



INSTRUCTIONS FOR USE

Warning:

Failure to follow any instructions or failure to heed any warnings or precautions could result in serious patient injury.

Indications For Use:

The LifeFlow[®] Blood System is an intravenous administration set that is intended for the rapid^{*} delivery of blood, blood components (red blood cells or plasma), and crystalloid and colloid resuscitative fluids from a container to a patient's vascular system. These devices may be used for any adult or pediatric patient, greater than 28 days old and greater than 3 kg, with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.

The delivery of blood products is intended for patients requiring volume replacement for hemorrhagic shock or life-threatening bleeding.

**Capable of rates greater than 100mL/min.*

Warnings:

- Do not mix lactated Ringer's or other solutions containing calcium and citrated blood products.
- Hyperkalemia and hypocalcemia are known risks of blood transfusion. Infants may be more susceptible to the adverse effects of hyperkalemia and hypocalcemia from rapid transfusion of blood products. Closely monitor serum potassium and ionized calcium and consider treatment as necessary. The risk of hyperkalemia may be reduced by the use of fresh (<7 day old) blood, the use of catheters 22G or larger, pre-transfusion washing, and minimization of the interval between irradiation and transfusion.
- Use only anticoagulated blood and blood components (red blood cells or plasma).
- Practice standard precautions when handling blood products.
- Ensure **all air is purged from the IV line and syringe before connecting to the patient.** Failure to do so may result in air embolism.

Precautions:

- Replace any component in contact with blood products every 4 hours or less to limit bacterial growth and maintain proper flow.
- Use aseptic technique.
- Monitor IV site for infiltration / extravasation during infusion.
- The LifeFlow[®] PLUS is intended for use with collapsible IV bags. Do not attempt to connect the LifeFlow[®] PLUS to a rigid or glass IV fluid container.
- This product is designed for the transfusion of blood or blood components (red blood cells or plasma) for patients with hemorrhagic shock or life-threatening bleeding. Hemolysis may be increased when delivering whole blood and PRBCs at high flow rates through small catheters. The risk to the patient from hemolysis with this product is small compared to the benefits of rapid blood delivery for patients with hemorrhagic shock.
- To minimize the risk of hemolysis, always use the largest catheter size possible when transfusing blood or blood components (red blood cells or plasma) and do not use excessive force when squeezing the Trigger Loop.
- When transfusing blood or blood components (red blood cells or plasma), use a 22G catheter or larger. When infusing other fluids, including crystalloids and colloids, use a 24G catheter or larger.
- The LifeFlow[®] Handle is only designed for use with the LifeFlow[®] PLUS Blood & Fluid Tubing.
- As with any emergency medical device, the availability of a backup device is strongly advised. The LifeFlow[®] PLUS can be set up and primed in less than 5 minutes. If the user is unable to set up and prime the device in this time frame, the user may consider switching to a backup device.
- 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[®] PLUS is compatible for use with all vascular access that is rated for contrast infusion pressures (300psi). LifeFlow[®] PLUS 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.**
- The LifeFlow[®] PLUS has been tested with PRBCs and FFP warmed to 42°C.
- If syringe slows down or filter clogs, restart infusion with a new tubing set or device.

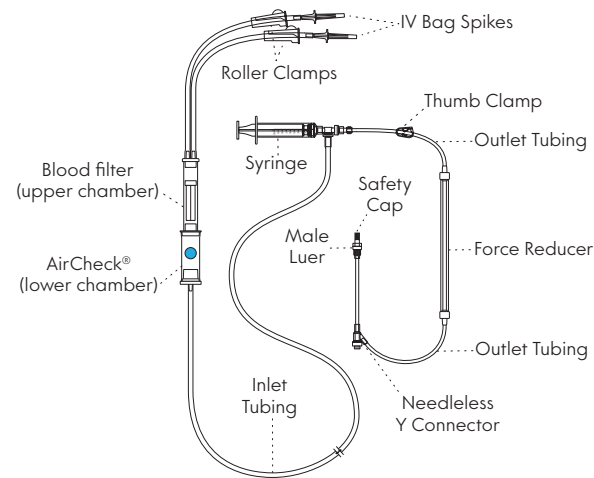
Product Description:

LIFEFLOW[®] PLUS BLOOD & FLUID TUBING (1)

The LifeFlow[®] PLUS Blood & Fluid Tubing with AirCheck[®] and Force Reducer is packaged sterile, single patient use, non-pyrogenic in a pouch intended for use with the LifeFlow[®] Handle.

