May 8, 2019

To: Hospitals

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

Reference: **ZFA2018-00529**

Affected Product: Oxford Unicompartmental Knee Drill Guides (Phase 3/Domed Lateral)

Item Number	Lot Number	Item Description	Item Number	Lot Number	Item Description
32-420321	ZB160201	Phase 3 Femoral Drill Guide Small	32-420323	ZB170301	Phase 3 Femoral Drill Guide Large
32-420321	ZB160401		32-420323	ZB170401	
32-420321	ZB161101		32-420323	ZB170901	
32-420321	ZB170401		32-420324	ZB110301	Phase 3 Femoral Drill Guide Extra Large
32-420321	ZB170601		32-421060	ZB160601	Phase 3 Femoral Drill Guide Extra Small
32-420321	ZB170801		32-421060	ZB170201	
32-420321	ZB170901		32-421060	ZB170601	
32-420322	ZB130801	Phase 3 Femoral Drill Guide Medium	32-421930	ZB160101	System Domed Lateral Femoral Drill Guide Small
32-420323	ZB161102	Phase 3 Femoral Drill Guide Large	32-421930	ZB160801	
32-420323	ZB170201		32-421931	ZB150901	System Domed Lateral Femoral Drill Guide Medium

Zimmer Biomet is conducting a lot specific medical device field action for the Oxford Unicompartmental Knee Drill Guides (Phase 3/Domed Lateral) due to the incorrect raw material used by the supplier in the manufacturing of the screw component, which material could potentially lead to corrosion.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None – alternative device obtained and used.	*Device used and corrosion identified during surgery – extension to surgery > 30 minutes to obtain new device.*
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 – alternative device obtained and used.	*Adverse tissue reaction/inflammatory response due to foreign debris. Potential revision surgery required as a result.*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between March 2016 and August 2018 (Local deployments may 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 field action 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,

……..
……..

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Oxford Unicompartmental Knee Drill Guides (Phase 3/Domed Lateral)

Field Action Reference: ZFA 2018-00529

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 parts:

All inventories for the affected parts have been checked and following parts are to be returned:

Reference	Lot Reference	Number of parts returned

OR

The affected parts which are unavailable for return have been: 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:** _____

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