

PAJUNK®

CoreCut

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: efu.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.

Fully automatic, disposable biopsy system

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 by means of punch biopsy.

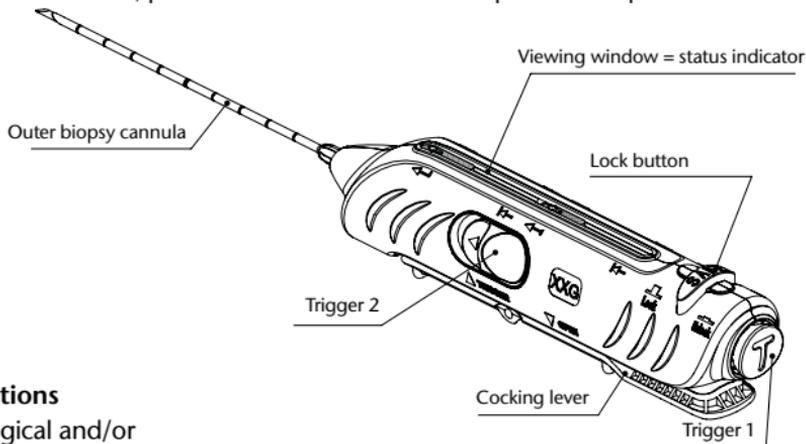
 **Warning:**
The cannula is not suitable for MRI use!

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

Cytological and/or histological examination

Contraindications

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.

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

Complications

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

i *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 re-sterilised under any circumstances!*

The materials used in the manufacture of this device are not suitable for reprocessing or re-sterilisation.

This device is not designed to be reprocessed or re-sterilised.

 **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 in combination with an ultrasound 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. The biopsy specimen may only be taken in clinical environments.
4. Before puncture, take suitable measures for securing a biopsy specimen for pathological evaluation.

 *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:

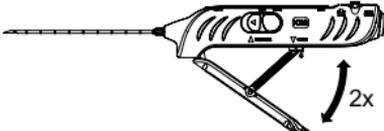
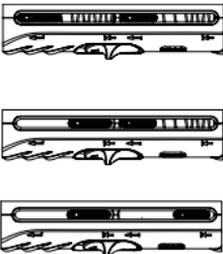
Always ensure that the injection site is aseptic.

 further warning indications:

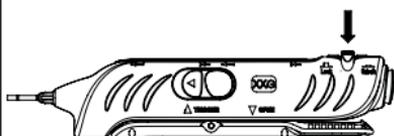
-  **Caution! Sharp object warning** The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. The most relevant ones in practice are the human immunodeficiency virus (HIV), the hepatitis B virus (HBV) and the hepatitis C virus (HCV).
- 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.
- 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.
- Store the device only with uncocked spring!

Sequence of use

Make the biopsy using adequate, sterile techniques.

To facilitate penetration, puncture the skin before positioning the system.		
	<p>Cocking the instrument</p> <p>Open and close the clamping lever twice completely by hand to cock the instrument.</p> <p>1st time: The cannula is retracted, the biopsy chamber is open</p> <p>2nd time: The system is completely cocked and ready for use</p>	
<p>Status indicator for biopsy cannula (green)</p> 	<p>Status indicator - cocked (red)</p> 	<p>Functional status indicators</p>  <ol style="list-style-type: none"> 1) System completely uncocked 2) Cannula retracted, biopsy chamber open 3) System completely cocked; ready for use

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

Press the lock button labelled "SAFE".

Option 1:
Trigger at the end of the biopsy system



Option 2: Lateral trigger of the biopsy system

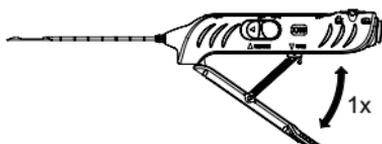


Triggering

It is activated by pressing the trigger at the end of the biopsy system or the lateral trigger.

The biopsy is triggered.

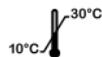
After starting the biopsy, the instrument can be retracted carefully.



The biopsy chamber is opened by cocking the biopsy system once; 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		Non-pyrogenic
	Use-by date		Dispensing with prescription only (the device may only be used by qualified medical staff for the intended purpose.)
	Item number		MR unsafe
	Sterilized using ethylene oxide		Advice
	Do not re-sterilise		Information
	Do not use if package is damaged		“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.
	Keep dry		Sharp object warning
	Humidity limitation		Does not contain phthalates
	Do not re-use		Natural rubber latex has not been used as a component in the manufacture of this product
	Caution		Quantity
	Date of manufacture		Translation
	Batch code		Medical device
	Keep away from sunlight		Single sterile barrier system
	Temperature limit		
	Consult instructions for use		
	Single sterile barrier system with protective packaging outside		



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The logo for PAJUNK GmbH, featuring a stylized black silhouette of a factory or industrial building with three peaks.

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