IIMPORTANT
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 urological sheaths are designed for diagnostic and operative urology surgeries to be used as operation/ irrigation/ aspiration channel, during the obturators are used through the sheaths to access to the urological tract.

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:

UROLOGICAL SHEATHS AND OBTURATORS REF

32-4067	32-4205ZV	32-4306
32-4068	32-4221	32-4308
32-4070	32-4221RR	32-4309
32-4071	32-4221ZV	32-4335
32-4075	32-4222	32-4340
32-4076	32-4225	32-4345
32-4080	32-4226	32-4367
32-4081	32-4227	32-4368
32-4085	32-4228	32-4370
32-4086	32-4229	32-4375
32-4090	32-4230	32-4376
32-4091	32-4231	32-4380
32-4095	32-4290	32-4510
32-4100	32-4291	32-4511
32-4105	32-4292	32-4512
32-4106	32-4293	32-4513
32-4110	32-4297	32-4514
32-4115	32-4298	32-4515
32-4205	32-4299	32-4520
32-4205RR	32-4306	32-4521

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	KIWA BELGELENDIRME HIZMETLERI A.Ş. İTOSB 9. CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL / TÜRKİYE

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 1984