Instructions for use

Leving, Lifting Instruments

Valid from:	15.01.2026	Version:	01

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1 Important note

Read these instructions carefully before each application and keep them easily accessible to the user or the appropriate qualified personnel.

Read the warnings indicated by this symbol carefully. Improper use of the products can lead to serious injury to the patient, users or third parties.

2 Scope of application

The instruments may only be used for their intended use in the medical specialties by appropriately trained and qualified personnel. The attending physician or user is responsible for the selection of the instruments for specific applications or surgical use, the appropriate training and information and sufficient experience for the handling of the instruments.

3 Products / Intended Use

The levering, lifting instruments are intended for surgically invasive and invasive treatments in various medical specialties (of less than 60 minutes). They correspond to risk class Ir.

ENT Elevatorium product family	
(Basis UDI-DI)	**Purpose**
ENT Elevatorium 405937500000177CJ	Instrument for lifting, positioning or pushing up anatomical structures or surgical materials.
Periostelevatorium product family	
(Basis UDI-DI)	**Purpose**
Periosteal Elevatorium 405937500000178CL	Instrument for elevation or tunneling of the periosteum.
Root lifter product family	
(Basis UDI-DI)	**Purpose**
Dental elevator tooth/root 405937500000179CN	Dental instrument used as a lever to extract a tooth or impacted roots
Product Family: Jawbone Separator	
(Basis UDI-DI)	**Purpose**
Maxillofacial bone separator 405937500000181C9	Instrument for pushing apart or splitting bones in the face, mouth and/or jaw.
Product Family: Uterine Elevatorium	
(Basis UDI-DI)	**Purpose**
Uterine elevatorium 405937500000180C7	A surgical instrument for lifting and manipulating the structure of the uterus to enable the examination and operation of the organ and/or surrounding organs/tissues during a surgical procedure.

4 Contraindications

The instruments may only be used for their intended use by appropriately trained and qualified personnel. The products are not intended for use on the heart and central circulatory and nervous systems.

The products are not intended for connection to active medical devices. There is a risk of injury to patients and users when using RF, RF or laser equipment at the same time.

The products are contraindicated for all other uses except the techniques mentioned in the intended purpose/indication(s).

Product-specific contraindications

- **No known contraindications.**

5 Unwanted side effects / complications / risks

⚠**General:**

- After contact with the instrument, hypersensitivity reactions can be triggered in a patient with material intolerances to stainless steel. In the event of such a reaction, the procedure must be stopped immediately and the necessary steps must be taken.
- Breakage of the instruments
- Injury to vessels, tissues, nerves
- Infections
- Perforation of tissues, vessels, and cavities
- Postoperative bleeding
- Necrosis
- Thrombosis

In the course of the market observation, further potential complications / side effects could be identified:

⚠**Treatment-related complications / side effects / risks**

- Swallowing of components
- Injury to the environment (tissues)
- Injury to the user
- Surgery extension
- Injury to surrounding teeth
- Remaining of remnants
- Bleeding

⚠**Product-related complications / side effects / risks**

In the course of the market observation, further potential complications / side effects could be identified:

- Fracture
- Deformation of components

6 Precautions and warnings

⚠**Attention!**

The instruments are designed for surgical use only and may not be used for any other purpose. Improper handling and care as well as misuse can lead to premature wear and tear of the instruments.

⚠**Material incompatibility.**

The medical devices should not be used under any circumstances if the user or the specialist becomes aware that the patient has material intolerances.

⚠**Functional impairment**

Surgical instruments corrode and are impaired in their function when they come into contact with aggressive substances. For this reason, it is imperative to follow the reprocessing and sterilization instructions.

⚠**Operating conditions**

To ensure the safe operation of the aforementioned products, correct maintenance and care of the products is essential. In addition, a functional or visual inspection should be carried out before each application. For this reason, we refer to the relevant sections in this instruction manual.

⚠**Combination with other products**

When instruments are reassembled after disassembly, individual parts must not be replaced with parts from other manufacturers! If parts are interchangeable due to the intended purpose of the product (e.g. different work inserts), no parts from other manufacturers may be used! We also recommend that you purchase other accessories (e.g. care products) from VeHu-Medical GmbH.

⚠**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.

⚠ **Creutzfeldt-Jakob disease**

With regard to the reprocessing of medical devices that have been used in persons suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) or persons suspected of having the disease, the requirements set out in the corresponding annex to the Guideline for Hospital Hygiene and Infection Prevention and the requirements specified in publications in the Federal Health Gazette must be complied with. The medical devices used in this group of patients can be safely disposed of by incineration (European Waste Catalogue EAK 18 01 03). Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing, but not inactivating, effect on TSE pathogens. Of the available sterilization methods, only steam sterilization (especially 134° C, 18 min) has been shown to have a limited effect.

