PAJUNK®

LOR Syringe

NRFit®

Regional Anesthesia

Instructions for use

These instructions for use were translated into the following languages: DE, EN, FR, IT, ES, PT, NL, DA, SV, EL, BG, ET, HR, LV, LT, PL, RO, SK, SL, CS, HU. The translations can be downloaded from our website: eifu.pajunk.com.

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 instructions 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 instructions for use invalidates the warranty and puts patient safety at risk.
If used in combination with other devices, it is essential that the compatibility information and user instructions for these other devices 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

Caution!
Only devices with NRFit® *80369-6 connector are compatible with each other.*

Caution!
Do not try to connect NRFit® *80369-6 connectors with other connectors.*

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

LOR (Loss-of-Resistance-) syringe for single use.

Hub connectivity: NRFit®

Intended use
Identification of the epidural space by loss of resistance (by means of air or saline).

Target user group
Medical staff only; anaesthesiologist, anaesthetist.

Target patient population
Adults and children.

Indications
Epidural anaesthesia/analgesia
The LOR syringe is only used in combination with an epidural cannula.

Contraindications
Using the LOR syringe for injections and aspirations. (The seal of the LOR syringe is not designed for injections.)

Complications
For applications with air: Pneumocephalus, spinal cord and nerve root compression, air accumulation in the retroperitoneum, subcutaneous emphysema, venous air embolism and possibly incomplete anaesthesia/analgesia and paraesthesia.

For applications with saline: Using saline delays the beginning and reduces the quality of the block by diluting the local anaesthetic injected afterwards.

Clinical complications

Identification and/or passage through the interspinous and flavum ligaments is difficult when they are softer than usual (e.g. interstitial oedema in late pregnancy) or hardened (e.g. in elderly patients). A patient's physical constitution can cause further difficulties. On the one hand, the assumption that the epidural space (e.g. in the lumbar region) is about 30-50 mm below the skin level does not apply to either big and obese or to particularly asthenic patients. On the other hand, the interspinous ligament may already be ossified and falsely indicate that the epidural space has been reached when the syringe passes through.

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 device:*

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

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 material to break down and lead to endotoxic reactions caused by the residues!

⚠ *Further warning indications:*

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

Sequence of use
The easy-gliding and easy-to-use LOR syringe is filled with either a physiological saline solution or air (depending on personal preference) and then connected to the cannula.
As the cannula passes through each tissue layer, pressure is applied to the syringe plunger until the tip of the cannula reaches the epidural space. A clear and sudden drop in pressure can be now felt at the syringe plunger.
Once the epidural space is identified, the syringe is removed and the cannula is left in place.

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 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, Deutschland.

Key to symbols used in labelling


Manufacturer


Use-by date

Item number

Sterilized using ethylene oxide

Do not resterilise


Do not use if package is damaged


Keep dry

Humidity limitation


Do not re-use


Caution


Date of manufacture

Batch code


Keep away from sunlight


Temperature limit


Single sterile barrier system


Single sterile barrier system with protective packaging outside


Consult instructions for use

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

MR unsafe


Advice


Information

"CE conformity marking" or "CE marking" = this marking shows that a device is in conformity with the applicable requirements as set out in the Medical Device Regulation or other European Union legislation on its affixing.


Sharp object warning

Does not contain phthalates

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

Quantity


Translation

Medical device

Unique device identification

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

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

CE 0124

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