

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.
- The LifeFlow Handle is only designed for use with LifeFlow tubing.
- 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
- (1) LifeFlow Handle

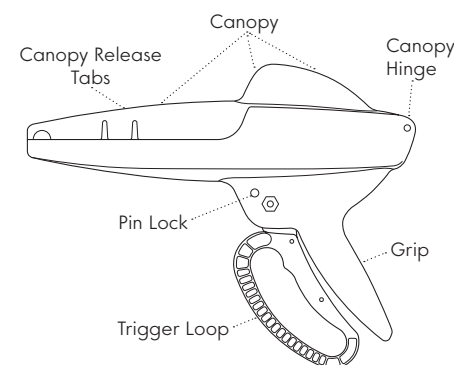
Storage:

-20° C TO 50° C (-4° F TO 122° F)

LIFEFLOW HANDLE

410 LifeFlow Handle

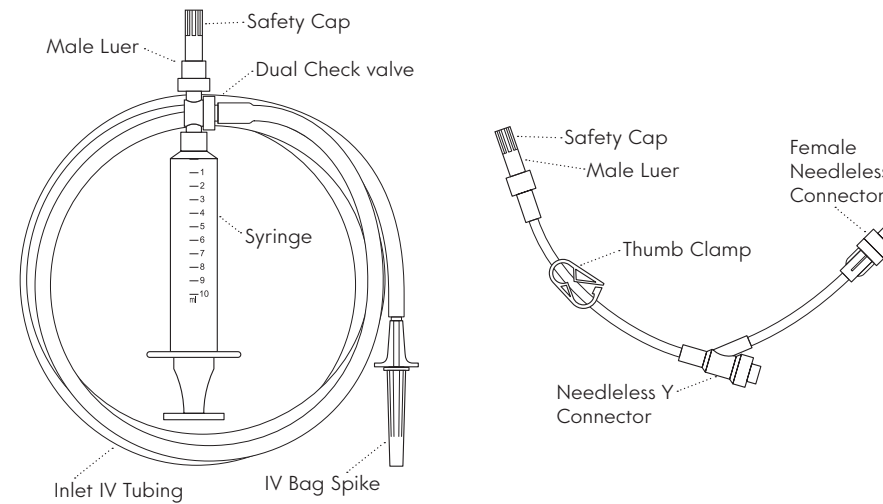
- Intended for use with the IV Tubing Set
- Non-sterile in foam-lined box



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



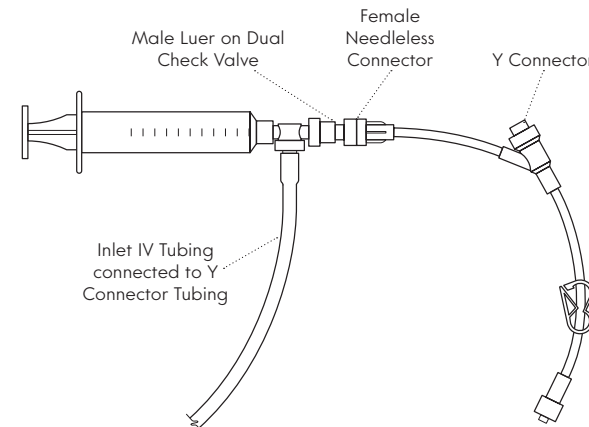
INSTRUCTIONS FOR USE

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.

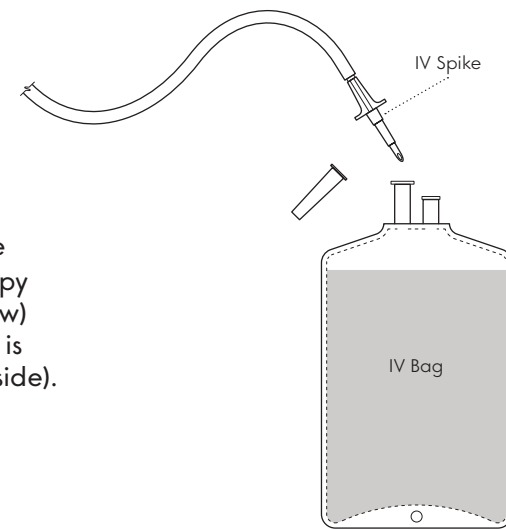
2. Optional: Assemble Y Connector Tubing to Inlet IV Tubing
 - a. Attach the Luer connectors as shown and check that they are firmly locked.

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."

