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.

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.

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

Device description/compatibility

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
Optional: Cornerstone-Reflektors
Hub connectivity: NRFit™

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	Non-pyrogenic
Use-by date	Caution: Federal law restricts this device to sale by or on the order of a physician
REF Catalogue number	MR unsafe
STERILE EO Sterilized using ethylene oxide	Advice
Do not resterilize	Information
Do not use if package is damaged	„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.
Keep dry	
Humidity limitation	
Do not re-use	Sharp object warning
Caution	Does not contain Phthalates
Date of manufacture	Natural rubber latex has not been used as a component in the manufacture of this product
LOT Batch code	QTY Quantity
Keep away from sunlight	NRFit™ Hub connection: NRFit™ according to ISO 80369-6
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	

Caution!
Only products with NRFit™ ISO 80369-6 connector are compatible with each other.

Caution!
Do not try to connect such NRFit™ ISO 80369-6 connectors with other connectors.

Intended use

Puncture to get access to the spinal space for aspiration and 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!

Target patient population

Target population are adults and children. The treating medical specialist staff is responsible for the selection of appropriate patients.

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 contrast media, dye or radioactive substances for myelography or 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 cisternography:

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.