PAJUNK®

ErgoSys Modular System for MIS

Minimally Invasive Surgery

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 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

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

ErgoSys system: Modular manual instruments with optional HF coagulation, consisting of handle, shaft tube (pull rod) and instrument insert. Inserts are available with different configurations.

Please observe the relevant instructions for use for MultiTip II and MonoTip II inserts (XS190133, XS190242).

NON STERILE REF *1292-30-00 ErgoFlex: reusable handle to be used with reusable components, MultiTip ll and MonoTip ll.*

NON STERILE REF *1292-30-10 ErgoGrip: reusable handle to be used with reusable components*

Compatibility overview:

Available handles	Compatible shaft tubes	Compatible pull rods	Compatible instrument inserts	Compatible cleaning adapter
1292-30-00	1292-13-xx 1292-14-xx	-	1292-83-xx, 1292-84-xx, 1292-63-xx, 1292-64-xx, 1292-93-xx, 1292-94-xx, 1292-95-xx, 1292-96-xx, 1292-53-xx, 1292-54-xx, 1292-73-xx, 1292-74-xx, 1292-42-xx, 1292-43-xx,	1292-43-98 (for instrument inserts)
	1293-15-xx 1293-16-xx	1293-20-xx 1293-21-xx	1293-53-xx, 1293-54-xx, 1293-93-xx, 1293-94-xx,	-
	1293-13-xx 1293-14-xx	1293-22-xx 1293-23-xx	1293-95-xx, 1293-96-xx,	-
1292-30-10	1292-13-xx 1292-14-xx	-	1292-83-xx, 1292-84-xx, 1292-63-xx, 1292-64-xx, 1292-93-xx, 1292-94-xx, 1292-95-xx, 1292-96-xx, 1292-53-xx, 1292-54-xx, 1292-73-xx, 1292-74-xx, 1292-42-xx, 1292-43-xx	1292-43-98 (for instrument inserts)

⚠ *Please make sure that lengths and diameters of shaft tubes and instrument inserts match.*

Modular manual instruments for electrosurgery may only be operated with HF generators having a nominal frequency of the HF voltage between 300 kHz and 1 MHz. Lower frequencies may cause nerve stimulation and thus uncontrolled convulsion. In case of higher frequencies, user/patient safety cannot be guaranteed because insulation may heat up (at approx. 4 MHz, usual value with RF generators) so that dielectric strength is no longer given.

⚠ *Maximum operating voltage is 2 kVp.*

Please note the instructions for use of the HF generator.

Use only monitorable neutral electrodes compatible with the generator and monitor. For compatibilities, please refer to the instructions for use of the generator or monitor. Devices may only be used when neutral electrodes are fastened according to guidelines.

Use only HF cables compatible with the generator and electrode. For compatibilities, please refer to the instructions for use of the generator or cable. PAJUNK® recommends to only use HF cables with article numbers 1299-00-xx. Other cables may cause failures because insulated sections are not adhered to.

Service life

The end of device life is determined primarily by wear, damage caused by use, careful handling and appropriate storage.

The instrument must be thoroughly checked by the manufacturer after every 200 reprocessing cycles. If the device is used after having clearly exceeded its service life, warranty expires and patient safety is put at risk. If the device is modified/manipulated (e.g. repair carried out by third parties), warranty expires and patient safety is put at risk.

Intended use

Instruments for mechanical cutting, gripping, holding, clamping and monopolar cutting and coagulation during minimally invasive procedures.

Target user group

Medical specialist staff only: surgeon

Target patient population

There are no limitations in patient population

Indications

Minimally invasive surgery

Contraindications

Clinical contraindications

Different specific contraindications of individual organs, residual conditions after previous surgeries, manifest coagulation disorders

Procedure-specific contraindications when using the electrosurgery function

Spray coagulation, the user's lack of basic knowledge, simultaneous use of electrosurgery function and suction-irrigation function, use on non-isolated patient, activation of electrosurgical device with the electrode being out of sight, wet operating table pads and covers during surgery, patients with active implantable devices (e.g. pacemakers), use of alcoholic agents near the operating field (disinfected skin areas must be completely dry before use), metal objects on the patient's body (e.g. piercing).

Complications

Clinical complications

Complications largely depend on the minimally invasive procedure to be performed.

