Surgitrac instrument range is compatible with this method of cleaning. Devices with delicate tips, in particular some Hooks and Probes are not recommended for an ultrasonic cycle.</p>
<p>Cleaning: Automated</p>	<p>Use only validated washer-disinfector machines compliant with HTM01-01 or equivalent guidance and low-foaming, non-ionizing cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles. It is recommended to disinfect thermally (at least 1 minute at 90-95°C) to reduce the risk of disinfectant residuals. Disinfectant solution may be used in accordance with label instructions of the disinfectant manufacturer. When preparing the devices for cleaning, ensure that they do not touch each other and the devices are in a relaxed state. Locks and hinges should be open.</p> <p>Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets. Place devices with concave surfaces, for example curette's, facing down to prevent pooling of water. Where available, use appropriate flushing adaptor attachments to flush inside devices with lumens or cannulations. Ensure lumens and cannulas have unobstructed flow prior to fitting flushing adaptors to ensure thorough cleaning and disinfection. Ensure that soft, freshly distilled or deionised water which is sterile or controlled for bacterial endotoxins is used in the final rinse stage. When unloading check cannulations, holes etc for complete removal of visible soil. If necessary repeat cycle / manual cleaning. Note: automated cleaning may not be suitable for all lumens and cannulations, in which case clean manually with a water jet gun, if available, and an appropriate brush that reaches the depth of the feature. After manually cleaning, pass all devices through an automated cleaning cycle to achieve disinfection.</p>

<p>Cleaning: Manual</p> <p>WARNING!</p>	<p>Care must be taken not to damage delicate tips on devices by the use of hard brushes, scouring agents or excessive force.</p> <p>Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following processes:</p>
<p>Manual Cleaning – General Devices</p>	<p>Method: 1. Rinse excess soil from device.</p> <p>2. Fully immerse device into a detergent solution not exceeding 30°C.</p> <p>3. It is recommended that the device be cleaned as soon after use as possible, however where blood, tissue, saline or viscoelastic has been left to dry it is recommended that the device is left to soak for 30 minutes in the detergent solution.</p> <p>4. Using a brush, wash and scrub vigorously applying detergent solution to all surfaces ensuring that hinged devices are cleaned in both open and closed positions.</p> <p>5. It is important to ensure that no air is trapped inside the devices with lumens or cannulations and that the detergent covers all surfaces. These devices should also be flushed through with a clean detergent solution for a minimum of 3 times.</p> <p>6. After manual cleaning, rinse the device for a minimum of 3 times. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied.</p>
<p>Manual Disinfection</p>	<p>Disinfectant solution may be used in accordance with label instructions of the disinfectant manufacturer. After manual disinfection, rinse the device with freshly distilled or deionised water for a minimum of 3 times. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied. Undertake the entire manual cleaning and disinfection process again if the last rinsing solution is not clear or if impurities are still visible on the device.</p>
<p>Packaging</p>	<p>Devices should be packaged in wrap or pouches compliant with ISO11607/EN868 as appropriate. Tip protectors should be used for delicate/sharp devices.</p>
<p>Drying</p>	<p>When drying is achieved as part of a washer disinfector cycle, do not exceed 170°C. Products may be dried using filtered compressed air.</p>
<p>Sterilisation</p>	<p>Instruments can be sterilized using steam at 134-137°C for 3 – 3 ½ minutes. Steam sterilisers should be compliant with HTM01-01 or equivalent guidance.</p>
<p>Maintenance/Testing</p>	<p>Apply a small quantity of surgical lubrication oil to hinges. Discard blunt or damaged devices.</p>
<p>Inspection & Function</p>	<p>Visually inspect and check:</p> <ul style="list-style-type: none"> • All devices for damage and wear. • Cutting edges are free of nicks and present a continuous edge. • Jaws and teeth align correctly. • All articulated devices have a smooth movement without excess play. • Locking mechanisms (such as ratchets) fasten securely and close easily. • Long, slender devices are not distorted. Remove for repair or replacement any blunt, worn out, fractured or damaged devices. If any soil or fluid is still visible, return the device for repeat decontamination. <p>Note: if a device is returned to the manufacturer / supplier, the device MUST be decontaminated and sterilised and be accompanied by the relevant Declaration of Decontamination.</p>

	<ul style="list-style-type: none"> • Any device with a measuring function should be checked prior to first use using a micrometer which is calibrated, traceable to national standards. <p>Other forms of cleaning (i.e. ultrasonic) and sterilisation (i.e. low temperature steam and formaldehyde, ethylene oxide and gas plasma) are available. However, always follow the instructions for use as issued by the processing equipment manufacturer and always consult with them if in any doubt over the suitability of any process used.</p>
Additional Information	<p>Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.</p>
Manufacturer 	<p>Sihong Surgitrac Co Ltd No.2 Xihu Road, Sihong Industrial Park Jiangsu, 223900 www.surgitrac.com info@surgitrac.com</p>
Storage 	<p>Once sterile, packs should be stored in accordance with the packaging manufacturers instructions. Always store sterile instruments in a clean, dry environment, away from sunlight.</p> <p>Keep dry</p> <p>Keep out of direct sunlight</p>
IFU 	<p>Consult instructions for use. Electronic version available at www.surgitrac.com, then go to: About us – Quality and Credentials.</p> <p>Instructions are available in PDF version. An internet connection and PDF reader is required. The IFU is available in English. If other languages are required, or a paper copy of the IFU is required, please contact: Surgitrac Instruments UK Limited Unit 10 Wharfside Business Park Irlam Wharf Rd Irlam M44 5PN UK Tel: 0161 7767626</p>