

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/62

Issued: 17 December 2004

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Neurosurgical sponges and urinary drainage devices manufactured by Tyco Healthcare.	▶ ①
<b>Problem:</b> The MHRA has been informed that several thousand neurosurgical sponges that are packaged and labelled as 'STERILE' have been stolen in transit prior to being sterilized. Two batches of urinary catheter and drainage devices were also stolen. If used, these non-sterile devices will present a risk of infection.	▶ ②
<b>Action by:</b> All staff responsible for the procurement of medical devices, and all medical and surgical staff.	▶ ③
<b>Action:</b> Ensure that relevant staff are aware of the theft of these devices and follow the actions on page 2.	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Manufacturer	Item Code	Product Name	Batch/Lot number
Tyco Healthcare	80002	Neuro Sponge	4307010659
	80003	Neuro Sponge	4307010660
	80004	Neuro Sponge	4307010661
	80008	Neuro Sponge	4307010663
	80009	Neuro Sponge	4307010664
	80050	Neuro Sponge	4307010665
	80062	Neuro Sponge	4307010666
	80101	Neuro Sponge	4307210667
	80104	Neuro Sponge	4307210668
	80148	Neuro Sponge	4307210676
	80160	Neuro Sponge	4307210677
90014	Neuro Sponge Set	4307210678	
Tyco Healthcare	10041	Urinary Catheter-Kit	4314110641
	5079	Mono-flo™ Day and Night closed urine drainage system	4317110306

## 2. PROBLEM:

The NIAIC has been informed that several thousand neurosurgical sponges that are packaged and labelled as 'STERILE' have been stolen in transit prior to being sterilized. Two batches of urinary catheter and drainage devices were also stolen. If used, these non-sterile devices will present a risk of infection.

## 3. ACTION BY:

All staff responsible for the procurement of medical devices, and all medical and surgical staff.

## 4. ACTION:

The list of devices and batches affected is provided above. Ensure that relevant staff :

- are aware of the theft of these devices and remain vigilant in the event that these are offered for sale
- check current and incoming stock and quarantine any affected devices in a secure location
- do not put the affected devices into use
- contact the manufacturer immediately if any of these affected devices are offered for sale or have already been purchased.

## 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- Theatre managers
- Practice Nurses
- Sterile Services Departments
- Operating Theatre Staff
- Infection Control Staff
- Accident & Emergency Departments
- Intensive Care
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes providing Nursing Care, through HSS Board R&I Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Alan Morley  
Directory Regulatory Affairs  
Tyco Healthcare UK Ltd  
154 Fareham Road  
Gosport  
Hampshire  
PO13 0AS

Tel: 01329 224202

Fax: 01329 224418

E-mail: alan.morley@emea.tycohealthcare.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/62 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:

None required



Robert Sergeant  
NIAIC Operational 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 MDEA(NI)2004/01. 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*