

**PART 5a: RECOMMENDED PRACTICES FOR
DENTAL SERVICES IN A CENTRAL
DECONTAMINATION UNIT**

**Health Service Executive
Code of Practice for
Decontamination of
Reusable Invasive Medical Devices**



Reader Information

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Part 5a

Part 5a
Recommended Practices for Dental
Services (Central Decontamination
Units)

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Design of designated area for decontamination of dental RIMD in a CDU

1 Design of designated area for decontamination of dental RIMD in a central decontamination unit (CDU)

1.1 Introduction

Dental clinics should have designated non-clinical space provided for dental reusable invasive medical devices (hereafter referred to in this document as dental RIMD), decontamination to minimise opportunities for cross-infection of patients, clinical staff and cross-contamination of the working environment.

1.2 Scope

The objective of this procedure is to outline the principles of a safe working environment for decontamination of dental RIMD.

1.3 Contents

Section One: Unit design

Section Two: Lighting and electrical power supply

Section Three: Ventilation and temperature

Section Four: Walls, floors and ceilings

Section Five: Workstations, furniture, shelving and equipment

Section Six: Restricted entry and movement between areas

Section Seven: Storage facilities

Section Eight: Environmental control

Section Nine: Cleaning

Design of designated area for decontamination of dental RIMD in a CDU

1.4 Procedure

Section One: Unit design

- The Central Decontamination Unit (CDU) should be designed so that it is physically separated from all other work areas.
- The CDU should be designed to allow segregation of 'dirty' and 'clean' activities.
- The CDU should be designed to facilitate a unidirectional flow from the 'dirty' area to the 'clean' area.
- The CDU should not be used for any other purpose.
- The CDU should not be used as a thoroughfare.
- There should be a designated changing area for donning work wear.
- The CDU area should be free from 'opening' windows, ledges, and uncleanable areas.
- The decontamination area should be designed to minimise the ambient sound levels. (This will require attention to the installation of equipment, building finish, etc.).

Section Two: Lighting and electrical power supply

- There should be adequate lighting available to permit good working practices and visual examination of dental RIMD.
- Task lighting and magnification should be installed.
- There should be sufficient electricity supply points, computer terminal points and work stations in the department.

Design of designated area for decontamination of dental RIMD in a CDU

Section Three: Ventilation and temperature

- All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22°Celsius and relative humidity should be controlled within the range 35-60%).

Section Four: Walls, floors and ceilings

- The finishes on the walls and other surfaces should be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning and/or disinfection.
- The junctions between the walls and floors should be coved and flush.
- The fitments (where possible) should be flush with wall surfaces.
- Floors should be covered in a washable non-slip material which is securely sealed.

Section Five: Workstations, furniture, shelving and equipment

- All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.
- The workstations should be equipped for the preparation of packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.
- There should be adequate space between workstations for equipment and staff movement.
- The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.
- The shelving should be of sufficient depth for all the materials to be held and should not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.

Design of designated area for decontamination of dental RIMD in a CDU

Section Six: Restricted entry and movement between areas

- The area should be managed by trained staff.
- Entry to the decontamination unit should be restricted to authorised personnel only.

Section Seven: Storage facilities

- Safe storage facilities should be provided for process chemicals used in decontamination.
- Storage facilities for bulk items should be provided external to the designated decontamination area.
- Required personal protective equipment should be easily accessible in each of the work areas.

Section Eight: Environmental control

- The environment in which clean non-sterile dental RIMD are inspected, assembled and packed should be microbiologically monitored periodically to demonstrate low levels of microbial contamination.

Section Nine: Cleaning

- The environment in which decontamination of dental RIMD takes place should be cleaned in accordance with methods, procedures and schedules as outlined by HSE Protocols).

Environmental cleaning

2 Environmental cleaning

2.1 Introduction

Adequate regular cleaning of all work areas is essential for decontamination to be effective. Environmental cleaning procedures and schedules adopted must ensure that contamination from dirty areas does not contaminate the clean areas.

2.2 Scope

The objective of this procedure is to provide guidelines in relation to environmental cleaning in decontamination facilities.

2.3 Contents

Section One: Cleaning equipment

Section Two: Cleaning frequency and cleaning efficacy

Section Three: Floor cleaning equipment and method

Section Four: Floor cleaning agents

Section Five: Records

2.4 Procedure

Section One: Cleaning equipment

- Separate cleaning equipment should be used for the clean and dirty areas.
- Cleaning equipment should be regularly cleaned and maintained.

Section Two: Cleaning frequency and cleaning efficacy

- Work surfaces should be cleaned daily and whenever necessary.
- Entire rooms should be deep cleansed annually. Air vents and filters should be serviced regularly.

Environmental cleaning

- There should be documented cleaning procedures for fixtures and fittings.
- There should be documented cleaning procedures for process equipment.

Section Three: Floor cleaning equipment and method

- Floors should be cleaned daily and also cleaned when visibly soiled.
- Adhere to colour coding policy for cleaning equipment.

Section Four: Floor cleaning agents

- Floors should be cleaned using a neutral detergent.
- If visible blood/body fluids are present it should be neutralised using chlorine based disinfectant, and then thorough cleaning should be completed.
- Disinfectants should be made up according to the manufacturers' instructions/ organisations policy.

Section Five: Records

- Records should be kept of the following:
 - Training of the personnel carrying out the cleaning.
 - Periodic inspection of cleanliness.
 - Vaccination Status of the cleaning staff.
- **Note:** The scope of responsibility shall include the competence of contractors where the organisation buys in services.

Decontamination equipment

3 Decontamination equipment

3.1 Introduction

All decontamination equipment that does not meet the requirements of current standards is identified and upgraded or replaced in accordance with a planned replacement programme. All new decontamination equipment must be procured in conformance with extant harmonised standards.

All decontamination equipment must be validated, maintained, periodically tested and monitored to current standards.

3.2 Scope

Decontamination equipment that does not meet current standards cannot be relied upon to meet current requirements for decontamination or to provide the required level of assurance.

Organisations must have a specialist group in place to consider the full implications of procurement of decontamination equipment.

Validation, maintenance, periodic testing and monitoring are required to demonstrate compliance of installed equipment with current standards.

3.3 Contents

Section One: Advisory user group (or relevant committee)

Section Two: Ultrasonic cleaning

Section Three: Washer-disinfectors

Section Four: Steam sterilisers

Section Five: Heat sealers

Decontamination equipment

3.4 Procedure

Section One: Advisory user group (or relevant committee)

- Each organisation should have a advisory user group (or relevant committee) in place to consider the decontamination equipment in the organisation with regard to the following:
 - i. Ability to meet current standards.
 - ii. Age and condition of equipment and availability of replacement parts.
 - iii. Cost of maintaining and repairing the equipment.
 - iv. Ability to interface with other equipment in the dental facility.
 - v. Ability to interface with user requirements.
 - vi. Ability to meet the requirements of current test methods.
 - vii. Ability to be validated and perform to intended purpose.
 - viii. Energy and water conservation.
 - ix. Ability for self-disinfection for washer-disinfectors.

- Key representatives on the specialist group should include (where available):
 - i. Decontamination Coordinator.
 - ii. Dental Staff.
 - iii. Microbiologist.
 - iv. Infection Prevention and Control.
 - v. Procurement.

The group may also include as required:

- i. Finance Manager/Budget Holder
- ii. Other relevant experts (Authorised Person/Sterivigilance Nurse).

Decontamination equipment

- The group should identify all decontamination equipment which needs to be replaced.
- The group should formulate a plan to replace or upgrade this equipment.
- The plan should be submitted to the senior management team and revised annually by the decontamination coordinator (or designated officer).
- The group should ensure that the decontamination equipment procured is compatible with the current stock of dental RIMD.
- There should be sufficient decontamination equipment available to meet the needs of the dental unit(s) and patient throughput.
- There should be clearly defined policies and procedures for maintaining, testing, validating and day to day operation of decontamination equipment.
- Validation and periodic testing should be carried out by qualified personnel.
- The validation and periodic testing data should be adequately audited annually by a qualified person (decontamination) registered with the Health Service Executive.
- The department should have a register of equipment that includes as a minimum, the date of purchase, supplier, commissioning data and cost.

Section Two: Ultrasonic cleaning

- A stand-alone ultrasonic cleaner should be provided for pre-treatment of those dental RIMD which are required to be cleaned by this method according to the manufacturers' instructions. Ultrasonic cleaning should preferably only be used as a pre-treatment for dental RIMD prior to further processing through a washer-disinfector.
- The ultrasonic cleaner should be fitted with a lid which is (preferably) interlocked to prevent operation of the ultrasonic cleaner when the lid is open.
- The dental RIMD manufacturer should be consulted to ensure that the enzymatic/detergent preparation is suitable for cleaning the dental RIMD they manufacture.
- Means should be provided to control the concentration of detergent. **Note:** An automated dispenser is preferable.

Decontamination equipment

- The ultrasonic cleaner should be used in accordance with the manufacturers' instructions.
- The ultrasonic cleaner should be validated, periodically tested, maintained and monitored in accordance with EN ISO 15883, part 1, 2006.
- **Note:** The only effective way of cleaning the lumen of a dental hand-piece is to process it through a washer-disinfector with each lumen connected to a flushing system.

Section Three: Washer-disinfectors

- The specification of the washer-disinfector should comply with requirements of EN ISO 15883 parts 1, 2 and 5, 2006.
- Each washer-disinfector should be fitted with a process monitoring system.
- When lumened devices are being reprocessed (e.g. dental handpieces), the washer-disinfector should be provided with load carriers that permit the irrigation of the lumened device.
- Washer-disinfectors and accessories should be specified, installed, validated, commissioned, tested and operated in accordance with EN ISO 15883, parts 1,2 & 5.
- The washer-disinfector should be subject to planned preventative maintenance.

Section Four: Steam sterilisers

- Sterilisers and accessories should be specified, installed, commissioned, tested and operated in accordance with the current standard EN 285 where relevant /EN 13060 and EN ISO 17665, part 1.
- The sterilisation hold period should be at 134-137°C for not less than 3 minutes or 121-124°C for not less than 15 minutes.
- The sterilisers should be subject to planned preventative maintenance.
- Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances.**

Decontamination equipment

- All dental RIMD, items and equipment for use on patients should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemiclaves are not appropriate for sterilising dental RIMD and should not be used.

Section Five: Heat sealers

- Where heat seal packaging is to be used, a rotary heat sealer should be provided.
- Heat-sealing equipment used as part of the terminal packaging process should be maintained and tested to manufacturer's performance criteria.
- The heat sealer should be validated and tested daily to verify the efficacy of the seal.
- The heat sealer should be subject to planned preventative maintenance.

Procurement of dental RIMD

4 Procurement of dental RIMD

4.1 Introduction

Procurement includes all activities from requisition, through payment to disposal and is the responsibility of all staff involved in the process. All staff engaged in procurement related activities are required to familiarize themselves with all relevant regulations. Any procurement undertaken must meet the terms of the Health Service Executive procurement policy.

4.2 Scope

The objective of this procedure is to provide guidelines on the procurement of dental RIMD and ancillary materials.

4.3 Contents

Section One: Advisory user group

Section Two: Procurement policy

Section Three: Specification

Section Four: General principles

Procurement of dental RIMD

4.4 Procedure

Section One: Advisory user group

- Each organisation should have an advisory user group (or relevant committee) in place to consider the procurement of dental RIMD.
- Key representatives on the specialist group should include (where available):
 - i. Dental Staff.
 - ii. Competent Infection Prevention and Control Advisor (e.g. microbiologist).
- The group should also include as required:
 - i. Procurement.
 - ii. Technical Services.
 - iii. Other relevant experts as required (Authorised person/Sterivigilance Nurse).

Section Two: Procurement policy

- Each organisation should have a documented procurement policy.

Section Three: Specification

- The procurement of dental RIMD should be based on agreed specifications and should comply with the documented procurement policy.
- There should be a detailed specification for each dental RIMD which complies with current standards.

Section Four: General principles

- Sufficient dental RIMD and accessories should be purchased to allow adequate time for reprocessing without adversely affecting throughput.
- A decontamination assessment should be undertaken prior to the purchase of dental RIMD to ensure that the organisation has the facilities to reprocess the dental RIMD in accordance with the manufacturers' instructions.

Procurement of dental RIMD

Note: The group should carefully check whether and how reprocessing can be properly conducted without having to effect fundamental and expensive changes to the processing procedure. Thus the manufacturers' validated instructions for the reprocessing of dental RIMD should be available prior to purchase and comply with local policies and procedures.

- Value for money issues should be considered when purchasing dental RIMD.
- All dental RIMD and accessories should be CE marked as this will constitute the manufacturer's assurance that a device will be safe and will perform as intended.
- Suppliers should be selected based on their ability to supply dental RIMD in accordance with the specified requirements and ability to provide service support over the lifetime of the dental RIMD, where applicable.
- Where parts are single-use or have restricted use, this information should be provided prior to purchasing.

Manufacturers' instructions

5 Manufacturers' instructions

5.1 Introduction

Each dental RIMD must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use.

As far as practicable and appropriate, the information needed to use the dental RIMD safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sale packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

5.2 Scope

The objective of this procedure is to outline the information that must accompany each dental RIMD to ensure the safe use of the device.

5.3 Contents

Manufacturer

Section One: Requirements to be met by the dental RIMD manufacturer

Section Two: Label

Section Three: The instructions for use

Section Four: Precautions and contraindications

Section Five: Information supplied on request

Procedure for packs or sets in the central decontamination unit

Section Six: Label

Section Seven: Instructions for use

Manufacturers' instructions

5.4 Procedure

Manufacturer

Section One: Requirements to be met by the dental RIMD manufacturer

- If the dental RIMD is intended by the manufacturer to be reused, the following information should be provided:
 - i. Appropriate processes to allow reuse, including cleaning, disinfection, packing and (if appropriate), the methods of sterilisation of the dental RIMD to be resterilised.
 - ii. The number of reuses.
 - iii. Any restriction to the reuse.
- If the dental RIMD is supplied with the intention that it can be sterilised before use, instructions for sterilization methods should be provided.
- If the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas should be provided.
- Instructions for use should be included in the packaging of every dental RIMD. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to the harmonised European Standards. In areas for which no Standards exist, the symbols and colours should be described in the documentation supplied with the dental RIMD.
- The degree of accuracy claimed for dental RIMD with a measuring function should be provided.
- If the intended purpose of the dental RIMD is not obvious to the user, the manufacturer should clearly state the intended purpose on the label and in the instructions for use.
- Detachable components of the dental RIMD should be identified.
- Action to detect any potential risk posed by the dental RIMD and detachable components should be provided.

