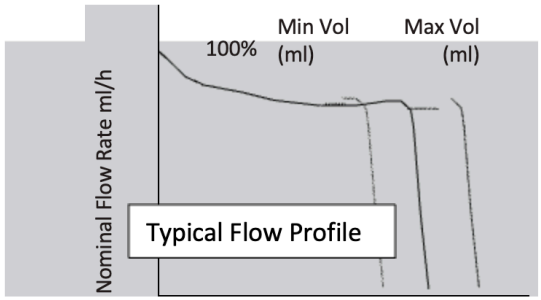


Nominal Fill Volume (ml)	Max / Min Volume (ml)	Residual Volume (ml)
100 ml - 125 ml 270 ml 400 ml	+ 5 ml / - 5 ml + 10 ml / - 10 ml + 5 ml / - 10 ml	5.0 ml

Mixing and Use Information

- Refer to drug manufacturer's package insert for drug reconstitution/dilution and storage procedures.
- Calculate the fill volume by multiplying the desired infusion time (hours) by the nominal flow rate (ml/h) and adding the residual volume.
- Dosage alteration is achieved by adjusting the drug concentration - the flow rate is fixed.

Refer to the list above for the volume range within which the flow rate remains essentially constant.

Product Cautions

Do not over tighten the connectors. • If you swab the connectors with alcohol, to prevent breakage, allow the luers enough time to dry out before connecting • The physician is responsible for selecting patients suitable for treatment. • Single use only. Do not re-use or re-sterilize. • Observe your facility policies in handling blood and body-fluids. • Use aseptic technique when preparing InfuLife for use. • Observe your facility policies for disposal.

Indications and Usage

Intended use: FMS InfuLife is a single-use, sterile, disposable elastomeric infusion pump intended for continuous and/or intermittent infusion of medications for general infusion at home, in a hospital, or in alternate sites.

First Medical Source

Delivering Safe & Effective Infusion Systems.

Important Information:
Manufactured in compliance with ISO 13485:2016. Conforms to EU MDR 2017/745, TIR101:2021 Fluid Delivery Performance Testing for Infusion Pumps & Particular requirement for non-electronically driven, portable infusion devices ISO 28620-2020.

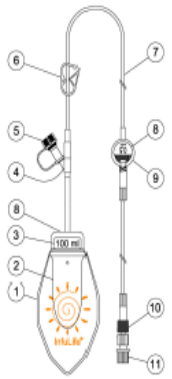
Warnings: **Read the entire instructions for use before using InfuLife.**

Description

InfuLife is an elastomeric infusion pump, using sustained pressure generated by an elastomeric bladder (balloon) filled with fluid to deliver a continuous infusion of medications. It is a single use prescription device to be used by a patient under the care or treatment of a physician or licensed healthcare professional at home, in a hospital, or in alternate sites. InfuLife is a sterile device, designed to deliver to a preset nominal volume +/- 12% within the nominal delivery time. The flow rate is affected by temperature and viscosity of drug solution (refer to Mixing and Use Information below).
The reservoir can be over/under filled by the specified amount in the flow profile below without a significant impact on the flow rate.

InfuLife Item List:

1. Soft outer cover
2. Elastomeric bladder
3. Label: Volume, Lot, UDI
4. Filling connector
5. Cap with Strap connector
6. Clamp, On/Off
7. PVC tube, non-DEHP
8. Label: Flow Rate ml/h
9. Filter 1.2-micron, air eliminating
10. Flow control, distal connector
11. Cap, distal connector



USA

Better Care for Better Life. InfuLife®

InfuLife® Infusion Pump

Instructions for Use

Restricted to sale by or on the order of a physician (US Only)

Not made with natural rubber Latex or DEHP

Single Use

Expiration date

Fluid path and areas under undisturbed caps are sterile and non-pyrogenic

First Source Medical, LLC USA:
Laguna Niguel, CA 92677

To report a problem or file a complaint, please contact your provider.

WARNING: Lots produced presently have an endotoxin level of 2.7 and are, until further notice contraindicated for epidural use.
November 13, 2024.

Indication for Use: InfuLife is indicated for delivery of antibiotics, chemotherapy, and pain management, as directed by a physician or licensed healthcare professional. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, and epidural. Additionally, InfuLife is indicated for continuous and/or intermittent delivery of medication, such as local anesthetics or narcotics, to surgical wound sites and/or proximity to nerves for preoperative, perioperative, and postoperative regional anesthesia and pain management.

