Medical Device/Equipment **ALERT**

Ref. MDEA(NI)2003/15

Issued: 17 July 2003

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	

	Section
Medical Device/Equipment: Expanding Haemostatic Agents and Expanding Tissue Sealants.	► ①
Problem: Risk of blockage or compression by expanding haemostatic agents or expanding tissue sealants.	► ②
Action by: All surgeons using these products, in particular orthopaedic and spinal surgeons	► ③
Action: Be aware of the guidelines listed under “Action” below.	► ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers **For onward distribution see Section 5**	► ⑤
Contacts NIAIC contact details	► ⑥
Feedback Requirements to NIAIC See “Feedback” section, below.	► ⑦

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

1. DEVICE/EQUIPMENT:

All haemostatic agents and tissue sealants that expand when in contact with body fluids to achieve haemostasis or adhesion.

2. PROBLEM:

NIAIC has been informed that MHRA is aware of a number of cases where the use of expanding haemostatic agents, when used in cavities or closed tissue spaces, has resulted in serious patient consequences. One case involved the use of a gelatin sponge to achieve haemostasis in the lumbar spine after routine surgery. Initially the patient appeared to be neurologically intact but over the next 24 hours developed a complete cauda equina lesion with bilateral foot drop and loss of all movement in the feet. It is likely that these symptoms were caused by compression of the spinal cord by the expanding sponge. The symptoms were relieved when the sponge was removed. A further two reported cases have resulted in cauda equina syndrome when haemostatic sponges were not removed from the site of application following spinal surgery. Similar problems of compression of nerve tissue have also been reported when expanding tissue sealants have been used in enclosed spaces. In a further case, a patient with a lacerated tongue developed tracheal obstruction after being treated with an expanding haemostatic agent.

The instructions for use for these products contain warnings and precautions about using in closed tissue spaces or in close proximity to anatomical structures sensitive to compression. Evidence from adverse incident reports made to MHRA suggests that users are sometimes unaware of these limitations.

3. ACTION BY:

All those who use haemostatic agents or tissue sealants. This will include:

All surgeons using these products, in particular orthopaedic and spinal surgeons
Accident & emergency specialists

4. ACTION:

- Read all instructions for use for any haemostatic agent or tissue sealant to establish the potential for expansion during use.

- Be aware of the maximum swell volume of any tissue sealant or haemostatic agent that expands when in contact with body fluids.

- Consider the effect of compression on surrounding anatomic structures potentially sensitive to compression.

- Do not compress expanding haemostatic agents before use or pack tightly into cavities.

- Use only the minimum amount of any haemostatic agent or tissue sealant necessary to achieve haemostasis or adhesion.

- Remove excess haemostatic agent once haemostasis is achieved.

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/Equipments Co-Ordinators
- Medical Directors
- Nursing Directors
- Theatre Managers
- Accident & Emergency departments
- Surgeons
- Independent Health and Social Care Providers including residential, nursing homes and private clinics

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/15 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:

Inform NIAIC and the relevant manufacturer of any adverse incident relating to medical device issues when using haemostatic agents or tissue sealants that expand when in contact with body fluids.

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