PAJUNK®

DeltaCut Biopsy Gun
DeltaCut Cannula

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.

Device description / compatibility

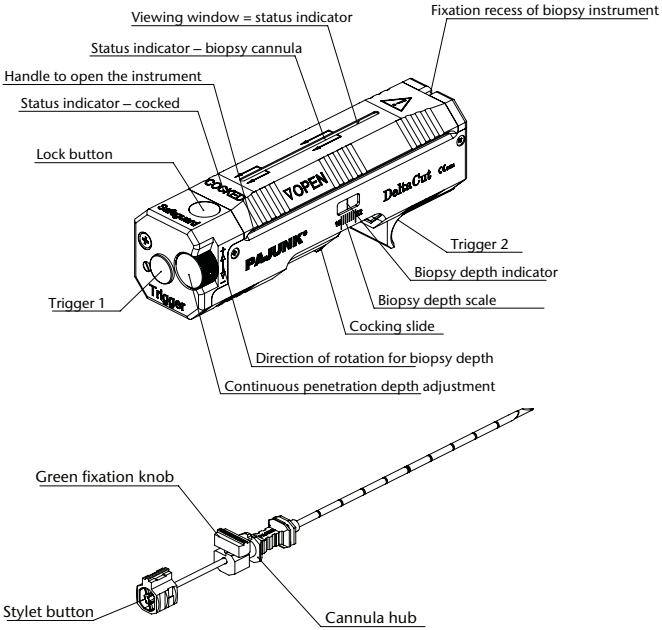
REF *Please see the current declaration of conformity for product numbers and the scope of these instructions for use.*

Fully automatic, reusable 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. 313Sxxxxxx) are available with different diameters and lengths (Instructions for use: XS190164).

Biopsy gun: reusable, non-sterile NON STERILE

Biopsy cannula: disposable, sterile STERILE EO

DeltaCut biopsy system



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; Urologist, Radiologist, Gynecologist

Target patient population

Adults and children.

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

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 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.

Warnings

⚠ *for reusable product:*

1. ⚠ NON STERILE *Please make absolutely sure that you clean and sterilise all devices delivered in non-sterile condition before using them for the first time!*
2. ⚠ NON STERILE *If an instrument has been contaminated, always process it immediately after use (see instructions for manual pre-cleaning)!*
3. Before every use, check the device visually, check its proper function and check tightness of the insufflation cock.
4. Sort damaged or faulty instruments and replace them.

⚠ *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.

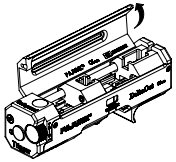
Sequence of use

Make the biopsy using adequate, sterile techniques.
Check the biopsy instrument before use: Cock the gun without inserted biopsy cannula by pulling the black cocking slide back twice. Check the instrument's function by first pressing the lock button and then one of the triggers.

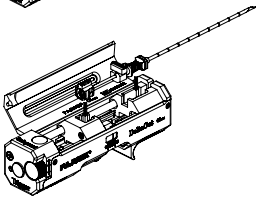
⚠ *Never check the PAJUNK® DeltaCut biopsy instrument with inserted PAJUNK® DeltaCut biopsy cannula. This might damage the cannula and/or cause injury.*

Preparation of the PAJUNK® DeltaCut biopsy cannula:

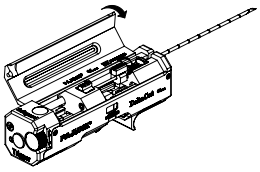
The cannula has a centimetre scale to measure the penetration depth and a green fixation knob, which, when closed, guarantees that the positions of stylet and cannula remain unchanged when the cannula is inserted in the PAJUNK® DeltaCut biopsy instrument. Before use, determine the correct diameter and length for the biopsy and select the matching cannula. Remove the cannula from the packaging while preserving sterility and remove the protective tube.



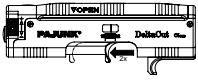
Open the cover.



Insert the biopsy cannula in the matching openings of the slide with the green fixation knob in closed position (transverse to the cannula tube). Alternatively, the biopsy cannula can also be inserted in the same way in the completely cocked instrument.

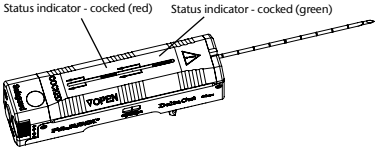


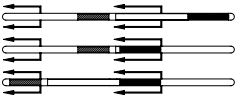
Turn the green fixation knob 90° in anti-clockwise direction (so that it is parallel to the cannula). Close the cover completely. The green fixation knob and the red stylet button now show that the device is loaded. If the cover cannot be closed correctly, check the position of the green fixation knob and move it to the correct position. Only proceed after the cover has been completely closed and correctly engaged.



