PAJUNK®

CoreCut

Biopsy

Instructions for Use

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 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.

Product specification / compatibility

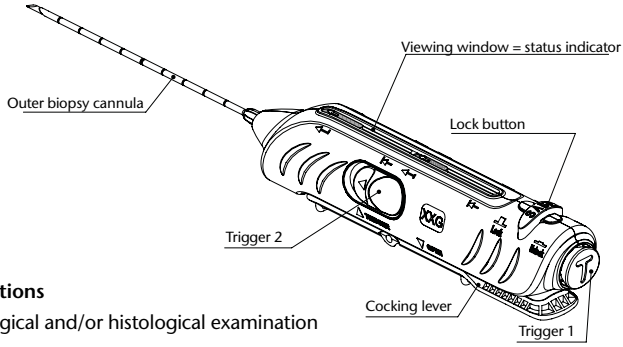
REF *Please see the current declaration of conformity for product numbers and the scope of these instructions for use.*

Fully automatic, disposable biopsy system
PAJUNK® coaxial cannulas can be used for multiple biopsy. 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.

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



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.*

Complication

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 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. 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.

⚠ *for injection:*

Always ensure that the injection site is aseptic.

⚠ *further warning indications:*

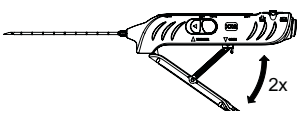
1. ⚠ Caution! Sharp object warning The device or device components may, depending on the type of tip, have sharp edges or tips. Various infectious pathogens can be transmitted if a stab wound occurs. For practical purposes, the most important of these are the human immunodeficiency virus (HIV), the hepatitis 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.
4. Store the device only with uncocked spring!

Sequence of use

Use adequate, sterile techniques for the biopsy.

To facilitate penetration, puncture the skin before positioning the system.



Cocking the instrument

Open and close the clamping lever twice completely by hand to cock the instrument.

1st time: The cannula is retracted, the biopsy chamber is open

2nd time: The system is completely cocked and ready for use

Status indicator for biopsy cannula (green)

Status indicator - cocked (red)

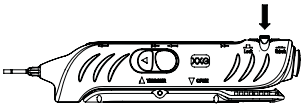
Functional status indicators

1) System completely uncocked

2) Cannula retracted, biopsy chamber open

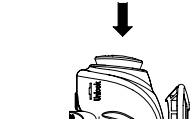
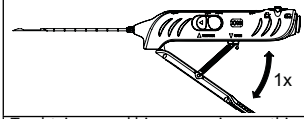
3) System completely cocked; ready for use

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

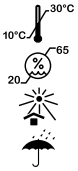


Releasing the safety

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 several 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 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.

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


Non-pyrogenic

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

MR unsafe


Advice


Information

"CE marking of conformity" or "CE marking" means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Medical Device Regulation and other applicable Union harmonisation legislation providing for 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

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