PAJUNK®

Coaxial Sleeve

Biopsy

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 be used only by qualified medical staff in accordance with these instructions for use.*

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.

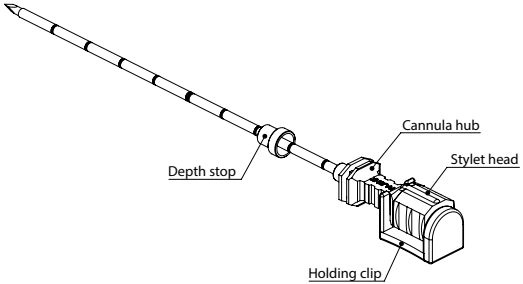
The device must not be used under any circumstances if there are good reasons to suspect incompleteness, damage or loss of sterility.

Only devices in perfect condition, which are within the sterile expiry date marked on the label, in undamaged packaging, may be used.

Product specification / compatibility

REF *Please see the current declaration of conformity for product numbers and the scope of these instructions for use.*

Accessory for PAJUNK® instruments for soft tissue biopsy, to be used solely with the PAJUNK® biopsy systems DeltaCut, CoreCut and PrimoCut.



Intended use

Accessory for the removal of tissue samples from soft tissue.

MR *Warning:*
The cannula is not suitable for MRI use!

Target User Group

Medical specialist staff only; Urologist, Radiologist, Gynecologist

Target patient population

Adults and children.

Indications

Cytological and/ or histological examination.

Contraindications

Lack of therapeutic consequence, uncooperative patient, ascites, poorly visible organs, severe coagulopathy, no safe access, aneurysm, pheochromocytoma, echinococcus, injury to neighbouring organs (lung, bile, intestine), infections, hypersensitivity reaction to the local anaesthetic, cardiovascular disturbances in the administration of analgesics or sedatives.

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

Complication

Device specific complications
Cannula bending, cannula breakage, not triggering gun spring mechanism, independent triggering of the gun spring mechanism.

Clinical complications
Failed puncture, coagulation disorder, poor general condition, haematoma in the target area, pneumothorax, hemothorax, vessel injury, arteriobiliary fistula.

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.

in the application:

1. When using the biopsy system, make sure that the biopsy cannula is not bent.
2. For safe and effective application of the biopsy gun, the physician performing the intervention must have relevant knowledge, experience and training in using this technique on the patient.
3. Compliance with good clinical practice and required precautions is an absolute necessity. Deep wound infections are serious post-interventional complications. Their elimination requires major surgical interventions.

4. The biopsy specimen may only be taken in clinical environments.
5. Before puncture, take suitable measures for securing a biopsy specimen for pathological evaluation.
6. Store the device only with uncocked spring!

⚠ *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.
3. In case of unexpected bone contact, slightly withdraw the cannula and change its direction.
4. Repeated bone contact will damage the tip. Under no circumstances should you continue to use a cannula damaged in this manner. In case of a previous bone contact remove the cannula in one step.

⚠ *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. 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

⚠ *When performing a biopsy, follow the correct procedure as laid down in the instructions for use of the biopsy system you are using.*

1. Use suitable, sterile techniques when performing the biopsy.
2. Before positioning the system, make a stab incision in the skin, where necessary, to facilitate penetration.
3. Pass the coaxial sleeve through the incision, with the help of an imaging system if necessary, until the tip of the coaxial sleeve is proximal to the area from which the biopsy is to be taken.
4. Remove the retaining clip and take the stylet out of the lock.
5. A DeltaCut, CoreCut or PrimoCut biopsy cannula can now be inserted. The procedure is described in the relevant instructions for use.

   Proceed as follows after obtaining the biopsy specimen:
6. Remove the instrument and/ or the cannula from the coaxial sleeve.
7. If further biopsy samples are to be taken, the coaxial sleeve can be left at the puncture site. It is vital that the conditions around the puncture site are hygienic and aseptic.
8. Once the procedure has been completed, carefully remove the coaxial sleeve.
9. Treat the incision site.

Operating 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.

 Non-pyrogenic

 *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.*

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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 with protective packaging outside

Unique device identification


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

Does not contain natural rubber latex

Quantity


Translation

Medical device

Non-sterile


Single sterile barrier system

CE 0124

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