

Elastomeric Infusion Pump

PORTABLE | DISPOSABLE | NON-PYROGENIC
Single Use for a Single Patient - Disposable

Portable single-use elastomeric infusion pump
 Manufactured under 21 CFR 820 QS Reg. and EN ISO 13485: 2016
 compliant quality management systems.

INSTRUCTIONS FOR USE

DESCRIPTION

The elastomeric pump has a specially designed multi-layered balloon-like reservoir to be filled with the drug or fluid intended for infusion. It exerts a mechanical pressure, thereby administering the contents through an orifice tube at a predetermined flow rate. The entire unit is sterile and is intended for single-use only. When filled at the nominal volume, flow rate accuracy is within +/- 15% of the nominal (label) flow rate (at 99% confidence level). Flow rate is affected by temperature and viscosity of the drug or fluid (see MIXING AND USE INFORMATION) and actual fill volume. Expected flow profile of the pump filled at nominal volume is shown in figure 1. Flow rate profiles of long infusion time and short infusion time are similar as shown in Figure 2.

Figure 1: Expected flow profile of a pump filled at nominal volume

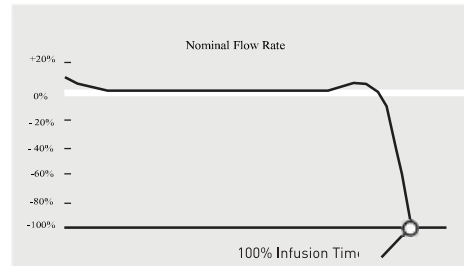
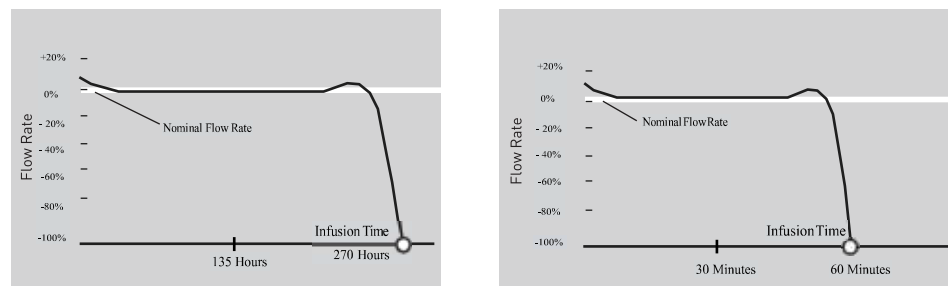


Table 1: Residual volumes

Nominal Volume	Residual Volume
50 - 125 mL	2.0 mL
200 - 300 mL	3.5 mL
400 - 500 mL	5.0 mL

Figure 2: Flow rate profiles of long infusion and short infusion time pumps are similar.



Indications for Use Statement

- The elastomeric pump (long infusion time article) is intended for continuous infusion for medications of general infusion use including pain management.
- Routes of administration: intravenous and subcutaneous. The elastomeric pump (short infusion time article) is intended for continuous infusion of medications for general infusion use including antibiotic delivery.
- Route of administration: intravenous. The elastomeric pump (chemotherapy article) is intended for continuous infusion of medications for chemotherapy.
- Routes of administration: intravenous and intra-arterial.

WARNINGS

- Do not use in infusion regimens by patients who do not possess the mental, physical, or emotional capability to self-administer their therapies or who are not under the care of responsible individuals. This warning includes pediatrics as they are not capable of using the devices by themselves.
- Do not use if packaging or product is damaged or opened.
- Do not immerse the pump in water. Prevent the filter from getting wet.
- Do not use with pressure infusion device.
- When administering through the intra-arterial and subcutaneous routes where back pressures are expected, flow rates will decrease.
- Do not exert pressure or play with filled device and take caution when used with immobilized patients and avoid device being slept on. Applied pressure may result in rupture or breakage and will result in increased flow rate. In case of spillage of medication, see drug SDS for appropriate actions.
- Do not re-sterilize. Strictly for single-use and pump must be discarded in accordance with local regulations.
- Store under general warehouse conditions at 68°F to 77°F (20°C to 25°C). Protect from light sources and heat. Keep dry.
- Drug products should be stored in their approved containers and closures.
- Do not store in freezer.

