

SN (NI) 2002/35

DATE: 13 December 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:

URETERIC STENT DEGRADATION BY LIGHT

MANUFACTURER/SUPPLIER

Cook Urological

PROBLEM

The Cook Sof-Flex® Multi-Length ureteric stent may degrade and become unfit for use before the indicated expiry date, if it has not been stored in the dark.

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
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff
- Sterile Services Departments
- Operating Theatre Staff
- Urologists
- Gynaecologists
- All Staff involved in the storage of devices
- Private Clinics

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

- Do not use Cook Sof-Flex® Multi-Length ureteric stents that have not been stored away from artificial light as well as daylight.
- Store medical devices under the conditions indicated on the label.
- Ensure that appropriate storage facilities are available at relevant sites (wards, operating theatres, storage rooms, etc.).

SAFETY

NOTICE

BACKGROUND

Recently a case has come to Medical Devices Agency (MDA) attention where two polymeric ureteric stents became friable within the stated shelf life of the product. One stent crumbled upon explantation, two weeks after insertion into the patient. A nephrostomy was needed to remove the stent parts. A second (unimplanted) stent from the same hospital was examined and also found unsuitable for use. It appears that storage of these devices in glass cabinets with exposure to artificial lighting had caused the materials to degrade. The individual products were packaged in transparent foil. Product labelling indicated that the devices should have been stored in the dark.

MDA is currently discussing packaging changes with the stent manufacturer to afford improved protection from light. However, polymeric materials are generally susceptible to ageing and this phenomenon may cause them to become brittle over time. The Medical Devices Regulations require that manufacturers should state the expiry date on the label of their devices. This is the date until which the device can be safely used when stored in accordance with the product labelling. If the recommended storage conditions have not been observed, the effective lifetime of the device could be less than that stated on the label.

ENQUIRIES

Enquires to the manufacturer should be addressed to:

Mr Adrian Parfitt
Cook UK Ltd
Munroe House
Letchworth
Hertfordshire SG6 1LN

Tel: 01462 473100
Fax: 01462 473195

Enquires to the NIAIC should quote the reference number SN(NI) 2002/35 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

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

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



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