Best Practice Guide for

Decontamination Processing of Re-usable Medical Devices

WarwickSASCo
Moulding The Future of Medical Plastics

The aim of this guide is to give guidance on processing re-usable medical devices through the decontamination cycle.

The Decontamination Cycle

Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to render a re-usable item safe for further use on patients and handling by staff. The effective decontamination of re-usable surgical instruments is essential in minimising the risk of transmission of infectious agents.

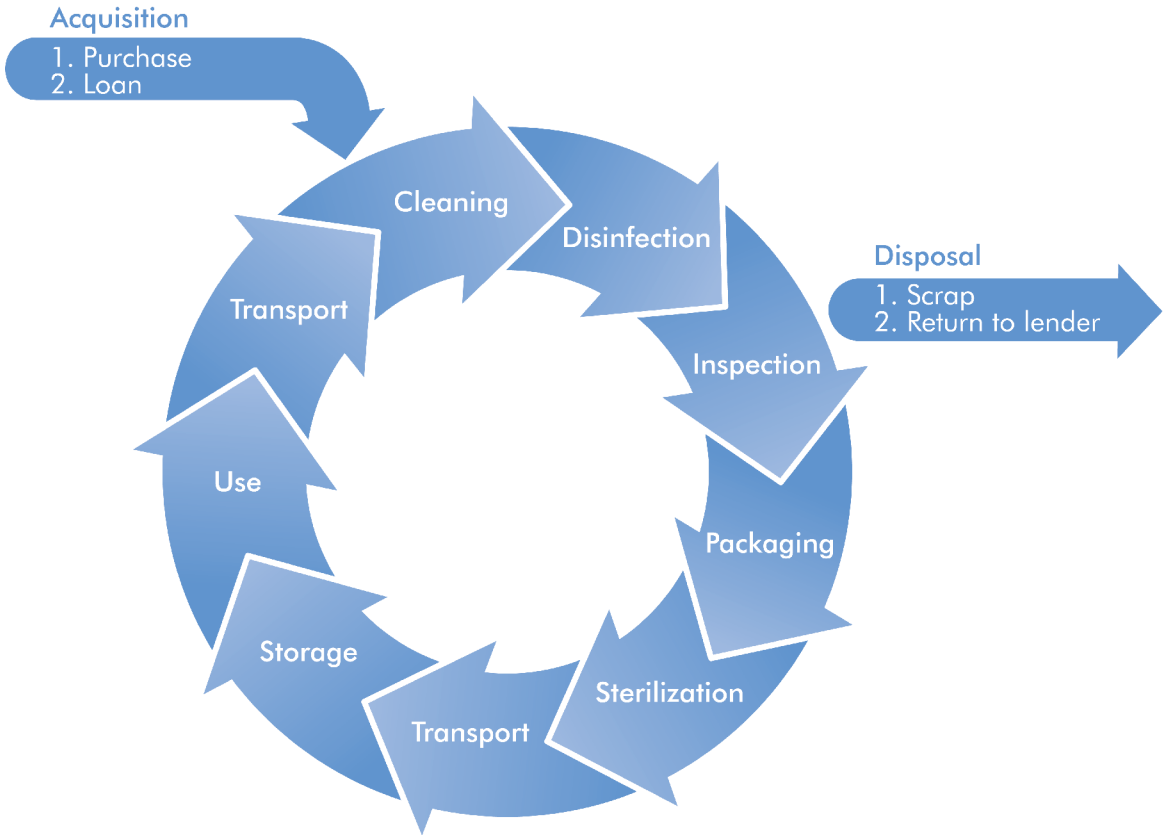


Figure 1

Figure 1 highlights each stage of the decontamination process through which surgical instruments and medical devices must pass through before use. Effective decontamination requires the attainment of acceptable standards at all stages of the life cycle.

Medical devices can be classified in a variety of ways, such as purpose for use, materials of construction, and the risk of contamination/infection transmission to a patient. A further classification is if the device is for single use (on a single patient) or can be re-used (with many patients).

A single use device can be simply defined as a device that has been designed and manufactured for use on a single patient and then discarded.

A re-usable device is designed to be used on a patient, decontaminated and then used again with another patient. The process can be repeated many times with re-usable devices until it is no longer needed, is damaged, unsafe to use or otherwise replaced. The emphasis is therefore placed on ensuring that the device is safely handled and decontaminated between patients.

Devices enter the cycle as either new devices provided by a manufacturer or on loan (that need to be prepared for first time use) or following actual clinical use.

Failure to effectively process devices in any of these stages will result in inadequate decontamination, rendering the device or instrument non-sterile and non-usable.

1.0 Acquisition

Purchasing

It is appropriate for an organisation or hospital to have a clearly stated policy outlining requirements for the purchasing of medical devices. This should include a consultation process to ensure that all those involved in the purchase, decontamination and use of the device are given the opportunity to discuss the suitability of an instrument or medical device before a purchase is made.

Lack of consultation has often resulted in devices being purchased which cannot be adequately decontaminated, as they are subsequently found to be incompatible with the decontamination processes available within the organisation. For example, some devices manufactured outside of the UK cannot be processed at 134°C.

Best practice suggests automated washing processes are the preferred option. Therefore, devices that can be mechanically cleaned and thermally disinfected should be purchased whenever possible.

