PAJUNK®

IntraLong Cath
EpiLong Cath
EpiLong Soft Cath

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: ifu.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.

Product specification / compatibility

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

Catheter: with optional internal coil, stylet, tip geometry: central distal or lateral openings

Direct accessories: Catheter introductory aid, Clamping Adapter

Compatibility with: cannula of suitable and correct size for placing a catheter, filter, FixoLong and FixoCath.

Hub connectivity: LUER

Intended use

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

Do not use catheters with an internal spiral or stimulation electrode or cannulas for MRI procedures! After placement, be sure to attach the supplied "Not suitable for MRI" label to the catheter or label it clearly and comprehensibly for third parties in accordance with the specifications of your institution.

Target User Group

Medical specialist staff only; anaesthesiologist, anaesthetist.

Target patient population

There are no limitations in patient population (ethnic, age, etc.)

Indications

Continuous epidural/ spinal anaesthesia and 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

Complication

Device-specific complications

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

Procedure-specific complications

During placement:

Inability to locate catheter tip within subarachnoid 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 can be 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)
- 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
- 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

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

ⓘ *PAJUNK® cannulas and catheters can be introduced into the body under ultrasound or fluoroscopic guidance.*

⚠ *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 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 regularly check the connection between the cannula/catheter and the infusion devices.
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 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. 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.
2. 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.
3. Do not administer drugs that are not indicated for the intended use.
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

Catheter placement is performed with the patient in asitting or lateral decubitus position with his back archedto maximize the opening of the vertebral interspaces.
Puncture site is identified and marked. After skin disinfection and sterile covering of the puncture site local anesthesia of the skin and the subcutaneous tissue is performed by injecting local anesthetic.
A perforating incision is performed at the puncture point using a lancet or an injection cannula with a large lumen.

Placement of a catheter in the epidural space

1. An epidural cannula is advanced into the interspinal ligament. The stylet is removed and a LOR-syringe filled with NaCL or air is attached to the cannula.
2. The cannula is advanced carefully into the epidural space. Entrance of the epidural space is characterized by a loss of resistance. The content of the LOR-syringe can be emptied out easily. (Loss of resistance technique)

Alternatively the cannula can be advanced without a LOR-syringe attached to the cannula hub. In this case the epidural space is identified by a hanging drop which is attached to the cannula hub when the interspinal ligament has been reached and is sucked in the cannula hub when reaching the epidural space.

3. Careful aspiration is performed to exclude intravascular cannula placement.
4. The distal end of the catheter is introduced into the cannula. The catheter is advanced through the cannula up to the desired depth. The catheter should not be advanced more than 5 cm beyond the cannula tip.
5. Then the cannula is retracted carefully over the catheter.
6. The catheter is fixed in this position under sterile conditions with a FixoLong.
7. The catheter is now connected to a Clamping Adapter. The proximal end of the catheter is therefore introduced into the central opening of the adapter and advanced up to the marking of insertion depth and locked in this position.
8. A bacterial filter is attached to the Luer-Lock connector of the Clamping Adapter and a test dose of local anaesthetic is administered through the catheter.

Placement of the spinal catheter

1. Place the spinal cannula into the subarachnoid space.
2. Place the catheter container on the cannula hub.
3. Push the catheter with the marked end into the target area until it has reached the required depth.
4. Take the catheter out of the catheter container and withdraw the container until the mandrin has also been completely pulled out of the catheter.
5. The correct catheter position must be checked by means of CSF reflux.
6. Once it is in place, remove the cannula via the catheter. Hold the catheter tightly with the other hand, if necessary.
7. After removing the cannula, connect the catheter to the Clamping Adapter.
8. 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).
9. Connect the catheter adapter to the filter hub.
10. Fill the syringe with the selected anesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
11. Secure the catheter at the exit site using the optionally supplied FixoCath.

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


"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.


Does not contain Phthalates


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


Quantity


Translation


Medical device


Unique Device Identifier


Single Sterile Barrier system

PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen/ Germany
Phone +49 (0) 7704 9291-0
Fax +49 (0) 7704 9291-600
www.pajunk.com

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