

Instructions for use

Holding, grasping 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 holding, grasping instruments are intended for surgically invasive and partly also for non-surgical invasive treatments in various medical specialties (of less than 60 minutes). They correspond to risk class I/Ir.

Reusable Surgical invasive Instruments

Forceps product family	
(Basis UDI-DI)	Purpose
Surgical forcep 4059375000000 49C8	Instrument for gripping and manipulating soft tissues.
Ophthalmic forceps 4059375000000 50BR	Instrument for gripping or manipulating ophthalmic soft tissues and/or removing foreign bodies from them.
ENT forceps 4059375000000 52BV	Instrument for grasping, holding or manipulating the anatomical structures during ENT procedures.
Implant Handling Forceps 4059375000000 53BX	Instrument for gripping and manipulating surgical implants/devices during implantation.

Product family Clamp atraumatic	
(Basis UDI-DI)	Purpose
Intestinal clamp 4059375000000 56C5	Instrument for atraumatic grasping, compressing or supporting of the intestine during a surgical procedure.
Rectal clamp 4059375000000 57C7	Instrument for atraumatic grasping or compressing of the rectum and/or anal canal.
Uterine clamp 4059375000000 58C9	Instrument for grasping or manipulating the uterus during surgical procedures.
Bronchus clamp 4059375000000 59CB	Instrument for temporary, atraumatic compression of a bronchus.
Pyloric clamp 4059375000000 60BU	Instrument for temporary atraumatic compression of the pylorus during a surgical procedure.

Dissecting forceps 4059375000000 82C6	Instrument for gripping, manipulating, compressing or merging tissues.	Dressing forceps 4059375000000 93CB	Instrument for applying or handling dressing material to tissue during a surgical procedure.
Spermatic cord clamp 4059375000000 62BY	Instrument for temporary atraumatic compression of the spermatic cord.	Tampon forceps 4059375000000 94CD	Instrument for grasping a surgical swab or tampon during a surgical procedure.
Product Family Vascular Clamp		Wire Holding / twister forceps 4059375000000 96CH	Instrument for grasping, pulling and/or twisting wires during a surgical procedure.
(*excluded vessels: pulmonary artery, ascending aorta, descending aorta up to the bifurcation aorta, coronary artery, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachiocephalic vein, cordis vein, pulmonary vein, superior vena cava and inferior vena cava)		Surgical stone retrieval forceps 4059375000000 98CM 4059375000000 99CP	Instrument for grasping and/or manipulating a kidney or gallstone during a surgical procedure.
(Basis UDI-DI)	Purpose	Intestinal / tissue drum forceps 4059375000001 00BF	Instrument for atraumatic holding/grasping and/or compressing of intestinal structures, tissues and certain organs during a surgical procedure.
Vascular clamp 4059375000000 68CC	Instrument for the direct compression of a blood vessel* for temporary hemostasis.	Hemorrhoid clamp 4059375000001 04BP	Instrument for holding and compressing hemorrhoidal tissue during a surgical procedure on the rectum.
Arterial clamp 4059375000000 69CE	Instrument for the atraumatic compression of an artery* for the purpose of transient hemostasis.	Tendon forceps 4059375000001 05BR	Instrument for interlacing, grasping, threading, holding or merging tendons during a surgical procedure.
Vascular clamp 4059375000000 70BX	Instrument for the direct compression of a blood vessel* for temporary hemostasis.	Bone holding Forceps 4059375000001 06BT	Instrument for grasping and holding a bone during a surgical procedure.
Bulldog clamp 4059375000000 71BZ	Instrument for grasping, merging, compressing or holding an organ, tissue or vessel*.	Rigid endoscopy grasping forceps 4059375000001 08BX	Instrument for grasping tissue or foreign bodies during endotherapeutic procedures.
Product Family: Clip Applicators			
(*excluded vessels: pulmonary artery, ascending aorta, descending aorta up to the bifurcation aorta, coronary artery, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachiocephalic vein, cordis vein, pulmonary vein, superior vena cava and inferior vena cava)			
(Basis UDI-DI)	Purpose	Product Family: Stripper	
Applicator for surgical clamp 4059375000000 72C3	Instrument for attaching clamp for ligation of blood vessels or similar tubular structures.	(Basis UDI-DI)	Purpose
Product Family: Pliers		Vein Stripper 4059375000001 13BQ	Instrument for manual excision of a vein section.
(Basis UDI-DI)	Purpose	Tendon Stripper 4059375000001 14BS	Instrument for excising a piece of a ligament, tendon or fascia.
Ear forceps 4059375000000 77CD	Instrument for gripping and manipulating soft tissues/anatomical structures during ENT surgery.	Intraluminal Artery Stripper 4059375000001 15BU	Instrument to perform an endarterectomy.
Middle ear malleus nipper 4059375000000 78CF	Instrument for circumcision of the hammer (ossicles in the middle ear).	Product Family: Rubber dam clamp	
ENT Forceps 4059375000000 84CA	Instrument for grasping, holding or manipulating the anatomical structures during (ENT) procedures	(Basis UDI-DI)	Purpose
Lung forceps 4059375000000 89CL	Instrument for atraumatic grasping, manipulation or support of the lungs during a surgical procedure.	Rubber dam clamp 4059375000001 23BT	Instrument for grasping and holding a bone or – when used in pairs on both sides of a fracture.
Kidney gripper forceps 4059375000000 90C5	Instrument for grasping and lifting a kidney during a surgical procedure.	Product Family: Cotton Wool Carrier	
Gallbladder forceps 4059375000000 91C7	Instrument for grasping and manipulating the gallbladder during a surgical procedure.	(Basis UDI-DI)	Purpose
Reusable Invasive Instruments		Cotton Wool Carrier 4059375000001 24BV	Instrument for holding an absorbent material, such as a cotton ball, to clean a superficial wound or orifice.
Forceps product family			
(Basis UDI-DI)	Purpose		

