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.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay of procedure ≤ 30 minutes	*Delay of procedure > 30 minutes*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Infection*

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.netherlands@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 per.nl@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,

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……
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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.netherlands@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.netherlands@zimmerbiomet.com .