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Instructions for Use

Description

SMARTez® elastomeric infusion pumps are designed to give clinicians and nurses the option of delivering pre-determined amounts of medication to the patient in a continuous and accurate manner either at the hospital or at home.
SMARTez ® is independent of main power supplies or batteries, enabling the patient to be treated in an ambulatory manner.
Medication is delivered to the patient by positive pressure applied by the elastomeric membrane. The flow rate is determined by the combination of the flow regulation device (flow restrictor) and the positive pressure of the elastomeric membrane. This pressure delivers the solution against the back-pressure of catheters and blood pressure in the veins.Back-pressure affects the flow rate.

Indications

Elastomeric pump devices are intended to infuse medication for either continuous intravenous, subcutaneous or epidural infusion (according to pump model). Chemotherapy, antibiotics, anesthesia and pain management are the most common therapies where elastomeric pumps can be used, either in adult or pediatric patients.
For detailed information about the range of drugs typically administered via elastomeric pumps please refer to Drug Stability List.

Contraindications

Elastomeric pumps are contraindicated for the delivery of blood, blood products, insulin, total parenteral nutrition and lipid emulsions.

Complications

Common complications associated with the use of elastomeric pumps for continuous infusion are:
• Catheter-related complications (catheter migration, dislodgement, obstruction, insertion site infection, penetration of the vessel, nerve injury, needle trauma)
Note: After initial correct positioning of an intravenous catheter, it may get dislodged. If this is the case, the infusion may be delivered paravenous, e.g. into the tissue. In case of paravenous infusion, severe tissue reactions and necrosis might occur. In such situations, please stop the infusion immediately, leave the catheter in place and contact your physician. Intravenous catheters may also lead to infusion site infections.
• Tubing-related complications (kinking)
• Infusion-related complications (inaccurate flow, leakage, obstruction)
Note: In case of over-infusion severe side effects may occur, depending on the infused medication. In case of under- delivery or stopped delivery , the treatment may be compromised.
In case of leakage, being exposed to a medication not intended for that use might lead to side effects.
• Drug toxicity
Any drug may lead to side effects and toxicity. Please refer to the specific summary of the drug manufacturer.

Warnings:

Do not use if package has been opened or is damaged. Single use only. Do not re-sterilize or re-use. Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness, or death of the patient.
Elastomeric pumps should not be used in patients with known hypersensitivity to any of the materials of the device.
Elastomeric pumps should only be applied by healthcare workers who have been adequately trained in this technique.

Classification

SMARTez® elastomeric pumps are manufactured according to ISO 13485 and are in conformity with the following standards:
• European Community (CE Mark) class IIb Medical Device Directive (MDD)
• Product certified by British Standards Institute (BSi) in accordance with 93/42/EEC
• ISO 28620:2010(E) Medical devices - Non-electrically driven portable infusion devices

Directions for Filling

Elastomeric pumps can be filled with a Luer Lock syringe or a similar device using an aseptic technique. The tubing should be primed with 0.9% sodium chloride solution (0.9% NaCl) before adding medication.
Priming
(use aseptic technique):
1. Close the clamp
2. Twist off the closing cone from the filling port and place it on a sterile surface
3. Attach the filling device to the filling port. Push down the syringe plunger until syringe is empty
4. Remove the filling device from the filling port and close all caps
5. Open the closing cone of the patient connector
6. Open the clamp and prime the system
7. Close the clamp and reattach the closing cone of the patient connector
Note: Please make sure, that you hold the filter upwards during the priming process. The filter needs to be fully wetted with the carrier solution in order to ensure complete functionality.
Adding medication (use aseptic technique):
Repeat steps 2-5 until required volume is achieved
Note: Please make sure, closing cones of filling port and patient connector are properly dosed after filling a and prior to use.
Patient Connection:
1.Open the closing cone of the patient connector
2. Disinfect the connection ports and consider the exposure time
3. Connect the patient connector of the pump to the patient's Access device
4. Make sure, that the flow restrictor is completely taped on the patient's skin
5. Make sure, that the filter is not covered by any dressing
6. Open the clamp for starting the infusion

Cautions

• Temperature dependency: SMARTez® is designed to work at room temperature 23°C +/- 2°C (73°F +/- 3.6° F). The flow restrictor is calibrated to work at 31 °c (88°F). To maintain a stable flow rate the flow restrictor should be in dose contact to the patient's skin at all times (31°C). For every I °C above or below this temperature, the flow rate will increase or decrease by approximately 2.5%. An increase in temperature results in an increase in flow rate and vice versa (figure 1).
• If SMARTez® pumps needs to be stored in the refrigerator or freezer, allow the unit to warm up to room temperature before usin g. Storage in the freezer should not exceed a maximum duration of 30 days, deducting the pump specific nominal infusion time. (Example: Maximum 30 days - nominal infusion time 5 days = 25 days maximum storage)
• Ambient pressure dependency: SMARTez® pump should be used within an ambient pressure between 86 kPa and 106 kPa.
• Underfilling/overfilling: filling the pump less than nominal volume generally results in a faster flow rate. Filling the pump more than the nominal volume results in a lower flow rate.
• Diluent dependency: SMARTez® pump flow rates are calculated on the basis of using 0.9% NaCl. Using dextrose (D5W) as diluent or the addition of any drug of a higher viscosity than normal saline will increase delivery time (e.g. by 10%in case of dextrose [D5W], see figure 2).
When filled to nominal volume, the flow accuracy is +/-15% of the labeled flow rate for SMARTez® pump.

Fig. 1

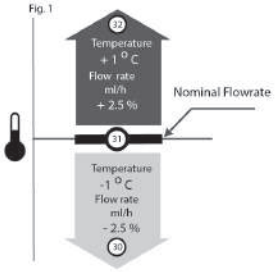


Fig. 2

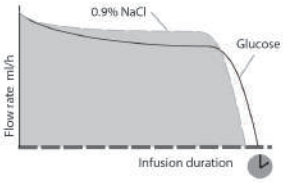
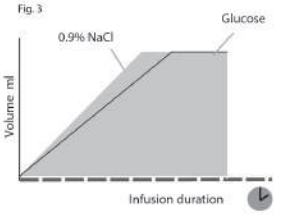


Fig. 3



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