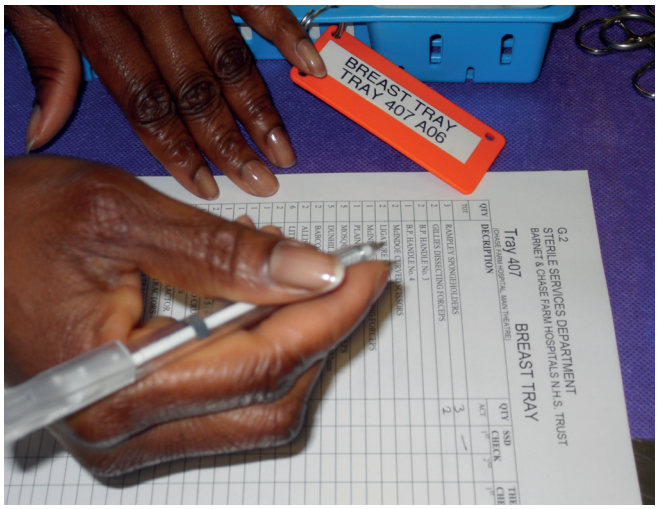
Loan Surgical Instruments and Devices

It may sometimes be necessary to borrow equipment from another organisation or manufacturer. Such instrument sets are known as 'loan sets'.

All surgical instruments and devices, including loan sets, should be cleaned and sterilized before and after use in accordance with manufacturer instructions.

Tracking and Traceability of Medical Devices

It is important to be able to trace medical devices and instruments through the decontamination cycle, to identify their processing, who was responsible and the patient on whom the devices were used.



The ability to track and trace surgical instruments and equipment through the decontamination cycle enables corrective action to be taken when necessary. For example, in the unlikely event of a sterilization cycle failure, products can then be easily recalled.

Department of Health, commented in 2000

"It is important that systems are in place to allow sets of surgical instruments to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively. Systems should also be implemented to enable the identification of patients on whom the instrument sets have been used. This is important so that the relevant patients can be identified in the event of exposure to potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instruments is in addition to the measures for identification and tracking of flexible endoscopes set out in Health Services Circular 1999/178."

2.0 Cleaning

Effective cleaning of instruments (medical devices) before sterilization is of the utmost importance to reduce the risk of transmission of infectious agents. This may be achieved by either manual or automatic washing. Whenever possible, cleaning should be undertaken using an automated and validated process in preference to manual cleaning. Manual cleaning should be considered only where manufacturer's instructions specify that the device is not compatible with automated processes.

Research suggests that instruments cleaned as soon as possible after use are more easily cleaned than those left for a number of hours before reprocessing. Where instruments have to be transported from the point of use to the processing centre, collections should be made at frequent intervals throughout the day to ensure processing takes places as soon as possible after use.

It should be noted that certain solutions, in particular blood, saline and iodine, are corrosive to stainless steel instruments and will cause pitting and then rusting if allowed to remain on instruments for any length of time.

First Use of Surgical Instruments

Many re-usable items are manufactured in non-sterile environments and some are handled extensively during this process. In addition, many manufacturers leave anti-corrosive agents on the surface and in the joints of the item for protection during transit. New items should therefore be cleaned and sterilized before being put into use. Manufacturer's instructions should be followed where available.

Disassembly of Instruments

Equipment consisting of more than one component must be dismantled so that each part can be adequately cleaned. Information on the methods of disassembly of surgical instruments should be sought from the manufacturers. Manufacturer's instructions are commonly known as Instruction for Use documents (IFUs).

Automated Cleaning

• Washer Disinfectors

Each stage of the decontamination process should contribute to the reduction of bioburden on the device being reprocessed. Bioburden is the microbial load or number and type of micro-organisms on a surface or object.

The full range of cleaning operations (washing, rinsing, disinfecting and drying) is usually carried out in an automated washer disinfector.

The machine is pre-programmed at installation, often with a number of cleaning cycles, and the operator selects the appropriate cycle based on the type of load being processed.

Stage	Action	Result
Pre-wash	Flushing with cold water (below 35°C to prevent protein coagulation)	Removes gross contamination
Washing	Washing using a solution of hot water and detergent	Removes remaining soil using water jets, ultrasonic action, or both
Rinsing	Flushing with high quality water	Removes cleaning agents used in the previous stage
Disinfection	Flushing with very hot water or steam, usually for between 1 and 10 minutes, depending upon the temperature. Standard is 90°C for 1 minute.	Destroys most micro-organisms, except spores
Drying	Circulation of very hot air.	Removes all remaining moisture from the chamber and load

Figure 2

•Ultrasonic Cleaners

Ultrasonic cleaners are used to clean instruments and devices that have a complex design which would restrict their effective cleaning by hand or in a washer disinfector machine; or for devices that have a heavy bioburden residue that may not initially be removed in a washer disinfector cycle.

Ultrasonic cleaning should be used only if instructed by the device manufacturer. Ultrasonic action helps to thoroughly clean devices with joints or multiple components that are difficult to clean manually.

3.0 Disinfection

Disinfection is defined as a process used to reduce the number of viable micro-organisms in a load, but which may not necessarily inactivate some viruses and bacterial spores. Disinfection in the clinical setting may be achieved by a number of methods – the two most common being moist heat and liquid chemicals.

Moist heat is the method of first choice as it is easily controlled, leaves no toxic residues and is relatively safe to those involved in the process. Disinfection can be achieved by washing and rinsing devices in water at 90°C. See Figure 2 under Cleaning.

Devices that cannot withstand high temperatures required for disinfection by moist heat may be disinfected using chemicals. Receptacles used for chemical disinfection solutions must be cleaned and steam sterilized before being used. Care must be taken to ensure that the device is scrupulously clean, that the correct chemical concentration is used, and that the device is properly submerged to ensure contact with all parts.