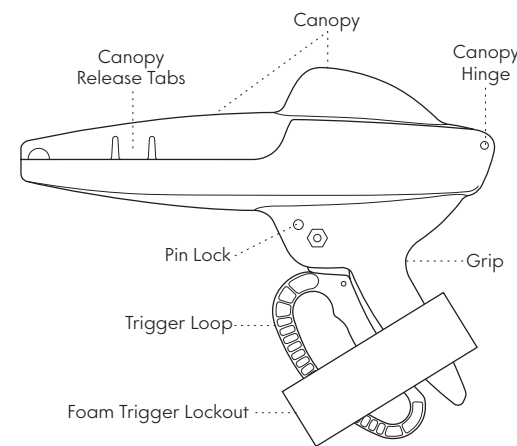
Total approximate priming volume: 62 mL

Approximate outlet tubing priming volume: 5mL



LIFEFLOW[®] HANDLE (1)

Non-sterile, single patient use, with removable foam trigger lockout.



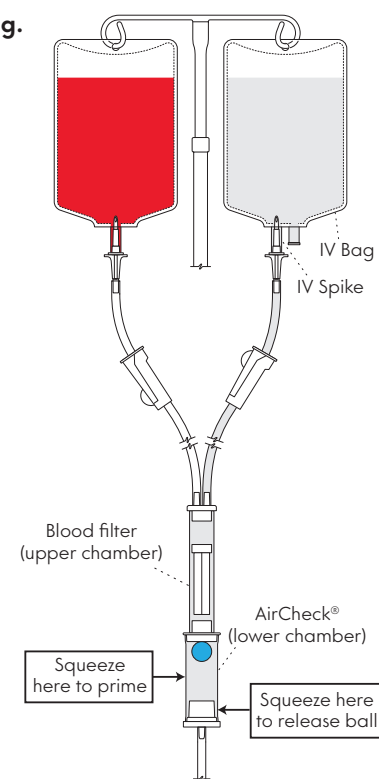
INSTRUCTIONS FOR USE

1. Unpackage the LifeFlow[®] PLUS Blood & Fluid Tubing.

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

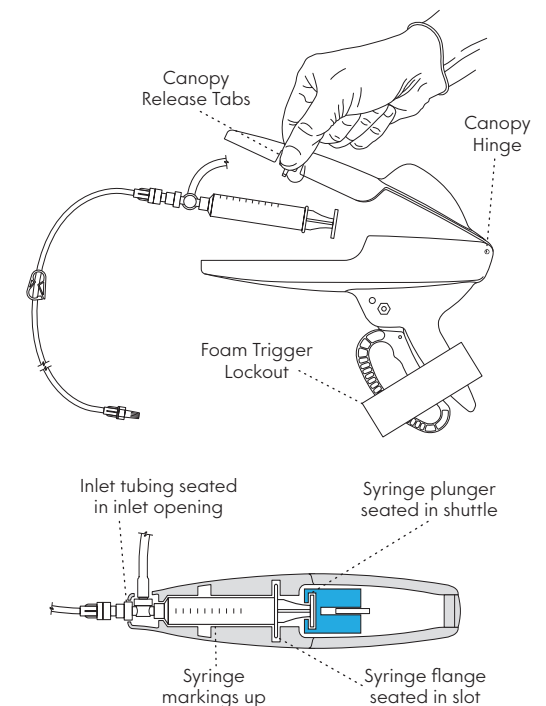
2. Prime the IV spike leads and both upper (Blood Filter) and lower (AirCheck[®]) chambers.

- Close all roller clamps.
- Spike IV fluid bag with one spike.
- Spike blood bag with remaining spike.
- Open roller clamp below IV fluid bag.
- Squeeze lower chamber (AirCheck[®]) to prime tubing.



