December 16, 2020

To: Hospitals and Surgeons

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

Reference: **ZFA 2020-00331**

Affected Product: Vanguard 360 Revision System Posterior Augment Block with Bolt

Item Number	Lot Number	UDI Number
185422	098780	(01) 00880304482739 (17) 290501 (10) 098780

As a precautionary measure Biomet Orthopedics LLC is conducting a medical device Field Safety Corrective Action (Removal) for a single lot of Vanguard 360 Revision System Posterior Augment Block with Bolt due to potentially having an incorrect bolt. The investigation determined that tibia augment bolts were likely issued to lot M098780 instead of the required femoral augment bolts. The issue was identified during surgery when the surgeon tried to use the bolt for the augment block but was unable to fix the block with the bolt. In the event of an incorrect bolt, it is easily recognized by the user and a replacement bolt could be obtained from another distal or posterior augment from the same system to complete the surgery. To date no adverse events are reported.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant extension in surgery to find replacement part.	Non-clinically significant extension in surgery to find replacement part.
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	None

Our records indicate that you may have received one or more of the potentially affected products. The potentially affected products were distributed between May 2019 and July 2019. (Local deployment may differ).

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that all involved personnel are aware of the contents.
2. If you have potentially affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected products. Your Zimmer Biomet sales representative will remove the potentially affected products from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com . This form will be returned even if you do not have potentially affected products at your facility.
4. Retain a copy of the acknowledgement form with your Field Safety Corrective 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 Field Safety 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 units 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 Field Safety 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 Safety Corrective Action.

Sincerely,

_____

xxx

ZIMMER BIOMET

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Vanguard 360 Revision System Posterior Augment Block with Bolt

Field Safety Corrective Action Reference: ZFA 2020-00331

Please return the completed form to your Zimmer Biomet contact person or by e-mail
fieldaction.netherlands@zimmerbiomet.com

□ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

□ The potentially 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:** _____

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