TEAR BAG TO OPEN

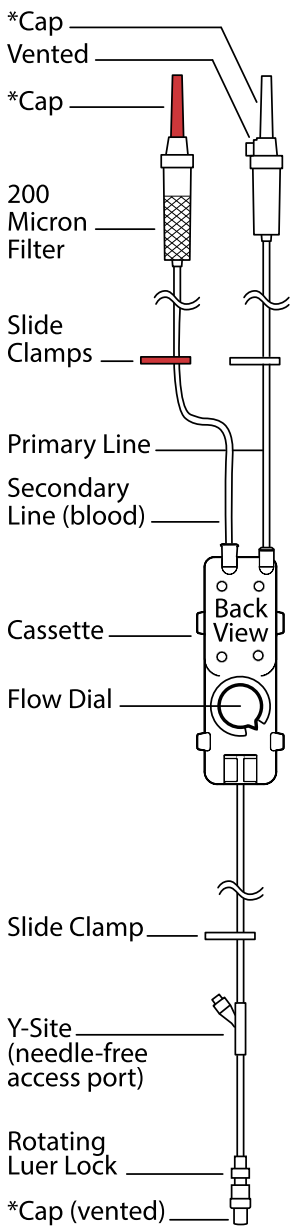
IVENIX INFUSION SYSTEM

LVP Blood Products Administration Set

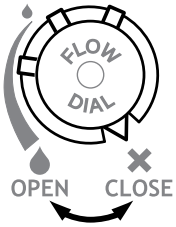
Dual-Inlet, Low-Sorbing, Y-Site, Mesh Filter

15 mL 15 mL

FOR BLOOD PRODUCTS
Contains Filtered Drip Chamber



Prime Set - Flush



1. Check to be sure the Flow Dial is closed (in the X, CLOSE position).
2. Clamp the Secondary (blood) line.
3. Use the Primary line and spike the flush bag. Use only with 0.9% sodium chloride injection (USP).
4. Fill the drip chamber 1/3 full.
5. Open the Flow Dial (turn the dial to the large droplet, OPEN position).
6. With the cassette held upright, prime the tubing. Rapidly tap the cassette while priming.
7. Once fluid has moved through the cassette and into the downstream tubing, stop tapping and watch fluid reach the patient connector (luer).
8. When the fluid reaches the luer lock, close the Flow Dial (turn the dial to the X, CLOSE position).

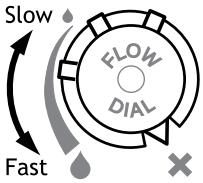
Load Set

9. Lift the lever on the Ivenix Large Volume Pump (LVP).
10. Slide the cassette onto the 4 loading posts.
11. Close the lever.

Prime Set - Blood

12. Use the Secondary line and spike the blood bag.
13. Unclamp the Secondary line.
14. Use the pump option to back prime until the drip chamber is 1/3 full.

Infuse by Gravity (Optional)



1. Position the cassette at least 12" below the container.
2. Prime the primary and secondary lines. Attach to the patient.
3. Rotate the Flow Dial to adjust the flow.

Warnings and Cautions

- Do not use if the caps (see the figure to the left*) are not connected.
- See reverse side for all additional warnings and cautions.

More Info

- Single Use Only.
- For use with an Ivenix Large Volume Pump only.
- Change a Blood Products Administration Set every 4 hours.
- Includes a 200-micron inline filter.
- Overall length 105" +/- 3".
- Approximate contained volume 16 mL (drip chamber 1/3 full).
- Fluid path is sterile and non-pyrogenic.
- Fluid path not made from materials that contain natural rubber latex or phthalates (DEHP).
- Tubing is polyethylene lined (low-sorbing).
- No medications or solutions may be added to or infused through the same tubing simultaneously with blood or blood components with the exception of 0.9% sodium chloride, unless: 1) they have been approved for this use by the FDA, or 2) there is documentation available to show that the addition is safe and does not adversely affect the blood or blood component.
- Infusion Flow Rate Range: 0.5–500 mL/hr
- See reverse side for more information.

FRESENIUS KABI
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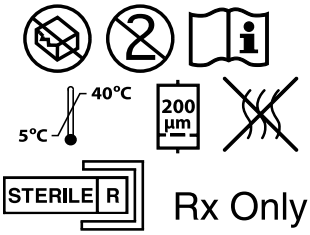

Rx Only

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REF	SET-0014-1
LOT	
Qty:	1 each

Assembled in

Doc #: 800-0014-01 Rev G

Warnings, Cautions, and Notes

⚠ Warnings

- The administration set Flow Dial or slide clamp must be closed to prevent uncontrolled flow if a patient-connected administration set is not loaded in an LVP. Use the Flow Dial and monitor flow rate using the drip chamber to administer a controlled gravity infusion.

- Prime all administration sets with fluid to remove air bubbles from the cassette, line (tubing), and injection sites. Infused air bubbles may cause embolisms.
- Do not prime or purge an administration set while attached to a patient. Infused air bubbles may cause embolisms. Disconnect the set from the patient and prime the line to remove the air bubbles.

⚠ Cautions

- Inspect the cassette and downstream line for leaks that indicate a defective set after priming an administration set. Replace a defective set to ensure that the patient receives all of the medication.
- Do not pierce a needle-free connector with a blunt cannula, needle, or end cap which can activate the membrane. Their use damages the connector and causes leakage. Use a luer-lock injection-site adapter for administering medications to a downstream Y-site.
- Avoid excessive activations of the needle-free connector. More than 48 activations may compromise its prevention of microbial ingress.
- The needle-free connector can only be used with standard luer devices with an internal diameter greater than 1.6mm (equal 0.063"). Usage of smaller devices may damage the injection port.
- Do not pressurize an administration set by infusing into a hyperbaric chamber at a pressure greater than 525 mmHg (10 psi). High pressure can damage the cassette and, if connected to a patient, cause blood loss.
- Practice aseptic technique (per your facility's policy) when using the administration set fluid-path connections to prevent contamination and reduce the risk of infection. Wear personal protective equipment (e.g., gloves) to avoid microorganism transmission. Sanitize the needle-free connector by applying a 70% isopropyl alcohol wipe for 10 to 15 seconds in a scrubbing motion. Allow to dry for at least 15 seconds.
- Administration sets are intended for single use only. Reuse or re-sterilization of a set might cause damage, infections, or allergic reactions.
- Do not use the slide clamp to regulate a gravity infusion. The clamp can become dislodged inadvertently and cause an overdose. Use the Flow Dial.
- Remove any residual air bubble (approximately 40 mcL) with a syringe from the downstream Y-site connector before use. The air bubble can cause an embolism.
- Do not invert the administration set cassette during priming. Inverting the cassette inhibits air bubble removal. Air bubbles that are retained in the cassette will be detected and may stop an infusion.
- Dispose of an administration set only per the institution’s disposal policy.

Notes

- Fill the administration set drip chamber (1/3 full) before opening the Flow Dial to avoid entraining air bubbles during priming.
- Do not administer blood products via the primary inlet. The primary inlet does not contain a filter to remove clots and microaggregates.
- Programming a flow rate greater than 500 mL/hr for blood products may lead to an increased level of hemolysis.
- The soft copy of the Instructions For Use (English/French) is available at http://www.fresenius-kabi.ca. *(*La copie électronique du Mode d'emploi (anglais/français) est disponible sur http://www.fresenius-kabi.ca*)*