4.0 Inspection and Function Testing

The importance of inspecting each instrument cannot be over-emphasised. A visual check for cleanliness and dryness should be made for all items washed as part of the decontamination process. All non-conforming products, i.e. dirty, wet or stained, should be rejected and returned to the wash area for manual cleaning, following by an automated wash process, before continuing through to packaging and sterilization.

The condition of the instrument has a significant effect on how adequately it can be cleaned.

Instruments that are subjected to rough handling will develop scratches and damage to surfaces, which will harbour dirt. Instruments that have an outer insulation coating, for example diathermy forceps, require close inspection to ensure that the insulation remains intact. Damaged surfaces not only allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and patients.

As part of the decontamination process, all instruments should be subject to function-testing following the cleaning process to ensure that they will perform the tasks for which they are designed. Basic tests should be undertaken to ensure that:

- there is free movement of all parts and that joints do not stick
- the edges of clamping instruments meet with no overlap and that teeth mesh together
- scissor edges meet to the tip and move freely across each other with no overlap or burrs
- all screws on jointed instruments are tight and have not become loose during the cleaning process

In preparing instruments for wrapping and sterilization, it is essential that all surfaces are exposed to the sterilization method (steam or chemical) and that, where devices can be taken apart, they are sterilized in this state where possible.

It is vital to have a procedure whereby the users of surgical instruments will inform those responsible for reprocessing about defects and the need to have items repaired or replaced.

5.0 Packaging

Packaging materials should be used that comply with the appropriate packaging standards for sterilization (BS EN868). The packaging materials must be compatible with the sterilization process and may be of either a rigid or flexible material.

The reasons for packaging instruments are:

- containment of the product through the different stages of the decontamination process
- to allow sterilization to take place
- to protect the product during sterilization and transportation from deterioration and damage
- to maintain sterility to the point of use
- to prevent contamination of the device following decontamination

There are a variety of packaging materials available for individual surgical instruments. The choice of type and size will depend on the item to be packaged. Peel-apart pouches or specialist paper bags are often used for single instruments or small loads.

Other forms of packaging suitable for larger devices or multiple items include metal or plastic containers, metal or polypropylene trays of varying dimensions, sterilization paper, plain and crepe.

Once a surgical pack is assembled it must be wrapped in medical grade packaging material, ready for sterilization. The wrapping material must permit the steam or gas to pass freely through the tray and instruments, and once sterilized it must act as a protective barrier during handling and transportation.

Tray Selection

Surgical instruments and sundries are organised into sets for surgical procedures. Sets will contain instruments specific for surgical procedures and may include sundries such as bowls, receivers, trays, gallipots, dressings, drills, implants etc. Complex procedures may require instruments to be packed into several sets.

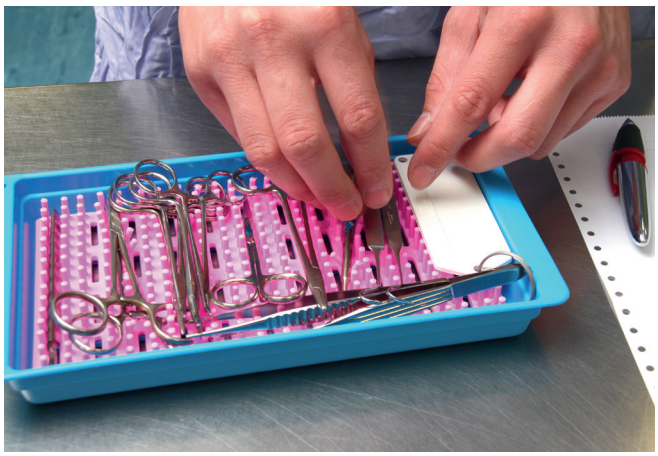
- Always select the tray that is the most suitable for the type of sterilization process being used.
- Perforated base and sides improve steam penetration and air circulation.

Perforated or mesh bases assist the permeation of sterilizing agent and give improved decontamination results

- Metal accessories can lead to condensation and wet packs.
- Trays should be smooth with no sharp edges that tear the packaging.
- Metal containers and lids should not be damaged and lids should close completely.
- Complex or heavy procedure packs should be split down into multiple sets to avoid damage by heavy instruments.
- Heavy packs can lead to staff injury. Pack handling should be limited to 7kg for female staff and 10kg for male staff as per guidelines.
- A tray pick list should be used to ensure that all components are included; this can then be used for tracking the pack (traceability).

Use a pick list for traceability

- Tray size should be appropriate for the size of the procedure; small trays for small to medium procedures, larger trays for theatre packs and orthopaedic sets.



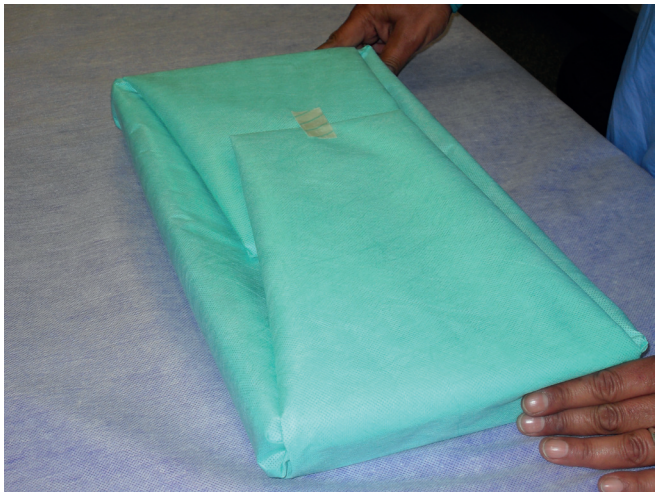
Correctly packed tray for size of procedure.

