PAJUNK®

Clamping Adapter
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!

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

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

The Clamping Adapter enables the use of a NRFit® connection.

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

Connection option for a catheter without a hub.

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

Target user group

Medical staff only; anaesthesiologist, anaesthetist.

Target patient population

Adults and children.

Indications

Continuous regional anaesthesia, analgesia.
Clamping Adapter is only used in combination with a catheter. The device itself has no independent indication.

Contraindications

Incompatible diameters between catheter and Clamping Adapter.

Complications

The catheter is not introduced completely into the Clamping Adapter, which may cause jamming of the catheter. This makes it impossible to administer an anaesthetic.

ⓘ *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!

⚠ *Further warning indications:*

1. If flow is impeded, check the locking mechanism of the Clamping Adapter.
2. When connecting the catheter to the Clamping Adapter, always make sure that the catheter is fully inserted into the Clamping Adapter as far as the stop (at least as far as the orientation mark). Never preflush before making the connection.
3. Avoid build-up of fluid film between the catheter and Clamping Adapter (e.g. through fluids on gloves). Fluids on the proximal end of the catheter can affect the holding force and result in disconnections and/or leakage.

Sequence of use

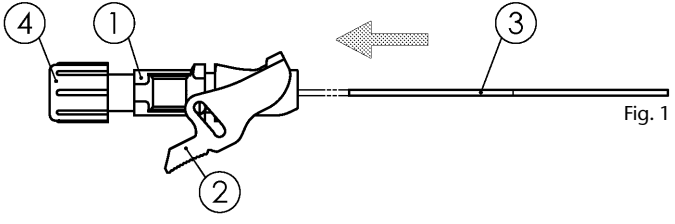

Fig. 1

Legend: (1) Clamping Adapter, (2) clamping lever, (3) catheter with marking, (4) locking cap

1. First check whether the clamping lever of the Clamping Adapter is in the open position (2). Introduce the proximal catheter end (3) into the Clamping Adapter opening provided for this purpose.

⚠ *Make sure that the catheter is properly introduced as far as it will go. To this end, the proximal marking (3) can be used as a guide.*

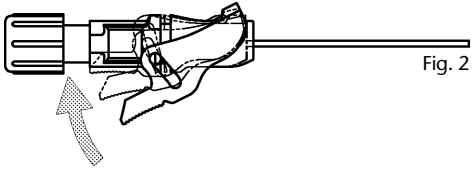

Fig. 2

2. Close the Clamping Adapter by pressing against the clamping lever. Secure closing is indicated by a distinctly audible and perceptible click.

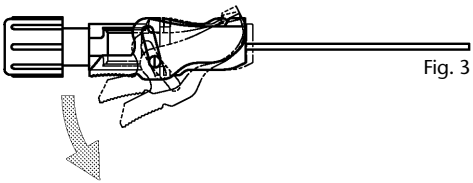

Fig. 3

If the catheter is not securely seated in the Clamping Adapter, release the Clamping Adapter using little force and repeat steps 1 and 2.

3. Remove the locking cap to connect the filter.

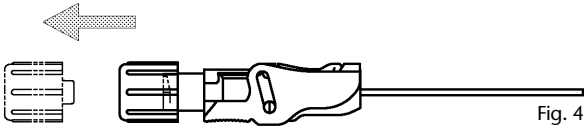

Fig. 4

4. Connect the filter (5) and start the injection.

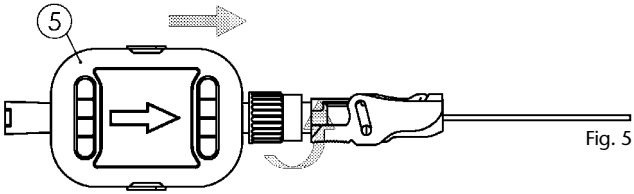

Fig. 5

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.

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

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


Single sterile barrier system with protective packaging outside


Consult instructions for use


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


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


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

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

CE 0124

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