ZIMMER BIOMET

December 20, 2018

To: Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- CORRECTION**

Reference: **ZFA2018-00039**

Affected Product: Max VPC Tray Base & Max VPC Screw Caddy Brackets

Item Number:	**231201002**	**Description:**	**MAX VPC Tray Base**		
Lot Numbers:	453392	453918	453919	469917	475577
481064	481065	486820	498695	506818	512868

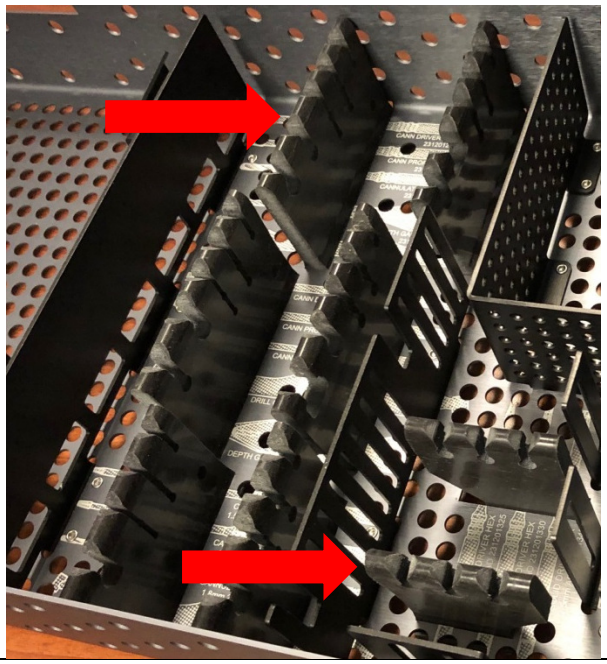
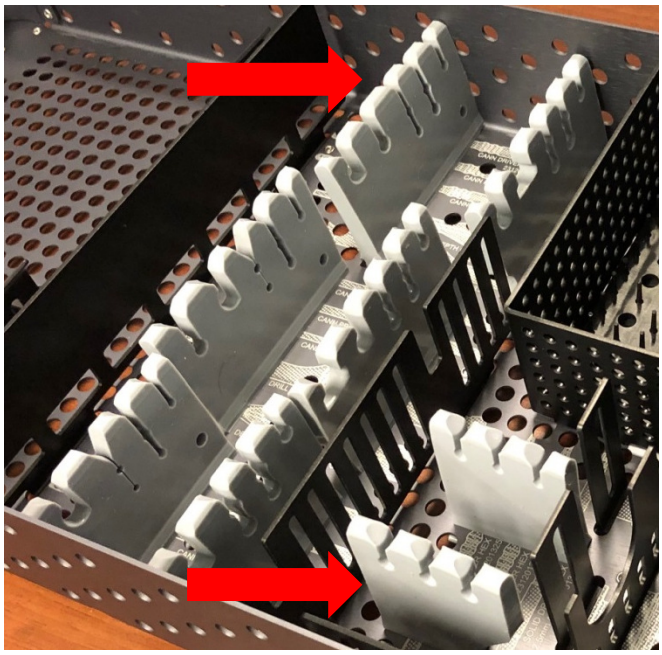
Item Number:	**231201003**	**Description:**	**MAX VPC Screw Caddy**		
Lot Numbers:	453392	453918	453919	469917	475577
481064	481065	486820	498695	506818	512867
512868					

Zimmer Biomet is conducting a lot specific medical device field safety notice/ correction for the Max VPC Tray Base and Max VPC Screw Caddy brackets due to potential silicone shedding during cleaning and sterilization.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None problem detected before use	*Surgical Delay >30 min. Problem detected during use and requiring additional cleaning and reserialization*
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 Patient experiences no reaction	*Adverse tissue reaction*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between August 2016 and January 2018.

This will be a field based correction. A Zimmer Biomet sales representative will retrieve the product from your account. The brackets being corrected are subcomponents of the Max VPC Tray Base and Max VPC screw caddy, and will be replaced with good brackets. Affected units are identifiable by black brackets. Please use the table on page 2 to identify between affected and already replaced brackets.

Affected Brackets (black), please return to Zimmer Biomet Sales Representative	Replaced Brackets (gray), do not return the product, it is conforming.
	

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility (black brackets), assist your Zimmer Biomet sales representative and quarantine all affected product. Your sales representative will coordinate the replacement of the affected brackets.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to 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 acknowledgement form with your 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 sales 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 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 action.

Sincerely,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Max VPC Case & Max VPS Screw Caddy Brackets

Field Action Reference: 2018-00039

Please return the completed form to your Zimmer Biomet contact person:
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 **Yes**, we currently have one or more cases or caddy with black brackets. The affected instruments sets have been reworked with the support of your Zimmer Biomet representative according to the instructions of this letter.

Product Reference	Lot Reference	Number of instruments cases/ caddy **reworked**

OR

The affected parts which are unavailable for correction have been: discarded lost other: _____

The complete reworking has been conducted and closed on (date- dd/mm/yy): _____

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:**_____