Reprocessing instruction

reusable surgical instruments

Manufacturer:

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Products:

- Anoscopes
- Eye magnets
- Belt tensioners
- Cups
- Drills
- Dilators
- Dissectors
- Elevators
- Rasps
- Hooklets
- Hooks
- Malleus
- Cannulas
- Catheters
- Clips
- Clamps
- Abrasors
- Legators
- Spoons
- Mouth gags
- Needles
- Needle holders
- Tweezers
- Rasps
- Rectoscopes
- Saws
- Bowls
- Loop Instruments
- Probes
- Spatulas
- Speculas
- Mirrors
- Sterilisation Container
- Syringes
- Tuning Forks
- Tablets
- Tonometers
- Trocares
- Retractors
- Forceps

Important Note

With the purchase of this instrument, you have acquired a high-quality product. The proper handling and use is described below. In order to minimize hazards to patients and users, we ask that you carefully observe the instructions for use. Only trained professionals may use, disinfect, clean and sterilize the instruments.

Carefully read the warnings indicated by this symbol. Improper use of the products may result in serious injury to the patient, the user or third parties.

Description of used symbols

Manufacture

Catalogue number

Batch code

Caution

Consult instructions for use

Non-sterile

Keep dry

Conformity to the Essential Requirements

Medical Device

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1 Area of use

The products listed above may only be used by suitably trained and qualified personnel. We manufacture our instruments as standard instruments for operative use in general surgery. The treating physician, however, is responsible for the selection of instruments for certain applications or for operative use. It is mandatory that the user and the appropriate specialist familiarize themselves with the instruments before he / she applies them.

2 Contraindication

The instruments of VeHu-Medical GmbH may not be used in the area of Heart-Thorax and Neurosurgery.

3 Precautions and Warnings

Attention!

The suction and irrigation instruments are designed for surgical use only and may not be used for any other purpose. Incorrect handling and care as well as misuse may result in premature wear of the instruments.

Material incompatibility

Under no circumstances should the medical devices be used if the user or healthcare professionals have knowledges that the patient has material incompatibilities.

Functional impairment

Surgical instruments corrode and impair their function when they get in touch with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilization instructions.

Operating Conditions

To ensure the safe operation of the products mentioned above, proper maintenance and care of the products is essential. In addition, a functional or visual check should be carried out before each application. For this reason we refer to the corresponding sections in this manual.

Storage

There are no specific requirements for the storage of the products. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

4 Liability and warranty

VeHu medical GmbH, as a manufacturer, is not liable for consequential damage resulting from improper use or handling. This applies in particular to non-compliant use for the defined purpose or disregard of the treatment and sterilization instructions. This especially applies to repairs or changes to the product made by unauthorized staff of the manufacturer. These disclaimers also apply to warranty services.

5 Sterility

Delivery condition

The medical devices are delivered in a non-sterile condition and must be prepared and sterilized by the user before the first and any further use according to the instructions below.

6 Lifetime of the product

The instruments may - with due care and provided that they are undamaged and fully functional – be reprocessed and reused.
The instruments may not be overstressed by twisting or levering, since this can lead to instrument parts becoming damaged or broken. The lifetime is limited by damage and normal wear; these products should be reject after processing. If the instruments have been used in a patient with Creutzfeld-Jakob disease or HIV infection, the instruments should not be reused. Since the medical products of VeHu Medical GmbH are made of durable and long-term proven materials in the field of medical technology, it is not possible to define an exact lifespan. The service life depends on the wear and frequency of use. For this purpose, please observe the instructions below for the function test before use.

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7 Reprocessing instructions

Process:	• **Cleaning** • **Disinfection** • **Sterilization with hot steam (EN ISO 17665-1)**
Warnings:	• The instruments are delivered non-sterilized and must be cleaned before use, and disinfected and sterilized, if necessary. • Frequently reprocessing affects the quality of the products • Municipal water to be used must comply with Council Directive 98/83 / EC of 3 November 1998 concerning the quality of water intended for human consumption. • In this preparation instruction is specifies the cleansing and disinfection agents used for the validation. When using an alternative detergent and disinfectant (RKI or VAH listed) it is the responsibility of the processor • Reassemble disassembled products before sterilization

