

SMARTeZ® Elastomeric Infusion Pump

The Safe, Accurate and Simple Solution for Short and Long-Term Infusion Therapy

The SMARTeZ® pump has a specially designed multi-layered balloon-like reservoir to be filled with the drug or fluid intended for infusion. It exerts mechanical pressure to administer the contents at a predetermined flow rate. The entire unit is sterile and is intended for single use only.

FEATURES

- Pump components are not made with natural rubber latex and are DEHP Free
- Easy to use, portable, durable and ergonomic design
- Extensive collection of flow rates and fill volumes available
- Color-coded for filling accuracy and reduced medication errors
- Air and particle eliminating filter plus air eliminating membrane

INDICATIONS

SMARTeZ® disposable elastomeric pumps are intended for administration of antibiotics, chemotherapy and pain management.

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.

PRECAUTIONS

- 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. Avoid device being slept on. Applied pressure may result in rupture or breakage and will result in increased flow rate.
- 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.
- In case of spillage of medication, see drug MSDS for appropriate actions.
- Do not re-sterilize. Strictly for single use.
- Pump must be discarded in accordance with local regulations after single use.
- Store under general warehouse conditions at 68°F to 77°F (20°C to 25°C).
 - Protect from light sources and heat.
 - Keep dry.
 - Do not store in freezer.
- Drug products should be stored in their approved container and closures.

MIXING AND USE INFORMATION

- See the drug manufacturer's package for drug reconstitution / dilution and storage procedures.
- See drug package insert for drug compatibility with ABS, silicone elastomer, PVC not made from phthalate (DEHP), acrylic, cellulose acetate or 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 (mL/h) and adding the residual volume. Alteration of dosage is achieved by adjusting the drug concentration - the flow rate is fixed.

OPERATING CONDITIONS AND SAFETY

- The device is designed to deliver the nominal volume within +/- 15 % of the nominal delivery time.
- The impact on flow rate due to overfilling or underfilling is negligible. See the Flow Profile below for maximum and minimum volume pre-determined for the device. This defines the range that will not appreciably affect the flow rate. A detailed table is included on the following page.
- To achieve claimed flow rate accuracy infusion should be started one (1) hour after filling the device.
- The safety of the device is validated based on infusion time and an additional 8 hour drug/device contact time.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.
- Actual infusion times 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.
 - Temperature will affect viscosity. Higher temperature lowers viscosity resulting in shorter delivery times, while lower temperature increases viscosity resulting in longer 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 the patients clothing. For an increase of every one (1) deg C, the flow rate may increase by 2.5% and conversely for every one (1) deg C 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.

FIGURE 1: Expected flow profile of a pump filled with nominal volume.

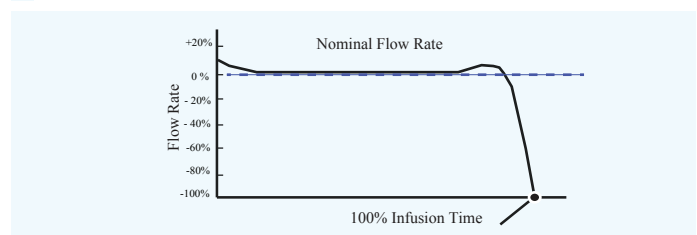
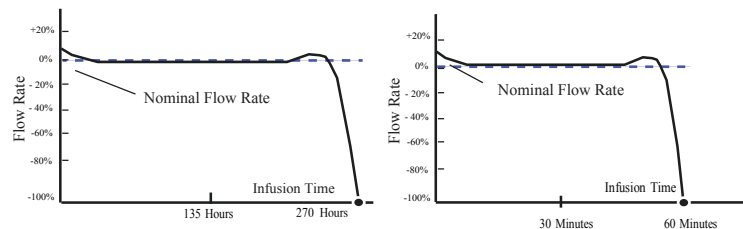
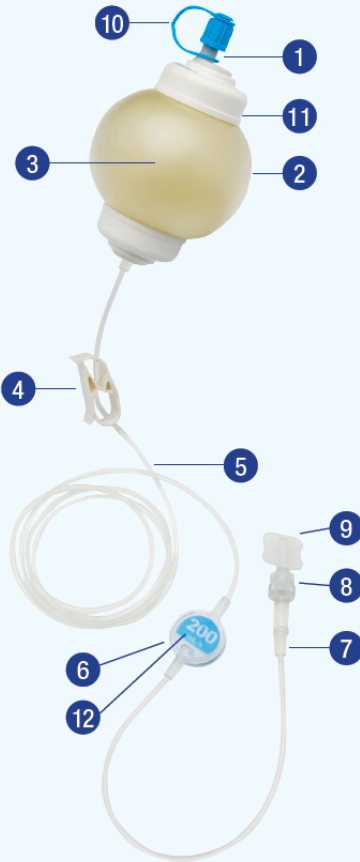


FIGURE 2: Flow range profiles of long infusion time and short infusion time pumps are similar.





