ZIMMER BIOMET

2 December 2019

**To:** Hospitals

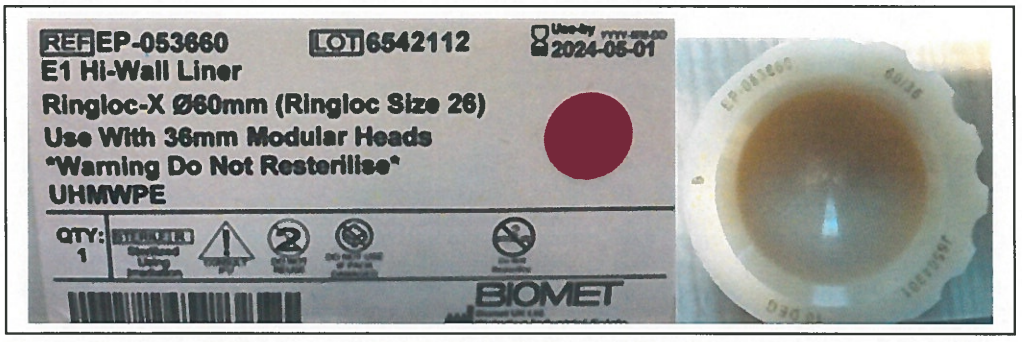
**Subject:** **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - REMOVAL-LOT SPECIFIC**

**Affected Product:** Ringloc Acetabular Liners

**Reference:** ZFA 2019-00326

| Item Number | Lot Number | UDI Number |
|---|---|---|
| EP-053660 | 6542112 | 0 5019279 297269 240501 6542112 |
| 11-105923 | 6450836 | 0 0880304 202559 240106 6450836 |

Biomet UK Ltd. is conducting a medical device Field Safety Corrective Action (removal) for specific lots of Ringloc Acetabular liners indicated in the table above due to the implants not matching the packaging label.




EP-053660 Ringloc-X E1 **HiWall** Lot number 6542112
contains EP-063660 (Ringlox-X E1 **10 Degree**) Lot J6504901


11-105923 Ringloc Liner HiWall **size 23** Lot number 6450836 contains
11-105924 Ringloc Liner HiWall **size 24 Lot J6403948**

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The liners are engraved correctly and would be noticed when removing the item from the package. It is likely that the issue is noticed by the user prior to the implantation of the liner due to the difference in dimensions and geometry.

Should the issue not be noticed when the item in the packaging labelled EP-053660 is removed from the package, then the range of motion assessment conducted by the surgeon during the procedure to ensure that all implants are positioned and aligned optimally as per surgical technique would detect any difficulties with the range of movement.

Should this issue not be noticed when the item in the packaging labelled 11-105923 is removed from the package, then when implanting the liner it will not fit into the shell.

| **Risks** | | |
|---|---|---|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
| | Less than significant extension to surgery | Immediate revision with potential additional bone damage during extraction of shell to refit alternative shell |
| 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 | Potential early revision due to bone loss or increased wear |

Our records indicate that you may have received one or more of the affected products. The units were distributed from January 2019. (Local deployment may be different )

**Hospital Responsibilities:**

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

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**Surgeon Responsibilities:**

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.nordics@zimmerbiomet.com
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 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.dk@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. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this field action.

Sincerely,

02-DEC-2019

Martin Rudkin

QA/QC Associate Director

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# ATTACHMENT 1
## Certificate of Acknowledgement

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: Ringloc Acetabular Liners  Field Action Reference: ZFA 2019-00326**

**Please return the completed form to your Zimmer Biomet contact person or:** fieldaction.nordics@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 ☐discarded ☐lost ☐other:

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

**Printed Name:** _____ **Signature:** _____

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

**Facility Name:** _____

**Facility Address:** _____

**City:**_____ **Postcode:**_____

**Country:** _____

**Note:** This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to fieldaction.nordics@zimmerbiomet.com