

March 10, 2017

**To:** Risk Managers and Surgeons

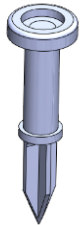
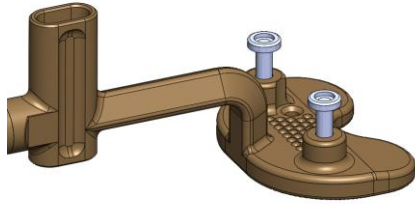
**Subject:** **URGENT MEDICAL DEVICE REMOVAL – LOT SPECIFIC**

**Affected Product:** iASSIST Validation Tool

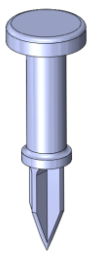
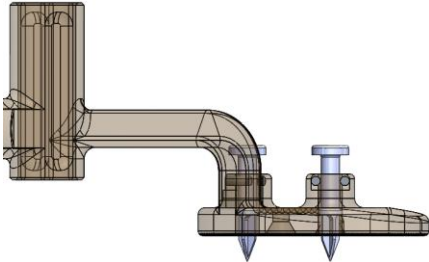

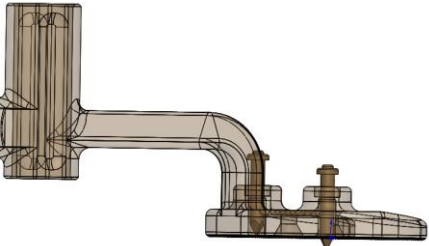
See **Attachment 2 – Affected Product List**

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:**

<p>Validation tool 20-8011-021-00 Rev M-P</p> <p><b>Affected by the field action</b></p>		
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**Unaffected drawing Revision R and drawing Revision L of Drive Pin:**

<p>Validation tool 20-8011-021-00 Rev R</p> <p><b>Not affected by the field action</b></p>		
<p>Validation tool 20-8011-021-00 Rev L</p> <p><b>Not affected by the field action</b></p>		

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.


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

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of August 2014 and June 2016.

This letter is initiating Phase I of the lot specific field removal of the iASSIST Validation Tool field removal. 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 technique in order to minimize the chance of any failure pending a replacement. A separate field removal notification will be issued to risk managers with detailed instructions in June 2017. **Your sales representative will be notified when a replacement is available. Do not return any product at this time as a part of this field action.**

**Risk Manager Responsibilities:**

1. Review this notification and ensure affected personnel 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:

 **WARNING**

Do not apply excessive force to the instruments as this may cause deformation or breakage.


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 Attachment 1 – Certificate of Acknowledgement – Phase I
  - a. Return a digital copy to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).
  - b. Retain a copy of the Acknowledgement Form with your field removal records in the event of a compliance audit of your facilities documentation.
6. If after reviewing the notice you have further questions or concerns please discuss them with your Zimmer Biomet sales representative.

#### Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field removal that are recommended beyond your existing follow up schedule.
3. 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:

 **WARNING**

*Do not apply excessive force to the instruments as this may cause deformation or breakage.*

4. 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.



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6. Complete Attachment 1 – Certificate of Acknowledgement – Phase I



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  - b. Retain a copy of the Acknowledgement Form with your field removal records in the event of a compliance audit of your documentation.
7. If after reviewing the notice you have further questions or concerns please discuss them with your Zimmer Biomet sales representative.

### **Other Information**

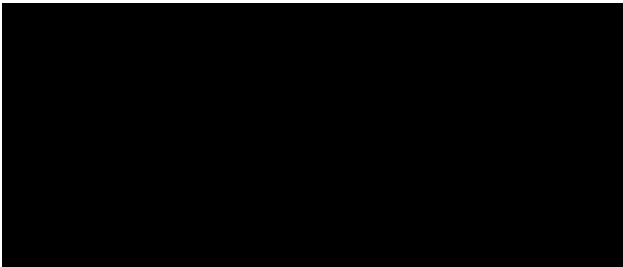
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance.

Sincerely,





**ATTACHMENT 1**  
**Certificate of Acknowledgement – Phase I**  
**Affected Product: iASSIST Validation Tool**

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Removal Notice.

**Hospital Facility**                       **Surgeon**      (Please check one as applicable)

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (    ) \_\_\_\_\_ - \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Facility Name:** \_\_\_\_\_

**Facility Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

**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](mailto:fieldaction.emea@zimmerbiomet.com).**

**ATTACHMENT 2**  
**Affected Product List**

Item Number	Lot Number	UDI Number	Item Description
20-8011-021-00	130542A1	(01) 0 0889024 30531 1 (10) 130542A1	Validation Tool
20-8011-021-00	1405941	(01) 0 0889024 30531 1 (10) 1405941	Validation Tool
20-8011-021-00	140146	(01) 0 0889024 30531 1 (10) 140146	Validation Tool
20-8011-021-00	140146-1	(01) 0 0889024 30531 1 (10) 1401461	Validation Tool
20-8011-021-00	140147	(01) 0 0889024 30531 1 (10) 140147	Validation Tool
20-8011-021-00	140407A	(01) 0 0889024 30531 1 (10) 140407A	Validation Tool
20-8011-021-00	140407A-1	(01) 0 0889024 30531 1 (10) 140407A1	Validation Tool
20-8011-021-00	140407B	(01) 0 0889024 30531 1 (10) 140407B	Validation Tool
20-8011-021-00	140407-B-1	(01) 0 0889024 30531 1 (10) 140407B1	Validation Tool
20-8011-021-00	140860	(01) 0 0889024 30531 1 (10) 140860	Validation Tool
20-8011-021-00	140860-1	(01) 0 0889024 30531 1 (10) 1408601	Validation Tool
20-8011-021-00	141035	(01) 0 0889024 30531 1 (10) 141035	Validation Tool
20-8011-021-00	150120	(01) 0 0889024 30531 1 (10) 150120	Validation Tool
20-8011-021-00	B150120	(01) 0 0889024 30531 1 (10) B150120	Validation Tool
20-8011-021-00	B150711	(01) 0 0889024 30531 1 (10) B150711	Validation Tool