ZIMMER BIOMET

30 July, 2019

To: Hospital

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

Reference: **ZFA2019-00187**

Affected Product: Allofit®-S Alloclassic® shell size 52/II and size 54/JJ

Item Number	Item Description	Lot Number
4265	Allofit®-S Alloclassic®, shell with polar screw plug, uncemented, 52/II	2984922
4266	Allofit®-S Alloclassic®, shell with polar screw plug, uncemented, 54/JJ	2984958
		2984959

Zimmer GmbH is conducting a medical device field safety corrective action (removal) for above listed lots of Allofit®-S Alloclassic® shell due to a potential mix-up between size 52/II and size 54/JJ. As a precautionary measure it was decided to remove all affected products from the market.

The issue is detectable as the surgeon will notice the difference in size as the prepared bone area is too small or too big.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	A replacement device is available, the surgeon will complete the surgery by using another device (delay in surgery < 30min).	None
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	If a replacement device is not available, the surgeon will need to change the surgery approach (delay in surgery time > 30min) or postpone the completion of the surgery.	If replacement device is not available and surgeon does not change the surgery approach, this could lead to a bone fracture or implant dislocation / loosening, depending on the implanted device size.

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Our records indicate that you may have received one or more of the affected products. The affected units were distributed between February 2019 and May 2019. (local deployments might differ)

Hospital Responsibilities:

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

Sincerely,

Maik Koecher
Director Quality Assurance & Regulatory Compliance

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Allofit®-S Alloclassic® shell size 52/II and size 54/JJ

Field Action Reference: ZFA 2019-00187

Please return the completed form to your Zimmer Biomet contact person: fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Reference	Lot Reference	Number of parts returned

OR

☐ The affected products which are unavailable for return have been implanted

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:**_____