- Allowance should be made for extra length and irregular shaped instruments.
- Trays should not be overloaded, as this can prevent effective sterilization and cause damage to instruments.

Tray and instrument damage due to overloading.

- Instruments should be laid in the tray in the order that they are to be used. Too many instruments may cause the instruments to 'muddle' together, delaying operation time.
- Select the type of tray; solid base or a perforated/mesh base to allow penetration and evacuation of the sterilizing agent and give improved drying results.
- Devices should be dry and disassembled before packing.
- Instruments should be slightly open to allow sterilizing agent to touch all exposed surfaces.
- Absorbent tray liners may be used.
- Heavy instruments should be placed at the bottom of the pack to avoid damage to other instruments.
- Do not over pack tray or force instruments into tray, as they may become damaged.
- Tips of instruments should all be facing the same way.
- Select the correct material that is most appropriate for the type of sterilization process being used.
- Ensure the material chosen allows for penetration and dispersal of steam.
- Woven textiles, cotton and linen blends can be reprocessed by laundering.
- Non-woven textiles are intended for single use (consist of a bonded web made of textile and/or non-textile fibres). These textiles are suitable for steam sterilization, but not for use with Hydrogen Peroxide.
- Specialist medical papers are intended for single use. Crepe type papers are easily penetrated by steam and Ethylene Oxide but are not suitable for use with Hydrogen Peroxide.
- Pouches and reels are suitable for lightweight, small to medium sized packs.
- Incorrect selection of the wrapping material can cause the sterilization process to fail.
- Always use two sheets of sterilization wrapping material.
- Once the tray is wrapped, it must be effectively sealed and labelled to prevent recontamination.
- It is important to ensure the correct size of wrapping material is selected for each tray. If the package is wrapped tightly, the tray may distort during sterilizing, or the seal may loosen, leading to contamination and the need for reprocessing.
- Movement of the trays in the sterilizer, store room, and transfer to the surgical room can damage the wrapping paper.
- A carrier tray may be used to prevent wrapped trays becoming damaged in transit.
- Trays with damaged wraps must be considered non-sterile and will need to be reprocessed.
- Polypropylene trays are compatible with all types of packaging material.

Ensure the correct size of wrapping material is selected for each tray.



Wrapped trays must be sealed.

Always use 2 sheets of wrapping material.

Packs should be effectively wrapped and sealed to prevent recontamination.

Labelling of Sterile Medical Devices

Sterile packs and medical devices should be labelled for identification and tracking purposes in accordance with ISO 15223-1:2012 Medical Devices -- Symbols to be used with medical device label.

In addition to the above symbols, the following information should be available for the device being processed:

- name of device/pack
- name of the manufacturer and reprocessor
- date of manufacture/sterilization
- date of expiry where appropriate
- the method of sterilization used, i.e. steam, ethylene oxide etc.
- cycle number/machine number of the sterilizer used.

6.0 Sterilization

Saturated steam under pressure delivered at the highest temperature compatible with the product is the preferred method for the sterilization of most devices used in the clinical setting. To facilitate sterilization, items must first be thoroughly cleaned and disinfected.

There are a number of different types of sterilizer used within healthcare:

Porous-load sterilizers

These are more commonly known as steam autoclaves and use vacuum assistance to remove air from the chamber at relatively high temperatures. They are designed to process porous loads such as wrapped items (textiles, dressings, surgical instruments etc.), which may be either solid or hollow and items with lumens.

The typical stages to a porous-load sterilizer cycle include:

- air evacuation
- sterilizing
- post-vacuum or drying stage

Where surgical instruments are processed, specific time-temperature relationships exist for the standard operating cycle.

Autoclave Temperature and Time Pressures (standard practice)

Sterilizing Temperature	Autoclave Temperature	Sterilization Holding Time
134°C - 137°C	2.25 bar	3 minutes
273°F - 278°F	23.63 psi	3 minutes
126°C - 129°C	1.5 bar	10 minutes
258°F - 264°F	21.76 psi	10 minutes
121°C - 124°C	1.25 bar	15 minutes
249°F - 255°F	18.13 psi	15 minutes

Good management practice in a Sterilising and Decontamination Department defines the responsibility of the operator and users of these machines and provides information on how these sterilizers are used, validated, and maintained.

Bench top steam sterilizers

There are several types of bench top sterilizers available. They are most commonly used in small clinics and dental practices. The two most common types are:

- Non-vacuum:
  Commonly used for surgical instruments that are unwrapped, not hollow and do not have lumens
- Vacuum:
  Can be used for wrapped and hollow/lumen instruments

Loading the Sterilizer

Loading the sterilizer correctly is crucial to achieving an effective sterilization cycle. All surfaces of the device or instrument must come in to contact with the sterilizing agent for the prescribed amount of time. Devices and instruments need to be properly prepared and arranged in a way that allows the process to be effective.

- Devices and instruments should be dry before sterilization begins.
- All packaging material should be checked for damage before loading into the sterilizer.
- There should be sufficient space between items and packs to allow the sterilizing agent to permeate around the packages.
- Packages should not touch the top, bottom or sides of the sterilizer. It is advisable to allow at least 10cms from the sides of the chamber.
- Packages should not be placed on the floor of the sterilizer as this can block the dispersal of air and steam.

- Sterilizing trolleys should be loaded evenly, with packs separated to assist steam penetration.
- Trolleys should be loaded in a manner that ensures hands do not come into contact with the packs during transfer.
- Shelves should not be overcrowded.
- Trays should be flat and tidy when placed onto the trolley. Packs should not be touching or overlap with each other. This will allow the sterilizing agents to flow down effectively through the folds in the wrapping material.

