

**SN (NI) 2002/29**

**DATE: 30 August 2002**

**For Attention and Action by:  
Chief Executive of each HSS Trust  
General Manager/Chief Executive of each HSS Board  
Chief Executive of each Agency**



**HEALTH ESTATES  
ESTATE POLICY**

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**

**STEAM PENETRATION TESTS IN VACUUM  
BENCHTOP STERILIZERS**

**MANUFACTURER/SUPPLIER**

Various

**PROBLEM**

A daily steam penetration test is necessary to assist in the demonstration of the effectiveness of vacuum benchtop sterilizers that process wrapped, textile, hollow or tubular loads. Manufacturers of various sterilizers on the market do not provide information on the type of steam penetration test that is suitable and validated for their particular sterilizer. This could lead to failure to sterilize loads.

**DISTRIBUTION**

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Estates Managers
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Managers of all departments using benchtop (transportable) steam sterilizers
- Infection Control Doctors
- Infection Control Nurses
- Theatre Managers Accident & Emergency Departments
- General Medical Practitioners
- General Dental Practitioners
- Professions Allied to Medicine
- Practice Nurses
- Community Care Staff

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

**ACTION**

If you have a vacuum (forced air removal) benchtop sterilizer that processes wrapped, textile, hollow or tubular medical devices:

- ensure that a daily steam penetration test is carried out in accordance with the manufacturer's instructions
- if there is no test available, do not use the sterilizer for processing any wrapped, textile, hollow or tubular medical devices. Use these sterilizers only for non-wrapped, solid devices.

If you are considering purchasing a vacuum (forced air removal) benchtop sterilizer that processes wrapped, textile, hollow or tubular medical devices:

- ensure that a validated daily steam penetration test is available for the sterilizer
- if there is no test available, do not use the sterilizer for processing any wrapped, textile, hollow or tubular medical devices. Use these sterilizers only for non-wrapped, solid devices.
- NIAIC Device Bulletin DB2000/05(NI) has further information on points to consider.

Note: The term wrapping includes pouches and sterilization bags.

**SAFETY**

**NOTICE**

## BACKGROUND

Since publication of SN(NI)2002/02 “MATECHANA MINICLAVE MODEL 21Le VACUUM BENCHTOP STEAM STERILIZER”, we have become aware that various other manufacturers' models of vacuum benchtop steam sterilizers do not have the means to demonstrate the effectiveness of steam penetration into the sterilizer load.

Type B or Type S sterilization cycles (see explanatory note) are intended to process loads that can retain air. They usually have a vacuum pump to remove the air. Pressurized steam is an effective sterilizing agent provided that air has first been removed from the sterilizer chamber and load. Residual air can prevent direct contact between the steam and the devices to be sterilized. An effective vacuum air removal stage is required to remove air from loads that are wrapped, textile, hollow or tubular. Some sterilizers incorporate means (including a steam penetration test) to detect residual air, which will prevent sterilization.

Vacuum steam sterilizers should also be tested at the start of each day the sterilizer is used in order to check that the air removal stage is effective. This is termed the steam penetration test, which has to be validated to each specific sterilizer type to demonstrate that it can detect air that is present in sufficient quantity to interfere with sterilization. Some sterilizer manufacturers do not provide an acceptable test method for doing this.

In the absence of steam penetration tests there can be no certainty that the sterilizer is achieving sterilizing conditions. Therefore it should be used in the same way as a traditional benchtop steam sterilizer, applying the appropriate daily and other periodic test procedures, and only used to sterilize non-wrapped solid devices.

To produce sterile products consistently, benchtop steam sterilizers should be tested according to the protocols provided in Health Technical Memorandum (HTM) 2010, Part 3 Validation and verification\*, which are summarized in NIAIC Device Bulletin DB9605 (NI) – The purchase, operation and maintenance of benchtop steam sterilizers, or DB2000/05(NI) – The purchase, operation and maintenance of vacuum benchtop steam sterilizers. Appendix 1 sets out some good practice points based on those in DB2000/05(NI).

Explanatory Note: Type N sterilization cycles and traditional benchtop sterilizers do not use vacuum assisted air removal and should not therefore be used to process instruments that have been wrapped, or are hollow or tubular in construction. Type B sterilization cycles are intended to process porous loads e.g. wrapped instruments and fabrics. Type S sterilization cycles are designed to process air retentive loads e.g. tubular devices, as specified by the sterilizer manufacturer.

## ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2002/29 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stony Road, Dundonald, Belfast BT16 1US  
Tel: 02890 523714, Fax: 02890 523900, Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Brian Godfrey  
NIAIC Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety  
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sáisialta agus Sábháilteacht Phoiblí*



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