Manufacturers' instructions

Section Two: Label that is placed on the pack

The label should contain the following details:

- The name or trade name and address of the manufacturer.
- The details strictly necessary for the user to identify the dental RIMD and the contents of the packaging.
- Where appropriate (in the case of a single-use medical device), the method of sterilisation and the word 'STERILE'.
- Where appropriate, the batch code preceded by the word 'LOT', or the serial number.
- Where appropriate, an indication of the date by which the dental RIMD should be used, in safety, stating the month and the year.
- Where appropriate, an indication that the dental RIMD is for single use.
- If the dental RIMD is custom-made, the words 'custom-made dental RIMD'.
- If the dental RIMD is intended for clinical investigations, the words 'exclusively for clinical investigations'.
- Any special storage and/or handling conditions.
- Any special operating instructions.
- Any warnings and/or precautions to be taken.
- Year of manufacture.
- Batch or serial number.
- If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.

Section Three: The instructions for use:

The instructions for use should contain the following particulars:

- If the dental RIMD must be installed with, or connected to, other dental RIMD or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct dental RIMD or equipment to use in order to obtain a safe combination should be provided.

Manufacturers' instructions

- All the information needed to verify whether the dental RIMD is properly installed and can be operated correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the dental RIMD operates properly and safely at all times should be provided.
- Where appropriate, information to avoid certain risks in connection with the implantation of the dental RIMD should be provided.
- The necessary instructions in the event of damage to the sterile packaging and where appropriate, details of appropriate methods of resterilisation.
- If the dental RIMD is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the dental RIMD to be resterilised, and any restriction on the number of reuses.
- Details of any further treatment or handling needed before the dental RIMD can be used (for example, sterilization, final assembly, etc).

Section Four: Precautions and contraindications

The instructions for use should contain the following precautions and contraindications:

- Precautions to be taken in the event of changes in the performance of the dental RIMD.
- Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions; to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.
- Adequate information regarding the medicinal product or products which the dental RIMD in question is designed to administer, including any limitations in the choice of substances to be delivered.
- Precautions to be taken against any special, unusual risks related to the disposal of the dental RIMD.

Section Five: Information supplied on request

- The identity or information on the test methods used.
- If the manufacturer differentiates between critical and less critical areas of the product, the rationale for this distinction.

Manufacturers' instructions

Procedures for packs or sets processed in the central decontamination unit

Section Six: Label

The label should contain the following details:

- The details strictly necessary for the user to identify the contents of the packaging.
- Date of sterilisation.
- Cycle number.

Section Seven: Instructions for use

In general, Class I and Class IIa devices (see part 1, page 17) which comprise most of the dental RIMD processed by the local decontamination unit, do not require specific instructions for use. Exceptionally where these are required, copies should be retained by the clinical user and should be referenced on the label on the dental RIMD.

Personal protective equipment

6 Personal protective equipment

6.1 Introduction

Personal protective equipment (PPE) must be worn by personnel when decontaminating dental RIMD to reduce the risk of exposure to potentially infectious material. Managers must ensure that PPE is made available, that staff are trained in the use of PPE and all personnel are responsible for ensuring the correct use and disposal of same.

PPE involves use of protective barriers such as gloves, gowns, aprons, masks or protective eyewear. PPE also provides protection against other hazards in the healthcare facility such as chemicals and physical injury. Standard precautions and safe work practices are required to minimise the risk of infection to both patients and healthcare workers. They include, but are not limited to, good hygiene practices, particularly hand-washing, the use of PPE and the appropriate handling and disposal of waste. The provision of PPE is based on a risk assessment in accordance with Part V of the Safety, Health and Welfare at Work Act 2005 and (General Application) Regulations, 1993.

6.2 Scope

The objective of this procedure is the outline the PPE that must be worn by staff to reduce risk of exposure to potentially infectious material.

6.3 Contents

Decontamination unit

Section One: Attire

Gowning for entry to the wash area

Section Two: Head/hair cover

Section Three: Protective eyewear and face-shields

Section Four: Masks

Personal protective equipment

Section Five: Plastic aprons and gowns

Section Six: Gloves

Section Seven: Footwear

6.4 Procedure

Decontamination area

Section One: Attire

- All personnel working in the decontamination area should don freshly laundered low linting attire at the beginning of the working day.
- Low linting attire that minimises bacterial shedding and provides comfort and professional appearance should be selected.
- Freshly laundered attire should be changed daily or whenever it becomes visibly soiled or wet.
- Staff who are involved in the maintenance of decontamination equipment should be required to wear the same type of clothing.
- On leaving the decontamination area, staff should change into their normal day wear.
- After use, the attire should be discarded appropriately in a designated post use container/bag.
- Work attire should never be worn outside the decontamination area.

Gowning for entry to the wash area

Section Two: Head/hair cover

- The first item of to be donned should be a clean, single-use, low lint surgical hat or hood that confines all hair.
- The hat or hood should be designed so that microbial dispersal is minimised.
- All hair should be confined as well as covered.

Personal protective equipment

- After use, headgear should be discarded in the appropriate healthcare waste stream.
- Stud earrings may be worn and should be totally confined within the head cover.
- **Note:** Make-up or jewellery should not be worn in the decontamination area.

Section Three: Protective eyewear and face-shields

- All personnel working in the decontamination area should wear protective single use eyewear or face shields to reduce the risk of pathogenic organisms being transferred to the eyes, nose or mouth.
- Protective eyewear should be optically clear, antifog, distortion free, close fitting and shielded at the side.
- Protective eyewear or face shield should be single-use.
- Protective eyewear or face shields should be discarded in the appropriate healthcare waste stream.
- Face shields should cover the eyes, nose, mouth and chin.

Section Four: Masks

- All personnel working in the decontamination area should wear fluid repellent masks and/or face-shields to reduce the risk of pathogenic organisms being transferred to the nose or mouth.
- Fluid repellent masks and/or face-shields should be fitted and worn according to the manufacturers' instructions.
- Fluid repellent masks and/or face-shields should not be handled.
- Fluid repellent masks and/or face-shields should cover both mouth and nose while being worn.
- Fluid repellent masks and/or face-shields should be removed immediately if they become moist or visibly soiled and should be discarded in the appropriate healthcare waste stream.
- **Fluid repellent masks and/or face-shields should not be worn loosely around the neck.**

Personal protective equipment

Section Five: Plastic aprons and attire

- Healthcare Workers (HCWs) should wear impermeable attire with long cuffed sleeves and tuck-inside-gloves during procedures that are likely to generate splashes of blood or body fluids or during activities that may contaminate clothing, uniforms and/or personnel with microorganisms or infectious material.
- Fluid repellent attire and aprons should be changed daily or whenever they become visibly soiled or wet.
- After use, fluid repellent attire and aprons should be discarded in the appropriate healthcare waste stream.

Section Six: Gloves

- Gloves should be used for handling contaminated dental RIMD and waste and for performing environmental cleaning activities.
- Gloves should be selected and worn according to the task to be performed.
- Gloves should be changed and discarded after completion of tasks and/or when torn or perforated.
- When removing gloves, the outer surface of the gloves should not come into contact with skin.
- Avoid letting the gloves snap, as this may cause contaminants to splash into eyes or mouth or onto skin or other personnel in the area.
- **It is important to remove used gloves before touching anything that can become contaminated through contact, such as surfaces, or pens.**
- HCWs should wash their hands if visibly soiled or alternatively use alcohol hand gel on visibly clean hands before and after using gloves. Wearing gloves should not replace hand washing, as gloves may have defects that are not immediately obvious, or may become damaged during use.
- After use, gloves should be discarded in the appropriate healthcare waste stream.

Personal protective equipment

Section Seven: Footwear

- All personnel working in the decontamination area should wear non-slip enclosed footwear that are sufficiently robust to protect them from injury or contact with sharp objects (e.g. if sharps are dropped accidentally). **Note:** Shoes that are made from canvas or cloth material are unsuitable and should not be worn.
- Footwear should be regularly cleaned.
- Footwear should be appropriate to the area in which HCWs are designated.

Process chemicals

7 Process chemicals

7.1 Introduction

Chemicals such as detergents and disinfectants may have hazardous properties associated with them (may be irritant, corrosive, flammable), e.g. bleach and ammonia if mixed will release lethal chlorine gas. Process chemicals are potentially hazardous as they may cause irritation to the skin, eye, respiratory tract and mucous membranes. (Reference: The Safety, Health and Welfare at Work Act, 2005 (no. 10 of 2005). The Safety, Health and Welfare at Work (General Application) Regulations 1993, (S.I. no. 44 of 1993) as amended. The Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (S.I. no. 619 of 2001).

7.2 Scope

The objective of this procedure is to provide guidelines for staff in relation to the handling of chemicals.

7.3 Contents

Section One: Choice of process chemicals

Section Two: Control of process chemicals

Section Three: Material Safety Data Sheets and labels

Section Four: Training

Section Five: Spillage kit

Process chemicals

7.4 Procedure

Section One: Choice of process chemicals

- Process chemicals should be chosen to be compatible with:
 - i. The dental RIMD to be processed.
 - ii. The decontamination equipment to be used and the intended use of the dental RIMD.
- The least hazardous chemical that will fulfil a process requirement should be chosen.

Section Two: Control of process chemicals

- The methods to be used for handling and storage of process chemicals should be defined in written procedures.
- Chemicals that should not be stored together should be clearly identified.
- Chemicals should not be stored above shoulder height.
- Chemicals should be stored in locked cabinet.

Section Three: Material Safety Data Sheets (MSDS) and labels

- Suppliers of chemical agents should provide MSDS for all chemical agents (including cleaning agents and disinfectants).
- Copies of all MSDS should be available to all employees in a designated area at all times, so that appropriate action can be taken in case of exposure to a hazardous substance.
- If information is incorporated into policies and procedures, the original wording should be used and the MSDS referred to.
- Personnel should read and follow the precautions and instructions given on the MSDS and on the label prior to handling and use.

Process chemicals

Section Four: Training

All personnel who handle chemicals e.g. rinse aid, disinfectants, etc should be trained in following:

- Safe handling of chemicals.
- Method of cleaning process chemical spillages.
- First Aid required in the event of personal exposure.
- Correct disposal of material used.

Section Five: Spillage kit

- In each area where chemicals are used, a spillage kit should be available to allow safe and easy removal of spills.
- A first aid eye wash station should be available nearby or on hand.
- Where chemicals may contact HCWs eyes/skin, consideration should be given to the availability of chemical neutralisation within the department. (e.g. the hypertonic, polyvalent, amphoteric compound Diphoterine can be used to neutralise and inactivate up to 600 chemicals, including spills on environmental surfaces and inadvertent chemical contact with skin, eyes or mucous membranes).

Traceability

8 Traceability

8.1 Introduction

Systems should be in place to record the decontamination process used on dental RIMD/packs (tracking) and link them with patients on which they have been used (tracing).

The tracking system should record the progress of sets of dental RIMD, or individual supplementary dental RIMD, post sterilisation and allow retrospective demonstration that a particular set or supplementary dental RIMD has been correctly decontaminated.

8.2 Scope

The objective of this procedure is to provide guidelines for the effective tracking and traceability of dental RIMD through the decontamination process.

8.3 Contents

Section One: Processing

Section Two: Tracing

8.4 Procedure

Section One: Processing

Systems should be in place to allow the methods, operational cycles and personnel involved in the processing of a particular dental RIMD/dental RIMD set to be tracked through the decontamination (sterilization) processes in order to permit retrospective verification that the processes were carried out effectively.

Records should be maintained of:

- i. The cleaning, disinfection and sterilisation process cycle used.
- ii. The name of the person undertaking each stage of the decontamination process.
- iii. The date, time and test result.
- iv. Details of the RIMD being processed.

Traceability

- As a minimum, sets of dental RIMD should be individually identified. **Note:** RIMD should not be labelled with tape.
- Identification of individual dental RIMD may not be required. (The technology required for efficient and economical identification of individual dental RIMD is not sufficiently developed to recommend this as a requirement, although it is desirable).
- IT based systems are preferred. Manually based systems should only be used for small units with a very low turn-over or for back-up in the event of IT failure.
- Records relating to decontamination processes should be maintained for the lifetime of the dental RIMD/decontamination equipment plus eleven years.

Section Two: Tracing

- Systems should be implemented to enable the identification of patients on whom the dental RIMD/dental RIMD set have been used. This is important so that the relevant patients can be identified in the event exposure to potential risk.

Choice of decontamination process

9 Choice of decontamination process

9.1 Introduction

To prevent infection, all dental RIMD that come into contact with the patient should be systematically decontaminated after each procedure and attention must be given to all potential sources of contamination. All decontamination processes must be validated.

9.2 Scope

The objective of this procedure is to provide guidelines on the choice of decontamination processes.

9.3 Contents

Section One: General principles

Section Two: Choice of process

9.4 Procedure

Section One: General principles

- Decontamination processes should be chosen to be compatible with the dental RIMD to be processed.
- Decontamination processes should be chosen to be capable of providing the throughput required to maintain the desired level of clinical service.
- Decontamination processes should be chosen to be amenable to independent verification of the decontamination standards achieved.
- The decontamination methods selected should be economical and effective.
- The decontamination methods used should be compatible with recommended methods of validation.

Choice of decontamination process

Section Two: Choice of process

- In general, dental RIMD and equipment may be divided into three risk categories: high-, medium-and low-risk, according to the risk of infection associated with the subsequent use of each item of equipment.
- For **high-risk RIMD** (i.e. RIMD that become contaminated with blood, other body fluids, secretions or excretions), cleaning followed by heat sterilisation is the method of choice. In certain circumstances, it may be necessary to use chemical disinfection for heat-sensitive items. For dental procedures it is best to use only RIMD that will endure sterilisation by the moist heat method (i.e. autoclaving), as this is one of the safest, most effective and easiest to monitor and validate.
- **Medium risk items** consist of RIMD or equipment used in contact with mucous membranes in the oral cavity (e.g. light-curing units) that are not suitable for heat sterilisation and should be barrier protected prior to use. For reusable medium-risk items, the appropriate means of decontamination is cleaning followed by high-level disinfection or sterilisation.
- **Low-risk items** include RIMD, equipment or other items/surfaces in the dental clinic that come into contact with a patient's healthy intact skin, and equipment that does not have close contact with the patient. For these items, cleaning is sufficient. However, disinfection may be necessary if there is a known infection risk. Examples of low-risk items include surfaces, floors, walls and sinks.
- **Note:** Most RIMD and equipment used in dentistry come into direct contact with the patients oral cavity, so decontamination followed by sterilisation is the method of choice.

Transportation—return of used items for reprocessing

10 Transportation – return of used items for reprocessing

10.1 Introduction

After use, contaminated dental RIMD have to be removed from the dental surgery or dental clinical area and transported to the dedicated processing area for cleaning, decontamination and sterilisation.

10.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of contaminated dental RIMD.

10.3 Contents

Section One: General principles

10.4 Procedure

Section One: General principles

- RIMD should be removed from the surgery or clinical environment using a defined process.
- RIMD should be arranged in kits or cassettes for set procedures, (e.g. examination kit, scaling kit etc.) to prevent injuries during transportation and during decontamination.
- Contaminated dental RIMD should preferably be transported to the decontamination area in a covered container, as there is potential for dropping the RIMD en-route or indeed colliding with patients or staff resulting in injury. This will also prevent contact between contaminated and sterilised/disinfected RIMD which should always be transported separately.
- Depending on how long the RIMD are stored before cleaning, it may be necessary to store them in a disinfectant solution.