Insufficient space between packs and loaded unevenly – sterilizing agent cannot permeate around the packs.

Trays should be flat and tidy with no overlapping.

- Do not place packages directly on top of each other, as this will compress the packages, preventing effective sterilization.
- Place heavy packs in the lower part of the chamber, with soft, lighter packs at the top of the chamber.
- Plastic pouches may expand and contract during the sterilization cycle. Pouches should be arranged with the plastic of one pouch touching the paper side of the next pouch.
- Perforated or mesh based trays improve the sterilization and aeration process.
- The correct load for the sterilizer is determined by the size of the chamber and the number of items to be sterilized, their characteristics, the number of items and how they are positioned. The sterilizer manufacturer should specify these requirements.

A correctly loaded trolley.

7.0 Transportation of Decontaminated Surgical Instruments and Medical Devices

Central decontamination facilities are often located away from clinical areas and may be some distance from the point of use. It is therefore recommended that processed goods are stored in clinical areas ready for use. The method of transport used to transfer surgical instruments and equipment is determined by:

- the type of product being moved
- the distance between the decontamination centre and the point of use
- whether deliveries are being made to internal or external users

Transit containers must:

- protect the instruments and equipment
- prevent inadvertent contamination during transportation
- prevent contamination of staff and handlers when transporting used instruments for reprocessing

Containers should have the following characteristics:

- be waterproof
- be easy to clean (and ideally suitable for decontamination in an automated washer disinfector)
- be rigid in order to protect instruments from damage
- be capable of being closed securely
- be fitted with a tamper-proof seal
- be constructed in such a way so as to prevent damage to the devices being transported
- be clearly labelled to identify the delivery address.

Products must be stored above floor level away from direct sunlight and water, in a secure, dry, cool environment.

8.0 Storage of Sterile Medical Devices

Following the decontamination of medical devices, it is important to ensure that the storage conditions maintain the packs in the condition in which they are required for use. This will involve maintaining the sterility of wrapped products but may also include those packs which have been processed but are not required in a sterile condition at the point of use, simply disinfected.

Sterile products are usually stored at the point of use, i.e. wards, clinics, departments and operating theatres. However, regardless of the location, the storage area should be dedicated to that purpose and not used for other activities such as patient treatment etc.

- The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks.
- Shelving should be easily cleaned and allow the free movement of air around the stored product.
- Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.

Inadequate control of these areas may have an adverse effect on the integrity of the sterile product and subsequently render it non-sterile and unsuitable for use.

Rough handling of sterile packs can damage both the pack and the wrapping and render the pack non-sterile. Do not pack products tightly together on shelves, in drawers or in containers as this may also damage the packing. Packs found to be damaged or wet must be returned for reprocessing.

Before being used, the sterile pack should be checked to ensure that:

- the packaging is intact
- the sterilization indicator confirms the pack has been subjected to an appropriate sterilization process
- the product is still within the expiry date.

Transit containers must protect instruments and equipment and be closed securely.

9.0 Use of Surgical Instruments and Medical Devices

It is the responsibility of the staff involved with the surgical procedure to ensure that the equipment they intend to use is 'fit for purpose'. The implementation of a recognised Management System and Procedures is widely adopted in hospitals and commercial Sterilising and Decontamination departments.

Responsibility for ensuring that safe and effective decontamination of devices has taken place will fall to a number of healthcare professionals, depending on the setting in which they work:

- In hospitals, it is often the Sterile Services technician or surgical auxiliary where decontamination takes place in the clinical setting.
- In a primary care setting, it may be the practice nurse or dental technician who undertakes the reprocessing.

Each will have his/her own responsibility for elements of the decontamination process. In some circumstances, the transportation of devices may be the responsibility of the person who has also decontaminated the product; in others, it may be a different person or department, for example portering staff or other third parties.

Post-procedure sorting

It is good practice post-procedure for all instruments and devices to be sorted, separated and accounted for. This is important for a number of reasons:

- To ensure that all devices are present and not mislaid during the procedure.
- To keep the re-usable devices in designated sets for reprocessing together and subsequent re-use.
- To inspect the devices for any signs of damage and record any required repair or disposal of devices for biomedical or decontamination staff.
- To allow for traceability of individual devices or device sets so that Infection Control can identify which patient the devices have been used on.

During a procedure a variety of materials, single use devices, re-usable devices, linens, coverings, solids and liquids may have been used.

All reusable devices should be separated from soiled linens and disposable items at the point of use. It is good practice that re-usable devices are placed into the original instrument trays or containers in which they were issued. These must be leak-proof and puncture-resistant for transport and clearly labelled as a biohazard.

10.0 Transportation of Contaminated Surgical Instruments and Medical Devices

All used surgical instruments present a risk of infection. To minimise the risk, the used instruments must be placed in closed, secure containers and transported to the decontamination area as soon as possible after use.

Transport containers must protect both the device during transit and the handler from inadvertent contamination and therefore must be:

- leak-proof
- easy to clean
- rigid to contain instruments, preventing them becoming a sharps hazard to anyone handling the instruments and to protect them against accidental damage
- capable of being closed securely
- lockable, where appropriate, to prevent tampering
- clearly labelled to identify the user and the contents
- robust enough to prevent instruments being damaged in transit

This Guide has been written for a wide audience and whilst reflecting the basic principles of decontamination, it should not be used as a replacement for legislative documents, hospital policy, or washer disinfector and steam autoclave manufacturer instructions.

