NIPRO

EN

SUREFUSER™ +

100mL / 250mL (Amber Type)

AMBULATORY BALLOON INFUSER

Instructions for Use

Please read these instructions for use carefully before use.

Indications

Surefuser™ + (Amber Type) (Hereinafter abbreviated as Surefuser™ +.) is to be used for continuous drug infusion therapy: post operative pain control, carcinomatous pain control, chemotherapy for cancer etc. Follow instructions by medical professionals.

Contraindications

1. Oil-based medications, i.e., iodized ethyl ester of fatty acid obtained from poppy seed oil, etc., and etoposide medications and fatty emulsion medications should not be used.
2. This product is intended for single use only.

Operating Principle

A rubber balloon reservoir is filled and expanded with medication. The contractile force of the balloon forces out the medication. By running the medication through the casing (flow control) containing a very narrow tube, a specific flow rate can be maintained.

Method

1) Medication Procedures
   1. Refer to the drug insert from the pharmaceutical manufacturer for information about medication procedures.
   2. Before beginning patient infusion, make sure you thoroughly understand the infusion characteristics of Surefuser™ + being used.
   3. We recommend using Luer lock type syringe.
2) Priming Surefuser™ + with Medication (See Fig. 1-3 below)
   1. All operations must be performed under aseptic conditions.
   2. Fill the syringe with medication. Completely bleed all air bubbles from the syringe.
   3. If a syringe with needle is being used, remove the needle from the syringe.
   4. Verify correct closing of the robert clamp.
   5. Remove the port cap retaining it for later use and fill the balloon reservoir with the medication via the port. Filling operation must be done following the instruction: Place the syringe plunger on a solid surface and place both hands on the syringe for a secure grip. By pressing the syringe barrel slowly down, the solution flows into the balloon reservoir. Pressure must be applied only on the syringe, not on Surefuser™ +. Check the port section for leaks and make sure that there is no damage in the balloon reservoir. The use of a filter is recommended during filling operation. Make sure that the syringe does not separate from the port during filling. (See Fig.2)
   6. When the balloon reservoir is filled with the correct liquid volume, disconnect the syringe and close the port with the retained cap.
   7. Hold the infusion line filter so that the patient side is at the top. Open the robert clamp on the infusion line to prime the infusion line. After opening the robert clamp, the liquid automatically flows through the product. It is not necessary to remove all of the air from the back side of the filter; air in the back side cannot flow to the patient side.
   8. If the liquid does not flow through the product, tap the casing with your finger to expel the air.
   9. Priming is complete when all air bubbles have been bled from the infusion line and the liquid starts flowing from the connector.
   10. When priming is complete, close the infusion line with the robert clamp and replace the cap with the occlusive cap.
   11. If necessary, fill out the patient label with the required information and attach the label to the protector.
   12. Infusion should be started as soon as possible after the balloon body has been primed.
3) Administering the Medication
   1. Verify that there are no air bubbles in the infusion line and then attach the connector to the patient's line.
   2. Use adhesive tape, etc., to attach the casing (flow control) securely to the patient's skin.
      NOTE: If the casing (flow control) is not attached securely to the patient's skin, the medication flow rate may vary from the one desired.
   3. Open the robert clamp and start the medication infusion.
   4. The scale on the balloon body is only an indication of the volume in the balloon.

Fig.1 Structure

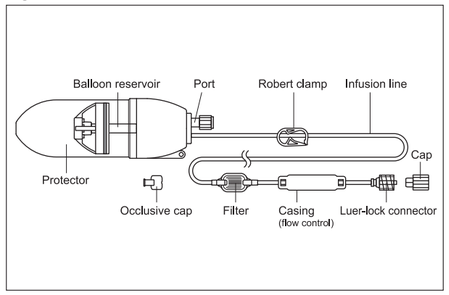


Fig.2 Operation Method

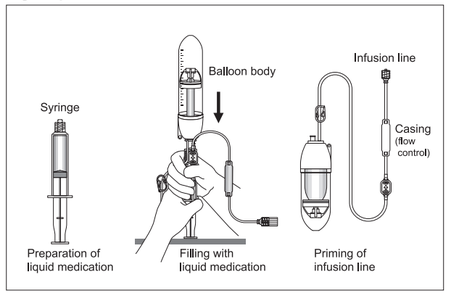
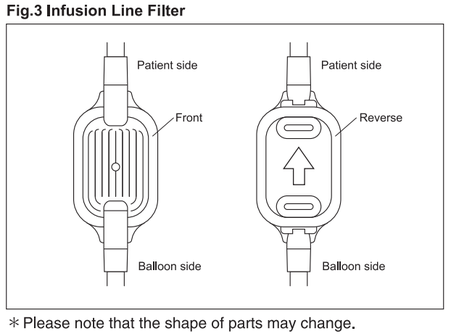


Fig.3 Infusion Line Filter



* Please note that the shape of parts may change.

