Fresenius Kabi Canada Ltd.

165 Galaxy Blvd, Suite 100
Toronto, Ontario
Canada M9W 0C8
T: 905.770.3711
F: 844.513.1522
W: fresenius-kabi.ca

Medical Device Recall – Type III

Customer Communication

IV Infusion Sets- Label Discrepancy

January 18, 2024

Dear Healthcare Provider,

Subject: Discrepancy on product label and in the Instructions for Use (IFUs) supplied with the VL PR 42-11, and VL PR 42-12.

Affected Devices:
VL PR 42-11, Product code M46445665 (MDL# 105146) and VL PR 42-12, Product M46445695 (MDL# 105146)

Fresenius Kabi Canada is issuing this letter to notify customers of a **Type III recall** initiated for VL PR 42-11, Product Code M46445665 and VL PR 42-12, Product Code M46445695. This product notification details the issue and the required steps for customers to perform.

Issue:

The discrepancy pertains to the statement on the label and IFU that indicates, "Not suitable for secondary infusion". Fresenius Kabi would like to clarify that both sets are designed to accommodate secondary infusion and a secondary infusion set can be safely added to the upstream needleless port. We apologize for any confusion this additional statement may have caused.

Safety and Customer Satisfaction:

At Fresenius Kabi Canada, we prioritize the safety and satisfaction of our customers. We take this labeling inconsistency seriously and have taken immediate steps to rectify it. A corrected version of the label will be available in the near future. The affected devices do **not** need to be returned. You can safely use the device including addition of a secondary infusion to the upstream needleless port.

Next Steps:

If you have any questions or concerns regarding the use of our product or this label correction, please do not hesitate to reach out to us. For information with respect to the proper utilization of our products, please reach out to 1-877-821-7724, option 4 or e-mail supportcentre.infusion@fresenius-kabi.com.

Please complete the Customer Reply Form attached to this letter to acknowledge receipt of this notification and return it to Fresenius Kabi Canada via the email address stated on the form.

Product does not need to be returned to Fresenius Kabi Canada. Product can continue to be used as intended.

Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this letter and the actions as described herein.

If you experience an incident, please contact Fresenius Kabi Canada Customer Service at 1-877-821-7724 and identify the device and lot associated with the incident. Adverse reactions or quality problems experienced with the use of this product should be reported to Fresenius Kabi Canada at 1-877-821-7724.

Fresenius Kabi Canada is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience this has caused and appreciate your understanding as we work to rectify this situation promptly.

Sincerely,

DocuSigned by:
Anabela Costa
Signer Name: Anabela Costa
Signing Reason: I approve this document
Signing Time: 18-Jan-24 | 1:22 PM EST
47888537775647CDA535261EA507915D

Anabela Costa
Vice President, Scientific Affairs
Fresenius Kabi Canada

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Medical Device Recall – Type III
List of Affected Lot Numbers
IV Infusion Sets - Label Discrepancy

January 23, 2024

The discrepancy on product labels and Instructions for Use (IFUs) for VL PR 42-11, Product Code M46445665 (Medical Device Licence 105146) and VL PR 42-12, Product Code M46445695 (Medical Device Licence 105146) communicated by Fresenius Kabi Canada on January 18, 2024 via Customer Communication (Type III recall) impacts the following lot numbers:

Product Description	Product Code	Lot Number
VL PR 42-11	M46445665	32163543
VL PR 42-11	M46445665	32175553
VL PR 42-11	M46445665	32184183
VL PR 42-11	M46445665	32194643
VL PR 42-11	M46445665	32194653
VL PR 42-11	M46445665	32205663
VL PR 42-11	M46445665	32205743
VL PR 42-11	M46445665	32205753
VL PR 42-11	M46445665	32215653
VL PR 42-11	M46445665	32215673
VL PR 42-11	M46445665	32215683
VL PR 42-11	M46445665	32225413
VL PR 42-11	M46445665	32225423
VL PR 42-11	M46445665	32225433
VL PR 42-11	M46445665	32235633
VL PR 42-11	M46445665	32235643
VL PR 42-11	M46445665	32245673
VL PR 42-11	M46445665	32271633
VL PR 42-11	M46445665	32345683
VL PR 42-11	M46445665	32355343

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Product Description	Product Code	Lot Number
VL PR 42-11	M46445665	32364783
VL PR 42-11	M46445665	32364793
VL PR 42-11	M46445665	32374833
VL PR 42-11	M46445665	32395603
VL PR 42-11	M46445665	32405503
VL PR 42-11	M46445665	32414713
VL PR 42-11	M46445665	32455643
VL PR 42-11	M46445665	32475503
VL PR 42-12	M46445695	32125563
VL PR 42-12	M46445695	32163733
VL PR 42-12	M46445695	32184373
VL PR 42-12	M46445695	32272603
VL PR 42-12	M46445695	32345713

Regards,

DocuSigned by:
Anabela Costa
Signer Name: Anabela Costa
Signing Reason: I approve this document
Signing Time: 23-Jan-24 | 11:22 AM EST
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Anabela Costa
Vice President, Scientific Affairs
Fresenius Kabi Canada

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Customer Reply Form

Medical Device Recall - Type III Customer Communication

IV Infusion Sets- Label Discrepancy

VL PR 42-11, Product code M46445665 (MDL# 105146)
VL PR 42-12, Product M46445695 (MDL# 105146)

January 18, 2024

Please complete and return this form to confirm receipt of this notification. Send to the following: • EMAIL: Canada_Product_Complaints@fresenius-kabi.com	
Facility Name and Address	
Reply Confirmation Completed By: *(Please Print Name)*	
Title: *(Please Print)*	
Phone Number: *Including Area Code*	

Please check the below box:

☐	We have received the above-mentioned letter, understand the instructions and have disseminated this information to our staff and to other centers or facilities who have received the affected devices, as applicable

Signature/Date:

_____

Print Name, Sign and Date