Guidelines for reprocessing Surgitrac Instruments' reusable surgical instruments

The following are guidelines for reprocessing all reusable medical devices supplied by Surgitrac Co. Limited (Surgitrac), 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 as actually performed, using equipment, materials and personnel in the facility, achieve the desired results. 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. 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 and sterilisation.

This document is valid from 1 August 2016.

WARNING:

- Products supplied by Surgitrac are non-sterile.
- Never use reusable instruments that have not been cleaned, disinfected and sterilised first.

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Category	Guidelines
WARNINGS:	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 DO NOT apply an ultra-sonic cycle to devices with fine delicate tips, such as hooks and probes *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 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.
Preparation for cleaning:	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.
Cleaning: **Ultrasonic**	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.
Cleaning: Automated	Use only either CE marked or validated washer-disinfector machines 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 10 minutes at 93°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.

	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 or repeat 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. *Note: these instructions have been validated using a washer-disinfector cycle validated to include a cold rinses at 30ºC, a detergent cycle and a rinse cycle, a disinfection cycle operating at a temperature of 93°C for a minimum holding time of 10 minutes and a 20 minute drying cycle. The detergent used was a Lancerzyme, a cleaning agent for metallic surgical devices and rinsed with sterile water.*
Cleaning: **Manual** **WARNING**	Care must be taken not to damage delicate tips on devices by the use of hard brushes, scouring agents or excessive force. Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following processes:
Cleaning: **Manual General** **Devices**	Method: 1. Rinse excess soil from device. 2. Fully immerse device into a detergent solution not exceeding 30°C. 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. 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. 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. 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.

Disinfection: Manual	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. Redo the entire manual cleaning and disinfection process if the last rinsing solution is not clear or if impurities are still visible on the device.
Drying:	When drying is achieved as part of a washer disinfector cycle, do not exceed 170°C. Products may be dried using filtered compressed air.
Maintenance : Testing	Apply a small quantity of surgical lubrication oil to hinges. Discard blunt or damaged devices.
Inspection and function:	Visually inspect and check: • 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. **Note:** *if a device is returned to the manufacturer / supplier, the device MUST be decontaminated and sterilised and be accompanied by the relevant documented evidence.*
Storage:	Other forms of cleaning (i.e. ultrasonic) and sterilisation (i.e. low temperature steam and formaldehyde, ethyleneoxide 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.
Additional information:	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.
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