



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:

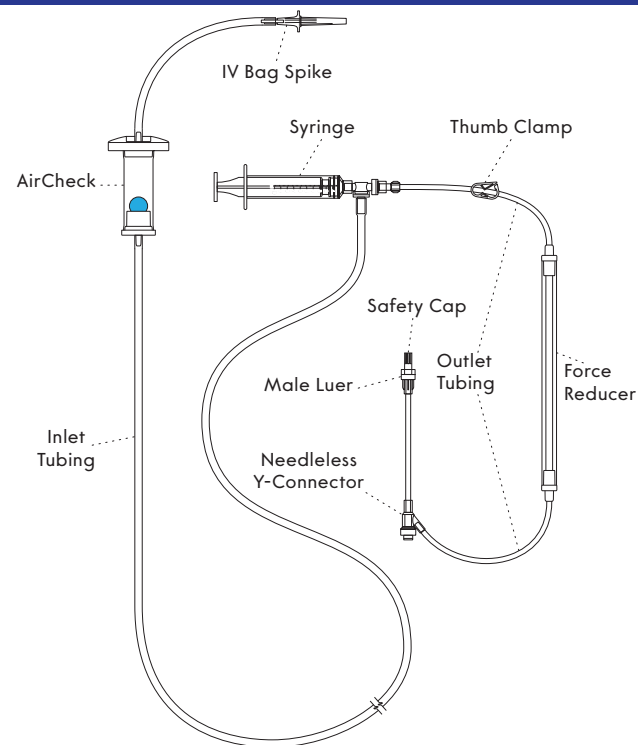
- Use aseptic technique.
- Monitor IV site for infiltration/extravasation during infusion.
- Ensure **all air is purged from the IV line and syringe**. Failure to do so may result in air embolism.
- The LifeFlow Device is intended for use with collapsible IV bags. Do not attempt to connect the LifeFlow Device to a rigid IV fluid container.
- The LifeFlow Handle is only designed for use with LifeFlow IV Tubing Set.
- 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.
- **To avoid risk of catheter disruption, do not use with non-power injectable ports, PICCs, and CVCs.**
- **LifeFlow is compatible for use with all vascular access that is rated for contrast infusion pressures (300psi). LifeFlow may be compatible with vascular access, extension tubing, and PIVs that are not pressure rated. Contact 410 Medical for additional guidance with specific non-pressure rated access.**

LIFEFLOW IV TUBING SET (1)

The LifeFlow IV Tubing Set with AirCheck® and Force Reducer™ is packaged sterile, single use, non-pyrogenic in a pouch intended for use with the LifeFlow Handle.

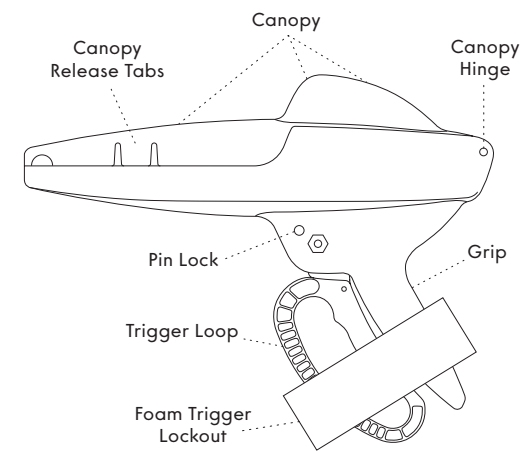
Total approximate priming volume: 50mL
Approximate outlet tubing priming volume: 5mL

Important - LifeFlow tubing may be used with catheters as small as 24G. Flow rates may decrease with smaller catheter sizes.



LIFEFLOW HANDLE (1)

Intended for use with the LifeFlow IV Tubing Set. Non-sterile with removable foam trigger lockout.



