

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 ≥36mm	
	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 >7ppb indicates potential for soft tissue reaction	If blood metal ion level >7ppb then second blood test required 3 months later
2nd blood metal ion level test	Yes - 3 months after 1st blood test if result was >7ppb	Yes - 3 months after 1st blood test if result was >7ppb
Results of 2nd blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously	If blood metal ion levels rising - further investigation required including imaging
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 Bridgend South Wales CF31 3XA



Certificate of Acknowledgement

Email:	(Local Zimmer Biomet Distributor) (Local Zimmer Biomet Distributor) (Local Zimmer Biomet Distributor)		
Regulatory Action: URGENT FIELD SAFETY NOTICE Description: M2a 38mm Acetabular System			
	pelow, I confirm that I have received and understand and have is SAFETY NOTICE.	implemented this	
Printed Name:	Title:		
Facility Name:			
Facility Address:			
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Telephone:	· ·		
Signature:	Date:		



ATTACHMENT 1

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

Item Number		
11-173666	Item Number	Item Description
11-173662 M2A 38MM MOD HO 51M NK 11-173663 M2A 38MM MOD HO 51M NK 11-173664 M2A 38MM MOD HO 54MM NK 11-173664 M2A 38MM MOD HO 54MM NK 11-173665 M2A 38MM MOD HO 54MM NK 11-173667 M2A MODIA HEAD DIAS8MM / 5-3 12/14 11-173665 M2A M2A MODIA HEAD DIAS8MM / 5-3 12/14 11-173667 M2A MODIA HEAD DIAS8MM / 5-3 12/14 11-173668 M2A M2A MODIA HEAD DIAS8MM / 5-7 12/14 11-173698 M2A MODIA HEAD DIAS8MM / 5-7 12/14 11-173698 M2A M2A MODIA HEAD DIAS8MM / 5-7 12/14 11-173699 M2A S8MM MORE PIECE CUP SZ 56MM 11-173699 M2A 38MM MORE PIECE CUP SZ 56MM 11-173690 M2A 38MM MORE PIECE CUP SZ 56MM 11-173690 M2A 38MM MORE PIECE CUP SZ 56MM 11-173690 M2A 38MM M0R PIECE CUP SZ 57MM 11-173690 M2A 38MM M0R PIECE C		
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