Medical Device Alert

Ref: MDA/2014/031 Issued: 24 July 2014 at 12:00

Device

Surgical instrument: Standard Offset Cup Impactor manufactured by Greatbatch, distributed in the UK by JRI Limited and Stryker UK Limited.

All lots.

Problem

Potential for infection from inadequately sterilized devices.

The manufacturer has validated new sterilization parameters for these devices to address this issue. These parameters are provided in the manufacturer's Field Safety Notice (FSN) issued in March 2014.

Action by

All staff involved in sterilization of these devices.
All orthopaedic staff that use these devices.

Action

- Identify affected devices.
- Follow the updated sterilization instructions described in the FSN.

CAS deadlines

Action underway: 07 August 2014

Action complete: 21 August 2014

Contact

Manufacturer
Jennifer C. Meng
Greatbatch Medical
Tel: +1 763 951 8235
Email: JMeng@greatbatch.com

Problem

Greatbatch originally sent a notification in January 2014, with one acceptable sterilization parameter, (validated to a Sterility Assurance Level (SAL) of at least 10^{-6}). Greatbatch has now validated an additional sterilization parameter for use with their device. Both acceptable parameters are provided in the updated FSN dated March 2014.

The MHRA is issuing this Medical Device Alert to ensure that all users are aware of the manufacturer's updated FSN.

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Equipment libraries and stores
- Equipment stores
- Fracture clinics
- Health and safety managers
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- In-house maintenance staff
- Medical directors
- Microbiologists
- Nursing executive directors
- Orthopaedic surgeons
- Physiotherapists
- Purchasing managers
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/031**or **2014/005/021/081/010**

Technical aspects
Ms Salma Husain or Miss Feza Haque
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6729 / 7066
Fax: 020 8754 3965

Email: salma.husain@mhra.gsi.gov.uk
feza.haque@mhra.gsi.gov.uk

Clinical aspects
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camilla.fleetcroft@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate,
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk