Surgical Instruments Cleaning & Sterilization

CARE, CLEANING AND HANDLING OF SURGICAL INSTRUMENTS

The following instructions are applicable for all reusable medical devices/ surgical instruments supplied by Empire Medical, unless stated otherwise with the packaging of the product.

These instructions conform to the Medical Directive 93/42/EEC (Annex 1 section 13)

These instructions are intended for use only by persons with the required specialist knowledge and training.

Precautions:

• 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.

• Do not clean instruments in Theatres with saline, use sterile water.

• Aluminium, Rubber, Plastic, Blackened, Insulated and Fibrelight devices may be damaged by high alkaline detergents pH > 11.

• As per HTM 0101 1.138 alkaline detergents in the pH range 8.0–11.0 are preferred.

• Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning

Limitations on Reprocessing:

• Repeated processing has minimal effect on these devices.

• End of life is normally determined by wear and damage in use.

• Any specific limitations on the number of reprocessing cycles are indicated in the IFU for the device.

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Empire

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Recommended Cleaning Instructions for Our Surgical Instruments. Proper care and handling is essential for satisfactory performance of surgical instruments.

The following steps should be taken to ensure long and trouble-free service.

DECONTAMINATION

- ✓ Inspect instruments before each use for broken, cracked, chipped or worn parts.
- ✓ Begin Decontamination within 20 minutes following a procedure.
- ✓ Pre-clean , spray or soak instruments with a pH neutral enzymatic solution. This will help dissolve any blood, mucous, tissue from the instruments and make the cleaning process easier and more effective. Let the instruments soak from 10-20 minutes.
- ✓ Never allow blood to dry on the instruments.
- ✓ Rinse the instruments with distilled, filtered water. Never use tap water as it contains minerals that could leave a residue (stain) on the instrument surface
- ✓ The instruments are now ready for cleaning.

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Surgical Instruments Cleaning & Sterilization

Automated Cleaning

Our Instruments are suitable to be processed through automated washer-disinfector machines and ultrasonic cleaners Cleaning.

Automated washer-disinfector machines

Our Instruments are suitable to be processed through automated washer-disinfector machines which are CE marked and validated to ISO 15883-2:2006.

Adhering to: HTM 01-01: Management and decontamination of surgical instrument: Part D - Washer- disinfectors

1. Load devices carefully, with any box joints and hinges open and so that any fenestrations in devices can drain.
2. Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets.
3. Place devices with concave surfaces (e.g., curettes) facing down to prevent pooling of water.
4. Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.
5. Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.

Cleaning parameters: Washer Disinfector (Thermal) 90°C (-0°C +5°C) for minimum of 1 minute

- ✓ The first stage of a washer disinfectors cycle is to clean the instruments within. Using cold water, the machine will perform a pre-rinse, removing any thick soiling.
- ✓ Next, a detergent cycle will work to remove any remaining agents to ensure instruments are thoroughly cleaned. Next, comes the disinfection. This is performed at a high heat, around 90°C, over a period of time that can be set by the user.

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Ultrasonic Cleaning

Note: Blood and tissue should be removed from instruments at a temperature below 40°C (104°F). That is because elevating the temperature can cause protein in blood to harden and become more difficult to clean.

- ✓ Use a pH neutral enzymatic cleaning solution.
- ✓ Instruments must be fully submerged with hinged instruments in an open position. Do not overload.
- ✓ Ensure that sharp-delicate instruments such as scissor blades do not touch other instruments in order not to damage blades and scratch surfaces.
- ✓ Separate dissimilar metals such as stainless steel from silver plated. Combining dissimilar metals could cause electrolysis which can result in pitting in the steel.

Note: Automated cleaning may not be suitable for all lumens and cannula 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 automatic cleaning cycle to achieve disinfection.

Note: Our surgical instruments have been validated using a washer-disinfector cycle validated to include two cold rinses at 50°C, a disinfection cycle operating at a temperature of between 80 °C and 90 °C for a minimum holding time of 1 minute. (actual holding time in excess of 2 minutes 50 seconds) and a 20-minute drying cycle.

