

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/82

Issued: 4th October 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Bioresorbable screw: CALAXO interference screw implants manufactured by Smith & Nephew Inc.	▶ ①
Problem: Recall due to pre-tibial soft tissue swelling after implantation of CALAXO screws leading to the need for surgical intervention to remove any remaining screw fragments.	▶ ②
Action by: <ul style="list-style-type: none"> • Orthopaedic surgeons • Supplies managers • Theatre managers 	▶ ③
Action: <ul style="list-style-type: none"> • Identify and quarantine any unimplanted affected devices. • Do not implant affected devices. • Return affected devices to the manufacturer. Do not implant affected devices. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> 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 Details of manufacturer contacts and NIAIC contacts for technical aspects	▶ ⑥
Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Recall due to pre-tibial soft tissue swelling after implantation of CALAXO screws leading to the need for surgical intervention to remove any remaining screw fragments.

All lot numbers and all item codes distributed since 2006.

2. PROBLEM:

Smith & Nephew Inc. is recalling all lot numbers and all item codes of CALAXO screws which were first distributed in the UK in 2006. This screw is used to secure the graft in anterior cruciate ligament (ACL) reconstruction.

Worldwide, 0.3% of patients have developed pre-tibial soft tissue swelling, which can mimic the appearance of an infection between 2 and 36 weeks after implantation. The manufacturer is currently investigating the cause of this problem.

Most cases resolved without intervention. A small number of cases needed local debridement and removal of any remaining screw fragments, or replacement with an alternative screw or bone graft.

The manufacturer estimates that about 2,550 devices have been used in the UK since 2006.

The manufacturer is aware of seven reported cases of inflammation in the UK of which two required implant revision.

The manufacturer wrote to chief executive officers of trusts, theatre managers, and surgeons who were known to use CALAXO about this product recall in August 2007 (see MHRA website). This notice is to facilitate the recall.

3. ACTION BY:

- Orthopaedic surgeons
- Supplies managers
- Theatre managers

4. ACTION:

- Identify and quarantine any unimplanted affected devices.
- Do not implant affected devices.
- Return affected devices to the manufacturer.
- Identify all patients implanted with this screw.
- If they present with pre-tibial swelling within 2-36 weeks of implantation, consider:
 - aspirating the area for routine cultures
 - local debridement and removal of any remaining screw fragments
 - replacement with an alternative screw or bone graft if necessary.
- Report all adverse incidents related to CALAXO screws to the implant 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:

- Infection prevention and control directors
- Medical directors
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Theatres
- Independent Health and Social Care Providers – Private Hospital & Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Dr Mike Eyre
Smith & Nephew Healthcare Limited
Healthcare House
Goulton Street
Hull HU3 4DJ

Tel: 01482 222 200

Fax: 01482 222 211

E-mail: Mike.Eyre@smith-nephew.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/82 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

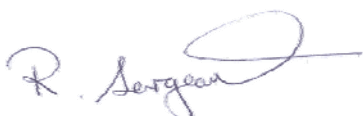
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

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

Deadline (Email received)	: 8th Oct 2007
Deadline (action underway)	: 18th Oct 2007
Deadline (action complete)	: 4th 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