ZIMMER BIOMET

March 10, 2020

To: Hospital

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

Reference: ZFA2020-00026

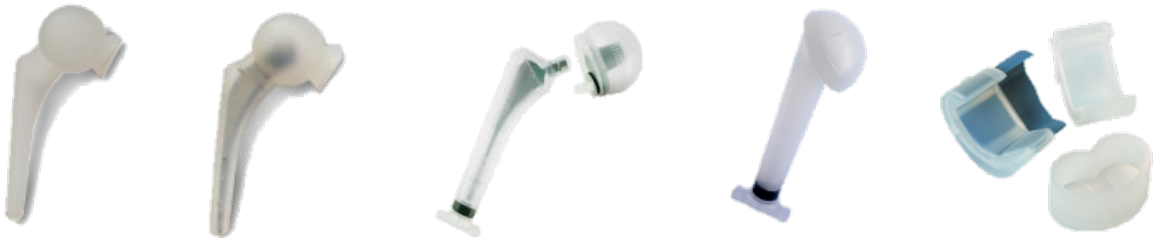
Affected Product: StageOne™ and StageOne™ Select Bone Cement Spacer Molds

All lots expiring prior to February 28, 2030			
Item Number	**Description**	**Item Number**	**Description**
431107	StageOne Hip Cement Spacer Mold, 9 X 125 MM, 43 MM	431207	StageOne Hip Cement Spacer Mold with Reinforcement, 9 X 125 MM, 43 MM
431109	StageOne Hip Cement Spacer Mold, 9 X 125 MM, 51 MM	431209	StageOne Hip Cement Spacer Mold with Reinforcement, 9 X 125 MM, 51 MM
431113	StageOne Hip Cement Spacer Mold, 13 X 145 MM, 57 MM	431213	StageOne Hip Cement Spacer Mold with Reinforcement, 13 X 145 MM, 57 MM
431117	StageOne Hip Cement Spacer Mold, 17 X 165 MM, 64 MM	431217	StageOne Hip Cement Spacer Mold with Reinforcement, 17 X 165 MM, 64 MM
431181	StageOne Select Hip Head Cement Spacer Mold with Insert, 48 MM	431406	StageOne Shoulder Cement Spacer Mold, 6 MM, 42 X 18 X 46 MM, Standard
431182	StageOne Select Hip Head Cement Spacer Mold with Insert, 52 MM	431408	StageOne Shoulder Cement Spacer Mold, 8 MM, 46 X 18 X 53 MM, Standard
431183	StageOne Select Hip Head Cement Spacer Mold with Insert, 56 MM	431410	StageOne Shoulder Cement Spacer Mold, 10 MM, 50 X 21 X 57 MM, Standard
431184	StageOne Select Hip Head Cement Spacer Mold with Insert, 60 MM	431412	StageOne Shoulder Cement Spacer Mold, 12MM, 54 X 21 X 64 MM, Standard
431185	StageOne Select Hip Head Cement Spacer Mold with Insert, 64 MM	431414	StageOne Shoulder Cement Spacer Mold, 14 MM, 58 X 24 X 64 MM, Standard
431190	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 9 X 125 MM	432160	StageOne Knee Femoral Cement Spacer Mold, 60 MM
431191	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 11 X 135 MM	432165	StageOne Knee Femoral Cement Spacer Mold, 65 MM
431192	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 13 X 145 MM	432170	StageOne Knee Femoral Cement Spacer Mold, 70 MM
431193	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 15 X 155 MM	432175	StageOne Knee Femoral Cement Spacer Mold, 75 MM
431194	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 17 X 165 MM	433165	StageOne Knee Tibial Cement Spacer Mold, 65 MM
431195	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 9 X 200 MM	433170	StageOne Knee Tibial Cement Spacer Mold, 70 MM
431196	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 11 X 200 MM	433175	StageOne Knee Tibial Cement Spacer Mold, 75 MM
431197	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 13 X 200 MM	433180	StageOne Knee Tibial Cement Spacer Mold, 80 MM
431198	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 15 X 200 MM	CP161972	StageOne Custom Hip Femoral Reinforcement, 9 X 125 MM
431199	StageOne Select Hip Stem Cement Spacer Mold with Reinforcement, 17 X 200 MM		

As a precautionary measure Zimmer Orthopedics is conducting a medical device Field Safety Corrective Action (removal) for StageOne™ and StageOne™ Select Bone Cement Spacer Molds. Certain devices may have been subject to a potentially insufficient cleaning process or to potentially inadequate process monitoring for cleaning parameters. For the more than 230,000 devices distributed, to date there have been five complaints for events which may be associated with this issue.

These devices are a single-use silicone mold intended to be filled with bone cement. Upon curing of the bone cement, a temporary bone cement spacer is created for patients undergoing a two-stage revision due to infection. The resulting bone cement spacer typically remains in place for less than six months with partial weight bearing until the second stage of the two-stage revision is performed to implant a conventional prosthesis.

Representative Devices



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	*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
	None	*Adverse Local Tissue Reaction, Pain or Ache (critical), Reaction to Allergen or Toxin (severe systemic)*

Our records indicate that you may have received one or more of the potentially affected products. The potentially affected units were distributed between January 2009 and January 2020. (Local deployment may differ).

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have any potentially affected implants at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected implants. Your Zimmer Biomet sales representative will remove the potentially affected implants from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.bridgend@zimmerbiomet.com. This form must be returned even if you do not have potentially affected implants 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 Field Safety Notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule. The potential long term risks would likely occur within one year of beginning the two-stage revision.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.bridgend@zimmerbiomet.com. This form must be returned even if you do not have potentially affected implants 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 Field Safety 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 units 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,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: StageOne™ and StageOne™ Select Bone Cement Spacer Molds

Field Action Reference: ZFA 2020-00026

Please return the completed form to your Zimmer Biomet contact person or by e-mail
fieldaction.bridgend@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

☐ The potentially affected units which are unavailable for return have been used

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:**_____