PAJUNK®

SonoPlex II

Regional Anesthesia

Instructions for Use

Special notice

Please read the following information and operating instructions carefully.

℞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.

Stimulation and injection cannula with cable (for Ø2 mm plug) and injection tube; facet, SPROTTE® tips; NanoLine coating, echogenic Cornerstone-Reflectors, detachable stimulation cable.

Injection tube: LUER or NRFit®

Compatibility with PAJUNK® MultiStim nerve stimulators has been tested and is guaranteed.

Always ensure that the correct function of the nerve stimulator being used is applied, and that suitable current strengths are being applied.

Do not use devices that emit electromagnetic radiation near the patient in order to rule out the possibility of electromagnetic interaction.

Intended use

Access to and injections at peripheral nerves, where appropriate with the help of ultrasound and/or nerve stimulation techniques.

PAJUNK® cannulas can also be introduced into the body under X-ray or CT guidance.

Warning:
The cannula is not suitable for MRI use!

Indications

Single-shot peripheral regional anesthesia, analgesia.

Contraindications

Contraindications regarding peripheral regional anesthesia

Clinically manifest coagulation disorders, diseases of central or peripheral nerves, chronic respiratory disease for blocks of the upper limb, infection of the puncture site, injury at the puncture site, allergy to local anesthetic, lack of patient consent.

No other device-specific contraindications are known.

Under no circumstances is the device to be used in the event of known material incompatibilities and/or known interactions.

Complications

Product-specific complications

cannula breackage, occlusion, leak at the cannula hub.

Procedure-specific complications

PNB-Specific complications are seldom but possible complications include: undesirable position like intravascular or intraneural, failed block, repeating puncture/ redirecting of the cannula.

Clinical complications

Infections, neurologic complications, local anesthetic toxicity.

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 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 significant functional properties.
- may cause materials to break down and lead to endotoxic reactions caused by the residues.

for puncture:

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. Check aspiration once the cannula has been positioned. Stop the procedure if you detect blood in the injection tube or syringe.
3. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.

for injection:

1. Do not administer drugs that are not indicated for the intended use.
2. Always ensure that the injection site is aseptic.
3. No injection of local anesthetic during stimulation, since the anesthetic has an inhibiting effect regarding further nerve stimulation with stimulation cannulas!

for use with other compatible products:

If several components are used, check connections and ducts before use to become familiar with the function.

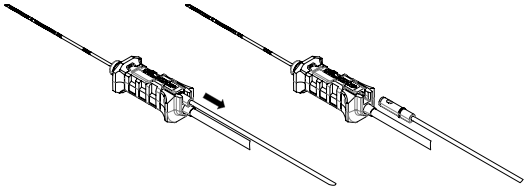
further warning indications:

1. Caution: Sharp object warning. The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. For practical purposes, the most important of these are the human immunodeficiency virus (HIV), the hepatitis B virus (HBV) and the hepatitis C virus (HCV).
2. 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.
3. 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

⚠ Decide on which method you will be using before puncture (ultrasound, nerve stimulation). If nerve stimulation is not going to be carried out, the stimulation cable can be removed before puncture. To do this, hold the cannula firmly by the hub and use the other hand to pull the stimulation cable out of the hub. Leave the protective tube on the cannula when performing this procedure.



1. Perform skin disinfection and cover puncture area with a sterile fenestrated surgical drape (aperture drape), local anesthesia.
2. Optional: Perforating incision (e.g. lancet etc.)
3. Optional: connecting a nerve stimulator to the cannula's stimulation cable.
4. Advancement of the stimulation cannula under the skin.
5. Determination of the position of the cannula (check aspiration if necessary).
6. Anesthetic may be administered as soon as the exact localization and the fixation of the cannula has been completed.

Use 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

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


Non-pyrogenic


Caution: Federal law restricts this device to sale by or on the order of a physician

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


Sharp object warning

Does not contain Phthalates (acc. to sec. 7.5 of Annex I 93/42/EWG)

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


Quantity


Hub Connection: NRFit® acc. ISO 80369-6

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

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