PAJUNK®

Sono TAP continuous

Regional Anaesthesia

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.

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.

Sterile disposable devices: Only intact devices in intact 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.

Cannula with (adapted) injection tube; Tuohy tip; echogenic Cornerstone stamps

Injection tube and hub connectivity: LUER

The cannula, catheter, and all relevant components may not be used for more than 72 hours.

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.

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.

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

PAJUNK® cannulas and catheters can be inserted into the body via ultrasound, X-ray or CT.

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.

In addition to these instructions for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.

Users must provide patients with information.

Purpose
Access to the peripheral target area and injection, where appropriate with the help of ultrasound; placement of catheters

Indications
Continuous peripheral regional anaesthesia, analgesia for minor abdominal operations

Specific Indications
Transversus Abdominis Planum- (TAP) Block for: example appendectomy, hernia operation, caesarean section, hysterectomy, prostatectomy
Rectus sheath block (RSB) for: Bilateral blocks for midline incisions, minor laparoscopic interventions

Device-specific contraindications
The device contains small amounts of nickel and very small amounts of ethylene oxide. Always bear in mind the risk of allergic reactions, especially with hypersensitive patients. Do not use the device if nickel intolerance has been diagnosed.
No other device-specific contraindications are known.

Contraindications
Clinically manifest coagulation disorders, diseases of central or periphere nerves, infection of the puncture site, injury at the puncture site, allergy to local anaesthetic, lack of patient consent

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

Complication
Vascular injury, nerve damages, paresthesia, pain, failed block, motor deficits, infection

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 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 significant functional properties.

… may cause materials to break down and lead to endotoxic reactions caused by the residues.

⚠ regarding puncture:

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. To avoid bending the cannula tip, never apply excessive force to the cannula
3. 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 tip of the cannula to bend.
4. Repeated bone contact will damage the cannula tip. On no account should you continue to use a cannula damaged in this manner.

⚠ regarding the placement and removal of the catheter:

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 exert 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 can you be sure that the entire catheter has been removed.

⚠ regarding injection:

1. Do not administer drugs that are not indicated for the intended use.
2. Always ensure that the injection site is aseptic.
3. Constantly check the connection between the cannula and the infusion equipment.

⚠ 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 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.

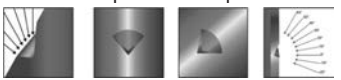
⚠ Further warning indications:

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.

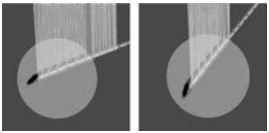
ⓘ Information

It applies to Sono cannulas:

The distal end is fitted with Cornerstone sections (graduated around the entire circumference, offset). To facilitate localisation, the section of the cannula that is visible under ultrasound is interrupted by an unstamped area after 10 mm.
The Cornerstone reflectors are designed so that all ultrasound waves are reflected with great precision, largely irrespective of the angle of insertion, when using either the in-plane technique or the out-of-plane technique.



The design of the reflectors and their positioning on the cannula optimises physical reflection properties while offering a broad spectrum of angles of insertion.



Application (Sequence of use)

Placement of the cannula

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

Placement of the catheter (continuous anesthesia)

1. Put the introductory aid on the cannula hub.
2. Push the catheter with the marked end up to the required depth into the target area.
3. After successful positioning, remove the cannula over the catheter. Hold the catheter tightly with the other hand, if necessary.
4. After removing the cannula, connect the catheter to the clamping adapter.
5. Fill the filter with the anesthetic solution designated to be used at the beginning of the anesthesia / analgesia to compensate for the dead volume (the filling volume of the filter is approximately 0.8 ml).
6. Connect the catheter adapter to the hub of the filter.
7. Fill a 10 ml or 20 ml syringe with the selected anesthetic or analgesic and connect it to the filter hub. The catheter system is now ready for the injection.
8. Fasten the catheter with the optionally available FixoLong or FixoCath in the vicinity of the exit point.

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 range from +10°C to +30°C

Air humidity 20% to 65%


Keep away from sunlight


Keep away from rain

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

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Key to symbols used in labelling

Manufacturer	Caution
REF Catalogue number	Consult instructions for use
STERILE EO Sterilized using ethylene oxide	Rx only Caution: Federal law restricts this device to sale by or on the order of a physician.
Do not resterilize	MR MR unsafe
Do not re-use	Advice
Do not use if package is damaged	N.B., information
Humidity limitation	CE 0124 Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a Notified Body.
Temperature limit	Sharp object warning
Keep away from sunlight	$\sum_n$ / QTY Pieces
Keep away from rain	
LOT Batch-Identification	
Date of manufacture	
„Use-by"-date	

CE 0124

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