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:

NON STERILE

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 arthroscopic punches are designed for all endoscopic arthroscopy surgeries to be used for cutting, grasping and punching 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 REPROCESSING

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:

ARTHROSCOPIC PUNCHES

REF

17-1850	17-2025	17-2110	17-2215	17-3021	17-3058	17-3100	17-3136
17-1855	17-2030	17-2111	17-2220	17-3022	17-3059	17-3101	17-3137
17-1856	17-2035	17-2115	17-2225	17-3023	17-3060	17-3102	17-3138
17-1860	17-2040	17-2116	17-2230	17-3024	17-3061	17-3103	17-3139
17-1865	17-2045	17-2120	17-2235	17-3025	17-3062	17-3104	17-3140
17-1870	17-2050	17-2121	17-2240	17-3026	17-3063	17-3105	17-3141
17-1880	17-2055	17-2125	17-2245	17-3027	17-3064	17-3106	17-3142
17-1885	17-2057	17-2126	17-2250	17-3028	17-3065	17-3107	17-3143
17-1890	17-2060	17-2130	17-2255	17-3029	17-3066	17-3108	17-3144
17-1895	17-2061	17-2131	17-2260	17-3030	17-3067	17-3109	17-3145
17-1900	17-2065	17-2135	17-2261	17-3031	17-3068	17-3110	17-3146
17-1905	17-2066	17-2136	17-2262	17-3032	17-3069	17-3111	17-3147
17-1910	17-2070	17-2140	17-2263	17-3033	17-3070	17-3112	17-3148
17-1915	17-2071	17-2141	17-2264	17-3034	17-3071	17-3113	17-3149
17-1920	17-2075	17-2145	17-2265	17-3035	17-3072	17-3114	17-3150
17-1925	17-2076	17-2146	17-2266	17-3036	17-3073	17-3115	17-3151
17-1926	17-2077	17-2150	17-3000	17-3037	17-3075	17-3116	17-3152
17-1930	17-2078	17-2151	17-3001	17-3038	17-3076	17-3117	17-3153
17-1935	17-2080	17-2155	17-3002	17-3039	17-3077SET	17-3118	17-3154
17-1940	17-2081	17-2156	17-3003	17-3040	17-3078SET	17-3119	17-3155
17-1945	17-2085	17-2157	17-3004	17-3041	17-3080	17-3120	17-3156
17-1950	17-2086	17-2158	17-3005	17-3042	17-3081	17-3121	17-3157
17-1955	17-2090	17-2160	17-3006	17-3043	17-3082	17-3122	17-3158
17-1960	17-2091	17-2161	17-3007	17-3044	17-3083	17-3123	17-3159
17-1965	17-2095	17-2162	17-3008	17-3045	17-3084	17-3124	17-3160
17-1970	17-2096	17-2163	17-3009	17-3046	17-3085	17-3125	17-3161
17-1975	17-2097	17-2170	17-3010	17-3048	17-3086	17-3126	17-3162
17-1980	17-2098	17-2171	17-3011	17-3049	17-3087	17-3127	17-3163
17-1985	17-2099	17-2175	17-3012	17-3050	17-3088	17-3128	17-3164
17-1990	17-2101	17-2176	17-3013	17-3051	17-3089	17-3129	17-3165
17-1995	17-2102	17-2180	17-3014	17-3052	17-3090	17-3130	17-3166
17-2000	17-2103	17-2190	17-3015	17-3053	17-3091	17-3131	17-3167
17-2005	17-2104	17-2195	17-3016	17-3054	17-3095	17-3132	17-3168
17-2010	17-2105	17-2200	17-3018	17-3055	17-3096	17-3133	17-3169
17-2015	17-2105/6	17-2205	17-3019	17-3056	17-3098	17-3134	17-3170
17-2020	17-2106	17-2210	17-3020	17-3057	17-3099	17-3135	17-3171

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 DAMAGAED
MANUFACTURING DATE	PRODUCT NUMBER	KEEP OUT OF DIRECT SUNLIGHT	PROTECT AGAINST MOISTURE
BATCH CODE	CAUTION, CONSULT ACCOMPANYING DOCUMENTS	PRESCRIPTION USE ONLY	CE-MARKING

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