PAJUNK®

CauDal
Crawford

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.

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

Product specification / compatibility

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

Cannula with Crawford tip
Hub shapes: Standard
Stylet
Hub connectivity: LUER

Intended use

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

Target User Group

Medical specialist staff only; anaesthesiologist, anaesthetist.

Target patient population

There are no limitations in patient population

Indications

Caudal epidural anesthesia and analgesia, Interventional Pain Mananagement.

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

Relative contraindications for caudal technique:

- Pylonidal cysts
- Congenital anomalies of the dural sac and its contents

Complication

Device-specific complications

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

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)
- Toxicity of local anesthetic

Complications due to incorrect technique by caudal cannula placement

- Intraosseous injection into the blood vessels rich vertebral body, as the cancellous bone can be easily injured by the puncture cannula.
- Puncture cannula is placed on the sacrum: by injecting air, saline or local anesthetic, crepitations or subcutaneous swelling may be noted.
- Subperiosteal position: manifested by severe resistance during injection.
- Cannula placed in front of the sacrum: The cannula is positioned near the coccyx. Further advancement of the cannula could lead to perforation of the rectum and, in obstetric caudal anaesthesia, may result in injury to the foetal head.
- Infections
- Intravascular injection
- Intrathecal injection with high or spinal anesthesia
- Massive epidural anesthesia
- Hypotension, bradycardia, nausea, vomiting
- Bladder dysfunction
- Post dural puncture headache
- Neurological complications
- Cauda equina syndrome
- Epidural abscess
- Epidural hematoma

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

PAJUNK® cannulas can also 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.

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.

during 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 spinal injection of medication. If you observe blood (or spinal fluid during the epidural anaesthesia) in the cylinder of the syringe, then the cannula has been introduced improperly. TERMINATE THE PROCEDURE.
4. Be sure to regularly check the connection between the cannula/catheter and the infusion device.

⚠ *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. 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.

Sequence of use

Placement of the cannula (caudal epidural anesthesia, single shot)

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. Retract the stylet from the cannula.
5. 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).

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	Non-pyrogenic
Use-by date	Caution: Federal law restricts this device to sale by or on the order of a physician
REF Catalogue number	
STERILE EO Sterilized using ethylene oxide	MR unsafe
Do not resterilize	Advice
Do not use if package is damaged	Information
Keep dry	„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.
Humidity limitation	
Do not re-use	
Caution	Sharp object warning
Date of manufacture	Does not contain Phthalates
LOT Batch code	Natural rubber latex has not been used as a component in the manufacture of this product
Keep away from sunlight	QTY Quantity
Temperature limit	Translation
Consult instructions for use	MD Medical device
Single Sterile Barrier system	UDI Unique Device Identifier
Single Sterile Barrier system with protective packaging outside	

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