PAJUNK®

MammaLoc (Sono)

Radiology

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.

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 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.*

Puncture cannula with ultrasound tip, puncture cannula with graduated fixing wire and centring reinforcement, with depth stop
Hub connectivity: LUER

Intended use

Location and preoperative marking of mamma results

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

Target user group

Medical specialist staff only

Target patient population

No limitations with regard to target patient group

Indications

Biopsy, lumpectomy

Contraindications

Device-specific contraindications

⚠ *Under no circumstances is the device to be used in the event of known material incompatibilities and/or known interactions.*

Clinical contraindications

Allergic reactions to local anaesthetics, infections in the region of the puncture point, sepsis/bacteraemia

Complications

Haematomas, pain at the insertion point, bleeding, circulatory disorders (collapse), infections, perforation of the pleural cavity (pneumothorax).

ⓘ *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 puncture:*

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.

⚠ *for injection:*

Always ensure that the injection site is aseptic.

⚠ *for use with other compatible products:*

When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).

⚠ *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.

Sequence of use

Performance of a mamma puncture/localisation under sonographic control:

1. Perform skin disinfection.
2. Administer local anaesthesia if the patient desires.
3. Position the patient in the supine position (hands folded behind the head).
4. Position the chest in an unchangeable, compressed position.
5. Using imaging procedures (e.g. ultrasound), insert the puncture cannula with the flush inserted wire into the lesion for the intervention.
6. The graduation on the fixing wire allows you to see when the hook is fully deployed as it advances through the cannula.
7. Retract the cannula.

   ⚠ *The position of the localisation wire can no longer be changed after placement.*
8. Now secure the wire to the skin with a plaster until the surgery.
9. If necessary, provide the patient with a brassiere to additionally secure the chest and the wire.
10. Remove the wire together with the tissue for minor surgery (biopsy, resection).

Performance of mamma puncture/localisation using mammography:

1. Perform skin disinfection.
2. Administer local anaesthesia if the patient desires.
3. Position the patient in the prone position or sitting position.
4. Position the chest in an unchangeable, compressed position.
5. Prepare a mammography of the chest with a raster (so-called perforated plate). Determine the puncture point using this raster.
6. Using imaging procedures (e.g. ultrasound), insert the puncture cannula with the flush inserted wire into the lesion for the intervention.
7. Release the compression.
8. Prepare a control recording in a second examination level.
9. Correct the position of the cannula if necessary.
10. The graduation on the fixing wire allows you to see when the hook is fully deployed as it advances through the cannula.
11. Retract the cannula.
12. Perform two further control recordings to check the position of the wire.
13. Now secure the wire to the skin with a plaster until the surgery.
14. If necessary, provide the patient with a brassiere to additionally secure the chest and the wire.
15. Remove the wire together with the tissue for minor surgery (biopsy, resection).

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


Single sterile barrier system


Single sterile barrier system with protective packaging outside


Consult instructions for use


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


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

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