3. Insert the 10mL syringe from the LifeFlow[®] PLUS Blood & Fluid Tubing into LifeFlow[®] Handle.

- Open the transparent Canopy by squeezing tabs (see right) and pulling up.
- Place 10mL syringe from the LifeFlow[®] PLUS Blood & Fluid Tubing 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 the system

! WARNING: Transfusion of air trapped in the tubing set can cause air embolism and serious injury to the patient.

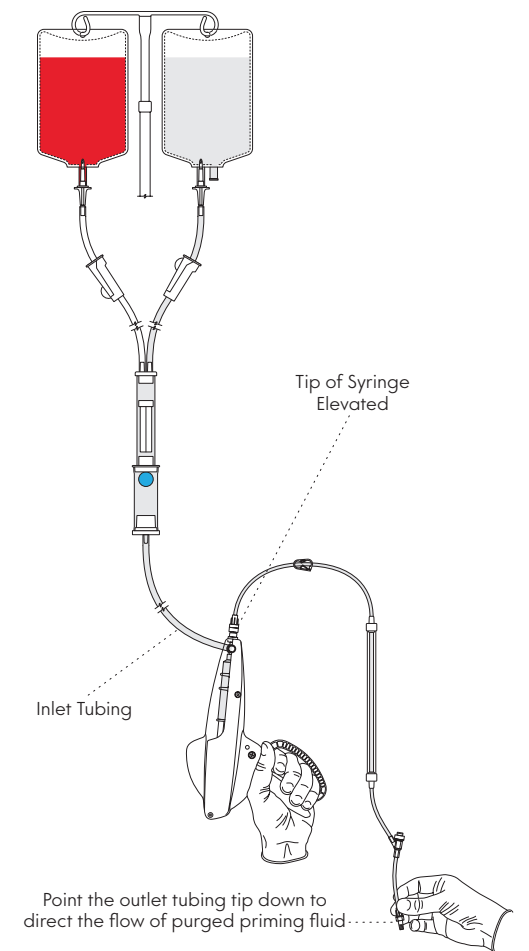
The following steps will eliminate trapped air in the tubing set and must be completed prior to infusing:

- With the IV fluid roller clamp open, point Handle (syringe tip) up during priming. Failure to elevate the syringe may allow air to remain in the syringe.
- Cycle the Trigger Loop until the entire LifeFlow[®] PLUS Blood & Fluid Tubing is primed.
- With syringe elevated to a vertical position, tap ON outside of canopy as necessary to fully evacuate all visible air bubbles.
- Tap and invert Needleless Y-valve and Force Reducer as necessary to remove any air bubbles.

Note - Priming can be completed while the vented sterile cap remains in place.

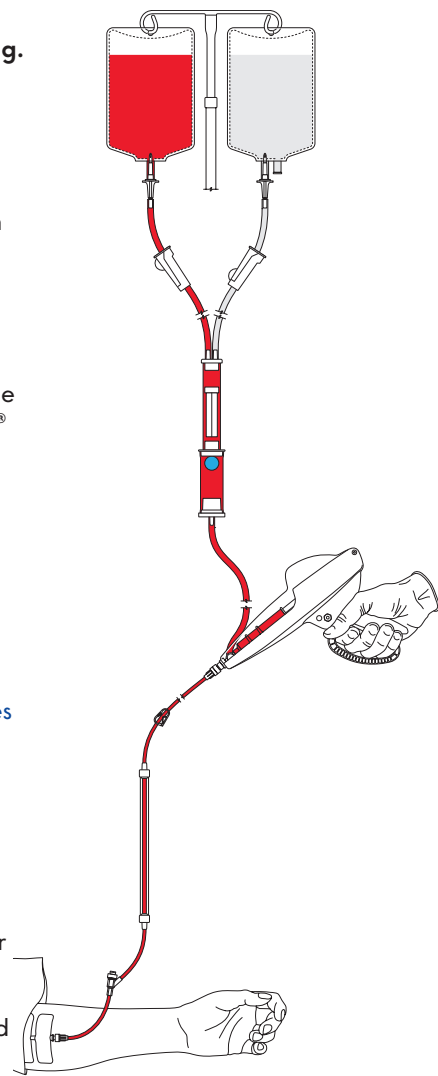
! WARNING: Make sure all air is purged from the IV line and syringe before attaching to patient IV access, and ensure AirCheck[®] remains vertical during infusion. Failure to do so may lead to air embolism.

