

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/50

Issued: 23 August 2006

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	✓



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Orthopaedic implants manufactured by Proconcept SA France: CIFEC cervical cages; LIFEC lumbar cages; ALIFEC lumbar cages; SRE/SEO spinal screw systems; CANALETTO carpal tunnel protection implants.</p>	▶ ①
<p>Problem: Invalid CE certification; deficiencies in technical documentation, production and traceability.</p>	▶ ②
<p>Action by:</p> <ul style="list-style-type: none"> Orthopaedic surgeons; Spinal surgeons; Neurological surgeons and Hand surgeons 	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Do not implant affected devices. If any affected devices are in stock, isolate, quarantine and inform NIAIC. Inform NIAIC of any adverse incidents relating to these devices. 	▶ ④
<p>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</p>	▶ ⑤
<p>Contacts Details of NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC Details of Compliance Assurance</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Orthopaedic implants manufactured by Proconcept SA France:

CIFEC cervical cages; LIFEC lumbar cages; ALIFEC lumbar cages; SRE/SEO spinal screw systems; CANALETTO carpal tunnel protection implants.

2. PROBLEM:

MHRA has been informed by the French Medical Device Regulator (Afssaps) that orthopaedic implants manufactured by Proconcept SA have invalid CE certification, a lack of technical documentation as well as production and traceability deficiencies.

Afssaps has informed MHRA that Proconcept SA in France has now ceased trading and gone bankrupt.

Afssaps has also informed MHRA that some of the affected products (LIFEC lumbar cages) have been distributed in the UK by Kuma Trading Ltd of Basildon Essex. MHRA has been unable to trace Kuma Trading Ltd.

MHRA has received no reports of adverse incidents involving implantable devices manufactured by Proconcept SA. There is currently no evidence to suggest that clinical problems are more likely in patients implanted with these devices.

3. ACTION BY:

- Orthopaedic surgeons
- Spinal surgeons
- Neurological surgeons
- Hand surgeons

4. ACTION:

- Do not implant affected devices.
- If any affected devices are in stock, isolate, quarantine and inform MHRA. Inform
- MHRA of any adverse incidents relating to these devices.

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
- Clinical Directors
- Independent Health and Social Care Providers
– Private Hospitals and Clinics through RQIA
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- Medical Directors
- Medical Libraries
- Neurosurgeons
- Nursing Executive Directors
- Operating Theatres
- Purchasing Managers
- Radiologists (Skeletal)
- Risk Managers
- Safety Officers
- Spinal, Hand, Orthopaedic, And Neurological Surgeons
- Supplies Managers
- Theatre Managers

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2006/50 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

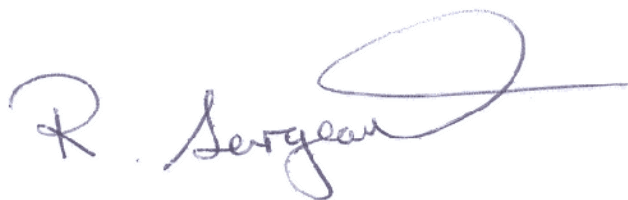
7. FEEDBACK:

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

Deadline (Email received) : 25 August 2006

Deadline (action underway) : 08 September 2006

Deadline (action complete): 22 September 2006

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a large loop at the end of the last name.

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