IRISH MEDICINES BOARD
SAFETY NOTICE

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Safe and Effective Use of Bench-top Steam Sterilisers

IMB Safety Notice: SN2009(04) [replacing SN2008(07)]
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MANUFACTURER/SUPPLIER
Various

TARGET GROUPS
This safety notice is targeted at individuals responsible for placing bench-top sterilisers for use and those using bench-top sterilisers in various settings:

General Practitioners
General Practice Nurses / Assistants
Dentists / Dental Nurses
Dental Hygienists / Dental Auxiliaries
Public Hospital Surgical Theatres
Theatre Managers
Orthodontists
Public Health Nurses
Community Healthcare Workers
Accident & Emergency Staff
Outpatient Departments / Nurse Managers
Podiatrists / Chiropodists
Risk Managers
Healthcare Procurement Managers / Officers
Infection Control Departments
Sterile Service Departments
Non-healthcare workers – Tattooists, Body Piercers, Acupuncturists, Beauticians, Cosmetic Practitioners (Note: This document is for information purposes only, as sterilised instruments used in this setting are not medical devices.)

ISSUE
The purpose of this notice is to highlight issues impacting the safe and effective use of bench-top steam sterilisers to sterilise reusable medical devices in clinical settings and other instruments and non-clinical settings.

BACKGROUND
Bench-top steam sterilisers are used to sterilise reusable invasive medical devices (RIMDs) and are considered medical devices in this capacity. They are regulated as class IIa medical devices in accordance with the Medical Devices Directive 93/42/EEC and must bear a CE mark.

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Bench-top steam sterilisation of RIMDs is:

- Used to sterilise RIMDs that penetrate skin, mucous membranes or a body orifice
- Aimed at preventing the transmission of infection to patients and healthcare workers, by eliminating microbial growth
- The preferred method for sterilising reusable medical devices, once the devices are suitable for sterilisation i.e. can withstand the particular temperature, moisture and pressure conditions
- Achieved through direct contact of the device with steam at the required temperature, pressure and duration, by gravity displacement or active vacuum systems.

The optimal performance of a bench-top steam steriliser throughout its working life can be adversely affected by the:

- Use of the wrong type of steriliser or steriliser cycle
- Failure to follow the manufacturer's instructions
- Failure to properly install, calibrate and validate steriliser at commissioning
- Ineffective cleaning of devices to be sterilised, prior to their sterilisation
- Inappropriate wrapping or packaging of devices to be sterilised
- Inappropriate loading of the steriliser
- Supply of poor quality water or facilities to sterilisers
- Inadequate management of steriliser training, validation, calibration, use, maintenance, servicing or audit.

ACTION OR RECOMMENDATIONS

Steriliser Selection

Users of sterile medical devices have three initial options to consider:

- employ sterile single use devices,
- have reusable devices sterilised by a certified Sterile Services Department (SSD) or
- reprocess the devices themselves.

If reprocessing reusable devices is the option chosen, the choice of bench-top steriliser should be based on the suitability of the steriliser for the type of devices to be sterilised e.g. wrapped / unwrapped. A steam steriliser unit should be chosen with adequate capacity to sterilise the required number of devices at the desired frequency. Advice should be sought from the steriliser manufacturer or an independent advisor, who should be able to confirm whether a particular bench-top steriliser is suitable for sterilising particular instruments and meets the user requirements. The types of bench-top steam sterilisers are:

Vacuum sterilisers (See Table 1)

- B-cycle sterilisers are capable of effective sterilisation of pre-wrapped devices, porous devices such as fabrics, and devices that are hollow or have lumen.
- S-cycle sterilisers only process devices specifically as advised in the manufacturer's instructions.
- Vacuum sterilisers have a vacuum pump that causes forced air removal from the chamber and assists steam penetration, but they require a post-sterilisation drying phase which increases cycle duration.
- The most common type of steriliser used is a B-cycle steriliser.

