ZIMMER BIOMET

May 21, 2019

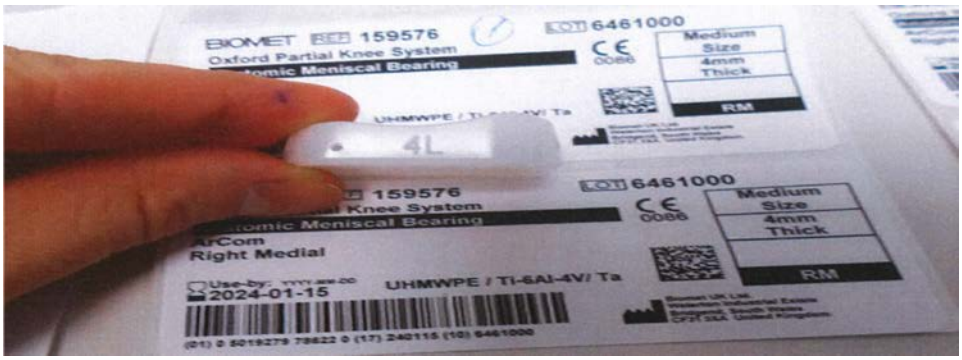
To: Hospitals

Subject: **URGENT FIELD SAFETY NOTICE - REMOVAL**

Reference: **ZFA2019-00113**

Affected Product: Oxford Anatomic Meniscal Bearing ArCom -Size 4, Medium

Item Number	Lot Number	UDI Number
159576	6461000	0 5019279 79622 0 240115 6461000



Biomet UK Ltd. is conducting a medical device Field Safety Notice Action (removal) for lot specific **Oxford Anatomic Meniscal Bearing ArCom -Size 4, Medium**. A complaint investigation revealed that a left handed bearing had been supplied within the package labeled for a right handed bearing. The bearing is engraved correctly and would be noticed when removed from the package. It is likely that the issue is noticed by the user prior to the implantation of the bearing due to the difference in geometry and it is etched as a left handed bearing. In the unlikely event that the user may attempt to implant the left handed bearing, it will be recognized that it does not feel like the trial bearing which has to be used per applicable surgical technique.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Extension to surgery <30 minutes	Extension to surgery >30 minutes due to change of the surgical approach
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Potential for revision surgery due to pain and or/loss of knee function

Our records indicate that you may have received one or more of the affected products. The product was deployed from 21 February 2019 till May 2019 (local deployment might differ).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

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 per.nl@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,

_____
Zimmer Biomet

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Oxford Anatomic Meniscal Bearing ArCom -Size 4, Medium

Field Action Reference: ZFA2019-00113

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.netherlands@zimmerbiomet.com

○I received and understood the Field Safety Notice.

Regarding the products:
○All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

OR
○The affected products which are unavailable for return have been: ○used ○discarded ○lost ○ other:

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: Date: /_ /_

Title: _____ Telephone: ( ) -

Facility Name:_____ Facility Address: _____

NOTE: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to fieldaction.netherlands@zimmerbiomet.com .