PAJUNK®

InfiltraLong

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.

Product specification / 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. Length of the infiltration segment: length of perforated range between 25 mm and 300 mm, between 10 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 with hub (optional: 2)
– Puncture cannula (split cannula, Tuohy cannula) or tunneling device/awl or tunneling instrument
– Filter
– Adapter (optional)
– FixoLong (optional)

– Y adapter/injection tube (optional)
– FuserPump (optional, see XS190193)
Compatible with all commercially available (non-active) analgesic pumps

Hub connectivity: LUER

⚠ *The InfiltraLong catheter may be used for a maximum of 120 hours. Please note that the risk of infection increases depending on the dwell time.*

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

MR *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.

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

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, 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. Contraindications according to the current state of teaching and training apply in addition to those mentioned in these instructions for use.

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/analgesics 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 adapter.
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 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. 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. For practical purposes, the most important of these 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.

4. Avoid build-up of fluid film between the catheter and ClampingAdapter (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

Preparing the catheter

1. Connect the catheter to the syringe filled with anaesthetic/analgesic or saline solution.
2. Fill the catheter by means of the filled syringe connected to it. Regular drops must be produced along the multi-perforated catheter part.

Catheter placement (with Tuohy cannula)

1. To facilitate penetration, puncture the skin before positioning the system.
2. Puncture the skin at a short distance (30-50 mm) from the operated part/wound using a Tuohy cannula.
3. Advance the catheter completely through the Tuohy cannula until reaching the wound edge. The stainless steel coil inside the catheter ensures stability, bending resistance and long-term functionality.
4. Retract the cannula through the catheter.
5. Make sure that the proximal end of the catheter is clean and dry. Connect the catheter to the adapter. Introduce the catheter into the adapter as far as it will go and fix it. This guarantees tightness and, at the same time, a tight seat of the catheter.
6. Screw the filter onto the adapter and connect it (via pump tube) to the analgesic pump and/or container.
7. Close the wound.

Catheter placement (with split cannula)

1. To facilitate penetration, puncture the skin before positioning the system.
2. Puncture the skin at a short distance (30-50 mm) from the operated part/wound using a split cannula.
3. Remove the metal cannula from the split cannula.
4. Advance the catheter completely through the split cannula until reaching the wound edge. The stainless steel coil inside the catheter ensures stability, bending resistance and long-term functionality.
5. Pull the split cannula apart to split it and then remove it.
6. Screw the filter onto the connector and connect it (via pump tube) to the analgesic pump and/or container.
7. Close the wound.

Catheter placement (without cannula, with tunneling device/awl - see XS190184)

1. Position the catheter in the wound. The stainless steel coil inside the catheter ensures stability, bending resistance and long-term functionality.
2. Move the catheter subcutaneously to the desired exit point using the premounted tunneling device.
3. Release the catheter from the tunneling device by turning it counterclockwise. Please make sure that the proximal opening remains undamaged.
4. Make sure that the proximal end of the catheter is clean and dry. Connect the catheter to the adapter. Introduce the catheter into the adapter as far as it will go and fix it. This guarantees tightness and, at the same time, a tight seat of the catheter.
5. Screw the filter onto the adapter and connect it (via pump tube) to the analgesic pump and/or container.
6. Close the wound.

Catheter placement with tunneling instrument

– Patient's position: lateral position
– Access:
  - Opening of the thorax through an intercostal space, passage through the tissue along the lower edge of the ribcage
  - Passage of intercostal muscle tissue and pleura (parietal and visceral)

⚠ *The lung collapses due to the air that enters the thorax*

– Placing the infiltration catheter:
  - The infiltration catheter is positioned at the transition from the costal arch to the spine between the parietal pleura and muscle tissue
  - The catheter is thus located in the area where the spinal nerves emerge from the spinal canal/in the area of the spinal ganglia
  - The lateral openings of the catheter should extend over 5 intercostal spaces.
  - The catheter is advanced from the thorax (not percutaneously!) from caudal to cranial. This requires blunt tunneling.
  - The tunneling instrument is advanced by means of the handle.
  - Remove the tunneling instrument from the split cannula.
  - Advance the catheter until the end of the split cannula is reached.
  - Pull the split cannula apart to split it and then remove it.
  - Screw the filter onto the connector and connect it (via pump tube) to the analgesic pump and/or container.
  - Close the wound.

Fixing the catheter

If you want to fix the InfiltraLong catheter with a suture, make sure not to block the catheter!

1. Place the catheter in large loops and fix it with a dressing.
2. Place an occlusive dressing over the puncture site. Be sure not to include the filter and the adapter in the dressing.

Fastening of the FixoLong (optional)

3. Fasten the PAJUNK® adhesive bandage with the fixed catheter cross in the vicinity of the catheter exit.
4. Engage the catheter with the fastening clips. This guarantees maximum freedom of movement while simultaneously fixing the catheter.
5. Place the filter base on the catheter cross.
6. Secure the flat filter on the filter base.

Removing the catheter

1. Gently peel off the dressing and remove it.
2. Hold the catheter close to the skin and carefully pull it out. It must be easy and painless to remove the catheter. Do not remove it by quickly and/or abruptly pulling or dragging. 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.

Use 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
- Use-by date
- REF Catalogue number
- STERILE EO 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
- LOT Batch code
- Keep away from sunlight
- Temperature limit
- Consult instructions for use
- Rx only Caution: Federal law restricts this device to sale by or on the order of a physician
- MR unsafe
- Advice
- Information
- CE 0124 "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.
- Sharp object warning
- PHT Does not contain Phthalates
- LATEX Natural rubber latex has not been used as a component in the manufacture of this product
- QTY Quantity
- Translation
- MD Medical device

CE 0124

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