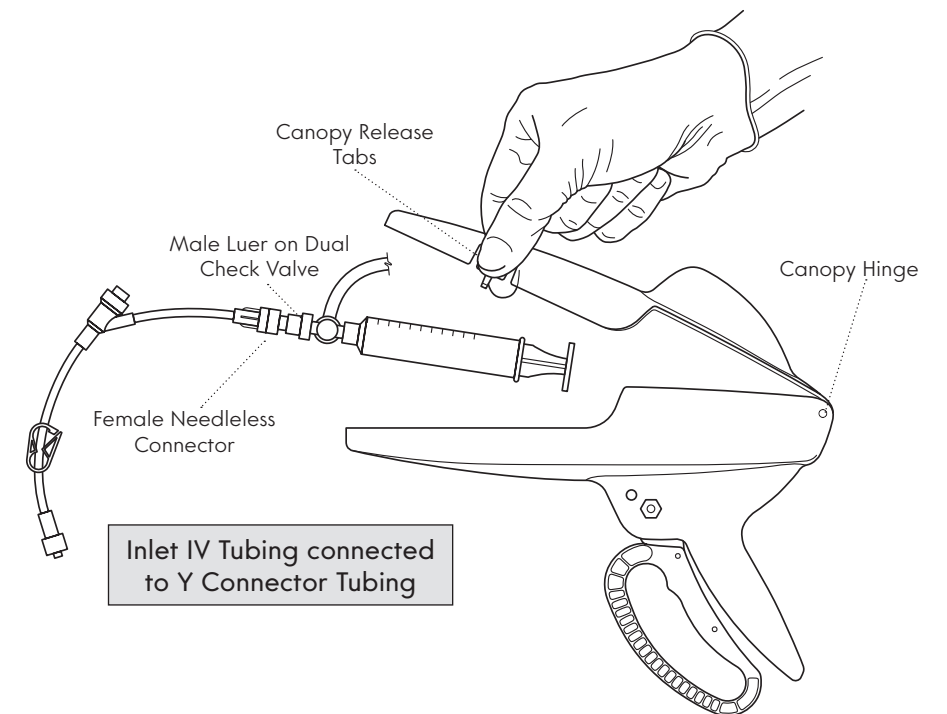


Important Use aseptic technique when handling all IV set connections. Before connecting, disinfect needleless connectors with alcohol per institutional protocol.

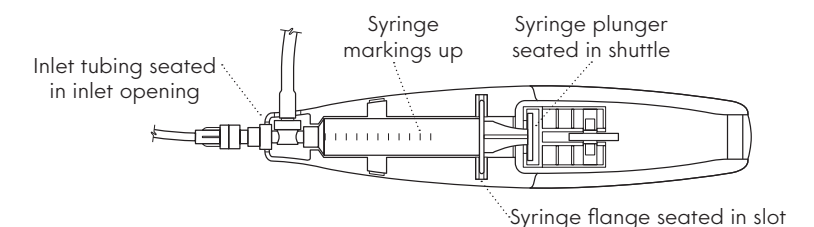
3. Spike IV fluid bag
 - a. Remove safety cap from IV Bag Spike
 - b. Insert into IV fluid bag
4. Insert the 10mL syringe from the IV Tubing Set into LifeFlow Handle
 - a. Open the transparent Canopy by squeezing tabs (see below) and pulling up. The Canopy is hinged at the rear (handle side).



Squeeze Canopy Release Tabs and lift Canopy



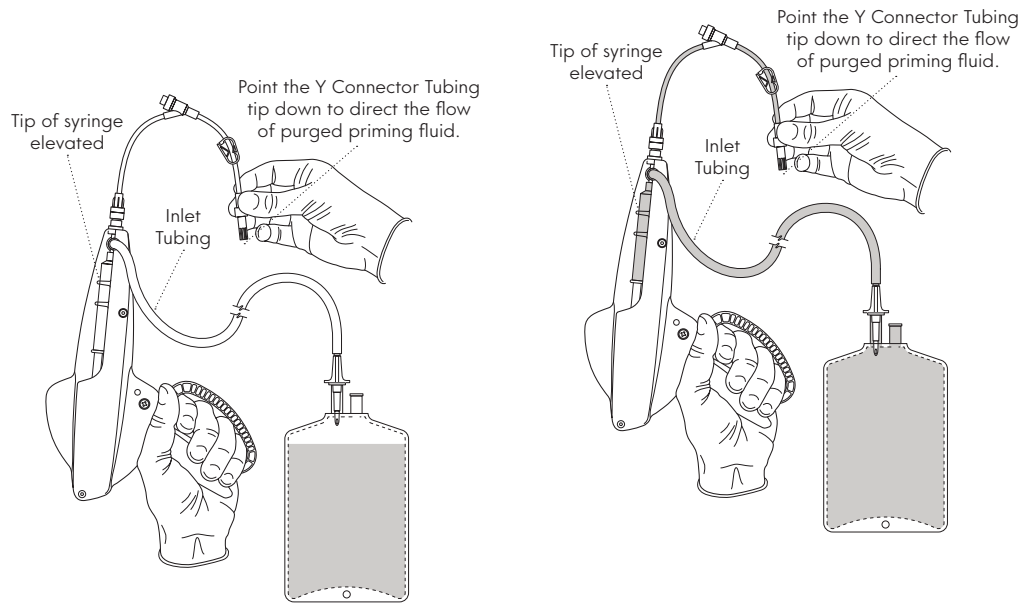
- b. Place 10mL syringe from IV Tubing Set into LifeFlow Handle with numbers facing up.
- c. Make sure the plunger is firmly seated in the shuttle and the flange is firmly seated in the Handle slot.
- d. If the plunger does not fit easily into shuttle, it may be necessary to manually move the plunger 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.

