April 10, 2019

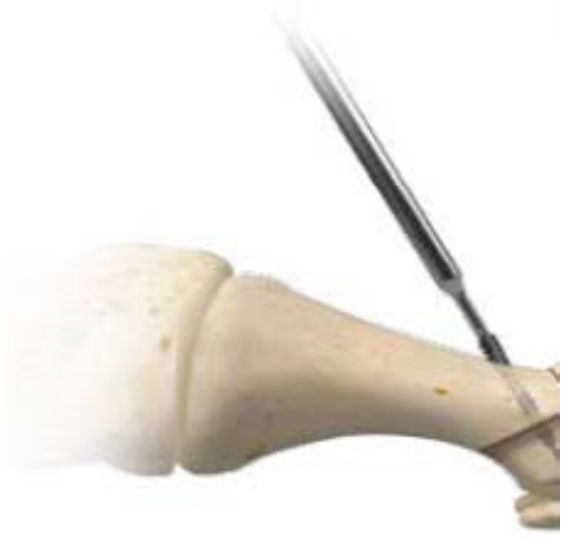
**To:** Hospitals

**Subject:** **URGENT MEDICAL DEVICE REMOVAL AND NOTICE OF DISCONTINUATION**

**Reference:** ZFA2019-00046

**Affected Product:** T7 Cannulated Driver AO and T7 Driver Solid AO

| Item Number | Description | Lot Numbers |
|---|---|---|
| 110018541 | T7 Driver Solid AO | All Lots |
| 110018531 | T7 Cannulated Driver AO | All Lots |



Zimmer Biomet is conducting a removal of the T7 Cannulated Driver AO and T7 Driver Solid AO due to the potential of fracture, bending or shearing of the T7 Driver. The T7 Driver is being redesigned. All distributed product remaining in the field is being removed. The T7 Driver will be replaced with a new design with new part numbers. This letter also serves as a notice for the discontinuation of the current design product.

| 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 extension of surgery generally <30 minutes to find replacement* | *Major extension of surgery generally >30 minutes to find replacement and to remove foreign particles.* |
| 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* | *Retention of foreign particle leading to adverse tissue reaction* |

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2015 and March 2019.

**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 actions 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 local Zimmer Biomet representative.

**Other Information**

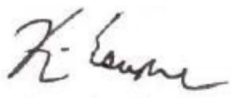
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

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,



Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

# ATTACHMENT 1
## Certificate of Acknowledgement

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

**Affected Product: T7 Cannulated Driver AO and T7 Driver Solid AO**

**Field Action Reference: ZFA 2019-00046**

Please return the completed form to your Zimmer Biomet contact person:
**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
☐ 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: _____

NOTE: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to fieldaction.emea@zimmerbiomet.com .