Instructions	
Place of use:	The first steps of a proper preparation starts already in the operation room. Gross soiling, residuum of e.g. haemostatic-, skin disinfectants, lubricants and corrosive medicines should be removed before put down the instruments. Wherever possible, the dry disposal (humidified, closed systems) is to be preferred. Drying of residues should be avoided! Long waiting times until preparation, e.g. overnight or over the weekend, are avoid by both disposal types (< 6 hours).
Transport	The products must be immediately disposed of after use. This means that the products are to be transported moist in a closed container from the place of application to the treatment, so that no drying of the products takes place.
Preparation for decontamination:	If instruments can be taken apart, do this before treating them or in the open state to supply the further processing steps. Rinse shadow should be avoided. The products must be prepared in suitable baskets or bowls (select size by product). The products should be fixed with a minimum distance to each other in the cleaning basket. Overlap is to be avoided in order to prevent damage to the products during the cleaning process.
Pre-cleaning	Rinse the products under cold drinking water quality (< 40°C) until all visible contaminations has been removed. Moving parts on the instrument are to be moved. Cavities, lumens, cracks and slits are to be flushed intensively (> 60 sec) with cold city water drinking water quality (<40 ° C) by means of a water pressure gun (or similar). Place the products in an ultrasonic bath (<40 ° C) with an alkaline cleaner (0.5% neodisher® MediClean forte), sonication time of 5 min. and a frequency of about 35 kHz. Follow the instructions of the detergent manufacturer. Briefly rinse instruments under cold water (<15 sec). Moving parts have to be moved. Rinse cavities, lumens, gaps and slots again with cold water (<40 ° C) using a water pressure gun (or equivalent) (> 30 sec.).
Automatic Cleaning and disinfection	(Washing machine RDG) 1 minutes Pre-cleaning with cold city water drinking water quality <40°C Water drain 3 minutes Pre-cleaning with cold city water drinking water quality <40°C Water drain 5 minutes cleaning by 55°C ± 5°C with 0,5% alkaline detergent (0.5% MediClean) water drain Neutralization for 3 minutes (0.1% Neodisher® Z) with cold city water Drinking water quality <40 ° C water drain 2 minutes rinse with deionised water <40 ° C The special instructions of the manufacturer of the cleaning machine are to be observed.
Automatic disinfection	Automatic thermal disinfection in washer-disinfector, taking into account national requirements for A0 value; e.g. A0- value 3000: > 5 minutes at 92 ° C ± 2 ° C with VE water.
Automatic drying	Automatic drying according to the automatic drying process of the washer-disinfector for at least 30 minutes (at 60 ° C ± 5 ° C in the washing room). Possibly subsequent manual drying with lint-free cloth and lumen blowout using sterile, oil-free compressed air.
Packaging	• The used disinfecting solution must be suitable for disinfecting steel products. • Place cleaned instruments in a tub with a disinfecting solution. • Fill all channels and hollow spaces with the disinfecting solution, free of air bubbles. • Cover the tub with its lid. • Prepare the disinfecting solution concentration and allow the instruments to soak in it according to manufacturer specifications. • Remove the instruments from the disinfecting solution with fresh disposable gloves.
Packaging:	The instruments should be placed in a suitable container or sterilization packaging according to DIN EN ISO 11607 or DIN EN 868 prior to sterilization.

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	Use a sterilization indicator for the packaging and write down the sterilization and expiration date on the packaging.
Sterilization:	Sterilization of the products based of fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into account of the respective national requirements. The sterilization is to be carried out with a fractionated pre-vacuum method, with the following parameters: 132 ° C / 270 ° F, ≥4 minutes holding time, 3 pre-vacuum cycles Drying in vacuum for 20 to 30 minutes Flash sterilization is not suitable for lumen products! The instructions for use of the autoclave manufacturer and the recommended guidelines for the maximum loading of sterilized goods must be observed. The autoclave must be properly installed, maintained, validated and calibrated.
Additional information:	It is the responsibility of the processor to ensure that the treatment actually carried out with the equipment, materials and personnel used in the treatment facility achieves the desired results. Thi usually requires validation and routine monitoring of the process and the equipment used.

8 Functional test

Check products after preparation and before sterilization for the following aspects:

- Cleanliness
- Damage, including u. a. Signs of corrosion (rust, pitting), discoloration, deep scratches, peeling, cracks and abrasion.
- Proper function, including u. a. Sharpness of the cutting tools, flexibility of flexible products, flexibility of hinges / joints / box locks and moving parts, such. B. Handles and ratchets.
- Missing or removed (abraded) part numbers.
- Do not use improperly functioning or defective and over worn products or products with unrecognizable markings, missing or removed (abraded) part numbers.

Check products for flawless surfaces, correct assembly and functionality. Do not use heavily damaged products, products with unrecognizable markings, signs of corrosion or blunt cutting edges.
Reassemble dismantled products before sterilizing.

9 Service and repair

Service and repair

Do not carry out any repairs or changes to the product on your own. For this purpose only authorized personnel of the manufacturer are responsible and intended. If you have any complaints, complaints or comments regarding our products, we ask you to contact us.

Re-transport

Defective or non-compliant products must have pass through the entire reprocessing process before being returned for repair / service.

10 Storage and disposal

Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures.
For instruments prior to the first sterilization there are no special storage conditions.
The manufacturer's medical devices should be stored in individual packaging, boxes or protective containers. Please handle the instruments with utmost care during transport, storage and preparation. The maintenance of the sterile state after the sterilization process is to be ensured by the user or the qualified personnel provided for this purpose.
The disposal of the products, the packaging material and the accessories must be carried out in accordance with the applicable national regulations and laws. A specific instruction for this is not made by the manufacturer.

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