PAJUNK®

SonoLong Curl Echo

Regional Anesthesia

Instructions for use

These instructions for use were translated into the following languages: DE, EN, FR, IT, ES, PT, NL, DA, SV, EL, BG, ET, HR, LV, LT, PL, RO, SK, SL, CS, HU. The translations can be downloaded from our website: eifu.pajunk.com.

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 instructions for use invalidates the warranty and puts patient safety at risk.
If used in combination with other devices, it is essential that the compatibility information and user instructions for these other devices 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.*

SonoLong Curl Echo is a catheter whose tip automatically curls up after leaving the cannula.

SonoLong Curl Echo is primarily supplied by PAJUNK® in convenient sets. They consist of:

- Cannula: SonoLong NanoLine with echogenic Cornerstone embossments
- SonoLong Curl Echo catheter (with internal spiral; tip geometry: lateral openings) in catheter container
- Clamping Adapter
- Bacterial filter: 0.2 µm
- Filter/FixoLong catheter fixation

Hub connectivity: LUER

The exact list can be found on the label.

Intended use

Puncture and positioning of cannula and catheter on peripheral nerves (sometimes using ultrasound and/or nerve stimulation techniques). The catheter is intended to remain in the target area and constantly deliver a local anaesthetic from an external source.

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 spiral or stimulation electrode or cannulas for MRI procedures! After placement, be sure to attach the supplied "Not suitable for MRI" label to the catheter or label it clearly and comprehensibly for third parties in accordance with the specifications of your institution.

Target user group

Medical specialist staff only

Target patient population

Adults and children. Professional medical staff are responsible for patient selection.

Indications

Continuous peripheral regional anaesthesia/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 peripheral nerves, chronic respiratory disease for blocks of the upper limb, infection of the puncture site, lesions at the puncture site, allergy to local anaesthetic, patient refusal

Complications

Device-specific complications

Cannula breakage, tissue/bone resistance and the resulting necessity of cannula realignment, significant vascular injuries during puncture, neuronal damage during puncture.
Allergic reactions, resistance during catheter removal, catheter migration, catheter tearing, catheter shearing, catheter bending, reduced/missing flow.

Complications of peripheral anaesthesia

Vascular damage, neurological damage, paraesthesias, pain, failed block, motor deficits, epidural spread of local anaesthetic, 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 device:

This is a disposable medical device for use on one patient only!

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. Immediately before use, check that the catheter will pass through the cannula.
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 Clamping 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 can you 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.

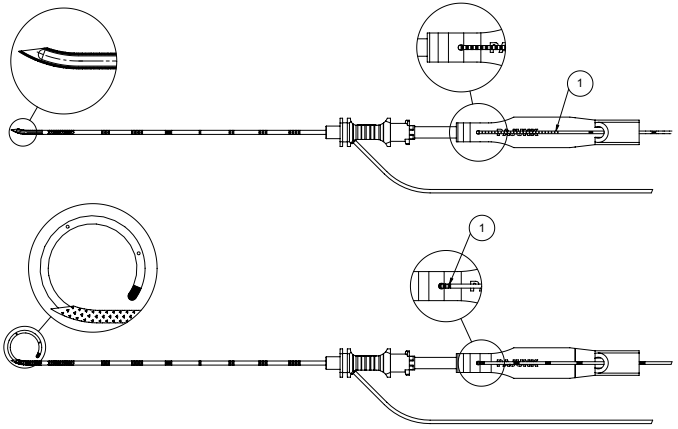
⚠ *for use with other compatible products:*

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 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. The locking cap must be screwed on before you disinfect the filter.

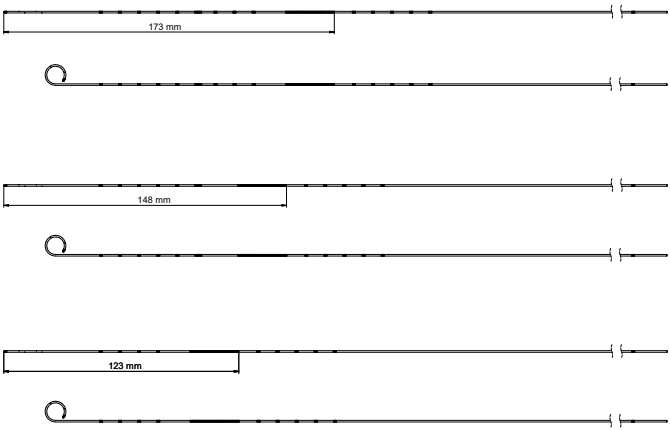
further warning indications:

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 body 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 Clamping Adapter (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.

Curl catheter markings



In the position shown, the marking indicates that the curl area of the catheter has completely exited from the cannula tip.



Coding of different curl catheter variants when being used with Tuohy cannula.

Sequence of use

Cannula placement (single shot)

1. Disinfect the skin and cover the puncture area with a sterile fenestrated drape (optional: perform local anaesthesia).
2. Make a stab incision (optional: lancet, etc.).
3. Advance the cannula through the skin.
4. Localise the cannula
5. As soon as the cannula has been precisely localised and fixed, anaesthetic can be administered.

Catheter placement (continuous anaesthesia)

1. Ensure aseptic conditions.
2. Prepare the catheter system and vent all components.
3. Fix the insertion aid of the catheter container on the cannula hub.

Make sure that during the puncture the cannula opening is always in the direction in which the catheter is to be placed later on.

4. Push the catheter with the marked end into the target area until it has reached the required depth.
5. Once it is in place, remove the cannula via the catheter. Hold the catheter tightly with the other hand if necessary.
6. After removing the cannula, connect the catheter to the Clamping Adapter.
7. Fill the filter with the anaesthetic to be used to compensate for the dead volume.
8. Connect the catheter adapter to the filter hub.
9. Fill a syringe with the selected anaesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
10. Secure the catheter in the vicinity of the exit site using suitable fixation aids (optional: FixoLong and/or FixoCath).

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 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

Item number

Sterilized using ethylene oxide

Do not resterilise


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

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

MR unsafe


Advice


Information

"CE conformity marking" or "CE marking" = this marking shows that a device is in conformity with the applicable requirements as set out in the Medical Device Regulation or other European Union legislation on 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

Unique device identification


Single sterile barrier system with protective packaging outside

PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Strasse 1
78187 Geisingen/ Germany
Phone +49 (0) 7704 9291-0
Fax +49 (0) 7704 9291-600
www.pajunk.com

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