October 31, 2018

To: Hospitals/ Surgeons

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

Reference: **FA2018-06 (ZFA2018-00572)**

Affected Product: Avenir® Müller Stem, size 1

Item Number	Item Description	Lot Number
01.06010.001	Avenir Müller Stem Standard, uncemented HA, 1, Taper 12/14	2955599

Zimmer GmbH is conducting a medical device field safety corrective action (removal) for one single lot of Avenir Müller Stem due to comingle between the labeling on the packaging and the stem contained in the package. Indeed the label on the packaging is size 1 (reference 01.06010.001- lot 2955599) whereas the stem inside the packaging is an Avenir Müller Stem size 2 (reference 01.06010.002- lot 2956599).

The issue is detectable through the marking on the stem while inspecting the product prior to final implantation.

Picture 1: View of the label showing size 1

Picture 2: Confirmation of size 2 on implant

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Another stem of the planned size is used to complete the surgery (< 30min).	*When there is no planned size implant available, re-prepare the bone for the available lager size (surgical extension >30min). Risk of cortical bone fracture due to re-preparing the bone.*
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	*Extended anesthesia time might impact rehabilitation of the patient. A potential revision surgery might be needed at a later stage due to the larger size implanted (fracture, dissymmetry in patient`s leg and/or limited range of motion).*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between mid of September 2018 and end of October 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 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,

Said Djaouat
VP EMEA QARC

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Avenir® Müller Stem, size 1 **Field Action Reference: ZFA2018-00572**

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:**_____