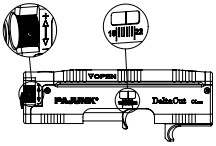
Cock the instrument by pulling the black cocking slide back twice (please note the function status indicators). This step can be skipped if the biopsy cannula has been inserted in an already completely cocked instrument.

Status indicators



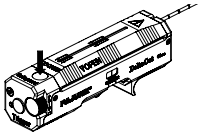


1) System completely uncocked
2) Cannula retracted, biopsy chamber open
3) System completely cocked; ready for use



Set the penetration depth on the lateral scale to a value between 15 mm and 22 mm by turning the adjusting wheel at the back of the instrument until it shows the desired value.
Please note that the red status indicator for a ready-to-use instrument is now in the area marked with "COCKED". The instrument is now ready for use.

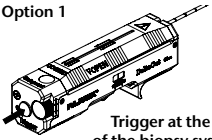
To facilitate penetration, puncture the skin before positioning the system.
Position the cannula and approach the cannula tip until it reaches the target area (lesion), always checking with an adequate imaging technique.



Releasing the safety

Press the lock button labelled “Safeguard”.

Option 1

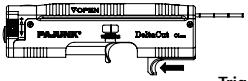


Trigger at the end of the biopsy system

Triggering

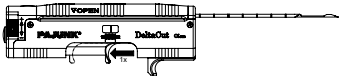
The biopsy is triggered by actuating either the trigger at the end of the biopsy system or the trigger at the bottom side.

Option 2



Trigger at the bottom side of the biopsy system

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.

Assembly/disassembly

The DeltaCut gun does not need to be disassembled.

Processing

General information

Whenever you are working with contaminated instruments, follow the personal protection guidelines of the trade association and similar organisations. Wear appropriate protective equipment and ensure that you have had the necessary vaccinations.

Risk of infection: Incorrect processing of instruments puts patients, users and third parties at risk of infection and can impair the performance of the instrument.

Instruments used on patients known to have or suspected of having Creutzfeldt-Jakob disease or other prion diseases must be disposed of after one use in accordance with specific national requirements.

Always comply with the procedures, equipment and devices validated for the user / operator / central sterilisation unit and check them for compatibility with the information provided here.

When making up and using solutions, comply with the information on concentration and exposure time provided by the manufacturers of the chemicals. Non-compliance can damage the instrument.

Further information on instrument processing can be found at www.a-k-i.org

Preparation at the place of use

If an instrument has been contaminated, always clean it immediately after use. To prevent material from drying and adhering to the instrument, large particles of contamination, corrosive solutions and medicinal products must be removed immediately after application of the medicinal product, for example by wiping and rinsing (dry disposal).

Transport

Use suitable transport containers to transport instruments to the reprocessing site in order to rule out the possibility of them constituting a hazard or undergoing external contamination.
Dry disposal is always preferred, whenever possible. Avoid long storage times.

Preparation before mechanical cleaning

If an instrument has been contaminated, always process it immediately after use. If the instrument is a multi-piece device, dismantle it into its constituent parts.

Pre-cleaning the surfaces:

Use a brush (no steel brush) or sponge to remove visible contamination or heavy dirt from the surface of the instrument under cold running water (<40 °C; drinking water quality).

Pre-cleaning cavities / lumens:

Use a suitable brush (no steel brush) to clean the working channels, lumens and cavities of the instrument under cold running water (<40 °C; drinking water quality). Rinse gaps, grooves and cavities approx. 10 seconds with a pressurised water pistol, fitted with an irrigation attachment if necessary.

Manual cleaning / manual disinfection

Manual disinfection is not necessary.

⚠ *Warning: Exclusively manual processing is not permitted. Manual cleaning must always be followed by mechanical cleaning and disinfection.*

Mechanical cleaning and disinfection

Instrument sets must only be cleaned and disinfected in a suitable cleaning and disinfection machine (CDM).
Use the Vario TD programme to clean thermostable instruments.
PAJUNK® has validated and approved the following cleaning and disinfection process in accordance with DIN EN ISO 17664 or DIN EN ISO 15883:

- Vario TD process parameters:
  - 1 minute pre-washing with cold tap water, drinking water quality, <40 °C
  - Draining
  - 3 minute pre-cleaning with cold tap water, drinking water quality, <40 °C
  - Draining

If Neodisher® Mediclean forte is used:

- *10 minutes cleaning at 55 °C (+5/-1 °C), dosage acc. to the following table and demineralised water*

If Neodisher® MediZym is used:

- *10 minutes cleaning at 45 °C (+5/-1 °C), dosage acc. to the following table and demineralised water*
- Draining
- 3 minutes rinsing with demineralised water (<40 °C)
- Draining
- 2 minutes rinsing with demineralised water (<40 °C)
- Draining
- 5 minutes thermal disinfection at 93 °C (± 2 °C) (A0 =3000) and demineralised water
- Draining
- 30 minutes hot air drying at >60 °C (in the cleaning chamber)

Chemical	Manufacturer	Category	pH value	Dosage
Neodisher Mediclean forte	Dr. Weigert	Alkaline detergent	10.4 - 10.8*	0.5 % (5 ml/l)
Neodisher MediZym	Dr. Weigert	Enzymatic detergent	7.6 - 7.7 *	0.5 % (5 ml/l)

* Data in accordance with manufacturer data sheet

Connect individual parts with lumens and channels directly to the cleaning and disinfection machine. Connect non-dismountable instrument sets with cleaning channel, if any, directly on the Luer-Lock port to the special lumen-cleaning element in the cleaning and disinfection machine.

When selecting the cleaning programme, bear in mind the material from which the instrument to be cleaned is made (e.g. stainless steel for medical instruments, chromed surface, aluminium).

⚠ *Always comply with the instructions of the device and detergent manufacturers.*

Drying

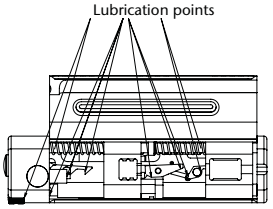
! *The instrument may need to be manually dried after cleaning.*

Maintenance, inspection and care

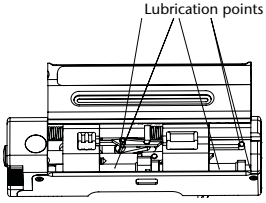
Leave the instrument set to cool to room temperature.
Perform a visual check on the cleaned and disinfected instrument, paying attention to cleanliness, completeness, damage and dryness.
If any contamination or residue is found during this check, the instrument must undergo another complete cleaning and disinfection process.
Any parts of the instrument that are found to be damaged, incomplete, corroded, bent, broken, torn or worn must be removed or replaced.
Dry the instrument again if there is any residual moisture.

Lubricate all movable parts. For medical devices, use a lubricant approved for the described sterilisation methods. We recommend paraffin oil (art. no. 1292-00-97), which has good creeping and lubrication properties. This helps to keep the parts mobile and also protects the entire instrument surface from mineral deposits, which could lead to impaired function. Please note that the instrument should be lubricated regularly after each cleaning and before each sterilisation.

Uncocked



Cocked



PAJUNK® *recommends that instruments be handled carefully and gently, and that this user manual be closely followed, in order to maximise their useful life. The useful life of the instrument depends to a very large extent on careful handling and the performance of appropriate care and maintenance measures.*

Packaging system

Only use standardised and permitted packaging systems in accordance with EN 868 parts 2-10, EN ISO 11607 parts 1+2, DIN 58953.

Sterilisation

Warning: Instruments used on patients known to have or suspected of having Creutzfeldt-Jakob disease or other prion diseases must be disposed of after one use in accordance with specific national requirements.

PAJUNK® has validated and approved the following process:

Steam sterilisation

The fully mounted instrument must be sterilised in accordance with a validated steam sterilisation process (e.g. steriliser according to DIN EN 285 and validated according to DIN EN 17665-1).
When following the fractionated vacuum procedure, sterilise according to the 134 °C/ 3-bar programme, with a minimum holding time of 5 minutes (in accordance with the recommendations issued by the Robert Koch Institute and the German Federal Institute for Drugs and Medical Devices). The drying time is 30 minutes.
Allow devices / instruments to cool to room temperature before using them again. Keep instrument sets that have undergone steam sterilisation in suitable containers used only for this purpose.

Transport to the place of use

Use suitable transport systems.

Reprocessing restriction

The end of device life is determined primarily by wear, damage caused by use, careful handling and appropriate storage.
Frequent reprocessing in accordance with the reprocessing instructions supplied by the manufacturer does not affect the instruments' performance.

Repair

Devices sent to PAJUNK® for repair under warranty or at the user's expense must be thoroughly cleaned and sterilised before being sent back. Sterility must be noted on the covering letter or package.

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 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


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

XS190059P_Englisch 2023-11-14

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