⚠**Pointed / sharp instruments**

Care should be taken when handling instruments with sharp points or sharp edges.

7 Combination Products & Accessories

The products are not used with other products and are offered without accessories.

8 Liability and warranty

VeHu-Medical GmbH, as the manufacturer, is not liable for consequential damages resulting from improper use or handling. This applies in particular to non-compliant use for the defined purpose or disregard of the reprocessing and sterilization instructions. This also applies to repairs or modifications to the product made by unauthorized personnel of the manufacturer. These disclaimers also apply to warranty services.

9 Sterility

⚠**Delivery condition**

The medical devices are delivered in a non-sterile condition and must be prepared and sterilized by the user in accordance with the following instructions before the first and any subsequent use.

10 Preparation

⚠ **Warnings**

- Frequent reprocessing affects the quality of the products.
- Urban water to be used must comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- This preparation instruction specifies the cleaning agents and disinfectants used for validation. If an alternative cleaning agent and disinfectant is used (RKI or VAH listed), the responsibility lies with the conditioner.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be carried out by medical professionals. The machine processing must be qualified and validated by the user. The cleaning and disinfection

devices must fully comply with the requirements of DIN EN ISO 15883.

⚠**Place of use**

The first steps of proper reprocessing begin in the operating room. Coarse soiling and residues should be removed, if possible, before putting down the instruments. To do this, the instruments should be rinsed under cold tap water (< 40°C). If this process is not enough to remove the obvious dirt, a soft plastic brush can be used to remove dirt. Dry disposal is preferable wherever possible, as in wet disposal, the prolonged lying of the medical devices in solutions can lead to material damage (e.g. corrosion). Drying of residues must be avoided! Long waiting times until processing, e.g. overnight or over the weekend, must be avoided with both types of disposal (<60 minutes).

⚠**Transport**

The products must be disposed of in a dry place immediately (<60 min) if possible after application. This means that the products have to be transported in a closed container from the place of application to the processing area, so that the products do not dry.

Preparation for decontamination

If possible, the products must be dismantled before the subsequent reprocessing steps or, if open, fed into the further reprocessing steps. Dishwashing shadows are to be avoided. The products must be prepared in suitable strainer baskets or rinsing trays (select size by product). The products should be fixed in the cleaning basket with a minimum distance from each other. Overlapping with each other must be avoided in order to be able to exclude damage to the products by the cleaning process.

Pre-cleaning

1. Pre-clean products completely with a soft brush under cold water (city water drinking water quality <40°C).
2. Rinse cavities and hard-to-reach areas, gaps and slots on the instrument with a water pressure gun for 60 sec with cold water (city water drinking water quality <40°C).
3. Soak the products in an alkaline cleaner (0.5% Neodisher Mediclean forte) in an ultrasonic bath at 35 kHz for 5 minutes.
4. Rinse products under cold water (city water drinking water quality <40°C) for 15 sec.
5. Rinse cavities and hard-to-reach places, gaps and slits on the instrument with a water pressure gun for 30 seconds with cold water (city water drinking water quality <40°C).

Preparation

Automatic reprocessing

(Miele Disinfector G7835 CD according to ISO 15883):

- 1 minute pre-clean
- Water drainage
- 4 minutes pre-cleaning
- Water drainage
- 6 minutes clean with an alkaline cleaner (0.5% Neodisher Mediclean forte) at 58°C +/- 1°C
- Water drainage
- 3 minutes neutralization (0.1% NeodisherZ) with cold water
- Water drainage
- 2 minutes clean with cold demineralized water.

Automatic disinfection

Automatic thermal disinfection in washer and disinfection device, taking into account the national requirements for A0 value; e.g. A0 value >3000: With 5 minutes at >95°C

Automatic drying

Automatic drying according to the automatic drying process of the washer and disinfector for 30 minutes at 92°C +/- 2°C.

11 Sterilization

(Type B autoclave of Tuttmauer according to DIN EN 13060)

Sterilization of the products using a fractional pre-vacuum process (in accordance with DIN EN ISO 17665-1/ DIN EN 285), taking into account the respective national requirements. The sterilisation of the products must be carried out in suitable sterilisation packaging in accordance with DIN EN ISO 11607-1 and EN 868.

