PAJUNK®

StimuLong Plus
StimuLong NanoLine
StimuLong Sono
StimuLong Sono II

Plexus Anesthesia

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.*

StimuLong Plus/ StimuLong NanoLine/ SimuLong Sono are provided by PAJUNK® in convenient kits consisting of:

- Cannula: PlexoLong NanoLine with echogenic Cornerstone stamps
- Stimulong Catheter (with/ without stylet, with/ without helical coil) in catheter container
- Stimulong Clamping Adapter
- Sealing cap
- Filter bacterial filter 0,2 µm
- FixoLong filter/catheter fixation
- FixoCath catheter fixation
- Adapter cable/intermediate cable

Hub connectivity: LUER

The exact composition may be gathered from the label.

Intended use

Puncture and positioning of cannula and/ catheter at the peripheral nerves (where appropriate with the help of ultrasound and/ or nerve stimulation techniques) and injection of anaesthetic.

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

Make sure (particularly before injection) that the injection tube is firmly in place.

PAJUNK® cannulas or catheters 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 peripheral regional anesthesia, 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 peripheral anaesthesia

Clinically manifest coagulation disorders, diseases of central or periphere nerves, chronic respiratory disease for blocks oft he upper limb, infection of the puncture site, injury at the puncture site, allergy to local anaesthetic, lack of patient consent

Complication

Device-specific complications

Cannula breakage, tissue/ bone resistance and the related need to reposition the cannula, significant vascular injuries during the puncture, neuronal damage during the puncture
Allergic reactions, resistance when removing the catheter, catheter migration, catheter shearing, catheter kinking, reduced/ absence of flow

Complications of peripheral anaesthesia

Vascular injury, nerve damages, paresthesia, pain, failed block, motor deficits, spread of local anaesthetic into the epidural area, infection

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 puncture:

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. For cannulas with stylets: Only perform the puncture (even when removing the cannula) with the stylet in place.
3. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
4. If you unexpectedly come into contact with bone, change the direction of the cannula. Do not try to overcome bone resistance. Failure to adhere to these rules could cause the cannula to bend or break.
5. Repeated bone contact will damage the tip. On no account you should continue to use a cannula damaged in this manner. In case of previous bone contact remove the cannula (with introduced stylet) and introducer in one step.

⚠ *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 the procedure is interrupted, remove the catheter and the cannula together if possible.
5. If flow is impeded, check the locking mechanism of the adapter.
6. 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 needle to ensure unimpeded injection!
7. Never insert the catheter more than 50 mm. It is more likely to become knotted if it is inserted more than 50 mm.
8. Ensure that the catheter is not kinked on fixing.
9. Be sure to check the connection between the catheter and the infusion devices regularly.
10. Do not tug the catheter or pull it sharply when removing it from the patient.
11. Do not use excessive force when removing the catheter. Do not continue to pull the catheter if it starts to stretch too much.
12. If you detect resistance while removing the catheter, do not withdraw it any further. 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.
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 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 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. Disinfectants based on or containing alcohol can damage the filter.
4. Ensure the correct function of the nerve stimulator used and make sure to use adequate amperages.
5. In any case, follow the Instructions for use of the nerve stimulator used.
6. For stimulating cannulas and catheters: Do not use any devices with electromagnetic radiation near the patient. This avoids any electromagnetic interactions.
7. 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

Placement of the cannula (single shot)

1. Perform skin disinfection and cover puncture area with a sterile fenestrated surgical drape (aperture drape), local anesthesia.
2. Perforating incision (optional: lancet, etc.)
3. Advancement of the cannula under the skin.
4. Determination of the position of the cannula.
5. Anaesthetic may be administered as soon as the exact localization and the fixation of the cannula has been completed.

Catheter placement (continuous anesthesia)

1. Place the catheter container on the cannula hub.

   ❗ *Make sure when you perform the puncture that the opening of the cannula is pointing in the direction in which the catheter will later be inserted.*

2. Push the catheter with the marked end into the target area until it has reached the required depth.

3. Stimulation catheter: Connect to stimulator, safe and sure identifi cation of the desired position.
4. Once it is in place, remove the cannula via the catheter. Hold the catheter tight with your other hand if necessary.
5. Once the cannula has been removed, use the clamping adapter to connect the catheter.
6. Fill the filter with the anaesthetic to be used for anesthesia in order to compensate for the dead space volume.
7. Connect the catheter adapter to the filter hub.
8. Fill a syringe of suitable size with the selected anaesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for injection.
9. Connect the catheter with the appropriate fixing aids (either FixoLong or FixoCath) close to the outlet site.

Fastening of the FixoLong (optional)

1. Fasten the PAJUNK® adhesive bandage with the fixated catheter cross in the vicinity of the catheter exit.
2. Lock the catheter in the fastening clips. This guarantees maximum freedom of movement while simultaneously fixating the catheter.
3. Place the filter adapter on the catheter cross.
4. Secure the flat filter on the filter adapter.

Fastening of the FixoCath (optional)

1. Hold the catheter over the incised side of the FixoCath securing plaster at the position of the catheter outlet.
2. Remove the three adhesive strips at the lower part of the securing plaster and fasten the plaster to the skin.
3. Now remove the longitudinal adhesive strips on the foam padding and place the catheter over it,
4. Remove the adhesive film of the perforated cover plaster and secure this over the catheter.

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.

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

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

MR unsafe


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.


Sharp object warning

Does not contain phthalates

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

Quantity


Translation

Medical device

CE 0124

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