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.

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 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.

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:

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 1523-1)

	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE		CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DATE OF MANUFACTURE	REF	CATALOGUE NUMBER	CE	CE-MARKING
LOT	BATCH CODE	NON STERILE	NON-STERILE	Rx Only	PRESCRIPTION USE ONLY

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