

December 28, 2018

To: Hospitals

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

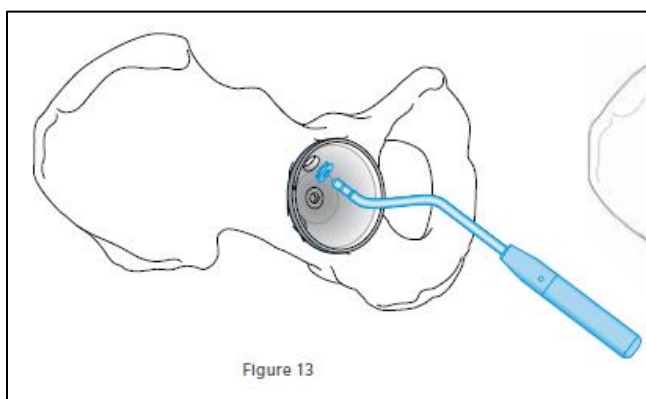
Reference: FA 2018-07 (ZFA 2018-00632)

Affected Product: Allofit Alloclassic Screw Plug

Item Number	Item Description	Lot Number
01.00004.001	Allofit Alloclassic Screw Plug	2955750

Zimmer GmbH is conducting a medical device field safety corrective action (removal) for one single lot of Allofit Alloclassic Screw Plugs due to missing screw plugs in the packaging. The packaging should contain seven (7) Screw Plugs, but one (1) Screw Plug was inserted in the packaging.

The issue is detectable through a visual inspection of the packaging prior use. Please note that the Allofit Alloclassic Screw Plugs are optional and don't need to be use during the surgery. Therefore there is no patient risk.



Picture 1: Insertion of Screw Plug,
Extract of ST 06.01205.012-REV07-1216 A4 (page 10)



Picture 2: Missing Screw Plugs

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>Use of an alternative box with Screw Hole Plugs (<30min); if requested by the surgeon.</i>
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>None</i>

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between mid of August 2018 and end of November 2018 (local deployments might differ).

Hospital Responsibilities:

1. Review this notice and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fielddaction.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.

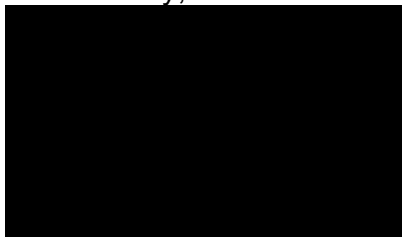
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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,



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Allofit Alloclassic Screw Plug **Field Action Reference:** **ZFA 2018-00632**

Please return the completed form to your Zimmer Biomet contact person or by e-mail
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

Printed Name: _____ **Signature:** _____ **Date:** ____/____/____

Title: _____ **Telephone:** () ____ - ____

Facility Name: _____ **Facility Address:** _____

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