Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands
T: +31-(0)24-3501603
E: info@spierings.biz
I: www.spierings.biz
Registration no: 09127228

August 22, 2019

To: Hospital
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE-REMOVAL**
Reference: PS/ps/SO-BRF-19x041
Affected Product: REX Cement Stop™

Item Number	Description	Lot Number	Distribution period
REX-0709-9	REX Cement Stop Ø 9	011801	From July 22nd, 2019
REX-0709-10	REX Cement Stop Ø 10	021805 101703 111801	From July 22nd, 2019
REX-0709-11.5	REX Cement Stop Ø 11.5	111801	From July 22nd, 2019
REX-0709-13.5	REX Cement Stop Ø 13.5	111801	From July 22nd, 2019
REX-0709-16	REX Cement Stop Ø 16	011904	From July 22nd, 2019

Spierings Orthopaedics B. V. is conducting a voluntary medical device Field Safety Corrective Action (Removal) for above listed lots of Rex Cement Stops distributed between Monday July 22nd, 2019 and Thursday July 25th ,2019. The REX Cement Stop™ contains a gelatin bushing which will melt and deform at higher temperatures. The storage and transportation temperature must be between 5 and 30 degrees Celsius as indicated on the labelling and Instructions For Use. Due to the extreme high temperatures in Western Europe between Monday July 22nd, 2019 and Thursday July 25th, 2019, the products with above listed lots may have been subject to a temperature above the maximum allowable threshold during transport. As precautionary measure Spierings Orthopaedics B. V. in cooperation with Zimmer Biomet, the distributor, has decided to remove all potentially affected products from the market.
In case the REX Cement Stop™ is exposed to high temperatures, the gelatin bushing may deform. Depending on the amount of deformation, the bushing might no longer fit in the intramedullary canal and as a consequence of such it cannot be placed at the reamed and desired depth in the canal. The deformation can be detected by the user while opening the product's packaging or during its insertion, if in accordance with the Instruction for Use, the product's depth is monitored by means of the depth indicator on the insertion instrument.

Risk	**Probability**	**Severity**
The REX Cement Stop is minimally deformed and will function properly	Unknown	Negligible
The REX Cement Stop is deformed and cannot be used. A replacement device is available, the surgeon will complete the surgery without a clinically relevant delay	Unknown	Negligible
The REX Cement Stop is deformed and cannot be used. There is no replacement device available. The surgeon completes surgery without using a cement restrictor, which may result in earlier revision surgery in the future.	Unknown	Serious

Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands
T: +31-(0)24-3501603
E: info@spierings.biz
I: www.spierings.biz
Registration no: 09127228

Our records indicate that you may have received one or more of the potentially affected products. The potentially affected units were distributed between Monday July 22nd, 2019 and Thursday July 25th ,2019 (Local deployment may differ).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Identify and quarantine the REX Cement Stop™ in scope as described in the table above. Please contact your local Zimmer Biomet representative to have these products returned and replaced.
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 the potentially affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall 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 rev. 8 in Europe.

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 apologize for any inconvenience occurred due to this field action.

Sincerely,

[redacted]

Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands
T: +31-(0)24-3501603
E: info@spierings.biz
I: www.spierings.biz
Registration no: 09127228

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: REX Cement Stop™

Field Action Reference: PS/ps/SO-BRF-19x041

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 potentially affected products have been checked and following products are to be returned:

Reference	Lot Reference	Number of products returned

OR

☐ The potentially 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:**_____