WaisMed
A PerSys Medical Company

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Urgent Field Safety Notice – NIO-A

Device Name: NIO-A

Date: August 16, 2016

Type of action: return of NIO-A device to the supplier (Recall)

To whom it may concern

Details on affected devices:

The following NIO-A lots are subjected to recall and should be returned to WaisMed Ltd.

Product Batch Information Table		
Lot	**Manufacturing Date (MM/YYYY)**	**Expiration Date (MM/YYYY)**
WS1630025	03/2016	03/2021
WS1630024	02/2016	02/2021
WS1630023	01/2016	01/2021
WS1530021	12/2015	12/2020
WS1530017	10/2015	10/2020
WS1530016	09/2015	09/2020
WS1530014	08/2015	08/2020
WS1530012	06/2015	06/2020

Description of the problem:
During the operation of the NIO-A, the needle was not released from the device as expected. The device was placed on the floor and after several minutes the needle was released spontaneously.

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Risk to Health:
As the device is intended to penetrate the bone into the marrow cavity, it is designed in such way that the needle is released intensely due to a compressed spring force. Spontaneous release of the needle from the device may result in serious injury of the patient, caregiver or any of the surrounding people.

Root Cause of the Fault
WaisMed performed an extensive and comprehensive investigation in order to find the root cause of the problem. It was concluded that the malfunction of the activation mechanism occurred due to galling process between two metallic components with similar hardness properties.
In all lots manufactured before March 2015, the metallic components of the activation mechanism were made of two materials with different hardness and therefore, the malfunction may occur only in lots that were manufactured after March 2015.

Advise on action to be taken by the user:
1. Locate and quarantine all NIO-A devices from the affected lots which you received
2. Inform all users to immediately discontinue the use of devices from the affected lots and return any unused devices.
3. Return all devices from the affected lot to WaisMed
4. Complete the attached questionnaire and return to WaisMed.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
Please transfer this notice to other organizations on which this action has an impact.
Please maintain awareness on this notice and resulting action.

Contact reference person:
Einat Swisa
WaisMed Ltd.
Cell: +972 54 8188267
Email: einat@persysmedical.com
Address: 10 Amal St. Afek Industrial Park, Rosh Ha'Ayin, 4809234, Israel

The undersign confirms that this notice has been notified the appropriate Regulatory Agency:

Einat Swisa, CTO

WAISMED LTD.
511937054

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Please complete the questionnaire and return it utilizing:
e-mail: einat@persysmedical.com
fax to: +972 9 9517666.

If you are returning product, please contact Attar Rozenrot for instructions:
e-mail: attar@persysmedical.com
Cell: + 972 54 2122764

1. Did you receive shipments of the NIO-A devices being recalled? ☐ Yes ☐ No
   (If NO, terminate questioning, sign the form and return to WaisMed)
2. Do you have all the affected devices on hand? ☐ Yes ☐ No
   (If NO, please fill-in the table below, sign the form and return to WaisMed)
3. If question 2 was answered YES, do you intend to return the devices to WaisMed as requested? ☐ Yes ☐ No
4. If the answer to 3 is NO, please explain your intentions:

_____

_____

Please provide a listing of products in the space below:
(if more space is required, please attach a list, attachment ☐ Yes ☐ No)

Lot Number	Quantity		
	Received From WaisMed	Inventory	Shipped to End user (Please provide details of End user)

Individual completing this form:

Organization	Name and Title	Date	Signature