



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 sinuscopy punches are designed for all endoscopic sinuscopy and nasal surgeries to be used for cutting, grasping and punching biopsies, bone and ligaments.

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:

SINUSCOPY PUNCHES



22-3001	22-3052	22-3103
22-3002	22-3053	22-3104
22-3003	22-3054	22-3105
22-3004	22-3055	22-3106
22-3005	22-3056	22-3107
22-3006	22-3057	22-3108
22-3007	22-3058	22-3109
22-3008	22-3059	22-3110
22-3009	22-3060	22-3111
22-3010	22-3061	22-3112
22-3011	22-3062	22-3113
22-3012	22-3063	22-3114
22-3013	22-3064	22-3115
22-3014	22-3065	22-3116
22-3015	22-3066	22-3117
22-3016	22-3067	22-3118
22-3017	22-3068	22-3119
22-3018	22-3069	22-3120
22-3019	22-3070	22-3121
22-3020	22-3071	22-3122
22-3021	22-3072	22-3123
22-3022	22-3073	22-2720
22-3023	22-3074	22-2725
22-3024	22-3075	22-2730
22-3025	22-3076	22-2735
22-3026	22-3077	22-2740
22-3027	22-3078	22-2745
22-3028	22-3079	22-2750
22-3029	22-3080	22-2751
22-3030	22-3081	22-2755
22-3031	22-3082	22-2760
22-3032	22-3083	22-2765
22-3033	22-3084	22-2766
22-3034	22-3085	22-2767
22-3035	22-3086	22-2770
22-3036	22-3087	22-2775
22-3037	22-3088	22-2780
22-3038	22-3089	22-2785
22-3039	22-3090	22-2786
22-3040	22-3091	22-2790
22-3041	22-3092	22-2800
22-3042	22-3093	22-2805
22-3043	22-3094	22-2809
22-3044	22-3095	22-2810
22-3045	22-3096	22-2815
22-3046	22-3097	22-2823
22-3047	22-3098	22-3124
22-3048	22-3099	22-2700
22-3049	22-3100	22-2703
22-3050	22-3101	22-2705
22-3051	22-3102	22-2710

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

