

PAJUNK®

SonoTAP

Regional Anesthesia



Instructions for Use

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.

Product specification / compatibility



1185-3xxxx series



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

Cannula with (adapted) injection tube; bevel tip; Cornerstone embossments
Injection tube and hub: LUER

Intended use

Access to the peripheral target area and injection, sometimes using ultrasound



PAJUNK® cannulas can also be introduced into the body under ultrasound, fluoroscopic or CT guidance.



*Warning:
The cannula is not suitable for MRI use!*



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

Indications

Peripheral regional anaesthesia, analgesia for minor abdominal surgery

Specific indications

Transverse abdominis plane (TAP) block for: appendectomy, hernia operation, Caesarean section, removal of the uterus, removal of the prostate gland

Rectus sheath block (RSB) for: bilateral blocks for midline cuts, smaller laparoscopic interventions

Contraindications

Clinically manifest coagulation disorders, diseases of central or peripheral nerves, infection of the puncture site, injury at the puncture site, allergy to local anaesthetic, patient refusal

Device-specific complications

 *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.

Complication

Vascular damage, neurological damage, paraesthesias, pain, failed block, motor deficits, infection

Device-specific complications

Cannula breakage, tissue/bone resistance and the resulting necessity of cannula realignment, significant vascular injuries during puncture, neuronal damage during puncture, allergic reactions

 *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 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.

- 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

- Disinfect the skin and cover the puncture area with a sterile fenestrated drape; perform local anaesthesia.
- Incision (optional: lancet, etc.).
- Advance the cannula under the skin.
- Localisation of the cannula (e.g. using ultrasound).
- 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



Catalogue number



Sterilized using ethylene oxide



Do not re-sterilize



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

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



Sharp object warning

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



Translation



Medical device



XS190256B_Englisch 2020-01-21



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