ZIMMER BIOMET

October 4, 2018

To: Surgeons/ Hospitals

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

Affected Product: StageOne Hip Cement Spacer Mold

Item Number	Lot Number	UDI Number	Size
431207	705550	(01)00880304447165(17)270927(10)705550	43 MM
431209	705570	(01)00880304447141(17)270916(10)705570	51 MM
431209	705580	(01)00880304447141(17)270916(10)705580	51 MM

Zimmer Biomet is conducting a lot specific medical device field safety corrective action for the 43MM and 51MM sized StageOne Hip Cement Spacer Molds due to a potential commingle.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Delay of surgery > 30 minutes*
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	*None*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between September 2017 and January 2018 from the legal manufacturer (local deployment dates might vary).

Hospital Responsibilities:

1. Review this notification 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.eire@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.

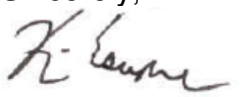
Other Information
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.uk@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,



Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: StageOne Hip Cement Spacer Molds Field Action Reference: ZFA 2018-00366
By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

[ ] **Hospital Facility** [ ] **Surgeon** (Please check one as applicable)

Printed Name: _____ Signature: _____

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

Facility Name: _____

Facility Address: _____

City:_____ ZIP:_____ Country:_____

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.eire@zimmerbiomet.com.

Even if you have no product to return, this form must be completed, signed and returned.

Choose the following options:

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 parts which are unavailable for return have been: discarded lost other: _____