PAJUNK®

VascularSono

Vasopuncture

Instructions for Use

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.
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.

VascularSono: single- part introducer cannula with Cornerstone-Reflectors.
Hub connectivity: LUER

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: The cannula is not suitable for MRI use!

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.

Intended use
Vascular puncture, if necessary placement of a guidewire.

Indications
Vascular interventions

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.

Clinical contraindications

Sepsis/ bacteremia, uncooperative patient, no safe approach route available, aneurysm, hypovolemia, shock, specific cardiovascular disorders, coagulation disorders, specific neurological disorders, infections in the vicinity of the puncture point, allergic reactions to local anesthetics, vessel perforations followed by formation of hematomas and vascular insufficiency.

Complications

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

Clinical complications

Mispuncture, poor general condition, hematothorax, arteriobiliary fistula, systemic toxicity of the local anesthetics used (observe dosage!), infections, hematoma, alterations of the vessel wall (aneurysm), vessel lesions by the guidewire or the catheter with sudden closure of the vessel (particularly if alterations of the vessels have been established previously, such as distinctive calcifications/ calcinosis accompanied by constrictions and vascular obliteration, or upon the appearance of blood clotting).

❗ 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. 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.
3. Repeated bone contact will damage the cannula tip. On no account should you continue to use a cannula damaged in this manner.
4. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.

⚠ 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 check the connection between the cannula and the infusion device regularly.

⚠ Special warnings when using with other compatible products:

If several components are used, check connections and ducts (cannulas, adapters) before use to become familiar with the function.

⚠ 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.

Sequence of use

1. Perform skin disinfection and cover area to be punctured with a fenestrated surgical drape (aperture drape).
2. Administer a local anesthetic.
3. If necessary, perform a perforating incision of the area to be punctured (lancet, or similar).
4. Push the cannula (under visual control/ ultrasound) in the blood vessel.
5. Further procedure in accordance with the individual indication.

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.

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

Caution: Federal law restricts this device to sale by or on the order of a physician

MR unsafe


Advice


Information

Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body


Sharp object warning

Does not contain Phthalates (acc. to sec. 7.5 of Annex I 93/42/EWG)

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

Quantity

CE 0124

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