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

Document ID: FSN_2026-01
FSCA Reference: *TBD*

Urgent Field Safety Notice

Date: 31/05/2026
FAO: [Customer/ Distributor Name]

Dear Valued Customer,

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

The purpose of this letter is to advise you that WaisMed, the legal manufacturer of the **NIO-P**, is voluntarily issuing a field correction regarding the above-mentioned product **LOT Number** 2620195. 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 a labelling error described herein.

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

Device Information	
Device Name:	NIO Intraosseous Device Pediatric
Device ID No.:	NIO Pediatric
Device Description:	NIO devices are spring-based, automatic intraosseous access devices that are supplied Sterile and single use. Indicated for Intraosseous access to the Proximal Tibia in pediatric population aged 3–12 years, in emergent situations.

	
UDI:	0 7290008325 04 2
Primary Clinical Purpose of Device(s):	NIO Devices are intended to provide intraosseous access, as an alternative to IV access during emergencies.
Affected Serial or LOT Number Range:	2620195
FSN Type:	New
Further Advice or Information Already Expected in Follow-Up FSN?	**No**
Reason for Corrective Action	
Description of issue	Incorrect expiration date displayed on the Tyvek packaging. The device has a 5-year shelf life and should have been labelled with an expiration date of 01-2031. Instead, the date shown on the label is 01-3031.
Hazards Involved	There is no immediate risk to the patient or end user when the device is used within its validated shelf life. The potential risk exists only if the incorrect expiration date results in the device being used beyond its actual expiration date, which may affect product performance and/or package integrity (for example loss of sterility, which may lead to infection, or loss of penetration force). Following the actions outlined in this FSN eliminates this risk, resulting in no expected residual risk to the patient or end user.
Probability of problem arising	The likelihood of the device being used after the expire date is remote. The actual expiration date of the product is 2031 (5 years from the date of manufacture), and it is expected that all units in the field will be used before reaching this expiration date. Therefore, the potential risk would only arise if the device were retained and used beyond its validated shelf

	life as a result of reliance on the incorrect expiry date indicated on the labeling. .
Predicted risk to patient/user	The anticipated risk is derived from the risk evaluation, where use of the device beyond its actual expiration date may result in loss of device and/or packaging integrity, potentially leading to loss of sterility, reduced performance, and an increased risk of patient or end-user injury or infection. Accordingly, the overall risk (severity × probability) is considered as Medium Risk. However, when the device is used within its shelf life, the risk remains within acceptable limits and no residual risk is expected.
Further information to help characterise the problem	The issue is limited to a single affected batch. The products remain within their validated shelf life and are safe for use. Customers typically consume their inventory before the end of the five-year shelf life. Therefore, the issue represents a potential risk only if the devices are retained and used beyond their actual expiration date.
Background on Issue	WaisMed became aware of the issue following a complaint received from a distributor who identified a discrepancy between the expiration date printed on the Tyvek pouch and the expiration date printed on the other product labels. The issue was confirmed to be limited to the affected batch only.
Other information relevant to FSCA	The issue is limited to an incorrect expiration year printed on the Tyvek pouch label and does not affect the device itself, its performance, sterility, safety, or effectiveness during its validated shelf life. This is a point-in-time labeling error with no immediate impact on patients or users. If the device has already been used, there are no lingering concerns or expected adverse effects for the patient or end user. The potential risk exists only if the device is retained and used beyond its actual validated expiration date due to reliance on the incorrect date printed on the Tyvek label.

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?	Within 30 days
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 has been issued/supplied to another facility or customer, contact them to arrange a return. 3. Follow the instructions provided within this document. 4. Complete the **Annex I: Acknowledgement and Receipt Form** and return it to Waismed LTD either via email to: vigilanceil@safeguardmedical.com or our representative at [DISTRUBUTOR NAME and EMAIL], or post to Waismed LTD 10 Amal st' Afek park Rosh Ha'Ayin, 4809234, ISRAEL 5. 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	We apologise for the inconvenience this may cause. If you require any further information or support concerning this issue, please contact < WaisMed at vigilanceil@safeguardmedical.com or our representative at [DISTRUBUTOR NAME and EMAIL].
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
Annex I to FSN 2026-01

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.

Organisation Name:	
Organisation Address:	
Email Address:	
Telephone Number:	
Form Completed by *(Print Name):*	
Action Taken	e.g., units returned/destroyed/corrected etc.
Signature:	
Date:	