

A guide to the decontamination of reusable surgical instruments

2003

STATUS IN WALES

APPLIES



A guide to the decontamination of reusable surgical instruments



A guide to the decontamination of
reusable surgical instruments

**APPENDIX 1 – Processing of flexible
endoscopes**

page 39

APPENDIX 2 – References

page 41

APPENDIX 3 – Glossary

page 45

Acknowledgements

page 48

1.0 Introduction

AIM

The aim of this guide is to provide information on the decontamination of surgical instruments. It can be applied to any healthcare setting where reusable surgical instruments are reprocessed.

SCOPE

This guide covers the broader issues relating to the reprocessing of re-usable surgical instruments (for example trays), and is intended for people working in multi-disciplinary healthcare fields who are involved in any aspect of the management of surgical instruments and equipment. This may involve the actual cleaning and sterilization of surgical instruments and equipment, or their transportation, storage and use.

AUDIENCE

It is written for a wide audience, and whilst reflecting the basic principles of decontamination, **it should not be used as a replacement for legislative documents or detailed guidance issued by the Department of Health and other recognised bodies.**

Since the National Decontamination Initiative began in 1999, NHS Estates have issued a number of CD-ROMs to the NHS, which have contained decontamination guidance documents relating to decontamination standards and their application. The latest edition

was issued in July 2003. References to guidance contained on the CD-ROM are given throughout this guide to allow for more detailed information to be obtained by the reader as required. A full description of these references is listed in [Appendix 2](#). These documents can also be accessed through the NHS Estates website.

STRUCTURE

The guide is divided into specific sections for ease of reference following the order of the “decontamination life-cycle” shown in [Figure 1](#). This allows healthcare workers involved in particular areas of decontamination to focus directly on those topics that are of interest to them.

DECONTAMINATION LIFE CYCLE

The decontamination life cycle model highlights the extent to which decontamination affects the whole of an organisation and not just those areas processing equipment.

Traditionally, decontamination has been the responsibility of the departmental heads of specialist units, for example sterile services, endoscopy units, theatre suites etc. Management arrangements within organisations often divided these functions and made it difficult for a totally co-ordinated approach to the application of decontamination standards and practices to be achieved. However, regardless of the location, the same

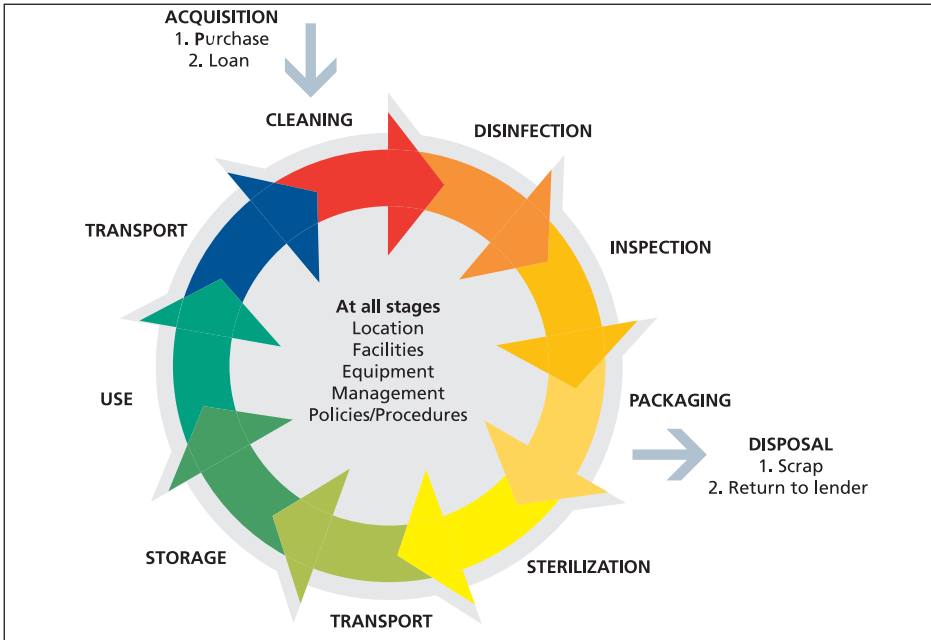


Figure 1

standards should be applied to decontamination practices throughout an organisation.

Figure 1 highlights each stage of the decontamination process through which surgical instruments pass before every use. Effective decontamination requires the attainment of acceptable standards at all stages of the life cycle. Failure to address issues in any of these stages will result in inadequate decontamination.

At all stages of reprocessing, the following issues need to be taken into account:

1. the location and activities where decontamination takes place;
2. facilities and equipment at each location;

3. ensuring that equipment used is validated, maintained and tested in accordance with manufacturer's guidelines and legislation;

4. the existence of effective management arrangements;

5. the existence of policies and procedures for all aspects of decontamination work.

BASIC REQUIREMENTS FOR DECONTAMINATION

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

In maintaining and developing organisation-wide decontamination standards and practices, the following should be included:

- an effective management control system must be in place to cover all aspects of the decontamination life-cycle;
- every organisation should have a nominated lead with responsibility for decontamination, either at director level or someone who has line management responsibility to a senior responsible person at that level;
- documented robust and comprehensive policies and procedures to ensure that decontamination processes are undertaken in a controlled manner to protect the health and safety of patients and staff;
- a procurement policy which ensures that all purchased instruments are compatible with decontamination processes available within the organisation;
- manual cleaning of devices to be restricted to those items deemed incompatible with automated processes;
- reprocessing of surgical instruments to be undertaken in dedicated facilities and outside the clinical/patient environment, preferably in central facilities;
- equipment used to decontaminate surgical instruments and associated equipment must be fit for purpose, validated and tested in accordance with current recommendations;
- organisations should have systems in place to trace instrument sets and endoscopes through decontamination processes and to the patient (see below; see also HSC 2000/032 and HSC 1999/178);
- a documented training scheme must be in operation with individual training records for all personnel, including management involved in decontamination activities.

