

June 18, 2019

To: Hospitals and Surgeons

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

Reference: ZFA2019-00071

Affected Product: DVR® Crosslock ePAK™ Screw Driver, DVR® Crosslock ePAK™ Depth Gauge, K-Wire Trochar Tip

Item Number	Item Description	Prior to Expiration Date
212000002	DVR® Crosslock ePAK™ Screw Driver	April 30, 2024
212000003	DVR® Crosslock ePAK™ Depth Gauge	April 30, 2024
212000008	K-Wire Trochar Tip	April 30, 2029



Zimmer Biomet is conducting a medical device field safety corrective action (removal) for the DVR® Crosslock ePAK™ Screw Driver, DVR® Crosslock ePAK™ Depth Gauge, and the K-Wire Trochar Tip due to potential weak seals of the sterile packaging. All individually packed sterile instruments for item numbers 212000002 and 212000003 packaged with an expiration date prior to April 30, 2024 are included in this removal. Additionally, all individually packed sterile instruments for item number 212000008 packaged with an expiration date prior to April 30, 2029 are included in this removal.

Note: Item number 212000008 can potentially be in DePuy labeled boxes.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>Minor extension of surgery generally less than 30 minutes to find a replacement part that is readily available.</i>	<i>Significant extension of surgery generally greater than 30 minutes to find a replacement part that is not readily available.</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>Surgical intervention due to infection.</i>

Our records indicate that you may have received one or more of the affected products. The affected units were distributed by Zimmer Biomet between June 2013 and March 2019.

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, 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 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 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.

Surgeon 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** and send to fieldaction.emea@zimmerbiomet.com
4. Retain a copy of the acknowledgement form 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.

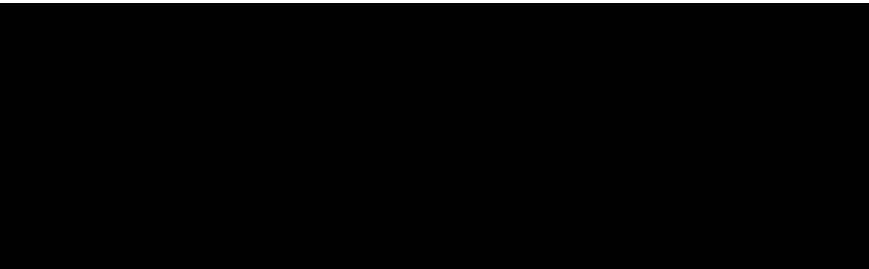
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.uk@zimmerbiomet.com or to your local Zimmer Biomet contact.

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 action.

Sincerely,





ATTACHMENT 1 Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: DVR® Crosslock ePAK™ Screw Driver, DVR® Crosslock ePAK™ Depth Gauge, K-Wire Trochar Tip

Field Action Reference: ZFA 2019-00071

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 products:

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

Product Reference	Lot Reference	Number of products 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: _____

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