PAJUNK®

MonoTip II Disposable Inserts for the Economic Laparoscopic Instrument System

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.

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, damage or loss of sterility.

Only devices in perfect condition, which are within the sterile expiry date marked on the label, in undamaged packaging, may be used.

Device description / compatibility

STERILE EO REF 1293-53-xx series, 1293-93-xx series, 1293-95-xx series

The MonoTip II inserts are ready for use together with a reusable handle system.

Modular manual instruments with optional electrosurgery function, consisting of handle, shaft tube, pull rod and instrument insert. Handles, shaft tubes and pull rods can be reused; the MonoTip II inserts of the 1293-53-xx, 1293-93-xx and 1293-95-xx series are for single use (the economic instrument system for laparoscopic surgery).

Compatibility overview:

Available instrument inserts	Compatible handles	Compatible pull rods	Compatible shaft tubes
1293-53-xx 1293-93-xx MonoTip	1292-30-00 ErgoFlex	1293-20-xx 1293-21-xx	1293-15-05 1293-16-05
	1293-10-00 1293-10-20 Standard	1293-17-xx 1293-18-xx	1293-15-05 1293-16-05
1293-95-xx MonoTip II	1292-30-00 ErgoFlex	1293-22-05 1293-23-05	1293-13-05 1293-14-05

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

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.

Intended use

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

Target user group

Medical specialist staff only; surgeon

Target patient population

Adults and children

Indications

Laparoscopy

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 laparascopic 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 sterile device:*

This is a disposable medical device for use on one patient only!

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.

⚠ *in the application:*

1. Compliance with good clinical practice and required precautions is an absolute necessity. Deep wound infections are post-interventional complications. Their elimination requires surgical interventions.
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. Take care to use instruments of suitable dimensions (diameter, length), especially when treating obese patients.
4. Introduce the instrument carefully through the trocar sleeve. This avoids damage on the distal end.

⚠ *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.

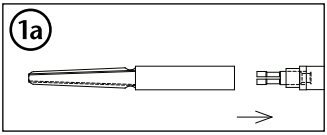
⚠ *in combination with electrical current*

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 to other metal instruments in the surgical area.
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.

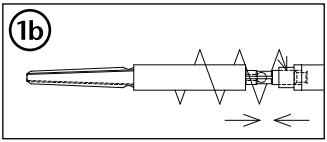
Sequence of use

Use the assembled instrument according to the selected indication (normally using a port/trocar sleeve). Disassemble after use. Safely dispose of disposable components. Reprocess reusable components.

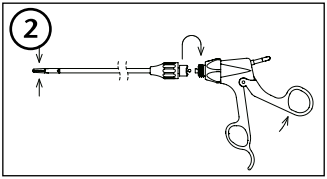
Assembly

1. 

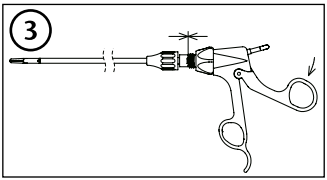
a) Attach the disposable insert to the pull rod (snap lock). With movable inserts (scissors, clamps), this is only possible when closed.



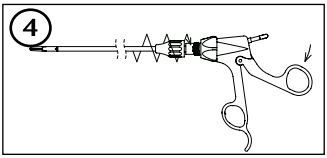
b) Now insert this unit into the guide tube and screw the insert tightly into the guide tube by means of the thread.

2. 

Now the unit, which consists of guide tube with inserted and screwed insert, is connected to the modular handle. In order to do this, the jaw must be completely closed. The 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.

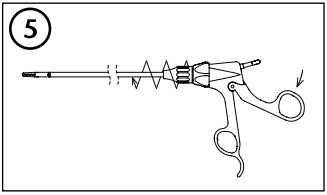
3. 

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

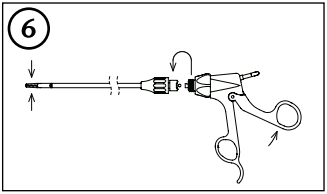
4. 

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

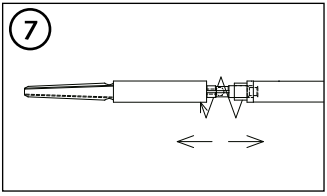
Dismantling

5. 

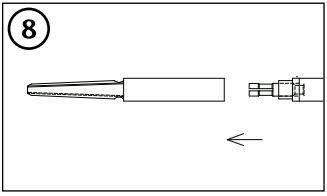
Secure the instrument against twisting by closing the handle. Now unlock the system by unscrewing the black union nut. The union nut must be unscrewed completely.

6. 

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 screwed insert, from the handle. In order to do this, the jaw must be completely closed. Now remove the 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.

7. 

The closed disposable scissors insert can now be unscrewed from the guide tube and pulled out the guide tube together with the pull rod.

8. 

Now the disposable insert can be removed from the pull rod and disposed of properly.

Operating and storage 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.#

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


Use-by date

Catalogue number

Sterilized using ethylene oxide

Do not resterilize


Do not use if package is damaged


Keep dry


Humidity limitation


Do not re-use


Caution


Date of manufacture

Batch code


Keep away from sunlight


Temperature limit


Translation


Pressure range

Unique Device Identifier


Consult instructions for use

Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)


Do not dispose of with domestic waste


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.


Consult instructions for use (ISO 7010-M002)

Does not contain phthalates

Does not contain natural rubber latex

Quantity

Medical device


Single Sterile Barrier system with protective packaging outside


Single Sterile Barrier system

CE 0124

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