Transportation—return of used items for reprocessing

- Some commercial disinfectant products recommended for this purpose result in corrosion if in contact with RIMD for extended periods.
- Preferably, RIMD should be cleaned and disinfected immediately or shortly after use.
- In the case of heavily contaminated RIMD (e.g. RIMD used for oral surgery) it is best to remove as much of the contamination as possible prior to collection for transport to the decontamination area; e.g. RIMD heavily contaminated with blood should be wiped carefully with damp gauze using a single-handed technique.
- The spent gauze should then be disposed of appropriately as healthcare risk waste.
- All disposable items should be removed from the kit prior to transportation, e.g. disposable needles, cartridges etc.
- Broken RIMD or RIMD that require repair should be decontaminated and sterilised prior to disposal or repair.
- Policies and procedures for transportation (return of used items for reprocessing) of contaminated dental RIMD should be developed, reviewed periodically, and readily available within the practice setting.

Sorting and disassembly of contaminated dental RIMD

11 Sorting and disassembly of contaminated dental RIMD

11.1 Introduction

Effective and timely decontamination of dental RIMD should be performed where feasible. Sorting, disassembly and cleaning should be performed in a manner that minimises risk to those performing the task.

11.2 Scope

The objective of this procedure is to provide guidelines in relation to the sorting and disassembly of contaminated dental RIMD.

11.3 Contents

Section One: Sorting of items in the decontamination area prior to cleaning

Section Two: Disassembly of dental RIMD

11.4 Procedure

Section One: Sorting of items in the decontamination area prior to cleaning

- On receipt at the decontamination area, dental RIMD should be sorted according to the selected method of cleaning. The manufacturers' instructions for cleaning should be followed in order to ensure the dental RIMD is not damaged and is cleaned adequately.
- Policies and/or procedures should be developed for the handling, sorting and disassembly of dental RIMD.
- There should be written policies and/or procedures for handling specialised items.
- Care and handling of dental RIMD should be in accordance with manufacturers' instructions and organisation policies and procedures.

Sorting and disassembly of contaminated dental RIMD

Section Two: Disassembly of dental RIMD

To facilitate effective cleaning, the following activities should be completed:

- Place dental RIMD in mesh basket in a manner which ensures effective cleaning of RIMD. Do not place dental RIMD one on top of the other. **Overloaded baskets will result in ineffective cleaning due to masking.**
- Arrange dental RIMD in an orderly fashion in mesh trays so that all surfaces are exposed to the action of an automated cleaner, if used.
- Place each jointed dental RIMD in the open position in the mesh basket.
- If extra mesh baskets are required for cleaning purposes of an dental RIMD set, a marker should be placed in the extra baskets to identify the set name and number.
- Place heavy dental RIMD on the bottom or in a separate tray.
- Secure small and light items with a hold down screen or by other means, to ensure they are not free to move around during the cleaning process. Place scissors, light-weight dental RIMD, and microsurgical RIMD next.
- Separate all sharp dental RIMD from general dental RIMD. This is to ensure ease of identification for personnel assembling the dental RIMD after cleaning, in order to prevent sharps injury.

Cleaning (including pre-cleaning)

12 Cleaning (including pre-cleaning)

12.1 Introduction

Cleaning is an essential prerequisite for all effective disinfection and sterilisation processes, as organic residue may prevent the disinfectant or sterilant from contacting the item being processed and may also bind and inactivate chemical disinfectants (Muscarella, 1998). **If the item cannot be cleaned, it cannot be disinfected or sterilised. This process must not be used for items intended for single-use only.**

12.2 Scope

The objective of this procedure is to provide guidelines in relation to cleaning of contaminated dental RIMD. Cleaning is the initial and most crucial step in breaking the chain of disease transmission. Cleaning should remove all visible soil, dirt, dust or other foreign material.

12.3 Contents

Section One: Manufacturers' instructions

Section Two: Automated versus manual cleaning

Section Three: Automated cleaning

Section Four: Manual cleaning

Section Five: Dental handpieces

Cleaning (including pre-cleaning)

12.4 Procedure

Section One: Manufacturers' instructions

- The manufacturers' instructions should be consulted for specific guidance on cleaning and decontamination and to determine whether the dental RIMD will tolerate immersion.
- Dental RIMD should be cleaned, handled and inspected according to manufacturers' instructions. Manufacturers' instructions provide direction for care, cleaning and handling of dental RIMD. The instructions for cleaning and sterilisation should be such that if correctly followed the dental RIMD can be reused, without causing injury to the patient or personnel using the dental RIMD.

Section Two: Automated versus manual cleaning

- The use of mechanical cleaners such as washer-disinfectors and ultrasonic tanks is preferred to the manual cleaning of items.
- The advantage of using automated cleaning equipment is that it provides an efficient, validated, reproducible process which can be more easily controlled than manual methods.
- Automated processes are generally more convenient and also provide protection for the user in reducing exposure to contaminated dental RIMD and chemicals.

Section Three: Automated cleaning

- Automated washer disinfectors can significantly reduce the risks of transmission of infectious agents from contaminated dental RIMD.
- A washer disinfectant is an automated piece of equipment similar to a domestic dishwasher that is specially designed to clean, decontaminate and thermally disinfect RIMD and equipment.
- The washer disinfectant runs a washing cycle with detergent followed by a disinfection cycle and a drying cycle.
- Disinfection is performed by flushing with hot water of approximately 90°C for 1-10 minutes.

Cleaning (including pre-cleaning)

- The machine renders equipment clean, disinfected, dry and safe for further handling.
- Washer disinfectors are fast and are easy to operate. They usually have set programmes for different types of loads and allow for minimum RIMD handling, however, they are unsuitable for use with heat-sensitive items.
- Care should be taken not to over-load the washer disinfectant as this can result in some RIMD being shielded and not being properly cleaned or disinfected.

1. Washer-disinfectors

a. Introduction

- All washer-disinfectors used for decontamination of dental RIMD should conform to ISO/FDIS 15883 parts 1, 2 and 5, 2006. The water for the final rinse stage should be compliant with the manufacturers' recommendations.

b. Factors to be considered when determining if the RIMD is compatible with the washer-disinfectant

- Manufacturers' instructions.
- If the dental RIMD can be immersed in water.
- Maximum operating temperature. (In general if a RIMD is suitable for autoclaving it is suitable for decontamination in a washer/disinfectant).
- Mechanical damage which may occur from the impact of the water jets or other items in the load.
- The compatibility of the process chemicals.

c. Equipment

- See decontamination equipment section, page 18.

Cleaning (including pre-cleaning)

d. Procedure

- Ensure the washer-disinfector and all services are operational. The washer-disinfector should not start if any anomalies are present.
- Wearing protective clothing, load the rack/machine ensuring that the loading configuration does not impede the cleansing process and that the rotary spray arms can rotate.
- Only use load carrier and racks with the items for which they were intended.
- Keep a record of each RIMD/RIMD set processed in each washer-disinfector and each cycle in order to trace the RIMD/RIMD set through the decontamination process.
- Load the load carrier into the washer-disinfector.
- Secure the door (if fitted), select and start the cycle.
- On completion of the cycle ensure that all stages and parameters have been achieved. When the automated cleaning process is complete all the RIMD processed should be inspected.
- A typical cycle comprises the following phases:
 - i. Cold rinse.
 - ii. Warm wash.
 - iii. Rinse.
 - iv. Disinfection rinse.
 - v. Drying.
- Information should be recorded for each washer-disinfector cycle. Documentation is required for every washer-disinfector cycle and should contain the following. This information may be recorded in a log book.
 - i. Washer-disinfector identification number.
 - ii. Cycle number.
 - iii. Type of washer-disinfector.
 - iv. Type of cycle used.

Cleaning (including pre-cleaning)

- v. Date and time of start of cycle.
 - vi. Critical parameters for the specific washer-disinfector cycle.
 - vii. Results of washer-disinfector process
 - viii. Signature of a qualified person (decontamination) confirming whether or not the process cycle was within recommended parameters
 - ix. Any notes or observation for the process cycle
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
 - Cycles which were aborted should be documented with the action taken in a log book.
 - Where single-ended washer-disinfectors are used adequate segregation of unprocessed goods from processed goods should take place.
- e. **Validation**
- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the washer-disinfector is functioning correctly and that it will produce cleaned and disinfected loads consistently.
 - The effectiveness of the disinfection process cannot be verified retrospectively by inspection or testing of the product, and can only be guaranteed if correct conditions are created throughout the washer-disinfector chamber and the load during every cycle.
 - Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:
 - i. Commissioning (installation qualification and operational qualification).
 - ii. Performance qualification.
 - iii. Periodic testing.
 - iv. Annual and revalidation tests.

Cleaning (including pre-cleaning)

1. *Commissioning*

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

It consists of:

Installation qualification

- Verification of calibration, automatic control test, water quality tests, water supply temperature, water supply pressure.

Operational Qualification

- Weekly safety checks, automatic control test, verification of calibration of washer-disinfector RIMD, water system, drainage, venting system, doors and door interlocks, fault interlock, water vapour discharge test, aerosol discharge test, chemical additive dosing tests, load carriers, test for air quality, cleaning efficacy test, chamber wall and load carrier temperature tests, over-temperature cut-out test, thermometric tests for thermal disinfection, load dryness test and sound pressure.
- These tests should be carried out when a new washer-disinfector is purchased or when a used washer-disinfector has been relocated to another premises or following critical repairs.
- The tests should be carried out before the washer-disinfector is used for the first time. Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of washer-disinfector. Data from the commissioning tests provide assurance that washing/efficacy conditions are attained through most loads i.e. the washer-disinfector is functioning correctly.
- Even though the manufacturer should have tested a washer-disinfector before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **working correctly**.

Cleaning (including pre-cleaning)

2. *Performance qualification*

Performance qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean/disinfect. Performance qualification is indicated for initial use of a new/relocated washer-disinfector or when the load profile changes (e.g. new dental RIMD). It should be carried out by a Test Person (or suitably qualified person). These tests consist of:

- Thermometric tests of all dental RIMD/loading equipment to be processed, load dryness test (of RIMD requiring reprocessing), cleaning efficacy test, water / detergent penetration/contact times of all test loads and process residues.

3. *Periodic testing*

- After validation and when the washer-disinfector has been passed for use, it is subject to a schedule of periodic tests at daily, weekly quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the washer-disinfector is still operating within the limits established during commissioning.
- Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.
- **Daily:** Spray arm rotation, spray nozzles, remove and clean strainers and filters.
- **Weekly:** Automatic control test, safety checks, daily tests, water hardness, water conductivity and cleaning efficacy test (residual soil detection).
- **Quarterly:** Weekly safety checks, automatic control test, verification of calibration of instruments, thermometric test for thermal disinfection and cleaning efficacy test.
- **Annual:** Yearly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, doors, door interlocks, fault interlocks, water vapour discharge, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, over-temperature cut-out, thermometric tests for thermal disinfection, load dryness test and process residues.

Cleaning (including pre-cleaning)

f. Monitoring and Control

- Cycle variables should be monitored to ensure that the specified parameters are obtained for each cycle. The critical cycle variables are temperature, time and enzymatic detergent concentration.
- Validation, routine monitoring and control should be carried out in accordance with documented procedures in accordance with European standard EN ISO 15883, part 2, 2006.

g. Maintenance

- Preventative maintenance should be planned and performed in accordance with International Standards ISO 15883-1 and ISO 15883-2 and manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The washer-disinfector should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.
- Maintenance records for washer-disinfector and the repair log book should be maintained for each washer-disinfector.
- Planned preventative maintenance should be undertaken in accordance with European standards, manufacturers' instructions and/or local policy, including:
 - i. Inspecting and cleaning all filters.
 - ii. Dismantling and cleaning spray arms and nozzles.
 - iii. Efficacy tests during operational conditions.

Cleaning (including pre-cleaning)

2. Ultrasonic Cleaners

a. Introduction

- Ultrasonic cleaners work by the use of high intensity, high frequency sound waves which cause soil to be dislodged from the dental RIMD, or to be sufficiently loosened to be removed during the rinsing process. Plastics and other similar materials cannot be successfully processed by this method. Cemented glass syringes and lenses will be damaged if repeatedly subjected to this process. The manufacturers' instructions should be considered in relation to the suitability of dental RIMD for ultrasonic cleaning.

b. Equipment Required

- See decontamination equipment, page 18.

Figure 12-1: Loading the ultrasonic cleaner



Cleaning (including pre-cleaning)

c. Procedure

- Staff should wear personal protective equipment at all times while handling contaminated dental RIMD and working with the ultrasonic cleaner.
- Fill the tank with potable water (drinking quality) to the manufacturers' designated level; add the detergent solution as recommended by the manufacturer.
- Bring the solution up to the operating temperature.
- De-gas the water as recommended by the manufacturer.
- Place the opened/dismantled dental RIMD into the basket.
- Ensure all dental RIMD are fully immersed.
- If the dental RIMD is not for further cleaning, e.g. automated cleaning, record the following:
 - i. Method used.
 - ii. Solution dilution and temperature.
 - iii. Healthcare worker carrying out procedure.
 - iv. Date.
- Place the basket of dental RIMD into the tank. Never put dental RIMD directly onto the base of an ultrasonic washer.
- Close the lid and initiate the cleaning cycle.
- 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.
- The ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until further use, as per the manufacturers' instructions.
- It is recommended that the tank be emptied regularly. This should be at intervals not exceeding four hours, or when the water is visibly soiled.
- Combine only dental RIMD made of similar metals in the ultrasonic cleaner to avoid ion transfer. Ion transfer may result in RIMD etching and pitting.
- Avoid placing chrome-plated RIMD in the unit because the mechanical vibrations can cause the plating to flake.

Cleaning (including pre-cleaning)

d. Validation

- Validation, maintenance, periodic testing and record keeping are necessary to demonstrate that the ultrasonic cleaner is functioning correctly.
- Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is considered as a process which comprises:
 - i. Commissioning (installation qualification and operational qualification).
 - ii. Performance qualification.
 - iii. Periodic testing.
 - iv. Annual and revalidation tests.

2. Commissioning

This is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications *by the supplier*, that it is safe to operate (installation qualification) and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions (operational qualification).

It consists of:

Installation qualification

- Verification of calibration, automatic control test, water quality tests—hardness, and water supply temperature.

Operational qualification

- Weekly safety checks, verification of calibration, safety interlocks, automatic control test, cleaning efficacy test, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, chamber wall and load carrier temperature test, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasound activity and sound pressure.
- These tests should be carried out when a new ultrasonic cleaner is purchased or when a used ultrasonic cleaner is has been relocated to another premises or following critical repairs.

Cleaning (including pre-cleaning)

- Installation and commissioning checks and tests should be performed by an Authorised Person or other person with specialist technical training in commissioning of ultrasonic cleaner.
- Even though the manufacturer should have tested the ultrasonic cleaner before it left the factory, there is no guarantee that it will function correctly following delivery. Therefore, it should be tested before use to ensure that it is **working** correctly.

