

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/070

Issued: 22nd September 2008

For:

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|------------------|---|
| IMMEDIATE ACTION | |
| ACTION | ✓ |
| UPDATE | |
| INFORMATION | |



HEALTH ESTATES

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| | Section |
|--|---------|
| Medical Device/Equipment: Instrumentation for total knee replacement surgery: NexGen Articular Surface Insertion Instrument manufactured by Zimmer Inc (specific lot numbers). | ▶ ① |
| Problem: Recall of instruments that do not meet material specifications. | ▶ ② |
| Action by: <ul style="list-style-type: none"> • Orthopaedic surgeons • Theatre Procurement Co-ordinators • Theatre managers • Senior Theatre Nurses | ▶ ③ |
| Action: <ul style="list-style-type: none"> • Identify and quarantine affected instruments • Do not use affected instruments • Follow manufacturers instructions for return of the affected instruments (see appendix). | ▶ 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 | ▶ ⑤ |
| Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects. | ▶ ⑥ |
| Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS) | |
| Acknowledge Receipt of Alert: 25 th Sept 2008 | ▶ ⑦ |
| Action Under Way: 6 th Oct 2008 | |
| Action Complete: 22 nd Oct 2008 | |

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

1. DEVICE/EQUIPMENT:

NexGen Complete Knee Solution Articular Surface Insertion Instrument manufactured by Zimmer Inc

Catalogue number: 00-5977-020-00.

Lots: 60577285, 60582624, 60587308, 60603255 & 60610860.

2. PROBLEM:

Zimmer Ltd initiated a product recall on 15 May 2008. The manufacturer's letter has been published on the MHRA website (www.mhra.gov.uk) and is attached to this alert.

There are 21 instruments affected. Despite additional attempts since their recall action, the manufacturer has been unable to recover 7 of the 21 affected instruments.

The affected devices do not meet the material specification required for the manufacture of this instrument. As a result, the instrument may be more prone to fracture during use.

Fracture of the instrument yields a metal fragment that is at risk of being left in the patient. Should this occur there is a risk that the fragment could migrate on to the articular surface, damaging it and the femoral component, leading to the need for implant revision.

The manufacturer has informed MHRA that they have not received any reports of fractured instruments from customers in the UK.

3. ACTION BY:

- Orthopaedic surgeons
- Theatre Procurement Co-ordinators
- Theatre managers
- Senior Theatre Nurses

4. ACTION:

- Identify and quarantine affected instruments
- Do not use affected instruments
- Follow manufacturers instructions for return of the affected instruments (see appendix).

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
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Surgical managers
- Theatre managers
- Senior theatre nurses
- TSSU/CSSD managers
- Theatre procurement co-ordinators
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Mr James Halliday
Zimmer UK Ltd
The Courtyard
Lancaster Place
South Marston Park,
Swindon, Wiltshire
SN3 4FP, United Kingdom

Tel: 01793 584645

Fax: 01793 584569

E-mail: james.halliday@zimmer.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/070 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

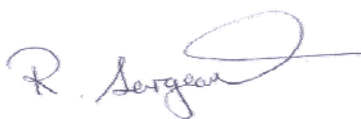
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
25th Sept 2008

Action Under Way:
6th Oct 2008

Action Complete:
22nd Oct 2008



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)2008/01. 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

APPENDIX to MDEA(NI)2008/070

Zimmer Ltd
The Courtyard
Lancaster Place
South Marston Park,
Swindon, Wiltshire
SN3 4FP, United Kingdom

Telephone: +44 (0)1793 584500
Facsimile: +44 (0)1793 584569

Our ref: Zimmer FSCA 1822565-2008-01

Urgent Field Safety Notice: NexGen® Complete Knee Solution Articular Surface Insertion Instrument

Zimmer is initiating a product recall of the NexGen® Complete Knee Solution Articular Surface Insertion Instrument, involving Catalogue Number 00-5977-020-00, Lot Numbers 60577285, 60582624, 60587308, 60603255, & 60610860.

This action is being conducted because Zimmer has determined that one of our suppliers did not meet our material specifications for the manufacture of this instrument. As a result, the instrument may be more prone to fracture during use. Fracture of the instrument yields a metal fragment that is at risk of being left in the patient.

Our distribution records indicate that your account has received product from the affected lots. We kindly request that you immediately check your stock and locate any product you may have remaining at your location and follow the steps outlined below:

1. Quarantine implicated product.
2. Complete and fax back the enclosed response form.
3. Once Zimmer UK receives the response form, arrangements to supply a replacement device can be made.
4. Zimmer will arrange collection of any of the affected products from your location. Be sure to include a copy of the response form with the return for our records.

Even if you have none of the affected batches left in stock, please return the response form as this would preclude the need for further notices.

Zimmer would like to thank you for your co-operation and regret any inconvenience caused by this recall. Should you require any further information regarding this matter, please do not hesitate to contact us.

Yours sincerely

Miranda Smith

**Quality & Compliance Manager
Zimmer UK Ltd**

Encl: Response form
CC: MHRA; RSM; SE

Appendix to MDA/2008/070



FAX-BACK FORM

To : Miranda Smith, Quality & Compliance Manager, Zimmer UK Ltd
 Fax No. : 01793 584636

DESCRIPTION: NexGen® Complete Knee Solution Articular Surface Insertion Instrument

PRODUCT CODE: 00-5977-020-00
LOT NUMBER: 60577285, 60582624, 60587308, 60603255, & 60610860

This is to confirm that the Hospital does have/does not have* the **NexGen® Complete Knee Solution Articular Surface Insertion Instrument** in stock:

| Product Code | Lot Number | YES # We have in stock | NO # We do not have in stock |
|---------------------|-------------------|-----------------------------------|---|
| 00-5977-020-00 | 60577285 | | |
| 00-5977-020-00 | 60582624 | | |
| 00-5977-020-00 | 60587308 | | |
| 00-5977-020-00 | 60603255 | | |
| 00-5977-020-00 | 60610860 | | |

* Please indicate quantities as appropriate

Zimmer will arrange for replacement product to be sent to you, if applicable.

Hospital Name: _____

Collection Address: _____

Name: _____
 (please print)
 Position: _____

Signed: _____ Date _____
 (Hospital Representative)

**PLEASE FAX BACK THIS COMPLETED FORM TO MIRANDA SMITH, QUALITY & COMPLIANCE MANAGER,
 ZIMMER UK LTD ON 01793 584636 AS SOON AS POSSIBLE.**

This would preclude the need for further notices.