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MEDICAL DEVICE CORRECTION

To: Surgeons using the Ardis® Interbody System

Subject: *Ardis* Inserter Medical Device Correction

Affected Product: *Ardis* Inserter (part number 3256-01)

Dear Surgeon:

Zimmer Spine, Inc. is initiating a voluntary device correction to the *Ardis* Inserter (part number 3256-01) by providing additional guidance in the *Ardis* Surgical Technique, L1467, Rev C. Zimmer Spine routinely monitors product performance data and customer experience reporting for opportunities to improve our Quality. As part of this quality monitoring process an opportunity was noted for enhanced guidance in the *Ardis* Surgical Technique related to use of the inserter during implant insertion. This letter is providing you revised surgical technique guidance in advance of a planned update to the *Ardis* Surgical Technique and the inserter to minimize the risk for off-axis loading on the implant during insertion.

Description

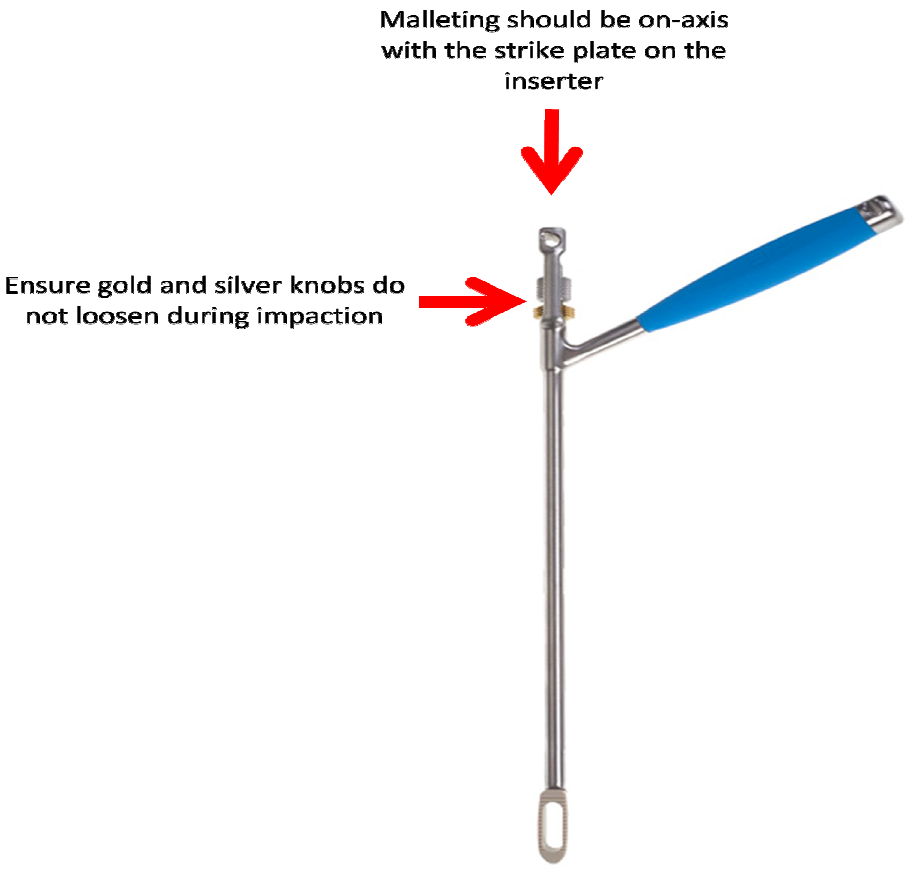
The *Ardis* Inserter is intended for delivery of the *Ardis* interbody spacer into the prepared disc space. The *Ardis* System implant may break when excessive lateral forces are applied to the implant during insertion. Zimmer Spine has received complaint reports at a 0.47% occurrence rate associated with this issue (data from a 54 month monitoring period).

Of the two implant width size offerings (9mm and 11mm), the 9mm width shows more occurrences of breakage.

	9mm Width	11mm Width
Occurrence Rate	0.44%	0.03%

Implant breakage events have occurred when the implant is subjected to excessive lateral forces and/or off-axis loads during insertion. Attachment A contains enhanced surgical technique steps that incorporate the actions listed below to prevent off-axis loading of the implant with the inserter.

Implant Insertion Actions	**Process Precautions**
Select the implant size based on proper fit of the *Ardis* Trial.	Insufficient disc space preparation or inaccurate trial sizing may lead to excessive force needed for implant insertion, which can increase the risk of implant breakage.
Ensure the silver and gold locking knobs on the inserter are fully engaged during the insertion process.	Incomplete or incorrect tightening of the silver and gold implant locking knobs may result in a loose or off-axis connection between the inserter and implant. In addition, mallet impact to the inserter may loosen the locking knobs that secure the implant. An improper connection of the implant to the inserter increases the risk for an off-axis load on the implant during the insertion process.
Do not rotate the implant during insertion by twisting the inserter.	Lateral forces applied by the inserter to the implant after the implant has been partially inserted into the disc space can put increased stress on the implant / inserter interface raising the risk of implant breakage.
Maintain ideal on-axis inserter loading on the implant during insertion (see figure below).	Off-axis loading increases risk of lateral forces that can damage the implant.



