



Zimmer Spine
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Minneapolis, MN 55439
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August 08, 2014

MEDICAL DEVICE RECALL

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

Subject: Trinica ALP Instrument Tray - part number 07.01058.001

Dear Risk Manager and/or Surgeon:

On October 21, 2013 Zimmer Spine, Inc. notified you of a Medical Device Correction regarding the Trinica[®] ALP Instrument Tray, part 07.01058.001 and sterilization of the Ratchet Handles, part 07.00438.001. Enhanced sterilization instructions provided in the October 2013 Notice specified sterilizing the ratchet handles external to the instrument tray. Zimmer committed to a phase 2 action for replacement of the trays with a new design to support sterilization of the ratchet handles within the tray.

Zimmer Spine is now informing their hospital and surgeon customers that a redesigned tray is immediately available to replace the current tray. Zimmer has obtained FDA clearance for the new tray design. Zimmer completed a steam sterilization validation with the redesigned tray that demonstrates sterilization of the ratchet handles within the tray. Your Zimmer Representative will conduct a swap-out of the current Rev A tray for the new Rev B design tray.

The Instrument Tray part number 07.01058.001, is not changing with the new design, but the revision printed on the tray will now be "REV B," the current trays are marked "REV A."

Surgeon's Responsibilities:

- Use the redesigned Trinica[®] ALP Instrument Tray, part 07.01058.001, REV B for your cases with the Trinica[®] Anterior Lumbar Plate (ALP) System.
- Be informed that Trinica[®] ALP Instrument Trays, REV A are being replaced.

Other Information: Notifications of this recall are being sent to all affected facilities using the Trinica[®] Anterior Lumbar Plate System. For any related questions or assistance about this please contact Zimmer Spine Customer Service at 866-774-6368.

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

A handwritten signature in black ink that reads "David J. Kunz". The signature is written in a cursive style and is positioned above a horizontal line.

David J. Kunz
Vice-President Quality Assurance & Regulatory Affairs