Zimmer Spine
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October 21, 2013

NOTIFICATION OF A MEDICAL DEVICE CORRECTION

Zimmer reference: 2184052-10-02-2013-002-R

To: Facilities and surgeons using the Trinica® Anterior Lumbar Plate (ALP) System.

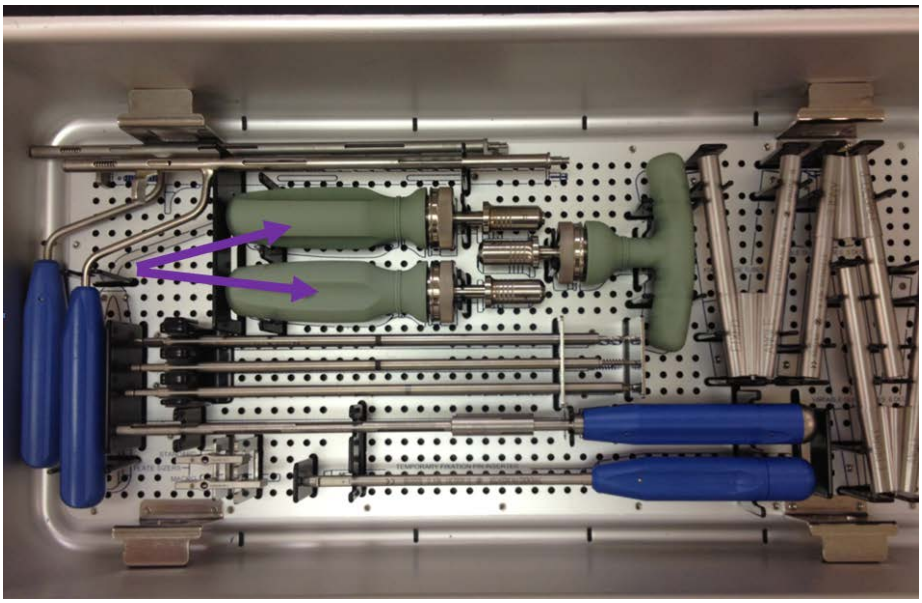
Subject: Sterilization of the Ratchet Handles used with the Trinica® ALP System

Products:

Item Number	Lot Number
07.01058.001	P060509
07.01058.001	P061255
07.01058.001	P070617
07.01058.001	P080422
07.01058.001	P090046

Zimmer Spine, Inc. is initiating a device correction/ notification regarding the Trinica ALP Instrument Tray, part 07.01058.001 (all lots) distributed from September 11, 2006 through April 29, 2013. The Ratchet Handles, part 07.00438.001 may not be effectively sterilized if left in their designated location(s) in the instrument tray. This is due to the current bracketing in the tray potentially interfering with complete steam penetration into the cannulated handle. To assure effective sterilization, the Ratchet Handles must be sterilized **external** to the instrument tray. This issue was identified during an internal Zimmer Spine engineering evaluation. No complaints have been reported.

Cannulated ratchet handles (Item #07.00438.001) indicated by arrows, below:



Risks: Ineffective sterilization may result in patient infection that is difficult to treat potentially resulting in any of the following:

- extended hospitalization,
- reoperation,
- transmission of disease.

Your Responsibilities:

Phase 1:

a) Review this notification and ensure affected personnel are aware of its contents.

b) Only sterilize the Ratchet Handles **external** to the instrument tray. It is recommended that high temperature steam sterilization be used, following AAMI/ISO Steam Sterilization standards and a validated cycle. Please refer to Trinica ALP IFU, 07.01085.001. Please note that local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.

Phase 2:

Replacement trays with a new design are currently being designed. You will be notified again when replacement trays are available to arrange a change-out with the new design. Pending FDA clearance, the new design should be available in the 2nd quarter of 2014.

If after reviewing this notification you have further questions or concerns please your Zimmer contact person.

Vigilance Information
This voluntary notification will be reported to the U.S. Food and Drug Administration and to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 to the local health authority in your country.

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 zimmer.per@zimmer.com, or to your local Zimmer representative.

Kind regards

[redacted]
Vice-President Quality Assurance & Regulatory Affairs

Attachment 1:

Confirmation of Receipt of Notice of Urgent Safety
FSA/FSCA: 2184052-10-02-2013-002-R

For confirmation of receipt of this notice, please complete and sign this document.

Please send this form to your Zimmer local contact.

Fax / Email: _____ _____

Don´t hesitate to contact Zimmer if you need further details.

This document confirms that you have received the Urgent Field Safety Notice on the product Trinica® ALP System

I certify that to it is my knowledge the content of the Urgent Field Safety Notice on the product Trinica® ALP System, and that it was given to me by Zimmer, for the protection of the interests and safety of patients.

(Printed Name of Surgeon)

(Signature and Date)

(Name of Hospital)