PAJUNK®

E-Cath
E-Cath Plus
NRFit®

Regional Anesthesia

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.

Rx only *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 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.*

E-Cath system consisting of:
- Stimulation and injection cannula with cable (for connector with diameter 2 mm) and injection tube; bevel-S tip; NanoLine coating, echogenic Cornerstone reflectors
- Indwelling cannula matching the stimulation cannula (length, diameter)
- E-Cath: Catheter with injection tube, glued, central opening, length adapted to indwelling cannula, protruding length at distal end of the catheter (a few millimetres)
- E-Cath Plus: Catheter with injection tube and stylet, glued, distal end closed, with 3 lateral openings, 15 mm protruding with regard to the indwelling cannula

- FixClip
- FixoLong (optional)
- FixoCath (optional)
- Filter
- Locking cap

Compatibility tested and guaranteed with nerve stimulators of PAJUNK® MultiStim series.

Hub connectivity: NRFit®

⚠ *Caution!*
Only devices with NRFit® 80369-6 connector are compatible with each other.

⚠ *Caution!*
Do not try to connect NRFit® 80369-6 connectors with other connectors.

Intended use

Access and injections to peripheral nerves, sometimes using ultrasound and/or nerve stimulation techniques; catheter placement.

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

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

MR *Warning:*
Do not use catheters with an internal spiral or stimulation electrode or cannulas for MRI procedures! After placement, be sure to attach the supplied "Not suitable for MRI" label to the catheter or label it clearly and comprehensibly for third parties in accordance with the specifications of your institution.

⚠ *Ensure the correct function of the nerve stimulator used and make sure to use adequate amperages.*

❗ *Do not use any devices with electromagnetic radiation near the patient to avoid any electromagnetic interactions.*

❗ *Make sure (particularly before injection) that the injection tube is firmly in place.*

Target user group

Medical specialist staff only

Target patient population

Adults and children. Professional medical staff are responsible for patient selection.

Indications

Continuous peripheral anaesthesia/analgesia.

Contraindications

Contraindications of peripheral anaesthesia

Clinically manifest coagulation disorders, diseases of central or peripheral nerves, chronic respiratory disease for blocks of the upper limb, infection of the puncture site, lesions at the puncture site, allergy to local anaesthetic, patient refusal.

Device-specific contraindications

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

No other device-specific contraindications are known.

Complications

Device-specific complications

Catheter obstruction, catheter dislocation, leakage, separation from pump system, catheter breakage, catheter shearing, skin irritation or allergic reaction to catheter dressing, cannula breakage.

Procedure-specific complications

Complications specific to continuous peripheral nerve blocks occur rarely. They include, among others, inaccurate placement of the catheter tip too far away from the target nerve so that analgesia fails, or placement at undesired position (e.g. intravascular, intrathecal), failed block, repeated puncture, realignment of the cannula.

Clinical complications

Infections, neurologic complications, local anaesthetic toxicity.

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 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. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
3. In case of unexpected bone contact, slightly withdraw the cannula and change its direction.
4. Repeated bone contact will damage the cannula tip. Under no circumstances should you continue to use a cannula damaged in this manner. In case of previous bone contact, remove the cannula in one step.

⚠ *for catheter placement and removal:*

1. E-Cath Plus: The indwelling cannula must be introduced minimum 1-2 cm into the patient's tissue. Only then can the inner catheter of the E-Cath Plus system be introduced up to the completely available catheter length of 15 mm protruding over the tip of the indwelling cannula.
2. Immediately before use, check that the catheter will pass through the cannula.
3. Do not tear or pull rapidly when removing the catheter.
4. When the catheter is at its final position, clean and dry the exit point of the catheter. Always ensure that the access intended for injections is aseptic.
5. Be sure to check the connection between the catheter and the infusion devices regularly.
6. If you detect resistance while removing the catheter, do not withdraw it any further. If necessary, reposition the patient. Then try to withdraw the catheter again. If this is still difficult, investigate with fluoroscopy or an X-ray before taking any further action.
7. Always replace the FixoLong when you exchange the filter!

