

SMARTeZ[®] Technical Guide for Using Elastomeric Infusion Pumps

The safe, accurate and simple solution for short and long duration infusion therapy. SMARTeZ[®] disposable elastomeric pumps are intended for intermittent and continuous antibiotic infusion, chemotherapy, pain management and general infusion therapies. 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

- Transparent design to allow visual product inspection during pharmacist verification
- Double cap to protect sterility during filling
- Extensive collection of flow rates and fill volumes available
- Color-coded by flow rate to assist in filling accuracy and reduce the risk of medication errors
- Air and 1.2 micron particle eliminating filter plus air eliminating membrane
- Expanded drug stability data available including longer dating for several medications when compared to competitor data and in commonly dispensed drug concentrations not previously studied in elastomeric pumps (see SMARTeZ Stability Data for Drugs Using Elastomeric Infusion Pumps)
- Chemotherapy (5-FU) rated pumps are designed to prevent occlusion when used with medications prone to precipitation and feature light protection tubing.
- Automated manufacturing provides a consistent and reliable supply, diversified therapy options and customizable volume and rate combinations
- Easy to use and simple to fill design for smoother and faster filling
- Disposable and single use
- Components are not manufactured with natural rubber latex and are DEHP Free

INDICATIONS

- SMARTeZ[®] disposable elastomeric pumps are intended for intermittent and continuous antibiotic infusion, chemotherapy, pain management and general infusion therapies.

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 in a way 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.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.
- 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 children 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.
- 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 (see Nominal Flow Rate Chart on page 2).
- The impact on flow rate due to overfilling or under filling is negligible when filled within the min./max. volume recommended. Please refer to chart on page 2 for over and under filling data.
- Actual infusion times may vary due to the following:
 - Filling the device less than the nominal volume generally results in faster flow rate.
 - Filling the device more than the nominal volume generally results in slower 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% & conversely for every one (1) deg C reduction flow rate may decrease 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.
- Biocompatibility Testing was conducted on SMARTeZ pumps to confirm the absence of leachables or extractables with polar and nonpolar solutions for the infusion plus an additional 8 hours of contact time.
- Allow the device time to reach room temperature (~23 deg C +/- 2 deg C) prior to infusion. Estimated times below:

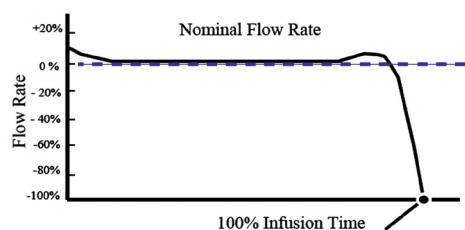
Nominal Fill Vol.	Refrigerated Temp	Estimated Time to Reach Room Temp
50ml - 100ml	+2 to +8 deg C	6 hours from refrigerator
50ml - 100ml	-18 deg C	12 hours from refrigerator
100ml+	+2 to +8 deg C	12 hours from refrigerator
100ml+	-18 deg C	18 hours from refrigerator

- Estimated Residual Volume:

Nominal Fill Vol.	Estimated Residual Vol.
50ml - 100ml	<2.0ml
200ml - 270ml	<3.5ml
400ml - 500ml	<5.0ml

NOMINAL FLOW RATE PROFILE

Expected flow profile of a pump filled with nominal volume.



SHORT INFUSION DURATION PUMPS

Item #	SE0050-050	SE0050-100	SE0050-250	SE0100-100	SE0100-200	SE0100-250	SE0100-400	SE0125-250	SE0175-250	SE0200-100	SE0200-200	SE0200-400	SE0250-250	SE0250-500
Nominal Fill Volume (ml)	50	100	250	100	200	250	400	250	250	100	200	400	250	500
Nominal Flow Rate (ml/h)	50	50	50	100	100	100	100	125	175	200	200	200	250	250
Min. Fill Volume (ml)	50	75	150	50	175	200	275	150	140	50	150	200	150	360
Max. Fill Volume (ml)	60	110	275	125	250	300	550	300	300	125	300	500	300	550

LONG INFUSION DURATION PUMPS

Item #	SE0002-060	SE0002-100	SE0002-270	SE0002-300	SE0004-120	SE0004-270	SE0004-400	SE0005-060	SE0005-125	SE0005-270	SE0005-400	SE0010-270	SE0010-400	SE0020-500
Nominal Fill Volume (ml)	60	100	270	300	120	270	400	60	125	270	400	270	400	500
Nominal Flow Rate (ml/h)	2	2	2	2	4	4	4	5	5	5	5	10	10	20
Min. Fill Volume (ml)	50	75	150	300	96	210	270	60	90	230	270	180	270	360
Max. Fill Volume (ml)	60	120	336	360	150	360	500	100	175	360	500	360	500	500

PRODUCT DIAGRAM

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. Fill port 2. Outer soft cover 3. CLEAR multi-layered elastomeric membrane 4. ON - OFF clamp 5. Non DEHP PVC administration tubing 6. Air and particulate eliminating filter | <ol style="list-style-type: none"> 7. Flow restrictor 8. Patient connector 9. Patient end cap 10. Sterile color-coded fill port cap 11. Disposable protective port cap 12. Labeling - Fill volume & infusion duration 13. Labeling - Flow rate |
|---|---|



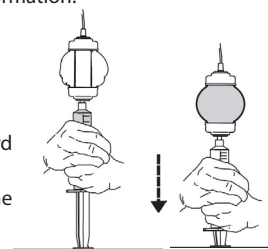
The double cap design includes a disposable protective port cap. The winged design allows for easy removal and stands upright to protect the sterility of the color-coded fill port cap while filling the device. After filling the device reattach the color-coded port cap and discard the disposable winged cap¹¹.

INSTRUCTIONS FOR FILLING (USE ASEPTIC TECHNIQUE)

1. Unscrew the disposable protective port cap from the pump keeping the sterile color-coded fill port cap attached to allow the disposable port cap to protect the sterility of the color-coded fill port cap until after filling.
2. SMARTeZ[®] pump can be filled with a syringe or automatic filling pump. Remove trapped air from the filling device and attach it to the fill port. When connecting a syringe or the male luer connector on a filling pump tube set to the SMARTeZ pump, DO NOT overtighten the connection to the fill port. (see Recommended Syringe Filling Technique below)
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 the disposable protective port cap from the sterile color-coded fill port cap. Attach the color-coded fill port cap to the filled SMARTeZ pump.
5. Label with appropriate pharmaceutical and patient information.

RECOMMENDED FILLING TECHNIQUE

- When filling with a syringe, it is recommended that the syringe is kept in an upright position with the plunger base resting on a work bench.
- Always push the barrel of the syringe downwards toward the work bench.
- Filling the SMARTeZ pump by pushing the plunger of the syringe towards the barrel with the SMARTeZ in a fixed position may result in a broken syringe tip or fill port.



PRIMING THE ADMINISTRATION TUBING (USE ASEPTIC TECHNIQUE)

1. Open the ON-OFF clamp.
2. Loosen the patient end cap. Hold the patient connector above the filter while priming the tubing. 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 5-10mL of diluent first.
2. Using the above priming method, prime the tubing.
3. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication. Close the On-OFF clamp.
4. Fill the remaining volume with diluent and medication.
5. 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. Verify that the ON-OFF clamp is closed.
3. Clean patient access site as directed by the hospital or healthcare provider. Close the ON-OFF clamp.
4. Attach the patient connector to the access site and turn to tighten. Ensure the connection is secure.
5. Begin infusion by opening the ON-OFF clamp. If kinks are observed in the tubing, roll between your fingers to release.

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