PAJUNK®

SonoPlex
SonoPlex STIM

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.

Product specification / compatibility

REF 001185 series, 001187 series

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 connector with diameter 2 mm) and (adapted) injection tube; bevel, Tuohy 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 ultrasound, fluoroscopic 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.

Indications
Peripheral regional anaesthesia

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.

Complication

- 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 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.

⚠ *for puncture:*

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
3. If you unexpectedly come into contact with bone, change the direction of the cannula. Do not try to overcome bone resistance. Failure to adhere to these rules could cause the cannula to bend or break.
4. Repeated bone contact will damage the 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 and Introducer 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/catheter 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 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

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. As soon as exact localisation and fixation of the cannula has been performed, the anaesthetic can be applied.

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

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

MR unsafe

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.

Sharp object warning

PHT Does not contain phthalates

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

QTY Quantity

Translation

MD Medical device

CE 0124

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