Instructions for use

SHAVER-BLADES

PART NOS.: HLM-25000 ET SEQ., HLM-35000 ET SEQ., HLM-42000 ET SEQ., HLM-55000 ET SEQ., HLS-25000 ET SEQ., HLS-35000 ET SEQ, HLS-42000, HLS-55000 ET SEQ.

Please read before using / operating VOMED instruments and accessories

⚠ GENERAL INFORMATION

Please read these instructions for use thoroughly before using the surgical instruments. Improper and / or incorrect handling may cause far-reaching consequences for the patient and/or user or lead to premature wear. The surgical instruments must be properly cleaned and sterilised prior to their first use and before each further use. The user is ultimately responsible for checking the proper functioning and the sterility. Surgical instruments or components that are damaged and / or not fully functional must not be used.

A functional check (test run) must be performed before the surgical procedure, i.e. the exact movement of the Shaver-Blades must be determined outside of the surgical field.

The surgical instruments and component parts must only be used by persons who possess appropriate knowledge and skills in the use and application thereof. VOMED will assume no liability for any direct or consequential damage caused by incorrect handling, improper use, failure to observe the intended purpose or by improper preparation or maintenance.

⚠ ATTENTION
The Shaver-Blades must not run dry in order to prevent the Shaver-Blades from being jammed or blocked by ablated tissue. They must be rinsed with isotonic, sterile 0.9 % NaCl solution under constant suction also before the beginning of treatment. Different tubes with various geometries may be replaced or used during surgery.

⚠ INDICATION

The medical devices are used in arthroscopic surgery to sever or to remove tissue parts, cartilage remnants, etc., from the bone.

⚠ CONTRAINDICATION

The medical devices are not intended to be used on the central nervous system or the central circulatory system! The use of the component parts is contraindicated if the surgical intervention is contraindicated.

⚠ HANDLING AND RISKS

VOMED® Shaver-Blades must not be used any more and immediately replaced if:
- The inner or outer blade is mechanically damaged.
- The cutting capacity is no longer adequate.
- The Shaver-Blades do not move perfectly or smoothly, e.g. due to deposits, mechanical deviation or other causes.
- Surface damage (cracks, etc.) exists.

Mechanical damage and deformation of the Shaver-Blades during operative use must generally be avoided before, during and after use since grit can form between the outer and inner tube or on their cutting surfaces and this grit can pose a danger when it remains in the body.

The following must be observed for **VOMED®** Shaver-Blades:
- The blades may only be replaced when the handpiece is not moving.
- The rotating tip must not come into contact with fingers or clothing since there is otherwise a risk of injury.
- The blades must not be strained by vigorous poking. They could break otherwise, which poses a danger for the patient and user.
- The Shaver-Blades can easily be damaged if they are are knocked, thrown or dropped, the use of wire brushes or abrasive cleaners should be avoided.
  Therefore it must be ensured that they are always handled carefully.
- Use a surgical cleaning brush to clean the suction cutting blades from the inside and to remove possible residues. For manual cleaning, never use metal brushes or metal sponges.

In addition, the usual techniques described in the literature must be applied and observed.

⚠ INTENDED PURPOSE

The medical devices of this group are used in arthroscopic surgery to sever or to remove tissue parts, cartilage remnants, etc., from the bone.

+ ⚠ OPERATING INSTRUCTIONS

The VOMED® Shaver-Blades are compatible with Linvatec and Arthrex (HLM-xxxxx / HLS-xxxxx) handpieces. Adaption is unsuitable for other systems. The Shaver-Blades are adapted in the handpiece provided. When inserting the coupling into the handpiece, it must be ensured that the side pins fit into the groove provided. The Shaver-Blades must be coupled tightly to the handpiece by turning the locking ring of the handpiece. The handpiece is connected to a control device and a suction pump by means of a cable or connecting hose. It is mandatory to observe the instructions for use of the connected devices and of the Shaver-Blades. After the control device is switched on, the Shaver-Blades are inserted into the surgical field where, in a vacuum channel open at the top, the rotating inner tube (hollow blade) is rotated by a motor or is moved in an oscillating manner towards the outer tube, which remains rigid, to cut off / sever tissue, bones, cartilage, etc. The respective cutting window geometry as well as the suction force should be adapted by the surgeon to the individual situations to prevent complications. The Shaver-Blades may only be used in those areas which are listed under “Intended Purpose” and only when adapted to appropriate handpieces. The appropriate use and application of the Shaver-Blades group must be adequately determined and defined by the user. Based on his/her training and technical qualification, the user must be able to use them professionally without endangering himself or herself, the patient or any third party. In addition, the usual techniques described in the literature must also be applied. The safe speed range for cutting Shaver-Blades is maximally 1,200 RPM, for milling Shaver-Blades it is maximally 5,000 RPM. The Shaver-Blades can also be operated at a higher speed, however this will result in a shorter service life, reduced ablation capacity and increased “jamming” of the cutting blades. At the same time, tissue mass, etc., is suctioned through the lumen of the inner tube by means of a suction pump and a connecting hose. If possible, all instruments must be disassembled for cleaning, but such tools as pliers or the like must not be used.