2. *Performance qualification*

Performance Qualification is required to show that washing/efficacy conditions are attained even for loads and test loads that are assessed by the user to be difficult to clean. Performance qualification is indicated for initial use of a new/relocated ultrasonic cleaner or when there is a requirement to process a new type of product. It should be carried out by a Test Person (or suitably qualified person). These tests consist of:

- Cleaning efficacy test and process residue test.

3. *Periodic testing*

- After validation and when the ultrasonic cleaner has been passed for use, it is subject to a schedule of periodic tests at daily, weekly, quarterly and yearly intervals.
- The daily, weekly and quarterly tests supply evidence that the ultrasonic cleaner is still operating within the limits established during commissioning.
- Annual tests (revalidation procedure) prove that the data collected during commissioning and performance qualification are still valid. Revalidation may also be required under certain circumstances.
- **Daily:** Remove and clean strainers and filters.
- **Weekly:** Daily tests, automatic control test (if using an automated ultrasonic cleaner) safety checks, and cleaning efficacy test (residual soil detection).
- **Quarterly:** Weekly safety checks, automatic control test, verification of calibration of instruments, test for ultrasonic activity and cleaning efficacy test.

Cleaning (including pre-cleaning)

- **Annual:** Weekly safety checks, automatic control test, verification of calibration of instruments, water system, drainage, doors and door interlocks, fault interlock, aerosol discharge, chemical additive dosing, load carriers, air quality, cleaning efficacy, chamber wall and load carrier temperature test, over-temperature cut-out test, thermometric test for thermal disinfection, load dryness test, test for ultrasonic activity and sound pressure test.

e. Monitoring and control

Validation, routine monitoring and control should be carried out in accordance with documented procedures as recommended by the manufacturers' instructions. 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 washers' cleaning process. The following simple test may be undertaken to establish that there is ultrasonic action in the tank.

f. Test for Ultrasonic Activity (reference HTM 2030)

The activity of an ultrasonic cleaner may be tested by the erosion pattern which is created on aluminium foil exposed in a bath for a short period. Note: the activity will not be uniform throughout the bath. The exposure time will depend on the thickness of the foil, the hardness of the foil, the operating frequency, the watt density and the temperature of the ultrasonic bath.

Equipment

- Aluminium foil (sold as aluminium foil wrap for cooking).
- Steriliser indicator tape.
- Stopwatch.
- Ruler/tape measure graduated in mm.

Cleaning (including pre-cleaning)

Method

- Measure the depth of the bath from the level of the lid to the bottom of the bath.
 - Cut strips of foil 15mm to 20mm wide and 120 (+ depth of bath) mm long.
 - Carry out the manufacturers recommended start-up procedure.
 - Ensure that the water in the tank is at the required level, that the amount of chemical additive specified by the manufacturer has been added and that the water in the tank is at the specified operating temperature.
 - Using strips of steriliser indicator tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.
 - The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should not be more than 10mm above, but not touching the bottom of the bath.
 - Operate the bath for the predetermined exposure time.
 - Remove the strips from the bath, blot dry and examine.
 - The zones of maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent (on visual inspection). Photostat pattern and save as documented record.
 - On re-testing, the extent of the erosion and the erosion pattern should have remained consistent with those originally determined during commissioning.
- g. Maintenance**
- Preventative maintenance should be planned and performed in accordance with documented procedures as recommended by the manufacturers' instructions.
 - The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
 - The ultrasonic cleaner should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
 - A qualified person (decontamination) should review the maintenance plan, main procedures and maintenance records periodically.

Cleaning (including pre-cleaning)

Section Four: Manual Cleaning

This is the least preferred method of RIMD decontamination and should be **strongly discouraged** due to the extremely high risk of percutaneous injury and splashing with infectious material during cleaning. Unfortunately this hazardous and clearly dangerous procedure is still widely practiced in dental clinics. Manual cleaning of RIMD is also inefficient, laborious and time consuming (and thus expensive). It is also impossible to validate such manual processes. Hand washing of dental RIMD should only be undertaken following pre-treatment in an ultrasonic cleaner.

a. Monitoring and control

Validated process control requires that the process can be replicated precisely; this is only possible with an automated process. Where a non-automated process is used, every effort should be made to control all the variables that affect the process. For manual washing, these include:

- i. Staff training/competence.
- ii. Water temperature.
- iii. Detergent concentration.
- iv. Nature of soil.
- v. Method of soil removal.
- vi. Accessibility of fluid to item.

If either the cleaning solution or rinse water becomes visibly soiled or contaminated, it should be changed and the process repeated.

b. Maintenance

Regularly inspect all receptacles, sinks, surfaces including water supply and drains, for damage. Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.

Cleaning (including pre-cleaning)

Section Five: Dental hand-pieces

- After each patient use, dental handpieces that are connected to the dental chair unit (DCU) air/water system should be operated for a minimum of 30 seconds to discharge water and/or air, taking care not to inhale the aerosol. This procedure is designed to dislodge any patient-derived material that may have been retracted into the air and/or water lines due to failure of antiretraction valves.
- These valves are designed to prevent material or fluids from being retracted or siphoned back into air and/or waterlines but studies have show that failure of antiretraction valves is not uncommon.
- Following air and waterline purging, handpieces should be detached from the DCU RIMD line, cleaned, decontaminated and sterilised according to the manufacturer's instructions and local policy.
- Automated pre-sterilisation cleaning of handpieces is the preferred method of handpiece decontamination.
- However, manual cleaning is still widely practiced. The outside of the handpiece should be cleaned with detergent and warm water (follow the manufacturers' instructions with regard to type of detergent recommended).
- If recommended by the manufacturer, lubricate the handpiece with pressurised oil until clean oil appears from the chuck or use automated oiler (wear protective clothing including gloves, glasses and a face-mask).
- Cover the working end of the handpiece with disposable paper towel to absorb the residual oil and clean away any excess oil.
- Following cleaning, package appropriately and sterilise in a steriliser with a pre-sterilisation vacuum phase.
- Dental handpieces should preferably be processed through a washer-disinfector equipped with lumen attachments.

Figure 12-2: Dental handpieces



Disinfection

13 Disinfection

13.1 Introduction

Disinfection is a process that inactivates infectious agents, using either thermal (moist or dry heat) or chemical means. The level of disinfection achieved depends on the temperature, exposure time and/or type of chemical disinfectant used.

13.2 Scope

The objective of this procedure is to provide guidelines in relation to disinfection of dental RIMD.

13.3 Contents

Section One: Disinfection process

13.4 Procedure

Section One: Disinfection process

- **Thermal disinfection** can be achieved in a thermal washer–disinfector by choosing the appropriate cycle.
- **Chemical disinfection** can be achieved with a compatible RIMD-grade disinfectant of the required level, used alone or in conjunction with a chemical washer–disinfector. This is the minimum treatment recommended for reprocessing dental RIMD that cannot be sterilised

Disinfection

1. *Thermal Disinfection*

a. Introduction

If items can withstand heat and moisture and do not require sterilisation (non-critical items such as disinfectant bottles), then thermal disinfection in a washer-disinfector is the simplest, most efficient and cost-effective method of disinfection. Please note that low level thermal disinfection of dental RIMD is not recommended. RIMD that can tolerate sterilisation should be used wherever possible.

2. *Chemical Disinfection*

a. Introduction

The ability of chemical disinfectants to effectively inactivate contaminating infectious agents depends on a number of factors, including the density of agents present, temperature, pH and concentration (Chiba, 1994). Only dental RIMD disinfectants or sterilants are suitable for use with dental RIMD. Healthcare facility or household/commercial-grade disinfectants should not be used on dental RIMD; they are suitable only for use on environmental surfaces (e.g. walls, floors, cupboards).

b. Equipment required

- Dental RIMD disinfectant or sterilant.
- Automated equipment.

Disinfection

c. Monitoring and control

- Chemical disinfection processes should provide adequate assurance of the required microbial lethality.
- Chemical disinfection processes should be validated microbiologically (usually by the disinfectant manufacturer). This should define the concentration, contact time and minimum/maximum temperatures.
- Chemical disinfection processes should be designed to ensure that all surfaces to be disinfected will be wetted by the disinfectant solution.
- All surfaces should be immersed and channels flushed whether manually or automatically to ensure the solution is present within the channels during ensuring the decontamination process.
- Chemical disinfection processes should be controlled and monitored to demonstrate attainment of the required concentration at the required temperature for the required time.
- After chemical disinfection, dental RIMD should be free from toxic residues and should be rinsed free from disinfectant with purified water free from microbial contamination. The quality of water used should be appropriate to the clinical procedures being undertaken.
- When rinsing channels should be flushed thoroughly if performed manually.

Drying

14 Drying

14.1 Introduction

Drying minimises rusting, staining and reduces the risk of recontamination during inspection and assembly of dental RIMD. Residual moisture interferes with the sterilization process, and can damage dental RIMD.

14.2 Scope

The objective of this procedure is to provide guidelines in relation to the drying of dental RIMD.

14.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Monitoring and control

Section Four: Maintenance

14.4 Procedure

Section One: Equipment

- See decontamination equipment, page 18.

Section Two: Procedure

- The preferred method of drying is to use a washer-disinfector with a validated drying cycle. Alternatively a drying cabinet can be used. If neither are available a clean disposable lint-free, absorbent wipe should be used, taking care to prevent percutaneous injury.
- Care should be taken not to exceed the temperature tolerances advised by the manufacturer.
- Dry the dental RIMD in a sloping position to facilitate drainage.

Drying

Section Three: Monitoring and control

- Manual drying should be avoided unless a single-use lint free cloth.
- Items should not be left to dry in ambient air.
- Alcohol or other flammable liquids should not be used as drying agents, other than in automated equipment designed for this purpose, e.g. some endoscopes washer–disinfectors.

Section Four: Maintenance

- Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- A qualified person (decontamination) should review the maintenance plan, maintenance procedures and maintenance records periodically.

Post cleaning inspection and function testing

15 Post cleaning inspection and function testing

15.1 Introduction

Inspection, maintenance and testing of dental RIMD should be carried out by trained persons in accordance with the manufacturers' instructions. All dental RIMD should be inspected to ensure that they are intact and that there are no chips, worn spots, flaking or other damage. The functionality of all dental RIMD should be tested or checked before being packaged for further processing or storage. The area where inspection takes place should be designated and controlled to optimise the effect of the sterilisation process and minimise contamination of the dental RIMD/dental RIMD sets.

15.2 Scope

The objective of this procedure is to provide guidelines in relation to the post cleaning inspection and function testing of dental RIMD.

15.3 Contents

Section One: Equipment

Section Two: Procedure

Section Three: Documentation post automated cleaning

Section Four: Inspection and function testing

Section Five: Monitoring and control

Section Six: Maintenance

Post cleaning inspection and function testing

15.4 Procedure

Section One: Equipment

- Work bench.
- Magnifying glass and/or stereo microscope.
- Light source.
- Diathermy pin hole detector

Section Two: Procedure

When the automated cleaning process is complete, the following should be carried out:

- Check that the chart record for the cycle conforms to the information established during validation and that all recorded variables are within the parameters permitted.
- Check that the operating cycle is in accordance with the specification for the load used.
- Check that arms rotate. If arms do not rotate, loads should be rejected as the load has not been exposed to the water spray effectively.
- Make a visual inspection of the load in order to ensure that there is no obvious damage, staining or residue.
- If the load is damaged, this may be due to the configuration of the load, i.e. rotating arm may be hitting off the dental RIMD or dental RIMD may not be compatible with automated washing.
- If staining and/or residue are present, this may be due to the configuration of the load, overloaded cart or malfunction in the washing cycle.
- Make a visual inspection of the load for dryness.
- Where a load may not be properly cleaned, the entire load is rejected and returned for re-cleaning.
- Any load or items rejected should be documented as a non conformance; this non conformance should also be documented into the washer-disinfector log book for further investigation.

Post cleaning inspection and function testing

- The diathermy pin hole detector should be used in accordance with the manufacturers' instructions to ensure safe use of equipment.

Section Three: Documentation post automated cleaning

- All documentation for automated cleaning should contain the following information:
 - i. Washer-disinfector identification number.
 - ii. Cycle number.
 - iii. Type of washer-disinfector.
 - iv. Type of cycle used.
 - v. Date and time of start of cycle.
 - vi. Critical parameters for the specific washer disinfector cycle.
 - vii. Results of washer-disinfector process.
 - viii. Any notes or observation for the process cycle.
- All records should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- Before commencing inspection the person carrying out inspection should ensure that:
 - i. The dental RIMD/dental RIMD set has been recorded as being through the specific cleaning process.
 - ii. If there is no record of cleaning, the dental RIMD/dental RIMD set is rejected and returned for re-cleaning. Items which have been manually cleaned should also be recorded as being cleaned through the manual cleaning process.
 - iii. The signature of identified responsible person confirming that the cycle has passed.

Post cleaning inspection and function testing

Section Four: Inspection and function testing

- Each dental RIMD/dental RIMD set should be inspected separately.
- Box joints, serrations and crevices, should be critically inspected for cleanliness.
- Hinges should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should be checked for security.
- Ratchets should close easily and hold firmly.
- Any damaged, incomplete or malfunctioning dental RIMD should be reported immediately.
- Cannulated dental RIMD should be checked to ensure channel is patent.
- Telescopes and light cables should be function checked as per manufacturers' instructions.
- Each dental RIMD set should be checked for completeness and defects.
- The sharpness of cutting edges should be assessed.
- Dental RIMD that have an outer insulation coating, for example diathermy forceps etc., require close inspection to ensure that the insulation remains intact. Insulated dental RIMD should be checked using a diathermy pin point tester. Damaged surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and patients.
- Each dental RIMD should be checked that there is free movement of all parts and that joints do not stick. A water based lubricant may be used if required. The lubricant should be used as directed by the RIMD manufacturer.
- Each dental RIMD should be checked that the edges of clamping RIMD meet, with no overlap and that teeth mesh together.
- Each dental RIMD should be checked that all screws on jointed RIMD are tight and have not become loose during the cleaning process.

Post cleaning inspection and function testing

Section Five: Monitoring and control

The user should be aware of the factors that may alter the efficacy of the method:

- Staff training/competence.
- Age of the dental RIMD.

Section Six: Maintenance

- Preventative maintenance is to be planned and performed for all equipment, (e.g. light source and pin hole detector) in accordance with documented procedures as recommended by the manufacturers' instructions.
- Records of all maintenance, validation and servicing should be maintained in accordance with ISO 13485:2003(E).

Packaging

16 Packaging

16.1 Introduction

After cleaning and decontamination, dental RIMD have to be appropriately packaged prior to sterilisation by autoclaving. RIMD should be packed before sterilisation, because otherwise they become recontaminated with dust and microorganisms from the environment as soon as they are removed from the steriliser. Packaging allows the RIMD to be safely stored and transported within the clinical environment following sterilisation.