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Rinsing - Inspection

- ✓ After automated or manual cleaning, always rinse instruments thoroughly with distilled-filtered water.
- ✓ Try to avoid rinsing with tap water because the high mineral content could lead to staining.
- ✓ Proper rinsing will ensure removal of any residue/cleaning solution left on the instruments.
- ✓ Never allow instruments to air dry, always hand dry with a towel.

Lubrication

- ✓ Following rinsing, dry the instruments by hand with a towel.
- ✓ All hinged instruments require lubrication.
- ✓ Use a water soluble, steam permeable lubricant.
- ✓ Lubricant can be applied to the instruments by Spray or if processing many instruments at a time, the instruments can be submerged in a lubricant “milk’ bath.
- ✓ It is Important that the lubricant not be rinsed off the instrument before sterilization.
- ✓ Then proceed to prepare instruments for sterilization.

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Sterilization

- ✓ Following lubrication, the instruments are prepared for sterilization. While there are several sterilization methods, it is recommended that surgical instruments are sterilized using a steam autoclave.
- ✓ Instruments are placed in a perforated sterilization tray, then wrapped and labelled or placed in a closed sterilization container. Instruments can also be placed in a peel pouch.
- ✓ Ensure that hinged instruments are in an open position inside the pouch and the pouch is wide enough, labelled, ensure dissimilar metals are separated.
- ✓ Sterilize in a steam autoclave conforming to BS EN 285:2015 at a holding temperature of 134°C to 137°C for between 3 to 3.5 minutes.

Note: Validated to the following standard EN 17665-1:2006 Follow the Autoclave manufacturers' instructions to sterilize. It is important that the autoclave be cleaned on a regular basis and that all cycles, especially the drying cycle is properly working.

Note: It is important to know that most cold sterilization solutions are damaging to surgical instruments, especially on tungsten carbide needle holder jaws and scissor blades Our surgical instruments are compatible and will not affect the sterility of the instruments being processed on the UK standard parameters as below.

- Washer - 90-degree Temp - 1 minute exposure time
- Steriliser - 134 - 137-degree temp , 3 - 3.5 minutes exposure time

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Storage:

• Ensure devices are dry before storage, and stored in dry, clean conditions at an ambient room temperature.

Additional Information:

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 issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.

• Cleaning and sterilizing guidelines are detailed in:

Health Technical Memorandum 01-01: Management and decontamination of surgical instruments. Part C: Steam sterilization Part D: Washer-disinfectors.

https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care

• Note: It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

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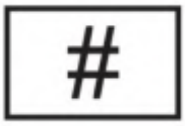
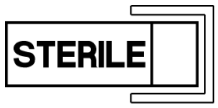
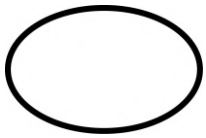
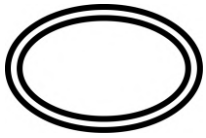
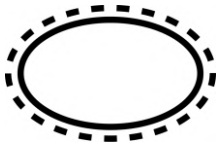
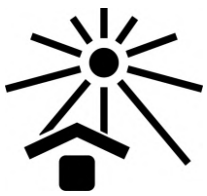
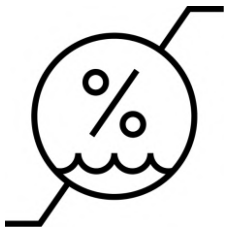
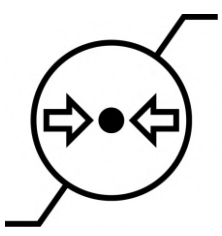
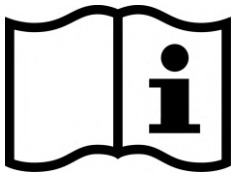
Symbols on product and packages

