PAJUNK®

Filter
NRFit®

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.

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 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

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

The bacterial filter consists of a through-membrane 0.2 µm in pore size on a hydrophilic support, which is housed in a liquid-tight, transparent housing.

Hub connectivity: NRFit®

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

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

Intended use
Filtration of drugs dissolved in water, in order to protect patients from microorganisms or microparticles during the injection.

Target User Group
Medical specialist staff only; anaesthesiologist, anaesthetist

Target patient population
Adults and children

Indications
Regional anaesthesia, analgesia.

Contraindications
⚠ *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.

⚠ *in the application:*

1. The filter can remain applied over a period of up to 7 days (168h).
2. In case of frequent administration of bolus doses from glass ampoules via the filter, the additional use of filter cannulas or filter straws is recommended.
3. A strictly aseptic procedure is required, in order to minimise the risk of inflammation.
4. For injection fluids, we recommend using a syringe (> 10ml) or a disposable elastomer pump, in order to avoid damage to the filter due to excessive pressure.
5. Do not hold the filter/clamping adapter on the patient side when removing it, to prevent the catheter from being disconnected accidentally from the catheter connection.
6. Make sure that the interface between the filter and the injection system remains clear of air, since air bubbles in the filter may result in air inclusion, preventing any further passage of fluid.
7. Prior to disinfection, screw the locking cap onto the filter, to prevent any disinfectant solution from entering the interior of the filter.
8. Do not allow the filter to come into contact with alcohol-containing solvent and disinfectant! Please make sure that no disinfectant solution enters the interior of the filter or the interior of connections!

Sequence of use

1. Evacuate air from the filter before use.
2. Adapt the filter to the connection of the clamping adapter or the cannula.
3. For continuous application, the filter can be secured by fastening it to the patient's skin or clothing with adhesive tape or with FixoLong.

Fastening of the FixoLong (optional)

1. Fasten the PAJUNK® adhesive bandage with the fixed catheter cross in the vicinity of the catheter exit.
2. Engage the catheter with 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.

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.*

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Key to symbols used in labelling

Manufacturer	Non-pyrogenic
Use-by date	Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)
Catalogue number	
Sterilized using ethylene oxide	Advice
Do not resterilize	Information
Do not use if package is damaged	„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.
Keep dry	
Single Sterile Barrier system with protective packaging outside	
Humidity limitation	Does not contain phthalates
Do not re-use	Does not contain natural rubber latex
Caution	Quantity
Date of manufacture	Hub connectivity: NRFit® acc. to ISO 80369-6
Batch code	Translation
Keep away from sunlight	Medical device
Temperature limit	Unique Device Identifier
Consult instructions for use	Single Sterile Barrier system

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