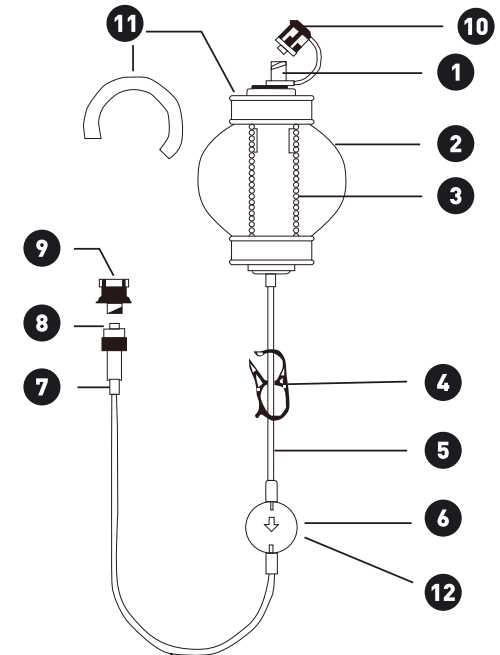
CONTRAINDICATIONS

- Infusion of insulin, blood, or blood products, TPN, lipids or fat emulsions.
- Infusion of any solutions that are not compatible. Consult the pharmaceutical manufacturer's precautions and guidelines to ensure that the medications used will not interact with the device that may possibly cause damage, leakage or precipitation.
- Intra-articular infusion of local anesthesia.
- Infusion of anesthetics in neonates, infants, and children below 5 years of age.

Mckesson™ Elastomeric Pump

Portable single use elastomeric infusion pump

1. Fill port
2. Outer soft cover
3. Multi-layered elastomeric membrane
4. ON-OFF Clamp
5. Non DEHP PVC administration tubing
6. Air and particulate eliminating filter
7. Flow restrictor
8. Patient connector
9. Priming cap
10. Fill port cap (tethered)
11. Labeling - Fill volume, Max Fill volume & Flow Rate
12. Labeling - Flow rate



OPERATING CONDITIONS AND SAFETY

Actual infusion time may vary due to the following:

- Filling the device less than the nominal volume generally results in slower flow rate.
- Filling the device more than the nominal volume generally results in faster flow rate.
- Infusion should be started within 1- 8 hours after filling the device. The performance and safety of the device is validated based on infusion time and an additional 8 hour drug/device contact time.
- 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 and pump should be under the patients clothing (25°C/77°F). For an increase of every one (1)°C/1.8°F, the flow rate may increase by 2.5% and conversely for every one (1)°C/1.8°F reduction flow rate may decrease by 2.5%.
- The nominal flow rates are based on sodium chloride (0.9%, 31°C/88°F) as reference. Use of 5% dextrose will result in 10% slower flow rate or correspondingly 10% longer delivery times.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.

MIXING AND USE INFORMATION

See the drug manufacturer's package insert for drug reconstitution/dilution and storage procedures. Drugs tested for stability and compatibility, representing each route of infusion, include Ceftriaxone, Deferoxamine, Floxuridine, and Vancomycin. Also see drug package insert for drug compatibility with ABS, silicone elastomer, PVC not made from phthalate (DEHP), acrylic, e-PFTE and for use suitability with an in-line 1.2µm filter. Calculate the fill volume by multiplying the desired infusion time (hours) by the nominal flow rate (mU/h) and adding the residual volume. Alteration of dosage is achieved by adjusting the drug concentration - the flow rate is fixed.

