LAPAROSCOPIC TROCARS & OBTURATORS

Ackermann©

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 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.

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:

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 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

Ackermann Instrumente GmbH
Eisenbahnstrasse 65-67
78604 Rietheim-Weilheim
Germany
Phone +49 (0)7461 966 17 0
Fax +49 (0)7461 966 17 70
E-Mail info@ackermanninstrumente.de
Web www.ackermanninstrumente.de

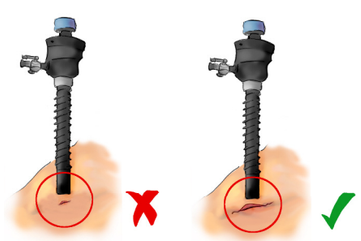
CE

Ackermann©

TROCAR SAFE HANDLING INSTRUCTIONS

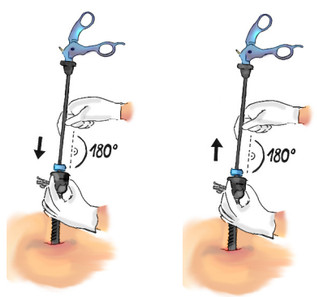
1. The trocar shall be used and handled only by a trained physician.

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



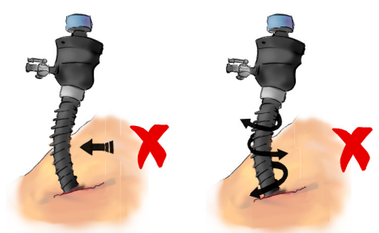
3. Do not grip the trocar very strongly and avoid placing heavy finger pressure or heavy objects on the cannula or any other parts of the instrument.

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.

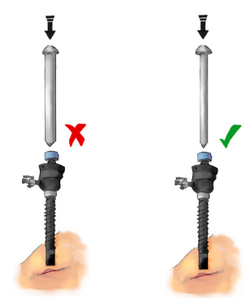


5. In case of unusual resistance during insertion or removal, stop pushing or pulling the trocar to prevent damage.

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.

Ackermann Instrumente GmbH
Eisenbahnstrasse 65-67
78604 Rietheim-Weilheim
Germany

Phone +49 (0)7461 966 17 0
Fax +49 (0)7461 966 17 70
E-Mail info@ackermanninstrumente.de
Web www.ackermanninstrumente.de

CE