ZIMMER BIOMET

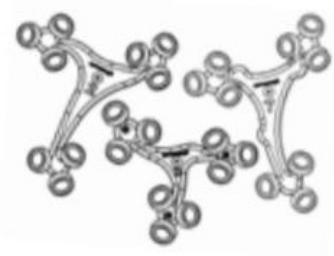
January 12, 2022

To: Distributors

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: NavitrackER Kit A – Knee

Item Number	Lot Number	Description	UDI Number
20-8000-000-07	110221A1	NavitrackER® Kit A : Knee	(01)00889024304222(17)231103(10)110221A1



Zimmer CAS is conducting a lot specific medical device Field Safety Corrective Action (removal) for one lot of the NavitrackER Kit A - Knee product, which is a non-patient contacting device used during computer and robotic assisted surgeries. The product in scope was released for distribution without passing sterilization results. This could potentially lead to insufficient sterility of the product, which may lead to the risks identified below. The issue was discovered internally, and there have been no complaints 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
	None	None
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 leading to surgical intervention

Our records indicate that you may have received one or more of the affected products. The affected units were distributed in December 2021.

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Your Responsibilities

1. Review this Field Safety Notice and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
    a. Complete **Attachment 1 – Inventory Return Certification Form** and send to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your country.
    b. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
    c. Mark "RECALL" on the outside of the returned cartons.
4. Retain a copy of your **Inventory Return Certification** and product return forms for your records in the event of a compliance audit of your facility.
5. 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 product or any other Zimmer Biomet product by emailing GSCC.Supplier.Quality@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 Field Safety 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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ZIMMER BIOMET

ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: NavitrackER Kit A – Knee
Field Safety Corrective Action Reference: ZFA 2022-00004

Country:_____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity.

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
Dock 20
Breda 4836 LD, Netherlands

	Check one of the following:	
This is the final return for the entire territory. An exhaustive search has been performed for the affected products.	Yes ☐	No ☐

Note: All products that are not available (for return) will be considered as dispositioned on location and therefore physical unavailable unless otherwise specified.

☐ **Credit My Account** ☐ **Send a Replacement**

Item Number	Lot Number	UDI Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.gscc@zimmerbiomet.com with this form.

Certificate of Acknowledgement:
By signing below, I acknowledge that I have received, read, and understand the contents of this Field Safety Notice communication. All required activities are complete or are being completed.

Printed Name:_____ **Signature:** _____

Title:_____ **Tel:** ( )_____ **Ext.**_____ **Date:** _____

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.gscc@zimmerbiomet.com.

Please do not return affected product with other returns.