FIELD SAFETY NOTICE				
Scope of Applicability				
SMT ☑	SMN ☑	FCP ☑	WM ☑	BPS ☑

Document ID: FSN_2025-01
FSCA Reference: TBD

Urgent Field Safety Notice

Date: 03/06/2025
FAO:

Dear Valued Customer,

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO ARE RESPONSIBLE FOR MONITORING AND/OR MAINTAINING THIS PRODUCT

This notice is to advise you that WaisMed, the legal manufacturer of the **NIO-A**, is voluntarily issuing a field correction regarding the above-mentioned product**.** Our records indicate that you have received one or more of the devices that are the subject of this field action.

WaisMed is initiating this voluntary field correction as a precautionary measure to advise customers of the remote possibility of the malfunction described herein and what steps you are to take to return this product.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Device Information	
Device Name:	NIO Intraosseous Device Adult
Device ID No.:	NIO Adult
Device Description:	NIO devices are a spring-based, automatic intraosseous access devices that are supplied Sterile and single use. Indicated for Intraosseous access to the Proximal humerus and Proximal Tibia in adult patients older than 12 years of age, in emergent situations. 
UDI:	0 7290008325 05 9
Primary Clinical Purpose of Device(s):	NIO Devices are intended to provide intraosseous access, as an alternative to IV access during emergencies.

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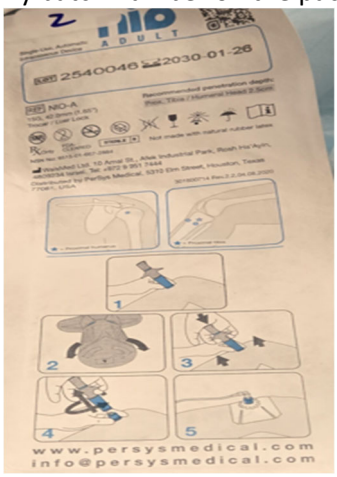
Affected Serial or LOT Number Range:	**2530151**	**2530153**
	2430145	**2430149**
	2430146	**2430148**
	2530150	**2430154**
FSN Type:	New	
Further Advice or Information Already Expected in Follow-Up FSN?	**No**	
Reason for Corrective Action		
Description of issue	Stabilizer unable to be removed from the device	
Hazards Involved	Once the device is fired the stabilizer may be unable to be removed from the device without compromising the insertion site.	
Probability of problem arising	Remote	
Predicted risk to patient/user	Delayed IO access if the stabilizer is unable to be removed from the device after firing, the user may be unable to achieve IO access at that site and an alternate method/site may be required.	
Further information to help characterise the problem	N/A	
Background on Issue	While investigating an unrelated complaint, an issue with the stabilizer being difficult to remove post-firing was identified while conducting benchtop and cadaver testing.	
Other information relevant to FSCA	The failure mode is a point in time failure with no lingering effects. For instance, if the device was used without issue, there are no lingering concerns for the patient on which it was used.	

Actions to be Taken by Customer/User:	
Is a Customer Response Required?	☒ **Yes** ☐ **No**
Actions to be Taken:	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-Site Device Modification/Inspection ☐ Follow Patient Management Recommendations ☐ Take Note of Amendment/Reinforcement of Instructions for Use (IFU) ☐ Other ☐ None
By when should the action be completed?	Immediately on receipt of this FSCA.
Details on Action to be Taken by Customer/User:	1. Examine your inventory immediately to determine if you have any affected stock.

	2. If any of the affected products were issued/supplied to another facility or customer, please contact them to arrange for the return of the products. 3. Complete the **Annex I: Acknowledgement and Receipt Form** and return it to Waismed LTD either via email to: WM: vigilanceil@safeguardmedical.com or our representative at WERO GmbH & Co. KG: tina.fuehrer@wero.de or post to: Waismed LTD 10 amal st' Afek park Rosh Ha'Ayin, 4809234, ISRAEL 4. Keep this notice visibly available until all affected products subject to this notice have been checked. While processing, maintain a copy of this notice with the product and keep a copy for your records.
How to Identify Affected Products	By batch number on the packaging 
Further Information and Support	If you require any further information or support concerning this issue, please contact Waismed at vigilanceil@safeguardmedical.com or our representative at WERO GmbH & Co. KG tina.fuehrer@wero.de.
Transmission of FSN:	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

List of Attached Documents:

Annex I: Acknowledgement and Receipt Form

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SAFEGUARD MEDICAL™

Acknowledgement and Receipt Form

Please return completed form immediately to:

WM Email: vigilanceil@safeguardmedical.com
<+1 713 723 6000> [Waismed LTD 10 amal st' Afek park Rosh Ha'Ayin, 4809234, ISRAEL].

Please check applicable box:

☐ We confirm receipt of this Notice and complete the required actions therein. We confirm our inventory does NOT include products affected by this notice.	☐ We confirm receipt of this Notice and complete the required actions therein. We confirm that our inventory DOES include products affected by this notice. The use and further distribution of the affected product has been stopped. All products are on hold and the quantity stated below will be returned for exchange	☐ We confirm receipt of this Notice and complete the required actions therein. We confirm that our inventory DOES include products affected by this notice. We have corrected the issue per the Instruction in **I-QMS-F071-001**.

Organisation Name:	
Organisation Address:	
Email Address:	
Telephone Number:	
Form Completed by *(Print Name):*	
Action Taken	
Signature:	
Date:	