PRODUCT DIAGRAM

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. Patient end cap
10. Fill port cap (tethered)
11. Labelling - Fill volume & infusion duration
12. Labelling - Flow rate

INSTRUCTIONS FOR FILLING *Use Aseptic Technique*

1. Unscrew the tethered fill port cap.
2. SMARTeZ® pump can be filled with a syringe or repeater filling 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 SMARTeZ® 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. Loosen the patient end cap. Medication will start to flow and fill the tubing. When all air is expelled, tighten the patient end cap.
3. Close the ON-OFF clamp.

PRIMING TECHNIQUE FOR DRUGS *(for drugs prone to precipitation)*

1. Fill SMARTeZ® Pump with 10mL of diluent first.
2. Using the above priming method, prime the tubing.
3. Fill the remaining volume with diluent and medication.
4. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication. If storage of filled pump becomes necessary, refer to drug manufacturer's package insert.

STARTING INFUSION *Use Aseptic Technique*

1. Allow SMARTeZ® Pump to warm to room temperature before use, especially when it has been stored in the refrigerator.
2. Infusion should preferably be started 0 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.

SHORT INFUSION DURATION PUMPS	Variant	100 - 0.5	250 - 0.5	50 - 1	100 - 1	200 - 1	250 - 1	250 - 1.5	100 - 2	200 - 2	250 - 2	400 - 2	500 - 2	250 - 2.5	400 - 4
	Ref #	481012	481022	481032	481042	481142	481052	481062	481092	481112	481132	481072	481082	481122	481102
	Item #	SE0200-100	SE0500-250	SE0050-050	SE0100-100	SE0200-200	SE0250-250	SE0175-250	SE0050-100	SE0100-200	SE0125-250	SE0200-400	SE0250-500	SE0100-250	SE0100-400
	Nominal Fill Volume (ml)	100	250	50	100	200	250	250	100	200	250	400	500	250	400
	Nominal Fill Rate (ml/h)	200	500	50	100	200	250	175	50	100	125	200	250	100	100
	Minimum Fill Volume (ml)	50	200	40	60	150	200	200	60	150	200	350	450	200	300
	Maximum Fill Volume (ml)	120	275	60	120	250	275	275	120	250	275	500	600	275	500
	Residual Volume (ml)	< 2	< 3.5	< 2	< 2	< 3.5	< 3.5	< 3.5	< 2	< 3.5	< 3.5	< 5	< 5	< 3.5	< 5

STORAGE Time to reach Room Temperature (approximately 23 deg C +/- 2 deg C)	Hours from refrigerator (approx +2 to +8 deg C)	6	12	6	6	12	12	12	6	12	12	12	12	12	12
	Hours from refrigerator (approx -18 deg C)	12	18	12	12	18	18	18	12	18	18	18	18	18	18

OVER & UNDERFILLING DATA	Approximate Delivery Time (Hours shown h:mm)	Table Cells Indicate Fill Volume													
		50	-	-	-	-	-	-	-	-	-	-	-	-	-
0:15	50	-	-	-	-	-	-	-	-	-	-	-	-	-	-
0:20	60	-	-	-	-	-	-	-	-	-	-	-	-	-	-
0:25	80	200	-	-	-	-	-	-	-	-	-	-	-	-	-
0:30	100	250	-	-	-	-	-	-	-	-	-	-	-	-	-
0:35	120	275	-	60	-	-	-	-	-	-	-	-	-	-	-
0:40	-	-	-	65	-	-	-	-	-	-	-	-	-	-	-
0:45	-	-	-	70	150	-	-	-	-	-	-	-	-	-	-
0:50	-	-	40	80	160	200	-	-	-	-	-	-	-	-	-
0:55	-	-	45	90	180	220	-	-	-	-	-	-	-	-	-
1:00	-	-	50	100	200	250	-	-	-	-	-	-	-	-	-
1:05	-	-	-	-	-	275	-	-	-	-	-	-	-	-	-
1:10	-	-	-	-	-	-	200	60	-	-	-	-	-	-	-
1:15	-	-	60	120	250	-	-	-	-	-	-	-	-	-	-
1:25	-	-	-	-	-	-	250	-	-	-	-	-	-	-	-
1:30	-	-	-	-	-	-	-	75	150	-	-	-	-	-	-
1:35	-	-	-	-	-	-	-	275	80	160	200	-	-	-	-
1:40	-	-	-	-	-	-	-	-	84	165	-	-	-	-	-
1:45	-	-	-	-	-	-	-	-	88	175	220	350	-	-	-
1:50	-	-	-	-	-	-	-	-	90	180	230	360	450	-	-
1:55	-	-	-	-	-	-	-	-	95	190	240	380	475	-	-
2:00	-	-	-	-	-	-	-	-	100	200	250	400	500	200	-
2:10	-	-	-	-	-	-	-	-	110	-	275	-	500	200	-
2:15	-	-	-	-	-	-	-	-	-	225	-	450	-	-	-
2:25	-	-	-	-	-	-	-	-	120	-	-	600	-	-	-
2:30	-	-	-	-	-	-	-	-	-	250	-	500	-	250	-
2:45	-	-	-	-	-	-	-	-	-	-	-	-	-	275	-
3:00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	300
3:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	325
3:30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	350
3:45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	375
4:00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	400
4:15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	425
4:30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	450
4:45	-	-	-	-	-	-	-	-	-	-	-	-	-	-	475
5:00	-	-	-	-	-	-	-	-	-	-	-	-	-	-	500



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