September 27, 2017

To: Surgeons/ Hospitals

Subject: URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (CORRECTION)

Reference: ZFA2017-266

Affected Product: Zimmer Biomet Pulsavac Plus Device

Recommendations Regarding Zimmer Biomet Pulsavac Plus Device

Picture 1: Pulsavac Plus

Zimmer Biomet has received reports of incidents associated with the battery pack in the Pulsavac Plus device. The Pulsavac Plus product numbers within scope are shown below:

00515042000	00515048200
00515042001	00515048201
00515047500	00515049500
00515047501	00515049501

These reports are related to users cutting the battery pack power cable as part of device disposal following a procedure. Zimmer Biomet wishes to emphasize and reiterate the battery disposal recommendations both within the instruction for use (IFU) of the device and on the Tyvek® lid of the device tray. The following warning appears in both IFU 06001400236 Rev Original and on device lid 06001400227 Rev A:

"**DO NOT** cut the battery pack cable. Cutting through the battery pack cable could lead to shock, excessive heat and/or sparks, and could result in fire and/or personal injury."

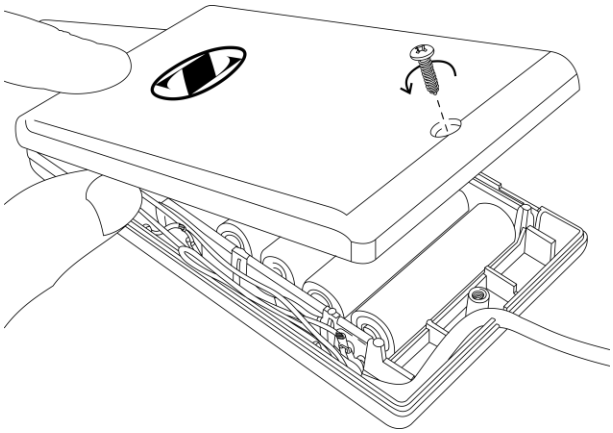
Additionally, the IFU contains the following statement regarding battery disposal:

"The **Batteries Directive 2006/66/EC** introduced new requirements from September 2008 on removability of batteries from waste equipment in EU Member States. To comply with this Directive, this device has been designed for safe removal of the batteries at end-of-life by a waste treatment facility. Contaminated units should be de-contaminated before they are sent for recycling. In the case that it is not possible to decontaminate the unit for recycling, the hospital should not attempt to remove the batteries from waste equipment. Continued disposal of small amounts of portable batteries to landfill and incineration is allowed under the **Batteries Directive 2006/66/EC** and Member State regulations."

The highest risk associated with a user cutting the battery pack power cable includes contact irritation or burns due to the potential of direct contact with expelled battery contents.

Further, if users wish to access and remove batteries as part of device disposal, the IFU contains the following instructions and graphic:

"**INSTRUCTIONS FOR BATTERY REMOVAL**
1. Using a Phillips head screwdriver, loosen and remove the single screw securing the battery pack halves together.
2. At the end closest to the battery pack cable, lift up on battery pack half to open the battery pack and expose the batteries.
3. Remove batteries by hand and dispose or recycle properly."



Again, in light of the risks noted in the warning statement contained in the IFU as well as printed on the Tyvek® lid of the device tray, Zimmer Biomet strongly recommends that users follow product labeling and refrain from cutting the battery pack power cable.

The Pulsavac Plus meets all applicable electrical safety requirements and is safe and effective for its intended use of removal of debris from an operative area through pulsatile lavage.

Surgeon/ Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
3. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.netherlands@zimmerbiomet.com.
    b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your documentation.
4. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field safety notice.

Sincerely,
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Post Market Surveillance and Regulatory Compliance Director

ATTACHMENT 1

Certificate of Acknowledgement ZFA2017-266

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

[ ] Hospital Facility [ ] Surgeon (Please check one as applicable)

Printed Name:_____Signature:_____
Title:_____Telephone: ( )____-_____Date:___/___/____
Facility Name: _____
Facility Address: _____
City:_____ZIP:_____Country:_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.netherlands@zimmerbiomet.com.