

Fresenius Kabi Canada Ltd.

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March 15, 2025

VL PR 44-12 IV Administration Set Allocation Notification

Dear Valued Customer,

Fresenius Kabi Canada would like to advise you that **our VL PR44-12 Primary IV Administration Set** will be on **50% allocation effective March 15, 2025**.

Fresenius Kabi	Product Description	Allocation	Estimated Full
Product Code		Quantity	Availability Date
M46445780	VL PR 44-12 Primary Infusion Set	50%	May 30, 2025

In the interim period, please consider use of M46445695 VL PR 42-12 IV administration set as a substitute. A copy of the Instruction For Use is attached for your convenience. This substitute is available at equal to or less than your contract pricing for M46445780. We apologize for the impact of this supply interruption and thank you for your patience and understanding in this matter.

If you have any questions or concerns, please do not hesitate to contact your Fresenius Kabi representative.

Sincerely,

Lucy Chen Senior Marketing Manager, MedTech Fresenius Kabi Canada



Volumat™ Line

VL PR42-12

1x1 REF M46445695

7.1 mL/m (104°F/40C°) 8.1 mL/m (104°F/40C°/1125mmHa) Length: ~105" (~265cm)
Priming Volume: ~26.3mL
Inner diameter: ~0.118" (3.0 mm)
Outer diameter: ~0.161" (4.1 mm)

IV administration set for infusion pumps (Agilia VP MC pumps/Volumat MC Agilia pump or gravity only)

With (1) protective cap, (2) spike, (3) air vent, (4) drip chamber, (5) upstream pinch clamp, (6) backcheck valve (7) upstream needle-free port, (8) rollerclamp, (9) green connector, (10) SafeClip, (11) downstream pinch clamp, (12a) downstream needle-free port, (12b) downstream needle-free port, (13) rotating male luer lock, (14) flow stop cap. Not made with natural rubber latex and DEHP.

Storage conditions: Store at room temperature, Keep dry, Keep away from sunlight,



2

Do not reuse.







Do not

resterilize



Sterilized by Ethylene Ox



20 drops / ml











(01)04250273750355 (17)YYMMDD (10)XXXXXXXX





Do not use if



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3

7

(B)

9

10 (11)

12a

-(12b)

(13) (14)



CAUTIONS:

Do not use if protection caps are detached. Check set integrity. Do not reuse due to a potential risk of patient or user infection. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the structural integrity of the device.

of the device.

Do not use needle-free port with luer devices having an internal diameter smaller than 0.063" (1.6mm). The needle-free port may be incompatible with some glass pre-filled syringes. Users should confirm the internal diameter of the male-luer connector of the mating glass syringe

CONTRAINDICATIONS:

Do not use for epidural administration. Some drugs may be incompatible with tubing materials ar components (e.g. light sensitive drugs): check drug labeling and hospital protocols.

REPORTING OF INCIDENTS:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

FLUID PATH MATERIAL:

PVC. PS. Silicone, MABS Nontoxic, non-pyrogenic fluid path.

SPIKING:

Use aseptic technique. Close roller clamp (8). Remove cap (1) from spike (2). Insert spike into bag. To avoid potentially puncturing the solution bag with the spike, it is recommended to place the bag on a clean, flat surface, and/or spike the bag while holding by the inlet port to ensure the inlet port is straight.

PRIMING:

Hang bag and fill drip chamber (4) to approximately 1/2 full. Slowly open the roller clamp (8) for priming. Air vent (3) should remain in a closed position unless infusing from a rigid bottle. When set is fully primed, close roller clamp (8), and check carefully for the absence of air bubbles. Prime the needle-free ports (7, 12a, 12b) before the first use

SET INSTALLATION IN PUMP:

Open the pump door by lifting the door lever. Align the tubing set horizontally with the green connector (9) positioned to the right and the SafeClip (10) positioned positioned to the right and the SafeClip (10) positioned in front of the clamp guide. Insert the green connector (9) in the green slot. Position the SafeClip (10) in the blue slot with the spherical hinge in the top position. Push the SafeClip (10) into the clamp guide. Ensure that the tube is in the left tube guide, then push the door lever to close the pump door. Hang the container 8 to 32 inches above the pump. Before turning on the pump, check the complete infusion setup.

NEEDLE-EREE PORTS:

Disinfect the needle-free port prior to each use with Disinfect the needle-free port prior to each use with 70% Isopropyl alcohol or according to CDC guidelines or hospital protocol, but for no less than 10 seconds. Upstream needle-free port (7) is for automatic secondary infusion only. The downstream needle-free port (12a, 12b) may be used to administer a manual bolus; when accessing the needle-free port, recommend that the infusion is stopped and the downstream pinch clamp is closed (11). Flush needle-free port (7, 12a, 12b) with normal salinie or according to hospital protocol after each use.

Do not use needle-free port:

- for more than 300 activations
- with blunt cannulas, needles or dead end caps. with luer slip if unattended.
- with non-compliant ISO luer devices.

Disinfection caps can be used

SET REMOVAL FROM PUMP:

Stop infusion. Close roller clamp (8), open door, remove infusion set from pump. Disconnect the set from IV access and container in accordance with hospital protocol. Set should not be used for more than 96 hours or 10 liters infusion, replace per hospital protocol or CDC guidelines. Discard biohazardous waste according to hospital protocol.

For Gravity use, ensure roller clamp (8) is closed, then open SafeClip (10) as shown below. Flow rate is regulated by roller clamp (8). Ensure roller clamp wheel moves freely when roller clamp (8) is in full open position.



Closed position after using in Pump. (stops flow)



Opened position (allows flow and gravity use)

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caring for life



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Symbol glossary: www.fresenius-kabi.com/us

- French information is available on request. fr - Les renseignements français sont disponibles sur demande.)

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