February 26, 2018

To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Reference: **FA 2018-01 (ZFA2018-03)**

Affected Product: Innex Tibia Insert (Knee implant) and Modular Bipolar Insert (Hip implant)

Item Number	Description	Lot Number
01.02001.379	INNEX TIB INSERT FIXUC L/12.5	2892898
61.27.28-42	MODULAR-BIPOLAR INSERT 28 / 42	2891591

Table 1: Affected products

Zimmer GmbH is conducting a voluntary medical device field action (removal) for two specific lot numbers as indicated above.

Internal investigation revealed that the outer blister packaging of the above two lots were potentially not sealed in a correct and complete manner as the sealing temperature was not met. Further investigation confirmed that the issue is limited to the above two lots. To date we have not received any complaints for these specific lots which suggests there exist a connection with the packaging issue.

As a precautionary measure it was decided to remove all remaining implants in the markets.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	Issue might be detected prior use intraoperatively (not continuously sealed outer Blister) and a slight delay might occur (less than 30min) to obtain a new implant.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	Non-sterile implant might lead to local infection leading to potential revision surgery, systemic infection conducting in potential loss of limb.

Our records indicate you may have received one or more of the affected lots which were released in March 2017.

Surgeon/ Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. Assist your Zimmer Biomet sales representative to quarantine all affected implants.
3. Your Zimmer Biomet sales representative will remove the affected implants from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.emea@zimmerbiomet.com.
    b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your documentation.
5. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

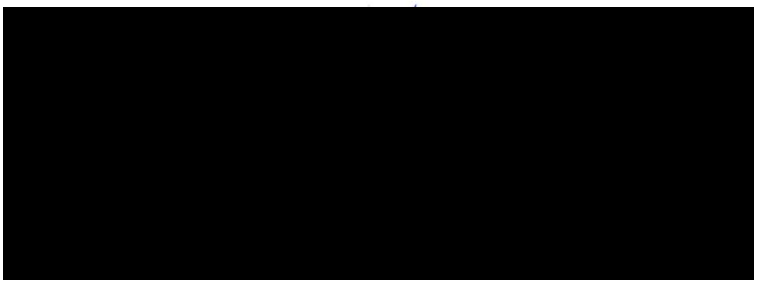
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@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.



ATTACHMENT 1
Certificate of Acknowledgement FA2018-01 (ZFA2018-03)

Affected Product: Innex Tibia Insert (Knee implant) and Modular Bipolar Insert (Hip implant)

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: fieldaction.emea@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	Number of products returned

Comments (if needed): _____