April 30, 2019

To: Hospitals

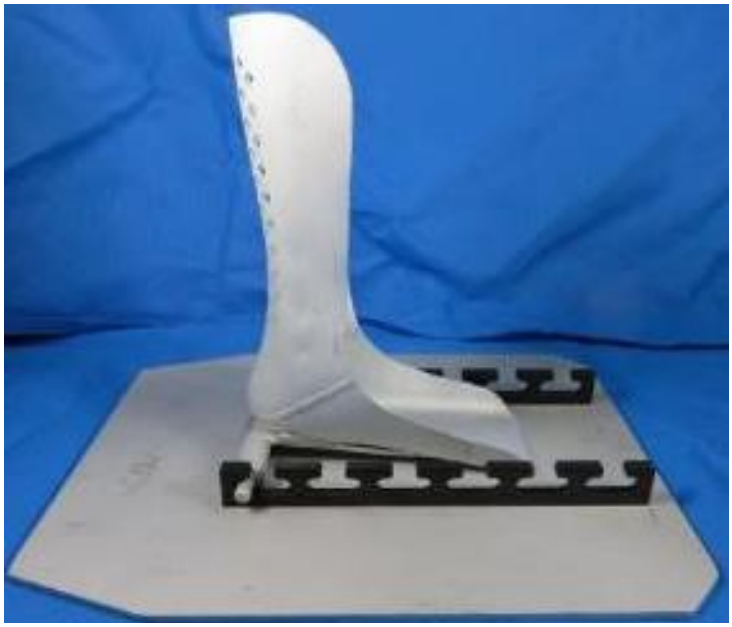
Subject: **URGENT MEDICAL FIELD SAFETY NOTICE- REMOVAL**

Reference: ZFA2019-00020

Affected Product: Alvarado™ Knee Holder Base Plate Assembly and Foot Piece, & Alvarado™ II Base Plate and Foot Piece

Item Number	Description
00-1320-010-00	Alvarado Foot Piece
00-1320-011-00	Alvarado™ Knee Holder Base Plate Assembly
00-1320-210-00	Alvarado™ II Foot Piece
00-1320-211-00	Alvarado™ II Base Plate

*Note: These items may have been ordered as a component in the Alvarado™ Systems Kit (00-1320-000-00) and the Alvarado™ II System Kit (00-1320-200-00). The kits themselves are not being recalled/ removed. Please remove the affected items listed in the table above from the kit and return the affected items only.



Zimmer Biomet is conducting a medical device field safety action/ removal for all lots of the Alvarado™ Knee Holder Base Plate Assembly and Foot Piece and all lots of the Alvarado™ II Base Plate and Foot Piece due to potentially inadequate cleaning procedures.

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	Infection
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	Revision Surgery

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between January 1982 and February 2019 (local deployment might differ). All distributed product is being removed from the field.

Hospital Responsibilities:

1. Immediately locate and quarantine affected product in your inventory.
2. Immediately return all affected product from your facility. **ONLY RETURN THE FOOT PIECE AND BASE PLATE**. For each return:
    a. Send a copy of **Attachment 1** to fieldaction.netherlands@zimmerbiomet.com regardless of whether your facility has affected product.
    b. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
3. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
4. 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,

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ZIMMER BIOMET

ATTACHMENT 1

Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Alvarado™ & Alvarado™ II Base Plate & Foot Piece
ZFA Number: ZFA 2019-00020

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: ☐ 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.