PAJUNK®

EpiSpin Lock

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

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

EpiSpin Lock is provided by PAJUNK® in convenient kits consisting of:

- Cannula: Tuohy tip, backeye, retaining plate, stylet
- Cannula: SPROTTE®-tip
- Catheter (with/without mandrin, with/without helical coil) in bag
- Clamping Adapter
- Catheter insertion aid („feeder“)
- Locking cap
- EpiSpin Fixation System
- Bacterial filter 0,2 µm
- LOR-Syringe

Hub connectivity: LUER

The exact composition may be gathered from the label.

Intended use

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

The catheters are intended to remain in the target area (epidural space) and constantly deliver a local anaesthetic from an external source.

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

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

Warning:
The cannula is not suitable for MRI use!

Indications

Combined spinal-epidural anaesthesia, analgesia.

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

Special contraindications regarding spinal 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: Cannula bending, breakage, occlusion, leakage at the cannula hub.

Catheter: Catheter breakage, catheter shearing, catheter bending, catheter knotting, reduced/absence of flow (occlusion), catheter disconnection.

Procedure-specific complications

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

Catheter:

During placement:
Inability to locate catheter tip within epidural space, Inability to place catheter tip within epidural space (result in catheter knotting or shearing on the introduction cannula tip), accidental intravascular catheter placement, accidental subarachnoid catheter placement, difficulty in advancing the catheter (may result in catheter kinking).

During application:

- Technical problems resulting in the premature discontinuation of epidural analgesia due to catheter disconnection, catheter obstructions (occlusion); leakage at the catheter exit site.
- Primature discontinuation of epidural analgesia due to catheter-related infections
- Catheter migration

During removal:
Resistance when removing the catheter resulting in catheter breakage.

Clinical complications

- Local and systemic infections
- Neuronal damage (during cannula/catheter placement, which may result in temporary increase in pain, temporary motor weakness, transient back or extremity pain, numbness 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)

- 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
- Toxicity of local anesthetic

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.

during 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. In case of unexpected bone contact, withdraw and 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. Check that the catheter will pass through the cannula immediately before use.
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 Clamping 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. 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.
4. Be sure to check the connection between the cannula/ catheter and the infusion device constantly.

⚠ *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 Clamping Adapter, always make sure that the catheter is fully inserted into the Clamping Adapter 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 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.
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

Procedure for combined spinal/epidural anaesthesia

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. First push a Tuohy Backeye cannula (Tuohy cannula) into the intervertebral ligaments while orientating the lateral opening in the cranial direction.
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, remove the LOR-syringe from the Tuohy cannula.
8. Now introduce a SPROTTE® cannula of suitable size through the fixation adapter and the Tuohy puncture cannula.
9. There is a marking on the proximal cannula shaft of the spinal cannula. The spinal cannula has arrived at the backeye opening of the Tuohy cannula as soon as this marking disappears in the fixation adapter.
10. Press down the violet lever on the fixation adapter to secure the spinal cannula in the Tuohy cannula. In this way, the position of the cannula tip of the spinal cannula can no longer be unintentionally changed.
11. Retract the stylet from the spinal cannula and check the correct position of the cannula by the corresponding return flow of cerebrospinal fluid.
12. Inject the anesthetic.
13. Remove the fixation adapter, including the spinal cannula, from the Tuohy cannula by rotating it counterclockwise.
14. Place the introductory aid on the hub of the Tuohy Backeye cannula (Tuohy cannula).
15. 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.
16. After successful placement, remove the cannula over the catheter. Hold the catheter tightly with the other hand, if necessary.
17. After removing the cannula, connect the catheter to the Clamping Adapter.
18. 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).
19. Connect the Clamping Adapter to the hub of the filter.
20. Fill a10 ml or 20 ml syringe with the selected anesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
21. Fasten the catheter with the optionally available FixoLong or FixoCath in the vicinity of the exit point.

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.


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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


Non-pyrogenic

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

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


Translation

Medical device

CE 0124

XS190065X_Englisch 2020-11-10

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