



Apr 02, 2020

To: Hospital

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

Reference: ZFA2019-00268

Affected Product: **Comprehensive® Humeral Tray Taper Extraction Pliers -Replacement Tips**

| Item Description | Comprehensive® Humeral Tray Taper Extraction Pliers - Replacement Tips |        |        |         |        |
|------------------|--|--------|--------|---------|--------|
| Item Number      | Lot Numbers  |        |        |         |        |
| 110028522        | 079630   | 197900 | 364910 | 494350  | 516230 |
|                  | 175100   | 233080 | 465800 | 494350R | 742760 |
|                  | 175110   | 362370 | 489000 |         |        |

Biomet Orthopedics, LLC is conducting a medical device Field Safety Corrective Action for Comprehensive® Humeral Tray Taper Extraction Pliers - Replacement Tips due to unknown bioburden levels prior to sterilization, which may affect sterility of the potentially affected products.

| Risks   |               |   |
|---|---------------|---|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.  | Most Probable | Highest Severity                                  |
|   | <i>None</i>   | <i>None</i>                                       |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity                                  |
|   | <i>None</i>   | <i>Infection leading to surgical intervention</i> |

Our records indicate that you may have received one or more of the potentially affected products. The potentially affected products were distributed between January 2016 and August 2019 (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 products at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected products. Your Zimmer Biomet sales representative will remove the potentially affected products from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [fieldaction.uk@zimmerbiomet.com](mailto:fieldaction.uk@zimmerbiomet.com). This form must be returned even if you do not have potentially 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 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 Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [fieldaction.uk@zimmerbiomet.com](mailto:fieldaction.uk@zimmerbiomet.com). This form must be returned even if you do not have potentially affected products at your facility.
4. Retain a copy of the acknowledgement form with your Field Safety Corrective 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.

**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.

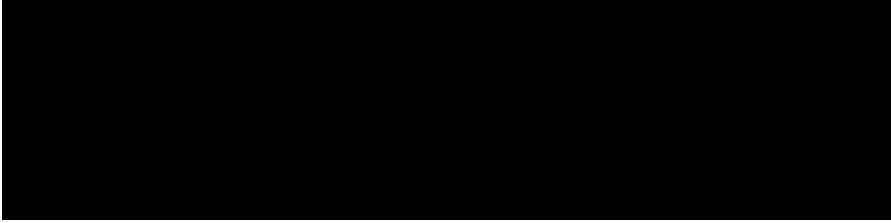
Please keep Zimmer Biomet informed of any adverse events associated with this units or any other Zimmer Biomet product by emailing [per.uk@zimmerbiomet.com](mailto:per.uk@zimmerbiomet.com) or to your local Zimmer Biomet contact.

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 Safety Corrective Action.



Sincerely,



# ATTACHMENT 1

## Certificate of Acknowledgement

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

**Potentially Affected Product:** Comprehensive® Humeral Tray Taper Extraction Pliers -Replacement Tips

**Field Safety Corrective Action Reference:** ZFA 2019-00268

Please return the completed form to your Zimmer Biomet contact person or by e-mail [fieldaction.uk@zimmerbiomet.com](mailto:fieldaction.uk@zimmerbiomet.com)

I received and understood the Field Safety Notice.

**Regarding the parts:**

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

| Item Reference | Lot Number | Number of parts returned |
|----------------|------------|--------------------------|
|                |            |                          |
|                |            |                          |

**OR**

The potentially affected products 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:** \_\_\_\_\_