Ackermann© medical

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.ducts featuring plastic components).

INTENDED USE

The Ackermann t|spine instruments are designed for spinal lumbar reconstructive surgery to be used for implantation of the t|spine implant. The set of instruments serves the purpose of determining the size individually needed, as well as for the positioning and application of the implant itself.

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:

TRIALS REF

70-7677	70-7679-20	70-7690
70-7677-20	70-7681	70-7690-20
70-7678	70-7681-20	70-7691
70-7678-20	70-7689	70-7691-20
70-7679	70-7689-20	

INSTRUMENTS REF

70-7670	70-7671	70-7674

INSTRUMENTATION SET REF

70-7478SET

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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