Risks

The most probable risk observed is implant breakage that results in surgical delays up to 60 minutes to remove fragments from the patient. The immediate health consequence could be a prolongation of surgery while trying to retrieve the fragment(s) from the surgical site, resulting in a patient's extended exposure to anesthesia. Potential extended surgery time could also expose patients to the standard risks associated with general anesthesia.

In certain occasional cases, fragments have been left in the patient. The long range health consequence of leaving a fragment in-vivo is unknown. The interbody spacer is made from PEEK-Optima material and is considered to be biocompatible for long term implantation. Implant fragments which are not retrieved carry the risk of migrating within the body and could result in pain and the related need for medical intervention.

The worst case observed occasional risk is patient injury associated with dural tears and significant blood loss. Sharp edges of the broken implant may contact and damage adjacent structures, requiring surgical intervention.

Your responsibilities

1. Review this notification and ensure you are aware of the content.
2. Follow the updated surgical technique guidance in Attachment A during surgery to mitigate potential implant breakage.

Questions and Additional Information

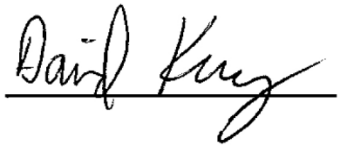
We appreciate your cooperation. Please be aware that the names of user facilities notified are routinely provided to the applicable competent authority for audit purposes. This action is being taken with the knowledge of the applicable competent authorities and is in compliance with their regulations. Your urgent cooperation in needed.

Vigilance Reporting

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. 7 to the local health authority in your country.

Should you have any questions or concerns, please contact your local Zimmer Representative. Thank you.

Sincere Regards,



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

Attachment A: Revised surgical technique guidance to prevent implant breakage

Zimmer is providing you with the following revised surgical technique guidance to help mitigate potential implant breakage when inserting the *Ardis* spacer into the prepared disc space using the inserter. These revisions re-enforce the *Ardis* Surgical Technique instructions for use and are intended to heighten surgeon awareness of the potential for lateral forces or off-axis loads being applied to the implant by the inserter:

Revised *Ardis* Surgical Technique (L1467, Rev C) Guidance (Steps 14-16):

Final Implant Preparation - Step 14a

Select the implant size based on the Ardis Trial's fit. There is no need to undersize or oversize the implant. With the Bone Tamp, pack the implant with graft material. Ensure that the silver and gold knobs on the Inserter are flush (gold knob is proximal). Attach the implant to the inserter.

Finger Tighten Implant to Insert - Step 14b

First tighten the silver knob finger-tight to engage with the implant's posterior threaded hole. Then finger-tighten the gold knob to complete engagement with the implant. Use the Bone Funnel/Bone Tamp to pack autograft material into the disc space prior to inserting the implant.

Note: The silver and gold knobs must be fully engaged for secure connection of the implant to the inserter. An improper connection of the implant to the inserter increases the risk for an off-axis load on the implant during the insertion process.

Note: Insufficient disc space preparation or trial sizing prior to implant insertion may lead to incorrect levering action or rocking the implant on the inserter after partial insertion into the disc space.

Implant Insertion - Step 15

Insert the implant into the disc space. A mallet can be used for insertion. Ensure the implant is securely attached to the inserter and remains secure while malleting into final position by checking that the silver and gold knobs are finger tight. If loosening of either the gold or silver knobs occurs, or is suspected to have occurred, the knobs should be retightened to ensure maximum implant stability and on-axis loading.

Confirm position radiographically and detach the implant from the inserter. First loosen the gold knob, then the silver knob (on the inserter).

DO NOT rotate the implant during insertion by twisting the inserter. The *Ardis* System is not designed to be inserted on its side and then rotated into position.

DO NOT apply lateral forces from the inserter to the implant once the implant has been partially inserted into the prepared disc space in an attempt to change the implant's trajectory. Off-axis loading of the implant with the inserter increases the risk of damage to the implant.

Final Positioning - Step 16

Mate either the Straight or Angled Tamp onto the posterior portion of the implant. Use caution while malleting the Tamp to drive the implant in the desired direction. Ensure the center nub of the Angled Tamp is engaged in the posterior hole of the implant.

Note: If an implant needs to be removed from the disc space, either attempt to reengage the inserter or thread the Extractor into the posterior threaded hole at the end of the implant. The Extractor should not be inserted at a severe angle. Engage the Extractor perpendicular to the posterior end of the implant. The Slaphammer can be used. A new implant should be implanted.