

Field Safety Notice

FSCA identifier: 2014-74

Type of Action: Field Safety Corrective Action

Description: Zimmer® Universal Power System Handpieces

Affected Products

Description	Item Code
Modular Electric/Battery Double Trigger Handpiece	89-8507-400-00
Modular Electric/Battery Single Trigger Handpiece	89-8507-400-10
Modular Electric/Battery Double Trigger Handpiece	89-0000-400-00
Modular Electric/Battery Single Trigger Handpiece	89-0000-400-10

Dear Customer,

Zimmer Surgical SA has initiated a Field Safety Corrective Action affecting the above referenced product numbers with manufactured serial numbers that are below 400000.

Upon review of customer complaints, Zimmer Surgical SA identified a malfunction on the above referenced handpieces. It is possible that the handpiece could start by itself when the power source is connected. The unexpected output of the device (start by itself) could lead to an injury to the user during usage or preparation of the device. Please note that the actual complaint rate for this occurrence is 0.5% per distributed device.

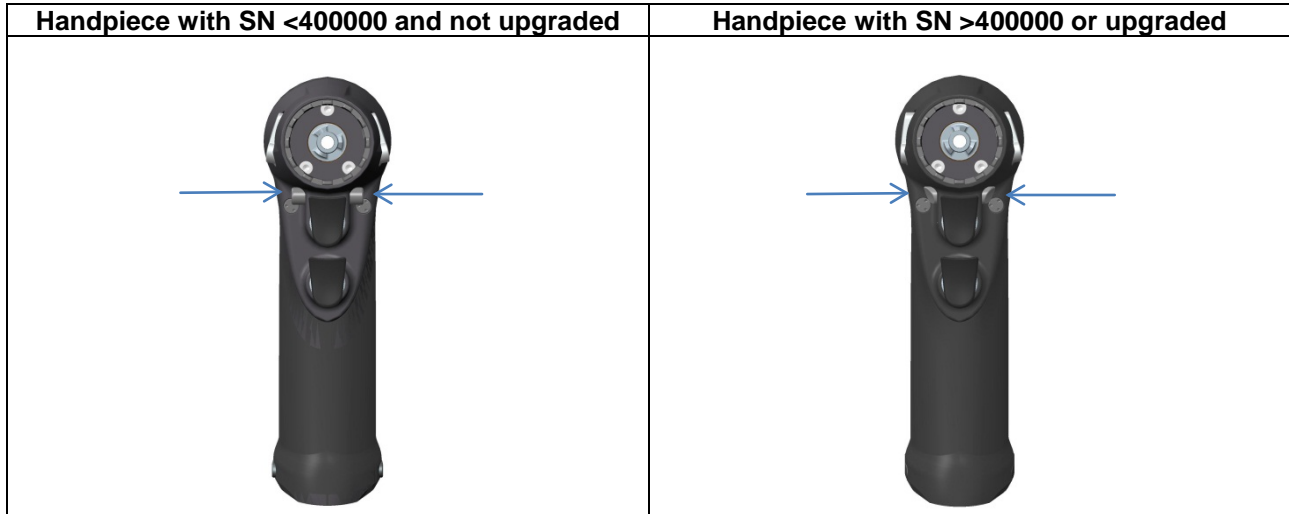
It is very important to review and understand the correct operating procedure for your handpieces, therefore, please ensure that your facility strictly follows the procedural operating steps for the handpiece that are described in the Instructions for Use

1. When the device is not in use, the handpiece Safety Switch should be placed in the neutral position, i.e. the safety switch should be in the safe position "0".
 - o Please note that the handpiece should be put in "0" position before every manipulation and before placing the tool back on the table
2. Connect the attachment to the handpiece
3. Connect the battery or power supply to the handpiece **before** connecting any blades or drill
4. Avoid contact with blades or drills after connecting the power source to the handpiece
5. Check the functionality of the handpiece, before the device is used in surgery
6. Do not use any handpiece, that has not passed your check

It is Zimmer's recommendation to follow these steps during the setting and mounting of the handpiece or during the kit inspection outside of the surgery theatre. If the unexpected output occurs it will do so during the setting and mounting phase of the handpiece, and therefore can be managed by the individual preparing the equipment. In case of defect, Zimmer recommends following the warnings and precaution section found in the Instruction for Use:

1. "To reinitiate the system, disconnect the battery and reconnect it."

All Zimmer Universal Power System handpieces with serial numbers starting at 400000 and above are manufactured with new electronics. With the new electronics, the "self-start" issue is prevented from happening. In addition to the serial number, a visual indicator that the handpiece has upgraded electronics is the Safety Switch located next to the trigger mechanism. If it is tapered as shown in the below figure the device has the new electronics.



In addition to this field safety action, we will upgrade your device(s) with the new electronics that are used in the serial numbers >400000. This upgrade will happen during the annual preventive maintenance of your device. During that preventive maintenance we will also check and possibly exchange other components as appropriate. Zimmer would like to remind you that the Universal Power System should be returned every twelve months for inspection and preventive maintenance, as indicated in the Instructions for Use.

We would like to ask for your support during the Field Safety Corrective Action by following the below actions:

1. Please read this information carefully and forward to all people within your organization that may utilize this product.
2. Please identify the number of handpieces in your ownership and indicate them on the attached Response Form.
3. Please sign and return the Response Form to the listed contact below via Fax or e-mail. This serves as confirmation that you have received the Field Safety Notice and that you understand that Zimmer will upgrade your affected handpieces via the Preventive Maintenance program during the next 12 months.
4. You will be contacted by a Zimmer representative to make an appointment for the maintenance during the next 12 months.
- 5.

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We regret any inconvenience caused by this Field Safety Corrective Action, and thank you in advance for your support.

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