West Pharma. Services IL, Ltd.
4 Hasheizaf St.
Ra'anana 4366411, Israel
www.westpharma.com

West Pharma. Services IL, Ltd.
(formerly Medimop Medical Projects)
West Pharmaceutical Services, Inc.

URGENT: MEDICAL DEVICE RECALL

VIAL2BAG
VIAL2BAG (DC) 13mm
VIAL2BAG (DC) 20mm
I.V. FLUID TRANSFER SETS

January 28, 2019

To: West Pharma. Services Distributor / Customer,
[redacted]

West Pharma. Services IL, Ltd. (formerly Medimop Medical Projects) and West Pharmaceutical Services Inc. has issued a voluntary recall for the product codes and lot numbers listed as follows:

Product Code	Product Description	Lot #	Expiry Date
6070101	Vial2Bag™ Transfer Device	A451	30-Jun-2021

Reason for the Voluntary Recall:

West is recalling these products due to the possibility that the device may not adequately transfer the drug contents to the IV bag. If inadequate transfer occurs there is the potential that the device may deliver variable or unpredictable dosing.

We are aware of sixteen (16) products with complaints of a similar nature since March 8, 2017, reported with the use of oxytocin in conjunction with the Vial2Bag DC 13mm in pregnant women, in connection with labor and delivery.
These complaints occurred in the U.S. only.

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Risk to Health:

The reports conveyed that healthcare professionals had observed effects of the drug oxytocin being unpredictable or variable when administered with the Vial2Bag DC 13mm. The events reported include severe and rapid uterine contractions (uterine tachysystole), deceleration in fetal heart rate (with subsequent cesarean section), and hemorrhage. West has not determined whether the observed variable or unpredictable dosing is limited to oxytocin delivery through the affected medical devices.

Variable and unpredictable dosing of medications, generally speaking, may lead to overdosing or under-dosing, with the effects depending upon the specific drug, the specific patient, and the condition for which the drug was ordered. Adverse health consequences may range from minor to serious injury and/or death.

There have been no reported events for any Vial2Bag, Vial2Bag DC 13mm, Vial2Bag DC 20mm product with an outcome of death.

Actions to be taken by the Customer/User:

Our records indicate that you have received products consisting of the Lots (the "Affected Product") that are subject to this voluntary recall.

1. If you have any affected product in your inventory, please immediately discontinue use, remove it from your inventory, and quarantine the product to prevent inadvertent use.

2. Please notify Keren Dahan by email at keren.dahan@westpharma.com (PHONE +972-9-760-9398) when complete responses are available to schedule return of Affected Products.
3. ***Please complete the Recall Acknowledgement and Receipt Form*** and return to Ilanit Goldgraber at ilanit.goldgraber@westpharma.com when complete responses are available (See attached form). This will allow us to document your receipt of this letter.
4. Alternative Options to Admix Medication:

   We recommend that you rely on the current standard of practice of medicine for admixing medications for I.V. therapy.

Actions to be taken by the Distributor

1. Please examine your inventory and quarantine product subject to recall.
2. If the product was distributed to your customers, please identify your customers.
3. Notify and provide this letter to all accounts/customers where the Affected Product was distributed.

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4. Follow up with each account/customer to locate and identify all Affected Product per the attached recall return response document and establish the number of units of Affected Product in possession of each account/customer.
5. Please complete the **Recall Acknowledgement and Receipt Form** below and return (via email) to recall@westpharma.com when complete responses are available (See attached form).

REFUND / REPLACEMENT FOR RETURNED PRODUCT -

Returned product will be credited by the distributor.

OTHER INFORMATION:

You should report any adverse events or quality problems with these devices to the manufacturer, West Pharma. Services IL, Ltd.

West regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. This action is being undertaken to ensure the highest level of patient safety and customer satisfaction.
Customers who have questions or need additional information regarding this correction may contact Ilanit Goldgraber at ilanit.goldgraber@westpharma.com.

This letter can also be found on the West Pharmaceutical Services, Inc. website at: www.westpharma.com/support/alerts-and-notices

Sincerely,

Ilanit Goldgraber
Director, RA

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URGENT MEDICAL DEVICE RECALL
ACKNOWLEDGEMENT AND RECEIPT FORM
Response is Required

Vial2Bag
Vial2Bag DC 13mm
Vial2Bag DC 20mm

Product Number(s): 6070101

Check the appropriate box and return this form

☐ I have read and understand the recall actions to be taken provided in the 24 January 2019 Letter.

☐ We have no inventory within the scope of this recall.

☐ We have the following Affected Product at our facility and have discontinued use and distribution. The Affected Product has been quarantined, and the following quantities shall be returned.

Product Code	Lot Number	Quantity

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Please Print Legibly

(Print Name)	**(Date)**
(Signature)	**(Telephone Number)**
(Institution Name)	**(Email Address)**
(Institution Street Address)	**Alternate Mailing Address**
(Institution City, State, Zip)	**(Street Address)**
(Country)	**(City, State, Zip)**