

December 28, 2018

To: Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - CORRECTION**

Affected Product: Mobi-C® Cervical Disc Prosthesis

Reference: ZFA2018-00570

Item Number	Lot Number	UDI Number
MB 2795	L080841	(01)3662663018838(17)190801(10)L080841



Image 1: External label with correct height of H5mm



Image 2: Inner label with wrong height of H4,5mm

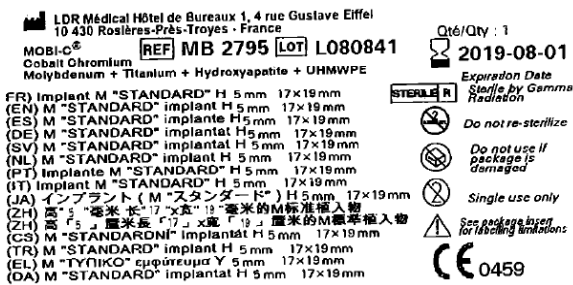


Image 3: Correction: Inner label with correct height of H5mm

LDR Medical is conducting a medical device field action (correction) for one lot of the Mobi-C® Plug & Fit device due to an error in the height listed on inner label.

The potential hazard associated with this problem are:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>Minor delay without patient harm</i>	<i>Rescheduling of the surgery as no other product is available and noticed prior to disc removal. If noticed after disc removal, surgical time extension <15 min or patient is fused.</i>
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>None</i>

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between November 2014 and December 2016.

This will be a field based correction to update patient history records for product already implanted or to replace the inner label of remaining inventory.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Ensure you have received the correct inner labels (see Image 3).
3. If you have affected product that were already implanted, please:
 - a. Locate the patient history for the affected product that was already implanted.
 - b. Remove the wrong inner label (see Image 2) and add the correct inner labels in the patient history to add clarification.
 - c. Scrap the wrong inner labels.
4. If you have affected product remaining in your inventory remove and scrap the existing inner label, then replace with the correct inner label. Alternatively, you can contact your sales representative to return the affected product.
5. Complete **Attachment 1 – Certificate of Acknowledgement** and send to Complaint-LDR@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
6. Retain a copy of the acknowledgement form with your correction records in the event of a compliance audit of your facility's documentation.
7. If you have further questions or concerns after reviewing this notice, please send an e-mail to Complaint-LDR@zimmerbiomet.com

8. If you have further questions or concerns after reviewing this notice, please call customer service at (+33) 3 25 82 32 63 between 8:30 am and 5:00pm (GMT-01:00, Brussels, Madrid Paris), Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to Complaint-LDR@zimmerbiomet.com.

Other Information

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

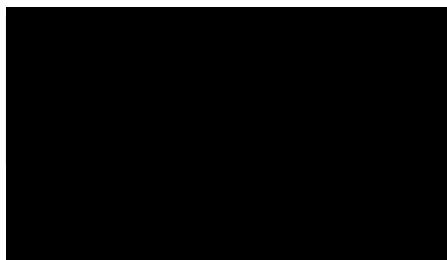
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Complaint-LDR@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Mobi-C Plug&Fit MB2795 lot L080841
ZFA Number: 2018-00570

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

☐ **Hospital Facility** ☐ **Surgeon** (Please check one as applicable)

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** () _____ - _____ **Date:** ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ **ZIP:** _____ **Country:** _____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: Complaint-LDR@zimmerbiomet.com

Even if you have no product to return, this form must be completed, signed and returned.

Choose the following options:

☐ All received products were used (implanted)

Or complete the chart below for remaining products:

Product Reference	Lot Reference	Quantity Replaced

Comments (if needed): _____