

PAJUNK®

**TrocaTec MAN
TrocaTec AUTO
TrocaPort**

Minimally Invasive Surgery



Instructions for Use

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 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



REF 1285-13-xx TrocaTec MAN with automatically and manually operated trap-door valve

Model	Instrument diameters	Two-way valve	Colour of the rubber cover
TrocaTec MAN	12 mm	•	Signal red
TrocaTec MAN	11 mm	•	Gentian blue
TrocaTec MAN	5.5 / 5.8 mm	•	Signal green
TrocaTec MAN	5.5 / 5.8 mm	–	Signal green



REF 1285-26-xx TrocaTec AUTO with automatically operated trap-door valve

Model	Instrument diameters	Two-way valve	Colour of the rubber cover
TrocaTec AUTO	11 mm	•	Gentian blue
TrocaTec AUTO	5.8 mm	–	Signal green



Model	Instrument diameters	Two-way valve	Colour of the rubber cover
TrocaPort	11 mm	•	Gentian blue
TrocaPort	5.5 / 5.8 mm	•	Signal green
TrocaPort	5.5 / 5.8 mm	–	Signal green

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

Hub connectivity: LUER

Reusable valves can be used for the modular TrocaTec and TrocaPort trocar systems or in combination with EcoBalloons.

! The valve inserts and valve housings of the TrocaTec and TrocaPort series are not compatible to each other.

Compatibility overview of the valves with EcoBalloons:

Valve diameter 5.8 mm	Valve diameter 11 mm		Valve diameter 12.5 mm
Long, 105 mm	Short, 80 mm	Long, 105 mm	Long, 105 mm
RA diameter 5.8 mm	RA-S diameter 11 mm	RA diameter 11 mm	–
URO diameter 5.8 mm	URO-S diameter 11 mm	URO diameter 11 mm	–
–	–	SB diameter 11 mm	–
–	–	DIL diameter 11 mm	–
–	–	DIL-XL diameter 11 mm	DIL-XL diameter 12.5 mm
–	–	DIL-BI diameter 11 mm	–

i The useful life of the instrument depends to a very large extent on careful handling and the performance of appropriate care and maintenance measures.


Intended use

Ensuring tightness of trocar/balloon systems; regulating the gas flow.

Indication

Minimally invasive procedures that require the use of trocar systems.
Minimally invasive procedures that require the use of balloon systems.


Contraindications


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

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


Complication



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 reusable product:*

-  *Please make absolutely sure that you clean and sterilise all devices delivered in non-sterile condition before using them for the first time!*
-  *If an instrument has been contaminated, always process it immediately after use (see "Preparation prior to mechanical cleaning")!*
- Subject the device to a visual and functional check before every use.
- Sort damaged or faulty instruments and replace them.

 *in the application:*

- Take care to use products of suitable dimensions (diameter, length), especially when treating obese patients and children.
- 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.

 further warning indications:

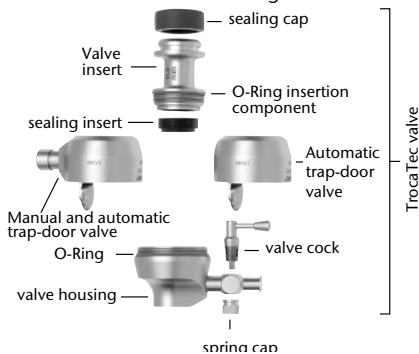
1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages.
2. You must routinely take general precautions for handling blood and bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.

Sequence of use

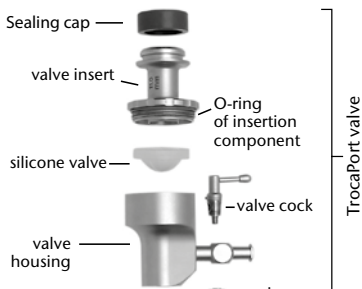
1. Attach the TrocaTec/TrocaPort valve to a trocar system / EcoBalloon system.
2. Further applications depend on the system used.

Dismantling

1. Unscrew the valve insert from the valve housing.
2. Remove the colour-coded sealing cap from the opening of the valve insert and/or insertion component.
3. Unscrew the guide tube/balloon from the valve housing.
4. Valves with an insufflation cock: Unscrew the spring cap from the valve cock of the maintenance-free insufflation cock on the valve housing and remove the valve cock.
5. a. *TrocaTec valve (with trap-door valve)*: Unscrew the insertion component from the trap-door valve insert and take the colour-coded sealing insert out of the installation opening. Now unscrew and remove the trap-door valve insert from the valve housing.



5. b. *TrocaPort valve (with silicone valve)*: Unscrew the valve insert from the valve housing and take the silicone valve out of the valve insert.



6. Remove O-rings on the insertion component, guide tube and valve housing (for TrocaTec).
7. Now clean the components according to the instructions in chapter "Processing".
8. Perform maintenance according to the instructions in chapter "Maintenance, inspection and care".







Assembly

1. Valves with an insufflation cock: Insert the valve cock into the insufflation cock on the valve housing. Make sure the small stop pin is in the correct position. Screw the spring cap onto the thread of the valve cock in the insufflation cock and tighten it.
2. Screw the guide tube/balloon into the valve housing.
3. Check all O-rings, silicone seals, sealing caps and sealing inserts for damage and embrittlement; replace them if necessary.
4. a. *TrocaTec valve (with trap-door valve)*: Insert the colour-coded sealing insert into the installation opening of the insertion component so that the thin sealing lip is facing the trap-door lid. Then press the sealing insert with your fingertip all the way into the installation opening. Make particularly sure that the sealing insert size and/or colour matching the size of the trocar sleeve is used. Then screw the insertion component with the sealing insert into the trap-door valve insert and tighten it. Make sure that the green O ring is correctly positioned on the insertion component. Then screw the assembled unit onto the trap-door valve housing and tighten it. Make sure that the green O ring is correctly positioned on the valve housing.

4. b. *TrocaPort valve (with silicone valve)*: Insert the silicone valve into the valve insert. Make sure that the valve protrusion is pointing in the direction of the guide tube. If the silicone valve is damaged, replace it; otherwise, it will compromise the functioning of the instrument. Screw the valve insert into the valve housing. Make sure that the green O ring is correctly positioned on the valve insert.
5. Place the colour-coded sealing cap onto the insertion opening of the valve insert and/or insertion component. Make particularly sure that the sealing cap size and/or colour matching the size of the valve insert is used.
6. Make sure that the correct O-ring for the size of the trocar sleeve is properly attached to the thread of the guide tube.
7. *Only for TrocaTec*: Use the opener (1287-00-00) for sterilisation. The opener must be inserted completely in the proximal opening.
8. Now autoclave (sterilise) the components according to the instructions in chapter "Processing".
9. Perform a tightness test and a function test.

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.

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.

Disposable wearing parts must be used only once. Always check wearing parts (silicone seals, sealing caps, O-rings, sealing inserts) for damage prior to use, and replace them if necessary.


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 opener (only TrocaTec) is used and 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.


Use 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.*

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Key to symbols used in labelling

	Manufacturer		Consult instructions for use
	Catalogue number		Caution: Federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged		Advice
	Keep dry		Information
	Humidity limitation		Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body
	Caution		Quantity
	Date of manufacture		Translation
	Batch code		Medical device
	Non-sterile		
	Keep away from sunlight		
	Temperature limit		



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