PAJUNK®

FuserPump

Infiltration

Instructions for Use

Special notice

Please read the following information and operating instructions carefully.

Rx only *Caution: Federal law restricts this device to sale by or on the order of a physician. The device may only be used by qualified medical staff in accordance with these user instructions.*

PAJUNK® does not recommend any particular treatment method. Professional medical staff are responsible for the way in which the device is used and for patient selection.
In addition to these instruction for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.
Failure to comply with the user instructions invalidates the warranty and puts patient safety at risk.
If used in combination with other products, it is essential that the compatibility information and user instructions for these other products are taken into account. A decision regarding the combined use of devices from different manufacturers (where they do not constitute treatment units) is the responsibility of the user.

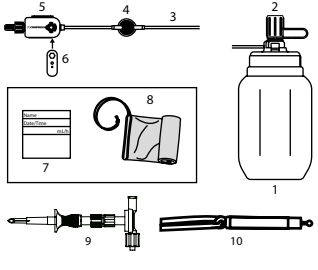
The device must not be used under any circumstances if there are good reasons to suspect incompleteness, damage or loss of sterility.

Only devices in perfect condition, which are within the sterile expiry date marked on the label, in undamaged packaging, may be used.

Device description / compatibility

REF *Please see the current declaration of conformity for product numbers and the scope of these instructions for use.*

Hub connectivity: LUER or NRFit®



Key

1. FuserPump container (volume: 350 ml)
2. Injection port
3. Infusion tube (length: approx. 120 cm)
4. Ventilation and bacterial filter
5. Flow regulator
6. Adjustment wrench
7. Patient label
8. Carry pouch
9. FuserPump Filler (optional)
10. Spring balance

The FuserPump system (see figure) is a portable, disposable elastomer pump that is connected to a catheter.

The mentioned flow rates were adjusted using isotonic saline solution at room temperature (23 °C) and with pump and flow regulator being at the same height. The system's precision is ± 10 % of the nominal flow rate. The flow rate depends on the filling volume of the pump, the adjustment of the flow regulator (options: 3 ml/h, 5 ml/h, 8 ml/h), the height difference between pump and flow regulator, the length, diameter and quality of the connected catheter and the temperature, concentration and viscosity of the drug used.
Since the flow rate was calibrated at room temperature, it is not necessary to fasten the flow regulator to the patient's skin.

Intended use

Administration of liquid drugs with a constant flow rate and low pressure using an indwelling catheter.

Indications

Pain management, regional anaesthesia

Contraindications

– Administration of lipid emulsions or solutions containing lipid emulsions, solutions with oil-containing ingredients, surface-active substances or highly viscous solutions, or drug solutions with solvents such as ethanol.
– Administration of blood or blood components.
– Use with negative pressure or overpressure.
– Use of organic solvents (alcohol) to wipe the surface of the device, the parts near the injection port, the ventilation/bacterial filter or the connection.
– Exceeding the specified filling volume (350 ml) of the pump.
– Use of the filled pump after having dropped it. This might cause liquid leakage or other damage.
– Flushing through the adapter while it is not connected to the catheter.

Complication

Complications of continuous analgesia

– Catheter disconnection
– Unsteady flow rate (insufficient analgesia or overdose)
– Blocked catheter
– Infections

Users must inform patients of complications typically associated with the procedure.

If complications occur while using the device, follow the protocols of your organisation. If this does not resolve the complications, or if they are regarded as serious or untreatable, carefully stop the procedure and remove invasive device components from the patient.

Warnings

⚠ *for sterile product:*

This is a disposable medical device for use with only one patient!

This device must not be re-used under any circumstances!

This device must not be resterilised under any circumstances!

The materials used in the manufacture of this device are not suitable for reprocessing or resterilisation.
This device is not designed to be reprocessed or resterilised.

⚠ Unauthorised re-use or reprocessing
- can cause the device to lose the essential performance properties intended by the manufacturer.
- leads to a significant risk of cross-infection/ contamination as a result of potentially inadequate processing methods.
- may cause the device to lose functional properties.
- may cause materials to break down and lead to endotoxic reactions caused by the residues.

⚠ *in the application:*

1. Do not administer any drugs that are not indicated for the intended use. This can result in serious injuries to the patient.
2. It is absolutely necessary to adhere to the instructions for each drug solution used.
3. Always ensure that the injection site is aseptic.
4. Be sure to check the connection between the catheter and the infusion devices regularly. After each use, consider flushing the catheter with 1 to 2 ml physiological saline solution (0.9 % sodium chloride).
5. Please note that there are lower flow rates if filled with less than 300 ml.
6. After completing the treatment, dispose of any residual medication in accordance with local regulations.
7. You can influence the flow rate by means of length and inner diameter of the catheter and its position.
8. If you use drugs that might crystallise, make sure that the injection path is not blocked by crystals.
9. Select a flow rate in accordance with medical prescription.
10. Do not remove the locking cap at the end of the tube to vent the system before having filled the pump.

