Date: May 14, 2015

To: Risk Managers and Surgeons

Subject: **URGENT MEDICAL DEVICE RECALL CORRECTION NOTICE**

Affected Product: Tibial Alignment Guide – iAssist Knee System

Tibial Alignment Guide Part Number:	Lot Numbers:
20-8011-013-00	**110623, 120265, 120659, 120659-1, 120793, 120793-1, 120794, 120794-1&2, 130134, 130135, 120431-1&2, 130539-A**

Issue:

Based upon complaint investigation, Zimmer CAS has determined that the potential exists for the spikes on the iASSIST Tibial Alignment Guide to bend or break during insertion or extraction from the tibia during use. The bending or breakage of the spikes is due to a stress riser at the junction of the spike and the main body of the instrument in combination with the presence of repeated high cyclic bending stresses from the impaction method utilized. These stresses are significantly increased when the proper steps of the surgical technique are not followed. Although unlikely, if a spike breaks and goes unobserved, there is the possibility of a spike being left in the surgical site. There have not been any complaints for this instrument associated with a spike being left in a patient. Product manufactured after May 2014 is not affected as they have a different assembly method of the spike that reduces the risk of fatigue. The affected devices were distributed to the US from December 2012 through December 2013.

Figure 1: Missing spike

Figure 2: Bent spike

Risks:

Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	The spike is bent or broken and removed from patient. No immediate health effect.	The spike is broken and left in the patient. No immediate health effect.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	The spike is bent or broken and removed from patient. No long range health effect.	The spike is left behind in the patient potentially requiring reoperation. There is a possibility for a biocompatibility reaction (17-4PH Stainless Steel not assessed for long term biocompatibility) or interference with MRI because of the magnetic stainless steel.

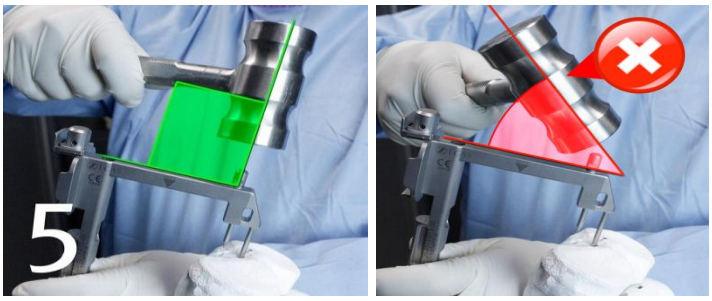
Zimmer is currently making preparations for repair/replacement activities to follow. This document is provided to alert all users of the potential issue and to highlight the proper usage of the instrument per existing surgical technique to minimize the chance of any failure pending a replacement unit. A separate recall removal notice will be issued with detailed instructions beginning in July 2015. **Your sales representative will be notified when a replacement is available. Do not return product at this time as part of this action.**

Your Responsibilities:

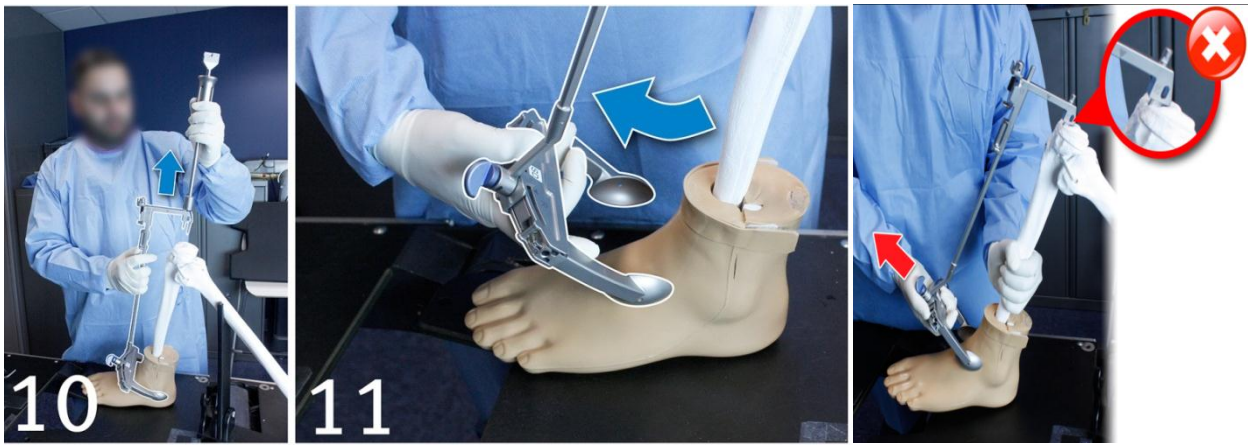
1. Please carefully review this letter and ensure users of the iASSIST Knee system at your facility have been informed of this notice.
2. During use, to minimize the chances of bending or breakage, please follow the iASSIST Surgical Knee technique, as highlighted below (Reference 97-9001-101-00).
3. Inspect the device before and immediately after use to confirm that the spikes are not bent or broken. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at cas-support@zimmercas.com along with the return any affected device(s).
4. Please complete and sign the attached Certificate of Acknowledgment and return it to CorporateQuality.PostMarket@zimmer.com.

Proper usage to follow per the iASSIST Knee Surgical Technique, reference , 97-9001-101-00:

1. Loosen the blue knob on the distal part of the Tibial Alignment Guide.
2. Position the rod of the Tibial Alignment Guide to an initial starting orientation per the preset position (L or R) on the distal part of the Tibial Alignment Guide. For a left knee procedure, the preset position is L. For a right knee procedure, the preset position is R.
3. Install the distal part of the Tibial Alignment Guide on the ankle by positioning the distal clamps on the malleoli.
4. Partially insert (2-3 mm) the longer spike of the proximal part of the Tibial Alignment Guide through the mechanical axis entry point, without engaging the shorter spike.
5. During insertion of the Tibial Alignment Guide in the Tibia, the mallet should be parallel to the spikes to avoid off-axis impaction.



6. Set rotation using the Tibial Alignment Guide. Orient the instrument shaft to align with the medial third of the tubercle.
7. Impact the instrument until both spikes are fully inserted in the tibia. **Once again care should be taken to align the mallet parallel to the spikes to avoid off-axis impaction.**
8. Continue with the Tibia Registration steps per the iASSIST Knee surgical technique
9. Once the Tibia registration is completed, to remove the instrument from the tibia start by loosening the blue knob on the distal end of the Tibial Alignment Guide.
10. As shown below, extract the upper assembly with the spikes from the proximal tibia,
11. Then remove the lower part of the instrument from the malleoli.



CAUTION: Do not pull on the Lower part of the instrument if the spikes are still inserted in the Tibia.

Contact and Manufacturer Information:
If you have questions concerning this notice or availability of replacement devices, please contact Customer Service at the following address/phone number.

Customer Service / Zimmer CAS
75 Queen Street, Suite 3300
Montreal, Quebec, Canada H3C 2N6
Email : cas-support@zimmercas.com
Telephone : 1-514-395-8883, toll free for North America 1-866-336-7846
Fax : 1-866-978-3801

Zimmer, Inc. is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may. Please be aware that the names of user facilities notified are routinely provided to the FDA and other Competent Authorities for audit purposes. This action is taken the knowledge of the U.S. Food and Drug Administration (FDA) and is in compliance with regulations set forth by the U.S. FDA. Your urgent cooperation is required.

Other Information:
This is part of a **voluntary removal** which will be reported to the U.S. Food and Drug Administration.

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 regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at cas-support@zimmercas.com.

Certificate of Acknowledgment

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall notice.

Printed

Name:_____ Signature: _____

Title: _____ Telephone: ( ) _____-_____

Date: ___/____/____

Hospital Name: _____

Hospital Address: _____

Note: Complete and return this form to Zimmer at CorporateQuality.PostMarket@Zimmer.com. Please keep a copy of your completed form for your records.

ZFA 2015-33