


**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:



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

**INTENDED USE**

The Ackermann monopolar urology electrodes with active or passiv working element are designed for operative and diagnostic urology surgeries to be used for coagulating and dissecting. Monopolar coagulation current may be selectively applied to the tissue as indicated. Coagulation is achieved by using electrosurgical power under laparoscopic visualisation. The monopolar electrodes are intended to be used with the outputs of compatible electrosurgical generators. Do not exceed 450 Watts in the monopolar coagulation mode of a generator.

**CONTRAINDICATIONS**

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 INCLUDE**

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 AND PRECAUTIONS**

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.

**RISKS 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 may 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.

**RISKS RELATED TO INTERFERENCE WITH HF-ACCESSORY AND 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.

**REPROCESSING**

**WARNING**

The following instructions only apply to reusable Ackermann products.

Please note that any deviation from these instructions, including the use of cleaners / detergents not specifically indicated in these instructions will require an evaluation of device-specific efficacy and suitability of the actually performed cycle. Respective evaluation usually requires equipment qualification and device specific performance qualification / Validation.

**LIMITATIONS ON REPROCESSING**

With proper cleaning, sterilization, and handling, the reusable Ackermann products can be used a maximum of 50 times. Careful handling and strict adherence to these instructions is essential to ensure safe usage up to 50 times. Continued use beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

Failure to observe the following reprocessing instructions or improper handling of the devices may significantly increase wear and thus reduce the service life of the devices. Carefully inspect the devices prior to each use in regard to functionality and insulation (see also section testing and inspection).

**REPROCESSING INSTRUCTIONS**

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard of hospital hygiene and sterilization technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilization is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

**WARNING**

Before initial use and any subsequent use, all reusable Ackermann products have to be subjected to reprocessing as described in the following sections. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.

**PREPARATION PRIOR TO FIRST USE**

The reusable Ackermann products are delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use.

The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

**PREPARATION AT THE POINT OF USE PRIOR TO REPROCESSING**

Remove all traces of contamination and disassemble the instrument immediately after use to avoid incrustation. Do not use fixative agents or hot water (>40°C). Avoid using a metal brush, steel wool or other cleaning devices containing metal in order to avoid risk of insulation damage or corrosion. Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container.

**CLEANING**

**WARNING**

Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or in inadequate sterilization.

**MANUAL PRE-CLEANING**

The fully dismantled instruments shall be brushed under cold water until all visible contamination is removed. After manual brushing, rinse the lumen of the sheath via its flushing port with a water jet pistol (static pressure above 4 bar) for at least 10 seconds.

**AUTOMATED CLEANING**

Associated parts are to be stored together in order to facilitate a subsequent identification. Make sure that instruments do not contact each other. Devices from different materials such as titanium, brass, aluminium, stainless steel, etc. need to be cleaned separately in order to avoid formation of a rust film. Composite instruments particularly stainless steel combined with ceramics) need to be placed with sufficient distance to other products so they do not break due to the pressure of different thermal expansions.

**RECOMMENDED PROCESS-EQUIPMENT**

- ▶ Washer: Miele Type G7836 CD
- ▶ Cleaners: TWIN PH10 and TWINZYME (Borer Switzerland)

**AUTOMATED CLEANING CYCLE**

- ▶ Two-component alkaline-enzymatic Cleaning Program:
- ▶ 3 min pre washing with cold tap Water
- ▶ Drain
- ▶ 10 Min washing at 45°C w tap water and
  - ▶ 0,3% dosing TWIN PH10 at 35°C
  - ▶ 0,2% dosing TWIN ZYME at 40°C
- ▶ Drain
- ▶ 2 min intermediate rinsing with warm deionised water (>30°C)
- ▶ Drain
- ▶ 1 min intermediate rinsing with cold deionised water
- ▶ Drain
- ▶ 5 min Thermal disinfection at >90°C
- ▶ 30 min Drying

**MAINTENANCE**

Apply a small amount of high-grade surgical lubricant on all joints or other moveable parts which are supposed to move smoothly. Sort out all blunt or damaged instruments. Clearly damaged instruments (cracks on the insulation, breakage, strongly bleached polymer handles or coatings) are NOT to be reused but repaired or disposed of.