Non-vacuum, bench-top sterilisers (See Table 1)

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- Non-vacuum, bench-top sterilisers utilise an N-cycle.
- They are **NOT** capable of sterilising porous devices, devices that are hollow, have lumen or are pre-wrapped. This is because in non-vacuum sterilisers, the chamber air is passively displaced by the steam entering the chamber and the displacement of air from 'hard to access' devices can be ineffective, causing reduced steam-instrument contact.
- They should only be used for solid, unwrapped instruments for **immediate use only**, where the devices are transported aseptically to point of use. This is because devices risk becoming contaminated once the steriliser is opened.

Table 1 Bench-top Steriliser Cycle Types

Steriliser Type:	Non-Vacuum	Vacuum	
Cycle Type:	N	B	S
Air Removed by:	Passive displacement- (using steam)	Vacuum (forced air removal)	Vacuum-pulsed (forced air removal)
Devices that can be sterilised:	Solid only	Solid Hollow	Solid Hollow
	Unwrapped only	Wrapped Unwrapped Porous	Wrapped Unwrapped
Notes	Most basic & least expensive. Totally unsuitable for wrapped devices or devices in pouches. Devices must be used immediately.	More complex & expensive. Most common.	Expensive to purchase and maintain. Specialist sterilisers to sterilise devices specified by the manufacturer.

Installation and Validation

Whilst bench-top sterilisers undergo some degree of validation and testing prior to leaving the manufacturing facility, purchasers of sterilisation units should check what installation, commissioning and validation is required before the steriliser is put into service.

- The bench-top steam steriliser should be installed and commissioned, by testing to the relevant standard, by the manufacturer or suitably qualified field service technician or engineer before first use.
- Pressure testing should be completed by a suitably qualified person, approved by the organisation's insurance provider.
- Certification should be obtained that the steam steriliser is fit for use.
- Manuals on the operation and maintenance of the steriliser should be provided at installation and available at the point of use.
- On-the-job staff training should be performed at installation by a suitably qualified field service technician and documented.
- A logbook should be initiated and maintained to document the person responsible for and the date of: installation, pressure vessel testing, sterilisation batches, cleaning, maintenance and servicing etc.
- Details of sterilisation batches such as cycle parameters and devices sterilised should be documented in a sterilisation record,

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- Procedures or SOPs should be written that capture all quality system elements including operation, training, verification, failures, cleaning, record keeping, product release, calibration, maintenance, servicing, auditing etc., identifying the person(s) responsible for each.
- All documentation/records should be retained for review and audit.

Loading

The bench-top steriliser must be loaded according to the manufacturer's instructions and relevant code of practice.

- Items to be sterilised must be pre-cleaned e.g. surfaces cleaned and dried, preferably in an automated washer/disinfector for safety reasons. If the instrument is not clean, it cannot be sterilised.
- Instructions for use should be available at the point of use.
- Chamber trays should not be overloaded beyond the recommended loading capacity, as this will adversely affect steam circulation causing 'cold-spots' that reduce the sterilisation efficiency.
- Bladed devices such as scissors should be placed on chamber trays in an open position and bowls should only be placed either upside down or tilted downwards.
- Instruments must not be stacked but must be loaded to expose the greatest surface area possible to the steam.
- The chamber door should be securely closed, to prevent serious injury due to sudden changes in the chamber pressure.

Sterilisation Cycle

- The sterilisation cycles should be validated for use with particular RIMDs, as per the manufacturer's recommendations, and should define the critical cycle parameters such as sterilisation temperature, duration.
- The air removal effectiveness of vacuum steam sterilisers should be verified daily using a suitable test e.g. the Bowie-Dick, Helix Test etc.
- All devices must be allowed to dry and cool down before they are removed from the steriliser, to prevent microbial growth.
- Sterilising cycle records should be kept for traceability purposes.

Storage

- If the medical device must be sterile for use, it may be:
  - wrapped prior to sterilisation and stored in its wrapping to maintain sterility, in a location where its sterility will not be compromised or
  - stored clean until required and sterilised immediately prior to use.
- Ensure that clean and dirty instruments are kept in distinctly segregated areas to prevent cross-contamination or mix-ups.