16.2 Scope

The objective of this procedure is to provide guidelines in relation to the packaging of dental RIMD.

16.3 Contents

Section One: General principles

Section Two: Packaging systems

Section Three: Packaging materials

Section Four: Single use packaging

Section Five: Types of packaging

Section Six: Packaging techniques

Section Seven: Sealing of packs and bags

Section Eight: Labelling

Section Nine: Monitoring and control

Section Ten: Maintenance

Packaging

16.4 Procedure

Section One: General principles

- The choice and type of wrapping material will depend on the type of sterilisation process used.
- Materials used should comply with EN ISO 11607-1 and EN ISO 11607-2, 2006 and EN 868 parts 2-10, inclusive. Dental RIMD may be packaged in any of the following products: papers/non-wovens, polypropylene, containers, and plastic/paper pouches.
- When selecting packaging system each specific products capability to meet predetermined requirements and criteria should be evaluated.
- The appropriate size wrapping material should be chosen to attain adequate coverage of the item being packaged.
- Hollowware, RIMD or dressings should not be placed in textile (linen) packs as difficulty may be experienced in drying the combined pack materials and sterilisation may be compromised as the temperature increases in these materials at different rates.
- Single use wraps should be used once only and should be discarded after use in the appropriate healthcare waste stream.
- Dental RIMD packs should be packed in a manner that prevents damage to delicate items.
- Trays used for packaging RIMD should be perforated to allow for penetration of the sterilant.
- Hollowware items packaged together should be separated by non-porous material to permit efficient steam circulation.
- Hollowware should be packaged so that all openings face the same direction.
- Only the minimum of raw materials commensurate with daily production should be held within the clean room.
- Compatibility of the packaging material with the sterilisation process should be established.

Packaging

- If chemical indicators are used inside the pack, they should conform to European Standard EN ISO 11140-1 and should be compatible with the pack.
- All RIMD should be cleaned and thoroughly dry before packaging and sterilisation.
- The packaging material should be compatible with the sterilisation process (i.e. allow passage of air and steam) and should provide an effective barrier against recontamination by microorganisms (i.e. the packaging should be robust and allow handling and transportation while maintaining the sterility of the packaged RIMD).
- Primary packaging consisting of sterilisation pouches or bags is generally sufficient for the dental clinic environment.
- Alternatively, RIMD in kits or cassettes may be packaged prior to sterilisation as they are frequently perforated.
- Packaging should also contain clearly visible chemical indicator strips that give a colour change when sterilising conditions have been achieved during autoclaving.
- Finally, packaging should be appropriately labelled so that the packaged RIMD(s) is clearly identified.

Section Two: Packaging systems

Packaging systems should:

1. *Be appropriate to the items being sterilised, i.e.*
 - Permit identification of contents.
 - Permit complete and secured enclosure of items.
 - Protect package contents from physical damage.
 - Permit delivery of contents without contamination.
 - Maintain sterility of package contents until opened.
 - Should facilitate aseptic technique at all times including opening of package.

Packaging

2. *Be appropriate to the method of sterilisation, i.e.*

- Provide adequate seal integrity.
- Provide an adequate barrier to particulate matter and fluids.
- Be compatible with and able to withstand physical conditions of the sterilisation process.
- Allow penetration and removal of sterilant.
- Maintain integrity of the pack.
- Permit use of material compatible (i.e. non-degradable) with the sterilisation process.

3. *Be used according to the manufacturers' instructions*

4. *Be of the following*

- Resistant to punctures, tears and other damage which may break the barrier and cause contamination.
- Resistant to penetration by micro-organisms from the surrounding environment.
- Free of holes.
- Be free of toxic ingredients.
- Low-linting.
- Tamper proof and able to seal only once.
- Provide an adequate barrier to particulate matter and fluids.

Section Three: Packaging materials

Packaging materials should:

- Be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product.
- Not be stored adjacent to external walls or other surfaces which may be at a lower temperature or a higher temperature than the ambient temperature of the store room.

Packaging

- Be stored on shelves and clear of the floor.
- Be rotated to ensure it does not exceed its shelf life.

Section Four: Single use packaging

The medical device regulations include a requirement that sterile dental RIMD should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile. There is thus a clearly stated preference for single-use packaging as the primary packaging for sterile dental RIMD.

Section Five: Types of packaging

1. *Papers and non-wovens*

- Both papers, which are made from cellulose fibres, and non-wovens made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilization and most gas processes because they are permeable to air, steam and other gases.
- Appropriate lain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky items.
- Non-wovens are generally less effective as a microbial barrier and may need to be used in, or as one of, two layers; they are however generally softer with better handling and drape characteristics.

2. *Containers*

Rigid reusable non-perforated containers:

- Should be easily disassembled for cleaning, drying and storage.
- Should be suitable for the method of sterilisation being used.
- Should be compatible to the cleaning method and cleaning agent being used
- Should be suitable to the storage configuration.
- Should have locking devices which are tamperproof and non resealable.

Packaging

- Should be packed in a manner which allows for penetration of the sterilising agent.
- Lid and contents should be removable without the risk of contamination of the contents.
- Rigid containers should have filter and/or valve systems that are secure and in proper working order before sterilisation.
- The filter plate should be examined for integrity both before installation and after the sterilisation process.
- If the filter is damaged or dislodged or has holes, tears, or punctures, the contents should be considered contaminated. It is recommended that only components of the rigid container system specified by the manufacturer and compatible with the system should be used in the practice setting.
- The integrity of the rigid container system is essential to permit sterilisation of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.
- Loosened rivets, improperly maintained valves, worn gaskets or dents compromises to the integrity of the container system, will compromise the sterilisation process and may not permit the contents to remain sterile or be delivered aseptically.
- When re-usable containers are being evaluated it is important that the sterilisation, cleaning, inspection, maintenance and storage procedures and methods are also evaluated for their ability to be consistently re-used and for their compatibility with the process being used.
- Containers should be cleaned between each use; automated cleaning is the preferred method of cleaning.

Section Six: Packaging techniques

- Dental RIMD may be packaged in any combination of **flat wrapping material** (sheets, bags, pouches, or reels) or **containers** to maintain the integrity of the product. Devices wrapped with sheet material using either the **envelope** or **parcel fold** technique.
- Dental RIMD should be wrapped in a manner which minimises the risk of contamination during opening and removal of contents.

Packaging

1. *Flat wrapping material*

a. **Equipment required**

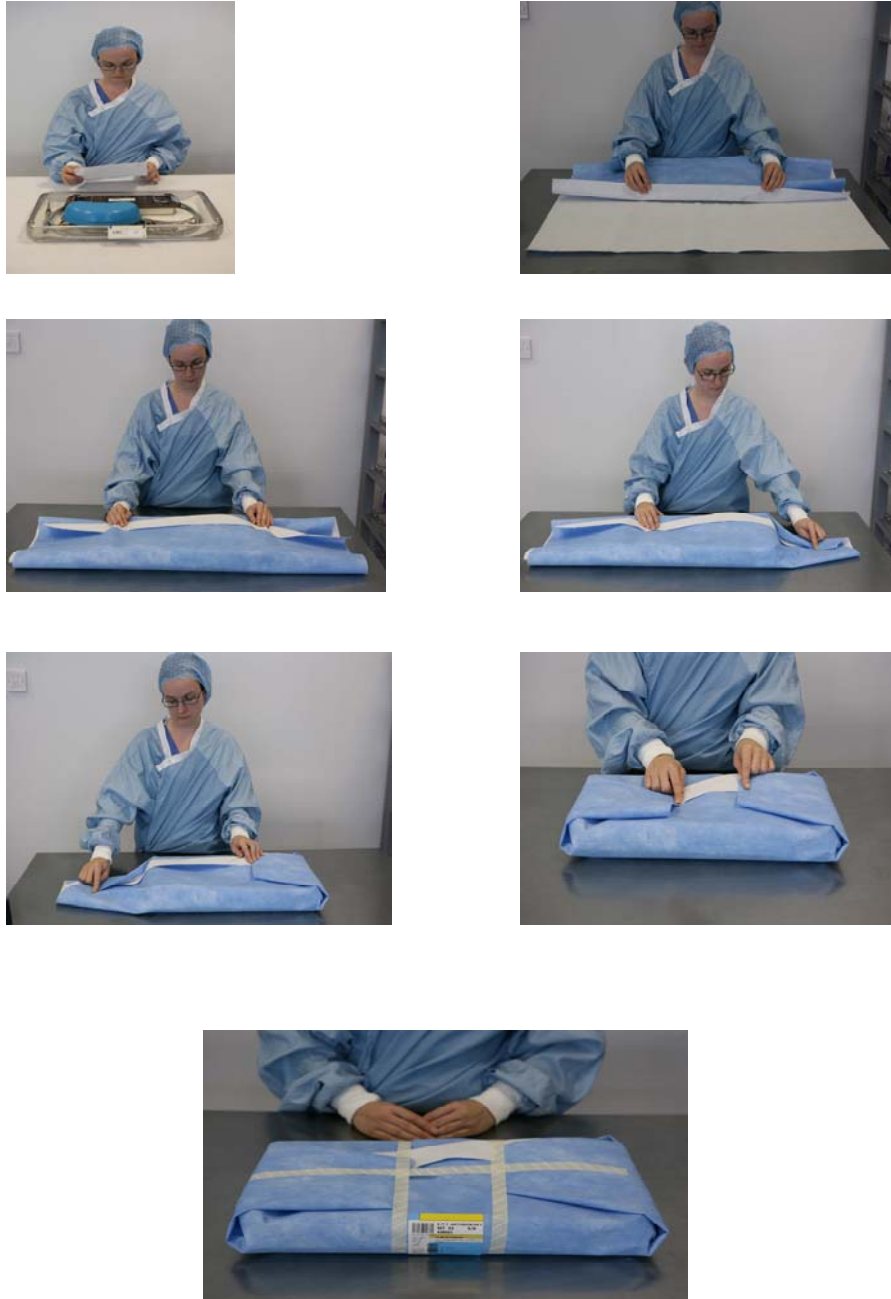
- Packaging material.
- Sterilisation chemical indicator tape.
- Indelible marking pen.
- Label (where applicable).
- Tray liners.

b. **Procedure (parcel-fold wrapping method)**

- Select appropriate packaging material and place on work top.
- The dental RIMD set is placed on the wrap, approximately in the centre of the packaging material.
- Verify the accuracy of the dental RIMD identification label with the dental RIMD/dental RIMD set, (i.e. corresponds to dental RIMD list, internal tray label, etc).
- The long edge of the tray should be aligned parallel to the long edge of the wrap.
- One of the long edges of the wrap is folded over the pack contents to the base of the tray, and the edge of the wrap is turned back on itself. The fold made by the turning back of the wrap should overlap the centre line of the contents.
- The opposite side of the wrap is then folded over the pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself.
- The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents.
- The same procedure may then be repeated for an outer wrap(s).
- The wrap is secured in position using sterilisation indicator tape.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- The dental RIMD identification label is placed on outside wrap.

Packaging

Figure 16-1: Parcel-fold wrapping method



Packaging

- c. Procedure (envelope wrapping method)
- Select appropriate packaging material and place on work top.
 - The dental RIMD set is placed on the wrap diagonally and slightly off the centre line.
 - Verify the accuracy of the dental RIMD identification label with the dental RIMD/dental RIMD set (i.e. corresponds to the dental RIMD list, tray internal label, etc).
 - The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre.
 - This is repeated with the corners to the right and left of the first folded corner.
 - In each case the corner is turned back to provide a flap for opening.
 - Finally the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding, to facilitate aseptic opening.
 - The same procedure may then be repeated for an outer wrap(s).
 - The wrap is secured in position using sterilisation chemical indicator tape.
 - It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
 - The dental RIMD identification label is placed on the outside wrap.

Packaging

Figure 16-2: Envelope wrapping method



Packaging

Pouches and bags (requiring folding)

Folding is the simplest method to obtain a satisfactory closure for both pouches and bags, although it may not be a convenient method for high volume production.

a. Equipment required

- Pouches and/or bags.
- Sterilisation chemical indicator tape.
- Indelible marking pen.
- Label (where applicable).

b. Procedure

- The corners at the open end of the pouch are folded diagonally to give mitred corners.
- The top of the pouch is then folded over three times in succession.
- The same procedure may then be repeated for an outer wrap(s).
- The pouch is secured in place with sterilisation chemical indicator tape. It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.
- It is important to wrap the item securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- The dental RIMD identification label is placed on the outside wrap.

3. *Self-seal Pouches*

When closing self seal bags follow manufacturers' instructions for sealing.

Packaging

4. *Paper and paper/plastic pouches using heat seal*

a. General Principles

- The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above or below those specified by the packaging manufacturer.
- Packaging intended for heat sealing may be film coated, grid lacquered, or have an adhesive band.
- Heat seal pouches should be sealed using suitable heat sealing equipment.
- Heat seal pouches should be hermetically sealed.
- Heat seal pouches should provide a seal of proven integrity and not allow resealing.
- Before commencing wrapping procedure ensure that work area and packaging equipment are clean.
- Check size of edges for easy aseptic opening by user.

b. Equipment required

- Heat-seal Pouches.
- Heat sealer.
- Indelible marking pen.
- Label (where applicable).

c. Procedure

- Select appropriate size heat seal pouch.
- Place dental RIMD into pouch.
- Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal.

Packaging

- As much air as possible should be removed from the pouches before sealing. Air acts as a barrier to heat and moisture. Expansion of air during the sterilisation process may cause the bag to rupture during the sterilisation process.
- Place open end of pouch in heat sealer.
- Apply heat and pressure to the surface of the open end of the heat seal pouch.
- Check should be made that the seal is complete, especially over the gusset folds of the pouches.
- A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.
- The heat-sealing process should be undertaken with care. Creases in the packaging material can result in inadequate or uneven seal.
- When double wrapping using heat seal pouches the packages should be used in such a way as to avoid folding the inner package to fit into the outer package.
- Edges of inner heat seal pouches should not be folded as air may be entrapped in the folds and inhibit sterilisation.
- When double wrapping using paper/plastic heat seal pouches the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the dental RIMD to be viewed.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the sterilant into and out of the package.
- If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.
- It is important to wrap the dental RIMD securely to avoid gapping, bellowing and air pockets from forming which could compromise sterility.
- Use adhesive dental RIMD identification label, do not write on the paper side of the pouch.
- The dental RIMD identification label is placed on the outside packaging.

