PAJUNK®

# InfiltraLong TUN

Infiltration Analgesia

# Instructions for Use

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

The InfiltraLong is a catheter with numerous openings. It guarantees a continuous flow of the active substance throughout the application. The length of the infiltration segment (length of perforated range) is between 25 mm and 300 mm (between 15 and 88 perforations). The total length of the catheter is 420 mm to 900 mm.

The InfiltraLong is primarily supplied by PAJUNK® in convenient sets. It consists of:

– Perforated infiltration catheter (optional: 2)
– Awl
– Bacterial filter
– ClampingAdapter (optional)
– FixoLong (optional)

– Y adapter/injection tube (optional)
– FuserPump (optional, see XS190193)

Compatible with all commercially available (non-active) analgesic pumps

Hub connectivity: LUER or NRFit®

**Intended use**

Dwell in the target area, continuous administration of anaesthetic/analgesic

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

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

*Warning:*
*Do not use catheters with an internal stylet, internal spiral or stimulating electrodes and cannulas for MRI techniques!*
*After fitting, it is essential that you either attach the „Not suitable for MRI" label supplied to the catheter or mark it clearly to this effect according to your institution's rules so that third parties are aware of this.*

**Indications**

Continuous analgesia

**Contraindications**

*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.

*Contraindications of continuous analgesia*

Infections at the puncture site, patient's lack of consent, significant coagulation disorders with cervical and/or thoracic application (also with oral anticoagulation), use in the immediate vicinity of natural cartilage tissue, simultaneous use of drainages in the infiltration area, many wounds where the catheter is positioned, inappropriate ratio of wound size and length of the infusion segment of the catheter, known hypersensitivity to catheter components or the solution to be infiltrated, known neurological abnormalities.

**Complication**

*Device-specific complications*

Allergic reactions, resistance during catheter removal, catheter tearing, catheter shearing, catheter bending, reduced/missing flow

*Complications of continuous analgesia*

Pain, toxicity of anaesthetics used, wound infection, coagulation disorders, haematomas

*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.

*for catheter placement and removal:*

1. Check that the catheter will pass through the cannula immediately before use.
2. The tip of the cannula can be damaged by bone contact during insertion. If a catheter is passed through a cannula that is damaged in this way, it can itself become damaged. If this happens, use a new cannula.
3. Once the catheter has left the tip of the cannula, do not retract the catheter as there is a risk of shearing.
4. If blood is visible in the catheter return window or in the piston chamber of the syringe, remove the catheter and reattempt puncture. The catheter was incorrectly positioned.
5. If the procedure is interrupted, remove the catheter and the cannula together if possible.

6. If flow is impeded, check the locking mechanism of the ClampingAdapter.
7. When using catheters with a closed tip and lateral openings, extend the catheter at least 15 mm (no more than 50 mm) beyond the tip of the cannula to ensure unimpeded injection.
8. Never insert the catheter more than 50 mm. It is more likely to become knotted if it is inserted more than 50 mm.
9. Ensure that the catheter is not kinked on fixing.
10. Be sure to check the connection between the catheter and the infusion devices regularly.
11. Do not tug the catheter or pull it sharply when removing it from the patient.
12. Do not exert excessive force when removing the catheter. Do not continue to pull the catheter if it starts to stretch too much.
13. After removing the catheter, check the distal tip to see whether it is complete. The tip should be intact. Only in this case you can be sure that the entire catheter has been removed.

⚠ *for injection:*

1. Always ensure that the injection site is aseptic.
2. Do not administer any drugs that are not indicated for the intended use.
3. Be sure to regularly check the connection between the cannula/catheter and the infusion device.

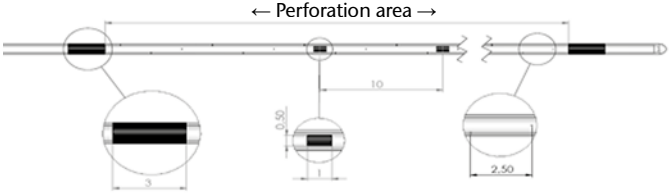
⚠ *for use with other compatible products:*

1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).
2. When connecting the catheter to the ClampingAdapter, always make sure that the catheter is fully inserted into the ClampingAdapter as far as the stop (at least as far as the orientation mark). Never preflush before making the connection.
3. Disinfectants based on or containing alcohol can damage the filter.
4. The locking cap must be screwed on before you disinfect the filter.

⚠ *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 bodily 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**



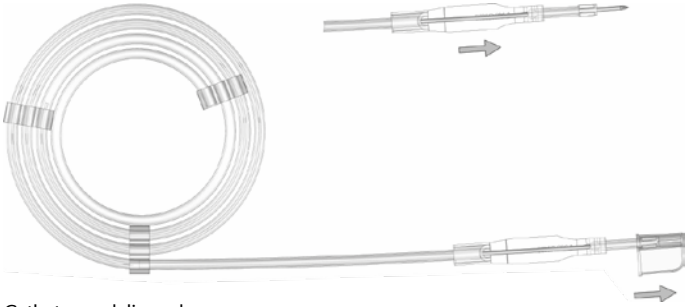

Proximal length graduation Length graduation Microperforation

Beginning and end of the microperforation are marked each by a 3 mm wide length graduation.