Water Quality

- Water that contains contaminants can have a serious effect on the patient. Contaminants present on sterile instruments can be directly introduced into parts of the body that are normally protected by skin or mucous membranes.
- Contaminants include harmful micro-biological substances that are resistant to sterilisation (e.g. endotoxins) and water impurities (e.g. metal deposits).
- Water that contains impurities can adversely affect the quality of the steam used in the sterilisation cycle causing:
  - staining and pitting corrosion of the instruments and steriliser
  - build-up of residue on the steriliser's elements, reducing heat transfer.
- The water reservoir should be:

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- emptied daily after use, rinsed (ideally with sterile water) and left to dry overnight to avoid standing water.
- Refer to the manufacturer's recommendations to determine the minimum acceptable water quality, to ensure low levels of micro-organisms and impurities.

Maintenance

- Routine maintenance should be carried out, as per the manufacturer's instructions, to monitor and ensure consistent steriliser performance.
- Maintenance procedures should be documented and available at the point of use.
- Steriliser cleaning should be carried out as per the manufacturer's recommendations. The purpose of surface cleaning is to minimise the build-up of:
  - dust particles on the exterior steriliser surface that may result in cross-contamination
  - residue on the interior steriliser surface that may reduce sterilisation efficiency and effectiveness.
- Maintenance of water quality is as listed in the Water Quality section.
- Completed maintenance operations should be recorded in a logbook.

Servicing

Bench-top sterilisers must be maintained and serviced according to the manufacturer's recommendations.

- Bench-top sterilisers should be fully serviced by a suitably qualified service technician, in accordance with the manufacturer's instructions, industry standards and relevant codes of practice. Note that the frequency of servicing (e.g. yearly, quarterly etc.) will also depend on the manufacturer's instructions and industry standards.
- The service should include (i) equipment cleaning, (ii) filter, equipment, control valve maintenance or replacement and (iii) equipment operation & calibration.
- All servicing activities and the results should be documented.

In following recommended practices, standards and legislation that cover steriliser installation, validation, operation, maintenance, training, safety and insurance, the risks to users, owners, operators and patients are significantly reduced.

REPORTING OF ADVERSE INCIDENTS

All adverse incidents should be reported to the IMB via our on-line vigilance reporting system, on the home page of www.imb.ie, or by completing a Medical Device Incident User Report Form (SUR-F0001), which is available on request from the IMB or may be downloaded from the IMB website. Adverse incidents include any actual or potential malfunction or deterioration in the characteristics and performance of a device that might lead to impaired health or death of the patient, user or other persons (reference Guidance Note 13 (SUR-G0003) on www.imb.ie for more details).

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ENQUIRIES

If you have any enquiries, you may contact the Human Products Safety Monitoring Department at:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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Website: www.imb.ie

APPENDIX 1: FURTHER READING

EN866 - Biological Standards

EN 867 - Chemical Indicators (non-biological)

EN ISO 13060 - Small Steam Sterilisers

ISO 17665 - Sterilisation of health care products — Moist heat — Part 1: Requirements for the development, validation, and routine control of a sterilisation process for medical devices.

Dental Council Of Ireland Code of Practice Relating to Infection Control in Dentistry, 2005.

HSE Code of Practice for Decontamination of RIMD (Reusable Invasive Medical Devices), Parts 1 to 7. Version 1.0, 2007.

IMB Safety Notice SN2003(08) - Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment

IMB Safety Notice SN2003(09) - Equipment Management: Some Basic Principles of Equipment Management

IMB Guidance Note 13 (SUR-G0003) - Incident Reporting for General Medical Devices and Active Implantable Medical Devices

MDA Device Bulletin DB 2000/05 NI - Guidance on the Purchase, Operation and Maintenance of Vacuum Bench-top Steam Sterilisers