**LifeFlow® Rapid Infusion System**

**Instructions for Use**

**Warning:** Failure to follow any instructions or failure to heed any warnings or precautions could result in serious patient injury. Do not use with blood or blood products.

**Indications For Use:**
The LifeFlow® Rapid Infusion Device is an intravenous administration set with Handle intended for rapid delivery of fluids from a container into a patient’s vascular system. The device is intended to deliver only crystalloid and colloid resuscitative fluids. These devices may be used for any adult or pediatric patient population with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.

*Capable of rates greater than 150mL/min through a 20G needle.

**Precautions:**
- Use aseptic technique.
- Monitor IV site for infiltration/extravasation during infusion.
- Ensure all air is purged from the IV line, syringe, and fluid bag. Failure to do so may result in air embolism.
- The LifeFlow Device is intended for use with collapsible IV bags. Do not attempt to connect the LifeFlow Device to a rigid IV fluid container.
- As with any emergency medical device, the availability of a backup device is strongly advised.
- Rx Only: Federal Law (US) restricts this device to sale by or on the order of a physician.
- Compatible for use with vascular access that is rated for contrast infusion pressures (300psi).
- The LifeFlow Device has not been tested with fluids warmed above 30°C.

**Product Description:**
The LifeFlow Rapid Infusion System contains:
- (1) LifeFlow IV Tubing Set
  - Inlet IV Tubing Set & Detachable Y Connector Tubing Set
  - Intended for use with the LifeFlow Handle
  - Sterile, single-use, non-pyrogenic in sterile pouch
  - Inlet tubing: Approximate priming volume 25mL
  - Y tubing: Approximate priming volume 2mL
  - Total approximate priming volume: 27mL
- (1) LifeFlow Handle

**LIFEFLOW IV TUBING SET**
- **Inlet IV Tubing Set & Detachable Y Connector Tubing Set**
  - Intended for use with the LifeFlow Handle
  - Sterile, single-use, non-pyrogenic in sterile pouch
  - Inlet tubing: Approximate priming volume 25mL
  - Y tubing: Approximate priming volume 2 mL
  - Total approximate priming volume: 27 mL

**INSTRUCTIONS FOR USE**

1. **Assemble IV set**
   a. Remove Inlet IV Tubing and Y Connector Tubing from Tyvek® pouch.
   b. Remove paper band.

   **Important**
   - Use aseptic technique when handling all IV set connections.
   - Before connecting, disinfect needleless connectors with alcohol per institutional protocol.

2. **Optional: Assemble Y Connector Tubing to Inlet IV Tubing**
   a. Attach the Luer connectors as shown and check that they are firmly locked.

   **Important**
   - Only connect the male Luer to the female Luer connection as shown below. Do not connect the male Luer to the needleless "Y connector."

3. **Spike IV fluid bag**
   a. Remove safety cap from IV Bag Spike
   b. Insert into IV fluid bag

4. **Insert the 10mL syringe from the IV Tubing Set into LifeFlow Handle**
   a. Open the transparent Canopy by squeezing tabs (see below) and pulling up. The Canopy is hinged at the rear (handle side).
   b. Place 10mL syringe from IV Tubing Set into LifeFlow Handle with numbers facing up.
   c. Make sure the plunger is firmly seated in the shuttle and the flange is firmly seated in the Handle slot.
   d. If the plunger does not fit easily into shuttle, it may be necessary to manually move the plunger in or out until it drops into place.
   e. Close the Canopy until it latches.
   f. Grasp the Handle and squeeze the Trigger Loop until the pin lock disengages with an audible click.

