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.

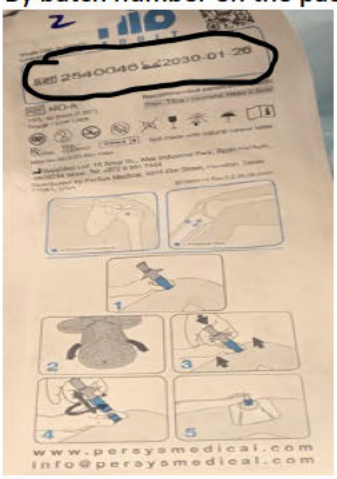
The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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.

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

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: [redacted] 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 [redacted]
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

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

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:	

WaisMed Ltd.
+972-9-9517444
10 Amal St. Afek Industrial Park
Rosh Ha'yin 4809234, Israel
safeguardmedical.com

URGENT: MEDICAL DEVICE RECALL

NIO Intraosseous Needle

June ##, 2025

Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Customer,

The purpose of this letter is to advise you that Waismed Ltd. is voluntarily recalling specific lots of the NIO A and NIO+ (Single-Use, Automatic Intraosseous Device for Adults 15G, 42.0mm (1.65in)) intended to provide intraosseous (IO) access in the proximal tibia or humeral head as an alternative to emergency intravenous access for use in adult patients.

While the vast majority of devices in these lots are expected to function as intended, a small number have exhibited a manufacturing issue that could impact performance. This voluntary action is being taken out of an abundance of caution to ensure continued patient safety.

Recent internal testing identified a potential manufacturing issue affecting the device's built-in stabilizer mechanism, which in some cases may not be released properly after deployment and insertion. This malfunction has been observed in a limited number of units, but because it may impact on critical emergency care, we are initiating a field action for all potentially affected lots.

Reason for the Voluntary Recall

The NIO Intraosseous Needle has been found to have a manufacturing issue where the built-in stabilizer mechanism may fail to release properly from the device following deployment and insertion.

Risk to Health

The identified issue may prevent the device from functioning as intended, potentially causing delays in care due to the inability to establish functional intraosseous access. When the stabilizer becomes stuck and cannot be removed following standard Instructions for Use (IFU) procedures requiring twisting and upward pulling motion, clinicians may experience treatment delays while attempting device removal or may need to discontinue use of the initial insertion site. In cases where the stabilizer cannot be freed despite following IFU instructions, healthcare providers would be required to deploy a new device at one of three alternative anatomical sites on the patient, further prolonging time to treatment initiation. Healthcare providers should immediately discontinue use of affected devices and consider alternative intraosseous access products to ensure continuity of patient care without compromising treatment timelines in critical situations.

Actions to be taken by the Customer/User:

Upon receipt of this recall notice, customers and users must immediately quarantine and remove all NIO A and NIO+ devices from the affected lots from all points of use, including emergency kits, crash carts, ambulances, and clinical storage areas. Discontinue use of any devices from the recalled lots and verify your inventory against the specific lot numbers listed in this recall notice to identify all affected products. Please complete the attached Recall Acknowledgement and Receipt Form and return it to Waismed Ltd. per the instructions on the form.

WaisMed Ltd.
+972-9-9517444
10 Amal St. Afek Industrial Park
Rosh Ha'yin 4809234, Israel
safeguardmedical.com

Product and Distribution Information
A complete list of the devices received by your company that are subject to this recall can be found in the Acknowledgement and Response Form attached to this letter.

Action by Waismed Ltd.:
Waismed Ltd. is committed to ensuring minimal disruption to your clinical operations during this recall process. Upon receipt and processing of your completed Recall Acknowledgement and Receipt Form, we will promptly evaluate your replacement product requirements and expedite shipment of suitable alternative intraosseous devices to maintain your emergency care capabilities.

OTHER INFORMATION:
Any questions directly associated with this recall should be directed to:

[redacted]
10 amal st' Afek park
Rosh Ha'Ayin
APO-EU/ME/AF&CA. 4809234
Israel
Email: vigilanceil@safeguardmedical.com
Phone: +972-9-9517444
Website: safeguardmedical.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the appropriate Global Regulatory Agency (example: EU Authorized Representative or Competent Authority) or FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

[redacted]

WaisMed Ltd.
+972-9-9517444
10 Amal St. Afek Industrial Park
Rosh Ha'yin 4809234, Israel
safeguardmedical.com

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

PRODUCT NAME NIO-A and / or NIO+
Lot numbers: shown in table below

I have read and understand the recall instructions provided in the <date of> letter. Yes ☐ No ☐

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain in detail (be sure to include the dates, quantities, and provide all available information).:

Affected Product Information: The following products were received by your Company. Please confirm inventory below.

Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot Number shipped to Customer	Quantity shipped to Customer	Quantity in Customer inventory	Quantity used without issue	Quantity to be returned

Return Response Box:

Please provide any additional information, if applicable.

SIGNATURE _____ DATE _____

Name/Title	
Telephone	
Email address	

PLEASE EMAIL COMPLETED RESPONSE FORM TO: **RECALLS@SAFEGUARDMEDICAL.COM**
OR MAIL TO: FIRM NAME AND ADDRESS IN THE LETTER ABOVE