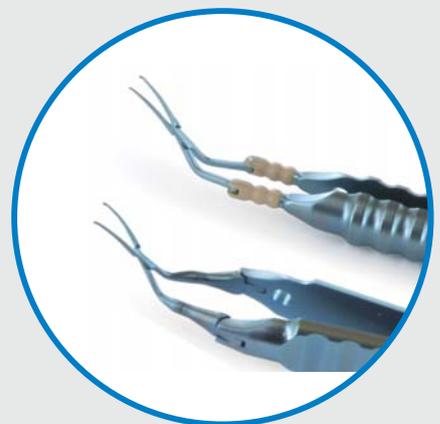
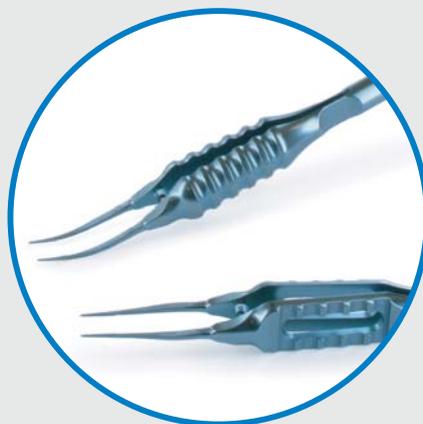
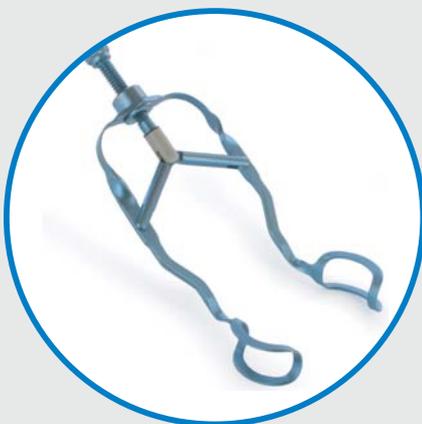
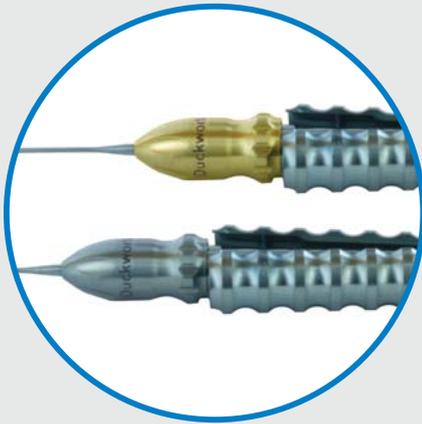




Guidelines for Reprocessing

Duckworth & Kent Ltd reusable surgical devices



General Remarks :

The following are guidelines for reprocessing for all reusable medical devices supplied by Duckworth & Kent Ltd, 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 maybe 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 the Duckworth & Kent Ltd. 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 was current at time of print; please contact Duckworth & Kent Ltd. to ensure you have the current Guidelines for Reprocessing.

Products unless stated otherwise are supplied from Duckworth & Kent Ltd in a non-sterile state and are not to be used without being cleaned, disinfected and sterilised.

Products unless stated are not to be sterilised in delivery packaging.

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.

Duckworth & Kent Ltd 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 diamond blades or 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.

Any specific limitations on the number of reprocessing cycles shall be made available with the device.

Point of 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.

Containment and transportation :

If supplied, ensure protective caps and guards are fitted to devices.

Ensure that cutting edges are protected and diamond blades are retracted into their handle.

Preparation for cleaning :

Reprocess all devices as soon as it is reasonably practical following use.

Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device.

To remove all blood, debris or bodily fluids use a soft bristled brush, soft enough to avoid damaging delicate tips.

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 D&K devices and always follow the guidelines set by the detergent manufacturer and mechanical cleaner manufacturer.

Care must be taken, as not all the Duckworth & Kent Ltd range is compatible with this method of cleaning. Devices with delicate tips, in particular some Hooks and Probes and diamond knives are not recommended for an ultrasonic cycle.

Cleaning : Automated

Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturers 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 unlocked, hinges open etc).

Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets.

Place devices with concave surfaces (e.g. curettes) 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 30°C, 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.

Cleaning : Manual Diamond Knives

Method:

1. Rinse excess soil from device.
2. Extend diamond blade from handle and gently wipe the blade from back to tip with a detergent wipe.
Note: We would NOT recommend that any type of brush be used on the diamond blade.
3. Retract the diamond blade back into it's handle (where option is available) and fully immerse device into a detergent solution not exceeding 30°C.
4. 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.
5. Using a brush, wash and scrub vigorously applying detergent solution to all surfaces.
6. 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.
7. After manual cleaning, rinse the device in clean water for a minimum of 3 times. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied.

Disinfection : Manual	<p>Disinfectant solution may be used in accordance with label instructions of the disinfectant manufacturer.</p> <p>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.</p>
Drying :	<p>When drying is achieved as part of a washer disinfector cycle, do not exceed 170°C.</p> <p>Products may be dried using filtered compressed air.</p>
Maintenance Testing :	<p>Apply a small quantity of surgical lubrication oil to hinges.</p> <p>Discard blunt or damaged devices.</p>
Inspection and Function :	<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. - any component parts fit and assemble correctly with mating components. - where devices form part of a larger assembly, check assembly with mating components. <p>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> <p>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.</p>
Packaging :	<p>Singly: A standard packaging material may be used. Ensure that the pack is large enough to contain the device without stressing the seals.</p> <p>In sets: devices may be loaded into dedicated device trays, or general-purpose sterilisation trays. Wrap the trays using appropriate method.</p> <p>Ensure that cutting edges are protected, diamond blades are retracted into their handle and if supplied protective caps are fitted to delicate tips.</p>
Sterilisation :	<p>Moist heat (steam) in autoclavable bags is the preferred method of sterilisation.</p> <p>Only products that have been cleaned and disinfected can be sterilised.</p> <p>Use either CE marked or validated vacuum autoclave - always following the instructions of the machine manufacturer. When sterilising multiple devices in one autoclave cycle ensure that the steriliser's maximum load is not exceeded. Ensure devices are dry before sterilisation.</p> <p>Do not exceed 170°C.</p> <p>Note: A sterilisation cycle of: 1) a temperature of 126°C with a holding time of 26 minutes and 2) a temperature of 134°C with a holding time of 3-3.5 minutes have been validated.</p>
Storage :	<p>Ensure devices are dry before storage, and stored in dry, clean conditions at an ambient room temperature.</p>
Additional Information :	<p>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.</p> <p>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.</p> <p>Note: <i>DO NOT</i> apply an ultra sonic cycle to devices with diamond blades or fine delicate tips, such as hooks and probes.</p>
Manufacturer Contact :	<div style="display: flex; align-items: center;">  <div style="flex-grow: 1;"> <p><u>Duckworth & Kent Ltd</u> 7 Marquis Business Centre Royston Road, Baldock Herts SG7 6XL England</p> </div> <div style="margin-left: 20px;"> <p>Tel: +44 (0)1462 893254 Fax: +44 (0)1462 896288 Email: info@duckworth-and-kent.co.uk</p> </div> <div style="margin-left: 20px; align-self: center;">  </div> </div>
<p>See brochure for telephone and address of local representative</p>	

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