⚠ *further warning indications:*

You must routinely take general precautions for handling blood and bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.

Sequence of use

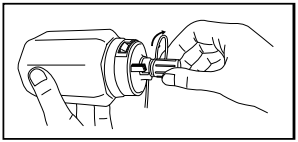
I. Catheter placement
II. Filling and venting the pump
III. Connecting and starting the system

I. Catheter placement:

Position the catheter in accordance with good clinical practice.

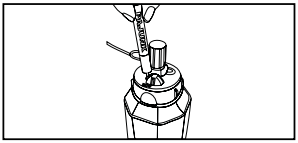
II. Filling the pump:

Remove the sterile system from the packaging. Unscrew the locking cap from the injection port.

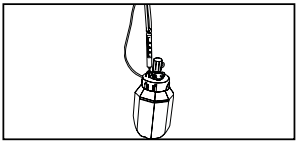


Checking the volume in the pump:

Use the spring balance to check the volume while filling the pump.
When delivered, the spring balance is already fastened to the string of the carry pouch.



Hang the spherical end of the spring balance into the recess provided for it in the lid of the pump. Hold the system by the string of the carry pouch and let the pump hang freely. Now you can read the filling volume of the pump on the spring balance.



IIa. Filling with a syringe:

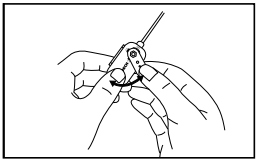
Fill the injection syringe with the drug and connect it to the injection port of the pump. Now you can fill the drug into the pump.

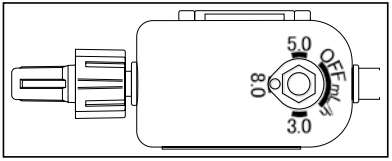
IIb. Filling with the FuserPump Filler:

The FuserPump Filler guarantees a direct connection between solution bag and pump system. The integrated check valve prevents liquids from flowing back again. This allows a faster, safe and sterile filling of the pump.
You can leave the pump filled up to 14 days without impairing its function. Make sure that the flow regulator is in "OFF" position for storage. If you store the filled pump in the fridge (3 °C, max. 14 days), leave it at room temperature for min. 10 h before use on a patient.

⚠ *With regard to shelf life and tolerance of the drugs used, please consult the drug manufacturer.*

Venting and adjusting the flow rate





Adjust the desired flow rate on the flow regulator. Use the adjustment wrench fastened to the back of the regulator. The black markings on the flow regulator show the range in which the regulator is fully functional for the shown flow rate. If the regulator is outside the black markings, application is not possible.
Please make sure that application starts immediately after having adjusted the flow rate and that the system is vented. When the system is completely vented, anaesthetic flows unhindered from the flow regulator.

III. Connecting catheter and pump:

1. After having vented the catheter completely and adjusted the desired flow rate, connect the pump to the catheter.
2. Note down all required information on the patient label and attach it to the pump.
3. You can now put the pump in the carry pouch provided for this purpose.
4. Please note that the remaining volume after finishing the application is approx. 4 ml.

Operating and storage conditions

	Temperature limit	+10 °C to +30 °C
	Humidity limitation	20 % to 65 %
	Keep away from sunlight	
	Keep dry	

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

Non-pyrogenic

Any serious incident that has occurred while using the device should be reported to the manufacturer and the corresponding authorities of the country the user and/or patient are residing in.

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling

Manufacturer

Use-by date

REF Catalogue number

STERILE EO Sterilized using ethylene oxide

Do not resterilize

Do not use if package is damaged

Keep dry

Humidity limitation

Do not re-use

Caution

Date of manufacture

LOT Batch code

Keep away from sunlight

Temperature limit

Consult instructions for use

Non-pyrogenic

Rx only Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)

Advice

Information

CE 0124 „CE marking of conformity“ or „CE marking“ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Medical Device Regulation and other applicable Union harmonisation legislation providing for its affixing.

PHT Does not contain phthalates

LATEX Natural rubber latex has not been used as a component in the manufacture of this product

QTY Quantity

NRFit® Hub connectivity: NRFit® acc. to ISO 80369-6

Translation

MD Medical device

NRFit®
is a trademark of GEDSA, used with their permission.

CE 0124

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