

June 04, 2020

To: Hospital

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE – REMOVAL**

Reference: ZFA 2020-00102

Affected Product: Comprehensive® VRS Inserter

Item Number	Lot Number	UDI Number
110019068	814100	(01) 0 0880304 82950 3 (10) 814100
110019068	570640	(01) 0 0880304 82950 3 (10) 570640
110019068	728890	(01) 0 0880304 82950 3 (10) 728890
110019068	977300	(01) 0 0880304 82950 3 (10) 977300



Biomet Orthopedics LLC is conducting a medical device Field Safety Corrective Action (removal) for certain lots of the Comprehensive® VRS Inserter, because the central screw drill seized inside the Comprehensive VRS Inserter (Item 110019068). The above issue is due to an adjustment of the drill hole diameter during product improvement which was not reflected in one of the drawings used for manufacturing. During the procedure, the central screw drill wiggles inside the VRS inserter when being incarcerated and can be easily recognized by the user.

The issue was identified through a complaint review. To date no adverse outcome is reported.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant extension of surgery to find a replacement that is readily available	Clinically significant extension of surgery to find a replacement that is not readily available.
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	None

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between September 2016 and July 2018. (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 any affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all affected products. Your Zimmer Biomet sales representative will remove the affected products from your facility.
3. If the affected product has been further distributed, provide your customers with the Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.uk@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
5. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this Field Safety 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 units or any other Zimmer Biomet product by emailing per.uk@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,

A handwritten signature in black ink, appearing to read "K. Escapule".

Kevin Escapule
Director, Post Market Surveillance



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Comprehensive® VRS Inserter

Field Safety Corrective Action Reference: ZFA 2020-00102

Please return the completed form to your Zimmer Biomet contact person or by e-mail

fieldaction.uk@zimmerbiomet.com

I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	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: _____