ZIMMER BIOMET

April XX, 2019

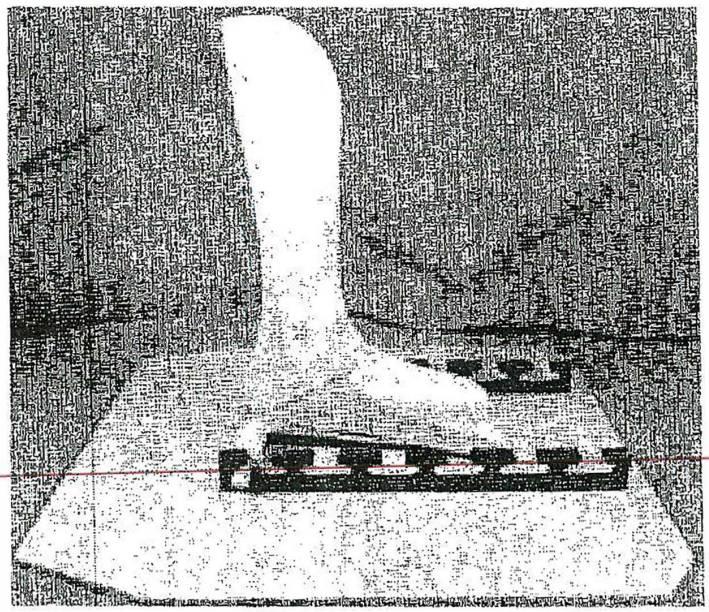
To: Risk Managers

Subject: URGENT MEDICAL DEVICE RECALL

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. 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 recall 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.

As product becomes available, Zimmer Biomet will provide a 1-for-1 exchange for all Alvarado™ Knee Holder Base Plate Assembly and Foot Piece product returned and for each Alvarado™ II Base Plate and Foot Piece product returned. Additional details can be provided by contacting your Zimmer Biomet Sales Rep.

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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. All distributed product is being removed from the field.

Risk Manager 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 CorporateQuality.PostMarket@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.
   c. Include a copy of **Attachment 2– Certificate of Sterilization**
   d. Mark "RECALL" on the outside of the returned cartons.
3. Retain a copy of the acknowledgement form with your recall 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 call customer service at 800-830-0970 between 8:00 am and 5:00pm EST, 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 CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

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Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing SurgicalRegulatoryReporting@zimmerbiomet.com.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

_____

Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director

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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

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer Surgical, Inc.
ATTN: QA/RA Dept. – Recall
200 West Ohio Avenue
Dover, OH 44622

After reviewing the account for affected inventory please check "Yes" or "No" for the following statements:		
There are affected products at this account to return. (if yes is checked, complete the table below with the item and lot information)	**Yes** ☐	No ☐
This is the final return for the entire account. An exhaustive search has been performed for the affected products.	**Yes** ☐	No ☐

Note: Any product not returned or found in your territory is considered lost and unavailable for use.

Item Number	Lot Number	UDI Number	Quantity Returned

Note: Only the Foot Piece and Base Plate products (item numbers: 00-1320-010-00, 00-1320-011-00, 00-1320-210-00 and 00-1320-211-00) are recalled and should be returned.

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to CorporateQuality.PostMarket@zimmerbiomet.com with this form.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) _____ **Ext.** _____ **Date:** _____

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 CorporateQuality.PostMarket@zimmerbiomet.com. Include a copy of this completed form with your product returns. **Please do not return affected product with other returns.**

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ATTACHMENT 2
Certificate of Decontamination

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

By signing below, I acknowledge that the instrumentation being quarantined has been cleaned and sterilized prior to being returned to Zimmer Biomet.

Describe method of disinfecting: _____

Printed Name: _____ Signature: _____

Title: _____ Phone: ( ) _____-_____ Date: ____/____/_____

Attachment 2, Certificate of Sterilization, is only required when returning used instruments from the field or when returning product that has been removed from its sterile packaging and held in a clinical environment where there is a potential for exposure to biological contamination.