⚠ GENERAL INFORMATION ABOUT PROCESSING AND STERILISATION

The following must be observed for VOMED® Shaver-Blades “multi-use“ with regard to processing and sterilisation
- The Shaver-Blades are generally supplied in an unsterile condition. Stock goods should be stored in appropriate containers until initial sterilisation in order to avoid damage.
- Cleaning and sterilisation must be performed before initial use and every further use
- The Shaver-Blades must be rinsed and cleaned correctly immediately before or after every use. The inner and outer tubes must be separated from one another for cleaning, but such tools as pliers, etc., must not be used. Sufficient flow to the distal end must be ensured. Remove residues such as blood or tissue particles.
- After cleaning, the inner tube must be lubricated lightly with commercially available and approved instrument oil.

For sterilisation, the device manufacturer`s instructions for use with regard to the recommended use must be exactly observed. Steam sterilisation must be performed at least at 134 °C / 273 °F. Appropriate indicators must be used to check for a perfect sterilisation result.

Warning: The instruments can corrode if they are not rinsed sufficiently or remain too long in the disinfection or cleaning agent. For dwell times, please refer to the package insert of the respective cleaning or disinfection agent. The steriliser operator is responsible for validating the sterilisation process and thus for the sterility of the treated product. Furthermore, it must be ensured that the tubes are labelled with a 3-digit code which enables unambiguous sorting for clear identification of the inner tube and the corresponding outer tube. Only inner and outer tubes with the same number may be assembled and used.

⚠ DISPOSAL

Disposal must take place under the following aspects: Risk of injury or infection must be reliably prevented during instrument disposal. Sharp and pointy instruments must be collected and sealed in puncture- and break-proof containers. They must be stored so that they are protected from unauthorised access. Furthermore, they must be disposed of as hazardous waste.

Contaminated products must be treated before disposal so that contamination of third parties is not possible.

⚠ REPROCESSING INFORMATION

If the reprocessing information described herein are observed, a damage to the medical device and thus an impairment of the service life through the reprocessing will not have to be expected. Frequent reprocessing will have little impact on the service life of the medical devices. The end of the service life of the medical device is normally determined by wear and damage through usage, and the medical device must then be disposed of as defined by the user.

⚠ PROCEDURE FOR MANUAL CLEANING

A manual cleaning/conditioning method is unsuitable because a brush must be used, and in case of heavy contamination or improper handling during the cleaning procedure, this may result in damage to the surface or the medical devices and thus to an impairment of patient safety. With manual cleaning/disinfection a consistent and reproducible cleaning result cannot be ensured, and therefore automatic/mechanical cleaning/conditioning must be used.

⚠ PROCEDURE FOR MECHANICAL CLEANING

Instructions:

Due to the product design and the materials used, no defined maximum limit of processing cycles can be specified. The service life of the medical devices is determined by their function and gentle handling. Defective products must undergo the complete reprocessing process before they are returned for repair.

Reprocessing instructions:

General: The values / parameters specified herein for the different processes described were used during the validation performed and must be adopted accordingly depending on the conditions existing locally.

Preparation at the place of use: Immediately after use, coarse dirt must be removed from the instruments. Do not use fixing agents or hot water (>40 °C) as this would lead to the fixation of residues which might impair the cleaning result.

Transportation: Safe storage and transportation of the instruments in a closed container to the reprocessing area to avoid any damage to the instruments and contamination of the environment.

Preparation for decontamination: The instruments must be disassembled or opened for reprocessing.

Pre-cleaning: Place the Shaver-Blades in cold water for at least 5 minutes. Then disassemble them and use a soft brush to clean them under cold water until no residues are visible. Use a water jet pistol to pressure rinse (pulsed process) cavities, bores or threads for at least 10 seconds. Place instruments in an ultrasound bath at 40 °C with 0.5 % enzymatic cleaner and treat them with ultrasound for 15 minutes. Remove the instruments and rinse them off with cold water.

