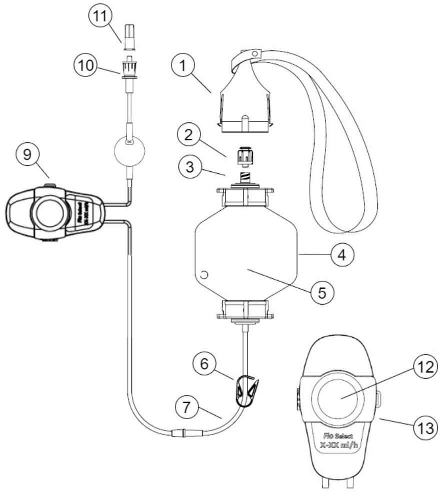
SMARTeZ™ Plus – PainBloc
Variable Flow
Disposable elastomeric infusion pump

1. Hanger clip (only on REF number with suffix HC)
2. Fill port cap
3. Top fill port (ISO 80369-7 Female Luer Lock)
4. Soft cover
5. Fluid reservoir (elastomeric membrane)
6. ON-OFF clamp
7. Administration tube
8. Air and particulate eliminating filter
9. Flow selector module
10. Patient connector
    - ISO 80369-7 Male Luer Lock
    - ISO 80369-6 NRFit (REF number with suffix N)
11. Patient end cap
    - Priming cap for MLL
    - Vented cap for NRFit
12. Selection knob
13. Selector cover



MIXING AND USE INFORMATION

- Calculate the fill volume per infusion prescription and adding the residual volume.

b2Yꞁyl·f ±2fdzYŜ	wŜăꞁŘdzl·f ±2fdzYŜ
pл ꞁ мpл Yf	н5 Yf
мpм ꞁ o5л Yf	4.0 Yf
351 ꞁ 6лл Yf	p5 Yf

INSTRUCTIONS FOR FILLING
- Use Aseptic Technique
1. Unscrew the fill port cap.
2. SMARTeZ™ Plus 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 (Refers to operating manual of automated filling device).
3. Prior to filling, ensure the ON-OFF clamp is CLOSE.
4. 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.
5. Remove filling device from the fill port. Screw on the fill port cap.
6. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING
- Use Aseptic Technique
1. Turn selection knob to set the flow selector module to its highest flow rate setting.
2. Open the ON-OFF clamp.
3. Loosen the patient end cap. The medication will start to flow and fill the tubing. When all air is expelled, tighten the patient end cap.
4. For models use MLL at patient connector, maintain the priming cap on patient connector during priming. The hydrophobic filter on the cap could stop the liquid flow once the tubing is fully primed.
5. Close the ON-OFF clamp after priming.

PRIMING TECHNIQUE FOR DRUGS
- for drugs prone to precipitation
1. Fill SMARTeZ™ Plus 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™ Plus 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 patient connector to the female Luer Lock or female NRFit connector on the patient access site.
4. Turn the selection knob to set the flow selector module to desired flow rate setting.
5. Remove the selection knob and close the selector cover after flow rate setting.
6. Begin infusion by opening the ON-OFF clamp.

AFTER INFUSION
- Use Aseptic Technique
1. Close the ON-OFF clamp.
2. Detach patient connector from patient access site.
3. Discard used device in accordance to disposal procedures for bio-hazardous materials of your facility.

OPERATING CONDITIONS AND SAFETY
When filled at the nominal volume
- Flow accuracy is within +/- 20% of the nominal (label) flow rate.
Note: Flow accuracy is maintained on every selectable flow.

Actual flow rate 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 longer delivery times. The nominal flow rate is calibrated at (22 °C / 72 °F). For an increase of every one (1) °C, the flow rate may increase by 2.5% and conversely for every one (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.

SMARTeZ ™ Plus - PainBloc
Variable Flow
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™ Plus is a soft shell elastomeric pump. 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 at the nominal volume, flow accuracy is within +/- 20% of the nominal (label) flow rate. Flow rate is affected by temperature and viscosity of the drug or fluid.

INDICATIONS FOR USE STATEMENTS
SMARTeZ™ Plus – PainBloc is intended to provide continuous delivery of medication (such as local anesthetics) to or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and/or pain management. Route of administration include: intraoperative site, peripheral nerve block, percutaneous and epidural.

SMARTeZ™ Plus is intended to be used in ambulatory, clinical setting and home environment for users 18 years of age and older.

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.
- Infusion from routes other than indicated.

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 an in-line 1.2 µm filter.

PRECAUTIONS
- SMARTeZ™ Plus 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

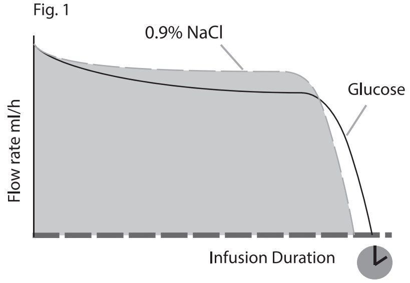


Fig. 2

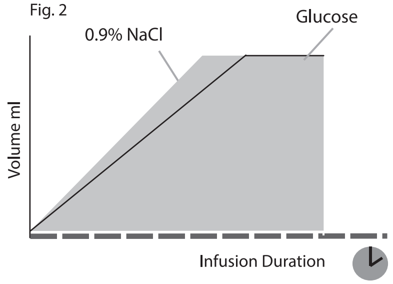
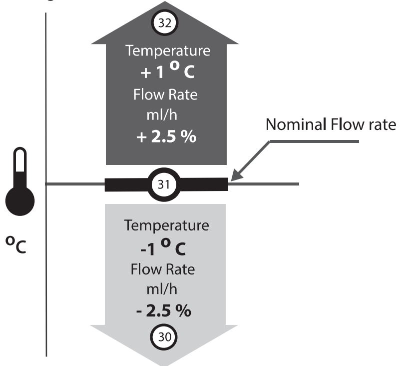


Fig. 3



STERILE EO — Sterilized using ethylene oxide

Do not use if package is damaged

Non-pyrogenic fluid path

Do not re-use

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

Epic International (Thailand) Co., Ltd.
WHA Eastern Seaboard Industrial Estate
500/73 Moo 2, Tasit, Pluakdaeng, Rayong
Thailand 21140

EC REP — MT Promedt Consulting GmbH
Altenhofstr. 80
66386 St.Ingbert Germany
49-6894-581020

CE 0123

780185 Rev.01 / Date of issue 2022-09-15