Packaging

Figure 16-3: Using the heat sealer



Figure 16-4: Heat seal pouch



Packaging

Section Seven: Sealing of packs and bags

a. Introduction

The purpose of sealing is to maintain pack integrity, this can be achieved by the use of heat sealers, sterilising chemical indicator tape and seal secures. The indicator tape should meet European standard EN 867-1.

b. Accessories used to close or secure packages should be able to perform the following:

- Allow sterilisation.
- Avoid constriction of the package.
- Maintain package integrity.
- The accessories should also be recommended by the manufacturer.

c. The following accessories should not be used:

- Tape (other than sterilisation chemical indicator tape).
- Safety pins.
- Paper clips.
- Staples.

d. Sterilising indicator tape

Sterilising indicator should be:

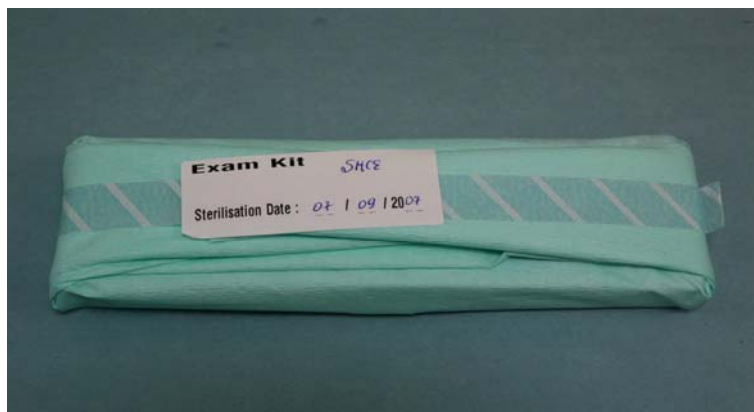
- Specific to the method of sterilisation being used and which will change colour when exposed to the relevant sterilisation agent.
- Pressure sensitive.
- Non toxic, adhere to clean surfaces and leave no adhesive residue on removal.
- Compatible with the wrapping material used.
- Heat stable.
- Moisture-stable and permeable to the sterilising agent.

Packaging

Section Eight: Labelling

- Packages to be sterilised should be labelled after sterilisation.
- The information of the label should include the following:
 - i. Name of product.
 - ii. Sterilisation date.
- Label information should be documented on sterilisation chemical indicator tape or label and not on the packing material. Plastic/paper pouches can be labelled on the plastic portion.
- Marking pen used to label the pack should be indelible, nonbleeding, and non-toxic. Sharp tipped water based or ball type pens should not be used as these may compromise the integrity of the pack.
- Label fixed to the surface of the packaging should be able to withstand exposure to the sterilisation process.
- Policies and/or procedures for wrapping and labelling and sealing of dental RIMD to be sterilised should be developed, reviewed periodically, and readily available within the practice setting.

Figure 16-5: Labelling



Packaging

Section Nine: Monitoring and control

The following should be monitored during labelling:

- General appearance of the packaging material.
- Whether packages are complete.
- Whether the correct products and packaging material are used.
- Whether the labelling is correct on the product.
- Whether the sealing is correct.
- Whether the correct performance of packaging equipment, i.e. temperature gauge reading on heat sealing equipment.
- Material should be checked for tears, flaws and holes.
- Containers seals and filters should be checked.
- Containers should be checked for dints which may interfere with maintaining sterility.

Section Ten: Maintenance

- Reusable containers should be subject to thermometric performance tests.
- Containers should be validated periodically for reuse according to manufacturers' instructions.
- Planned preventative maintenance should be undertaken in accordance with European Standards, manufacturers' instructions and/or local policy.
- Heat seal efficiency, integrity and strength test should be performed on each heat sealer daily.
- Routine monitoring of processed heat sealed products should be undertaken by checking the quality of the output.
- Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal.

Packaging

- Preventative maintenance should be planned and performed for all equipment, and utilities in accordance with documented procedures as recommended by the manufacturers' instructions.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The heat sealer should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all maintenance, validation and servicing should be maintained for a period of time equivalent to the life-time of the equipment plus eleven years.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.

Sterilisation

17 Sterilisation

17.1 Introduction

Steam sterilisation is the most practical method for sterilising reusable medical devices in dental clinics. It is rapid, non-toxic and can effectively destroy microorganisms and thus is the method of choice for sterilising dental RIMD.

17.2 Scope

The objective of this procedure is to provide guidelines in relation to the sterilisation of dental RIMD.

17.3 Contents

Section One: Types of sterilisers

Section Two: Choice of sterilisation process

Section Three: Steam sterilisation

Section Four: Loading the loading trolley prior to sterilisation

Section Five: Loading the steriliser

Section Six: Steam sterilisation of dental RIMD

Section Seven: Criteria for release of processed dental RIMD

Section Eight: Sterilisation records

Section Nine: Validation

Section Ten: Monitoring and control

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17.4 Procedure

Section One: Types of sterilisers

- Sterilisers can be divided into those based on exposure to elevated temperature (thermal processes) and those based on exposure to microbicidal chemical agents. (Low temperature processes).
- Thermal processes include dry heat (not covered in this document) and high temperature steam sterilisation. The steam sterilisers intended to be used for sterilisation of wrapped dental RIMD are referred to as porous load sterilisers.
- The preferred method of low temperature sterilisation is Hydrogen Peroxide Plasma.
- Sterilisers that have a pre-vacuum stage are the most appropriate for sterilisation for heat-tolerant dental RIMD and other items and should conform to current European Union Standards (e.g. EN285, EN17665 EN556 (for large sterilisers) and EN13060 (for benchtop sterilisers).
- The manufacturer's instructions for correct use of equipment should always be followed and the equipment should be used by trained and competent personnel.
- Many dental practices use sterilisers without a pre-sterilisation vacuum phase in which air is removed from the steriliser chamber by steam displacement (i.e. downward displacement sterilisers).
- Downward displacement sterilisers are not appropriate for sterilising wrapped loads of RIMD or for items that contain a lumen (e.g. dental handpieces), and **should not be used for these purposes under any circumstances.**
- All dental RIMD, items and equipment for use on patients should be packaged or wrapped prior to sterilisation and therefore the use of sterilisers without a pre-sterilisation vacuum phase cannot guarantee proper sterilisation.
- Flash sterilisers rely on natural air displacement and should not be used for wrapped goods, hollow devices or tubing.
- Boiling water sterilisers, hot air ovens, ultra violet light treatment, hot bead sterilisers and chemoclaves are not appropriate for sterilising dental RIMD and should not be used.

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Section Two: Choice of sterilisation process

- Steam sterilisation is the most practical method for sterilising reusable invasive medical devices (RIMD) in dental clinics. It is rapid; non-toxic can effectively destroy micro-organisms and thus is the method of choice for sterilising dental RIMD.
- Steam sterilisation requires direct contact between saturated steam and all surfaces of the load at one of the pressure, time, and temperature relationships shown in table 17-1 below. The highest temperature compatible with the RIMD/equipment to be sterilised should be used.
- **Note:** The manufacturers instructions for dental RIMD purchased from the United States will often specify steam sterilisation cycles that are different from the standard cycle given above, e.g. 132°C for ten minutes. In most cases these dental RIMD can be processed through the standard cycle but confirmation should be obtained from the dental RIMD manufacturer.

Table 17-1: Sterilisation temperatures, steam pressures and hold times

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold Time	Dental RIMD Category
121°C	1.03 bar gauge	124°C	15 minutes	Dental handpieces
134°C	2.30 bar gauge	137°C	3 minutes	Dental RIMD

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Section Three: Steam sterilisation

- Effective steam sterilisation requires the removal of air from all parts of the chamber and load so that steam can reach all of the surfaces to be sterilised.
- For hollow devices, tubing, fabrics and wrapped goods, natural displacement of air by steam cannot be relied upon to remove the air effectively and a forced air removal system is required.
- Porous load sterilisers provide an operating cycle which has forced air removal and a drying stage after the sterilisation stage.
- These sterilisers have a pump to remove air from the steriliser chamber and load. When loading the steriliser, RIMD and other items to be sterilised should be arranged to facilitate free circulation of steam and care should be taken not to over-fill the steriliser chamber.
- Sterilised RIMD packs should be allowed to dry inside the steriliser before removing and handling.
- Many modern vacuum sterilisers have a post-sterilisation drying cycle that facilitates drying of RIMD packs.
- The operating cycle of a porous load steriliser generally has five stages:
 - i. Air removal.
 - ii. Steam admission.
 - iii. Sterilisation holding time.
 - iv. Vacuum drying.
 - v. Filtered air admission.

Section Four: Loading the loading trolley prior to sterilisation

a. Equipment

- See decontamination equipment, page 20.
- Loading trolley.

Sterilisation

- IT based/Manual tracking system and accessories, i.e. paper, pen, scanner.
- Batch control labeller.
- Personal protective equipment—(heat resistant gloves).

b. Procedure

- Healthcare workers (HCWs) should wear personal protective equipment.
- HCWs should ensure that that all items within the load are compatible with the process to which they are to be exposed.
- Loading should allow for free circulation of steam around each pack and each item.
- RIMD should be loaded within the boundaries of the loading cart so that they do not touch the chamber walls or fall off.
- Heavy RIMD should be placed below the light RIMD to avoid the condensate wetting the light RIMD.
- Folded drapes packs should be loaded with layers vertical, allowing air to be removed for the drape pack rapidly.
- Hollowware should be placed upside-down or tilted, to prevent collection of condensate.
- When loading paper/plastic pouches into the steriliser the packages should be placed in the same direction (i.e. paper/plastic, paper/plastic). Do not place two plastic surfaces together as plastic impedes the movement of the air and steam into and out of the package.
- Containers should be loaded onto the trolley such that an air space is formed between each container layer.
- When using the basket system Healthcare Workers (HCWs) should ensure that the appropriate size basket is used. Select the height of the basket so that there will always be a few centimetre air gap between the pack and the basket above.
- When loading HCWs should ensure that each RIMD is labelled.
- When loading is complete each item on the loading trolley should be recorded using the IT (or manual) tracking system.

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Section Five: Loading the Steriliser

- Healthcare Workers (HCWs) should load the steriliser using the loading trolley.
- HCWs should never let the RIMD touch the chamber walls since it may cause the RIMD to become wet.
- Doors should be open only when loading and unloading. An open door will cause the chamber to cool down and may cause condensation during the subsequent process.
- Manufacturers' instructions and protocols agreed during validation should be followed for loading.
- Overloading of sterilisers may compromise the process.

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Section Six: Steam sterilisation of dental RIMD

- Healthcare Workers (HCWs) should wear personal protective equipment.
- HCWs should ensure that all necessary tests and maintenance have been carried out satisfactorily before using the steriliser.
- HCWs should ensure that the cycle recorder(s) has sufficient paper and ink to record the cycle.
- HCWs should ensure that the correct operating cycle has been selected (**Note:** test cycles such as a Bowie and Dick test and leak rate test cannot be used for sterilising product).
- HCWs should initiate the cycle in accordance with the steriliser manufacturers' instructions.
- When cycle is complete the steriliser will indicate either a pass cycle or a fail cycle.
- The fail cycle will require a special key to open the steriliser door.
- On a pass cycle, the load should be removed and held in the cooling area until the sterile produce release procedure has been completed.
- Dental RIMD pouches should then be labelled.

Figure 17-1: Un-loading the Steriliser



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Section Seven: Criteria for release of processed dental RIMD

In order to release processed dental RIMD evidence is required that the sterilisation cycle was satisfactory, i.e. within the limits established during validation, and that the load items are undamaged and fit for use. There is a documented procedure specifying the actions to be taken and the criteria to be met in accepting the sterilisation cycle and releasing product as sterile. The sterilisation release procedure is only carried out by staff that have been trained to undertake this task.

a. Sterilisation cycle verification

- The cycle records should be examined to confirm that the cycle variables were within the limits established as satisfactory during validation. This should include:
 - i. The number and extent of air removal pulses.
 - ii. The temperature and duration of the sterilisation plateau period.
 - iii. The depth and duration of the drying vacuum.
 - iv. The data should be read from the independent recorder not from the automatic controller record.
- Any cycle not meeting the criteria, although indicated as a pass by the automatic controller, should be rejected. The load should be repacked and sterilised and the steriliser removed from service until the cause of the fault has been established and remedied.
- A failure of the cycle recording device should also be a cause to reject the sterilisation cycle.

b. Inspection of sterilised load

- Each item sterilised should be inspected to ensure that:
 - i. Chemical process indicators have changed colour as described in the indicator manufacturers' instructions. (Chemical process indicators, e.g. autoclave tape, do not indicate sterilisation; they are evidence only that the load has been exposed to the sterilising process).
 - ii. The packaging is in place and undamaged (i.e. seals, taped joints have not come undone, packs are not torn).
 - iii. The packaging is dry and free from visible dampness.
 - iv. All labels are intact and legible.

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- Any load dental RIMD not meeting these criteria should be rejected and quarantined, non conformance must be recorded and the dental RIMD returned to the clean room for repacking and sterilisation.

Section Eight: Sterilisation records

Sterilisation cycle records should contain the following information for each sterilisation cycle:

- i. Steriliser identification.
 - ii. The cycle number and batch number if applicable.
 - iii. Name of the loading operator and unloading operator.
 - iv. Type of cycle used.
 - v. Date and time of start of cycle.
 - vi. Contents of the load.
 - vii. Chart record and/or print-out from steriliser cycle.
 - viii. Signature of identified responsible person, confirming whether or not the process cycle was within recommended parameters and authorising release or rejection of load contents.
 - ix. Any notes or observation for the process cycle.
 - x. Read out results of physical, chemical or biological indicators that are used.
 - xi. All records should be retained for the lifetime of the steriliser plus eleven years.
- Many modern sterilisers are supplied with integral recording equipment that print out sterilisation cycle details, such as cycle time, temperature and pressure. Larger autoclaves, such as those used in hospitals, may also have a remote data archiving facility that allows data for each autoclave cycle to be recorded automatically in a database on a laptop computer.

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Section Nine: Validation:

Sterilisation cannot be confirmed by inspection and testing of the product. In order to ensure that a steriliser is functioning properly and will consistently produce sterile loads, validation, maintenance, periodic testing and record keeping are necessary.

Validation is the documented procedure for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with pre-determined specifications. It is comprised of:

- Commissioning (installation qualification and operational qualification).
- Performance qualification.
- Periodic testing.
- Revalidation.

Confirmation that the steriliser continues to function correctly is provided by periodic testing and revalidation.

1. Commissioning

Commissioning is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the manufacturer, that it is safe to operate and that it functions within predetermined limits when operated in accordance with the manufacturer's operating instructions.

Installation qualification is the process of obtaining and documenting evidence that the equipment has been supplied and installed in accordance with its specifications by the supplier and that it is safe to operate.

Installation checks and tests

- Preliminary checks.
- Electrical checks.
- Functional checks.
- Response to faults.

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Operational qualification is the process of obtaining and documenting evidence that the equipment functions within predetermined limits when operated in accordance with the manufacturer's operating instructions. It consists of:

- i. Air leakage test.
 - ii. Thermometric test.
 - iii. Calibration.
 - iv. Steam Penetration test.
- These tests should be carried out when a new steriliser is purchased, when a used steriliser has been relocated to another premises or following critical repairs.
 - The tests should be carried out before the steriliser is used for the first time.
 - Installation and operational checks and tests should be performed by a person with specialist technical training in testing of sterilisers.
 - Data from the installation and operational tests provide evidence that the steriliser is functioning correctly.