INSTRUCTIONS FOR USE

1. Unpackage the LifeFlow IV Tubing Set

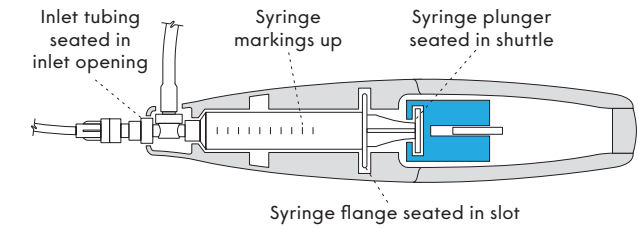
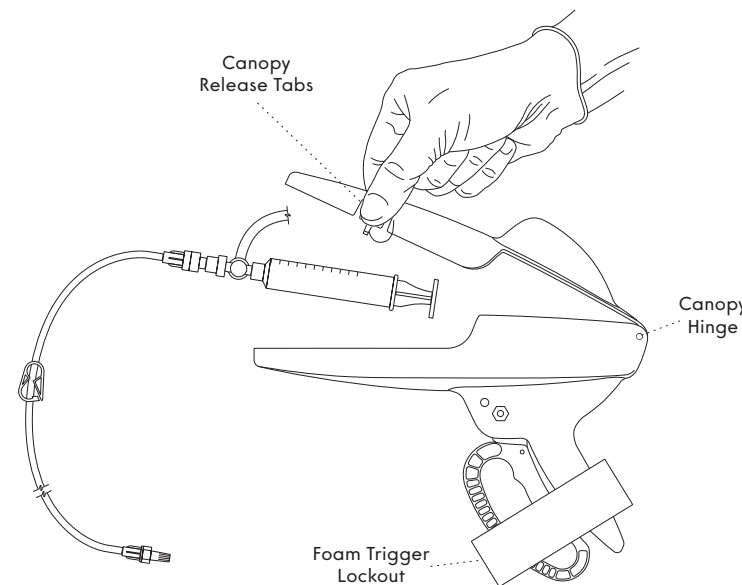
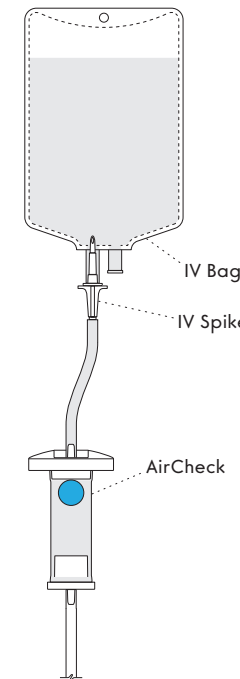
Important - Use aseptic technique when handling all IV set connections. Before connecting, disinfect needleless connectors per institutional protocol.

2. Spike IV fluid bag

- Remove safety cap from IV Bag Spike
- Insert into IV fluid bag

3. Insert the 10mL syringe from the LifeFlow IV Tubing Set into LifeFlow Handle

- Open the transparent Canopy by squeezing tabs (see below) and pulling up.
- Place 10mL syringe from the LifeFlow IV Tubing Set into LifeFlow Handle with numbers facing up.
- Make sure the plunger is firmly seated in the blue shuttle and the flange is firmly seated in the Handle slot.

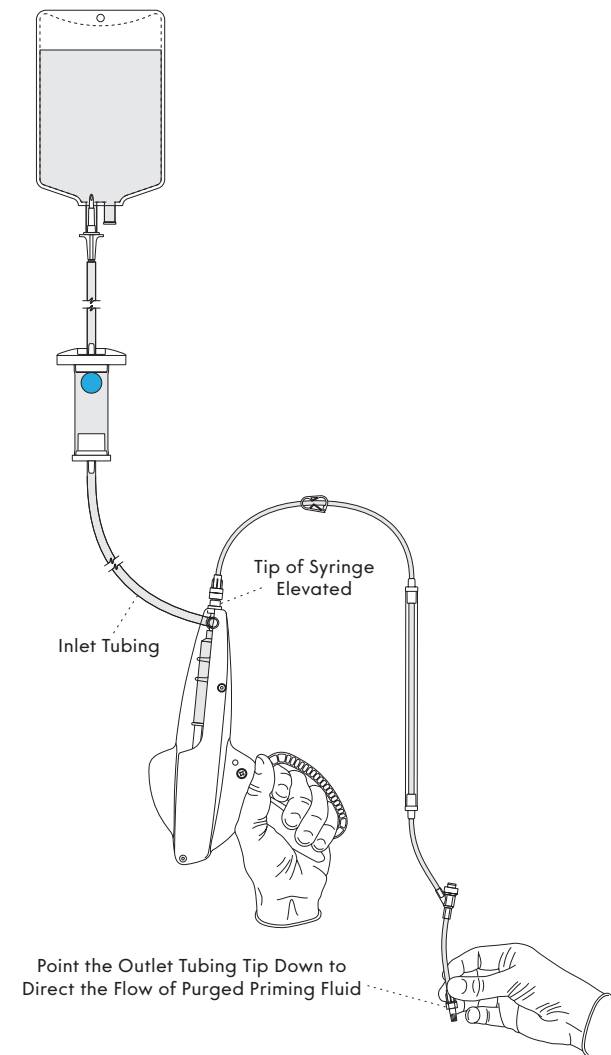


- If the plunger does not fit easily into the blue shuttle, it may be necessary to manually move the plunger in or out until it drops into place.
- Close the Canopy until it latches.
- Remove the foam trigger lockout.
- Grasp the Handle and squeeze the Trigger Loop until the pin lock disengages with an audible click.

