

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/94

Issued: 5th November 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	✓



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Spinal implants - locking nuts used in the Medtronic Colorado II spinal implant system.</p> <p>Catalogue number 8634111. Lots: W07G2386, W07G2387, W07G2388, W07G2389, W07G2751, W07H0440, W07H1809 and W07H1810.</p>	▶ ①
<p>Problem: Recall due to a manufacturing defect.</p>	▶ ②
<p>Action by:</p> <ul style="list-style-type: none"> Orthopaedic surgeons; Supplies managers and Theatre managers 	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Do not use affected devices. Quarantine affected devices. Return affected devices to the manufacturer. Report all adverse incidents associated with this device to the manufacturer and the NIAIC. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p>For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Spinal implants - locking nuts used in the Medtronic Colorado II spinal implant system.

Catalogue number 8634111.

Lots: W07G2386, W07G2387, W07G2388, W07G2389, W07G2751, W07H0440, W07H1809 and W07H1810.

2. PROBLEM:

Medtronic is recalling implicated lots of Colorado II locking nuts.

According to the manufacturer's report, two thread grooves are missing on the locking nuts. Final tightening may cause the locking nuts to tilt and loosen, causing damage to the thread of the bone screw such that the nuts and the bone screws have to be replaced during the same surgical procedure.

The manufacturer has identified that the problem was caused by a manufacturing error and estimates that about 644 potentially affected devices have been distributed in the UK. The manufacturer wrote to users about this recall in September 2007 (see MHRA website).

The MHRA is not aware of any adverse incidents in the UK associated with this problem.

Medtronic is recalling this implant as a precautionary measure. This alert is being published to facilitate the manufacturer's recall.

3. ACTION BY:

- Orthopaedic surgeons
- Supplies managers
- Theatre managers

4. ACTION:

- Do not use affected devices.
- Quarantine affected devices.
- Return affected devices to the manufacturer.
- Report all adverse incidents associated with this device to the manufacturer and the NIAIC.

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:

- Medical directors
- Nursing executive directors
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers –
Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Dr David G Dunham
Medtronic Limited
Suite One
Sherbourne House
Croxley Business Centre
WD18 8WW

Tel: 01923 212 213

Fax: 01923 241 004

E-mail: david.dunham@medtronic.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/94 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

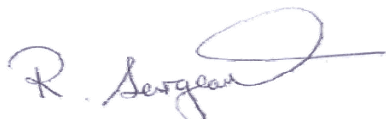
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 7th Nov 2007
Deadline (action underway)	: 16th Nov 2007
Deadline (action complete)	: 31st Dec 2007



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)2006/01. 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