Troubleshooting Guide

If you are experiencing problems in your sterilization process, there are a number of factors that can affect your sterilization results. Our Trouble Shooting section below identifies the most common causes and influencing factors.

Common steam sterilization problems, causes and solutions

Problem	Cause	Solution
Scorched Packs or Packaging Material Damage	• Pack touching the chamber wall • Excessive heat from the chamber metal walls • Superheated (unsaturated or super-dry) steam. This is steam at a very high temperature for its saturation process and can be created by water impurity. Superheated steam can act as hot air, which is less efficient as a sterilization medium.	• Review procedures and train staff on how to pack sets, load correctly, pack size, pack weight or pack density and proper wrapping technique. • Check steam supply; test steam quality and water purity. • Check steam supply is correct (e.g. steam pressure, not only to the chamber but also to the jacket) and associated supply/drain valves are functioning correctly. • Check calibration of pressure/temperature sensors.
Wet Packs	• Intermittent operation (chamber cold) or jacket heating not working. • Steam supply is wet. • Sterilizer installation, including improper insulation of steam pipes or excess water in steam. • Packs placed on the floor of the sterilizer are blocking the discharge of air, trapping pockets of sterilizing agent. • Excessive moisture on the chamber wall. • Heavy metal packs have been placed at the top of the chamber. Condensation from steam that comes into contact with cool metal may drip onto the packs below. • Insufficient drying time. • Improper loading or overloading. • Large overweight packs/sets (in particular metals). Overloading may not only cause improper sterilization but may result in excessive condensation. • Clogged or malfunctioning drain or steam supply systems.	• Pre-warm the sterilizer before using and check steam supply valves/traps (chamber and jacket) • Check steam supply; test steam quality and water purity. • Check that steam pipes are insulated. • Review with manufacturer or consider using a drying cabinet. • Review procedures and train staff on how to pack sets, load correctly, pack size, pack weight or pack density and proper wrapping technique. • Review sterilizer manufacturer's recommendations on proper loading. • Clean debris from the chamber drain daily. • Ensure any associated valves/traps controlling incoming or draining steam are functioning. A preventative maintenance schedule should be established to ensure these are functional.
Distorted Packs	• Overloading with heavy instruments. • Wrapping material is too small for pack size. • Heavy metal objects placed near to packs. • Packs placed too close to heat in the sterilizer. • Incorrect positioning of instruments in the tray, causing a vacuum effect. • Incorrect positioning of packs in the sterilizer.	• Review procedures and train staff on how to pack sets, load correctly, pack size, pack weight or pack density and proper wrapping selection and technique.

Common steam sterilization problems, causes and solutions – Continued

Problem	Cause	Solution
Failed Chemical or Biological Indicators	• Inadequate sterilization. The fault may be with the sterilizer (mechanical or electrical), steam supply (superheat or wet) and/or load being sterilized. Always confirm that the correct indicator has been used (and used correctly) for monitoring the steam sterilization cycle in use.	• Confirm the sterilizer is operating correctly. • A common cause is the way the sterilizer chamber has been loaded. It is essential that packs are not too dense and are loosely loaded into the sterilizer to ensure that air is not trapped and can easily circulate.
Failed Bowie-Dick Test	• Incomplete air removal. Trapped air may be due to human error, mechanical failures, and/or water quality. • Typical causes include: • Faulty door seals/gaskets • Problems with the vacuum pump • Incorrect loading • Incorrect packaging • Incorrect cycle parameters for the load • Clogged drain • Low steam pressure or high water pressure • High levels of dissolved gases in the feed-water/steam.	• A routine maintenance schedule should be followed to ensure the sterilizer is operating correctly. Ensure daily inspections by staff (e.g. ensure the sterilizer chamber drain is not blocked) are completed, and maintenance of the sterilizer/utilities (such as routine maintenance of the vacuum pump and any steam/water pre-treatment).
Instrument Staining	• Improper instrument cleaning procedures, including incomplete removal of soil, inadequate rinsing or using water with high mineral content. • Poor steam purity, where any chemicals present will react with the steam or precipitate out on surfaces.	• Standardized effective cleaning procedures and post-cleaning inspections should be established. • Check the water quality used in the generation of steam (including the dosing of any chemicals used in the boiler). The water purity can vary seasonally and often from day to day.
Excessive Rusting of Stainless Steel Instrument Trays	• Damage to stainless steel surfaces that result in the development of ferric oxide or rust as a reddish-brown material on the surfaces on trays and instruments. • Can also result in "pitting" or the development of small pin-holes on the surface of the device. This can make the future removal of blood proteins and other fluids more difficult.	• The main causes of rust are wear and tear on the device and the presence of high levels of chlorine/silica-based chemicals in water used to generate steam. • Check for the levels of chlorine/chlorides and/or silicates in the feed-water to the steam generator. • It is also good practice not to sterilize stainless steel instruments together in the same pack with aluminium, brass, copper or chrome-plated instruments because of the risk of "galvanic" corrosion that may result. • Consider replacing stainless steel instrument trays with re-usable polypropylene medical devices.

About Warwick SASCo Ltd

Warwick SASCo Ltd is an independent, family owned business established in 1981 to supply sterilizable polyware to hospitals.

We were the driving force in developing polypropylene medical devices for use in Healthcare. This led to the formulation of British Standards BS 5452, BS 2588 and BS 3215, We were one of the first companies to comply with EC Directive 9342 (Medical Devices), and from 1996 we achieved ISO 9001 status in recognition of our Quality Management. Over 18 years later, we still hold that certification today.