5. Prime System

- Release the Trigger loop by squeezing inward, and then release.
- Hold fluid bag upside down and **purge all air from bag** by cycling trigger repeatedly before moving to next step.
- Point Handle (syringe tip) up during priming. **WARNING: Failure to elevate the syringe may allow air to remain in the syringe.**
- Hang IV bag upright on pole and continue to cycle trigger until tubing is completely primed.



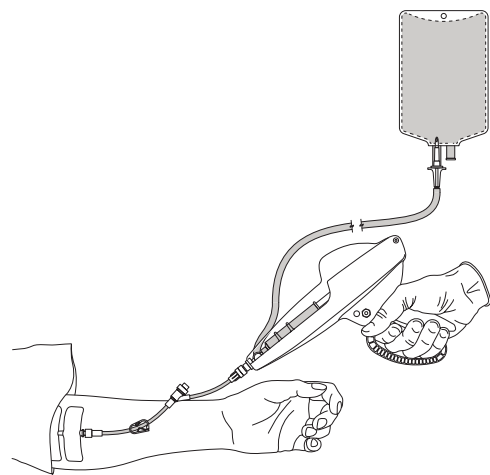
Important Make sure **all air is purged from the IV line, syringe and fluid bag before attaching to patient IV access.** Failure to do so may lead to air embolism.

Important Use of catheters smaller than 20G will result in a slower flow.

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

6. Connect primed IV tubing to IV access cannula and begin infusion

- Connect the male Luer lock of primed IV tubing to a previously established IV access cannula.
- Squeeze the Trigger Loop to begin infusing fluid.
- Release the Trigger Loop to draw fluid from the IV bag and refill the syringe.
- Continue to squeeze and release the Trigger Loop until the desired amount of fluid has been infused.
- 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.
- Stop compressing the Trigger Loop if air enters the proximal portion of the Inlet IV Tubing, and disconnect from the patient line.

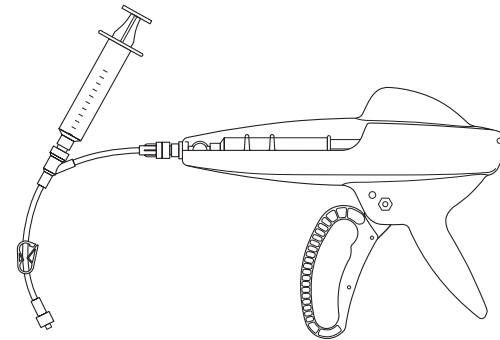


- If additional IV bags are required, disconnect tubing from the patient **and purge all air from the new bag** of fluid, by inverting the bag and squeezing trigger. Be sure to check that all tubing and the syringe is completely free of air before reconnecting to the patient.
- A Device (Handle and Tubing 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).

7. Using the Needleless Y Connector

- Liquids can be delivered through Needleless Y Connector. Remove the syringe from the Needleless Y Connector before resuming infusion.
- 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.
- 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.



Important Ensure IV access device is patent prior to infusion.

Important Monitor IV infusion site for infiltration/extravasation. If either is observed, immediately stop infusing. Reestablish IV access or switch to an alternate site before resuming infusion.

Important Clinician should observe and monitor for air in 10mL syringe, tubing and IV bag. If air is observed, disconnect line from patient and purge tubing.

Important Check resistance during fluid delivery to assure proper flow. Handle provides tactile feedback—if you notice a change in resistance, check line for air, patency of line, and all connections.

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

Important Fully compress the Handle. Note: Each compression will infuse approximately 10mL of fluid.

Important During use clinician should monitor number of 10mL syringe plunger compressions and volume of fluid in IV bag to account for total infused volume.

Important The Device should not be used for longer than 24 hours.

Important No fluid will free-flow to the patient unless the trigger is compressed by the clinician.

TROUBLESHOOTING

ISSUE	CHECK LIST
Canopy will not close	<ol style="list-style-type: none"> Ensure the Inlet IV Tubing is properly seated in the Handle with the syringe markings facing up. Ensure the Canopy is aligned. Ensure the syringe flanges are properly seated in the handle slots. Ensure the plunger is properly seated in the shuttle.
System does not prime / Infusing is difficult	<ol style="list-style-type: none"> Ensure the thumb clamp on the Y Connector Tubing is open. Ensure the Y Tubing Cap is removed. Ensure the IV bag still has fluid present.
No fluid flows when Trigger Loop is squeezed	<ol style="list-style-type: none"> Ensure the plunger is properly seated in the shuttle.
Trigger Loop will not release	<ol style="list-style-type: none"> Ensure the plunger is properly seated in the shuttle. Manually release the Pin Lock.
Trigger Loop breaks during use	<ol style="list-style-type: none"> Excessive force was used during compression of the Trigger Loop. Remove the syringe from the Handle and continue to infuse fluid into the patient by manually compressing the syringe or get backup unit.

STERILE R

LOT Lot number

REF Reference number

Do not use if package is damaged

Rx Only This device is restricted for sale by or on order of a physician

Do not resterilize

Single Use

Consult Instructions for use

Manufactured For:
410 Medical, Inc.
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Durham, NC 27701
USA

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