

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 pre-cleaned 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.

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 cardiorthoracoscopic instruments are designed for operative thoracoscopic surgeries to be used for cutting and manipulating tissue.

CONTRAINDICATIONS 

Not intended for use with patients that have allergic reactions to Ni- ; CR- steels or to brass or aluminium.

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 pre-cleaned 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:

For Europe: (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

For Switzerland and France:

Sterilizer type: Pre-vacuum

Preconditioning Pulses: 3

Preconditioning Pressure: 30 psia

Minimum temperature: 134°C

Cycle time: 18 min.

Sample configuration: Individually wrapped

Others:

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:

CARDIOTHORACOSCOPIC INSTRUMENTS 

30-3500	30-3712	30-3741
30-3505	30-3712R	30-3742
30-3510	30-3713R	30-3743
30-3515	30-3714	30-3744
30-3520	30-3714R	30-3745
30-3525	30-3715	30-3746
30-3530	30-3715R	30-3747
30-3535	30-3716R	30-3748
30-3540	30-3717R	30-3749
30-3540-33	30-3718R	30-3750
30-3540-33L	30-3719	30-3751
30-3540AAX	30-3719R	30-3751R
30-3541-33	30-3720R	30-3752
30-3542-33	30-3721R	30-3752R
30-3545	30-3722R	30-3753
30-3550	30-3723	30-3753R
30-3555	30-3723R	30-3754
30-3560	30-3724	30-3754R
30-3600	30-3724R	30-3755
30-3601	30-3725	30-3755R
30-3602	30-3725R	30-3756
30-3603	30-3726	30-3756R
30-3604	30-3726R	30-3757
30-3605	30-3727	30-3757R
30-3606	30-3728	30-3758
30-3607	30-3729	30-3758R
30-3608	30-3730	30-3759
30-3618	30-3731	30-3759P
30-3620	30-3731R	30-3760
30-3700	30-3732	30-3761
30-3700R	30-3732R	30-3762
30-3701	30-3733	30-3763
30-3701R	30-3733R	30-3764
30-3702R	30-3734	30-3765
30-3703R	30-3734R	30-3765VS
30-3704R	30-3735	30-3766
30-3705R	30-3735R	30-3766VS
30-3706R	30-3736	30-3767
30-3707R	30-3737	30-3767VS
30-3708R	30-3737R	30-3768
30-3709R	30-3738	30-3768VS
30-3710R	30-3739	30-3769
30-3711	30-3740	30-3769VS

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		CATALOGUE NUMBER		CE-MARKING
	BATCH CODE		NON-STERILE		PRESCRIPTION USE ONLY