TRACKING AND TRACEABILITY OF SURGICAL INSTRUMENTS

It is important to be able to trace products through the decontamination processes to which they have been subjected and also to the patient on whom they have been used. The ability to track and trace surgical instruments and equipment through the decontamination life-cycle enables corrective action to be taken when necessary. For example, in the unlikely event of a sterilization cycle failure, products can then be recalled.

HSC 2000/032 states:

“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

instrument is in addition to the measures for identification and tracking of flexible endoscopes set out in Health Service Circular 1999/178.”

Records should be maintained for all the sets cleaned, identifying:

- the cleaning and sterilization method used;
- the name of the person undertaking the decontamination; and
- details of the actual item being processed.

This information is required so that instrument sets can be traced, if required, in the event of a failure in the decontamination cycle or for infection control reasons.

Records relating to decontamination processes should be maintained by the organisation for a minimum of 11 years or in accordance with local data policies.

INFECTION CONTROL POLICIES

All organisations must have an infection control policy that contains:

- advice on decontamination and storage of surgical instruments;
- local policies on recommended disinfectants, their application, use, storage and disposal;
- protocols for the cleaning and disinfection of surgical instruments where instruments have to be processed in a local setting;
- protocols for the use of personal protective equipment (PPE);

- risk assessments for procedures used in the reprocessing of surgical instruments;
- spillage procedures;
- management and treatment of needle-stick/sharps injuries.

This policy should be written in collaboration with the infection control team.

Controls Assurance standards exist for the related issues of decontamination, the management of surgical instruments and associated equipment, and infection control. Organisations are legally required to undertake assessments and complete their returns as part of their risk management system.

DECONTAMINATION TRAINING

Members of staff undertaking decontamination must be competent, properly trained and supervised. A national training scheme is currently being devised and will describe basic training for staff involved in all aspects of the decontamination of surgical instruments.

Individual training records, detailing an individual's core competencies and any training received, must be maintained and updated regularly. Line managers are responsible for maintaining these records.

In the primary care setting, whoever owns or manages the practice is responsible for ensuring that systems are in place for ongoing staff training.

2.0 Transportation of contaminated surgical instruments and associated equipment

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

Transport containers must protect both the product 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 goods 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.

Where decontamination takes place in the clinical setting, the above principles

can be modified to suit local circumstances. However, the methods used must ensure that the product and handler are protected at all times. It is recommended that wherever contaminated items are transported, risk assessments should be undertaken relating to the safe movement of the device. Staff handling contaminated instruments and equipment must wear PPE in accordance with local policy and be vaccinated against hepatitis B. Without exception after each use, transport containers must be cleaned, disinfected and dried, or discarded (as appropriate), using agreed methods.

Where contaminated instruments are to be transported outside of the healthcare premises onto a public highway, those responsible for such transportation must refer to the requirements of the Carriage of Dangerous Goods by Road Act 1992 and the Health and Safety at Work etc Act 1974. It is essential to use a method of transportation that ensures the segregation of contaminated product from clean/sterile instruments.

3.0 Acquisition

PURCHASING

Organisations must have a clearly stated policy outlining how the purchasing of medical devices will be managed. 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 piece of equipment before a purchase is made. See the Microbiology Advisory Committee manual (MAC manual) and MDA DB 9801.

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 an organisation. For example, devices manufactured outside the UK may require processes that are not routinely available within the UK, such as those that require sterilization temperatures other than the standard 121°C and 134°C cycles (see MDA SN 2001 (28)).

To help organisations in purchasing decisions, the NHS Purchasing and Supply Agency (PASA) has established framework agreements for purchasing a number of medical products and devices, for example washer-disinfectors, surgical instruments etc. Details are available from the PASA catalogue and their website.

Best practice suggests that automated washing processes are the preferred option. Therefore, devices that can be mechanically cleaned and thermally disinfected should be purchased whenever possible. Some devices are, however, incompatible with automated washing processes and are recommended for manual cleaning by the manufacturer.

When considering the purchase of instruments, the following issues should be taken into account:

- Does the instrument have lumens/can the device be easily cleaned? If not, is there an alternative reusable device which is easier to clean, or is a single-use device available as an alternative?
- Does the instrument need dismantling before cleaning? Are instructions provided by the manufacturer describing how this can be done?
- Does the instrument have electrical components? If yes, does the organisation have the capability to clean and sterilize them in the manner described by the manufacturer?
- Does the instrument have a limited life? Is this specified by the manufacturer?
- What method of cleaning does the manufacturer recommend and is this process available within the organisation?

- What cleaning agents are recommended and does this comply with local infection control policies, COSHH and health and safety requirements?
- If the instrument needs to be sterilized, is the preferred method of steam sterilization (134°C for a minimum of three minutes) recommended? If another method of sterilization is recommended, is this available within the organisation?
- If the product is heat- or pressure-sensitive, what alternative means of sterilization is recommended? Is this process available within the organisation?
- Has a risk assessment been undertaken to determine whether a single-use or a reusable product is more appropriate for the circumstances?