4. Prime System

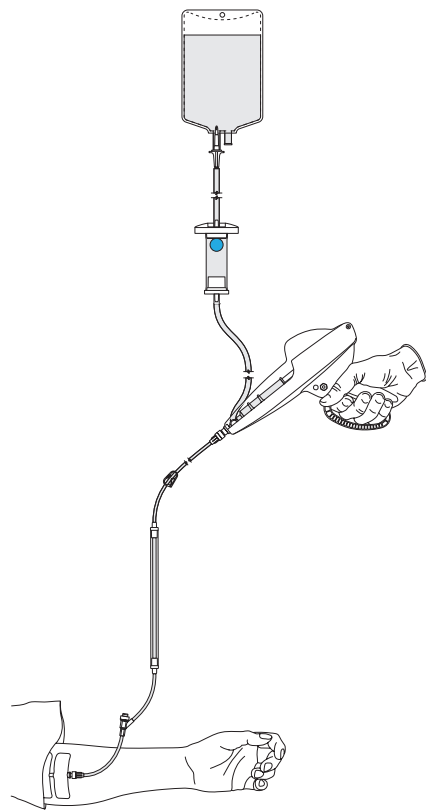
- Raise the IV bag above the AirCheck. Orient the AirCheck vertically and allow it to fill completely.
 - Squeeze below ball, if necessary, to release.
 - Point Handle (syringe tip) up during priming.
- Warning:** Failure to elevate the syringe may allow air to remain in the syringe.
- Priming can be completed while the vented sterile cap remains in place.
 - Cycle the Trigger Loop until the entire LifeFlow IV Tubing Set is primed
 - 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 and Force Reducer as necessary to remove any air bubbles.

Important - Make sure all air is purged from the IV line and syringe before attaching to patient IV access, and ensure AirCheck remains vertical during infusion. Failure to do so may lead to air embolism.

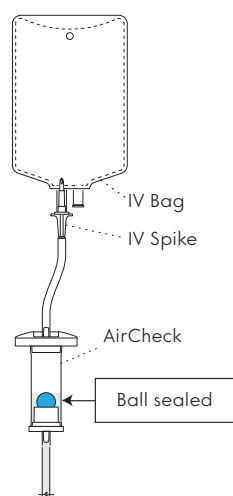


5. Check patency of IV access cannula and connect primed LifeFlow IV Tubing Set, then begin infusion.

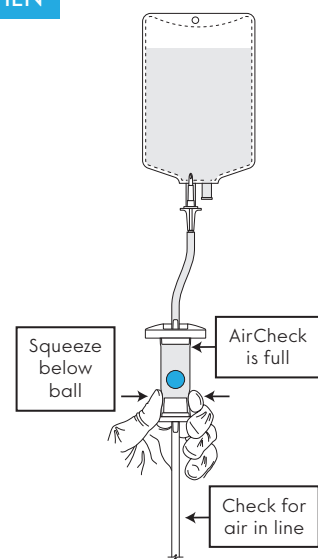
- Connect the male Luer lock of primed LifeFlow IV Tubing Set to a previously established IV access cannula.
- Squeeze the Trigger Loop to begin infusing fluid.
- Release the Trigger Loop to draw fluid from the IV bag and refill the syringe.
- Continue to squeeze and release the Trigger Loop until the desired amount of fluid has been infused. Fluid does not flow until the Trigger Loop is squeezed.
- Ensure that the AirCheck remains vertical while infusing so that air does not enter the LifeFlow IV Tubing Set.
- If the force to squeeze the handle changes during use, slow the rate of infusion and check the patient infusion site.
- Stop infusing fluids while a small amount of fluid remains in the fluid bag.
- If the AirCheck ball suctions to the bottom during use, the Trigger Loop will no longer return to its open position. If this happens, disconnect from the patient and check entire system for air.**
 - Spike a new bag.
 - Refill chamber completely with fluid.
 - Squeeze AirCheck below the ball until it floats.
- Check for air in the line. Re-prime the line if needed.**
- If any air is present in the LifeFlow IV Tubing Set, cycle the Trigger Loop until all air is removed.
- Reconnect to the patient and continue infusing.



IF



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6. If additional IV bags are required, spike new bag and suspend the bag vertically above the AirCheck making sure the AirCheck is vertical.

