PAJUNK®

Tuohy
Tuohy Sono

Regional Anesthesia

Operating instructions

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

Cannula with special Tuohy grinding, plastic hub, graduation and retaining plate (wings), incl. stylet (metal or plastic).

Optional: Cornerstone-Reflectors
Hub connectivity: LUER or NRFit®

Intended use

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

Indwelling time for the continuous system: 7 days (168h)

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

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

Warning:
The cannula is not suitable for MRI use!

Indications

Single-shot or continuous epidural block for surgical anesthesia, obstetrical analgesia, postoperative analgesia and treatment of chronic pain or as a complement to general anesthesia.

Interventional pain management in spine: epidural steroid injections, selective nerve root injections (periradicular therapy), facet joint injections (intra-articular, medial branch), sacroiliac joint injections.

Contraindications

Device-specific contraindications

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

Clinical contraindications

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

Complication

Device-specific complications

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

Procedure-specific complications

Undesirable positioning of the cannula (eg intravascular, intraneural etc), repeating puncture/ redirecting 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 hematoma, 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. Only perform the puncture (even when removing the cannula) with the stylet in place.
3. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
4. 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.
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 catheter placement and removal:*

1. Immediately before use, check that the catheter will pass through the cannula.
2. The tip of the cannula can be damaged by bone contact during insertion. If a catheter is passed through a cannula that is damaged in this way, it can itself become damaged. If this happens, use a new cannula.
3. Once the catheter has left the tip of the cannula, do not retract the catheter as there is a risk of shearing.
4. If blood (or cerebrospinal fluid in the case of epidural applications) is visible in the catheter return window or in the piston chamber of the syringe, remove the catheter and reattempt puncture. The catheter was incorrectly positioned.

5. If the procedure is interrupted, remove the catheter and the cannula together if possible.
6. If flow is impeded, check the locking mechanism of the adapter.
7. When using catheters with a closed tip and lateral openings, extend the catheter at least 15 mm (no more than 50 mm) beyond the tip of the cannula to ensure unimpeded injection.
8. Never insert the catheter more than 50 mm. It is more likely to become knotted if it is inserted more than 50 mm.
9. Ensure that the catheter is not kinked on fixing.
10. Be sure to check the connection between the catheter and the infusion devices regularly.
11. Do not tug the catheter or pull it sharply when removing it from the patient.
12. Do not exert excessive force when removing the catheter. Do not continue to pull the catheter if it starts to stretch too much.
13. If you detect resistance while removing the catheter, do not withdraw it any further. If necessary, reposition the patient so as to enlarge the gap between the vertebrae. Then try to withdraw the catheter again. If this is still difficult, investigate with fluoroscopy or an X-ray before taking any further action.
14. After removing the catheter, check the distal tip to see whether it is complete. The tip should be intact. Only in this case you can be sure that the entire catheter has been removed.

⚠ *for injection:*

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

⚠ *for use with other compatible products:*

1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).
2. When connecting the catheter to the adapter, always make sure that the catheter is fully inserted into the ClampingAdapter as far as the stop (at least as far as the orientation mark). Never preflush before making the connection.
3. Disinfectants based on or containing alcohol can damage the filter.
4. The locking cap must be screwed on before you disinfect the filter.

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.
4. Avoid build-up of fluid film between the catheter and Clamping Adapter (e.g. through fluids on gloves). Fluids on the proximal end of the catheter can affect the holding force and result in disconnections and/or leakage.

Sequence of use

Placement of the epidural cannula

1. Perform skin disinfection and cover area to be punctured with a sterile fenestrated surgical drape (aperture drape).
2. Administer a local anesthetic.
3. If necessary, perform a perforating incision of the area to be punctured (lancet, or similar).
4. Advance the cannula into the intervertebral ligaments.
5. Retract the stylet from the cannula.
6. Identify the epidural space, e.g. using the Loss-of-Resistance (LOR) method.
7. After positive identification of the epidural space, 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) or continue with “Placement of the epidural catheter” if a continuous technique should be used.

Placement of the epidural catheter

1. Remove the VPC and place the insertion aid on the cannula hub.
2. Push the catheter with the marked end into the epidural space until reaching the required depth. Do not advance the catheter forward any further, if you feel clear resistance.
3. After successful placement, remove the cannula over the catheter. Hold the catheter tightly with the other hand, if necessary.
4. After removing the cannula, connect the catheter to the ClampingAdapter.
5. Fill the filter with the anaesthetic solution to be used at the beginning of the anaesthesia/analgesia to compensate for the dead volume (the filling volume of the filter is approximately 0.35 ml).

6. Connect the catheter adapter to the hub of the filter.
7. Fill a syringe with the selected anesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
8. Fix the catheter at the outlet site with the optionally provided FixoCath.
9. Optionally, fix the catheter and filter with FixoLong in the vicinity of the catheter exit.

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.

Fastening of the FixoLong (optional)

1. Fasten the PAJUNK® FixoLong with the fixed catheter cross in the vicinity of the catheter exit.
2. Lock the catheter in the fastening clips. This guarantees maximum freedom of movement while simultaneously fixing the catheter.
3. Place the filter base on the catheter cross.
4. Secure the bacterial filter on the filter base.

Fastening of the FixoCath (optional)

1. Hold the catheter over the incised side of the FixoCath securing plaster at the position of the catheter outlet.
2. Remove the three adhesive strips at the lower part of the securing plaster and fasten the plaster to the skin.
3. Now remove the longitudinal adhesive strips on the foam padding and place the catheter over it.
4. Remove the adhesive film of the perforated cover plaster and secure this over the catheter.

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

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 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


Non-pyrogenic


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


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 sec.


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

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

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