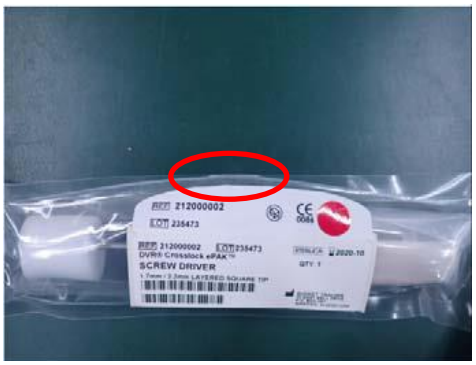
May 28, 2019

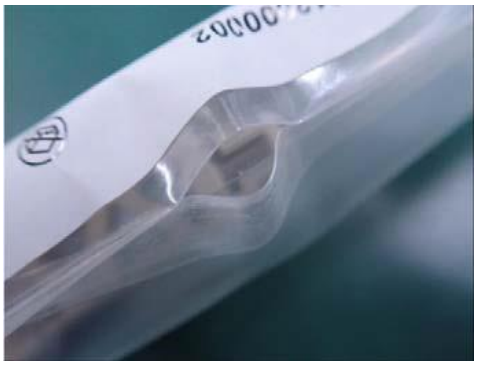
**Dear Healthcare Professional,**
**cc: Chairman Medical Board and relevant Head of Departments**

**Subject:** **URGENT MEDICAL DEVICE RECALL**

**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 recall 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 recall. Additionally, all individually packed sterile instruments for item number 212000008 packaged with an expiration date prior to April 30, 2029 are included in this recall.

**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 |
| | *Minor extension of surgery generally less than 30 minutes to find a replacement part that is readily available.* | *Significant extension of surgery generally greater than 30 minutes to find a replacement part 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* | *Surgical intervention due to infection.* |

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.

**Risk Manager 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 CorporateQuality.PostMarket@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 recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

**Surgeon Responsibilities:**

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

**Other Information**

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

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.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

[redacted]

Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director

# 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 check one as applicable**:

☐ Hospital Facility ☐ Surgeon

**Do you have affected product in your facility?**
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

**Printed Name:** _____ **Signature:** _____

**Title**: _____ **Telephone:** (  ) ____-_____ **Date:**____/____/____

**Facility Name:** _____

**Facility Address:** _____

**City:**_____ **State:**_____ **ZIP:**_____

**Note:** This form must be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-373-3589.