PAJUNK®

Veress
-semi-reusable-

Minimally Invasive Surgery

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 or damage.

Device description / compatibility

The reusable Veress cannula is a double-cannula puncture system consisting of a sharp outer cannula and an atraumatic inner cannula.

Connection: LUER

NON STERILE REF 1206-01xxx series (design with knurled sleeve), 1206-21xxx series (design with hexagonal sleeve)

STERILE EO REF 1206-19xxx series

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

Service life significantly depends on careful handling and appropriate maintenance and cleaning.

Modular Veress cannula consisting of reusable modular Veress body (REF 1206-01xxx, 1206-21xxx) and disposable outer cannula (REF 1206-19xxx). The sterile disposable outer cannulas REF 1206-19xxx may only be used with the modular Veress bodies REF 1206-01xxx and 1206-21xxx.

Connection: LUER

The modular basis REF 1206-01080 can be used for thoracentesis in combination with the thoracentesis set REF 1210-00-10. Please consult the separate Instructions for use of XS190092.

Intended use

Initial puncture, optionally followed by gas insufflation

Warning:
The cannula is not suitable for MRI use!

Indications

Laparoscopy, thoracoscopy

Contraindications

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

Infection at the puncture site

Lack of patient consent

Coagulation disorders

Contraindications usually depend on the minimally invasive procedure that is carried out.

Complication

- Cannula breakage
- Tissue/bone resistance and the related need to reposition the cannula
- Significant blood vessel trauma during puncture
- Neuronal trauma during puncture
- Allergic reactions (Ni, EO)

Complications usually depend on the minimally invasive procedure that is carried out.

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.

⚠ *for reusable product:*

1. *Please make absolutely sure that you clean and sterilise all devices delivered in non-sterile condition before using them for the first time!*
2. *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.

⚠ *for puncture:*

1. Take care to use devices of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. Optional: Perform a puncture incision beforehand on the area where the puncture is to be performed (blood lancet etc.)
3. To avoid bending or breaking of the cannula, never apply excessive force to the cannula.
4. 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.
5. Repeated bone contact will damage the cannula tip. On no account you should continue to use a cannula damaged in this manner. Remove the cannula (with introduced stylet) in one step.

⚠ *for use with other compatible products:*

1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages (cannulas, adapters).
2. Before disassembly and cleaning, make absolutely sure to keep the correct pairs together! Only correct Veress cannula pairs may be assembled and used for patients!

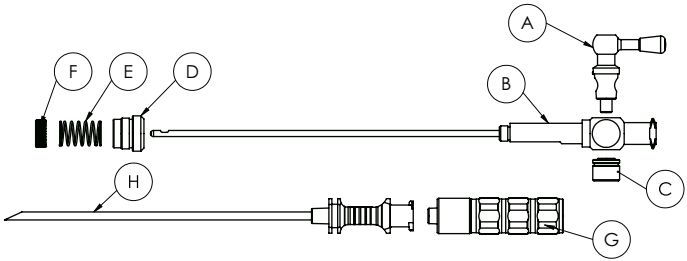
⚠ *further warning indications:*

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

1. Hold the assembled Veress cannula (puncture system) firmly at the cannula body during puncture.
2. Introduce the puncture system slowly at the puncture site with the bevelled tip pointing towards the cranium.
3. When the instrument enters the abdomen/thorax, the inner part moves forward with a noticeable click, rendering the puncture system atraumatic.
4. Optional: gas insufflation using connections at the insufflation device.
5. Remove the puncture system after finishing the puncture.

Assembly/disassembly



Dismantling

1. Unscrew the disposable sharp outer cannula (H) at the plastic hub in anti-clockwise direction. The disposable outer cannula must be disposed of properly after use.
2. Unscrew the spring cap (C) at the bottom side of the valve housing (B) and remove the valve cock (A) from its housing.
3. Disassemble spring stop (D), spring (E), knurled nut (F) and handle sleeve (G) as shown in the illustration.
4. Now clean the components according to the instructions in chapter "Processing".
5. Perform maintenance according to the instructions in chapter "Maintenance, inspection and care".

Assembly

1. Insert the valve cock (A) in the valve housing (B). Make sure that the lateral stop pin engages in the groove at the upper edge of the valve housing.
2. Screw the spring cap (C) onto the thread of the valve cock (A) at the bottom side of the valve housing and tighten it.
3. Assemble spring stop (D), spring (E), knurled nut (F) and handle sleeve (G) as shown in the illustration.
4. Remove the sterile, disposable sharp outer cannula (H) from the blister package. Slide it onto the blunt obturator (B) and screw it in clockwise direction onto the modular Veress body at the plastic hub.
5. Now sterilise the components according to the instructions in chapter "Processing".

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 (see chapter on instructions for dismantling).

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.
Particularly check the cannula tip for damage. 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.
Instruments with damaged or missing chrome coating may not be used.
Reassemble the dismantled instrument set according to the assembly instructions.

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:

Make sure that the insufflation cock is open.

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.

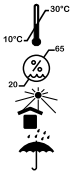
Reprocessing restriction

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.

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


Catalogue number


Do not use if package is damaged


Keep dry


Humidity limitation


Caution


Date of manufacture


Batch code


Non-sterile


Keep away from sunlight


Temperature limit


Consult instructions for use


Caution: Federal law restricts this device to sale by or on the order of a physician


MR unsafe


Advice


Information


Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body


Sharp object warning


Quantity


Translation


Medical device

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