**LIFEFLOW HANDLE**
- **410 LifeFlow Handle**
  - Intended for use with the IV Tubing Set
  - Non-sterile in foam-lined box
  - **Storage:** -20°C TO 50°C (-4°F TO 122°F)

**Syringe**
- **Inlet IV Tubing connected to Y Connector Tubing**
  - Syringe flange seated in slot
  - Syringe markings up
  - Syringe plunger seated in shuttle

**Canopy**
- **Canopy Hinge**
- **Tabs**
- **Canopy Release**

**Important**
- Use aseptic technique when handling all IV set connections.
- Before connecting, disinfect needleless connectors with alcohol per institutional protocol.
5. Prime System
   a. Release the Trigger loop by squeezing inward, and then release.
   b. Hold fluid bag upside down and purge all air from bag by cycling trigger repeatedly before moving to next step.
   c. Point Handle (syringe tip) up during priming. WARNING: Failure to elevate the syringe may allow air to remain in the syringe.
   d. Hang IV bag upright on pole and continue to cycle trigger until tubing is completely primed.

   g. If additional IV bags are required, disconnect tubing from the patient and purge all air from the new bag of fluid, by inverting the bag and squeezing trigger. Be sure to check that all tubing and the syringe is completely free of air before reconnecting to the patient.
   h. A Device (Handle and Tubing Set) can be used to infuse up to 4L of fluid; if more than 4L of fluid are needed, use a new Device (Handle and Tubing Set).

6. Connect primed IV tubing to IV access cannula and begin infusion
   a. Connect the male Luer lock of primed IV tubing to a previously established IV access cannula.
   b. Squeeze the Trigger Loop to begin infusing fluid.
   c. Release the Trigger Loop to draw fluid from the IV bag and refill the syringe.
   d. Continue to squeeze and release the Trigger Loop until the desired amount of fluid has been infused.
   e. As in any IV administration procedure, ensure the IV bag is suspended in its upright position above the height of the Handle to ensure air does not enter tubing.
   f. Stop compressing the Trigger Loop if air enters the proximal portion of the Inlet IV Tubing, and disconnect from the patient line.

7. Using the Needleless Y Connector
   a. Liquids can be delivered through Needleless Y Connector. Remove the syringe from the Needleless Y Connector before resuming infusion.
   b. A maintenance IV can also be connected to the Needleless Y Connector. The LifeFlow device can remain connected if an immediate need for additional rapid infusion is anticipated.
   c. A Device (Handle and Tubing Set) can be used to infuse up to 4L of fluid; if more than 4L of fluid are needed, use a new Device (Handle and Tubing Set).

   ***Important***
   Remove all other connections from Y tubing or patient tubing before infusing with the LifeFlow.

   e. Elevate syringe to a vertical position, and tap on outside of canopy as necessary to fully evacuate all visible air bubbles.
   f. Tap and invert Y valve as necessary to remove any air bubbles.
   g. Priming can be completed while vented sterile cap remains in place.

   g. If additional IV bags are required, disconnect tubing from the patient and purge all air from the new bag of fluid, by inverting the bag and squeezing trigger. Be sure to check that all tubing and the syringe is completely free of air before reconnecting to the patient.
   h. A Device (Handle and Tubing Set) can be used to infuse up to 4L of fluid; if more than 4L of fluid are needed, use a new Device (Handle and Tubing Set).

   **TROUBLESHOOTING**

   **ISSUE**
   - Canopy will not close
   - System does not prime / Infusing is difficult
   - No fluid flows when Trigger Loop is squeezed
   - Trigger Loop will not release
   - Trigger Loop breaks during use

   **CHECK LIST**
   - Ensure the Inlet IV Tubing is properly seated in the Handle with the syringe markings facing up.
   - Ensure the Canopy is aligned.
   - Ensure the Y Tubing Cap is removed.
   - Ensure the IV bag still has fluid present.
   - Ensure the trigger lock is engaged.
   - Ensure the plunger is properly seated in the shuttle.

   **REFERENCE**
   - Single Use
   - Sterile
   - Do not reprocess
   - Do not use if package is damaged
   - Rx Only
   - This device is restricted for sale by or on order of a physician

   **MANUFACTURER**
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