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



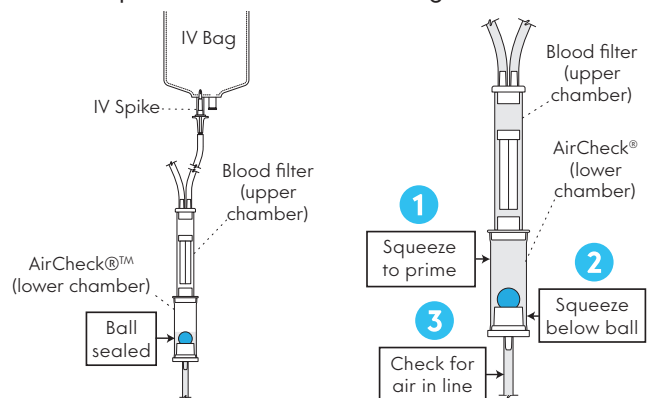
5. Check patency of IV access cannula and connect primed LifeFlow® PLUS Blood & Fluid Tubing.

- Connect the male Luer lock of the primed LifeFlow® PLUS Blood & Fluid Tubing to a previously established IV access cannula.
- Close the roller clamp below the saline bag. Open the roller clamp below the blood bag.
- Squeeze the lower chamber (AirCheck®) again to prime blood spike lead.
- Squeeze the Trigger Loop to begin infusing blood.
- Release the Trigger Loop to draw blood from the bag and refill the syringe.
- Ensure that the AirCheck® remains vertical while infusing so that air does not enter the LifeFlow® PLUS Blood & Fluid Tubing.
- Continue to squeeze and release the Trigger Loop until the desired amount of blood has been infused. Blood does not flow until the Trigger Loop is squeezed.
- If the force to squeeze the Handle changes during use, slow the rate of infusion and check the patient infusion site.
- 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. When using small gauge catheters noticeable swelling may occur in the Force Reducer. If this happens, slow down infusion and check the infusion site.
- Stop infusing fluids while a small amount of blood remains in the blood bag. Spike another fluid or blood bag.
- If any air is present in the LifeFlow® PLUS Blood & Fluid Tubing, disconnect from the patient and cycle the Trigger Loop until all air is removed.
- Continue infusing.



6. If the trigger slows down or stops returning during transfusion check the following:

- If AirCheck® is collapsed (vacuumed shut) check if the correct roller clamp is open.
 - Release roller clamps and continue infusion.
- If AirCheck® is collapsed (vacuumed shut) check if the IV bags still have fluid present.
 - Spike new fluid bag and re-prime if necessary.
- If AirCheck® is collapsed (vacuumed shut) and no other issues are visible, the blood filter may be clogged.
 - Dispose of current tubing set and restart infusion with a new tubing set or device.
- If the AirCheck® ball suction 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.**
 - Refill both chambers completely with blood by squeezing the lower chamber (AirCheck®).
 - Squeeze where it says "release" on AirCheck® until the ball floats.
 - Reconnect to the patient and continue infusing.