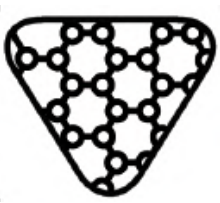
MANUFACTURER	
	Indicates the medical device manufacturer
	Indicates the authorized representative in the European Community / European Union
	Indicates the date when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.
	Indicates the manufacturer’s batch code so that the batch or lot can be identified.
	Indicates the manufacturer’s catalogue number so that the medical device can be identified.
	Indicates the manufacturer’s serial number so that a specific medical device can be identified.
	Indicates the entity importing the medical device into the locale

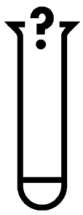
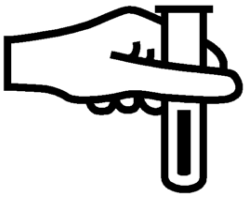
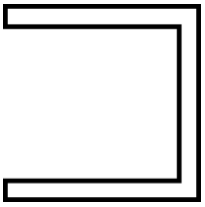
	Indicates the entity distributing the medical device into the locale
	To identify the model number or type number of a product
	To identify the country of manufacture of products
STERILITY	
	Indicates a medical device that has been subjected to a sterilization process.
	Indicates a medical device that has been manufactured using accepted aseptic techniques.
	Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates a medical device that has been sterilized using irradiation.
	Indicates a medical device that has been sterilized using steam or dry heat.
	Indicates a medical device that is not to be resterilized
	Indicates a medical device that has not been subjected to a sterilization process.

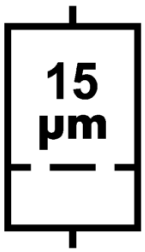
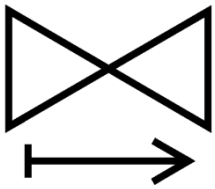
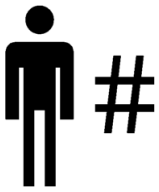
	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.
	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide
	Indicates a single sterile barrier system
	Indicates two sterile barrier systems
	Indicates a single sterile barrier system with protective packaging inside
	Indicates a single sterile barrier system with protective packaging outside
Storage	
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates a medical device that needs protection from light sources.

	Indicates a medical device that needs protection from heat and radioactive sources.
	Indicates a medical device that needs to be protected from moisture.
	Indicates the lower limit of temperature to which the medical device can be safely exposed.
	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the range of humidity to which the medical device can be safely exposed.
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Safe Use	
	Indicates that there are potential biological risks associated with the medical device.
	Indicates a medical device that is intended for one single use only.
	Indicates the need for the user to consult the instructions for use.
	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Indicates a medical device that contains or incorporates human blood or plasma derivatives.
	Indicates a medical device that contains or incorporates a medicinal substance

	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin
	Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin
	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties
	Indicates a medical device that contains nano materials
	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient
IVD Specific	
	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Indicates a control material that is intended to verify the performance of another medical device.
	Indicates a control material that is intended to verify the results in the expected negative range.

	Indicates a control material that is intended to verify the results in the expected positive range.
	Indicates the total number of IVD tests that can be performed with the IVD medical device.
	Indicates an IVD medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.
Transfusion / Infusion	
	Indicates a medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.
	Indicates the presence of a fluid path.
	Indicates a medical device that is non-pyrogenic.
	Indicates the number of drops per millilitre.

	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size
	Indicates a medical device with a valve that allows flow in only one direction.
Others	
	Indicates a unique number associated with an individual patient.
	Indicates the name of the patient
	Indicates the identification data of the patient
	Indicates a website where a patient can obtain additional information on the medical product
	To indicate the address of the health care centre or doctor where medical information about the patient may be found

	To identify the date that information was entered or a medical procedure took place
	Indicates the item is a medical device
	To identify that the original medical device information has undergone a translation which supplements or replaces the original information
	To identify that a modification to the original medical device packaging configuration has occurred
	Indicates a carrier that contains Unique Device Identifier information

Symbols	
	Use only on machines with exact UF control
	Max. TMP (physical limitation) 600 mmHg (80 kPa)
	Volume of blood compartment (blood tubing & OMNIfilter®)
	Suitable for Regional Citrate Anticoagulation
	Suitable for Heparin Anticoagulation
	Tubing length, cm
	Does not contain natural rubber latex
	Does not contain PVC