2. *Performance qualification*

Performance qualification is required to show that sterilising conditions are attained for typical loads and also test loads that are deemed by the user to be difficult to sterilise. Performance qualification is indicated for initial use of a new steriliser or when the load profile changes (e.g. new RIMD). It should be carried out by a suitably trained individual. It should be carried out by a Test Person (or suitably qualified person).

These tests consist of:

- Air leakage tests (automatic).
- Thermometric tests of all dental RIMD to be processed.
- Steam penetration test (e.g. Bowie and Dick).
- Load dryness test (only required for sterilisers with drying cycles).
- Microbiological tests (e.g. Spore tests).

The decontamination unit manager should identify all the types of load to be sterilised and identify the worst case loads to be tested. The performance qualification test protocol and data should be audited by the qualified person (decontamination).

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3. Periodic testing

Periodic testing consists of a programme of tests that are intended to show that the steriliser's performance is continually satisfactory. The appropriate tests should be carried out at daily, weekly and annual intervals. A suitably trained person(s), (usually the individual(s) that operates the steriliser on a daily basis), should draw up a schedule for periodic testing. It is the responsibility of the practice manager to ensure that these tests are performed.

After appropriate training the user should perform the daily tests. Many modern sterilisers have an integrated automated test facility that enables the steriliser to perform some of the specialised weekly tests itself. These can be undertaken by the user after appropriate training. Older sterilisers may require the services of a test person (or other suitably qualified person) to undertake weekly tests. Annual tests should be performed by a test person (or other suitably qualified person). Each cycle available to the user should be tested. If the steriliser is not tested periodically it will not be possible to know if it is working correctly. Failure of a test implies that the steriliser is not working to specification.

The user should have a written procedure for handling test failures but, in all cases, the steriliser must be withdrawn from service, the failure investigated, the cause rectified, and the steriliser re-tested successfully before being used. The user has the ultimate responsibility for certifying that the steriliser is fit for use.

Sterilisation

I. Daily Test—Steam Penetration Test /Bowie and Dick

a. Introduction

The steam penetration test is intended to show that steam will penetrate rapidly and evenly into a test device that is at least as difficult to sterilise as the intended load. The test device contains an indicator that responds (usually it changes colour – and should do so completely) only when steam penetration is adequate. If a cycle is provided specifically to test the effectiveness of steam penetration, it should have the same air removal stage as used during routine sterilisation cycles.

b. Test procedure

- A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.
- At the end of the process the test device is removed from the chamber.
- The test device is checked for a pass or fail in accordance with the manufacturers instructions. The test results should be recorded.
- If the test is failed, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.
- The sterilisation temperature for the operating cycle to be tested should be selected – this should be the highest temperature compatible with the load. The cycle should be commenced.
- A batch (cycle) process record should be made in the steriliser log book.

Figure 17-2: Bowie-Dick Test



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II. Weekly tests

The user should perform safety checks before starting the sequence of weekly tests. The schedule of weekly tests is summarised in Table 17-2 below.

Table 17-2: Summary of Weekly Tests for Steam Sterilisers (Note: All tests can be combined into one test)

Weekly Checks/Tests
Safety Checks
Vacuum Leak Test (automatic)
Air Detector Function Test
Automatic Control Test
Bowie-Dick Test for Steam Penetration

1. Safety checks

These tests are intended to ensure the steriliser is both safe to use and to test. They consist of:

- Examining the door seal for signs of deterioration or leaks.
- Checking the security and performance of door safety devices.
- No attempt should be made to open the door while the chamber is pressurised.
- Any defects should be corrected before attempting to perform the weekly tests or before using the steriliser.

2. Vacuum leak test

- The air leakage test is intended to check that air does not leak into the steriliser during periods of vacuum, at a rate that is greater than that specified by the steriliser manufacturer.
- Air leaking into the chamber can impair steam penetration into the load and prevent sterilisation and/or recontaminate the damp load during the drying phase.
- Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the steriliser and then the vacuum source is isolated and all valves connected to the chamber are closed.

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- The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into it - and the rate of pressure rise in the chamber is measured.
- Ideally the steriliser should be equipped with an automated test cycle so that the user can do the test. If there is not an automatic test facility, a Test Person should do the test using special, calibrated RIMD.

The pass/fail criteria are:

- The absolute pressure at the end of the air removal stage should be within the limits specified by the manufacturer. After an initial 5 minute equilibration period the rate of pressure rise should not be greater than 1.3 mbar per minute over a 10 minute period.
- A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

3. Air detector function test

The air detection system should be tested weekly to demonstrate that it is functioning correctly. There is such a wide variety of steam sterilisers that there is not a standard air detection system and each steriliser manufacturer should therefore specify the test method to demonstrate that the automatic air detection system is functioning correctly.

4. Automatic control test

- The purpose of this test is to verify that all the operational components of the steam steriliser are satisfactory and that no anomalies are observed.
- The test requires the temperature and pressure profiles, and the elapsed time of the cycle to be compared with the values obtained when the steriliser was validated to be working correctly, e.g. immediately after the Test Person had tested it using calibrated RIMD.
- The test should be performed using the sterilising cycle with the highest temperature compatible with the load. The following parameters should be noted during the sterilising (holding) stage of the cycle:
 - i. Chamber temperatures and pressures, their maximum values and duration in minutes and seconds.
 - ii. The values on the cycle record should be compared with those on the master process record.

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- i. The test can be considered satisfactory if at the end of the cycle if:
 - a. The chamber temperature and pressure is within the limits of the appropriate band, for the duration of the holding time, as specified in table 17-2.
 - b. A visual display of 'cycle complete' is indicated.
 - c. No mechanical or other anomaly is observed.

For vacuum sterilisers the test can be done at the same time as the steam penetration test but the steam penetration test must be performed with the chamber empty except for the test device. The test is not required if the steriliser is equipped with a recorder that provides a permanent record of the temperature, pressure and elapsed time during all sterilising cycles. Verification should be sought from the manufacturer as to whether it is necessary to pre-heat the steriliser chamber before performing these tests, as this can extend the test time.

5. Test Procedure for automatic control test of a steriliser without a cycle recorder:

- The elapsed time, and indicated chamber temperatures and pressures at all significant points of the operating cycle, e.g. the beginning and end of each stage or sub-stage, and the maximum values during the holding time should be observed and recorded.
- The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be recorded.
- All parameters recorded should be compared with the parameter results obtained during commissioning qualification.

6. Test procedure for automatic control test of a steriliser with a cycle recorder

- The recorder should make a batch process printout. The elapsed time and indicated chamber temperature and pressure at the approximate midpoint of the plateau period should be noted.
- All the parameters recorded should be compared with the parameter results obtained during validation.

Sterilisation

III. Quarterly tests

These require specialised test equipment and only a person (e.g. a Test Person or other suitably qualified person) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during commissioning validation remain consistent and accurate. Quarterly tests for steam sterilisers are summarised in table 17-3.

Table 17-3: Summary of Quarterly Tests for Steam Sterilisers (EN285)

Test Description
Safety Checks
Vacuum Leak Test
Vacuum Leak Test (temperature and pressure sensors connected)
Automatic Control Test
Verification of Calibration of Steriliser Instruments
Thermometric Test for a Small Load
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

Sterilisation

IV. Annual Tests

These require specialised test equipment and only a person (e.g. a Test Person or equivalent) who has the necessary training, experience, skills and equipment should perform them. The annual tests are intended to confirm that the data generated during validation remain consistent and accurate. Annual tests for porous load sterilisers are summarised in table 17.4.

Table 17-4: Summary of Annual Tests for Steam Sterilisers (EN285)

Test Description
Safety Checks
Vacuum Leak Test (automatic)
Vacuum Leak Test (temperature and pressure sensors connected)
Automatic Control Test
Verification of Calibration of Steriliser Instruments
Steam Non-condensable Gas Test
Steam Super-heat Test
Air Detector Performance Test for a Small Load
Air Detector Performance Test for a Full Load
Steam Dryness Test
Thermometric Test for a Small Load
Thermometric Test for a Full Load
Tests for Performance Requalification (as required)
Vacuum Leak Test (automatic) (sensors removed)
Air Detector Function Test (automatic)
Bowie-Dick Test for Steam Penetration

Sterilisation

Section Ten: Monitoring and control

- 134°C is the preferred sterilisation temperature. For dental RIMD, which may be damaged at 134°C, any of the other lower temperature bands may be used.
- There should be evidence through measurements, biological indicators or chemical indicators that the sterilisation process was within defined tolerance.
- Routine monitoring and testing should be carried out in accordance with documented procedures in line with I.S. EN ISO 17665 part 1.

Section Eleven: Maintenance

- Preventative maintenance should be planned and performed in accordance with documented procedures in line with manufacturers' instructions and European Standards.
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented.
- The steriliser should not be used to process dental RIMD until all maintenance tasks have been completed satisfactorily and recorded.
- Records of all tests, checks and maintenance should be retained as specified in EN ISO 17665, 2006.
- A nominated qualified person (decontamination) should review the maintenance plan maintenance procedures and maintenance records periodically.
- A record of mechanical testing, repairs and preventative maintenance should be recorded in a logbook for each steriliser. Records should be maintained in a designated storage area for the lifetime of the steriliser plus eleven years.

Revalidation may be required after steriliser relocation, engineering work, repair work, software control function modifications and when required by the user. Some examples of requirement for revalidation are:

- Adjustment to steam controls.
- Adjustment to microprocessor controls.
- Adjustment to control parts.

Sterilisation

Section Twelve: Chemical and Biological Indicators

Chemical indicators

- Chemical indicators are designed to show by a change of colour whether specified conditions have been attained.
- Chemical indicators should meet the requirements of relevant standards (e.g. EN ISO 11140).
- The type used should be in accordance with the steriliser manufacturers' recommendations.
- The indicator manufacturer's instructions should be followed precisely in relation to use and storage.
- The use of an inappropriate indicator may give dangerously misleading results; indicator performance can be adversely affected by the storage conditions and methods of use.
- Indicators should not be used beyond their expiry date.
- Spore tests provide the only absolute evidence of the sterilisation capability of a steriliser cycle.
- One disadvantage of spore tests is that test results usually take 24-48 hours. If spore testing is used as the principal parameter for assessing the sterility of a sterilised load of dental RIMD, the sterilised RIMD packs should be withheld from use until the results of the spore test are available.
- Two types of chemical indicator are commonly used:
 1. **Process indicators:** These indicators are intended to distinguish processed items from unprocessed items. They do not indicate that the item is sterile.
 2. **Integrating indicators and/or emulating indicators:** These indicators are intended to monitor the attainment of two or more critical variables in the sterilisation process, either by a graduated response or a defined end point reaction. These types of indicators are not currently available for hydrogen peroxide processes.

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Biological indicators

- Biological indicators are designed to show by the survival of a test microorganism whether specified sterilisation conditions have been attained.
- Biological indicators must meet the requirements of BS EN ISO 11138-1:2006.
- They are of limited value in routine process control (because of the delay before the results are available) and are restricted to a few special applications e.g. in process validation.
- When used for validation studies they should always be regarded as additional to the physical measurement of the critical control variables (e.g. temperature, pressure, sterilant concentration and time).

Storage

18 Storage

18.1 Introduction

All decontaminated dental RIMD must be stored in such a way that their integrity and microbial state is maintained (e.g. sterile, high-level disinfected). Dental RIMD packs should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging.

18.2 Scope

The objective of this procedure is to provide guidelines in relation to the storage of dental RIMD.

18.3 Contents

Section One: Storage areas

Section Two: Storage equipment

Section Three: Shelf life/rotation of stock

Section Four: Non-conforming stock

18.4 Procedure

Section One: Storage areas

The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks. The design should be conducive to good inventory management. All materials and processed goods should be stored in designated purpose built storage areas enabling different classifications of stored goods to be segregated and maintained in appropriate environmental conditions. There are two types of storage area:

- i. The processed goods store.
- ii. The raw materials store.

i. Processed goods store

Storage

- The processed goods store is for dental RIMD produced by the department and dental RIMD which have been commercially manufactured and sterilised.
- The outer packaging (shipper carton) should be removed from dental RIMD which have been commercially manufactured and sterilised – if stored in the same store as those dental RIMD which have been produced by the department.
- Raw materials should not be stored in the processed goods store.
- Packed, processed, single dental RIMD should be stored separately from those packed in cassettes or sealed containers.
- Storage areas should be kept secure and access should be restricted to authorised personnel.
- Sterile materials should be stored at least 20 to 80 centimetres from the floor, at least 18 inches from the ceiling, and at least 5 centimetres from outside walls.
- The items should be positioned so that packaging is not crushed, bent, compressed, or punctured and so that their sterility and integrity is not otherwise compromised.
- Medical and surgical process goods should not to be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they can become wet.
- Processed goods should be stored on appropriate designated shelving.

ii. Raw materials store

The storage area is for the reception, storage and supply of all non-sterile materials including textiles and where appropriate, bulk cased supplies of commercially sterilised RIMD. The raw materials store should be located between the goods reception and the clean room area.

- Materials should be segregated and stored separately according to their specific requirements.
- Sterile RIMD should not be stored in this area (unless supplies are bulk cased).
- Single items should be stored separately from those in cases.
- Storage areas should be kept secure and access restricted.

Storage

Section Two: Storage equipment

a. General principles

- Sterile items should not be stored anywhere but on, or in, designated shelving, counters, or containers, because other areas may not be sufficiently clean, and window sills collect condensate that forms due to differences in temperature between inside and outside.
- Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that may form on the interior surfaces of outside walls.
- Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile items that become wet are considered contaminated because moisture brings with it micro organisms from the air and surfaces.
- RIMD made of polymeric materials (especially latex) should not be stored adjacent to electric switch gear, laser printers, photocopiers or other sources of ozone. (Ozone can cause rapid degradation of these materials).

Figure 18-1: Storage of sterile items



Storage

b. Shelving and racking

- Shelves and racking should afford adequate space to store the required stock in line with local supply policy and production demands.
- Shelving and racking should be purpose built, easily cleaned and maintained.
- There should be enough space between shelves and racking to allow an adequate passageway between fixtures.
- Shelving or racking should enable items to be clearly labelled.

c. Closed or covered cabinets

- Closed or covered cabinets are recommended for the storage of seldom-used sterile supplies.
- Closed cabinets limit dust accumulation, discourage handling, and minimise inadvertent contact with stored sterile items.

Section Three: Shelf life/rotation of stock

- General factors which influence shelf life are event related and include the following:
 - i. Packaging materials.
 - ii. Storage and handling conditions.
 - iii. Likelihood of product material deterioration.
 - iv. Package design.
- Each designated dental decontamination area should develop a system of stock rotation based on the date of sterilisation. Good management practices demand that stock be maintained at adequate levels.
- 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.

Storage

Section Four: Nonconforming Stock

- A package should be considered nonconforming, i.e. non sterile and not suitable for use when:
 - i. It is incorrectly wrapped.
 - ii. It is damaged, opened or has been dropped.
 - iii. The product has been unused for six months.
 - iv. The sterilisation process indicator does not confirm that the pack has been subject to an appropriate sterilisation process.

