PAJUNK®

Hasson Cone

Laparoscopy

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!

℞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 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 or damage.

Device description / compatibility

Model	Diameters Ø	Illustration
NON STERILE REF 1287-43-xxx series Hasson cone with smooth surface	5.5 mm 10 mm 11 mm 12.5 mm	
NON STERILE REF 1287-43-xx series Hasson cone with fixing thread	10 mm 11 mm 12.5 mm	

Model	Diameters Ø	Illustration
NON STERILE REF 1287-44-xx series Hasson cone with fixing thread, modified version	11 mm 12.5 mm	

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

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

Intended use

Port for the introduction of obturator, endoscopes and endoscopic accessories into the surgical field; to ensure the tightness of system.

Target user group

Medical specialist staff only; surgeon

Target patient population

Adults and children

Indications

Laparoscopy in general surgery, gynecology and urology with the Hasson technique (open laparoscopy).

Contraindications

Device specific contraindications

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

Excessive use of force on the device during placement.

Clinical contraindications

Contraindications depend primarily on the laparoscopic procedure being performed.

Complications

Device-specific complications

Insecure pneumoperitoneum, leakage, gas problems, vascular/visceral injuries, bleeding/haematomas, intestinal lesions, organ injury, hernia, scars/ adhesions, infection at the insertion site

Clinical complications

Complications depend primarily on the laparoscopic procedure being performed.

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:*

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 "Preparation prior to mechanical cleaning")!*
3. Subject the device to a visual and functional check before every use.
4. Sort damaged or faulty instruments and replace them.

⚠ *in the application:*

1. Take care to use products of suitable dimensions (diameter, length), especially when treating obese patients and children.
2. 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. Perform a skin incision.
2. Fix the Hasson cone on the blunt obturator.
3. Insert the system with attached Hasson cone through or in the abdominal wall.
   a) Change if necessary the position of the Hasson cone toward the incision.
   b) Fix the Hasson cone again on the blunt obturator.
4. Pulling out of the trocar system can be prevented by wrapping the thread holder of the Hasson cone with the sutures on the fascia twice.
5. Remove the obturator.
6. Endoscopic instruments can now be introduced.

Assembly/disassembly

For processing, disassemble the Hasson cone in its 3 parts: Cone body, sealing cap and clamping sleeve.

Please note that the fixing screw cannot be removed.

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 (sealing caps) 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:

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, Deutschland.

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

 Unique device identification

 Consult instructions for use

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

 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.

 Quantity

 Translation

 Medical device

CE 0124

XS190258C_Englisch 2023-09-12

PAJUNK® GmbH
Medizintechnologie
Karl-Hall-Straße 1
78187 Geisingen/ Deutschland
Tel. +49 (0) 7704 9291-0
Fax +49 (0) 7704 9291-600
www.pajunk.com