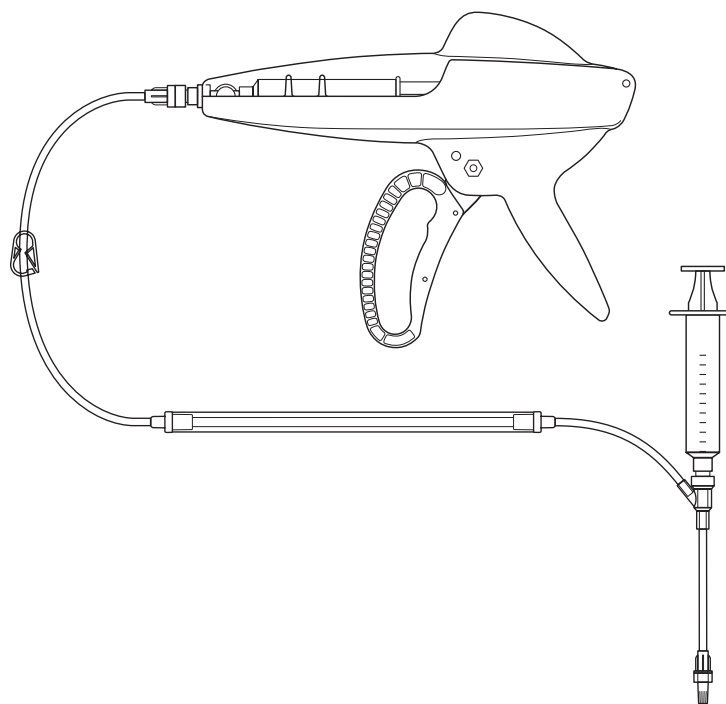
- If the Trigger Loop has stopped returning, but the ball is not suctioned to the bottom, then the blood filter may be clogged.
 - Dispose of current tubing set and restart infusion with a new tubing set or device.

7. If additional blood 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® PLUS Blood & Fluid Tubing 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 colloid and crystalloid fluids. If more than 4L of fluid is needed, use a new Device (Handle and Tubing Set).
- If squeezing the lower chamber to re-prime both chambers does not work, the filter is clogged. Replace with a new tubing set or device if this occurs.

8. Using the Needleless Y Connector

- Fluids can be delivered through the Needleless Y Connector.
- When delivering fluids through the Needleless Y Connector, use standard practice and remove air from the syringe prior to connecting.
- It is important to squeeze the Trigger Loop at least twice following delivery of the fluids to ensure the full volume of delivered fluid 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.



Important - Remove all other connections from outlet tubing or patient tubing before infusing with the LifeFlow® PLUS.

Important - Ensure IV access is patent prior to infusion. 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 - Fluid delivery requires the Trigger Loop to be squeezed by the clinician. Disconnect from the patient when not in use.

Important - Clinician should observe and monitor for vascular congestion during intraosseous (IO) use in the leg of an infant patient. If swelling due to vascular congestion is observed the rate of infusion should be slowed or stopped until swelling subsides.

Important - To account for the total infused volume, the clinician should add 10mL of infusion for every full squeeze of the Trigger Loop or assess the infused volume of fluid from the bag.

Important - The device should not be used for longer than 24 hours. If infusing blood products, the device should not be used for more than 4 hours.

Important - Always dispose of blood contaminated LifeFlow® PLUS Blood & Fluid Tubing and Handles in a manner consistent with established biohazard procedures.

TROUBLESHOOTING	
ISSUE	CHECK LIST
Canopy will not close	<ol style="list-style-type: none"> Ensure the LifeFlow® PLUS Blood & Fluid Tubing is properly seated in the Handle with the syringe markings facing up. Ensure the Canopy is aligned.
System does not prime/Infusing is difficult	<ol style="list-style-type: none"> Ensure all appropriate clamps are open. Ensure the IV bag has fluid present. Observe AirCheck® and ensure ball is floating. If it is not, squeeze where it says "release" on the AirCheck® until the ball floats. Confirm syringe plunger is properly loaded inside blue slot. Remove and reload if necessary. Remove foam trigger lockout. Ensure the Outlet Tubing Cap is removed. 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 stops moving during infusion	<ol style="list-style-type: none"> Ensure that the IV bags still have fluid present. Check roller clamps, ensure the desired clamp is open. Observe AirCheck® and ensure ball is floating. If it is not, check entire LifeFlow® PLUS Blood & Fluid Tubing for air, remove all air, re-prime, and squeeze where it says "release" on the AirCheck® until the ball floats. Check for occlusion at the patient site. Blood filter is clogged or syringe has slowed down. Get a new device or tubing set.
Trigger Loop returns slowly	<ol style="list-style-type: none"> Tubing may need to be replaced if syringe has slowed or filter is clogged. Do not force Trigger Loop open or closed if it does not move freely.

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.
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LifeFlow PLUS