# FIELD ACTION NOTIFICATION
# IMMEDIATE RESPONSE REQUIRED

February 23, 2017

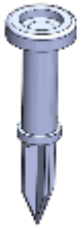
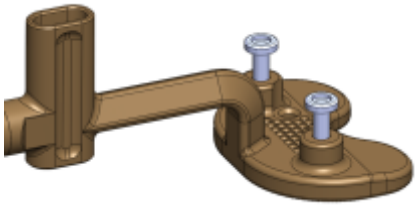
**To:** **Zimmer Singapore Pte Ltd**

**Subject:** **URGENT MEDICAL DEVICE REMOVAL – LOT SPECIFIC**

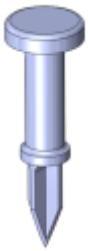
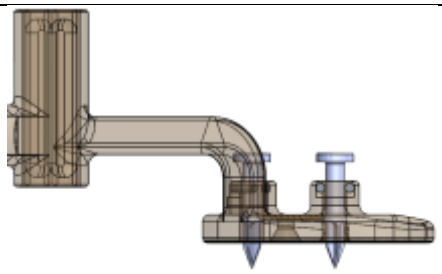
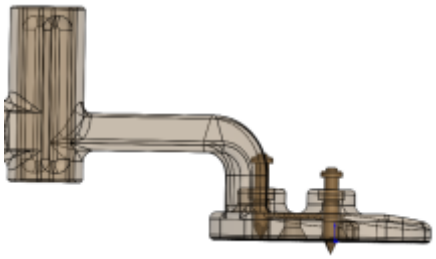
**Affected Product:** iASSIST Validation Tool

Zimmer Biomet is conducting a medical device field removal for the iASSIST Validation Tool. There has been an increase in the number of complaints regarding bent or broken Drive Pins of the Validation Tool manufactured with drawing Revision M to P, see red box below.

**Affected drawing Revision M to P of Drive Pin:**

| | | |
|---|---|---|
| Validation tool<br>**20-8011-021-00 Rev M-P**<br><br>**Affected by the field action** |  |  |

**Unaffected drawing Revision R and drawing Revision L of Drive Pin:**

| | | |
|---|---|---|
| Validation tool<br>20-8011-021-00 Rev R<br><br>**Not affected by the field action** |  |  |
| Validation tool<br>20-8011-021-00 Rev L<br><br>**Not affected by the field action** |  |  |

As indicated in the pictures above, drawing revision M to P of the Drive Pins has an X cross section instead of circular. Also, the Drive Pin head has a recess in the enlarged head. Only iASSIST Validation Tools with drawing revision M to P Drive Pins, in the red box above, are affected by this field removal.

| *Site* | *Item* | *Lot* | *Qty* | *Shipment date* | *Customer PO#* |
|---|---|---|---|---|---|
| **Zimmer Singapore Pte Ltd** | **20-8011-021-00** | 140860 | 1 | 24-Apr-15 | 4500005041 |
| | **20-8011-021-00** | 130542A1 | 1 | 13-Jun-14 | 140155 |
| | | | 2 | | |

Our records indicate that the above product was shipped to you. Please check your inventory and/or distribution records **immediately** for this particular product. If you have this product, secure it from possible use.

**Risks:**

| *Risks* | | |
|---|---|---|
| *Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.* | *Most Probable* | *Worst Case* |
| | Short delay in treatment, less than 30 minutes | Short delay in treatment, less than 30 minutes |
| *Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.* | *Most Probable* | *Worst Case* |
| | None | None |

This letter is initiating Phase I of the lot specific field removal of the iASSIST Validation Tool. You are receiving this letter because our records indicate that you have received an affected product that needs to be corrected. Zimmer Biomet is currently making preparations for replacement activities to follow. This document is provided to alert all users of the potential issue and to highlight proper usage of the instrument per the existing surgical techniques in order to minimize the chance of any failure pending a replacement. A separate field removal notification will be issued with detailed instructions in June 2017. You will be notified when a replacement is available. Do not return any product at this time as a part of this field action.

Your Responsibilities

1. Review this notification and ensure affected team members are aware of the contents.
2. The affected products can continue to be used until replacements are available. To minimize the chances of bending or breakage during use, please follow the iASSIST Knee Surgical Technique (Ref. 97-9001-101-00 Rev 9) and/or iASSIST Knee Surgical Technique (2-Pod Version) (Ref. 97-9001-004-00 Rev 2), specifically the following warning on pages 36 and 37, respectively:


3. Inspect affected devices before and immediately after use to confirm that the Drive Pins are not bent or broken. In case of breakage, the Drive Pin head will disassemble, as shown below. In the unlikely case of a breakage, make sure that both parts are retrieved from the wound.

4. Please keep Zimmer Biomet informed of any adverse events associated with this device by reporting any events to Zimmer Biomet on a Product Experience Report.

5. Complete the Certification of Acknowledgement portion of Attachment 1 – Inventory Return Certification Form – Phase I.
   a. Return a digital copy to Post-Market-Surveillance@zimmercas.com within three (3) days.
6. Note that any hospitals and/or surgeons that received direct shipments of this product from Zimmer Biomet will be sent a copy of the Risk Manager and Surgeon Field Removal Notice directly. It is important that you review the list of hospitals and/or surgeons included with the email notification sent to your facility to identify additional accounts Zimmer Biomet has not notified. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any additional hospitals and/or surgeons that are current users of the affected product. If there are no additional users to notify, please confirm this by annotating and returning the form provided indicating that no additional users have been identified.
7. Retain a copy of your field removal acknowledgement and product return forms for your records in the event of a compliance audit of your facility.

If after reviewing this notice you have further questions or concerns please call 514-395-8883 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to Post-Market-Surveillance@zimmercas.com

**Other Information**

This voluntary field removal was reported to the U.S. Food and Drug Administration, and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Cas-support@zimmercas.com

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. This action is being taken with the knowledge of Health Canada and is in compliance with regulations set forth by Health Canada. Your urgent cooperation is needed.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field removal.

Sincerely,

[redacted]
Isabelle Laframboise
Quality Assurance Manager
Zimmer CAS, Montreal, Quebec

# ATTACHMENT 1

## Inventory Return Certification Form – Phase I

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

**Affected Product:** iASSIST Validation Tool

**Territory Number:** _____ **Account Number:** _____

**Account Name:** _____

**Account Address:**

_____

**Certificate of Acknowledgement:**

By signing below, I acknowledge that I received, read, and understand the contents of this field removal communication. All required activities are complete or are being completed.

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

**Title:** _____ **Tel:** (  ) ____-_____ x _____ **Date:** _/___/_____

**Note: This form and affected product 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:** Post-Market-Surveillance@zimmercas.com