PAJUNK®

FixoCath

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: 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 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.

FixoCath is a disposable adhesive pad for catheter fixation.

Intended use
Catheter fixation

Indwelling time for the continuous system: 7 days (168h)

Target User Group

Medical specialist staff only

Target patient population

Adults and children

Indications
Continuous regional anaesthesia/analgesia

Contraindications
Infections at the exit site of the catheter.

⚠ *Under no circumstances is the device to be used in the event of known material incompatibilities and/ or known interactions.*

Complication
Inflammations

ⓘ *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!

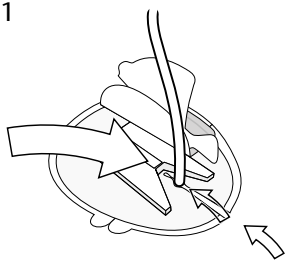
The materials used in the manufacture of this device are not suitable for reprocessing or resterilisation.
This device is not designed to be reprocessed or resterilised.

⚠ 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.

Sequence of use

Placement

1



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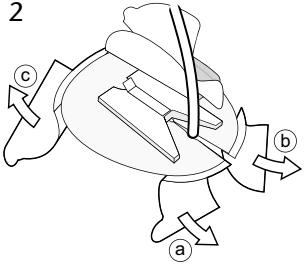

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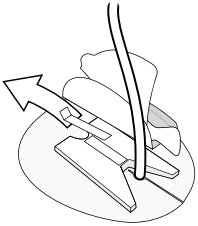

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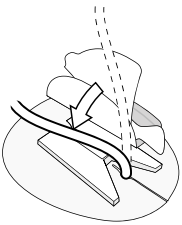

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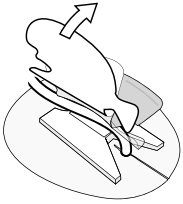

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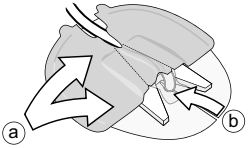
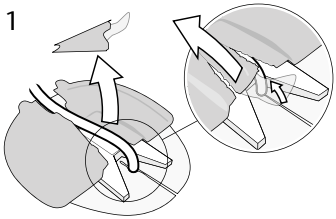


Removal



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.

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.

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling

- Manufacturer
- Use-by date
- REF — Catalogue number
- STERILE EO — 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
- LOT — Batch code
- Keep away from sunlight
- Temperature limit
- Consult instructions for use
- Rx only — Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)
- Advice
- Information
- CE 0124 — „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.
- PHT — Does not contain phthalates
- LATEX — Natural rubber latex has not been used as a component in the manufacture of this product
- QTY — Quantity
- Translation
- MD — Medical device
- UDI — Unique Device Identifier
- Single Sterile Barrier system
- Single Sterile Barrier system with protective packaging outside

CE 0124

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