PAJUNK®

FixoLong

Regional Anesthesia

Instructions for Use

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.

Device description / compatibility

FixoLong is a fixation device for catheter and filter; it is attached to the patient's skin. It consists of a filter base and a catheter cross with adhesive pad.

REF	Bacterial filter 	Bacterial filter 	Mini bacterial filter 
Filter disposable	001151-37Q	001151-62	001151-38K
FixoLong disposable	001151-47	001163-60	001151-43
FixoLong + filter	001151-48	001151-61	001151-44

REF	NRFit® Bacterial filter 	NRFit® Bacterial filter 
Filter disposable	001163-37X	001163-62
FixoLong disposable	001163-40	001163-60
FixoLong + filter	001163-41	001163-61

Intended use

Catheter and filter fixation

Target User Group

Medical specialist staff only

Target patient population

There are no limitations in patient population

Indications

Regional anaesthesia, analgesia

Contraindications

Infections and irritated skin in the desired fixation area of the catheter/filter.

⚠ *FixoLong may only be attached to clean, dry and non-greasy skin!*

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.

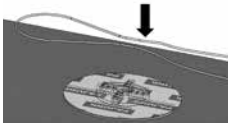
further warning indications:

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.

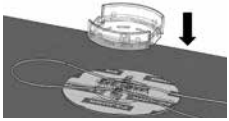
Sequence of use

Remove the adhesive film.

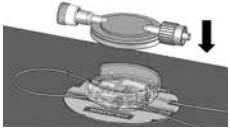
Apply the FixoLong to the desired skin area!



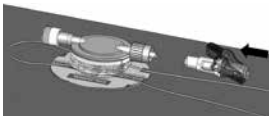
Carefully attach the catheter.



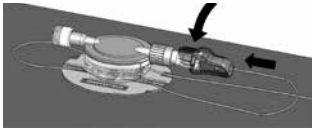
Place the filter base on the catheter cross.



Secure the filter onto the filter base.



Connect the ClampingAdapter to the filter!



Then connect the catheter to the ClampingAdapter.

Attach the enclosed label (individual for each application) to the proximal end of the catheter to avoid mix-ups.

Example: "Infiltration" LABEL

INFILTRATION	INFILTRATION

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 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


Catalogue number


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


Batch code


Keep away from sunlight


Temperature limit


Consult instructions for use


Single Sterile Barrier system


Non-pyrogenic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Advice


Information


„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.


Does not contain Phthalates


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


Quantity


Hub connection:
NRFit® according to ISO 80369-6


Translation


Medical device


Unique Device Identifier


Single Sterile Barrier system with protective packaging outside

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

CE 0124

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