PAJUNK®

PrimoCut Biopsy System

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.

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.

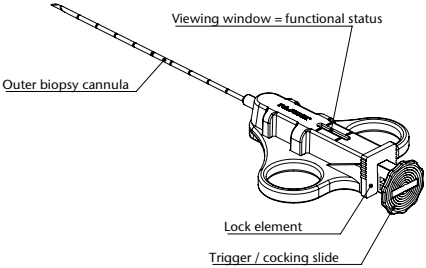
The device must not be used under any circumstances if there are good reasons to suspect incompleteness, damage or loss of sterility.

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

Device description / compatibility

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

Semi-automatic, disposable biopsy system to obtain histologically usable tissue material from soft tissue/organs.
PAJUNK® coaxial cannulas can be used for multiple biopsies. Use the compatible PAJUNK® accessories only.
The coaxial cannulas (art. no. 413Sxxxxxx) are available with different diameters and lengths (Instructions for use: XS190164).



Intended use

Extraction of tissue specimens from soft tissue.

Warning:
The cannula is not suitable for MRI use!

Target User Group

Medical specialist staff only Users must be trained and instructed according to the latest clinical technology.

Target patient population

Adults and children; professional medical staff are responsible for patient selection.

Indications

Biopsy

Contraindications

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

Skeleton and nervous system biopsy specimens. 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.

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 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.

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:*

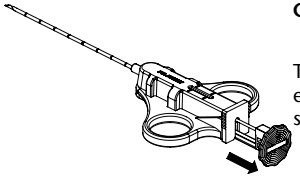
Always ensure that the injection site is aseptic.

⚠ *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.

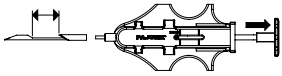
Instructions for use

Make the biopsy using adequate, sterile techniques.
To facilitate penetration, puncture the skin before positioning the system.



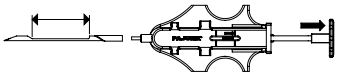
Cocking the instrument

The device must be cocked to different extents depending on the size of the biopsy specimen to be taken.



Function status indicators

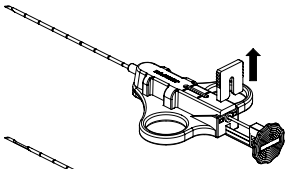
1st lock-in position: biopsy chamber is 9 mm open



2nd lock-in position: biopsy chamber is 18 mm open

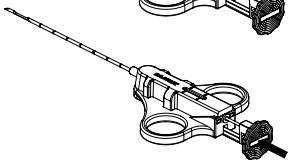
A click confirms that the cocking mechanism has engaged.

Position the needle and approach the needle tip until it reaches the target area (lesion), always checking with an adequate imaging technique.



Releasing the safety

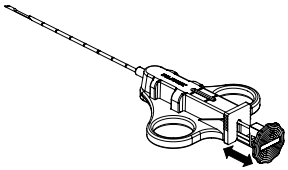
Remove the lock element before pressing the trigger.



Triggering

The inner cannula is advanced manually into the target area so that it is opened for puncture.

After reaching the target point, the biopsy is triggered by depressing the cocking piston.
After starting the biopsy, the instrument can be retracted carefully.



The biopsy chamber is opened by cocking the biopsy system in two steps (to 20 mm) and advancing the cannula; the specimen can now be removed.

To obtain multiple biopsy specimens, this process can be repeated several times.

Treat and dress the incision.

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.

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 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.)


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


Single sterile barrier system

CE 0124

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