LAPAROSCOPIC TROCARS & OBTURATORS

Ackermann©

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 trocars are designed for general endoscopic/ laparoscopic surgeries to be used as sealing port during the obturators are used through the trocars to access to the abdomen.

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:

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:

TROCARS REF

10-1000	10-1012-150	10-1065
10-1001	10-1012-20	10-1066
10-1002	10-1012-250	10-10660
10-1004	10-1012-60	10-1067
10-1005	10-1012S	10-1067-05
10-1006	10-1014	10-1067-10
10-1007	10-1015	10-1067-15
10-1007THC	10-1016	10-1067-20
10-1008	10-1016-150	10-1067-501
10-1008-100	10-1017	10-1067-502
10-1008-200	10-1017-125	10-1067-505
10-1008THC	10-1024THC	10-1067-506
10-1008V	10-1024VTHC	10-1100
10-1008VTHC	10-1050	10-1105
10-1008VTHM	10-1051	10-1105-80
10-1010	10-1052V	10-1115
10-1010-120	10-1052VTHC	10-1115THC
10-1011	10-1053	10-1115THC-6
10-1011OV	10-1054	10-1116
10-1012	10-1055	10-1116THC
10-1012-12,5	10-1055BL	10-1117
10-1012-120	10-1059	10-1117THC
10-1012-140	10-1060	10-1118
10-1012-15	10-1064	

OBTURATORS REF

10-1033	10-1039-10	10-1045
10-1031	10-1039-110	10-1046
10-1032	10-1039BL	10-1047
10-1032-07	10-1040	10-1047-12,5
10-1032-10	10-1040-10	10-1047-150
10-1032-12	10-1041	10-1048
10-1032-15	10-1042	10-1049
10-1034	10-1043	10-1049-13
10-1034BL	10-1044	10-1049-150
10-1035	10-1044-120	10-1049BL
10-1036	10-1044-13	10-1068
10-1037	10-1044-150	10-1069
10-1038	10-1044-200	10-1069-12,5
10-1039	10-1044BL	10-1069-13

REDUCER REF

10-1021-101	10-1021-200	10-1075
10-1021-102	10-1021-201	10-1076
10-1021-103	10-1021-202	10-1077
10-1021-104	10-1021-203	10-1078
10-1021-105	10-1070	
10-1021-106	10-1070-3	

SEALING CAPS REF

10-1029	10-1029-8	10-1030-15
10-1029-03	10-1030	10-1030-16
10-1029-04	10-1030-10	10-1030-20
10-1029-3,5	10-1030-12	10-1030-4
10-1029-7	10-1030-12,5	

TROCARS STOPS REF

10-1026	10-1028	10-1028-12
10-1027	10-1028-10	

SPARE PARTS REF

10-1001-200	10-1007HEAD	10-1012-400
10-1001-300	10-1008-300	10-1014NT
10-1001-400	10-1008-400	10-1017NT
10-1002-100	10-1008-50	10-1018
10-1002-200	10-1008BODY	10-1019
10-1002-300	10-1008VBODY	10-1019-12,5
10-1002-400	10-1011-200	10-1052V-100
10-1002HEAD	10-1011-300	10-1052V-300
10-1005-200	10-1011-400	10-1052V-400
10-1007-100	10-1012-100	10-1115BODY
10-1007-200	10-1012-15-100	10-1116BODY
10-1007-300	10-1012-200	
10-1007-400	10-1012-300	

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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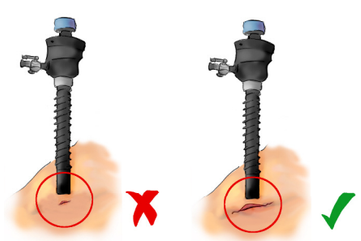
TROCAR SAFE HANDLING INSTRUCTIONS

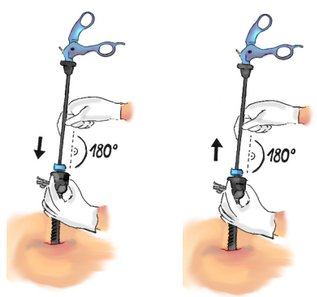
1. The trocar shall be used and handled only by a trained physician.

2. Ensure that the incision is large enough to accomodate the trocar.



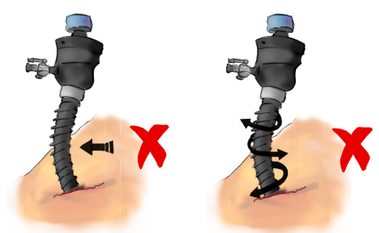
3. Do not grip the trocar very strongly and avoid placing heavy finger pressure or heavy objects on the cannula or any other parts of the instrument.

4. Always insert and remove the trocar and also any instruments which are to be used with the trocar slowly and cautiously and at the correct angle - perpendicular.

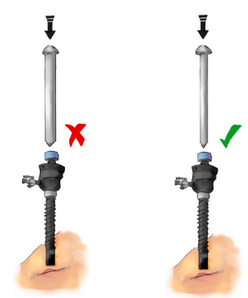


5. In case of unusual resistance during insertion or removal, stop pushing or pulling the trocar to prevent damage.

6. Do not bend or twist the trocar and also any instruments which are to be used with the trocar during insertion or removal.



7. Only use instruments which fit through the trocar. Do not force and never try to push larger instruments through the trocar.



8. To use smaller instruments with larger trocar, always use a reducer.

9. Never use any instruments which are half way inserted into the cannula.

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