Warwick SASCo has enjoyed over 30 years success in supplying plastic medical devices that continue to meet the demanding requirements of healthcare processing. We are now recognised as the market leader in the design and manufacture of high quality medical polyware and our products have an unrivalled reputation for quality in over 65 countries around the world.

Our product range includes a wide selection of re-usable and single use instrument trays, traceability tags, instrument protection, medical boxes, kidney dishes, gallipots, lotion bowls and theatre bowls.

- All of Warwick SASCo's polypropylene products meet the necessary sterilization standards for medical devices.
- All products are certified to comply with ISO 9001 Quality Management Systems and EU Medical Devices Directive 93/42.
- Our polypropylene is approved for use in medical devices. It is inert, non-combustible, non-toxic and non-carcinogenic. It is safe for use in medical and nursing applications and is resistant to damage from chemicals, cleaning solutions and medicines.
- Material complies with EC2002/72/EC, REACH Regulation EC No 1907/2006 and Phthalates European Directive 67/548/ EEC Annex 1.
- Polypropylene is identified as a Class 5 material, which can be recycled in accordance with regulations on clinical waste and hospital protocol.
- Warwick SASCo products are classified as Class 1 Medical Devices under Council Directive 93/42 EEC and show the CE Mark accordingly.
- Warwick SASCo is certified to ISO 9001 (Quality Management System) and ISO 13485 (Medical Devices Quality Management).
- Polypropylene has a high temperature tolerance, making it ideal for use in autoclaves. The Warwick and SteriLite ranges are designed to be steam autoclaved in autoclaves compliant with UK Directives HTM 2010/CFPP01-01, BS 3970, EN 285:2006 ,and ISO 17665, with a processing temperature of 134°C.
- Warwick and SteriLite products can be processed by ethylene oxide, gas plasma, electron beam and gamma ray. Refer to sterilizing manufacturer for more information.
- All products have smooth corners and surfaces which eliminate sterile packaging rips, and rounded feet on trays, bowls and kidney dishes keep the items clear of any spillages.
- Polypropylene delivers improved blood protein removal results when compared to stainless steel.
- Our gallipots, bowls and kidney dishes have a collar below the rim that strengthens the product and helps to maintain shape when autoclaved, The small pips on the rim help to prevent 'vacuum lock', enabling a clear passage for steam penetration and vacuum release.
- The shaped rim of our products give a sure grip when wearing latex gloves, and the smooth brim ensures no dripping or spilling when pouring liquids.
- Our range of perforated and mesh base trays improve steam penetration and drainage, which helps to eliminate wetness after autoclaving.

References

Medical Devices

ISO 13485: Medical devices – Quality Management Systems – requirements for regulatory purposes.

Medical Devices Directive 93/42 EC, EU Council Directive, 1995

Processing

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BS EN 867:2001: Non-biological systems for use in sterilizers, British Standards Institution, 2001

BS EN868: Packaging materials and systems for medical devices which are to be sterilized, British Standards Institution, 1997 – 2000

ISO 15223:2012 Graphical symbols for use in the labelling of medical devices

ISO 17664: Sterilization of medical devices

ISO 15883: Washer disinfectors – General requirements, definition and tests.

ISO 25424: Sterilization of medical devices at low temperatures

MDA DB 2000 (04): Single-use medical devices – implications and consequences of re-use, Medical Devices Agency, 2000

Decontamination Processing and Equipment

HTM 2010: UK Directive for Sterilization, NHS Estates, HMSO, 1994 – 1997

CFPP01-01 Choice Framework for Local Policy & Procedures – Management and decontamination of surgical instruments (medical devices) used in acute care, Department of Health, 2013

HTM 2030: UK Washer disinfectors, NHS Estates, HMSO, 1997

Infection Control/Risk Management

Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee (SEAC): Transmissible spongiform encephalopathy agents: safe working and the prevention of infection, Department of Health, 2001

Controls Assurance Standard: Infection Control, Rev (03), Department of Health, 2002

Controls Assurance Standard: Decontamination of reusable medical devices, Rev (02), Department of Health, 2002

Useful Website Addresses

Institute of Decontamination Sciences
www.idsc-uk.co.uk

Medicines and Healthcare Products Regulatory Agency (MHRA) – formerly the Medical Devices Agency
www.mhra.gov.uk

World Forum Hospital Sterile Supply
www.wfhss.com

Warwick SASCo Limited
www.sasco.co.uk

Glossary

Aerosol

Dispersion of solid or liquid particles in gas.

Aseptic

Free of microorganisms. An aseptic process means to keep something free of microbial contamination.

Automatic control test

A test designed to show that the operating cycle – as evidenced by the values of the cycle variables indicated and recorded by the instruments fitted to the sterilizer – functions correctly.

Bench top sterilizer

Apparatus designed to achieve sterilization, which requires no permanent connections or installation.

Bioburden

The "microbial load" or number and type of microorganisms on a surface or object. The bioburden from patient-derived materials such as body fluids or 'soil' may include non-viable (abiotic) substances such as proteins and lipids.

Bowie-Dick test

Test designed to indicate that the sterilizer is capable of removing air and non-condensable gases from a load.

Central decontamination

When reprocessing occurs in a central decontamination unit such as a Sterile Services Department (SSD).

Chemical indicator

A device designed to show, usually by a change of colour, whether specified values or one or more cycle variables have been attained.

Cleaning

The removal of contamination (often referred to as 'soil') from a surface to the extent necessary for further processing, e.g. disinfection, sterilization, or for intended use.

Contamination

The presence of dirt or "soil" that can include various materials, chemistries and bioburden such as microorganisms. Depending on the situation, contamination may be visible, such as blood spill, or invisible, such as the presence of microorganisms. Contamination of a device following patient use is generally referred to as "soiled".