Transportation—of sterile items

19 Transportation – of sterile items

19.1 Introduction

Sterile dental RIMD should be transported in a manner that will not compromise their status. Loss of sterility is event related and depends on the extent and nature of handling, environmental conditions during transportation and storage, and the quality of the packaging material.

19.2 Scope

The objective of this procedure is to provide guidelines in relation to the transportation of sterile dental RIMD.

19.3 Contents

Section One: General principles

Section Two: External transportation

19.4 Procedure

Section One: General principles

- Sterile dental RIMD should be transported in clean dry conditions in a manner that provides segregation from sources of water and contamination, and provides mechanical protection to prevent damage to devices and flexible packaging.
- Sterile dental RIMD should be cooled before they can be transported.
- Sterile dental RIMD should be transported in closed solid walled containers, or in covered or enclosed carts with solid-bottom shelves to protect them from exposure to environmental contaminants along the transportation route.

Transportation—of sterile items

Section Two: External transportation

- Where sterile dental RIMD are transported in vehicles, the vehicles should be dedicated to the purpose, should provide appropriate segregation for the transport of sterile and used dental RIMD and the loading area should be constructed so that it is easily cleanable.
- Where small quantities of sterile dental RIMD are to be transferred (e.g. school/domiciliary visits) or where it is only occasionally required, they may be transported in a socially clean general purpose vehicle provided they are contained within a closed solid walled container.

Water supply for washer-disinfectors

20 Water supply for washer-disinfectors

20.1 Introduction

The quality of water used at all stages in the cleaning process is critical to the successful outcome of the process.

20.2 Scope

The objective of this procedure is to provide guidelines in relation to provision of water of optimum quality for each stage of the cleaning process.

20.3 Contents

Section One: General requirements

Section Two: Water quality

Section Three: Water treatment

20.4 Procedure

Section One: General requirements

- At each stage in the cleaning process the water quality should be compatible with:
 - i. The components of the washer-disinfector.
 - ii. The dental RIMD to be processed.
 - iii. The process chemical to be used.
 - iv. The process requirements of that particular stage.

Water supply for washer-disinfectors

- The key quality elements to be considered are:
 - i. Hardness.
 - ii. Temperature.
 - iii. Ionic contaminants (e.g. heavy metals, halides, phosphates and silicates).
 - iv. Microbial population.
 - v. Bacterial endotoxins.
- The water supply should be controlled to ensure that it is of the required quality.

Section Two: Water Quality

i. Hardness

- Water hardness is caused by the presence of dissolved salts of the alkaline earths (calcium, magnesium and strontium) which come out of solution and deposit as hard mineral layers (lime-scale) when water is heated or evaporated.
- The deposition of lime-scale on electrical heating elements or heat exchange components, within pipes and around the edges of spray nozzles will seriously impair the performance of a washer-disinfector (WD).
- Hard water will cause scaling on the edges of spray nozzles even when fed with only cold water.
- Using hard water in the thermal disinfection and final rinse stages of the WD cycle is one of the major causes of white powdery deposits on load items. These are unsightly and act as a focus for soiling and recontamination of the item in use. In some applications (e.g. with optical systems) such deposits may seriously impair the utility of the item.

ii. Temperature

- The temperature at which water is supplied to each stage of the process has a major effect on the efficacy of the process.
- Water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to “fix” proteinaceous soil to the surface of the load items. EN ISO 15883 recommends that the initial temperature should not exceed 45°C. The initial flushing stage should be supplied with water from a cold supply.

Water supply for washer-disinfectors

- When enzymic cleaners are used the water temperature must be maintained close to the optimum temperature specified by the manufacturer; too high a temperature will inactivate the enzymes.
- The maximum temperature of rinsing water must be compatible with the items being processed; many items used in medical practice are temperature sensitive or may be damaged by thermal shock.

iii. Ionic contaminants

- Ionic contaminants in the water may react with materials such as stainless steel.
- Water used for stainless steel RIMD should have a chloride concentration less than 120 mg/l Cl⁻ to minimise the risk of corrosion.
- Tarnishing of stainless steel RIMD, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions – such as iron, manganese or copper – are present in the process water. In hot water (over 75°C) magnesium ions and silicates can cause similar discoloration.
- Total Dissolved Solids should be checked with conductivity meter at an agreed period with User Group or Authorised Person

iv. Microbial population

- The microbial population in the water used in the washer-disinfector (WD), particularly in the final rinse stage of process cycle should not increase the bioburden of the load items.
- For items which are intended to be used without further processing (e.g. flexible endoscopes processed in an endoscope washer-disinfector) the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient, either through infection or by leading to a erroneous diagnosis.
- Suitable Potable water with < 100 cfu/ml is suitable for final rinse

iv. Bacterial endotoxins

- Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria which, when introduced into the human body, can cause a fever-like reaction and other adverse. They are not readily inactivated at the temperatures used for disinfection or sterilization.

Water supply for washer-disinfectors

- Water used for the final stages of processing in a washer-disinfector, where there is a significant risk of residual water remaining on the load items, should not contain more than 0.25EU/ml when the WD is being used to process surgically invasive items or those which are intended to come into contact with parenteral solutions.

Section Three: Water treatment

There are three methods of water treatment generally used on water supplies for washer-disinfectors (WDs): *Note: Distilled water is not suitable.*

- i. “Base-exchange” softeners.
- ii. De-ionisers.
- iii. Reverse osmosis.

i. “Base-exchange” softeners

- Base-exchange softeners, consist of an ion exchange column containing a strong cation resin in the sodium form. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride).
- The concentration of total dissolved solids in the water is not reduced by this process. The sodium salts which remain do not readily form hard deposits to foul heat exchangers or spray nozzles but if used as the final rinse will leave white deposits on the load items as they dry.
- After regeneration high levels of chloride ions may be present in the initial output from the softener which should be configured to automatically run an initial volume to waste.

ii. Deionisers

- De-ionisation (demineralization) systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins either in a single column (mixed bed) or in separate columns.
- Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide). For most types of installation an exchange column service is available from the water treatment suppliers.

Water supply for washer-disinfectors

- De-ionised (DI) water may be heavily contaminated with micro-organisms and DI water stored at ambient temperatures will be colonised rapidly (The chloride ions normally present in drinking water to control microbial growth have been removed).
- DI water should not be used for the final rinse of products intended for invasive use without further decontamination processing.

iii. Reverse osmosis

- Reverse osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane against an osmotic gradient. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as ionic species.
- When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population.
- Appropriate measures include:
 1. A continuous recirculation system water.
 2. Filtration, e.g. through a 0.22 mm filter to remove microbial contaminants.
 3. Treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited (either by use of elevated temperature (e.g. >60° C) or by the use of UV irradiation (wavelength 260 ± 10nm; >2J. m⁻²)).
- The pipe work used to supply the various grades of water should be appropriate to the quality of water carried. Stainless steel pipes are preferred for all qualities of purified water.
- All pipe work should be run with a continuous fall to the discharge point so that it is free draining. It should be free from dead ends and other areas where water may become stagnant.

Water supply for washer-disinfectors

Table 20-1: Water quality for washer-disinfectors

Washer-disinfector process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Flush	Cold soft/mains	Cold mains
Wash	Reverse osmosis	Hot soft/mains
Rinse	Reverse osmosis	Reverse osmosis
Thermal disinfection	Reverse osmosis	Reverse osmosis
Chemical disinfection*	Reverse osmosis	Soft/mains
Post chemical disinfection	Reverse osmosis 0.22 mm filtered	De-ionised 0.22 mm

*Endoscope washer-disinfector only

Table 20-2: Water quality for cleaning dental RIMD

Washer-disinfector process stage	Water Quality	
	<i>Preferred</i>	<i>Acceptable</i>
Manual wash	Reverse osmosis @ 35-45°C	Soft/mains @ 35-45°C
Manual rinse	Reverse osmosis	Soft/mains ¹
Ultrasonic wash	Reverse osmosis @ 35-55°C	Soft/mains @ 35-55°C
Ultrasonic rinse	Reverse osmosis	Soft/mains ¹

¹ When the manually/ultrasonically cleaned RIMD are to be further processed through an automated washer-disinfector

Single use invasive medical devices

21 Single use invasive medical devices

21.1 Introduction

A single use invasive medical device (SIMD) is defined as a device intended by the manufacturer to be used on one patient during one procedure. The device is **not intended for reprocessing** and/or use on another patient or on the same patient at another time.

21.2 Scope

The objective of this procedure is to provide guidelines in relation to SIMD.

21.3 Contents

Section One: General principles

21.4 Procedure

Section One: General principles

- If an item is marked single-use, it should only be used on a single occasion and then it should be discarded into healthcare risk waste or a sharps box, as appropriate.
- A single-use item or device should not be used on multiple occasions either on an individual patient or on a different patient. Examples of single-use items include plastic syringes used for irrigation, suction tips, endodontic files, matrix bands and polishing cups.
- If a medical device is marked for single-patient-use, the item may be used on several occasions with the same patient and then must be discarded.
- The medical device should have cleaning and storage instructions attached.
- Before using a pre-packed sterile single-use or single-patient-use item, check that the packaging is intact and the product is within its use-by date.
- These devices should be stored in clean, designated areas where there is no risk of moisture, droplet and aerosol contamination.
- To avoid cross-contamination between patients, SIMD should be used wherever this is practical.

Single use invasive medical devices

- Single-use items should be used for a single patient and not reused on subsequent patients. Patient care equipment and supplies are potential vectors of microorganisms and can transmit infectious agents.
- RIMD intended for single-use and labelled ‘single-use’ by the manufacturer should be immediately disposed of after use.
- Users who disregard this information and prepare single use products for further use, are transferring legal liability for the safe performance of the product from the manufacturer to themselves, or to the organisation that employs them and have become the manufacturer of the device.
- The symbol for single use RIMD is as given in ISO EN 980:2003.
- Synonyms for “do not reuse” are “single use”, use only once”.
- See Council Directives 93/42/EEC concerning medical devices, Annex 1, 13.3 (f).
- Organisations should have well established criteria for their choice of SIMD or dental RIMD where both are available.

Figure 21-1 Do not reprocess symbol



Action on non-conforming product

22 Action on non-conforming product

22.1 Introduction

To ensure patient safety and compliance with the Safety, Health and Welfare at Work Act, 2005 and S.I. 252 of 1994, the organisation must establish procedures to expedite the retrieval of reprocessed items that are suspected to be non-sterile, contaminated or otherwise defective and to ensure appropriate follow-up actions. Follow-up actions may include quarantine of the dental RIMD, notification of clinicians and surveillance of patients as well as remedial action to prevent any recurrence.

22.2 Scope

The objective of this procedure is to provide guidelines in relation to action on non-conforming product.

22.3 Contents

Section One: Policies and procedures

Section Two: Recall procedure

Section Three: Recall order

Section Four: Recall report

22.4 Procedure

Section One: Policies and procedures

- Written policies and procedures for the recall of non-conforming product should be developed, available and implemented in the organisation.
- Where any occurrence gives cause for concern that the required assurance of sterility, functionality and freedom from contamination has not been met, the infection prevention and control nurse and risk manager should be notified so that follow-up surveillance of patients can be conducted.
- The nature and seriousness of the fault and the risk category of the product will determine whether it will be necessary to issue an advisory notice or to institute a recall. These factors will also determine the speed and extent of the action. Ref: EN 724:1994.

Action on non-conforming product

Section Two: Recall procedure

A recall procedure should:

- Be written.
- Outline the circumstances for issuing a recall order.
- Designate the person(s) authorised to issue a recall order.
- Designate the person(s) responsible for reporting on the execution of a recall order.

Section Three: Recall order

A recall order should:

- Be written.
- Identify by sterilisation lot number the products to be recalled.
- Identify the persons or departments to whom the order is addressed.
- Require the recording in terms of kind and quantity of the products obtained in the recall.
- Specify the action to be taken by the person or persons receiving the order (e.g. destruction or return of product).

Section Four: Recall report

A report of a recall order should:

- Identify the circumstances that prompted the recall or order.
- Specify the corrective action(s) taken to prevent a recurrence.
- State, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall.

Records management

23 Records management

23.1 Introduction

Records of maintenance, testing and operating cycles provide evidence that the process delivered sterile products consistently.

23.2 Scope

The objective of this procedure is to provide guidelines in relation to records management in dental facilities.

23.3 Contents

Section One: Steriliser logbook

Section Two: Master process record

Section Three: Traceability

Section Four: Recorders

23.4 Procedure

Section One: Steriliser logbook

- A permanent record should be kept for each steriliser to provide evidence that it was/is functioning correctly and achieving sterilising conditions consistently.
- This permanent record can take any convenient form e.g. a book, a loose-leaf folder, or an electronic device (provided that it will give a printout on demand). The record should be kept close to the steriliser so that it can easily be updated. It should provide a complete history of the steriliser and should include records of:
 - i. Commissioning and validation tests and checks. A master process record (see below) should be provided by the company that installed the steriliser.
 - ii. Routine monitoring of every sterilisation cycle – load type, cycle selected and whether or not the cycle was satisfactory.

Records management

- iii. Actions taken to correct any cycle failure and details of what happened to the unsatisfactory load
- iv. Results of all periodic testing: daily, weekly, quarterly and annual tests. Steam penetration indicator test sheets, (marked with the result of the test, dated and signed by the operator), should be retained for at least six months and stored under the conditions recommended by the manufacturer of the test sheet.
- v. Maintenance, repair, or any modifications
- vi. Operator training should include name of trainee, name of trainer, date of competency achieved in parameters as detailed in the staff training section.

Section Two: Master process record

- The master process record contains the information gathered during commissioning by the manufacturer. It includes details of the values and permitted tolerances of the cycle variables for each correctly functioning operating cycle, and for each load type that is to be processed.
- This is the record against which:
 - i. Production cycle records can be compared to verify that sterilising conditions have been achieved for each load.
 - ii. Results of weekly tests should be compared to establish whether the steriliser is functioning correctly and achieving sterilising conditions
 - iii. Results of periodic tests and performance re-qualification tests can be compared.

Section Three: Traceability

- A record of every load should be kept in the steriliser log book which should include the load number (unique identifier cycle number), date, time, and type of load, test result and identity of the operator.
- An adhesive load label bearing the load number and date should be created and manually placed on each RIMD pouch before sterilisation, and a duplicate should be placed in the patient's clinical chart when the RIMD is used.

Records management

Section Four: Recorders

- All sterilisers should be fitted with a recorder or a process evaluation system (EN 13060; EN 285 (2006)). These systems:
 - i. Provide a permanent record of daily tests and all production cycles
 - ii. Reduce time spent in performing daily tests
 - iii. Generate a unique cycle number that can be entered in the patients' notes to assist traceability
 - iv. Eliminate the possibility of transcription errors.
- The recorder printout should be kept securely in the steriliser logbook. Some types of cycle printouts fade quickly (e.g. from thermal recorders) and therefore special action may be required to preserve these records (e.g. photocopying). Electronic data storage can replace printed records and is strongly recommended.