

**HN (NI) 2002/04**

**DATE: 28 May 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  
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**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**  
**INTERSURGICAL BREATHING SYSTEMS,  
LOT NUMBERS 3021471 TO 3022477: POTENTIAL  
RISK OF INHALATION OF MANUFACTURING  
DEBRIS**

**MANUFACTURER/SUPPLIER**

Intersurgical

**PROBLEM**

A small piece of red plastic may migrate into the breathing system from incorrectly moulded 22mm red safety end caps. All Intersurgical adult and paediatric breathing systems with LOT numbers from 3021471 to 3022477 are affected.

**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/Advisers
- Device Managers
- Estates Managers
- Medical Directors
- Theatre Managers
- General Dental Practitioners
- Private Clinics
- Clinical Governance Departments
- Clinical Directors
- Nursing Directors
- Directors of Anaesthetics
- Adult & Paediatric Intensive Care Unit
- Maternity Department
- A&E Departments
- Special Care Baby Units
- Ambulance Services
- Operating Department Practitioners

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.

**IMMEDIATE ACTION**

- Identify and isolate affected breathing systems
- Do not use affected breathing systems.

**BACKGROUND**

NIAIC has been informed by the Medical Devices Agency (MDA) that they are aware of a manufacturing error where incorrect moulding of the 22mm red safety end caps has resulted in the possibility of a small piece of red plastic migrating into the breathing system. The use of a breathing system filter will prevent patient inhalation.

NIAIC and MDA recognise that in some hospitals alternative breathing systems may not be immediately available. For emergency/urgent procedures breathing systems from the affected batch might be considered for use with extreme caution but only after a full risk assessment has been carried out. In these circumstances the red end cap must be

**HAZARD  
NOTICE**

discarded, the breathing system must be flushed with oxygen and then inspected closely to ensure that no debris is present, and a breathing system filter must be incorporated at the patient end of the circuit.

Intersurgical are liaising closely with MDA and are undertaking immediate voluntary corrective action to their manufacturing processes. Intersurgical will exchange all affected systems as detailed in the attached bulletin (Annex A).

The problem identified in this Hazard Notice has been caused by a manufacturing failure. It is not related to the breathing system blockages identified in NIAIC Hazard Notice HN(NI)2002/27. However it reinforces the importance of users visually inspecting and functionally checking every breathing system component before each and every use.

### **ENQUIRIES**

Enquiries to the manufacturer should be addressed to:  
Intersurgical Customer Care Department  
Crane House  
Molly Millars Lane  
Wokingham  
Berkshire RG41 2RZ

Tel: 01189 656300  
Fax: 01189 656356  
E-mail [mct@intersurgical.co.uk](mailto:mct@intersurgical.co.uk)

Enquires to the NIAIC should quote the reference number HN(NI) 2002/04 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](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 Sóisialta agus Sábháilteacht Phoiblí*



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## ANNEX A



Crane House Molly Millars Lane  
Wokingham Berkshire RG41 2RZ  
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www.intersurgical.com mct@intersurgical.co.uk

### **MDA Hazard Notice reference number HN 2002 (03) Intersurgical 22mm Red Safety Caps (NIAIC Hazard Notice HN(NI)2002/05)**

#### **Background**

Some 22mm red safety caps used in Intersurgical Breathing Systems have been found with a small piece of excess material inside the cap. This material may become detached from the cap and enter the breathing system, from where it may subsequently enter the patient's respiratory tract. The caps are marked with the words "INTERSURGICAL. REMOVE BEFORE USE".

#### **Affected products**

We estimate that 0.1% of 22mm red safety caps may contain this loose material, which is a disc of red plastic 3 – 5 mm in diameter. All breathing systems with LOT numbers 3021471 – 3022477 are potentially affected.

#### **Action**

The affected systems may **ONLY** be used in emergency / urgent procedures in the following way.

1. After opening the packaging of the system, remove and dispose of the 22mm red safety cap immediately.
2. Flush-out the breathing system.
3. Inspect the system to ensure that no loose material is present.
4. Use a respiratory filter between the breathing system and the patient. This will stop any possibility of loose material entering the patient's respiratory tract.

#### **Exchange**

Customers who wish to have affected products exchanged can do so by contacting the Intersurgical Customer Care department as follows:

Tel 01189 656 300  
Fax 01189 656 356  
E-mail mct@intersurgical.co.uk  
27 May 2002