

SN (NI) 2002/14
DATE: 28 March 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:
**BENCHTOP VACUUM STEAM STERILIZERS –
THE “PRION CYCLE”**

MANUFACTURER/SUPPLIER

Generic

PROBLEM

Users and potential purchasers of benchtop vacuum steam sterilizers should not be misled that a so-called ‘prion cycle’ alone will minimise the risk of prion transmission.

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
- Medical Directors
- Nurse Directors
- Outpatient Departments
- Accident & Emergency Departments
- General Medical Practitioners
- General Dental Practitioners
- Podiatrists
- Practice Nurses
- Residential & Nursing Homes
- Private Clinics
- Trust Pharmacy Managers

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

1 Whenever practicable:-

- Use single use devices
- Use a Sterile Services Department to reprocess reusable devices.

2 Clean all instruments thoroughly, preferably using a mechanical method before sterilization.

3 Consult your infection control team if you consider that a patient has, or is in an ‘at risk’ category of having, Creutzfeldt-Jakob Disease (CJD).

4 Follow the Advisory Committee on Dangerous Pathogens (ACDP) Spongiform Encephalopathy Advisory Committee (SEAC) guidance on risk assessment of patients with, or at risk of having, CJD.

SAFETY

NOTICE

BACKGROUND

Many benchtop steam sterilizers being placed on the market now feature a so-called 'prion cycle', which is a cycle of 18 minutes hold time at 134-137°C. Exaggerated claims have been made for the effectiveness of that cycle for the inactivation of prions. Users and prospective purchasers should be aware that this cycle alone will **not** inactivate prions completely.

An abnormal form of prion protein (prion) is generally considered to be the probable means of transmission of CJD, which is one of a group of fatal degenerative brain diseases known collectively as Transmissible Spongiform Encephalopathies (TSEs).

Thorough cleaning is considered to give a substantial reduction in the level of contamination on devices and to minimise the theoretical risk of cross infection with CJD. This is a very rare disease and the risk of transmission through reuse of reusable medical devices is unknown.

The ACDP and the SEAC have jointly published guidance* on control of infection by these agents in clinical settings. It includes a sterilization cycle of 18 minutes hold time at 134-137°C (or 6 consecutive cycles of 3 minutes each at 134-137°C) in a properly functioning porous load steam sterilizer. This cycle alone will **not** inactivate prions completely.

TSE agents are unusually resistant to conventional chemical and physical decontamination methods and the recommended autoclaving cycles may not be entirely effective in inactivating prion protein. The Department of Health, Social Services and Public Safety has issued guidance on the importance of cleaning to minimise the risk of cross infection with TSEs via reusable medical devices (HSS(MD)15/99 – variant Creutzfeld-Jakob Disease (vCJD) : Minimising the Risk of Transmission).

The ACDP/SEAC guidance* on infection control in clinical settings contains a risk assessment to help medical practitioners to identify patients at risk of suffering with a TSE and also classifies the risk categories of various tissues that contain abnormal prion protein. Guidance is provided on appropriate measures to minimise the risk of cross infection via medical devices that have been used on those patients. The guidance is intended for both hospital and community care. You should refer to this guidance if you are treating a patient known, or suspected, to be suffering from neurodegenerative disorders.

**Transmissible spongiform encephalopathy agents: safe working and the prevention of infection.* Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee – The Stationery Office, London, 1998

ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2002/14 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US
Tel: 02890 523714, Fax: 02890 523900, Email: 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

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



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