



July 08, 2019

To: Hospital

Subject: **URGENT FIELD SAFETY NOTICE - REMOVAL**

Reference: ZFA2019-00062

**Affected Product:** Pulsavac® Plus Wound Debridement System and Pulsavac® Plus AC Wound Debridement System

| Item Number    | Item Description                           | Lot Number |            |            |            |            |
|----------------|--|------------|------------|------------|------------|------------|
| 00-5150-476-01 | Pulsavac® Plus AC Wound Debridement System | 27747399   | 28372668   | 28372669   | 28863700   | 29020139   |
|                |  | 29020142   | 29170926   | 29370103   | 29370104   | 29573465   |
|                |  | 29662033   | 30296156   | 30492167   | 30587759   | 32093077   |
|                |  | 29662033R  | 30587759R  | Z000012266 | Z000012341 | Z000012445 |
|                |  | Z000012468 | Z000012721 |            |            |            |
| 00-5150-482-00 | Pulsavac® Plus Wound Debridement System    | 27628395   | 28065216   | 28372601   | 29020105   | 29020106   |
|                |  | 29370092   | 29370093   | 29391248   | 30296158   | 30296159   |
|                |  | 30296158R  | 30296159R  | V02589     | V02591     | V02592     |
|                |  | Z000012344 | Z000012469 | Z000012505 | Z000012607 |            |
| 00-5150-482-01 | Pulsavac® Plus Wound Debridement System    | 28576610   | 29020119   | 29370100   | 29637550   | 30296161   |
|                |  | 30320496   | 30492169   | 30492170   | 30320496R  | 30412526R  |
|                |  | Z000012228 | Z000012267 | Z000012342 | Z000012610 | Z000012722 |
| 00-5150-486-01 | Pulsavac® Plus AC Wound Debridement System | 27747338   | 27773026   | 27807546   | 27983240   | 28065161   |
|                |  | 28065163   | 28576513   | 28863585   | 28863586   | 29020056   |
|                |  | 29370086   | 29370087   | 29370088   | 29370089   | 29518689   |
|                |  | 29518691   | 30296162   | 30296163   | 30296164   | 30296165   |
|                |  | 30871942   | 31070782   | 30296164R  | 30296165R  | Z000008612 |
|                |  | Z000012233 | Z000012268 | Z000012390 | Z000012413 | Z000012506 |
|                |  | Z000012507 | Z000012508 | Z000012609 | Z000012723 |            |



Zimmer Surgical, Inc. is conducting a medical device Field Safety Corrective Action (removal) for lot specific Pulsavac® Plus Wound Debridement Systems and Pulsavac® Plus AC Wound Debridement Systems. Following an investigation, it was determined that certain units have the potential for the tip lock to be easily dislodged and not properly secure the tip to the housing. This could lead to both the tip and the tip lock falling off of the housing resulting in delay of procedure to obtain a new device or poorly directed fluid flow with splash back.

| <b>Risks</b>  |  |   |
|---|--|---|
| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.  | Most Probable                          | Highest Severity                          |
|   | <i>Delay of procedure ≤ 30 minutes</i> | <i>Delay of procedure &gt; 30 minutes</i> |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable                          | Highest Severity                          |
|   | <i>None</i>                            | <i>Infection</i>                          |

Our records indicate that you may have received one or more of the affected units. The affected units were distributed between June 2018 and June 2019 (Local deployment may differ).

**Hospital Responsibilities:**

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.

3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com). This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

### Other Information

This 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.

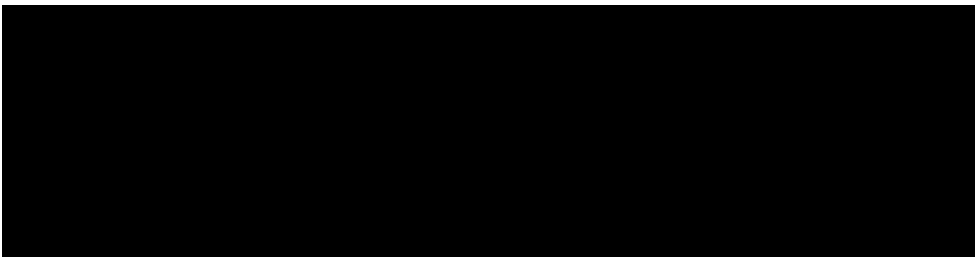
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [winterthur.per@zimmerbiomet.com](mailto:winterthur.per@zimmerbiomet.com) or to your local Zimmer Biomet contact.

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 Corrective Action.

Sincerely,





# ATTACHMENT 1

## Certificate of Acknowledgement

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: Pulsavac® Plus Wound Debridement System and Pulsavac® Plus AC Wound Debridement System**

**Field Action Reference: ZFA 2019-00062**

Please return the **completed** form to your Zimmer Biomet contact person:

[fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com)

I received and understood the Field Safety Notice.

**Regarding the parts:**

All inventories for the affected parts have been checked and following parts are to be returned:

| Reference | Lot Reference | Number of parts returned |
|-----------|---------------|--------------------------|
|           |               |                          |
|           |               |                          |
|           |               |                          |
|           |               |                          |

**OR**

The affected products which are unavailable for return have been:  discarded  lost  other: \_\_\_\_\_

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: \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

Title: \_\_\_\_\_ Telephone: (    ) \_\_\_\_ - \_\_\_\_\_

Facility Name: \_\_\_\_\_ Facility Address: \_\_\_\_\_

City: \_\_\_\_\_ ZIP: \_\_\_\_\_ Country: \_\_\_\_\_

NOTE: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com) .