PLASTIC ENDOSCOPY INSTRUMENTS

Ackermann©

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

WARNINGS

All instruments must be cleaned, disinfected and sterilized prior to each use.
All reusable Ackermann products are shipped in nonsterile condition. Before the first use transport packaging, coarse dust/pieces of paper/packaging remains need to be removed and each product processed and sterilized according to these instructions. All products have been precleaned to an extent which allows for processing and sterilization by use of the equipment stated here. This only applies to a processing method according to these instructions within a system that has been configured and validated in compliance with ISO 17665 and in which all cleaning/disinfecting devices comply with ISO 15883.
Thorough cleaning and disinfection is crucial for an effective sterilization!
Strong cleaning agents may cause fading of markings.

Special safety precautions should be observed when using electrosurgical instruments.
►Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly.
►Avoid touching or grounding electrosurgical instruments to non-insulated instruments, scopes, trocar sleeves, etc.
►All persons using such devices should be knowledgeable in the use and handling of laparoscopic instruments, coagulation equipment, their accessories and other related equipment.
►Test all instruments, accessories and equipment prior to each use.
►Do not use electrosurgical instruments on patients with pacemakers.
►Do not use in presence of flammable liquids or anaesthetics.
►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.
►The electrode tip must always be in full view before activating power. Apply power only when electrode tip is in full contact with the tissue selected for coagulation.
►Electrode tip must not come in contact with the laparoscope or other metal instruments during use.
►Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.

LIMITATIONS ON REPROCESSING

Instruments have been validated for 50 cycles, based on an average treatment.
Products that have been marked as single-use (acc. to EN 980 2008-11/figure 5.2) MUST NOT be reprocessed! With such products materials are being used that are NOT reprocessable under normal conditions or do not withstand more than one sterilization process and, therefore, may break during surgery if reprocessed! (this applies to practically all single-use products featuring plastic components).

INTENDED USE

The Ackermann plastic endoscopy instruments are designed for plastic endoscopic surgeries to be used for cutting, preparing and grasping tissue, as well as for biopsies and suturing. 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 MONOPLOAR 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 labeling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

INSTRUCTIONS (acc. to ISO 17664) PLACE OF USE (immediately after use)

IMMEDIATELY after each use (within no more than 10 min. or before drying of contaminants) the instruments need to get disassembled and impurities removed under running water, using a soft brush or cloth which are being used solely for this purpose. NEVER use a metal brush, steel wool or other cleaning devices containing metal in order to avoid the imminent risk of corrosion.
Rinse under cold, running water until all visible impurities and contaminants have been successfully removed.

STORAGE AND TRANSPORT

Place instruments in a container; make sure that associated parts are being stored together. Keep the inside of the container moist/wet (no contaminants may dry). Reprocess all instruments soonest possible.

PREPARATION FOR CLEANING

Dismantable products are ALWAYS to be disassembled as much as possible (see IFU). Soak instruments in cold water for at least 5 min. and clean them, using a soft brush or cloth which are being used solely for this purpose. NEVER use a metal brush, steel wool or other cleaning devices containing metal in order to avoid the imminent risk of corrosion. Afterwards, wash down the entire surface of the instrument for 10s. by use of a cleaning gun (min. continuous pressure of 4 bar); articulate moveable parts constantly during the preliminary cleaning. Instruments featuring lumina and/or LuerLock flush channels are to be rinsed for an additional 10s. after visibly clear water has emerged from the ports. Place the instruments in an ultrasonic bath for 10min. (35-40kHz for min. 5min. or longer acc. to specifications). Prior to switching on the ultrasonics make sure that all lumina, sheaths, etc. are filled with cleaning fluid! Note that the preliminary cleaning – even at the use of a disinfectant – is only intended as a preparatory step and DOES NOT replace the actual disinfection!

MECHANICAL CLEANING

Associated parts are to be stored together in order to facilitate a subsequent allocation. Make sure that multiple instruments do not touch; especially different materials such as titanium, brass, aluminum, 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.
Instruments have been tested with the following devices:
►Washer-Disinfector G 7735 CD (Miele):
1. washing cycle: alkaline program (No 105)
2. washing cycle: enzymology program (No 105)
►Washer-Disinfector G 7836 CD (Miele)
1. two component alkaline/enzymatic program
2. OxiVario
►Washer-Disinfector Niagara SI PCF (Medisafe) (RECOMMENDED)
1. Cleaning process with pulsed ultrasonic irrigation
2. Cleaning process without pulsed ultrasonic irrigation
The water which is to be used needs to be sterile or nearly sterile (<10 microbes/ml) and low in endotoxins (< 0.25 units/ml). The air which is being used for drying needs to be cleaned by means of micro filters which Processing and Sterilization Instructions of Medical Devices (acc. to ISO 17664) are regularly checked and maintained. A maintenance schedule has to be documented.

DISINFECTION

Place the instruments into the disinfecting bath (Caution: products need to be fully immersed; at least 1cm below the liquid surface). Multiple instruments may not touch; especially different materials such as titanium, brass, aluminum, stainless steel, etc. need to be disinfected 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. Rinse all the lumina of the instrument at least five times using a sterile syringe (min 50ml) and disinfectant.

