

April 17, 2018

To: Surgeons/ Hospitals

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

Reference: ZFA2018-00088

**Affected Product: Gentle Threads Interference Screw (Lot specific)**



Part number	Lot Number
905617	207910
905604	326860
905604	326880
905605	326900
905607	326920
905608	326960
905615	326980
905615	371540

Zimmer Biomet is conducting a medical device field action (removal) for specific lots of the Gentle Threads Interference Screws due to overexposure during EtO (Ethylene Oxide) sterilization. No adverse events have been reported. This field action is being initiated to recover any units from the above-referenced production lots that are available for return.

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	Revision due to infection from loss of sterile barrier during over-exposure cycle.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between February 2015 and August 2017.

### 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](mailto: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. 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.emea@zimmerbiomet.com](mailto: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.

## Other Information

This voluntary 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.

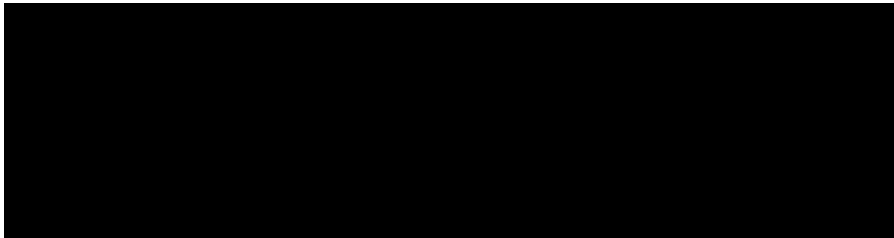
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [winterthur.per@zimmerbiomet.com](mailto:winterthur.per@zimmerbiomet.com) or to your local Zimmer Biomet contact.

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: Gentle Threads Interference Screw      Field Action Reference: 2018-00088**

Please return the completed form to your Zimmer Biomet contact person:  
[fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com)

I received and understood the Field Safety Notice.

**Regarding the products:**

All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

**OR**

All received products were used (implanted)

**OR**

The affected products which are unavailable for return have been:    discarded    lost    other: \_\_\_\_\_

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:** \_\_\_\_\_