ELASPUMP – ELASPUMP UV – SOFT ELASPUMP

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Please read the whole document before using the medical device.
Follow all the instructions carefully to ensure the safety of the patient and/or the user.

CAUTION: use only if the pack is undamaged and has not been tampered with. Do not use if the protection caps are missing or disconnected.

CAUTION: it is strictly prohibited to modify the medical device in any way. Any damage resulting from improper use of the device releases the manufacturer of all liability.

N.B.: report any incidents that occur in relation to the device to the manufacturer and the competent authority.

DESCRIPTION OF THE MEDICAL DEVICE

The elastomeric pump is a single-use medical device that was terminally sterilised using ethylene oxide, to be used for continuous infusions (fixed or variable flow rate) and/or for patient-controlled analgesia during clinical infusions.

The infusion pump consists of an elastic silicone device holding the solution to be infused, contained inside a transparent or semi-transparent protective shell that may be either hard or soft. A one-way flat-bottomed Luer lock filling valve, a flexible, a non-kinking DEHP-free PVC hose provided with a distal Luer lock fitting, an in-line particulate filter, a removable closure (fastening) clip, and a terminal capsule with a hydrophobic filter.

The fixed infusion rate model is also available in a lightproof PVC-free variant.

The variable infusion rate models are provided with a multiple flow controller making it possible to control the flowrate according to predefined flow rates.

Continuous or variable flow rate elastomeric pumps can be fitted with a patient-controlled analgesia (PCA) – additional bolus device provided with a solution reservoir: once the solution enters the reservoir, the patient will be able to press the PCA button to obtain an additional dose of the solution.

Each elastomeric pump is individually packed in a stiff PVC film blister heat-sealed with Tyvek paper, whereas the soft protection models are packed in a peel-away Tyvek paper and PE/PET plastic film sachet.

INTENDED PURPOSE

The elastomeric pump is a medical device to be used to deliver continuous infusions (fixed or variable flow rate) and/or for patient-controlled analgesia during clinical infusions, for example for administering analgesics and antibiotics, for intraoperative and postoperative care and for labour, as well as for chemotherapy for cancer patients.

INTENDED USERS

The device is intended for use by qualified healthcare professionals, such as oncologists, anaesthetists, clinical nurses, home care nurses and clinical pharmacists, as well as, once the medical device has been connected to the patient, by lay users, in the case of home care therapy.

CLINICAL BENEFIT

Epidural analgesia does not affect patient activities such as walking, but aims to improve patient comfort and the level of hospital services.
Effective postoperative analgesia permits earlier patient mobilisation, reduces episodes of lower limb thrombosis and pulmonary embolism and promotes early recovery of gastrointestinal function.

WARNINGS

- Use only if the pack is undamaged and has not been tampered with. Do not use if the protection caps are missing or disconnected.
- Medicinal products and fluids must be administered according to the instructions provided by the manufacturer of the medicinal product. Physicians are responsible for prescribing medicinal products depending on the clinical condition of each patient (e.g. age, weight, disease status, concomitant medication, etc.).
- As no alarm occurs when the flow is interrupted, life-support medication whose use may result in severe injury or death due to their interruption or insufficient delivery, are not recommended for infusion using the device.
- The pump does not have an infusion status indicator.
- It is the healthcare professional's responsibility to ensure that the patient has been duly educated on how to use the system properly.
- The fittings of the accessories used must comply with EN ISO 80369-7.

INDICATIONS

- Sterile, nontoxic, non-pyrogenic device.
- Do not remove the device from the pack until it is ready for use.
- The expiry data is 5 years after the date of sterilisation and applies to products that are distributed and stored in accordance with the instructions provided by the manufacturer.
- Store in a clean place at room temperature, away from heat and moisture.
- The mL scale on the hard body of the pump is provided for guidance purposes only.
- Single-use device. Do not fill twice. Do not reuse. Reusing the system may result in a loss of system functionality and a risk of infection for the patient.
- The writing in English on the PCA module of the elastomeric pump indicates the quantity of bolus: 0.5 mL/at a time and the lock time: 15 min.
- The writing in English in the flow rate controller in variable infusion rate elastomeric pumps indicates that the user must ensure that the arrow is in the maximum flow rate position during priming and must position the arrow on the desired flow rate for the infusion.
- After use, the medical device must be disposed of and may not be reused. The medical device is for single use. The device must be placed in a biohazard container and disposed of in accordance with applicable national/international legislation and hospital protocols.
- The elastomeric pump must be filled using a Luer lock syringe. It is advisable to use a filter during filling.
- Comply with the nominal fill volume indicated on the label of the device. The fill volume is obtained by adding together the nominal value and the residual value (not more than 10%). Do not fill the reservoir with a volume that is greater or less than the nominal volume. Fill volumes that differ from the nominal volumes may result in significant changes in the flow rate delivered.
- It is prohibited to apply the device to those who are allergic to analgesics or are suffering from respiratory diseases, severe cardiovascular disorders, shock or intense pain. In these cases, the satisfactory effects observed with common conditions are not achieved.
- Lightproof elastomeric pumps are suitable for the infusion of photosensitive solutions.
- The flow rate may vary depending on the viscosity and concentration of the medicinal product infusion and on the temperature of the environment and patient.
- Optimum flow rate is achieved when the elastomeric reservoir and the distal Luer lock are positioned at the same height.
- The infusion time may increase significantly after a prolonged period of storage: the temperature of the device should be allowed to stabilise before use.
- Before introducing the medicinal product, insert the saline solution used to dilute the medicinal product: this precaution will prevent the administration of undiluted medicinal product.

