PAJUNK®

SPROTTE® Standard
SPROTTE® Standard 2.G
SPROTTE® Standard Tapered
NRFit®

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.

The „Summary of Safety and Performance acc. to EU-2017-745 (SSCP)“ is available from EUDAMED.

Product specification / compatibility

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

Cannula (also: tapered cannula) with SPROTTE® tip (ogive-shaped tip geometry; lateral eye with rounded edge), incl. stylet.

Hub shapes: SPROTTE® standard, SPROTTE® standard with magnifying glass, SPROTTE® standard 2.G
Stylet
Optional: Introducer
Hub connectivity: NRFit®

Caution!
Only products with NRFit® *80369-6 connector are compatible with each other.*

Caution!
Do not try to connect such NRFit® *80369-6 connectors with other connectors.*

Intended use

Puncture, access to the target area, aspiration, injection.

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

Warning:
The cannula is not suitable for MRI use!

This cannula is not suitable for inserting a catheter!

Target User Group

Medical specialist staff only; anaesthesiologist, anaesthetist.

Additional for pain management: pain management specialist, orthopedist and radiologist

Target patient population

There are no limitations in patient population

For pain management additional: Target population are patients with chronic pain in spine. The treating medical specialist staff is responsible for the selection of appropriate patients.

Indications

Single-shot spinal anesthesia, analgesia; Interventional Pain Management

Contraindications

Device-specific complications

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

Clinical complications

Absolute contraindications:

- Patient refusal
- Poorly controlled bleeding diathesis or anticoagulation (coagulation disorders)
- Systemic infection (sepsis/ bacteremia)
- Local infection at the site of injection
- Local malignancy at the site of injection
- Weakened immune system
- Strong, de-compensated hypovolemia, shock
- Uncontrolled diabetes mellitus

Relative contraindications:

- Specific neurological disorders
- Specific cardiovascular disorders
- Allergic reaction/ hypersensitivity to the administered agents (contrast, anesthetic or corticosteroid)
- Severe deformations of the spine, arthritis, osteoporosis, spinal disc herniation or condition after spinal disc surgery
- Condition after spinal fusion, spinal metastasis
- Recent consumption of non-steroidal anti-inflammatory medications
- Unexperienced user

Special contraindications regarding subarachnoidal cannula placement:

- No free backflow of cerebrospinal fluid (neither after rotating the cannula in different plains and after repeated aspiration)
- Liquor mixed with blood (whisch is not clear even after repeated aspiration)

Complication

Device-specific complications

Cannula bending, breakage, occlusion, leak at the cannula hub

Procedure-specific complications

Undesirable positioning of the cannula (e.g. intravascular, intraneural, etc.), repeated puncture/redirection of the cannula, failed procedure.

Clinical complications

- Local and systemic infections
- Neuronal damage (during cannula placement, which may result in temporary increase in pain, temporary motor weakness, transient back or extremity pain, nubness and/ or tingling, paraplegia)
- Accidental vascular punctures with corresponding complications (vascular lesions, bleeding/ bruising, hematoma, vasovagal reactions, intravascular injection etc.)
- Intra-arterial injection (direct injection into the spinal cord, vertebral artery or radicular artery include spinal cord infarct, epidural hematoma and brainsteam hemorrhage, neurological events, vascular complications, thrombosis or thromboembolism)
- (Accidental) puncture of the dura with corresponding complications
    - *Dura puncture and liquor loss:* post-spinal head or back ache, nausea, vomitus, neurological damage, epidural abscess
    - *Anaesthetic in the subarachnoid space:* Circulatory disorders, decrease of the body temperature, urinary retention, respiratory side effects and complications, extremities weakness, total spinal anaesthesia, cauda-equina syndrome
- Multiple complications related to the pharmacology of steroids (transient hot

flushes, adrenocortical suppression, fluid retention, elevated blood sugars and mood swings, HPA axis suppression (typically self-limiting), osteoporosis, necrosis of bone, steroid myopathy, weight gain)
- Reactions on contrast agent (if applied)
- Toxicity of local anesthetic (if applied)

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. Use an introducer to insert the SPROTTE® cannula and/or perform an incision beforehand on the area where the puncture has to be performed (lancet, etc.).
3. Only perform the puncture (even when removing the cannula) with the stylet in place.
4. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
5. In case of unexpected bone contact, withdraw and change the direction of the cannula.

6. Repeated bone contact will damage the tip. On no account you should continue to use a cannula damaged in this manner. In case of previous bone contact remove the cannula (with introduced stylet) and introducer in one step.

⚠ *for injection:*

1. Always ensure that the injection site is aseptic.
2. Do not administer drugs that are not indicated for the intended use.
3. Aspirate before the injection of medication. If you observe blood in the cylinder of the syringe, then the cannula has been introduced improperly. TERMINATE THE PROCEDURE.

⚠ *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. 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 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

Single-shot spinal anesthesia

1. Perform skin disinfection and cover area to be punctured with a sterile fenestrated surgical drape (aperture drape).
2. Administer a local anaesthetic.
3. If necessary, make a stab incision at the intended puncture site (lancet, etc.).
4. Advance the introducer into the intervertebral ligaments.
5. Introduce the spinal cannula through the introducer and push it up to the subarachnoid space.
6. Retract the stylet from the cannula.
7. After positive identification of the subarachnoid space (by the respective return flow of cerebrospinal fluid), inject the anaesthetic (depending on age and weight of the patient, as well as on the type of the intervention and the composition of the anaesthetic).

Procedures of pain management

1. Perform skin disinfection and cover puncture area with a sterile fenestrated surgical drape (aperture drape), local anesthesia.
2. If necessary, perform a perforating incision of the area to be punctured (lancet, or similar).
3. Puncture by means of cannula.
4. Identification of the target area (optionally by administration of the contrast agent).
5. Administration of analgesia.
6. Further procedure in accordance with the individual indication.

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.


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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


Single Sterile Barrier system


Single Sterile Barrier system with protective packaging outside


Non-pyrogenic


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


MR unsafe


Advice


Information


„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


Does not contain Phthalates


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


Quantity


Hub connection:
NRFit® according to ISO 80369-6


Translation


Medical device


Unique Device Identifier

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

CE 0124

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