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Forceps for dental articulation paper 4059375000000 55C3	Instrument for holding articulation paper during application in the oral cavity.
Dental dressing forceps 4059375000000 54BZ	Instrument for holding bandages in the patient's oral cavity during application.
Product Family: Snare Instruments	
(Basis UDI-DI)	Purpose
Hemorrhoid ligator 4059375000000 74C7	Instrument for attaching a ligature (e.g. latex rubber band) to internal hemorrhoids in order to cause them to die by preventing blood circulation.
Polypectomy ligat or 4059375000000 75C9	Instrument used to form a ligation loop to prevent or stop bleeding after a polypectomy.
Product Family: Pliers	
(Basis UDI-DI)	Purpose
Tooth Extraction Forceps 4059375000000 76CB	Bite forceps for extracting teeth.
Rubber dam staple pliers 4059375000000 81C4	Instrument for attaching and removing suitcase dam clamp.
Tonsil tongs 4059375000000 61BW	Instrument for gripping, grasping and manipulating the tonsils during an (ENT) procedure.
Tongue depressor forceps 4059375000000 83C8	Instrument for easier grasping, blocking or manipulation of the tongue.
Birth forceps 4059375000000 85CC	Tool to support the birth of a fetus in difficult vaginal births.
Cranioclast 4059375000000 86CE	Instrument for shattering the fetal head after perforation to facilitate the delivery of a dead or abnormal fetus.
Uterustenaculum 4059375000000 87CG	Instrument with hook at the distal end for capturing and/or manipulating uterine tissue.
Gynaecology grasping forceps 4059375000000 88CJ	Instrument for grasping, pulling or compressing internal structures during a gynaeco-surgical procedure.
Hysterectomy forceps 4059375000000 92C9	Instrument for grasping, pulling or compressing the uterus in a hysterectomy.
Forceps for the removal of airway foreign bodies 4059375000000 97CK	an instrument for removing foreign bodies or substances from the oropharynx, trachea or upper bronchi.
Intubation forceps 4059375000001 07BV	Instrument for grasping a tube/tube (e.g. catheter or endotracheal tube) to insert or remove it into the airways, or for picking up and

