

PAJUNK®

SPROTTE® Lumbar Puncture

Neurology



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

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

Cannula (also: tapered cannula) with SPROTTE® tip (ogive-shaped tip geometry; lateral eye with rounded edge), incl. stylet.

Hub shapes: SPROTTE® standard, SPROTTE® standard with magnifying glass, SPROTTE® standard 2.G

Stylet

Optional: Wings

Optional: Introducer

Hub connectivity: LUER or NRFit®

Intended use

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

 PAJUNK® cannulas can also 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 in the diagnosis of suspected CNS infection, suspected subarachnoid haemorrhage, neurological diseases
 - Measurement of cerebrospinal fluid (CSF) pressure
 - Therapeutic reduction of cerebrospinal fluid pressure
2. Lumbar puncture for injecting a colourant (myelography) or radioactive substances (cisternography) into the cerebrospinal fluid for diagnostic imaging for the following diseases:
 - Abnormalities of spinal cord, spinal duct, spinal nerve roots and blood vessels supplying the spinal cord
 - Lesions in the spinal area caused by disease or trauma
 - Tumours in the vicinity of the spinal cord
 - Infections, inflammation of the arachnoid surrounding the spinal cord
 - Leakage of cerebrospinal fluid
3. Lumbar puncture for:
 - Obtaining a sample of CSF to aid the diagnosis of suspected CNS malignancy
 - Administration of chemotherapy into CSF in previously diagnosed lymphoma and leukemia with CNS involvement or high risk for CNS involvement

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 the skin in the area of the intended puncture site (absolute contraindication); systemic infection (bacteraemia); increased intracranial pressure (ICP), exception: pseudotumor cerebri; suspected spinal cord tumour or lesion due to intracranial mass (based on lateralising neurological findings or papilledema); insufficiently controlled bleeding diathesis or anticoagulation, unregulated diabetes mellitus; spine deformations (support by fluoroscopy may be required); allergy to local anaesthetic (consider alternative class of anaesthetics the patient is not allergic to), lack of patient cooperation

Additional contraindications in myelography or cisternography

Allergy to contrast media; history of seizures; pregnancy.

ComplicationDevice-specific complications

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

Procedure-specific complications

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

Complications of lumbar puncture and CSF removal

Post-lumbar-puncture headache (PLPH); other symptoms possibly connected to PLPH include: sickness, vomiting, hearing loss, tinnitus, vertigo, numbness, cranial nerve palsy and sensory disorders of the scalp and pain in the upper and lower extremities; cranial neuropathies; nerve root irritation; brain herniation; pain in the lower back; propagation of epidermal tumours.

Infections: Infections in the vicinity of the puncture site, meningitis.

Bleeding complications: Intracranial bleeding, traumatic lumbar puncture, spinal haematomas.

Other complications: Vasovagal syncope, cardiac arrest, seizures; subarachnoid cysts; low pressure condition in children with ventriculoperitoneal (VP) shunt; pseudotumor cerebri (incorrect measurement of opening pressure); incorrect lab analysis of cerebrospinal fluid.

Complications of chemotherapy

Toxicity of chemotherapeutic agent, ineffective therapy, deterioration of the previous state of health.

-  *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 re-sterilised under any circumstances!*

The materials used in the manufacture of this device are not suitable for reprocessing or re-sterilisation.

This device is not designed to be reprocessed or re-sterilised.

 **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. Use an introducer to insert the SPROTTE® cannula and/or make a stab incision beforehand at the intended puncture site (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 tip. On no account you should continue to use a cannula damaged in this manner. In case of previous bone contact, remove the cannula (with introduced stylet) 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.**

 *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:*

-  **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).
- 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.
- 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

- Perform skin disinfection and cover area to be punctured with a sterile fenestrated surgical drape (aperture drape).
- Administer a local anaesthetic.
- If necessary, make a stab incision at the intended puncture site (lancet, etc.).
- Puncture using a cannula/puncture using a sharp guidance cannula (introducer).
- Introduce the spinal cannula through the introducer and push it up to the subarachnoid 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.*

- After positive identification of the subarachnoidal space by the respective return flow of cerebrospinal fluid, conduct further procedure in accordance with the individual indication.

Operating 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		Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)
	Catalogue number		MR unsafe
	Sterilized using ethylene oxide		Advice
	Do not re-sterilize		Information
	Do not use if package is damaged		Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body
	Keep dry		Sharp object warning
	Humidity limitation		Does not contain phthalates (acc. to section 7.5 of Appendix I 93/42/EEC)
	Do not re-use		Natural rubber latex has not been used as a component in the manufacture of this product
	Caution		Quantity
	Date of manufacture		Hub connectivity: NRFit® acc. to ISO 80369-6
	Batch code		Translation
	Keep away from sunlight		Medical device
	Temperature limit		
	Consult instructions for use		

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