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Reusable Instrument Lines

⚠ Important

Before using these products, please read the following information thoroughly!

⚠ Warning

Reusable Ackermann products are delivered unsterile, indicated on the device label by the following symbol:

NON STERILE

Prior to their first use, the devices need to be cleaned and sterilized as described in the reprocessing section of this document.

⚠ Warning

The instruments may only be used by trained and, if applicable, instructed physicians. Disinfection, cleaning and sterilization may only be performed by specially trained medical personal.

Intended Use

The Ackermann Monopolar Laparoscopic Instruments are intended to be used as active electrosurgical devices where monopolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cut or coagulate selected soft tissue.

Contraindications

The devices are not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

Contraindications to Endoscopic Procedures, not necessarily monopolar Coagulation included

As identified in the Manual of Endoscopy available from the American Association of Gynecologic Laparoscopists. The presence of large pelvic or pelvic-abdominal masses, hypovolemic shock and severe cardiac decompensation.
Also, intestinal obstruction and marked bowel distention, increase possibility of pelvic and abdominal adhesions.
A significantly elevated diaphragm contra-indicates the use of insufflation which may be necessary for proper surgical visualisation and may increase the chance of inadvertent bowel injury.
Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.

⚠ Caution

Please refer to the labelling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

⚠ General Safety Precaution

Improper use of electro surgical equipment and accessories may pose a significant health risk to the patient, user or third party. Strict adherence to the intended use and safety precautions as well as a thorough understanding of biophysical principles of electro surgery is essential for the safe use of the devices! In this regard, the following safety measures shall always be taken into account:

- Always select the lowest possible power setting that provides the desired effect
- Use brief intermittent activation
- Do not activate in close proximity or direct contact with other instruments especially if they are made of metallic materials
- In order to minimize the chances of direct trauma; activate the electrode only when whole tissue is in the field of vision
- Do not activate in open circuit
- Choose the proper current waveform mode. In monopolar electrosurgery, either the cutting or coagulation waveform can be used to achieve a cutting effect or fulguration effect
- If available, use electrosurgical accessory safety equipment, such as active or return ground electrode monitoring systems when possible

⚠ Device specific Warnings & Precautions

The devices are indicated for a maximum power output of 450 Watts / 2.000 Vpeak. Excceeding the indicated maximum power output may result in serious burns and life threating injuries to the patient.
It is important to ensure that all active accessory and devices used in combination, such as neutral electrodes, high frequency cables and generators are suitable in terms of their respective dielectric strength.
Extreme care should be taken when handling instruments with insulation. Damage to the insulation may result in patient/ user injury. Prior to every use of the devices, the active insulation should be inspected carefully in regard to damages or inhomogeneity.
Do not try to modify the instrument. Do not try to repair the electrical insulation.
Do not place the instrument on the patient when not in use. Place the instrument in an insulated support or on a clean, dry, visible and non-conductive surface in order to avoid accidental electrical injuries.
After use, the temperature of the active electrode can remain high enough to cause burns to the patient user or third party, even when the electrical current is turned off.
Activating the electrode in the air when not in use will create an "open" circuit, which can also result in a capacitive coupling effect. Capacitive coupling is increased by open circuits, use of 5-mm cannulas (versus 10 mm), and higher generator voltages. This situation can be avoided by using brief intermittent activation that allows normal tissue to remain cool.

⚠ Risk related to the Application

- Thermal damage may cause carbonization at the excision margin, vessel thrombosis, and collagen denaturation. Therefore careful consideration regarding the advantages and suitability of the intended application is recommended
- Low frequency current my cause electrolysis at the interface between active electrode and tissue. Chemical effects of electrolysis disappear at higher frequencies
- A direct or low frequency current can depolarize cell membranes and cause neuromuscular excitation
- If the active electrode cable comes in close proximity to the patient's body, current leakage may result in a burn
- Bowel preparation is important if it is anticipated that the large bowel is at risk
- The chances of direct trauma are increased during laparoscopic surgery because surgeons are limited to visualization in only two dimensions, with their hands generally dissociated from their eyes, especially when operating on mobile organs. In order to minimize the chances of direct trauma; activate the electrode only when whole tissue is in the field of vision
- Do not use electrosurgical instruments on patients with pacemakers
- Do not use in presence of flammable liquids or anaesthetics

⚠ Risk related to interference with HF-Accessory & other Combination Devices

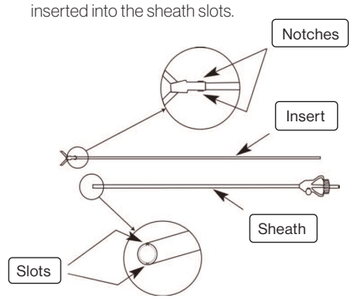
- Avoid hybrid trocar sleeves. The use of non-metal trocar cannulas can reduce the risk of capacitive coupling
- Apply the patient return electrode according to the recommendations of the generator manufacturer
- The entire surface of the neutral electrode should be securely connected to the patient's body and as close as possible to the surgical field
- The patient should not be in contact with grounded metal parts or parts having an appreciable capacity with respect to the ground (for example operating table, supports, etc.). Antistatic wrapping is recommended in this case
- Skin to skin contact (for example between the patient's arms and body) must be avoided, for example by separation with dry gauze
- Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator.

