

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/069

Issued: 19th September 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Total knee replacement implants: Stryker Orthopaedics Kinemax Plus Revision TS Tibial Inserts (specific product and lot codes – see Appendix).	▶ ①
Problem: Risk of loosening, excessive wear and fracture of knee replacement components, due to a manufacturing defect.	▶ ②
Action by: <ul style="list-style-type: none"> Orthopaedic surgeons Theatre managers. 	▶ ③
Action: <ul style="list-style-type: none"> Do not implant affected devices Identify any affected stock that has not been implanted, and return to manufacturer Follow the patient management recommendations in this alert. 	▶ 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	▶ 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: 23 rd September 2008	▶ ⑦
Action Under Way: 6 th October 2008	
Action Complete: 3 rd November 2008	

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

1. DEVICE/EQUIPMENT:

Total knee replacement implants: Stryker Orthopaedics Kinemax Plus Revision TS Tibial Inserts (specific product and lot codes – see Appendix).

2. PROBLEM:

Patients with revision knee replacements may have received a tibial insert with a manufacturing defect. The affected devices have an incorrectly machined stabiliser post recess, which prevents the tibial insert from fitting correctly over the stabiliser post. The manufacturer has contacted all UK users to recall the affected devices (see the manufacturer's Field Safety Notice in Appendix). 112 affected devices were distributed in the UK. As a result of the recall, 73 unused devices have been returned to the manufacturer. The remaining 39 devices may have been implanted in patients.

Patients who have received these implants are at risk of loosening, excessive wear and/or fracture of components. These could be caused by any of the following reasons:

- the gap between components was not detected during assembly
- excessive force was required to seat the insert with the base plate
- a smaller stabiliser post from a smaller sized insert was used to complete the surgery.

3. ACTION BY:

- Orthopaedic surgeons
- Theatre managers.

4. ACTION:

- Do not implant affected devices
- Identify any affected stock that has not been implanted, and return it to the manufacturer
- Identify which patients have been implanted with affected devices
- Ensure that affected patients, including those without symptoms, are followed up in accordance with usual standards of care for revision knee replacement patients (the manufacturer recommends follow-up at 6 weeks, 6 months, 12 months, and annually thereafter)
- Advise patients implanted with affected devices to report any increasing pain, or any symptoms of knee instability such as clicking
- Consider the need for revision for symptomatic patients.

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:

- Clinical governance leads
- Medical directors
- Orthopaedic surgeons
- Risk managers
- Theatre Managers
- Independent Health and Social Care Providers – Private Hospitals through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Jacqueline Fripp
Quality Assurance & Regulatory Affairs
Stryker UK Ltd
Stryker House
Hambridge Rd
Newbury
Berkshire RG14 5EG

Tel: 01635 262 465

Fax: 01635 262 464

E-mail: jacqueline.fripp@stryker.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/069 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

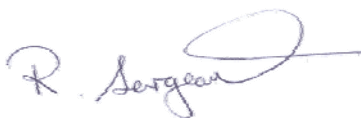
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
23rd September 2008

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6th October 2008

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3rd November 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)2007/01. 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

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www.stryker.co.uk



URGENT PRODUCT INFORMATION FIELD SAFETY CORRECTIVE ACTION

15 May 2008

STRYKER REF: RA 2008-033

DESCRIPTION: KINEMAX PLUS REVISION TS TIBIAL INSERT

CATALOG NO.:	64780412	64780415	64780418	64780421	64780425
	64781412	64781415	64781418	64781421	64781425
	64783410	64783412	64783415	64783418	64783421
	64783425	64785410	64785412	64785415	64785418
	64785421	64785425			

LOT CODES: VARIOUS – PLEASE SEE ENCLOSED LISTING

Dear Customer

Stryker Orthopaedics has become aware that the stabiliser post recess on certain Kinemax Plus Revision TS Tibial Inserts was machined with the incorrect geometry preventing the tibial insert from fitting correctly over the post and preventing the insert from assembling correctly with the tibial base plate.

The potential hazards arising from this are:

- The insert cannot be assembled flush with the base plate and the surgeon needs to use a different implant system to complete the surgery.
- The insert cannot be assembled flush with the base plate and the surgeon does not detect the gap and leaves the implant in the patient. Potential effects include loosening, excessive wear and/or fracture of components.
- Excessive force is used to make the insert seat flush which would result in potential damage and or increased stress on the insert. Potential effects include loosening, excessive wear and/or fracture of components.

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- d) The insert cannot be assembled flush with the base plate and the surgeon uses a smaller stabiliser post from a smaller size insert to complete the surgery. Potential effects include loosening, excessive wear and/or fracture of components. **Please note** that Stryker Orthopaedics does not recommend the use of this combination of devices. Clinical protocol under these circumstances would suggest that increased monitoring of the patient is advisable and revision should be considered. As every case is unique the decision to revise rests with the surgeon who should take account of the patient's individual details and circumstances as well as the performance of the implant.

