PAJUNK®

Spinal Manometer

Neurology

Instructions for use

These instructions for use were translated into the following languages: DE, EN, FR, IT, ES, PT, NL, DA, SV, EL, BG, ET, HR, LV, LT, PL, RO, SK, SL, CS, HU. The translations can be downloaded from our website: eifu.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 instructions 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 instructions for use invalidates the warranty and puts patient safety at risk.
If used in combination with other devices, it is essential that the compatibility information and user instructions for these other devices 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.*

Hub connectivity: LUER

Caution!
Only devices with 80369-7 connector are compatible with each other.

Caution!
Do not try to connect 80369-7 connectors with other connectors.

Intended use
Measurement of cerebrospinal fluid pressure. A spinal manometer can only be used together with a spinal cannula.

Target user group
Medical staff only; neurologists.

Target patient population
Adults and children.

Indications
Measurement of cerebrospinal fluid pressure.

Contraindications
There are no device-specific contraindications.
Contraindications specific to lumbar puncture must be taken into account.

Complications
CSF leaks can lead to herniation with brainstem compression, post-lumbar puncture headache (PDPH), cranial nerve deficits and other neurological deficits, migraine attacks and epileptic seizures.

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 device:

This is a disposable medical device for use on one patient only!

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 material to break down and lead to endotoxic reactions caused by the residues!

⚠ *in the application:*

1. Do NOT try to REINJECT cerebrospinal fluid!
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.

⚠ *for use with other compatible devices:*

1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages.

⚠ *Further warning indications:*

1. Please note that the continued use of a product of the same type must be assessed cumulatively as described in the medical device regulation, even after the product has been exchanged or replaced.

Sequence of use

1. Position the patient with flexed spine in the lateral decubitus position or sitting, held by another person.
2. Select the preferred cannula size and the spinal manometer. (For the USA only: Put the three-way stopcock on the spinal manometer).
3. Position the spinal cannula.
4. Remove the stylet. CSF flow confirms intrathecal placement. Connect the three-way stopcock of the spinal manometer to the cannula. Turn the three-way stopcock to vent the spinal cannula into the spinal manometer while closing the proximal port.
5. Allow the cerebrospinal fluid to flow into the spinal manometer. Once the fluid level in the spinal manometer has stabilised, read the pressure value in cmH_20 at the top of the fluid column. Normally, the CSF pressure of a patient in supine position is in the range of 10-25 cmH_20, but it can be much higher. Pressure measurement is less reliable if the patient is in a sitting position.
6. If the spinal manometer scale of maximum 34 cmH_2O is not sufficient for measuring the CSF pressure, an extension to 54 cmH_2O can be attached. Attach this extension to the riser tube of the manometer.
7. Close the three-way stopcock to the cannula and allow the fluid to drain from the spinal manometer into the sampling tubes for subsequent analyses.
8. When sampling is complete, remove the spinal cannula, introducer needle (if used) and spinal manometer, and apply a dressing to the puncture site.
9. Instruct the patient to lie flat for 1 to 2 hours before getting up. The lumbar puncture can cause dizziness, severe headaches and balance problems.

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 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


Use-by date

Item number

Sterilized using ethylene oxide

Do not resterilise


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


Single sterile barrier system


Consult instructions for use

Dispensing with prescription only (the device may only be used by qualified medical staff for the intended purpose.)


Non-pyrogenic


Advice


Information

"CE conformity marking" or "CE marking" = this marking shows that a device is in conformity with the applicable requirements as set out in the Medical Device Regulation or other European Union legislation on its affixing.

Does not contain phthalates

Does not contain natural rubber latex

Quantity


Translation

Medical device

Unique device identification


Single sterile barrier system with protective packaging outside

CE 0124

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