PAJUNK®

SonoTAP II

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.
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.

Cannula with injection tube; facet tip; echogenic Cornerston-Reflectors

Injection tube: LUER according to ISO 80369-7 or NRFit® according to ISO 80369-6

The cannula is not intended for stimulation.

PAJUNK® cannulas and catheters can be inserted into the body via ultrasound, X-ray or CT.

Warning:
The cannula is not suitable for MRI use!

In addition to these instructions for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.

Users must provide patients with information.

Intended use
Access to the peripheral target area and injection, where appropriate with the help of ultrasound

Indications
Peripheral regional anesthesia, analgesia for minor abdominal operations

English

Specific Indications
Transversus Abdominis Planum- (TAP) Block for: example appendectomy, hernia operation, caesarean section, hysterectomy, prostatectomy
Rectus sheath block (RSB) for: Bilateral blocks for midline incisions, minor laparoscopic interventions

Contraindications
Clinically manifest coagulation disorders, diseases of central or periphere nerves, infection of the puncture site, injury at the puncture site, allergy to local anesthetic, lack of patient consent

Device-specific contraindications
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.

ⓘ In addition to the information listed in the user instructions, contraindications apply according to the relevant specialist literature as well as the state of technology and training.

Complications
Device-specific complications
Cannula breakage, tissue/ bone resistance and the related need to reposition the cannula, significant vascular injuries during the puncture, neuronal damage during the puncture, allergic reactions

Clinical Complications
Vascular injury, nerve damages, paresthesia, pain, failed block, motor deficits, infection.

ⓘ In addition to the information listed in the user instructions, complications apply that correspond with the state of knowledge and training according to the relevant specialist literature as well as the state of technology and training.

❗ 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.

ⓘ Users must inform patients of complications typically associated with the procedure.

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.

regarding 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

regarding injection:

1. Do not administer drugs that are not indicated for the intended use. This can severely damage the patient.
2. Always ensure that the injection site is aseptic.

when using with other compatible products:

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

Further warning indications:

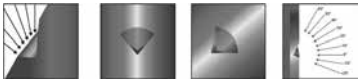
1. Caution: Sharp object warning. The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. For practical purposes, the most important of these are the human immunodeficiency virus (HIV), the hepatitis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

Information

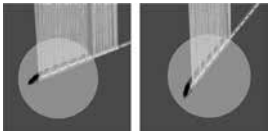
It applies to Sono cannulas:

The distal end of the cannula is provided with Cornerstone Reflectors over a length of 20 mm up to the cannula tip. This area is marked by a short section without Cornerstone Reflectors in the centre of the cannula. The Cornerstone Reflectors are arranged all around the cannula shaft to ensure 360-degree sonographic visibility.

The Cornerstone reflectors are designed so that all ultrasound waves are reflected with great precision, largely irrespective of the angle of insertion, when using either the in-plane technique or the out-of-plane technique.



The design of the reflectors and their positioning on the cannula optimises physical reflection properties while offering a broad spectrum of angles of insertion.



Application

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. Advancement of the cannula under the skin.
4. Determination of the position of the cannula with ultrasound (check aspiration if necessary).
5. 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
- 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
- Rx only Caution: Federal law restricts this device to sale by or on the order of a physician
- MR unsafe
- Advice
- Information
- CE 0124 Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body
- Sharp object warning
- PHT Does not contain Phthalates (acc. to sec. 7.5 of Annex I 93/42/EWG)
- LATEX Natural rubber has not been used as a component in the manufacture of this product
- QTY Quantity
- NRFit® Hub Connection: NRFit® acc. ISO 80369-6

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

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