⚠ *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. Be sure to constantly check the connection between the cannula and the infusion device.

⚠ *for use with other compatible products:*

1. Prior to disinfection, screw the locking cap tightly onto the filter to prevent any disinfectant solution from entering the interior of the filter.
2. When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).
3. Disinfectants based on or containing alcohol can damage the filter.
4. The locking cap must be screwed on before you disinfect the filter.
5. Ensure the correct function of the nerve stimulator used and make sure to use adequate amperages. In any case, follow the instructions for use of the nerve stimulator used.

⚠ *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. The most relevant ones in practice 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 body 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. The cannula and the catheter lumen should be irrigated with a sterile injection solution (e.g. 5 % glucose if used for electrical nerve stimulation, otherwise 0.9 % NaCl) to fill the dead volume before being used under sterile conditions.
2. Disinfect the skin; cover the puncture area with a sterile fenestrated drape (surgery drape with central opening).
3. Infiltrate the puncture area with a local anaesthetic.
4. Optional: Make a stab incision (e.g.: lancet, etc.).
5. Introduce the cannula through the skin.
6. The cannula placement can be controlled by means of electrostimulation and/or ultrasound.

6.1. With electrostimulation:

a) Connect the cable to the nerve stimulation device using the connecting cable.

b) Stimulate with adequate current intensity (e.g. 1 mA) and observe response to the stimulation.

c) A clear stimulus response at low current intensity (e.g. 0.5 mA) shows that the cannula is close to the nerves to be localised.

d) Pay attention to the perforation click when penetrating the nerve sheath.

e) Inject the injection solution through the injection tube.

f) When the cannula has reached its correct position, further solution can be injected in sufficient quantity to control and expand the perineural space.

⚠ *No injection of local anaesthetic during stimulation because the anaesthetic inhibits further nerve stimulation with stimulation cannulas!*

g) Turn the indwelling cannula in situ by 90° to detach it from the hub. Then pull out the stimulation cannula carefully.

h) The enclosed catheter is introduced through the positioned indwelling cannula.

i) Check the catheter position by aspiration.

6.2. With ultrasound:

a) The system is provided with an echogenic cannula with automatic irrigation function when the solution is injected.

b) Thanks to the auto-irrigation function of the cannula, the sonographic image of the cannula is especially good when the injection solution is in the cannula.

c) Due to the improved visualisation of the cannula, its position can be controlled again and again by injecting injection solution.

d) When the cannula has reached its correct position, further solution can be injected in sufficient quantity to control and expand the perineural space.

e) The stimulation cannula is pulled out carefully without moving the indwelling cannula.

f) The enclosed catheter is introduced through the positioned indwelling cannula.

7. After the enclosed catheter has been firmly locked in the indwelling cannula, the unit can be moved as a whole under ultrasound control and fine adjustment can be made for final placement.

Fastening of the FixoLong (optional)

1. Fasten the FixoLong with the fixed catheter cross in the vicinity of the catheter exit.
2. Lock the catheter in the fastening clips. This guarantees maximum freedom of movement while simultaneously fixing the catheter.
3. Place the filter base on the catheter cross.
4. Secure the bacterial filter on the filter base.

Fastening of the FixoCath (optional)

1. Hold the catheter over the incised side of the FixoCath securing plaster at the position of the catheter exit.
2. Remove the three adhesive strips at the lower part of the fixation plaster and attach the plaster to the skin.
3. Now peel off the longitudinal adhesive strip attached to the foam pad and place the catheter on it.
4. Remove the protective film from the adhesive strips of the perforated cover plaster and fix it over the catheter.

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 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


Consult instructions for use


Single sterile barrier system


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


MR unsafe


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.


Sharp object warning


Does not contain phthalates


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


Quantity


Hub connectivity: NRFit® acc. to ISO 80369-6


Translation


Medical device


Unique device identification


Single sterile barrier system with protective packaging outside

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

CE 0124

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