We are therefore initiating a product recall on the following Kinemax Plus Revision TS Tibial Inserts:

PRODUCT CODE	LOT CODE	PRODUCT DESCRIPTION
64780412	LAR297	Kinemax Plus Revision TS Tibial Insert XSM 12mm
64780415	LAK031	Kinemax Plus Revision TS Tibial Insert XSM 15mm
64780415	LAL880	Kinemax Plus Revision TS Tibial Insert XSM 15mm
64780415	LAP974	Kinemax Plus Revision TS Tibial Insert XSM 15mm
64780418	LAK033	Kinemax Plus Revision TS Tibial Insert XSM 18mm
64780418	LAK210	Kinemax Plus Revision TS Tibial Insert XSM 18mm
64780418	LAN793	Kinemax Plus Revision TS Tibial Insert XSM 18mm
64780421	LAK206	Kinemax Plus Revision TS Tibial Insert XSM 21mm
64780425	LAK207	Kinemax Plus Revision TS Tibial Insert XSM 25mm
64781412	LAK208	Kinemax Plus Revision TS Tibial Insert SM 12mm
64781412	LAS699	Kinemax Plus Revision TS Tibial Insert SM 12mm
64781412	LAU461	Kinemax Plus Revision TS Tibial Insert SM 12mm
64781415	LAK134	Kinemax Plus Revision TS Tibial Insert SM 15mm
64781415	LAK209	Kinemax Plus Revision TS Tibial Insert SM 15mm
64781418	LAK211	Kinemax Plus Revision TS Tibial Insert SM 18mm
64781418	LAR293	Kinemax Plus Revision TS Tibial Insert SM 18mm
64781418	LAS693	Kinemax Plus Revision TS Tibial Insert SM 18mm
64781421	LAR465	Kinemax Plus Revision TS Tibial Insert SM 21mm
64781425	LAR296	Kinemax Plus Revision TS Tibial Insert SM 25mm
64783410	LAN794	Kinemax Plus Revision TS Tibial Insert MED 10mm
64783410	LAR463	Kinemax Plus Revision TS Tibial Insert MED 10mm
64783412	LAL877	Kinemax Plus Revision TS Tibial Insert MED 12mm
64783412	LAS696	Kinemax Plus Revision TS Tibial Insert MED 12mm
64783415	LAK032	Kinemax Plus Revision TS Tibial Insert MED 15mm
64783415	LAN795	Kinemax Plus Revision TS Tibial Insert MED 15mm
64783415	LAR292	Kinemax Plus Revision TS Tibial Insert MED 15mm
64783415	LAS684	Kinemax Plus Revision TS Tibial Insert MED 15mm
64783418	LAK028	Kinemax Plus Revision TS Tibial Insert MED 18mm
64783418	LAL911	Kinemax Plus Revision TS Tibial Insert MED 18mm
64783418	LAS688	Kinemax Plus Revision TS Tibial Insert MED 18mm
64783418	LAW465	Kinemax Plus Revision TS Tibial Insert MED 18mm
64783421	LAP975	Kinemax Plus Revision TS Tibial Insert MED 21mm
64783425	LAL912	Kinemax Plus Revision TS Tibial Insert MED 25mm
64785410	LAS486	Kinemax Plus Revision TS Tibial Insert LG 10mm
64785412	LAS687	Kinemax Plus Revision TS Tibial Insert LG 12mm
64785415	LAK029	Kinemax Plus Revision TS Tibial Insert LG 15mm

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64785415	LAL915	Kinemax Plus Revision TS Tibial Insert LG 15mm
64785415	LAR298	Kinemax Plus Revision TS Tibial Insert LG 15mm
64785418	LAP973	Kinemax Plus Revision TS Tibial Insert LG 18mm
64785421	LAL878	Kinemax Plus Revision TS Tibial Insert LG 21mm
64785421	LAR299	Kinemax Plus Revision TS Tibial Insert LG 21mm
64785425	LAL913	Kinemax Plus Revision TS Tibial Insert LG 25mm
64785425	LAS698	Kinemax Plus Revision TS Tibial Insert LG 25mm
64785425	LAT906	Kinemax Plus Revision TS Tibial Insert LG 25mm

Please note only the lot codes that are identified in the table above are affected.

We are requesting that you assist us in this product recall by performing the following actions.

1. Please examine your inventory and determine if you have any of the affected product.
2. Remove and quarantine affected product from your inventory.
3. Complete and sign the attached customer response form and fax to 01635 262 464.
4. A Stryker representative will then contact you to organise collection of the product and/or replacement devices.

N.B. PLEASE COMPLETE AND RETURN THE FORM (Page 4) EVEN IF YOU HAVE NONE OF THIS PRODUCT IN STOCK.

We sincerely regret the inconvenience caused to you by this action, however we know that you share the desire to ensure the highest quality standards in our products. We would like to thank you for your co-operation in this matter. Should you require any further information or have any queries on the matter please do not hesitate to contact me on 01635 262 465.

Yours faithfully,

Jacqueline Fripp
Quality Assurance & Regulatory Affairs