Manufacturers of re-usable surgical instruments are required to supply information on the appropriate decontamination process to allow reuse, including cleaning, disinfection and where appropriate the method of sterilization (Consumer Protection Act 1997; Medical Devices Regulations 2002).

LOAN SURGICAL INSTRUMENTS AND EQUIPMENT

It may sometimes be necessary to borrow equipment from another organisation or manufacturer: for example, for a trial, to treat a patient where equipment is not routinely available or where workload dictates that additional equipment is required on a temporary basis. All surgical instruments and equipment entering the organisation, regardless of the source, should be cleaned and sterilized before and after use in accordance with manufacturers' instructions (see MDA SN 2000 (18)).

If staff are unfamiliar with on-loan equipment or newly purchased devices, it is essential to arrange training from the supplier/manufacturer to ensure equipment is decontaminated properly and to minimise the potential for damage. Items requiring disassembly during processing must be dismantled in accordance with manufacturers' instructions.

Device loans should be so arranged to give adequate time for learning about the equipment and for decontamination of the device before it is required for use on a patient.

4.0 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 in a number of ways. 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. Where manual cleaning is undertaken, it should be carried out in accordance with the 'Protocol for the local decontamination of surgical instruments' issued by NHS Estates.

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 place 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 reusable items are manufactured in uncontrolled environments and some are handled extensively during this process. In addition, many manufacturers leave anti-corrosive agents such as oil and grease on the surface and in the joints of the item for protection during transit. New items should be cleaned and sterilized before being put into use. Manufacturer's instructions should be followed, where available.

PRE-TREATMENT OF SURGICAL INSTRUMENTS

Under normal circumstances it should not be necessary to pre-treat surgical instruments at the point of use before being sent to the central processing unit (sterile services department).

Gross contamination may make decontamination more difficult if not removed immediately. In such circumstances it is suggested that instruments should be cleaned as soon as possible after use.

All staff undertaking pre-treatment cleaning of instruments should ensure their own safety by wearing appropriate PPE and carry out a risk assessment for the procedures being employed.

DISASSEMBLY OF INSTRUMENTS

Equipment consisting of more than one component must be dismantled so that each part can be adequately cleaned. Advice on the methods for disassembly of surgical instruments should be sought from manufacturers. Training should be updated to take into account any new instruments introduced into the organisation to ensure that the equipment is dismantled and that adequate cleaning and sterilization takes place. Personal training records should reflect the range of devices upon which an individual has been trained and is competent to decontaminate.

AUTOMATED CLEANING

Washer-disinfectors

All washer-disinfectors used for decontamination should be purchased against the Model Engineering Specification C30 and be capable of being validated in accordance with HTM 2030.

There are a number of different models of washer-disinfector that meet current standards. The size, model and type to be chosen should be considered against workload and throughput requirements, together with the availability of space.

Washer-disinfector logbooks and records should be kept by the designated “user” as defined in HTM 2030. Records should include a description of any loads processed, cycle parameters, product release together with details of routine testing and maintenance of the equipment used.

Each stage of the decontamination process should contribute to the reduction of bio-burden on the device being reprocessed. The recognised stages of the washing process may include a cool pre-wash (below 35°C to prevent protein coagulation), main wash, rinse, thermal disinfection and post-disinfection rinse (where appropriate). The use of ultrasonic cleaners may be considered to assist the process (see next section).

Ultrasonic cleaners

Ultrasonic cleaners may be of the stand-alone ultrasonic bath type or may be washer-disinfectors of Type 1 (single chamber) or Type 2 (multi-chamber).

Many Type 1 washer-disinfectors do not incorporate a disinfection stage and are intended for use as a pre-cleaning process before final cleaning and disinfection in a washer-disinfector for surgical instruments.

Cleaning in the primary care setting is usually undertaken in a stand-alone bath filled with potable water (drinking quality) and a measured amount of detergent, as per manufacturer’s instructions. Instruments are placed in a basket and into the water where the ultrasonic action will remove gross soiling. This method of cleaning should be seen as a first-stage cleaning process, which would normally be followed by cleaning in a washer-disinfector or, where this is unavailable, a thorough rinse before sterilization.

Where such cleaners are used, the equipment manufacturer’s operating instructions must be adhered to and staff given adequate training in the use of the machine. Ultrasonic cleaning should be

used only if recommended by the instrument/device manufacturer.

Ultrasonic action is generated by transducers that agitate the water by creating bubbles. The bubbles implode and dislodge dirt from the surface and joints of surgical instruments.

Ultrasonic action helps to thoroughly clean devices with joints or multiple components that are difficult to clean manually.

Ultrasonic cleaners are not recommended for cleaning certain items, in particular rubber products which will absorb the ultrasonic waves and reduce the efficacy of the cleaning process.

Directions for use of ultrasonic cleaners

Staff must wear PPE at all times while handling contaminated instruments and working with the ultrasonic cleaner.

1. Fill the tank with potable water (drinking quality) to the manufacturer's designated level. This ensures that the device being cleaned is not contaminated by water impurities.
2. De-gas the water as recommended by the machine manufacturer.
3. Add detergent, ensuring the manufacturer's recommendations are followed. It is advisable to use a suitable enzymatic detergent that is effective at low temperatures.
4. If the tank has a heater, set the temperature control to be comparable with the detergent manufacturer's recommendations.