Preparation of the Device

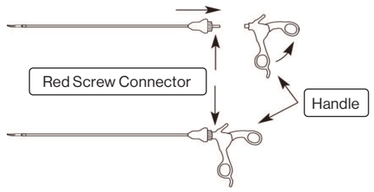
Assembly and Disassembly

Seculock™

1. Push the insert into the handle's sheath such that the insert fully seats into the sheath. Some rotation of the tip may be necessary to align the tip notches and outer sheath slots.
2. While holding the sheath, rotate the insert, with jaws closed counter clockwise 45° until tight. The device cannot be assembled further if the tip is not seated correctly. If the insert spins more than 45°, ensure the notches are fully inserted into the sheath slots.



3. Open the handle completely and insert the sheath assembly into the handle. Tighten the sheath by turning the red coloured screw connector. The jaw tips must be closed to ensure proper fit into handle.



4. To disassemble, open the handle completely. Loosen the sheath by turning the red connector. Then slide the sheath away from handle. While holding the sheath, rotate the insert clockwise 45° until loosened. Slide the insert from sheath.
5. Clean and sterilize insert, sheath and handle immediately

⚠ Limitations on Reprocessing

The reusable surgical instruments are designed for repeated use. The service life of the instruments results from reprocessing and handling. Therefore, a limit for the number of reprocessing cycles cannot be specified. Before each use, the product must be checked for function and damage. Damaged products must be disposed of.

⚠ Warning

If the instruments are used on patients infected with prion-based diseases (e.g. CJD) or HIV, the instrument must not be reused. Even after reprocessing and sterilization, the risk of cross-contamination cannot be eliminated and the instrument must be destroyed.

Inspection before Use

⚠ Warning

Before operating the instruments, a visual inspection and a functional test must be carried out in accordance with section "Functional control and maintenance of the products in the reprocessing cycle according to DIN 96298-4". Non-functional instruments must be discarded.

Reprocessing Instructions

⚠ Warning

Always ensure that the products are used and reprocessed by qualified personnel with appropriate experience in hospital hygiene and sterilization techniques. To ensure safe and effective reprocessing of the products, the following instructions have been validated by the manufacturer for effectiveness and compatibility with the instruments. It is the responsibility of the end user to ensure that cleaning and sterilization is indeed performed with appropriate equipment, materials and personnel to achieve the desired result. Any deviation from these instructions should be evaluated for effectiveness and possible adverse consequences.

⚠ Warning

All reusable Ackermann products must be subjected to reprocessing as described in the following sections before being used for the first time. Follow the instructions and warnings of the manufacturers of the decontamination, disinfection and cleaning agents to be used.

Preparation before Use

⚠ Warning

Ackermann reusable products are supplied non-sterile and must be cleaned and sterilized before first use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be disposed of before sterilization.

Cleaning

⚠ Warning

Improper cleaning, rinsing, and drying can result in potentially hazardous residues or inadequate sterilization.

Pre-Cleaning

Instruments, or fully disassembled instruments if applicable, must be brushed under cold water until all visible contamination is removed. If the instrument has a flushing port, the lumen of the shaft must be flushed for at least 10 seconds through the flushing port with a water jet gun (static pressure greater than 4 bar) after manual brushing. The instruments are then treated in a 0.5% alkaline enzymatic (e.g. Neodisher® Mediclean forte) ultrasonic bath for 10 minutes. Finally, rinse again for 30 seconds with a water jet gun.

Automated Cleaning[1]

The automated cleaning was validated with Neodisher® Mediclean forte (alkaline-enzymatic: pH-value 10,4 – 10,8) for cleaning and Neodisher® Z (acidic: pH-value 3,0 – 2,6) for neutralization.

Step	Parameter	
Pre-rinse	Rinsing temperature	Cold tap water
	Exposure time	180 secs. / 3 mins.
Cleaning	Cleaning temperature	55°C
	Exposure time	600 secs. / 10 mins.
	Detergent	Alkaline-enzymatic (e.g. Neodisher® Mediclean forte)
	Concentration	0.50%
	Rinsing temperature	Cold DI water
	Exposure time	60 secs. / 1 min.
	Neutralizing agent	acidic (e.g. Neodisher® Z)
	Concentration	0.10%
Rinse	Rinsing temperature	Cold DI water
	Exposure time	120 secs. / 2 mins.