- When using a catheter, consult the instructions for use provided by the manufacturer of the catheter. The length, diameter and position of the catheter can affect the flow rate. Do not use a catheter with a diameter smaller than 22 gauge (3 French).
- All the elastomeric pumps are DEHP-FREE or PVC-FREE.
- In the event of leakage from the pump or administration set, close the strap on the hose. Replace the pump if necessary.
- If leaks occur during use, replace the entire system.
- The device is suitable for use in outpatient clinic patients and for home care therapy.

CONTRAINDICATIONS

- The elastomeric pump is not intended for the administration of blood, blood products, lipids, lipid emulsions or total parenteral nutrition (TPN).
- The device is not suitable for use in neonatology settings.
- Avoid contact between cleaning agents (such as soap and alcohol) and the filter, as leakage from the air outlet may occur.
- Do not immerse the pump in water. Protect the pump and filter during any activity in which they might get wet, e.g. having a shower.
- Avoid air travel, since changes in pressure may cause the balloon of elastomeric pump to burst.
- Do not use a microwave, oven or water bath to heat the fluid.
- PVC models can be incompatible with some pharmacological solutions: consult the information leaflet inside the pack of the medicinal product and any other relevant information.
- Administer the prescribed volume of medicinal products: overdose may alter the outcome of therapy.
- This product must not be used for intramuscular injections.

STORAGE

Store in a clean, dry place, protected from moisture, direct sunlight and sources of heat.

PRECISION OF DELIVERY

The average flow rate must have a tolerance of ±15% of the nominal flow rate. The adjustable flow rate must have a tolerance of ±20%. At least 80% of the nominal volume must be delivered at an instantaneous flow rate within ±50% of the nominal flow rate.

USE

NOTE: the elastomeric pump must be filled using a Luer lock syringe. It is advisable to use a filter during filling.

NOTE: the following procedure must be carried out by medical and/or nursing staff.

NOTE: if the hose is bent, roll the bent part between the fingers to restore the shape of the hose and favour the flow of the fluid.

NOTE: use an aseptic procedure throughout the procedure.

1. Before administration, check that the solution is clear and do not use of it is not clear.
2. Check the integrity of the pack and remove the elastomeric pump immediately before use.

NOTE: to open the elastomeric pump pack, in the case of a rigid blister, lift the edge to remove the paper and in the case of a bag, pull the two flaps apart.

3. Remove the cap from the filling valve.
4. Close the line using the light blue (fastening) clip.
5. Attach the syringe to the filling valve without applying excessive pressure and introduce the medicinal product while holding the system in a vertical position (do not use the needle during filling).

NOTE: the filling valve used to add the solution is a non-return valve. When it is necessary to remove solution that has already been introduced into the elastomeric pump, use the needle/plastic fitting with sterile tip provided in each device pack. Connect the adapter to the syringe and insert it into the non-return valve to withdraw the medicinal product.

NOTE: to avoid the risk of precipitation inside the hose, the pump can be pre-filled and primed with a small amount of diluent, so that the medicinal product is not in the pump hose until the infusion is started. This technique can be used for any medicinal product subject to precipitation, such as fluorouracil (5-FU).

6. Make sure there is no air in the syringe during the infusion of the medicinal product (if only minimal air is incorporated, the reservoir autonomously releases it over a maximum of two hours).
7. Once the relevant volume has been introduced, remove the syringe and replace the protective cap on the filling port and open the clip.
   With PCA models, after opening the (fastening) clip, remove the yellow tab from the button.
8. The start of dripping from the end shows that the device is functioning properly.
   In models with a bolus device, press the button once or twice to infuse the fluid into the line.

NOTE: if the hose is twisted, roll the twisted part between the fingers to restore the shape of the hose and favour the flow of the fluid.

9. Having checked that fluid is present at the end of the line, close the clip and the male Luer lock fitting at the end to use the device at a later time.
   The PCA button is the function button that patients can use to control the additional medical product when in a continuous infusion position. By pressing the PCA button, the patient can add a limited quantity of medicinal product in accordance with the physician's instructions, as necessary.

CAUTION: if the administration set does not start, proceed as follows:

1) If the medicinal product does not flow, connect a Luer adapter or a three-way valve to the distal end of the elastomeric pump.
2) Attach a syringe to the other side of the valve and maintain suction until all the air has been removed.
3) Continue suction until all the air has been removed from the hose and fluid flows from the distal Luer lock. Repeat if necessary.
4) Detach the syringe and the valve and check that the fluid starts to flow out of the fitting and replace the protection cap on the distal part of the system.
5) If this is not successful, check whether something else is blocking the flow, e.g. medicinal product precipitate, a closed clamp or a twisted hose.