Cleaning: Rack disassembled instruments in a minimally invasive surgery trolley. Place instruments that cannot be racked in an open position on a minimally invasive surgery trolley. Then one of the following processes must be started.

Alkaline process
(validated with Miele washer / disinfector G 7735 CD)

Step	Time (min.)	Process	Reagents	Temp and conductivity
1	1	Pre-cleaning	Tap water	12°C – 16°C 440 µS / m
2		Draining		
3	3	Pre-cleaning	Tap water	12°C – 16°C 440 µS / m
4		Draining		
5	5	Cleaning	Tap water; 0.5 % alkaline cleaner (Neodisher FA, Dr. Weigert)	55°C
6		Draining		
7	3	Neutralisation	Tap water	12°C – 16°C 440 µS / m
8		Draining		
9	2	Intermediate irrigation	Tap water	12°C – 16°C 440 µS / m

Enzymatic process
(validated with Miele washer / disinfector G 7735 CD)

Step	Time (min.)	Process	Reagents	Temp and conductivity
1	1	Pre-cleaning	Tap water	12°C – 16°C 440 µS / m
2		Draining		
3	3	Pre-cleaning	Tap water	12°C – 16°C 440 µS / m
4		Draining		
5	5	Cleaning	Tap water; 0.5 % enzymatic detergent (deconex 23 Neutrazym, Borer, Switzerland)	45°C
6		Draining		
7	3	Intermediate irrigation I	Tap water	12°C – 16°C 440 µS / m
8		Draining		
9	2	Intermediate irrigation II	Tap water	12°C – 16°C 440 µS / m

Disinfection: The mechanical thermal disinfection must be performed, taking account of the national requirements as to the A0-value (see ISO 15883).

Drying: Drying of the exterior surface of the instruments through the drying cycle of washer / disinfector. If needed, additional manual drying can be performed by means of a lint free towel. Dry any cavities of instruments with sterile compressed air.

Functional testing, maintenance: Visual inspection for cleanliness; assembly of the instruments; maintenance and functional testing according to the instructions for use. If necessary, repeat the reprocessing process until the instruments are visually clean.

Packing: Packing of the instruments for sterilization according to ISO 11607 and EN 868 in conformance with standards.

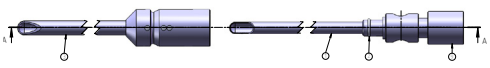
⚠ **Sterilisation:** Sterilisation of the medical devices using a fractionated pre-vacuum process (according. ISO 13060 / ISO 17665), giving due regard to the respective national requirements:
3 pre-vacuum phases with a pressure of
at least 60 millibars
Heating-up to a minimum sterilisation temperature of 132 °C;
maximum temp.: 137 °C
Minimum holding time: 4 minutes
Drying time: at least 10 minutes

⚠ **Storage:** Storage of the sterilised instruments and component parts in a dry, clean and dust-free environment at moderate temperatures of 5 °C to 40 °C.

Additional instructions: If the above-described chemical products and machines are not available the user must validate his process appropriately. It is the duty of the user to ensure that the reprocessing process, including resources, materials and personnel, is capable to achieve the required results. The state of the art and national laws require that validated processes are adhered to.

⚠ DISASSEMBLY

Pull the inner tube (1) out of the outer tube (3), whilst overcoming some slight clamping (2).



1 = Inner tube
2 = O-ring
3 = Outer tube
9 = Spring mechanism

⚠ ASSEMBLY

Both tubes must be checked for damage before they are assembled. The O-ring (2) on the inner part of the coupling and the spring mechanism (9) must also be checked. If no damage and/or wear is found, the inner tube (1) must be lubricated with commercially available instrument oil, and the inner tube can be inserted into the outer tube (3). Some slight clamping must be overcome so that the coupling will fully engage. The Shaver-blades must run quietly and smoothly; this can be determined by rotating a tube. When this is ensured, it can be inserted into the handpiece.

⚠ INFORMATION ON RESIDUAL RISKS ⚠

It must be ensured that the medical device is not overstrained by the user. It must be ensured and periodically checked that the function described in the “Operating Instructions” section is always working.

LABELLING

The symbols depicted on the medical device or its label or the instructions for use have the following meaning according to DIN EN ISO 15223-1:

= Symbol for “Observe the instructions for use”.

⚠ = Attention! Failure to observe the warning notes and / or precautionary measures may have serious consequences and result in most severe injuries.

LOT = Accompanying lot number / batch number of the manufacturer.

= Symbol for “Content not sterile”.

CE 0123 = CE mark and number of the certification authority.

= Manufacturer

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