INSTRUCTIONS FOR FILLING

- Use Aseptic Technique

1. Unscrew the tethered fill port cap.
2. Elastomeric pump can be filled with a syringe or automated fluid dispensing device. Remove trapped air from the filling device and attach it securely to the fill port.
3. Close the ON-OFF clamp and fill the elastomeric pump with no more than the maximum recommended volume. When using a syringe to fill, push the plunger to dispense the fluid. Do not push the barrel onto the fill port as the syringe tip or fill port may break. Repeat as necessary.
4. Remove filling device from the fill port. Screw on the tethered fill port cap.
5. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

- Use Aseptic Technique

1. Open the ON-OFF clamp.
2. Medication will start to flow and fill the tubing.
Air is expelled through the vented priming cap.
3. Close the ON-OFF clamp.

PRIMING TECHNIQUE FOR DRUGS

- (for drugs prone to precipitation)

1. Fill elastomeric pump with 10 ml of diluent first.
2. Using the above priming method, prime the tubing.
3. Fill the remaining volume with diluent and medication. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication.

STARTING INFUSION

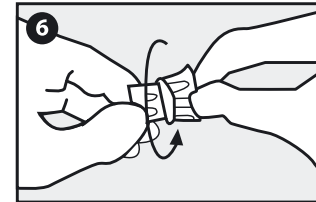
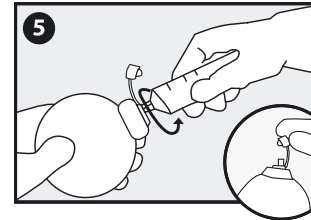
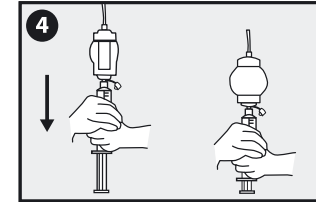
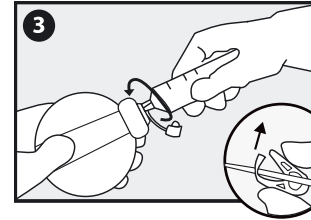
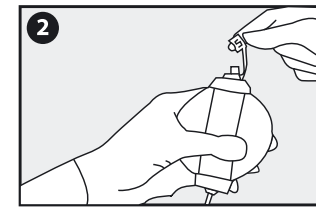
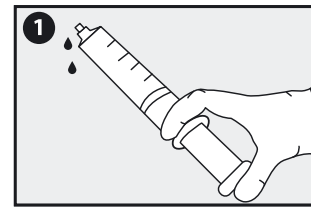
- Use Aseptic Technique

1. Allow elastomeric pump to warm to room temperature before use, especially when infusate has been refrigerated.
2. Infusion should preferably be started 1 hour to 8 hours after filling.
3. Verify that the ON-OFF clamp is closed.
4. Clean patient access site as directed by the hospital or healthcare provider. Attach the patient connector to the injection site.
5. Begin infusion by opening the ON-OFF clamp.

SINGLE USE ONLY

Elastomeric pump is designed for optimal performance, effectiveness, and safety as a single-use device and not for reuse. Performance, effectiveness, and safety may be compromised if the device is reused.

CAUTION: Federal (USA) Law restricts this device to be sold by or on the order of a physician.



Definitions of symbols

LOT	Batch code	EXP	Used by YYYY-MM-DD
MFD	Manufactured on YYYY-MM-DD		Consult instructions for use
	Sterilized using ethylene oxide		Single use only, do not reuse
R_x ONLY	CAUTION: Federal (USA) Law restricts this device to be sold by or on the order of a physician.		

Store under general warehouse conditions. Avoid storage in direct sunlight/fluorescent lighting and store in a cool, dry, well-ventilated area. Not made with natural rubber latex.

Questions? Call 1-800-777-4908

Satisfaction Guaranteed

For complete details, please visit
www.mckesson.com/mckesson-brands.

Distributed by McKesson Medical-Surgical Inc.
 Richmond, VA 23233
 PVN A0824
 Made in Thailand