Sterilization is to be carried out using a fractional pre-vacuum process, with the following parameters:

- 134°C,
- 5 minutes holding time
- 3 pre-vacuum cycles
- Vacuum drying for at least 20 minutes

The instructions for use of the autoclave manufacturer and the recommended guidelines for the maximum load of sterilized goods must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with regulations.

⚠ **Additional information**

It is the responsibility of the reprocessor to ensure that the actual reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the procedure and equipment used.

12 Maintenance-Control-Testing

Cooling the instruments to room temperature!

Visual inspection (before assembly):

Inspection of the surface of the instruments or the individual components before assembly. Particular attention should be paid to the control of joints (final part), profiles, grooves and other structures that are difficult to access:

- Are there still residual soiling or residues?

If so, manual post-cleaning and re-complete machine cleaning & disinfection.

- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the inscription on the instrument no longer legible?

If so, then the instrument in question must be marked and immediately discarded and replaced.

Assembly and maintenance

- Assemble the disassembled instruments in a functional manner.
- Manually treat moving parts, such as joints, threads and sliding surfaces, with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standards).
- Distribute the oil in the joint by opening and closing it several times, remove excess care product with a clean, lint-free cloth

Do not use mineral oil or silicone lubricant! Do not fully immerse instruments in the care product!

Functional testing

During functional testing, pay particular attention to the following aspects and possible malfunctions:

- No damage, such as broken tips, bent or loose parts (screws)
- Flawless closure of jaws
- Correct and safe function of detents and locks
- Easy and even movement of grips, with as little play as possible
- Flawless cutting function for scissors
- Secondary and spring pressure in order (punches, hollow chisel pliers, etc.)
- Lumen permeability
- No other signs of wear, e.g. on seals, insulation or coatings

If defects are found during the functional test, the instruments must be marked and absolutely excluded from further use.

13 Product lifespan

The useful life of the products results from the function, the gentle preparation, according to these instructions and the careful handling of the instruments. Therefore, a limit on the number of treatment cycles cannot be set across the board. Nevertheless, 100 reprocessing cycles were simulated that showed no impairment of the functionality, biocompatibility and identification of the products. The user recognizes the end of the useful life by the possible defects and limiting properties of the products indicated under Maintenance, Control and Testing.

14 Service and repair

⚠**Service and repair**

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this. If you have any complaints, complaints or information regarding our products, please contact us.

⚠**Return transport**

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

15 Packaging, warehousing and disposal

The instrument is placed in a standard-compliant packaging suitable for the respective product or in sterilization trays in accordance with DIN EN ISO 11607-1 and EN 868 and sealed.
Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures.
The manufacturer's medical devices should be stored and stored in individual packages, boxes or protective containers. Please treat the instruments with the utmost care during transport, storage and reprocessing. The maintenance of the sterile state after the sterilization process must be ensured by the user or the qualified personnel designated for this purpose.
The disposal of the products, packaging material and accessories must be carried out in accordance with the nationally applicable regulations and laws. The manufacturer does not provide any specific instructions for this.

16 Reporting obligations

Product defects that have occurred during the proper use of our products should be reported directly to us as the manufacturer or your supervising specialist dealer.
Defects in which patients, users or third parties have been harmed by the products (so-called reportable events) must be reported immediately to the manufacturer and, if necessary, to the manufacturer. competent authority. This reporting of incidents must be made immediately after the occurrence in order to meet important reporting deadlines.
The affected products must be sorted out, processed and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.
After receiving your report, we will inform you of the further necessary measures within a reasonable timeframe.

17 Additional information

If the chemicals and machines described here are not available, and the treatment process cannot be carried out as described, it is the responsibility of the user to validate his process accordingly.

Further information on the reprocessing of medical devices:

- Internet: http://www.rki.de
- Internet: http://www.a-k-i.org
- Requirements for hygiene in the reprocessing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for hygiene in the reprocessing of medical devices"
- DIN 96298-4 Function control in the reprocessing process

18 Applicable documents

Information on the proper disassembly of the listed products can be found on our homepage.
www.vehu.com

- Disassembly instructions instruments

19 Description of symbols used

	Attention!
	Follow the instructions for use
REF	Article number
LOT	Batch designation
CE 0483	CE marking, if applicable, identification number of the notified body.
	Indication for non-sterile product
	Name and address of the manufacturer
	Date of manufacture
SRN	Manufacturer's registration number in the EUDAMED database
MD	Medical device
UDI	Unique Device Identification, a code used to identify a product
	Store in a dry place
℞ ONLY	USA professionals only