5. When the specified temperature has been reached, place the opened/dismantled instruments into the basket.
6. Place the basket of instruments into the tank. Never put instruments directly onto the base of an ultrasonic washer.
7. Set the timer control to the time specified by the machine manufacturer.
8. After the cycle has been completed, remove the basket from the tank and rinse the items with clean, potable water – unless the machine has an automatic rinse stage, or the load is to be transferred directly into a washer-disinfector for further processing.
9. Drain and dry the items using a non-linting cloth or mechanical drying system.
10. Record the instrument(s) that has been processed, including the method and solutions used and details of the staff member who completed the procedure.
11. After use, the ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until required for further use, as per the manufacturer's instructions.

Testing of ultrasonic cleaners

In accordance with guidance contained in HTM 2030, a qualified "test person" should regularly maintain and test ultrasonic cleaners. The test requirements and the role of the test person can be found in HTM 2030. It is recommended that a soil test and a

residual protein test should be performed as part of the weekly tests to establish the efficacy of the washer's cleaning process.

The following simple test may be undertaken to establish that there is ultrasonic action in the tank. It should not, however, replace the detailed tests specified in HTM 2030:

1. Clamp the edge of a piece of aluminium foil (approximately 5 cm²) in a pair of metal forceps.
2. Hold in the centre of the bath for approximately three minutes.
3. Remove, dry and inspect the aluminium foil for changes.
4. File the strips of foil as a record of the test having been undertaken, together with all relevant test details, that is machine number, date, test result (pass/fail), name of operator etc.

(Note: Do not put hands into the tank of an ultrasonic cleaner while the machine is in use.)

Effective ultrasonic action will serrate the edge and pit/perforate the centre of the foil. However, if the aluminium foil is withdrawn without any noticeable change to its condition, this may indicate that the machine is not functioning properly and the manufacturer/supplier should be consulted. It should be noted however that the strength of the ultrasonic waves will vary throughout the tank.

(Note: the appropriateness of this test will depend on the frequency at which the ultrasonic cleaner operates. Consult the equipment manufacturer for further information.)

Points for consideration

Contamination of instruments can occur when the water in the ultrasonic bath is not changed regularly: if gross contamination is present on the surface of the water, debris can be deposited onto instruments when they are lifted out of the bath. Therefore, it is recommended that the tank be emptied regularly – as a minimum, every four hours, or when the water is visibly soiled.

PROCEDURE FOR MANUAL CLEANING

Manual cleaning would normally be carried out using either immersion or non-immersion methods depending on the construction of the device.

Immersion method

To minimise the risk to personnel undertaking manual cleaning, splashing and the creation of spray must be avoided at all times. Staff carrying out manual cleaning should wear PPE at all times.

1. Fill sink 1 (not a hand basin or other clean receptacle) with potable water to a predetermined level at the specified temperature and with the appropriate detergent. Sink 1 must be solely dedicated for the cleaning of instruments, and not for any other purpose.
2. Detergents used must be specifically designed to clean surgical instruments: washing-up liquid should not be used. Detergent dilution and water temperature should be in accordance with the manufacturer's instructions and local policy. Consideration should be given to the

use of an enzymatic detergent to facilitate the cleaning of surgical instruments with channels or complex parts.

3. Dismantle or open the instrument to be cleaned and fully immerse in the solution to displace trapped air and, in the case of hollow instruments, to ensure penetration of channels.
4. Brush, wipe, agitate, irrigate, jet-wash or hand-spray the item to dislodge and remove all visible dirt, taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosol (spray). Brushes should be made from nylon bristles and should be cleaned and sterilized daily, or preferably, should be single-use only.
5. If high-pressure-jet guns are used for cannulated instruments, they should be connected to the cold-water supply only. The gun is connected to the instrument and held under water during the irrigation process.
6. Remove the device from sink 1 and drain any excess cleaning solution before placing in sink 2 for rinsing.
7. Change the rinse-water after every batch of instruments or when it becomes visibly soiled or cloudy.
8. Rinse the item thoroughly with clean potable water using the water-jet gun when necessary (see point 5).
9. Remove and drain the item, and then dry using the preferred method: for

example, by using a clean, non-linting cloth or by mechanical drying. An alcohol wipe can be used to facilitate the drying process.

10. Cleaning materials should be safely disposed of in accordance with local waste policy.
11. Record the device that has been processed including the method and solutions used and details of the staff member who completed the procedure.

Non-immersion method

This method is appropriate for items whose working components will become compromised by soaking, for example dental drills, power tools or electronic equipment.

Cleaning information about the methods to be used for specific devices must be sought from individual device manufacturers.

Devices should be:

1. cleaned using a non-linting cloth, impregnated with the appropriate detergent solution, followed by a clean, damp, non-linting cloth; and then
2. dried using another clean, non-linting cloth.

Alcohol-impregnated wipes may be used following a manual cleaning process.

5.0 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 or rinsing devices in water at between 73°C and 90°C. Most of the washers manufactured for the reprocessing of surgical instruments incorporate a disinfection stage.

Devices that cannot withstand relatively high temperatures required for disinfection by moist heat may be disinfected using chemicals. Receptacles used for chemical disinfectant 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.

It is important to note that when preparing chemical disinfectants, staff involved must wear the appropriate PPE. The room used for chemical disinfection must be well-ventilated or contain an

appropriate Class 1 exhaust-protective cabinet or equivalent. COSHH assessments must be consulted regarding the toxicity of the substance(s) used. Staff should be aware that certain substances may require personal monitoring and/or monitoring by occupational health services as part of health and safety requirements.

In the case of devices with lumens, it may be necessary to agitate the device in the disinfectant to dislodge any air trapped inside. Disinfectants will be effective only if the solution reaches all surfaces of the device to be disinfected and appropriate exposure times recommended by the disinfectant manufacturer are adhered to.