Complications when using the electrosurgery function

Electric shock, burns (damage under the neutral electrode, burns / corrosion at the operating field, user injuries, damage to patients / users without presumption of causes, damage to patients / users due to malfunctions), scatter energy

damage, heat treatment-related damage to non-target organs, toxicity of surgical smoke, haemorrhage, vascular complications, postablation syndrome, infection, tumour seeding

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. *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 "Preparation prior to mechanical cleaning")!*
3. Subject the device to a visual and functional check before every use. Check continuity of the electrode from the electrode tip to the HF connection by means of an electrical continuity tester.
4. Sort damaged or faulty instruments and replace them.

in the application:

1. Take care to use devices 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.
3. Compliance with good clinical practice and required precautions is an absolute necessity. Deep wound infections are post-interventional complications. Their elimination requires surgical interventions.
4. Introduce the instrument carefully through the trocar sleeve. This avoids damage on the distal end.

in combination with electrical current:

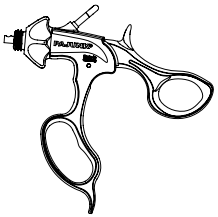
1. Special care is required when using electrosurgery for patients with internal or external pacemakers or other active implants. Interference generated when using electrosurgical units may cause the devices, such as a pacemaker, to change to asynchronous mode or to get blocked. Please obtain information from the manufacturer of the pacemaker or from the cardiology department of a hospital when the use of electrosurgical units on a patient with pacemaker is planned.
2. Deactivate the automatic switch-on mode of the HF generator.

3. The medical devices may not be used directly next to other devices or in a pile with other devices. If such use is inevitable, check whether the medical devices work properly in the intended configuration.
4. HF devices may affect the function of the monitors used in the procedure. The corresponding electrodes must be placed as far as possible from the treated area.
5. Use the instrument only if the rated voltage specified for the instrument is the same or higher than the maximum output voltage of the HF generator.
6. If the instrument is activated, hold it so that you always see the end you are working with. Before switching on the HF device, make sure that the end of the instrument does not touch conducting accessories or liquids.
7. Be aware of the safety risks caused by accumulation of leakage currents if several individual devices are connected to each other. This increases the probability of a risk of tissue damage.
8. The conductible parts of electrodes and the connectors for any application parts (including neutral electrode) must not get in contact with other conductible parts (including earth).
9. If it is not possible to exclude contact with active instruments during endoscopic procedures, use isolated accessories. To avoid short circuits, keep a sufficiently large safety distance.
10. Use the lowest possible setting of the output power for each indication.
11. Regularly check accessories, in particular, live parts and endoscopic accessories.
12. For safety reasons, make sure that the connected supply line does not get in contact with the patient.

⚠ *further warning indications:*

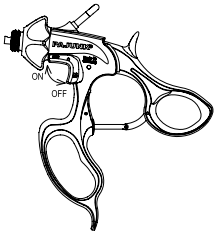
1. When using multiple components, familiarise yourself with their operation before use by checking connections and passages.
2. You must routinely take general precautions for handling blood and body fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.

Function



1292-30-00 ErgoFlex

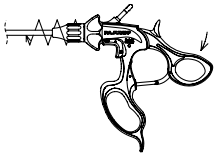
The jaw may be opened and closed by means of the two gripping rings. The spring integrated in the handle makes it easier to open the jaws. The large opening angle of both gripping rings allows adaptation and use of disposable instruments of the 1293 series. When the jaws are firmly closed, the brake function on the rotation wheel is activated, which prevents the chuck from turning.



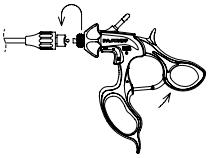
1292-30-10 ErgoGrip

The same function as 1292-30-00 but with continuous locking function. The locking function can be activated by pressing the area marked with ON. In this position, the jaws can be closed; opening the jaws is not possible. By pressing the area marked with OFF, you can generally deactivate the locking function or release the locked condition so that the jaws can be opened. When the jaws are firmly closed, the brake function on the rotation wheel is activated, which prevents the chuck from turning.

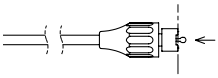
Dismantling



Secure the instrument against twisting by closing the handle. Now unlock the system by unscrewing the black union nut. The union nut must be unscrewed completely.

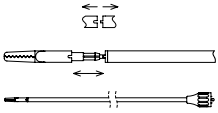


The handle must be opened completely to pull handle and guide tube apart. Now you can remove the unit, which consists of guide tube with inserted and locked instrument insert (diameters: 5 or 10 mm) or non-dismountable instrument attachment (diameter: 3 mm), from the handle. In order to do this, the jaw must be completely closed. Now remove the flattened end of the pull rod from the corresponding receptacle of the completely open handle. This works best when the white marking on the rotating ring of the handle is at 12 o'clock and the flattened part of the pull rod is also vertical.



a) Instrument inserts with diameters 5 mm and 10 mm: The insert can be released from the guide tube by pressing onto the flattened end of the insert. This works best by pressing the insert onto a tabletop.

b) Instrument attachments with diameter 3 mm: These attachments cannot be disassembled, i.e. guide tube and insert are an inseparable unit.

