

Urgent Field Safety Notice

Product: M2a 38mm Acetabular System
Product reference: All cups and heads in Attachment 1
Reference: FSCA20160307

Advisory Notice

Date: April 12, 2016

Attention: Dear surgeon

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) in relation to the M2a 38mm Acetabular System, manufactured by Biomet Orthopedics LLC, Warsaw, Indiana/USA and Biomet UK Ltd, Bridgend, UK (hereafter called Zimmer Biomet).

After discussion with the MHRA, Zimmer Biomet has initiated this Field Safety Corrective Action following on-going analysis of data collected by the National Joint Registry (NJR) for England, Wales and Northern Ireland which revealed that this hip system has a higher than expected revision rate. Our records indicate that some of your patients may have received this M2a 38mm Acetabular System.

Action to be taken:

While the M2a 38mm Acetabular System has not been marketed in Europe since December 2012 due to changing market demands and low product utilisation, this Field Safety Notice (FSN) is intended to make clinicians and healthcare professionals aware of the MHRA guidance MDA/2012/036 dated June 25, 2012 regarding the follow-up of patients implanted with metal on metal hip replacements, with the aim of enhancing the clinician's/healthcare professional's awareness of the guidance provided by the MHRA on patient management in general and to reinforce its application to all patients treated with the M2a 38mm Acetabular System. Zimmer Biomet encourages clinicians and healthcare professionals to continue to monitor their M2a38mm patients in accordance with this MHRA guidance. The details in the Appendix to MDA/2012/036 are as follows over the page:

	Stemmed MoM total hip replacements – femoral head diameter $\geq 36\text{mm}$	
	Symptomatic patients	Asymptomatic patients
Patient follow-up	Annually for the life of the implant	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases	Recommended if blood metal ion levels rising
1st blood metal ion level test	YES	YES
Results of 1st blood metal ion level test	Blood metal ion level $>7\text{ppb}$ indicates potential for soft tissue reaction	If blood metal ion level $>7\text{ppb}$ then second blood test required 3 months later
2nd blood metal ion level test	Yes - 3 months after 1st blood test if result was $>7\text{ppb}$	Yes - 3 months after 1st blood test if result was $>7\text{ppb}$
Results of 2nd blood metal ion level test	Blood metal ion level $>7\text{ppb}$ indicates potential for soft tissue reaction especially if greater than previously	<i>If blood metal ion levels rising - further investigation required including imaging</i>
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising

The Appendix to MDA/2012/036 continues:

"Table footnotes:

- Blood metal ion testing to be in whole blood
- 7 parts per billion (ppb) equals 119 nmol/L cobalt or 134.5 nmol/L chromium"

Guidance notes:

- On the basis of current knowledge, this chart has been produced as a guide to the management of these patients. It will not necessarily cover all clinical situations and each patient must be judged individually.
- MARS MRI scans (or ultrasound scans) should carry more weight in decision making than blood metal ion levels alone.
- Patients with muscle and/or bone damage on MARS MRI are those of most concern. A fluid collection alone around the joint in an asymptomatic patient, unless it is very large can be safely observed with interval scanning.
- Local symptoms include pain and limping.

Zimmer Biomet is not advising that patients should be proactively revised unless this is required in the clinical judgment made by the patient's clinician. Each patient should be considered in the light of their individual clinical situation. While Zimmer Biomet encourages clinicians and healthcare professionals to continue to monitor their M2a 38mm patients in accordance with the MHRA guidance detailed in MDA/2012/036, it is aware that certain regulatory authorities as well as national associations of orthopedic surgeons have issued individual patient follow-up programs for their local markets. It is the clinicians and healthcare professional's responsibility to select the appropriate patient follow-up program based on local clinical practices and local regulations.

Transmission of this Field Safety Notice:

This FSN needs to be passed on to all those who need to be aware within your organisation or to any other organisation to which the devices concerned have been transferred.

Please maintain awareness of this FSN and resulting action for an appropriate period to ensure effectiveness and ensure that you follow the most recent version of the guidance issued

Please complete and return the attached "Certificate of Acknowledgement" on page 4 of this FSN to your local Zimmer Biomet distributor by April 22, 2016. This confirms the fact that you have received, understood and implemented this FSN.

Any adverse events or quality problems experienced with the use of this product or any other products should be reported to your local Zimmer Biomet distributor and your local responsible competent authority.

Please contact your local Zimmer Biomet distributor if you may have any question regarding this Notice.

Yours sincerely



Natalie Wide
QA/RC Director
Biomet UK Ltd and authorised representative for Biomet Orthopedics LLC.

*Waterton Industrial Estate
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South Wales
CF31 3XA*

Certificate of Acknowledgement

ATTENTION: _____ (Local Zimmer Biomet Distributor)
Email: _____ (Local Zimmer Biomet Distributor)
Fax: _____ (Local Zimmer Biomet Distributor).