If the device is for immediate use after disinfection, staff must use an aseptic technique when removing it from the chemical solution. Then, the device must be thoroughly rinsed in sterile water and carefully dried using a sterile, non-linting cloth. The manufacturer's recommended method(s) and the compatibility of the device with the chosen process will also be important considerations.

If the device is to be stored before being used, it can be removed from the liquid, rinsed in sterile water, dried with a non-linting cloth and stored in a secure area. Where a sterile product is required, it should be processed immediately before being used and not stored before use.

6.0 Inspection and function testing

The inspection, maintenance or testing of devices must be carried out by suitably trained staff in accordance with the manufacturer's instructions and local policy. Where practical, the inspection and function-testing of surgical instruments should not be carried out by the same staff responsible for cleaning the devices. These staff members have a responsibility for ensuring the item is thoroughly cleaned and fit for reuse. Records should be kept of all inspection and testing work undertaken.

INSPECTION OF SURGICAL INSTRUMENTS

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 product – that is, dirty, wet or stained – should be rejected and returned to the wash area for manual cleaning, followed by an automated wash process (where this process is available and the device is compatible) 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 (despite being made of stainless steel!) will develop scratches and roughened surfaces, which will harbour dirt.

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

FUNCTION-TESTING

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. It is difficult to test surgical instruments to mimic their actual use; however, some basic tests can 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 (rough edges);
- all screws on jointed instruments are tight and have not become loose during the cleaning process.

Occasional use of a lubricant may be required where hinged instruments are found to be stiff. A non-oil-based

lubricant should be used to avoid it interfering (that is, preventing the steam coming into contact with the instrument surface) with the sterilization process.

In preparing instruments for wrapping and sterilization, it is essential that all surfaces are presented to the sterilization media (that is, steam or chemical) and that, where devices can be taken apart, they are sterilized in this state wherever practicable. For instruments with ratchets, to ensure steam can penetrate to all surfaces, they should be closed on the first ratchet only.

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 and/or replaced. In the case of instrument sets, the contents sheet may be used to indicate faulty instruments but the actual item must be identified in case there are a number of similar devices on the same set.

REPAIRS

Instruments may become damaged during use or suffer from general wear and tear over their life span. Instruments become damaged for a number of

reasons, but typically through inappropriate use, poor handling or contact with corrosive substances. The damage to instruments may take the form of physical damage, for example when an item is dropped or as a result of a reaction to contact with corrosive agents during use, for example iodine or saline solutions used in operating theatres. Typical damage includes rusting, pitting or general surface corrosion.

If devices are found to be faulty or damaged during inspection and function-testing, or if users identify that they are faulty, they should be taken out of use and either repaired or replaced. Instruments for repair should be returned to either the manufacturer or a reputable repair company. They should be decontaminated in accordance with MHRA DB 2003 (05) and be accompanied by a Decontamination Certificate (a sample of which can be found in the MHRA device bulletin; see the MHRA web-site). Where instruments are taken out of use, which are part of instrument “sets”, the set should be removed from use until the repair can be undertaken and the instrument returned to the set.

7.0 Packaging

It is not always necessary for instruments to be wrapped before being sterilized. Indeed, when certain types of sterilizers are used, for example non-vacuum benchtop or bowl and instrument sterilizers, packaging is not recommended. (Items sterilized in a non-vacuum benchtop sterilizer must not be packaged because this may impede the penetration of steam to all surfaces of the instrument and prevent sterilization taking place).

Where packaging is recommended, for example in porous-load and vacuum benchtop sterilizers, materials should be used which comply with appropriate packaging standards for sterilization as detailed in the BS EN 868 series. 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 product following decontamination.

Packaging of products after the sterilization process is not recommended.

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 plain paper bags are often used for single instruments or small loads, that is bags with a see-through front and paper backing.

- Sealing peel-apart pouches is essential to ensure that the product remains sterile after autoclaving. In self-sealing pouches, adhesive is manufactured into the open end of the bag or plain top and either a heat-sealing machine or autoclave tape is then required to create a seal.
- Paper bags can either be plain top (which requires autoclave tape for sealing) or have a heat-seal top (which requires a crimping and sealing machine).

Other forms of packaging suitable for larger devices or multiple items include metal or plastic containers, metal trays of varying dimensions, sterilization paper, plain and crêpe, and many more depending upon the chosen method of sterilization.

LABELLING OF STERILE SURGICAL INSTRUMENTS

Sterile surgical instruments should be labelled in accordance with the requirements of BS EN 980 – ‘Graphical symbols for use in the labelling of medical devices’.

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

1. Name of device/pack.
2. Name of the manufacturer, that is “reprocessor”.
3. The date of manufacture/sterilization.
4. Date of expiry (where appropriate).
5. The method of sterilization used, for example steam, ethylene oxide etc. (This may already be obvious by the sterilization indicator panel on the packaging material).
6. Cycle number/machine number of the sterilizer used.

8.0 Sterilization

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

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

- **Porous-load sterilizers.** These are steam autoclaves with an active air-removal stage designed to process wrapped goods or lumened devices. They are produced in various sizes ranging from portable benchtop design to large capacity (commonly 0.6 m³/21 ft³) machines and are usually located in sterile services departments (SSDs).
- **Bowl and instrument sterilizers.** These machines often have large capacity and may be found in operating theatres. They have cycle parameters similar to those of porous-load sterilizers but without an active air-removal stage or drying cycle, therefore prohibiting packaged loads from being sterilized. Their use is limited to sterilizing items which are solid and not hollow or cannulated.
- **Benchtop steam sterilizers.** There are several types available. 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.

