SMARTeZ ™ RS - Chemo CS

Disposable elastomeric infusion pump

Manufactured under EN ISO 13485 compliant quality management systems. The product conforms to international standard ISO 28620 Medical devices – Non-electrically driven portable infusion devices.

DESCRIPTION

The SMARTeZ™ RS is an elastomeric pump with rigid shell on the fluid reservoir. The device works independently of main power supplies or batteries, enabling patient to be treated in an ambulatory manner. Fluid is delivered to patient by positive pressure applied by the elastomeric membranes on the fluid reservoir. The flow rate is determined by the combination of the flow restrictor (capillary tube) and positive pressure of the elastomeric membrane. This pressure delivers the fluid against the back pressure of the catheters and infusion site.

When filled to the nominal volume, flow accuracy is within +/- 15% of the nominal (label) flow rate. Flow rate is affected by temperature and viscosity of the drug or fluid.

INDICATIONS FOR USE STATEMENTS

SMARTeZ™ RS – Chemo CS is intended for continuous infusion of medications for chemotherapy. Route of administration include: intravenous and intra-arterial.

SMARTeZ™ RS is intended to be used in ambulatory, clinical setting and home environment.

CONTRAINDICATIONS

- Infusion of insulin, blood or blood products, TPN, lipids or fat emulsions.
- Infusion of any solution 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.
- Infusion of critical or life-sustaining fluids.

WARNINGS

- Do not use in infusion regiments 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 paediatrics 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 routes where back pressures is expected, flow rates will decrease.
- In case of spillage of medication, see drug MSDS 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. Keep away from sunlight and heat. Keep dry.
- Drug products should be stored in their approved containers and closures.
- Do not store in freezer.
- See the drug manufacturer's package insert for drug reconstitution / dilution and storage procedures.
- See drug package insert for drug compatibility with ABS, silicone elastomer, PVC, TPU, acrylic, PES, PTFE and for use suitability with the in-line filter.

PRECAUTIONS

- SMARTeZ™ RS 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.

COMPLICATIONS

Common complications associate with the use of elastomeric pumps for continuous infusions are:

- Catheter-related complications (catheter migration, dislodgement, obstruction, insertion site infection, penetration of the vessel, nerve injury, needle trauma).
- Tubing-related complications (kinking).
- Infusion related complications (inaccurate flow rate, leakage, obstruction).
- Drug toxicity. Any drug may lead to side effects and toxicities. Please refer to the specific summary of the drug manufacturer.

Fig. 1

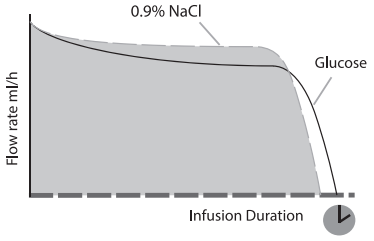


Fig. 2

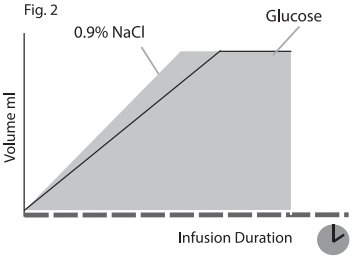
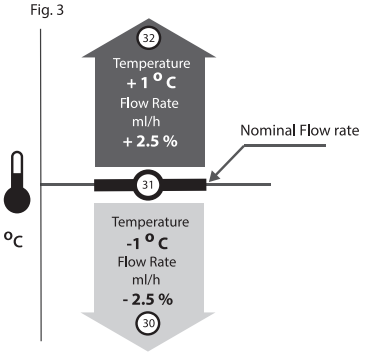


