April 21, 2017

To: Risk Managers/ Surgeons

Subject: **URGENT FIELD SAFETY NOTICE**
Reference: **ZFA2017-93**

Affected Product: **Bone Dowell Harvest Tube**

Item Number	Lot Number
900738	889990

This notice is to inform you of a lot specific VOLUNTARY URGENT FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet Orthopedics (Biomet Sports Medicine) affecting 1 lot of the Bone Dowell Harvest Tube.

The disposable Bone Dowel Harvest Tubes, used in conjunction with other instruments, provide a means for harvesting a bone plug while creating a tunnel for Anterior Cruciate Ligament/ Posterior Cruciate Ligament (ACL/PCL) reconstruction.

The reason for this action is that the harvest tube (PN 900738, LN 889990) was mislabeled as 8mm tube but it is actually 9 mm in size. A 9mm subcomponent was erroneously substituted and etched as 8mm for the actual 8mm subcomponent part.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Surgical Delay, Significant / User Dissatisfaction	Soft Tissue Damage Surgical Delays
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	Poor Joint Mechanics

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of July 2016 and March 2017.

Risk Manager Responsibilities:

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

Other Information

This voluntary Urgent Field Safety Notice will be reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Authorities.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this field action.

Sincerely,

_____

Zimmer Biomet

ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Field action Notice.

Hospital Facility

Printed Name:_____ **Signature:** _____

Title:_____ **Telephone:** ( )____-_____ **Date:**___/___/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

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.netherlands@zimmerbiomet.com