POROUS-LOAD STERILIZERS

These machines are more commonly known as 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 (that is 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:

134°C plus 3 minus 0 for a holding time of 3 to 3.5 minutes.

HTM 2010 defines the responsibilities of the operator and users of these

machines and provides information on how these sterilizers should be used, tested and maintained.

BOWL AND INSTRUMENT STERILIZERS

These sterilizers are similar in design and operate in a similar way to porous-load sterilizers, but without an active drying cycle or air removal. They must not be used for wrapped items or those which are hollow or have lumens. Machines located in operating theatres are gradually being phased out as the decontamination of surgical instruments is transferred to central processing units, that is SSDs.

BENCHTOP STERILIZERS

Benchtop sterilizers must be operated to ensure that:

- they are compliant with safety requirements;
- they are installed, validated and maintained appropriately (HTM 2010; MDA DB 9804 and MDA DB 2002 (06));
- they are operated in accordance with the equipment manufacturer's instructions.

Users should be aware of the cautionary notes relating to the improper use of small benchtop sterilizers. These include:

- Wrap instruments only where this is recommended by the manufacturer and where the sterilizer is vacuum-assisted. The sterilizer must be validated for the intended load.

- Rigid endoscopes cannot be processed in benchtop sterilizers unless designated as autoclavable by the manufacturer and the process has been validated for the instrument (see the Medical Devices Directive, Annex 1, ER 13.6(h)).
- Hollow or lumen instruments are not suitable for sterilization in non-vacuum sterilizers.

All steam sterilizers are subject to the Pressure Systems Safety Regulations 2000 and must be examined periodically by a Competent Person (Pressure Vessels).

Use and testing of benchtop sterilizers

To ensure the safety of this device, the following points must be adhered to:

1. Each sterilizer will have a reservoir chamber from which the water is delivered for steam generation; this must be filled daily using sterile water for irrigation BP. At the end of the day or following final use, the chamber should be drained (only when the water has cooled), cleaned, dried, covered with a lid and left empty for future use (see HTM 2031).
2. Testing is an integral part of ensuring a benchtop sterilizer consistently performs to operating parameters set during the machine's commissioning. Failure to carry out routine periodic tests and maintenance tasks could compromise safety and have legal and insurance-related implications for the user or owner of the sterilizer.

3. A schedule for periodic testing should therefore be planned and performed in accordance with documented procedures (see HTMs 2010 and 2031; and MDA DB 2002 (06)). The schedule should provide details of daily, quarterly and yearly testing. Each sterilizer should have a logbook (file) in which details of the following are recorded:

- maintenance;
- validation;
- faults;
- modifications;
- routine tests.

HSC 1999/053 provides guidance on the length of time for which records should be retained.

Details of each load processed should also be retained in this logbook.

Examples of logbook pages can be found in the Annex of MDA DB 2002 (06).

Daily testing and housekeeping tasks

Some benchtop sterilizers require a warm-up cycle before instruments can be processed. The manufacturer's instruction manual should be consulted to find out whether this is the case.

The daily tests should be performed by the operator or user and consist of:

- a steam penetration test (vacuum benchtop sterilizers only);
- an automatic control test (all benchtop sterilizers).

The tests may be carried out at the same time.

Sterilizers must not be used until the daily tests and housekeeping tasks have been carried out, and the results found to be satisfactory.

Before carrying out the daily tests, the user should:

- clean the rubber door seal with a clean, damp, non-linting cloth;
- check the chamber and shelves for cleanliness and debris;
- fill the reservoir with sterile water for irrigation BP;
- turn the power source on;
- record these tasks with the date and signature of the operator in the logbook.

If the sterilizer fails to meet any of the test requirements, it should be withdrawn from service and advice should be sought from the manufacturer and/or maintenance contractor (for example, the estates department).

A schedule of weekly, quarterly and annual tests may be found in MDA DB 2002 (06) or MDA DB 9804.

Steam penetration test procedure

- Place the Bowie–Dick type test pack (conforming to BS EN 867:2001) within the chamber in a position recommended by the manufacturer. This will ensure that the test presents the machine with the greatest challenge from which to remove air from the load.

- Select a standard cycle or the cycle specified by the sterilizer manufacturer. (The test should always be performed using the same cycle).
- At the end of the test, remove the test sheet from the middle of the pack and compare the results with the manufacturer's test sheet.
- The test is satisfactory if the indicator shows a uniform colour change.
- The test results PASS/FAIL should be recorded in the sterilizer logbook.
- The test result indicator paper should be marked with the result, date and cycle number and kept within the logbook for reference. (It should be stored according to the manufacturer's recommendations).
- If the sterilizer is fitted with a chart recorder, the test cycle print-out should also be retained within the logbook.

If the test result is unsatisfactory, the machine should be taken out of use and the fault investigated (this may require testing by a designated Test Person).

Automatic control test

Daily tests are referred to as automatic control tests. Details of how to undertake these tests can be found in the manufacturer's user manual. For accurate monitoring of the cycle parameters, a stopwatch is recommended for accurate timings. (An automatic control test is not required if the sterilizer is equipped with a recorder that provides a permanent record (print-out) of the temperature, pressure and elapsed time during all stages of the sterilization cycle/s in use.)