Intended Users: InfuLife is intended for use by physicians, clinicians, pharmacists, and other licensed healthcare professionals.

Intended Patient Populations: InfuLife is intended for use by adult patients, and children weighing more than 20 Kg.

Contraindications: InfuLife is contraindicated for intra-articular infusion of anesthetics and for infusion of blood and blood products, infusion of insulin, infusion of critical or life-supporting medications, infusion of any solution that is not compatible with the fluid path materials; and use in ambulatory regimens by patients not capable of self-administering their therapy or not under the care of a responsible individual.

Residual Risks: InfuLife is contraindicated for use on neonates, infants, and children weighing less than 20 Kg due to potential exposure to EO residuals.

Actual infusion times may vary due to the following:

- Filling the pump less than nominal volume generally results in lower flow rate.
- Filling the pump more than nominal volume generally results in faster flow rate.
- Temperature will affect viscosity, resulting in longer or shorter delivery times.
- The device flow restrictor should be close to or in contact with the skin (31° C / 88° F) and the tubing should be under patient's clothing. When the device is used with restrictor at room temperature (23° C / 73° F), delivery time will decrease approximately 9%.
- The nominal flow rates are based on sodium chloride (0,9%, 32° C) as reference, calculated per ISO 28620:2020, at 0 inch of head height.
- An increase/decrease of 10 inches in head height will increase/decrease the flow rate by 6%.
- Addition of drug or diluent may change flow rates. Use of 5% dextrose will result in 10% longer delivery time.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.
- The device may be started right after filling. No waiting time is required.
- Storage of filled device beyond 8 hours prior to starting infusion may result in a 10% longer delivery time. Do not store in freezer. If the device is stored in refrigerator, allow it to warm to room temperature before use.

DIRECTIONS FOR FILLING – Use Aseptic Technique in all that follows:

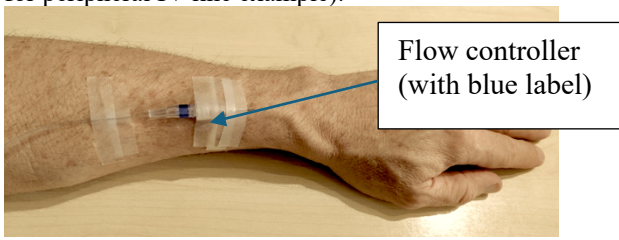
1. Remove the fill port cap (retain it for use later).
2. The device can be filled with a syringe or other filling device. Remove all air from the filling device and attach securely to fill port.
3. Close the clamp and fill the device with no more than the recommended maximum fill volume. Push down the syringe plunger until the volume is dispensed. Repeat as necessary.
4. Remove filling device from the fill port. Screw on the fill port cap
5. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

1. Remove the cap from the patient end of the tubing.
2. "Open the tubing clamp". "Fluid will begin to flow, filling the tubing set". When all air has been expelled, close the clamp.

STARTING THE INFUSION

1. Allow the device to warm to room temperature before using, especially if it has been stored in the refrigerator.
2. Infusion should preferably be started 0-8 hours after filling, prolonged storage of a filled device beyond 8 hours may result in a longer delivery time.
3. Verify that the clamp on the tubing is closed.
4. Clean patient access site as directed by hospital/healthcare provider. Attach the flow controller (item 10 above), along with a section of the attached tubing to the injection site (see picture for peripheral IV line example).



5. Begin infusion by opening the clamp.

Warnings

• For use only by trained clinicians. Refer to standard medical textbooks for specific infusion procedures. •Double check drug name and dose concentration. Improper dosage and unauthorized drugs are the most commonly USP reported errors. • Intravenous or intra-arterial injection of local anesthesia drugs may cause toxicity and possible cardiac arrest. • Do not use for intra-articular infusion of local anesthetics. • Medications or fluids must be administered per instructions provided by the drug manufacturer. • The physician is responsible for prescribing drug based on each patient's clinical needs. •There is no alarm or alert when flow interruption occurs, therefore InfuLife is not recommended for life-supporting medications. • The scale on the outer cover is not an accurate measurement. It provides only a general indication of remaining volume. There is no indicator of pump infusion status, therefore use caution where over-delivery of medications could result in serious injury or death. • Epidural infusion of analgesics is limited to use of specifically designed epidural catheters. Ensure that devices used epidural infusion be clearly differentiated from all other infusion devices. • It is the responsibility of the healthcare provider to ensure patient is educated in the proper use of the system.