Regulatory Action: URGENT FIELD SAFETY NOTICE
Description: M2a 38mm Acetabular System

By signing the below, I confirm that I have received and understand and have implemented this URGENT FIELD SAFETY NOTICE.

Printed Name: _____ Title: _____

Facility Name: _____

Facility Address: _____

Telephone: _____

Signature: _____ Date: _____

ATTACHMENT 1

Device details: M2a 38mm Cementless Cups and M2a 38mm Modular Heads

Item Number	Item Description
11-173660	M2A 38MM MOD HD -6MM NK
11-173666	M2A 38MM MOD HD +12MM NK
11-173661	M2A 38MM MOD HD -3MM NK
11-173662	M2A 38MM MOD HD STD NK
11-173663	M2A 38MM MOD HD +3MM NK
11-173664	M2A 38MM MOD HD+5MM NK
11-173665	M2A 38MM MOD HD+9MM NK
14-380351	M2A MODLR HEAD DIA38MM /-3.5 12/14
14-380352	M2A MODLR HEAD DIA38MM / STD 12/14
14-380353	M2A MODLR HEAD DIA38MM / +3.5 12/14
14-380354	M2A MODLR HEAD DIA38MM / +7.5 12/14
14-380355	M2A MODLR HEAD DIA38MM / +10.0 12/14
15-105048	M2A 38MM ONE PIECE CUP SZ 48MM
15-105050	M2A 38MM ONE PIECE CUP SZ 50MM
15-105052	M2A 38MM ONE PIECE CUP SZ 52MM
15-105054	M2A 38MM ONE PIECE CUP SZ 54MM
15-105056	M2A 38MM ONE PIECE CUP SZ 56MM
15-105058	M2A 38MM ONE PIECE CUP SZ 58MM
15-105060	M2A 38MM ONE PIECE CUP SZ 60MM
15-105062	M2A 38MM ONE PIECE CUP SZ 62MM
15-105064	M2A 38MM ONE PIECE CUP SZ 64MM
15-105066	M2A 38MM ONE PIECE CUP SZ 66MM
15-105068	M2A 38MM ONE PIECE CUP SZ 68MM
15-105070	M2A 38MM ONE PIECE CUP SZ 70MM
15-106048	M2A-38 48MM CUP NON FLARED
15-106050	M2A-38 50MM CUP NON FLARED
15-106052	M2A-38 52MM CUP NON FLARED
15-106054	M2A-38 54MM CUP NON FLARED
15-106056	M2A-38 56MM CUP NON FLARED
15-106058	M2A-38 58MM CUP NON FLARED
15-106060	M2A-38 60MM CUP NON FLARED
15-106062	M2A-38 62MM CUP NON FLARED
15-106064	M2A 38 64MM CUP NON FLARED
15-106066	M2A 38 66MM CUP NON FLARED
15-106068	M2A 38 68MM CUP NON FLARED
15-106070	M2A 38 70MM CUP NON FLARED
RD118848	M2A-38 CUP 48MM
RD118850	M2A-38 CUP 50MM
RD118852	M2A-38 CUP 52MM
RD118854	M2A-38 CUP 54MM
RD118856	M2A-38 CUP 56MM
RD118858	M2A-38 CUP 58MM
RD118860	M2A-38 CUP 60MM
RD118862	M2A-38 CUP 62MM
RD118864	M2A 38X64MM CUP
RD118866	M2A 38X66MM CUP
RD118868	M2A 38X68MM CUP
RD118870	M2A 38MM X70 MM CUP
CP161005	56MM M2A 38 TRISPIKE POR HAP
CP161006	58MM M2A 38 TRISPIKE POR HAP
CP161007	60MM M2A 38 TRISPIKE POR HAP
CP161008	62MM M2A 38 TRISPIKE POR HAP
CP161009	64MM M2A 38 TRISPIKE POR HAP
CP161073	M2A 38 TRISPIKE CUP POR HA 48MM
CP161074	M2A 38 TRISPIKE CUP POR HA 50MM
CP161075	M2A 38 TRISPIKE CUP POR HA 52MM
CP161076	M2A 38 TRISPIKE CUP POR HA 54MM
CP161095	M-68MM M2A 38 TRISPIKE POR HA
CP161096	M-68MM M2A 38 TRISPIKE POR HA
15-106048HA	M2A-38 CUP NON FLARED HA/PC SZ 48MM
15-106050HA	M2A-38 CUP NON FLARED HA/PC SZ 50MM
15-106052HA	M2A-38 CUP NON FLARED HA/PC SZ 52MM
15-106054HA	M2A-38 CUP NON FLARED HA/PC SZ 54MM
15-106056HA	M2A-38 CUP NON FLARED HA/PC SZ 56MM
15-106058HA	M2A-38 CUP NON FLARED HA/PC SZ 58MM
15-106060HA	M2A-38 CUP NON FLARED HA/PC SZ 60MM