Use of chemical process indicators

Chemical process indicators are a mechanism by which sterilizer loads can be identified as having passed through a process. The chemical indicator reacts when exposed to steam and demonstrates a change in character, usually colour. These chemical indicators can take the form of an autoclave tape, test tubes containing chemical indicator or sterilization packaging/bags. In all these cases, the chemical indicators will change colour when subjected to heat.

- Indicators must be stored in conditions that will not adversely affect the performance of the chemicals.
- Store in accordance with manufacturer's instructions.
- Do not use indicators beyond the expiry date stated by the manufacturer.
- Chemical process indicators should be used and read in conjunction with sterilizer-process print-outs or a sterilization cycle's parameters.

Microbiological testing of steam sterilizers is not recommended.

Processed devices for immediate use

Non-vacuum benchtop steam sterilizers are designed to process items for immediate use within a clinical environment.

Upon completion of the sterilization cycle, if the machine does not have a vacuum cycle, steam is condensed within the sterilizer's chamber, resulting in a wet load. Partial drying does occur by natural evaporation after the load is removed from the chamber, but once the door to

the sterilizer chamber has been opened, the load is compromised and subsequently exposed to recontamination. Benchtop sterilizers used to sterilize unwrapped items should therefore only be used to sterilize loads for immediate use.

It is not recommended that loads are packaged after sterilization.

(Note: where sterilized items are not required for immediate use, they should be dried using a clean, non-linting cloth before storage in clean, closed, secured containers until required. Such containers should be regularly cleaned and sterilized. Should unwrapped items need to be sterile at the point of use, the items should be resterilized immediately before being used.)

Vacuum benchtop steam sterilizers

Steam sterilization requires direct contact between dry saturated steam and all surfaces of the load at a specified temperature and pressure for a defined period of time. To enable sterilizing

conditions to be achieved, load items must, therefore, be cleaned thoroughly and air removed effectively from the sterilizing chamber and the load. Effective air removal is essential to enable steam to penetrate wrapped devices and those with lumens. This can be achieved only if the sterilizer is equipped with an active air-removal system, as are vacuum benchtop sterilizers. They can process porous loads (Type B cycle) or types of devices specified by the sterilizer manufacturer (Type S cycle).

The drying stage must reduce the moisture content of packages and porous materials to a level that will not permit bacterial recontamination.

Because vacuum benchtop steam sterilizers are more complex than their non-vacuum counterparts, they require more rigorous testing to demonstrate that they function correctly. Therefore, owners/users of benchtop sterilizers should ensure that the sterilizer is subject to a planned and documented schedule of preventative maintenance.

9.0 Transportation of decontaminated surgical instruments and associated equipment

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; and

- prevent contamination of staff etc when transporting used instruments for reprocessing.

They should have the following characteristics:

- be waterproof;
- be easy to clean (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 products being transported;
- be clearly labelled to identify the delivery address.

10.0 Storage of sterile products

Following the decontamination of surgical instruments and other medical devices and accessories, it is important to ensure that the storage conditions maintain the packs in the condition in which they are required for use. As a general rule, this would involve maintaining the sterility of wrapped products but may also include those packs which have been processed and which are not required in a sterile state at the point of use, that is disinfected.

Sterile products are usually stored at the point of use, for example wards, clinics, departments and operating theatres. However, regardless of the location, the storage area should be dedicated for the purpose and not used for other activities, for example patient treatment areas.

- 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 unsterile and unsuitable for use.

Rough handling of sterile products can damage both the product and the wrapping and may render the product unsterile. Do not pack products tightly together on shelves, in draws or in containers as this may also damage the packaging (see MDA SN 1999 (32)). Products found to be damaged or wet should be returned for reprocessing.

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

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

As a “rule of thumb”, product which has remained unused for more than six months should be deemed to be a product of over-stocking and an assessment undertaken as to its future need.

There are occasions where devices must form part of emergency stocks and as a result may not be used within this time frame. Procedures should be put in place to ensure that these products are subject to a reprocessing regime over time.

11.0 Use of surgical instruments and associated equipment

It is the responsibility of the “user”, that is nursing staff etc, to ensure that the equipment they intend using is “fit for purpose”. By this, it is meant that the product has been subjected to an appropriately validated process and that every reasonable precaution has been taken to ensure that the sterile condition (or otherwise) of the product has been maintained up to the point of use.

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

- In hospitals, it is often the sterile services technician or nursing 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 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-party.

Thus, for the product to reach the point of use safely and in good condition, all those involved in the different elements of the decontamination life-cycle must be appropriately trained and aware of their responsibilities in providing a product which is fit for purpose.

Users have a responsibility to notify those providing a decontamination service of any service problems, either about availability of devices or about the devices themselves. This may include surgical instruments which require repair or sharpening or about late deliveries which may have affected patient treatments.

Appendix 1 – Processing of flexible endoscopes

The environment in which flexible endoscopes are processed should be of the same high standards as those for other surgical instruments, dedicated for the purpose and separated from treatment areas.

In accordance with manufacturer's recommendations, the channels of flexible endoscopes should be flushed immediately after use and then manually cleaned before the automated cleaning process. Cleaning brushes should be of the single-use type.

Flexible endoscope accessories should be processed in accordance with manufacturer's instructions and identified so as to allow tracking/tracing through the decontamination process of the flexible endoscope and the patient on whom it is used.

An automated endoscope reprocessor with an integrated cleaning and drying

system is the preferred option for reprocessing flexible endoscopes (HTM 2030).

Flexible endoscopes should be stored by hanging in a dedicated cupboard where they can be protected against damage and potential recontamination.