	removing foreign bodies from the airways.
Product Family: Eye Magnet	
(Basis UDI-DI)	Purpose
Eye magnet, de-energized 4059375000001 16BW	Instrument for removing metallic foreign bodies from the eye tissue.
Product Family: Die band	
(Basis UDI-DI)	Purpose
Die band Tensioner, Dental 4059375000001 18C2	Instrument for tensioning a matrix band around a tooth.
Die band 4059375000001 19C4	Product for forming a shaped cavity around a tooth for filling in dental prosthesis material.
Product Family: Rubber Dam Clamp	
(Basis UDI-DI)	Purpose
Rubber dam clamp 4059375000001 20BM	Product for anchoring a rubber dam.
Product Family: Tray for Dental Impression material	
(Basis UDI-DI)	Purpose
Tray for dental impression material 4059375000001 21BP	Product for taking the tooth impression material for the extraction of the tooth or gum impression.

Reusable non-invasive instruments

Forceps product family	
(Basis UDI-DI)	Purpose
Eyelash forceps	
Eyelash forceps 4059375000000 51BT	Tool for gripping and removing eyelashes.
Product Family Clamp Non-Invasive	
(Basis UDI-DI)	Purpose
Penis clamp 4059375000000 63C2	Instrument to stop the flow of blood into the penis.
Umbilical cord clamp 4059375000000 64C4	Instrument for temporary compression of the umbilical cord immediately after birth.
Cloth clip 4059375000000 65C6	Instrument for holding drapes and/or other products, e.g. cables/leads, that need to be attached to the site of intervention.
Hose clamp 4059375000000 66C8	Instrument for disconnecting a tube during a surgical procedure.
Circumcision clamps 4059375000000 67CA	Instrument for the controlled removal of the foreskin of the penis during circumcision.
Product Family: Pliers	
(Basis UDI-DI)	Purpose

Wire holding/wire bending pliers 4059375000000 79CH	Instrument for grasping, pulling and/or bending wires during a surgical procedure.
Orthodontic forceps 4059375000000 80C2	Instrument for holding/bending/cutting metal strips or wires during orthodontic procedures.
Orthopaedic bending pliers 4059375000000 95CF	Instrument for bending orthopaedic products (e.g. bone plates).
Sterilizing forceps 4059375000001 01BH	Instrument for grasping / handling sterile instruments or packaging.
Plaster crusher 4059375000001 03BM	Instrument for gripping and breaking up hardened plaster.
Surgical stapler 4059375000001 09BZ	Instrument for the removal of wound staples.
Sterilizing clip 4059375000000 2BK	Forceps are mechanical gripping tools. They are used by the user to hold and secure cloths, bandages, and other materials. Application in general surgery
Product Family: Fusing Instruments	
(Basis UDI-DI)	Purpose
Hand extension device 4059375000001 11BL	Product for attaching the hand.
ENT headrest 4059375000001 10BJ	Instrument for fixing the skull during a surgical procedure.
Orthopedic Fixator External System 4059375000001 12BN	Assembly of products to stabilize fractured bones, except for the spine, to aid in treatment and promote healing.
Product Family: Scalp wound clip	
(Basis UDI-DI)	Purpose
Scalp wound clip 4059375000001 17BY	Brace for joining the edges of a scalp wound during a surgical procedure on the skull (not implantable).
Product Family: Blade Crusher	
(Basis UDI-DI)	Purpose
Blade Breaker 4059375000001 22BR	Instrument for cutting pre-scored razor blades into extremely sharp segments.