Thermal disinfection	Disinfection temperature	90 °C (A0 3000)
	Exposure time	300 secs. / 5 mins.
Drying	Drying	60 mins. / 1 hour

Steam Sterilization[2]

Procedure	Triple fractionated pre-vacuum
Temperature	min. 132°C
Duration	min. 3 mins.
Drying time	min. 20 mins.

The instructions provided above have been validated as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

[1] Validated with washer-disinfector Miele PG 8535

[2] Validated with steam autoclave Lautenschläger ZentraCert

Function Control and Maintenance of the Products in the Reprocessing Cycle acc. to DIN 96298-4

⚠ Warning

If the product is damaged or suspected of being damaged, do not attempt to repair the product yourself. Do not reuse damaged instruments.

⚠ Warning

If a product-specific inspection or maintenance is required, the relevant information can be found in the instruction of use for the respective product.

Maintenance

Maintenance is always performed prior to functional testing. Oils can be applied by squeeze, spray, or pipe. Oil the joints and sliding surfaces in a directed way, then move the joint and sliding surfaces several times and wipe off excess oil with a lint-free cloth.

Visual and Fuctional Inspection

Products marked as nonfunctional must be discarded. The following tests and maintenance must be performed by qualified personnel.

Visual Inspection

Visual inspection for cleanliness

- The instruments should be free of macroscopic contaminants.

Visual control for missing parts

- All parts such as screws, pins, springs, valves, hooks, etc. must be present. If this is not the case, the whereabouts of the missing parts must be clarified.

Visual control for breakage

- If parts (such as tips, teeth, springs, working ends, TC inserts) are missing due to material breakage, the whereabouts of the missing parts must be clarified.

Check for deformation

- Instruments with deformed working ends, cutting edges, tips, etc. need to be sorted out.

Visual inspection for corrosion

- Instruments with visible corrosion in the form of pitting, fretting, stress or crevice corrosion must be sorted out.

Visual inspection for discoloration

- Instruments with a discoloration must be sorted out.

Visual inspection for cracks

- Instruments with a crack must be sorted out.

Visual inspection of coatings

- Coatings must be free of imperfections and notches. If damage to a coating is detected, this instrument must be sorted out.

Visual inspection of markings

- The marking must be legible. If the instrument is marked with a machine-readable marking, this must be readable with an appropriate scanner. If the marking is no longer legible, the instrument must be sorted out.

Fuctional Check

- The instruments must run smoothly and without play.
- Any ratchet, if any, must hold securely in any position.
- The working ends must lie congruently on top of each other.
- The teeth, if any, must interlock without hooking.

Labeling and Storage

Labeling

⚠ Warning

Please pay attention to the symbols on the product label and in this instruction for use.
Care must be taken to ensure that the instruments are fully traceable at all times.

Storage Conditions

Storage conditions can be found on the product label.

⚠ Warning

The storage area must be dust-free, low in microbiological contamination, dark and free from temperature fluctuations.

Disposal

Environmentally sound disposal enables valuable raw materials to be recycled. Dispose of the device in an environmentally friendly manner in accordance with the valid hospital guidelines.

Repairs

Despite being used as intended, medical devices are subject to varying degrees of wear depending on the intensity of use.

- Please note that repairs may only be carried out by the manufacturer or authorised personnel.
- The medical devices must be cleaned, disinfected and sterilised before being sent in for repair. Soiled or contaminated medical devices must not be sent.

Additional Information

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

Packaging

Packaging suitable for steam sterilization must comply with the requirements according to ISO 11607 / ANSI / AAMI ST79 / AAMI TIR12, for example, disposable sterilization packs (single or double packs) temperature resistant up to at least 137°C (279°F) and sufficient steam permeability, which provide sufficient protection against mechanical damage, or sterilization containers which need to be maintained according to the manufacturer's instructions.

Warranty

A guarantee of two years from handover to the end customer is given for material and manufacturing defects. Transport costs and shipping risk are not assumed. In addition, the warranty stated in the General Terms and Conditions applies. This warranty does not apply to instruments that have been repaired, modified or improperly handled by unauthorised persons. In this case, no liability is assumed for the operational safety of the instrument either. In addition, the warranty becomes null and void.

⚠ Warning

Risk of infection due to non-sterile instruments.

- Prepare the instrument before returning it to the manufacturer.
- Return the reconditioned instrument in its original packaging to the manufacturer.

Contact

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Appendix

All product codes covered by these instructions are listed on the following pages:

Description of Symbols used

	Legal manufacturer
	Manufacturing date
LOT	Batch code
REF	Product number
NON STERILE	Non-sterile
	Do not use if package is damaged
	Keep dry
MD	Medical device
UDI	Unique device identifier
	Consult instruction for use
	Caution
	Keep away from sunlight
Rx ONLY	Only by prescription from medical doctor
QTY	Quantity

CE 0483

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