Where endoscopes have been cleaned and stored but are required to be used in a high-level disinfection state, the disinfection process must be repeated for each device immediately before use.

Detailed guidelines for the cleaning and high-level disinfection of endoscopy equipment can be found in MDA DB 2002 (05).

It is vital that the outer covering of the endoscope be tested before use for the safety of patient and staff. This is known as "leak testing" (see MDA DB 2002 (05)).

Appendix 2 – References

ACTS AND REGULATIONS (GENERAL)

(The) Carriage of Dangerous Goods by Road Act 1992, HMSO.

Consumer Protection Act 1998 (Product Liability), HMSO.

(The) Control of Substances Hazardous to Health (COSHH) Regulations 2002, HMSO.

Health & Safety at Work etc Act 1974, HMSO.

(The) Management of Health & Safety at Work Regulations 1999, HMSO.

Medical Devices Regulations 2002, HMSO.

Personal Protective Equipment at Work Regulations 1992, HMSO.

MEDICAL DEVICES

HSC 2000/032: Decontamination of medical devices, Department of Health, 2000.

MDA DB 9801: Medical device and equipment management for hospital and community-based organisations, Medical Devices Agency, 1998.

MDA SN 1999 (32): Storage of sterile medical devices, Medical Devices Agency, 1999.

MDA SN 2000 (18): Handling of surgical instruments on loan from another organisation, Medical Devices Agency, 2000.

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

MHRA DB 2003 (05): Management of medical devices prior to inspection, service & repair, Medicines and Healthcare Products Regulatory Agency, 2003.

PROCESSING

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

BS EN 868: Packaging materials and systems for medical devices which are to be sterilized, British Standards Institution, 1997-2000.

BS EN 980:1997 Graphical symbols for use in the labelling of medical devices, British Standards Institution, 1997.

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

MDA SN 2001 (28): Compatibility of medical devices and reprocessing units with decontamination agents, Medical Devices Agency, 2001.

MDA DB 2002 (05): Decontamination of endoscopes, Medical Devices Agency, 2002.

Protocol for the local decontamination of surgical instruments, NHS Estates, HMSO, 2001.

Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Agency (MDA) 1996, 1999, 2000, 2002, ISBN1 85839 518 6 (MAC Manual), Medical Devices Agency, 1993-2002.

DECONTAMINATION PROCESSING AND EQUIPMENT

C30 – Model Engineering Specification for Washer-disinfectors for surgical instruments, NHS Estates, The Stationery Office, 2001.

HTM 2010: Sterilization, NHS Estates, HMSO, 1994-1997.

HTM 2030: Washer-disinfectors, NHS Estates, HMSO, 1997.

HTM 2031: Clean steam for sterilization, NHS Estates, HMSO, 1997.

MDA DB 9804: The validation and periodic testing of benchtop vacuum steam sterilizers, Medical Devices Agency, 1998.

MDA DB 2002 (06): Benchtop steam sterilizers – guidance on purchase, operation and maintenance, Medical Devices Agency, 2001.

(The) Pressure Systems Safety Regulations 2000, HMSO, 2000.

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: Medical Devices Management, Rev(03), Department of Health, 2002.

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

HSC 1999/053: Preservation, retention and destruction of records. Department of Health, 1999.

HSC 1999/178: Variant Creutzfeld-Jakob Disease: Minimising the risk of transmission, Department of Health, 1999.

HSC 1999/179 – Controls Assurance in Infection Control – Decontamination of Medical Devices, Department of Health, 1999.

USEFUL WEBSITE ADDRESSES

Institute Of Sterile Services Management – <http://www.issm.org.uk>

Medicines and Healthcare products Regulatory Agency (MHRA) – (formerly the Medical Devices Agency) <http://www.mhra.gov.uk>

NHS Estates –
<http://www.decontamination.nhsestates.gov.uk>

NHS Purchasing and Supplies Agency –
<http://www.pasa.doh.gov.uk>

Appendix 3 – Glossary

Aerosol

Dispersion of solid or liquid particles in a gas.

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.

Benchtop sterilizer

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

Bio-burden

The population of viable infectious agents contaminating a medical device.

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, for example a sterile services department (SSD).

Chemical indicator

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

Clinical area/setting

Any medical and surgical ward, department or patient treatment area.

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.

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 disinfectant at any one time for the purpose of processing it by an operating cycle.

Load items

One of several discrete containers, packs or other items that together constitute a load.

Local decontamination

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

Medical device

Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; and control of conception: and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (source: EU Council Directive 93/42/EEC).

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.

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.

Reusable 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.

Sterile

Condition of a load item that is free from viable micro-organisms. BS EN 556-1:2001 details the requirements for a medical device to be designated as sterile.

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 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.

Type B (sterilization cycle)

Intended to process porous loads e.g. wrapped instruments and fabrics.

Type S (sterilization cycle)

Designed to process air-retentive loads e.g. tubular devices, as specified by the sterilizer manufacturer.

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. Also known as an automated endoscope reprocessor when dedicated to endoscope decontamination.

Acknowledgements

Our thanks to the following people for their contribution to the writing of this guide:

Mrs G. Sills – Chairman of International Federation for Sterile Supply's

Miss K. Woodhead – Past Chair of National Association of Theatre Nurses

Mrs P. Oliver – Past Director of Education Institute of Sterile Services Managers

Miss S. Meredith – Director of Education Institute of Sterile Services Managers

Mrs A. Fuller – Control of Infection Nurses Association

Mrs L. Davies – Senior Consultant for Decontamination

Mrs S. Morgan – Chairman of Infection Control Nurses Association

