PAJUNK®

EcoHF-Grip

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 EcoHF-Grip is a reusable handle with HF connection without attachment. The 2002 series is designed for use with trocar sleeves having a diameter of 5 mm.

Available versions:

REF *2002-00-00 Handle with HF connection without attachment, 340 mm*
2002-00-01 Handle with HF connection without attachment, 440 mm

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

Electrodes 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.

The maximum operating voltage is 1.5 kVp (3000 Vss).

Please note the instructions for use of the HF generator.

Use only PAJUNK® electrode tips of the 2002-00-xx series.

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

Application of high-frequency alternating current for monopolar cutting and/or coagulation of soft tissue, ablation.

Indications

Minimally invasive surgery.

Contraindications

Relative: liver cirrhosis, previous hepatectomy, portal hypertension, titanium implants, disinfection using alcohol/mineral spirits, implanted electronic devices (e.g. pacemakers, ventricular support systems, neurostimulators): malfunctioning!, body piercing

Absolute: spray coagulation, lack of basic knowledge (users), ignorance and carelessness regarding the usual safety protocols

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

Complication

Post-ablation syndrome, treatment failure, infections, bleeding, vascular complications, pneumothorax, haemobilia, neutral electrode burns, fulminant liver failure, tumour cell scatter, injuries caused by leakage current, organ perforation, patient morbidity and mortality, burns to intra-abdominal

tissues and organs, thermal damage, incorrect use of instruments, underestimation of the ablation area, miscalculation of the coagulation threshold, severe electric shock, fire in the operating room, smoke inhalation, gene mutations, burns elsewhere, burns due to capacitive coupling

Allergic reactions (Ni)

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. 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 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.
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:*

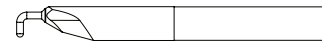
1. Special care is required when using electrosurgery for patients with internal or external pace-makers or other active implants. Interference generated when using electrosurgical units may cause the devices, such as a pace-maker, to change to asynchronous mode or to get blocked. Please obtain information from the manufacturer of the pace-maker or from the

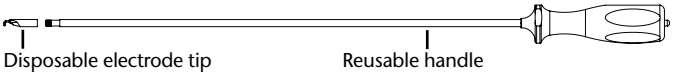
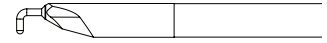
cardiology department of a hospital when the use of electrosurgical units on a patient with pace-maker is planned.
2. Deactivate the automatic switch-on mode of the HF generator.
3. The medical devices may not be used directly next to other devices or in a pile with other devices. If such use is inevitable, 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 bodily fluids when using and disposing of the device, due to the risk of contact with blood-borne pathogens.

Assembly/disassembly

Disassembly:	
	1. Unscrew the disposable electrode tip in anti-clockwise direction from the handle. The instrument is now completely disassembled into individual parts.
	ⓘ Properly dispose of the disposable electrode tip. Reprocess the handle in accordance with the reprocessing instructions.

Assembly:	
 Disposable electrode tip — Reusable handle	
	1. Screw the disposable electrode tip clockwise onto the handle.
	2. The electrode tip must be completely assembled. No metal of the thread should be visible. There must be no gap between electrode tip and handle as this can lead to a poor electrical connection and thus electrical safety is not guaranteed. Check that handle and electrode tip fit. The tip must be screwed tight.
	Completely assembled handle with electrode tip

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.

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 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
REF Catalogue number	Rx only Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)
Do not use if package is damaged	Do not dispose of with domestic waste
Keep dry	Advice
Humidity limitation	Information
Caution	CE 0124 Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body
Protection against electric shock, type BF	Consult instructions for use (SO 7010-M002)
Date of manufacture	QTY Quantity
LOT Batch code	Translation
NON STERILE Non-sterile	MD Medical device
Keep away from sunlight	
Temperature limit	
Pressure range	

CE 0124

XS190298B_Englisch 2020-01-21

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