Caution

1) This is a disposable, single-use-only product that must not be re-sterilized and reused. Discard the product immediately after use.
   *Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity.
2) Never fill the balloon reservoir beyond the specified liquid amount, doing so could cause the balloon reservoir to rupture.
3) Hold the Surefuser™ + upright with both hands and fill slowly.
4) Do not pull excessively on the infusion line; it might cause leakage or the infusion line to detach.
5) Air between the balloon reservoir and the filter is expelled by the filter.
6) If there is air in the infusion line, the liquid may not flow when the robert clamp is released.
7) Make sure there are no bends or twists in the infusion line or the connected catheter. Bends and twists can cause fluctuations in the infusion rate.
8) After the balloon reservoir is filled with liquid, use immediately.
9) The infusion rate will vary due to changes in the viscosity and density of the medication, temperature and arterial pressure. Please keep these factors in mind when using Surefuser™ +.
10) The stated infusion rate for Surefuser™ + is based on using a physiological saline solution with the casing (flow control) at a temperature of 32°C (skin temperature). In order to maintain consistent medication viscosity, the casing should be attached securely to the patient's skin using adhesive tape, etc. infusion rate accuracy is ±10%.
11) The specified priming time for Surefuser™ + is based on the use of physiological saline solution at normal temperatures. Additional priming time will be needed when using high-viscosity medications or when using Surefuser™ + at low temperatures.
12) Before closing the robert clamp, verify that the infusion line is in the center of the robert clamp. If the robert clamp does not clip the infusion line properly, the medication flow will not be stopped.
13) Oil-based medications, i.e., iodized ethyl ester of fatty acid obtained from poppy seed oil, etc., and etoposide medications can cause the balloon reservoir to rupture and should not be used with Surefuser™ +.
14) Do not use alcohol-containing medication on the filter for disinfection. It could damage its hydrophobic character and could lead to leakage.
15) During usage, check the condition of the Surefuser™ + and infusion line regularly for blood clots and leakage. Pay particular attention to each connection part for breakage, leakage or weak connections.
16) Using fatty emulsion medications can cause the infusion line filter to become clogged, so the use of such medications should be avoided.
17) Refer to the pharmaceutical manufacturer's drug insert for instructions on medication use and quantity.
18) If any abnormalities, such as balloon reservoir rupture, medication leaking into the protector, etc., are noticed during use, discontinue use immediately.
19) Never use a product if its package is damaged or if any product damage or Irregularities are noticed.
20) Some products/medication used can cause the connecting part to be loosened or to be broken. (e.g. the use of alcohol on the connecting parts can cause cracks.)
21) Store the product in a cool, dry place away from direct sunlight and excess humidity.
22) Select the administration volume and the flow rate of the medication in use as specified for that medication.
23) Dispose of the product in an approved biohazard container as per facility protocol.

Guarantee

1) Surefuser™ + is manufactured under strict quality control and quality is assured. We will not be responsible, however, for the injury to a patient or any person or for the damage to any object that is attributed to transport, storage, and operation in your institution.
2) If a patient or any person is injured or any object is damaged by the use of Surefuser™ +, we will not be responsible for the injury or damage unless we are clearly identified as being at fault.
3) If a patient or any person is injured or any object is damaged by the reuse of Surefuser™ +, we will not be responsible for the injury or damage of any nature.
4) We will not be responsible for any injury or damage caused by use of Surefuser™ + after the expiry date mentioned on the packages.

Surefuser™ + (Amber Type) Performance data

100 mL models						
Product reference	Nominal volume	Maximum fill volume	Infusion time	Flow rate	Tolerance	Residual volume
SFS-1001DPUV	100 mL	110 mL	1 day	4.2 mL/hr	±10 %	1.52 mL
SFS-1002DPUV	100 mL	110 mL	2 days	2.1 mL/hr	±10 %	1.52 mL
250 mL models						
Product reference	Nominal volume	Maximum fill volume	Infusion time	Flow rate	Tolerance	Residual volume
SFS-10-25PUV	250 mL	275 mL	1 day	10 mL/hr	±10 %	3.61 mL
SFS-5-25PUV	250 mL	275 mL	2 days	5 mL/hr	±10 %	3.61 mL

Length of tubing :
All types : 900 mm

• 100% filling volume
• The flow volumes are based on a physiological saline solution with the casing (flow control) at a temperature of 32°C (skin temperature).

Symbols used for labeling

	Do not re-use
	Consult instructions for use
STERILE EO	Sterilized using ethylene oxide
	Use-by date
LOT	Batch code
	Manufacturer
REF	Catalogue number
EC REP	Authorized representative in the European Community
	Fragile, handle with care
	Do not use if package is damaged
	Non-pyrogenic

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