

PAJUNK®

SonoPlex

Regional Anesthesia



Instructions for Use

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

Special notice

 Please read the following information and operating instructions carefully!

 **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 001185 series, 001187 series

 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 connector with diameter 2 mm) and (adapted) injection tube; facet and SPROTTE® tip; NanoLine coating, echogenic Cornerstone embossments

Injection tube and hub: LUER

Compatibility tested and guaranteed with nerve stimulators of PAJUNK® MultiStim series.

Intended use

Access and injections to peripheral nerves, sometimes using 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!

 *Ensure the correct function of the nerve stimulator used and make sure to use adequate amperages.*

 *Do not use any devices with electromagnetic radiation near the patient to avoid any electromagnetic interactions.*

 *Make sure (particularly before injection) that the injection tube is firmly in place.*

Target User Group

Medical specialist staff only; anaesthesiologist, anaesthetist.

Target patient population

Adults and children.

Indications

Peripheral regional anaesthesia, analgesia.

Contraindications

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

No other device-specific contraindications are known.

 *In addition to the relevant information in these instruction for use, contraindications according to the corresponding specialist literature and current state of the art and knowledge also apply.*

Complications

- Cannula breakage
- Tissue/bone resistance and the related need to reposition the cannula
- Significant blood vessel trauma during puncture
- Neuronal trauma during puncture
- Allergic reactions (Ni,EO)

 *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 re-sterilised under any circumstances!*

The materials used in the manufacture of this device are not suitable for reprocessing or re-sterilisation.

This device is not designed to be reprocessed or re-sterilised.

 **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.

 *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.
4. In case of unexpected bone contact, withdraw and change the direction of the cannula.
5. Repeated bone contact will damage the cannula tip. On no account you should continue to use a cannula damaged in this manner. In case of a previous bone contact remove the cannula in one step.

 *for injection:*

1. Always ensure that the injection site is aseptic.
2. Do not administer any drugs that are not indicated for the intended use.
3. Be sure to regularly check the connection between the cannula and the infusion device.

 *for use with other compatible products:*

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

 *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. The most relevant ones in practice 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 body 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

1. Disinfect the skin and cover the puncture area with a sterile fenestrated drape; perform local anaesthesia.
2. Incision (optional: lancet, etc.).
3. Optional: Connect a nerve stimulator to the connecting cable of the stimulation cannula.
4. Advance the stimulation cannula under the skin.
5. Localisation of the cannula (e.g. using ultrasound).

Optional: Determine the cannula position by electrostimulation. First use a higher stimulation current intensity, observing the response to the stimulus. A clear response to the stimulus at low current intensity means that the cannula is close to the nerves to be localised. The perforation click can clearly be noted when the nerve sheath is penetrated. When the stimulation cannula is correctly positioned, the nerve sheath can be widened by injecting 5 % glucose solution through the injection tube.

 *No injection of local anaesthetic during stimulation because the anaesthetic inhibits further nerve stimulation with stimulation cannulas!*

6. Verify correct position by aspiration if necessary.
7. As soon as exact localisation and fixation of the cannula has been performed, the anaesthetic can be applied.

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.

 *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



Item number



Sterilized using ethylene oxide



Do not re-sterilise



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



Does not contain natural rubber latex



Quantity



Translation



Medical device



Unique device identification



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