ZIMMER BIOMET

October 16, 2018

**To:** Hospitals and Surgeons

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

**Reference:** **ZFA2018-00271**

**Affected Product:** RapidFlap™ System SpinDown Clamp

| Item Number | Product Description | Lot Expiry Date Before |
|---|---|---|
| 75-1020 | 12MM RapidFlap SpinDown Clamp | 09/18/2023 |
| 75-1020-12 | 12MM RapidFlap SpinDown Clamp, 12 Pack | |
| 75-1030 | 16MM RapidFlap SpinDown Clamp | |
| 75-1030-12 | 16MM RapidFlap SpinDown Clamp, 12 Pack | |
| 75-1040 | 20MM RapidFlap SpinDown Clamp | |
| 75-1040-12 | 20MM RapidFlap SpinDown Clamp, 12 Pack | |

Zimmer Biomet is conducting a medical device field safety corrective action for the Spin Down RapidFlapTM for product manufactured prior to September 17, 2018 due to the nut that interfaces with the outer plate potentially being misassembled. The nut shown in the photo above should be located above the plate. It is estimated the misassembled conditioned occurred at a rate of 0.01% prior to process improvements implemented on September 17, 2018 to prevent the misassembled condition from occurring.

| Risks | | |
|---|---|---|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
| | Minor delay in surgery | Minor delay in surgery |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
| | No long range health consequences are anticipated. | Medical intervention due to post-operative device failure. |

Our records indicate that you may have received one or more of the affected products. The affected units were distributed from July of 2013 and September of 2018 (local deployment may 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.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.

**Surgeon Responsibilities:**

1. Review this notification for awareness of the contents.
2. The patients should be monitored frequently post operatively until boney fusion occurs (approximately 6-8 weeks).
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@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, please contact your Zimmer Biomet representative.

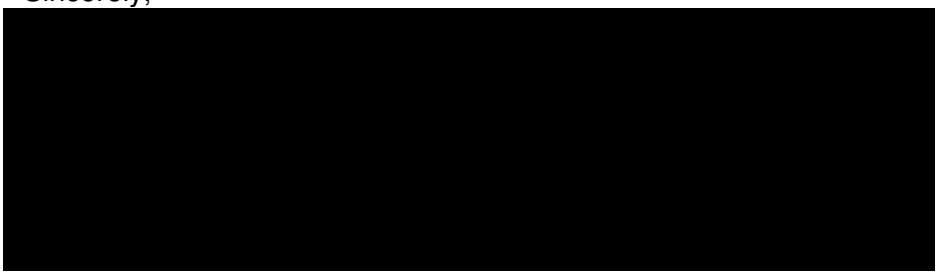
**Other Information**
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

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,



# ATTACHMENT 1
## Certificate of Acknowledgement

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

**Affected Product:** Spin Down RapidFlap™ **Field Action Reference: ZFA 2018-00271**

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.emea@zimmerbiomet.com.

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

**Choose the following options:**

☐ All received products were used (implanted)

*Or complete the chart below for remaining products:*

| Product Reference | Lot Reference | Number of products returned |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Comments (if needed): _____