10. Label the elastomeric pump with the date of preparation, patient's name, the medicinal products used and their dosage.
11. Check that the solution is clear both before positioning the system and in the following days.
12. Use an indelible marker to mark the level at the start of the infusion, in order to have a clear reference for checks on operation.
13. Connect the system to an appropriate device for administration to the patient.
14. The infusion is complete when the elastomeric membrane is no longer expanded. Close the (fastening) clip, disconnect the device and dispose of it in compliance with applicable legislation.

INFUSION RATE CHANGES (for variable flow rate models only)

WARNING: make sure the controller is not set between two volume settings, as the system could prove very imprecise.

- **FOR VARIABLE FLOW RATE MODELS:**
  follow the instructions provided above and:
  - turn the flow controller feather key to the highest permitted value,
  - prime the line by opening the light blue (fastening) clip,
  - turn the flow controller feather key to the desired value,

- remove and store the feather key.

WARNING: make sure the controller is not left between two value settings, as the system could prove very imprecise.

BOLUS ADMINISTRATION (for models with PCA only)

Before use, remove the yellow tab from the pump's PCA button.
The button for PCA bolus administration allows the patient to autonomously manage the infusion of an additional 0.5 mL of medicinal product during a continuous infusion.
As necessary, press the button to administer the bolus by PCA.
The following bolus will become available after 15 minutes.

CAUTION: should leaks occur at any point of the line during administration, interrupt the infusion cycle and check the origin of the leak. Replace the whole system if necessary.

COMPLICATIONS

Various complications may arise, depending on the different medicinal products used. They predominantly take the form of insufficient analgesia, nausea and vomiting, lethargy, urinary retention, severe lower limb itch or lower limb numbness.

MEASURES TO BE TAKEN IN CASE OF ADVERSE EVENTS

If an adverse reaction occurs during use, immediately discontinue use of the device. Keep the sample and seal all products in stock. Promptly report the event to the manufacturer and/or the competent authority of the Member State in which the user and/or patient is established.

PERFORMANCE CHARACTERISTICS

- For all models the dose of solution actually administered is > 80%.
- The flow rate may be slightly faster during the first 1-2 hours of use. This can be attributable to the physical characteristics of the silicone elastomer.
- Under testing conditions (i.e. temperature of [23±2] °C, relative humidity of [50±5]% and atmospheric pressure of 86 KPa~106 KPa), using purified water or distilled water for level infusion (i.e. with the balloon tank and the end of the Luer lock at the same level), the precision of the mean infusion rate is ±15%, and the adjustable flow rate must have a tolerance of ±20%.
- The flow rate may vary depending on:

1) Fill volume

An excessively high or low fill volume may result in an imprecise infusion flow rate.

A faster flow rate is obtained by filling the pump with a fill volume (nominal) lower than that indicated. Conversely, a slower flow rate is obtained by filling the pump with a fill volume (nominal) greater than that indicated.

2) Viscosity and/or concentration of the medicinal product

The flow rate was determined using purified or distilled water; infusing an excessively viscous liquid will result in a slower flow.

The flow rates indicated on the elastomeric pumps are based on the use of nominal sterile saline solution as a diluent.
Adding any medicinal product or using any other diluent may alter viscosity and increase or decrease the flow rate. Using a 5% dextrose solution increases administration time by 10%.

3) Position of the pump

Position the elastomeric pump approximately 40 cm (16 inches) below the catheter site.
Positioning the pump above this level increases the flow rate and, conversely, positioning the pump below this level reduces the flow rate.

4) **Temperature**
The flow rate was determined at a temperature of (23±2) °C; it will be faster when the device is used at higher temperatures and will be slower at lower temperatures.

5) **Atmospheric pressure**
The flow rate was determined under standard atmospheric pressure conditions: it will be faster when used at lower than standard atmospheric pressures and slower in the opposite case.
For SOFT PUMPs, squeezing the pump causes an increase in flow rate.

6) **Infusion level**
The product is intended for administering infusions, discontinuing infusions may result in a faster flow rate.

7) **Catheter/access devices**
When administration is performed using a central or peripheral catheter, follow the instructions provided by the manufacturer of the catheter.

8) **Storage**
The product must be used promptly after filling. The flow dispensed will be slower after long storage periods.

DISPOSAL

After use, the medical device must be disposed of and may not be reused. The medical device is for single use. The device must be placed in a biohazard container and disposed of in accordance with applicable national/international legislation and hospital protocols.

SYMBOLS

The following table describes the symbols included in the label of the device.

SYMBOL	DESCRIPTION
	CE
	Manufacturer
	Medical device
	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not re-use. For single use only
	Do not re-sterilize
	Consult instructions for use
	Caution
	**Keep away from sunlight** Store protected from direct sunlight and sources of heat.
	Keep dry

	Do not use if package is damaged. Consult instructions for use Use only if the pack is undamaged and has not been tampered with. Do not use if the protection caps are missing or disconnected.
	Non-pyrogenic
	Catalogue number
	Batch code
	Use-by date
	Date of manufacture
	Unique Device Identification