MDA/2018/011(Wales)

Medical Device Alert

Llywodraeth Cymru
Welsh Government

23rd April 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

Bone Cement: Optipac 40 Refobacin Revision and Optipac 80 Refobacin Revision – Risk of revision

1. Identify and quarantine all affected devices. (See table below for affected batches.)
2. Follow actions recommended in the manufacturer's Field Safety Notice.
3. If at time of use the setting time was longer than indicated in the manufacturer's instructions for use these patients may require more frequent follow up.
4. For all affected patients, surgeons will need to formulate a local risk assessment and follow-up plan based upon the length of time the device was in storage and relevant patient variables. The affected batches are known to have their mechanical strength reduced by half after 6 months in storage.
5. Complete the certificate of acknowledgment attached to the Field Safety Notice and return it to the manufacturer.

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/011 Issued: 20 April 2018 at 11:30 Valid until: April 2019

Bone Cement: Optipac 40 Refobacin Revision and Optipac 80 Refobacin Revision – Risk of revision

Summary

Manufactured by Biomet – risk of revision surgery from an increase in bone cement polymerisation time and reduced mechanical strength.

Action

1. Identify and quarantine all affected devices. (See table below for affected batches.)
2. Follow actions recommended in the manufacturer's Field Safety Notice.
3. If at time of use the setting time was longer than indicated in the manufacturer's instructions for use these patients may require more frequent follow up.
4. For all affected patients, surgeons will need to formulate a local risk assessment and follow-up plan based upon the length of time the device was in storage and relevant patient variables. The affected batches are known to have their mechanical strength reduced by half after 6 months in storage.
5. Complete the certificate of acknowledgment attached to the Field Safety Notice and return it to the manufacturer.

Action by
All users of the affected medical device.

Deadlines for actions
Actions underway: 30 April 2018
Actions complete: 14 May 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Device details

Catalogue number (Manufacturer product code)	Product Description	Batch/Lot number	Use-by date	Date of manufacture
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A648C04670	31/05/2018	19/12/2016
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A648C05100	30/06/2018	09/01/2017
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A705B05130	31/07/2018	09/02/2017
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A705B06130	30/09/2018	04/04/2017
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B08920	30/11/2018	20/06/2017
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A620A01788	31/01/2018	16/08/2016
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A620A0178A	31/01/2018	23/08/2016
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A705C05628	31/08/2018	30/03/2017
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	B705B05128	31/07/2018	09/02/2017

Problem / background

In December 2017 Biomet issued a Field Safety Notice informing healthcare professionals that the mechanical strength of the affected batches of bone cement may be reduced increasing the risk of revision. There is also a risk of prolonged surgery from increased polymerisation time when using affected batches of bone cement. The manufacturer suggests it would be prudent to monitor closely affected patients as part of their standard follow-up.

This Medical Device Alert is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to patients.

Manufacturer contacts

Zimmer Biomet UK Ltd
Peter Bevan
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Mobile: +447920007446
Email: Peter.Bevan@zimmerbiomet.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Day surgery units
- Equipment stores
- Equipment libraries and stores
- Medical directors

- Operating department practitioners
- Orthopaedic surgeons
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/011** or **[2017/012/019/071/001]**.

Technical aspects
Hasan Samee-Ahmed MHRA
Tel: 020 3080 6807
Email: hasan.samee-ahmed@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).