**TESTING AND INSPECTION**

Jointed instruments are to be tested for ease of movement (avoid too much backlash). The functionality of ratchet mechanisms needs to be checked. All instruments: visually check for damage and wear. Blades should be even and without notches. Long and narrow instruments (especially jointed instruments) should be particularly checked for damages. If instruments are part of a larger set they are to be checked together with all associated components.

**WARNING**

In case of present or suspected damage to the devices, do not try to repair the instrument. Avoid any further use of damaged instruments!

**PACKAGING**

Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607 / ANSI/ AAMI ST79 / AAMI TIR12:2010, 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.

**STERILIZATION**

**WARNING**

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Sterilization is preferably performed by steam sterilization. The following cycles has been validated in accordance with internationally harmonized standards in regard to its suitability and efficacy for the devices fractionated pre-vacuum Cycle

- 132°C, 4 mins (wrapped), minimum 20 mins drying or
- 134°C, 4 mins (wrapped), minimum 20 mins drying

**STORAGE**

For storage conditions, please refer to the information on the product label.

**ADDITIONAL INFORMATION**

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













**APPENDIX**

All product codes covered by these instructions are listed in the following table:

MONOPOLAR UROLOGY ELECTRODES <span style="float:right">REF</span>		
32-4150	32-4260DB	32-4295DB
32-4155	32-4261	32-4300
32-4200	32-4261DB	32-4300DB
32-4201	32-4263	32-4301
32-4201-3	32-4263DB	32-4302
32-4202	32-4264	32-4303
32-4203	32-4264DB	32-4304
32-4235	32-4265	32-4310
32-4235DB	32-4265DB	32-4310DB
32-4240	32-4266	32-4311
32-4240DB	32-4266DB	32-4312
32-4245	32-4267	32-4313
32-4245DB	32-4267DB	32-4314
32-4250	32-4268	32-4315
32-4250DB	32-4268DB	32-4315DB
32-4255	32-4269	32-4320
32-4255DB	32-4269DB	32-4320DB
32-4256	32-4270	32-4325
32-4256DB	32-4271	32-4325DB
32-4257	32-4271DB	32-4330
32-4257DB	32-4272	32-4330DB
32-4258	32-4272DB	32-4355
32-4258DB	32-4276	32-4360
32-4259	32-4277	32-4385
32-4259DB	32-4278	32-4385DB
32-4260	32-4279	32-4389DB
32-4260D	32-4295	32-4390DB

WORKING ELEMENTS <span style="float:right">REF</span>		
32-4215	32-4220DB	32-4365
32-4215DB	32-4275	32-4366
32-4216	32-4280	32-4530
32-4216DB	32-4285	32-4531
32-4216ECO	32-4294	
32-4220	32-4296	

**SYMBOLS USED ON LABELLING (ACC. DIN EN 980 / DIN EN ISO 15223-1)**

 LEGAL MANUFACTURER	 CONSULT INSTRUCTIONS FOR USE	 NON-STERILE	 DO NOT USE IF PACKAGE IS OPENED OR DAMAGED
 MANUFACTURING DATE	 PRODUCT NUMBER	 KEEP OUT OF DIRECT SUNLIGHT	 PROTECT AGAINST MOISTURE
 BATCH CODE	 CAUTION, CONSULT ACCOMPANYING DOCUMENTS	 PRESCRIPTION USE ONLY	 BSI ASSURANCE UK LIMITED, REGISTERED IN ENGLAND UNDER NUMBER 7805321 AT 389 CHISWICK HIGH ROAD, LONDON W4 4AL, UK