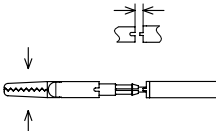


a) Instrument inserts with diameters 5 mm and 10 mm: After loosening the instrument insert from the guide tube, the insert can be pulled out the guide tube. The instrument is now completely disassembled into its three parts: handle, guide tube, instrument insert.

b) Instrument attachments with diameter 3 mm: not dismountable.

The instrument is now completely disassembled into individual parts: handle and instrument attachment.
For cleaning the instrument attachments with a diameter of 3 mm, a high-pressure cleaning adapter with Luer-Lock connection (art. no. 1292-43-98) is available.
Now clean the components according to the instructions in chapter "Processing". Perform maintenance according to the instructions in chapter "Maintenance, inspection and care".

Assembly

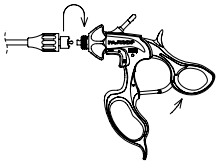


a) Instrument inserts with diameters 5 mm and 10 mm: Push the insert completely until the stop into the guide tube. Make sure that the lug on the guide tube engages in the corresponding groove on the instrument insert. This is achieved by pushing the two parts against each other while simultaneously twisting them. Both parts are now connected with rotation lock.

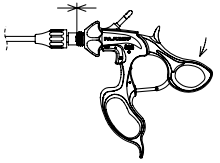
b) Instrument attachments with diameter 3 mm: These attachments cannot be disassembled, i.e. guide tube and insert are an inseparable unit.

For MonoTip II, see XS190133

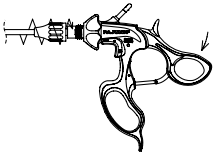
For MultiTip II, see XS190242



Now connect the unit, which consists of guide tube with inserted and locked instrument insert (diameters 5 or 10 mm) or non-dismountable instrument attachment (diameter: 3 mm), to the modular handle. In order to do this, the jaw must be completely closed. The flattened end of the pull rod is clipped in the corresponding receptacle of the completely open handle. This works best when the white marking on the rotating ring of the plastic handle is at 12 o'clock or the button of the axial metal handle points upwards and the flattened part of the pull rod is also vertical.



The clipped overall system is now centred by closing the handle.



To firmly lock the system, close it and then tighten the black union nut. Now the instrument is ready for use.

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-cleaning 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. Use cleaning adapter 1292-43-98 to clean and disinfect 3-mm instruments.

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.

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.

Storage / operating / transport conditions

Environmentally-friendly operation / storage

Atmospheric conditions

	Temperature limit	10 °C to 30 °C
	Humidity limitation	20 % to 65 % (non-condensing)
	Pressure range	700 hPa to 1060 hPa
	Keep dry	
	Keep away from sunlight	

Transport conditions and environmentally friendly transport

Atmospheric conditions

	Temperature limit	10 °C to 30 °C
	Humidity limitation	20 % to 65 % (non-condensing)
	Pressure range	700 hPa to 1060 hPa
	Keep dry	
	Keep away from sunlight	

Under normal, foreseeable environmental conditions, there are no known significant interactions or possible damages caused by magnetic fields, external electrical influences, electrostatic discharge, pressure or pressure changes, thermal ignition sources and accelerations.

General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

 *BF-type application part*

 *Dispose of all components and materials sorted and in an environmentally friendly way or have them recycled. If the medical device is no longer used, it must be disposed of according to the country-specific environmental regulations.*

 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
- REF Item number
- Do not use if package is damaged
- Keep dry
- Humidity limitation
- Caution
- Protection against electric shock, type BF
- Date of manufacture
- LOT Batch code
- Non-sterile
- Keep away from sunlight
- Keep away from sunlight
- Temperature limit
- Pressure range
- Consult instructions for use
- Rx only Caution: The sale of this device and its prescription by a physician are subject to legal restrictions
- Do not dispose of with domestic waste
- Advice
- Information
- CE 0124 "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.
- Consult instructions for use (ISO 7010-M002)
- QTY Quantity
- Translation
- MD Medical device
- UDI Unique device identification

CE 0124

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