Fig. 3



Sterilized using ethylene oxide

Do not use if package is damaged

Non-pyrogenic fluid path

Do not re-use

℞ Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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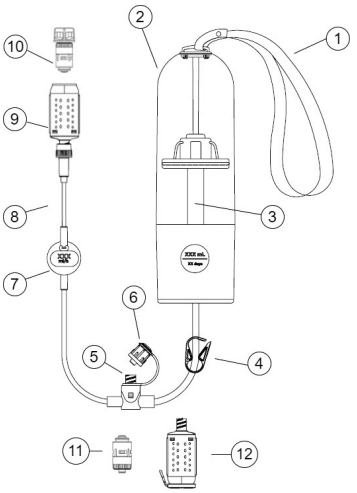
SMARTeZ™ RS – Chemo CS

Disposable elastomeric infusion pump

1. Hanger cap (only on REF number with suffix HC)
2. Rigid shell cover (with volume indicator)
3. Fluid reservoir (elastomeric membrane)
4. ON-OFF clamp
5. Fill port (ISO 80369-7 Female Luer Lock)
6. Fill port cap
7. Air and particulate eliminating filter
8. Flow restrictor
9. Patient connector (ProSeal™ CSTD Injector)
10. ProSeal™ CSTD Priming Cap
11. ProSeal™ CSTD Injection Site
12. ProSeal™ CSTD Injector



MIXING AND USE INFORMATION

- 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.

Nominal Volume	Residual Volume
≤120 mL	2.0 mL
121 - 300 mL	3.5 mL

INSTRUCTIONS FOR FILLING

- Use Aseptic Technique

1. Unscrew the tethered fill port cap.
2. SMARTeZ™ RS can be filled with a syringe or automated filling device. Remove trapped air from the filling device and attach it securely to the fill port.
3. Prior to filling, ensure the ON-OFF clamp is OPEN and priming cap is securely attached on patient connector.
4. Always fill the device with non-hazardous solution first.
5. Fill 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.
6. Remove filling device from the fill port. Screw on the fill tethered port cap.
7. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

- Use Aseptic Technique

1. Open the ON-OFF clamp.
2. Push to connect the ProSeal™ CSTD Priming Cap to patient connector for priming. The hydrophobic filter on the priming cap could stop the liquid flow once the tubing is fully primed.
3. Check the priming progress by observing the presence of liquid inside the transparent priming cap.
4. Close the ON-OFF clamp, and pull to remove ProSeal™ CSTD Priming Cap after priming.

PRIMING TECHNIQUE FOR DRUGS

- for drugs prone to precipitation

1. Fill SMARTeZ™ RS 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 SMARTeZ™ RS to warm to room temperature before use, especially when infusate has been refrigerated.
2. Infusion should preferably be started 1 hour after filling.
3. Connect the ProSeal™ CSTD Injection Site to the female luer lock connector on the patient access site.
4. Clean the top of injection site as directed by the hospital or healthcare provider.
5. Push to connect the patient connector (ProSeal™ CSTD Injector) to ProSeal™ CSTD Injection Site.
6. Begin infusion by opening the ON-OFF clamp.

AFTER INFUSION

- Use Aseptic Technique

1. Close the ON-OFF clamp.
2. For models with in line fill port, the administration tube can be flushed by connecting a syringe to in line fill port.
3. Pull to disconnect the patient connector (ProSeal™ CSTD Injector) from ProSeal™ CSTD Injection Site.
4. Discard used device in accordance to disposal procedures for bio-hazardous materials of your facility.

OPERATING CONDITIONS AND SAFETY

When filled to the nominal volume, flow accuracy is within +/- 15% of the nominal (label) flow rate.

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.
- 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.
- Temperature affects viscosity. Higher temperature lowers viscosity resulting in 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, the flow rate increase by 2.5% and conversely for ever (1) °C reduction flow rate may decrease by 2.5% (Fig.3).
- The nominal flow rates are based on Sodium Chloride (0.9%) as reference. Use of 5% dextrose will result in 10% slower flow rate (Fig. 1) or correspondingly 10% longer delivery times (Fig.2).
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.