PAJUNK®

NerveGuard

Regional Anesthesia

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 *NerveGuard, green, Luer (art no. 001151-38M) for cannula sizes from 18 G to 22 G*

REF *NerveGuard, violet, Luer (art no. 001151-38N) for cannula sizes from 24 G to 25 G*

According to current knowledge, a high injection pressure is a reliable warning signal for intrafascicular nerve injections. In case of peripheral nerve blocks of the upper and lower extremities, the risk of nerve injuries increases with increasing injection pressure.
The NerveGuard prevents an injection with excessive injection pressure by automatically blocking the flow of the local anaesthetic via a valve.

Hub connectivity: LUER or NRFit*

Dead volume max. 1 ml

Compatible with 5 to 20 ml syringes and PAJUNK® cannulas for peripheral applications.

Intended use

Limiting the injection pressure

Indications

Avoidance of too high intrafascicular, dynamic injection pressures and detection of faulty cannula positions (contact between cannula and epineurium or fascia) with hydrostatic start pressure during peripheral anaesthesia and analgesia.

Contraindications

No contraindications are known.

Complication

When used properly, no complications are known.

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 apply more pressure to the system than for an injection without NerveGuard.
2. In case of leakage, stop using the NerveGuard.
3. The NerveGuard prevents too high pressure during an injection; information on the correct positioning of the cannula tip is not provided.
4. The dynamic injection pressure is influenced by cannula length and size, syringe size, consistency of the injectate as well as injection rate. The hydrostatic (start) pressure is not affected by these factors.

⚠ *for use with other compatible products:*

When using multiple components, familiarise yourself with their operation before use by checking connections and passages.

⚠ *Further warning indications:*

1. 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.
2. Please note that the continued use of a device of the same type must be assessed cumulatively as described in the legislation on medical devices, even after the device has been exchanged or replaced.

Sequence of use

1. Connect the filled syringe to the female connector of NerveGuard and connect the injection tube with connected cannula to the male connector of NerveGuard.
2. Vent the system.
3. Position the cannula and locate the target nerve as usual.
4. Start the injection process. If the NerveGuard immediately blocks the injection, an increased opening pressure must be assumed, due to particles blocking the cannula's opening. Relieve the pressure from the syringe piston and reposition the cannula.

⚠ *If the NerveGuard blocks during injection, excessive, dynamic pressures can be assumed. Relieve the syringe piston to open the NerveGuard valve again, and continue injection at lower injection rate.*

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.

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


Catalogue number


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


Batch code


Keep away from sunlight


Temperature limit


Consult instructions for use


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


MR unsafe


Advice


Information


Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body


Does not contain phthalates (acc. to section 7.5 of Appendix I 93/42/EEC)


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


Quantity


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


Translation


Medical device

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

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PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen/ Germany
Phone +49 (0) 7704 9291-0
Fax +49 (0) 7704 9291-600
www.pajunk.com