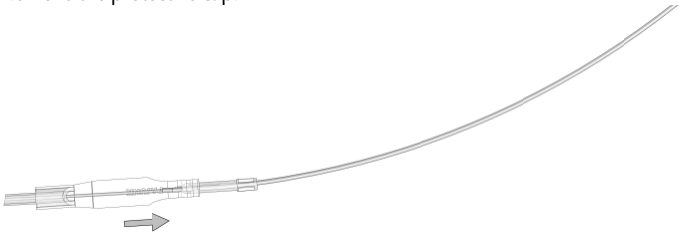
⚠ *Hold the catheter directly by the connecting point to the awl to avoid twisting the catheter when you unscrew it.*

*Step 1*

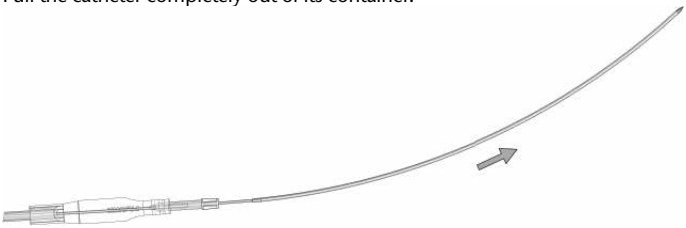
*Remove the catheter with the already fixed awl from its container.*



Catheter as delivered.
Remove the protective cap.

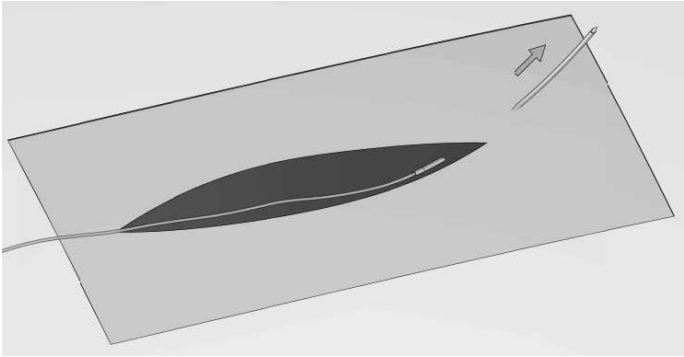


Pull the catheter completely out of its container.



*Step 2*

*Positioning the catheter*



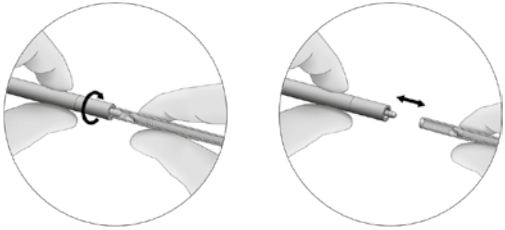
Puncture the skin at a certain distance from the wound from the inside out.

Position the catheter so that the microperforation section is located in the wound.

*Step 3*

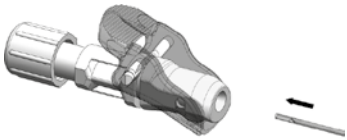
*Separating the InfiltraLong catheter from the awl*

Separate the awl from the catheter by turning in anti-clockwise direction. The proximal section must remain intact. Hold the catheter directly by the connecting point to the awl to avoid twisting the catheter when you unscrew it.



*Step 4*

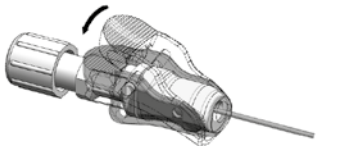
*Connecting the ClampingAdapter*



Introduce the catheter as far as it will go and then close the ClampingAdapter.

*Step 5*

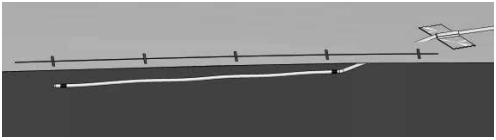
*Pre-filling the catheter*



Connect the syringe to the catheter. Pre-fill the catheter lumen evenly by carefully pressing.
The entire catheter length is filled when drops come out of all microperforations.

*Step 6*

*Closing the wound*



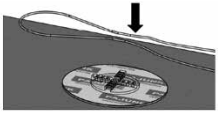
⚠ *When closing the wound, make sure not to sew on or damage the catheter.*

*Step 7*

*Using FixoLong*

Remove the adhesive film.

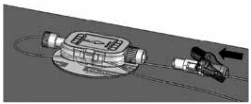
Fasten the FixoLong at the desired position to the skin!



Carefully fix the catheter.

Place the filter base on the catheter cross.

Secure the filter onto the filter base.



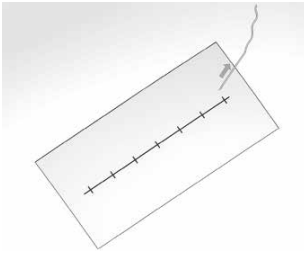
Connect the ClampingAdapter to the filter!

Attach the enclosed "infiltration label" to the proximal end of the catheter to avoid mix-ups.

| INFILTRATION | INFILTRATION |
|---|---|

*Step 8*

*Removing the catheter*



Remove the adhesive film; hold the catheter carefully right next to the exit point and cautiously pull it out. If you notice resistance, immediately stop the process. Take suitable measures (light massage, administration of physiological saline solution, repositioning of the patient, or similar) to make the tissue more flexible.
Make sure that the catheter has been completely removed by looking at the distal marking (width: 3 mm).

**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.*

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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.) |
| REF Catalogue number | |
| STERILE EO Sterilized using ethylene oxide | MR unsafe |
| Do not resterilize | Advice |
| Do not use if package is damaged | Information |
| Keep dry | „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. |
| Humidity limitation | |
| Do not re-use | Sharp object warning |
| Caution | Does not contain phthalates |
| Date of manufacture | Natural rubber latex has not been used as a component in the manufacture of this product |
| LOT Batch code | QTY Quantity |
| Keep away from sunlight | Hub connectivity: NRFit® acc. to ISO 80369-6 |
| Temperature limit | Translation |
| Consult instructions for use | MD Medical device |

NRFit®
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CE 0124

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