



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 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

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 RE-PROCESSING

Remove all traces of contamination 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 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 / 270°F, 4 mins (wrapped), minimum 20 mins drying
- Or
- 134°C/ 273°F, 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:

SINUSCOPY PUNCHES		REF
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 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	CE-MARKING

