PAJUNK®

Quincke Lumbar Puncture

Neurology

Instructions for Use

English

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.

Device description/ compatibility

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

Cannula with Quincke tip, incl. stylet.

Hub shapes: standard, standard with magnifying glass
Stylet
Optional: Introducer
Hub connectivity: LUER or NRFit®

Intended use

Puncture, access to the spinal space, aspiration, injection, obtaining of CSF.

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

Warning:
The cannula is not suitable for MRI use!

This cannula is not suitable for inserting a catheter!

Indications

1. Lumbar puncture for:
   – Obtaining a sample of CSF to aid the diagnosis of suspected CNS infection, suspected subarachnoid haemorrhage, neurological diseases
   – Measurement of cerebrospinal fluid (CSF) pressure
   – Therapeutic reduction of CSF pressure

2. Lumbar puncture to Inject dye (myelography) or radioactive substances (cisternography) into cerebrospinal fluid for diagnostic imaging of the following conditions:
   – Abnormalities of the spinal cord, the spinal canal, the spinal nerve roots and the blood vessels that supply the spinal cord
   – Spinal lesions caused by disease or trauma
   – Tumours near the spinal cord
   – Infection, inflammation of the arachnoid membrane that covers the spinal cord
   – CSF leakage

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

Local infections of skin over proposed puncture site (absolute contraindication); systemic infection (bacteraemia); raised intracranial pressure (ICP); exception is pseudotumour cerebri; suspected spinal cord mass or intracranial mass lesion (based on lateralizing neurological findings or papilloedema); poorly controlled bleeding diathesis or anticoagulation; uncontrolled diabetes mellitus; spinal column deformities (may require fluoroscopic assistance); allergy to local anesthetic (consider alternate class of anesthetic to which the patient is not allergic); lack of patient cooperation.

Additional contraindications for myelography or cysternography:

Allergy to contrast media; history of seizures; pregnancy.

Complications

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.

Complications of lumbar puncture and CSF removal

Post-dural puncture headache (PDPH); other symptoms that may associated with PDPH include nausea, vomiting, hearing loss, tinnitus, vertigo, dizziness, cranial nerve palsies and paraesthesia of the scalp, as well as upper and lower limb pain; cranial neuropathies; nerve root irritation; cerebral herniation; low back pain; implantation of epidermal tumours.
Infections: Infections in the vicinity of the puncture area, meningitis.
Bleeding complications: Intracranial bleeding, traumatic lumbar puncture, spinal hematomas.
Other complications: Vasovagal syncope, cardiac arrest, seizures; subarachnoid cyst; low pressure state in children with ventriculoperitoneal (V-P) shunt; pseudotumor cerebri (incorrect measurement of opening pressure); incorrect lab analysis of cerebrospinal fluid.

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. Optional: Use an introducer to insert the cannula and/ or perform a puncture incision beforehand on the area where the puncture is to be performed (blood 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. 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.
6. 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 (with introduced stylet) (optional: 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.

⚠ *when using 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 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.

Sequence of use

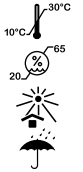
1. Perform skin disinfection and cover area to be punctured with a sterile fenestrated surgical drape (aperture drape).
2. Administer a local anesthetic.

3. If necessary, perform a perforating incision of the area to be punctured (lancet or similar).
4. Puncture using a cannula/ puncture using a sharp guidance cannula (introducer (optional)).
5. Introduce the spinal cannula (optional: through the introducer) and push it up to the subarachnoidal space.

   Guidance of the cannula using both hands: hold at the middle of the shaft and at the color-coded stylet holder.

   Complicated anatomical conditions and circumstances or the performance of therapeutical measures in the vessels may lead to a prolongation of the duration of the examination.
6. After positive identification of the subarachnoidal space by the respective return flow of cerebrospinal fluid, conduct further procedure in accordance with the individual indication.

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

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. 7.5 of Annex I 93/42/EWG)

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

 Quantity

 Hub Connection: NRFit® acc. ISO 80369-6

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

CE 0124

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