AFTER DISINFECTION

Remove products and rinse for at least 5 min. under running water until all disinfectant is removed from the instruments (the water which is to be used needs to be sterile or nearly sterile with <10 microbes/ml and low in endotoxins with < 0.25 units/ml). Constantly articulate moveable parts.
Rinse all the lumina of the instrument with water at least five times using a sterile syringe (min 50ml).
Disinfectants that have been successfully tested are:
1. Alkaline, Neodisher FA, pH 12.2, Dr. Weigert
2. Enzymatic, deconex 23 Neutrazym, pH 9.7, Borer
3. 2-Component Alkaline/Enzymatic, deconex TWIN PH, pH 10.9, deconex TWINZYME, pH 7, Borer
4. 2-Component Alkaline, Sekumatic FR, pH 12.1; Sekumatic OxiVario. PH 7.8; Neutralizer: Sekumatic FNZ, pH 2.2, Ecolab
5. Enzymatic; M20029 3E-Zyme Scope Plus, pH 6.1, Medisafe
6. Enzymatic + Ultrasound, M20029 3E-Zyme Scope Plus, pH 6.1, Medisafe

DRYING

After cleaning and disinfection place the instruments into suitable containers. Make sure that there is NO residue of the disinfectant. When drying as part of the cleaning/disinfection cycle is completed make sure that a temperature of 150°C/300°F is not exceeded. All operations need to take place in a clean, monitored environment!

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.

PACKAGING

Individually: a standardized packaging material may be used. The size of each bag needs to match the individual instrument so that there is no tension applied on the sealing.
Sets: sort instruments into designated trays or place on multi-purpose sterilization trays. Blades need to be protected; the weight of each tray may not exceed 8kg (18lbs). For the trays an adequate packaging procedure is to be used.

STERILIZATION

All products have been precleaned to an extent which allows for processing and sterilization by use of the equipment stated here. This only applies to a processing method according to these instructions within a system that has been configured and validated in compliance with ISO 17665 and in which all cleaning/disinfecting devices comply with ISO 15883. With the result of the sterilization process greatly depending on the equipment that is being used a sterilization validation acc. to ISO 17665 MUST be performed at the place of use prior to the first application. All products MAY be used only if the result of this validation is positive.
For the sterilization of medical devices various methods can be applied. Regarding products manufactured by Ackermann gravity steam sterilization with a fractionated process is recommended.
Temperature: 134°C (273°F)
Pressure: 3 bar
Duration: ≥ 5 min.
Please comply with all recommendations issued by the manufacturer of your sterilization device with regard to handling and loading. Instruments that are to be sterilized need to be thoroughly exposed to the steam, including inner surfaces. Before using the instruments they need to be cooled down to room temperature.
Other durations and/or temperatures may also be applied. However, when doing so deviations of parameters Processing and Sterilization Instructions of Medical Devices (acc. to ISO 17664) should be validated (Caution: contact the manufacturer of your autoclave to confirm temperatures and/or sterilization durations). Temperature inside the autoclave should not exceed 139°C/182°F. This could cause possible damage to handles, insulation or other non-metallic components. Do not sterilize using hot air or flash autoclave methods.
In case only pre-vacuum sterilization can be performed, please adhere to the following parameters:

<u>For Europe:</u> (except Switzerland and France)
Sterilizer type: Pre-vacuum
Preconditioning Pulses: 3
Preconditioning Pressure: 30 psia
Minimum temperature: 134°C
Cycle time: 5 min.
Sample configuration: Individually wrapped

<u>For Switzerland and France:</u>
Sterilizer type: Pre-vacuum
Preconditioning Pulses: 3
Preconditioning Pressure: 30 psia
Minimum temperature: 134°C
Cycle time: 18 min.
Sample configuration: Individually wrapped

<u>Others:</u>
Sterilizer type: Pre-vacuum
Preconditioning Pulses: 3
Preconditioning Pressure: 30 psia
Minimum temperature: 132°C/270°F
Cycle time: 4 min.
Sample configuration: Individually wrapped

STORAGE

Store instruments secured against mechanical damage. Use additional wrapping to protect against dust. Do not stack instruments which are packed sterile; especially do not place heavy items on top in order to avoid damage to the sterile packaging of other instruments.

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:

PLASTIC ENDOSCOPY INSTRUMENTS REF

20-2500	20-2520AXR	20-2530
20-2501	20-2520I	20-2531
20-2502	20-2525	20-2535
20-2505	20-2525-45	20-2536
20-2510	20-2526	20-2537
20-2515	20-2527	20-2538
20-2520	20-2528	
20-2520AX	20-2529	

SYMBOLS USED ON LABELLING (ACC. DIN EN 980 / DIN EN ISO 1523-1)

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE		CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DATE OF MANUFACTURE	REF	CATALOGUE NUMBER	CE 0086	BSI ASSURANCE UK LIMITED, REGISTERED IN ENGLAND UNDER NUMBER 7805321 AT 389 CHISWICK HIGH ROAD, LONDON W4 4AL, UK
LOT	BATCH CODE	NON STERILE	NON-STERILE	Rx Only	PRESCRIPTION USE ONLY

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