

1. DEVICE/EQUIPMENT:

Re-usable stainless steel vaginal specula.

2. PROBLEM:

Inadequate decontamination of re-usable stainless steel vaginal specula can occur if manufacturers' instructions are not followed, resulting in the potential for cross infection.

NIAIC has been informed that MHRA has recently received two reports where the manufacturer's instructions for decontamination were not followed. Decontamination is the combination of processes, including cleaning, disinfection and/or sterilization.

The Medical Device Regulations 2002 require the manufacturer of medical devices to supply information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization. If correctly followed, these instructions will ensure that the device will be safe for another episode of use.

3. ACTION BY:

Practice nurses, General Practitioners, all medical and nursing staff in Family Planning Clinics and Sexual Health Clinics, Obstetricians, Gynaecologists, Infection Control Teams, Sterile Services Managers.

4. ACTION:

It is essential that the manufacturer's instructions are followed. As far as we are aware, manufacturers' decontamination instructions usually recommend that re-usable stainless steel vaginal specula are cleaned and then steam sterilized.

If the device was purchased prior to 1998 it may not have been supplied with these instructions. Wherever possible the manufacturer should be contacted to obtain the appropriate instructions.

However if this is not possible, the following two stage decontamination process is recommended for stainless steel vaginal specula.

1. Cleaning is the essential first stage. Preferably, an automated cleaning process should be used to help ensure repeatable and reproducible results. However, further information on manual cleaning procedures can be found in the NHS Estates publication - A Protocol for Local Decontamination (www.decontamination.nhsestates.gov.uk). At this stage the specula should also be inspected to ensure that they are in good condition and fit for further use.
2. Stainless steel vaginal specula are compatible with steam sterilization and should be sterilized in a validated steam sterilizer with a sterilization hold temperature of 134 °C for 3 minutes. If the device is wrapped it should be sterilized in a vacuum steam sterilizer using the same parameters.

The publication "Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from the Microbiology Advisory Committee to Department of Health, Medical Devices Agency", issued under PEL(96)30, provides further information on relevant procedures and protocols. (SAB(94)22 "Instruments and Appliances used in the vagina and cervix: Recommended methods for decontamination" was withdrawn in 1998.)

All practices should be in line with the Decontamination of Re-usable Medical Devices Controls Assurance Standard (www.casu.org.uk).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Device/ Equipment Co-Ordinators
- Medical Directors
- Nursing Directors
- Theatre Managers
- Accident & Emergency Departments
- Obstetric and Gynaecology Departments
- Urology Departments
- Consultant Microbiologists
- Infection Control Teams
- Central Sterilizing Department Managers
- Decontamination Leads
- Sexual Health Clinics
- Out Patient Departments
- Practice Nurses
- Family Planning Clinics
- Cervical screening programme co-ordinators
- Independent Health and Social Care Providers including residential, nursing homes and private clinics

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/16 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Please feedback details of any problems found.



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) 2003/01. 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