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

Stripper:

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Varicose vein surgery should not be performed under the following circumstances (contraindications):

- Thrombosis
- Arterial circulatory disorders
- Pregnancy
- primary or secondary lymphedema

5 Complications / Side Effects

⚠ 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

General:

- Injuries to surrounding vessels and tissues
- Injury to nerves

Clip Applicators:

- Postoperative bleeding
- Permanent epilepsy
- Vascular occlusion with stroke as a result

Sling instruments:

- Postoperative bleeding
- Infections
- Postoperative pain
- Anal/rectum stenosis
- Incontinence
- Wound healing disorders
- Rectal perforation
- Urinary retention
- Recurrence rate

Pliers:

Dental forceps:

- Postoperative bleeding
- Hematomas
- Injuries to surrounding vessels, nerves and tissues
- Wound healing disorders
- Infections
- Tooth damage of the adjacent teeth
- Fracture of tooth roots
- Ankylosis
- Dislocation (dislocation of the jaw)

Obstetric forceps:

- Bruising in the child
- Abrasions on the child's head
- Bruises on the child's head
- Nerve damage to the child
- Perineal tear in the mother
- Injuries to the bladder and ureters in the mother
- Injury to the pelvic floor in the mother
- Pelvic floor lowering in the mother

Fixation instruments:

ENT headrest:

- Abrasions
- Nerve lesion
- Nerve damage
- Hematoma or oedema formation
- Soft tissue damage
- Tissue damage
- Circulatory disorders
- Eye damage

Extension units:

- Drilling channel infection
- Dislocation
- Drill Channel Osteomyelitis

Stripper

Tendon Stripper

- General risks and complications: hematoma, wound healing disorder, wound infection, joint infection, deep vein thrombosis, embolism, vascular injury, nerve injury (possibly neuroma formation), complex regional pain syndrome (CRPS, Sudeck disease)
- Special consequences: restriction of movement in the OSG and/or USG, renewed instability, pain persistence, intra-articular scarring (arthrofibrosis), osteoarthritis
- Nerve injury
- Cyclops
- Infections
- Thrombosis
- Removal of seam buttons

Vein Stripper

- Nerve damage
- Postoperative bleeding
- Swelling of the legs due to accumulation of lymphatic fluid
- Severity in the first few days
- Injury to vessels (usually lateral branch veins)
- Bruising, hardening and bruising
- Infections
- Wound healing disorders
- Thrombosis

Eye magnet

- Infections
- Retinal detachment

Wound staples

- Infections
- Scarring
- Chronic wound healing

Die Tape / Rubber Dam Clamp

- Tooth injuries
- Risk of aspiration and ingestion of small parts

Spoon for tooth impression compound:

- Tooth injuries

Bone retaining brace:

- Joint stiffening
- Tendon bonding
- Atrophy of muscles, ligaments, and cartilage due to inactivity
- Compartment syndrome
- Fat clot formation
- Failure to heal the fracture with the formation of a false joint (pseudarthrosis)
- Death of a piece of bone (bone necrosis)
- Infections of the periosteum or bone
- Bleeding during or after surgery

- Blood clot formation
- Bruising with possible need for surgical removal
- Injury to nerves
- Infection of the surgical area
- Unaesthetic scarring
- Anesthesia incidents
- Allergic reaction to materials used (latex, medication)

Cotton Wool Carrier

- Infections
- Scarring
- Chronic wound healing

⚠ Product-related complications / side effects / risks

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

Forces:

- Fracture
- Remaining of remnants
- Injury to the environment (tissues)

Clamp atraumatic:

- Fracture
- Remaining of remnants
- Injury to the environment (tissues)

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-Jakob disease (CJD) or its variant (vCJD) or persons suspected of having the disease, the requirements set out in the

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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

- Pre-clean products completely with a soft brush under cold water (city water drinking water quality <40°C).
- 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).
- Soak the products in an alkaline cleaner (0.5% Neodisher Mediclean forte) in an ultrasonic bath at 35 kHz for 5 minutes.
- Rinse products under cold water (city water drinking water quality <40°C) for 15 sec.
- Rinse cavities and hard-to-reach places, gaps and slots 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 disinfecter 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

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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

	Follow the instructions for use
	Article number
	Batch designation
	CE mark with identification number of the notified body for reusable surgical invasive instruments.
	CE mark for reusable invasive and non-invasive instruments
	Indication for non-sterile product
	Name and address of the manufacturer
	Date of manufacture
	Manufacturer's registration number in the EUDAMED database
	Medical device
	Unique Device Identification, a code used to identify a product
	Store in a dry place
	USA professionals only