Decontamination

A process which removes or destroys contamination and thereby prevents infectious agents or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are available. They are: cleaning followed by high level disinfection; or cleaning followed by sterilization, depending on the procedure and chemicals used. Also referred to as reprocessing.

Disinfection

A process used to reduce the number of viable micro-organisms in a load but which may not necessarily inactivate some viruses and bacterial spores.

Disinfector

An apparatus designed to achieve disinfection.

Fault

The recognition by the automatic controller that the pre-set cycle variables for the operating cycle have not been attained, and that sterilization or disinfection has been jeopardised.

Holding time

The period during which the temperature in all parts of the chamber, load and any coolant fluid is held within the sterilization temperature band. It follows immediately after the equilibration time.

Load

Collectively, all the goods, equipment and materials that are put into a sterilizer or disinfector at any one time for the purpose of processing it by an operating cycle.

Local decontamination

When instruments are reprocessed within the department where they are used.

Medical device

Any instrument, apparatus, appliance, material or other article which is intended to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or other medical/surgical use. A re-usable device is designed to be used many times on different patients, being provided with detailed instructions on how it can be safely reprocessed between each patient. A single use device has been designed to be used on a single patient only and then discarded. The term device and instrument are often used interchangeably.

Operating cycle

The set of stages of the sterilization or disinfection process carried out in sequence and regulated by the automatic controller. It is synonymous with the terms sterilization cycle for sterilizers and disinfection cycle for disinfectors.

Packaging system

Combination of the sterile barrier system and protective packaging.

Periodic tests

A series of tests carried out at specified intervals, for example daily, weekly, monthly, quarterly or annually.

Porous-load sterilizer

A clinical sterilizer designed to process, by exposure to high-temperature steam under pressure, porous items such as towels, gowns and dressings, and also medical devices that are wrapped in porous materials such as paper or fabrics.

Potable water

Water of suitable quality for drinking, cooking or food production.

Reprocessing

See Decontamination

Re-usable device

A medical device which can be reprocessed for repeated episodes of use.

Single use

A medical device that is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

Soil

Contamination on a surface following a patient procedure (see also Contamination and Bioburden).

Sterile

Condition of a load item that is free from viable micro-organisms. BS EN 556-1 details the requirements for a medical device to be designated as sterile.

Sterile barrier system

A package that provides a barrier to microorganisms and allows aseptic presentation of a product at the point of use.

Sterilization

A defined and validated process to render an item free from viable microorganisms, including bacterial spores.

Sterilization cycle

Automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization.

Sterilization process

The complete set of procedures required for the sterilization of a load, including the operating cycle and any treatment of the load before or after the operating cycle.

Sterilization temperature

Minimum temperature of the sterilization temperature band.

Sterilization temperature bands

The range of temperatures that may prevail throughout the load during the holding time. These temperatures are expressed as a minimum acceptable (the sterilization temperature) and a maximum allowable, and are stated to the nearest degree Celsius.

Sterilizer

An apparatus designed to achieve sterilization.

Validation

A documented procedure for obtaining, recording and interpreting data required to show that a sterilization process would consistently comply with predetermined specifications.

Washer disinfector

Automated machine intended to clean and disinfect medical devices used in the context of medical, dental, pharmaceutical and veterinary practice.

Product Processing and Technical Information

Warwick Products

Material

Products are manufactured from polypropylene plastic, unless where stated in product catalogue.

Processing

Decontaminate and wash in machines compliant with ISO 15883 and HTM 2010 (UK). Hand washing is permissible. Maximum washing temperature 90°C. Sterilize in compliance with ISO 17665, ISO 25424 and HTM 2010 (UK) in autoclaves compliant to BS EN285. Sterilization temperature 134.6 + 2°C.

Compatible with Ethylene Oxide (ETO), Gas Plasma/Hydrogen Peroxide sterilization, Electron Beam (E Beam) and Gamma Irradiation.

Validation

Products processed in accordance with ISO 17664 are validated for sterility after cleaning, disinfection and autoclaving. Further processing, validation, bio-burden, technical information, and compliance to ISO 17664 evidence is available on request. Products are designed and manufactured to meet the requirements of BS 5452.

SteriLite Products

Material

Products are manufactured from polypropylene plastic.

Processing

The SteriLite Range is single use and should not be re-processed. There are no instructions for re-processing.

Sterilize in compliance with ISO 17665, ISO 25424 and HTM 2010 (UK) in autoclaves compliant to BS EN285. Sterilization temperature 134.6 + 2°C. Compatible with Ethylene Oxide (ETO), Gas Plasma/Hydrogen Peroxide sterilization, Electron Beam (E Beam) and Gamma Irradiation.

Validation

Products processed in accordance with ISO 17664 are validated for sterility after cleaning, disinfection and autoclaving. Further processing, validation, bio-burden, technical information, and compliance to ISO 17664 evidence is available on request.

Material Compliance

The polyproplene used at Warwick SASCO Ltd complies with EC Directive: 2002/72/EC and EC Regulation No: 1907/2006. Further information on material compliance is available on request.

Polypropylene is classified as a Class 5 Recyclable plastic material. Hospital waste products must be disposed of in accordance with regulations on clinical waste and hospital protocol. Polypropylene is suitable for incineration.

Certification

Warwick SASCo Ltd is certified to ISO 9001 and ISO 13485.

Products are classified as Class 1 Medical Devices under EC Directive 93/42 (CE Mark).

The Warwick Range complies with BS 5452 Standards for Hospital Hollow ware.

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