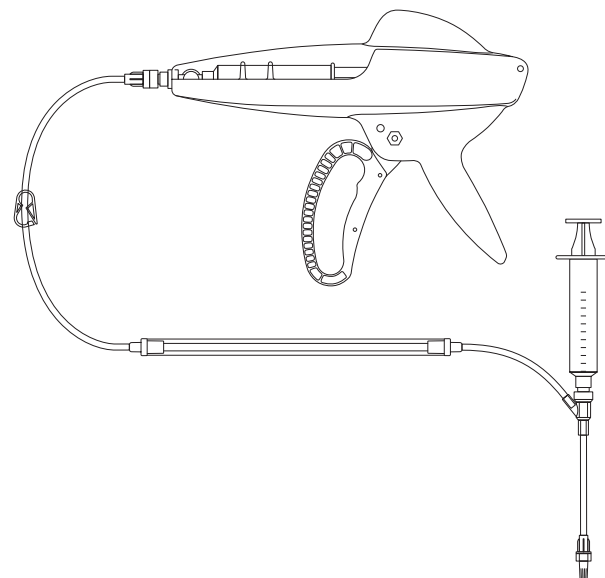
- Be sure to check that the LifeFlow IV Tubing Set and the syringe are completely free of air before continuing infusion.
- A Device (Handle and Tubing Set) can be used to infuse up to 4L of fluid; if more than 4L of fluid are needed, use a new Device (Handle and Tubing Set).

7. Using the Needleless Y Connector.

- Liquids can be delivered through Needleless Y Connector.
- When delivering liquids through the Needleless Y Connector, it is important to squeeze the Trigger Loop at least twice following delivery of the liquids to ensure the full volume of delivered liquid reaches the patient, as fluid may flow from the Y connector into the Force Reducer, even if the thumb clamp is closed.
- Maintenance IV bag(s) can also be connected to the Needleless Y Connector.

Optional Priming Procedure:

- Hold the IV bag upside down so air travels up towards the spike, while keeping AirCheck upright.
- Manually squeeze the fluid bag until all air is purged out through the AirCheck.
- Remove all remaining air from the LifeFlow IV Tubing Set by cycling the Trigger Loop.



WARNING: Failure to elevate the syringe may allow air to remain in the syringe.

Optional Method to Switch Bags:

- Spike a new bag.
- Hold the bag upside down so the air goes towards the spike and keep the AirCheck vertical.
- Manually squeeze the bag until no air remains in the bag.
- Once complete, make sure the AirCheck remains vertical.
- Be sure to check that the LifeFlow IV Tubing Set and the syringe are completely free of air before continuing infusion.

- Important** - Remove all other connections from outlet 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, and the LifeFlow IV Tubing Set. If air is observed, disconnect line from patient and purge tubing.
- Important** - Clinician should observe and monitor for vascular congestion during intraosseous (IO) use in the leg of an infant patient. The rate of infusion should be slowed or stopped, if vascular congestion is observed, until swelling subsides.
- 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. With small catheters (22G, 24G), if noticeable swelling occurs in the Force Reducer, slow down infusion and check the infusion site.
- Important** - Use aseptic technique when handling all IV set connections. Before connecting, disinfect needleless connectors per institutional protocol.
- Important** - Fully squeeze the Trigger Loop. Note: Each squeeze will infuse approximately 10mL of fluid.

- Important** - During use clinician should monitor number of 10mL syringe plunger cycles 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** - Fluid delivery requires the Trigger Loop to be squeezed by the clinician. Disconnect from the patient when not in use.

| TROUBLESHOOTING | |
|--|--|
| ISSUE | CHECK LIST |
| Canopy will not close | <ol style="list-style-type: none"> Ensure the LifeFlow IV Tubing Set 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 IV bag still has fluid present. Observe AirCheck and ensure ball is floating. If not, check entire LifeFlow IV Tubing Set for air, remove all air, squeeze below ball until it floats, then continue priming. Ensure the thumb clamp on the Outlet Tubing is open. Ensure the Outlet Tubing cap is removed. Ensure the plunger is properly seated in the shuttle. Remove the foam trigger lockout. Check for occlusion at the patient site. |
| Trigger Loop breaks during use | <ol style="list-style-type: none"> Excessive force was used when squeezing the Trigger Loop. Remove the syringe from the Handle and continue to infuse fluid into the patient by manually cycling the syringe or get backup unit. |
| Trigger Loop will not return when released during infusion | <ol style="list-style-type: none"> Ensure that the IV bag still has fluid present. Observe AirCheck and ensure ball is floating. If not, check entire LifeFlow IV Tubing Set for air, remove all air, and squeeze below ball until it floats. |

STERILE R

LOT Lot number

REF Reference number

Do not use if package is damaged

Tubing set is not made with DEHP plasticizer

Tubing set is not made with natural rubber latex

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.
201 W. Main St., Suite 207
Durham, NC 27701, USA

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LifeFlow Fluid Infuser