

# Instructions for use

## Holding, gripping instruments

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**SRN** DE-MF-000005584

### 1 Important note



Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist personnel.



Read the warnings marked with this symbol carefully. Improper use of the products can lead to serious injury to the patient, the user or third parties.

### 2 Area of application

The instruments may only be used for their intended purpose 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 handling the instruments.

### 3 Products / Intended use

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

Tweezers product family	
(Basis UDI-DI)	Intended use
Surgical forceps 404279662466BG CE 0123	Instrument for grasping and manipulating soft tissue.
Ophthalmic forceps 404279662674BR CE 0123	Instrument for grasping or manipulating ophthalmic soft tissues and/or removing foreign bodies from them.
ENT forceps 404279639995CY CE 0123	Instrument for grasping, holding or manipulating the anatomical structures during ENT procedures.
Implant handling forceps 404279635079AR CE 0123	Instrument for gripping and manipulating surgical implants/devices during implantation.
Forceps for dental articulating paper 404279631813A7 CE 0123	Instrument for holding articulating paper during use in the oral cavity.
Dental tampon forceps 404279631814A9 CE 0123	Instrument for holding dressing material in the patient's oral cavity during application.
Eyelash curler 404279663485BT CE 0123	Instrument for gripping and removing eyelashes.
Product family Clamps atraumatic	
(Basis UDI-DI)	Intended use
Bowel clamps 4042796108719Q CE 0123	Instrument for atraumatic grasping, compressing or supporting the bowel during a surgical procedure.
Rectal clamps 404279615671AH CE 0123	Instrument for atraumatic grasping or compression of the rectum and/or anal canal.

Uterine clamps 404279616453AC CE 0123	Instrument for grasping or manipulating the uterus during surgical procedures.
Bronchus clamps 4042796108679Z CE 0123	Instrument for temporary, atraumatic compression of a bronchus.
Pyloric clamps 404279646599CA CE 0123	Instrument for temporary atraumatic compression of the pylorus during a surgical procedure.
Dissecting forceps 404279615800A4 CE 0123	Instrument for grasping, manipulating, compressing or joining tissue.
Spermatic cord clamps 404279642468AW CE 0123	Instrument for temporary atraumatic compression of the spermatic cord.
Product family Clamps non-invasive	
(Basis UDI-DI)	Intended use
Penis clamps 4042796109089N CE	Instrument to stop the flow of blood into the penis.
Umbilical cord clamps 404279610876A2 CE	Instrument for temporarily compressing the umbilical cord immediately after birth.
Cloth clip 404279634961BC CE	Instrument for holding together drapes and/or other products, e.g. cables/leads, that need to be secured at the intervention site.
Hose clamps 4042796108759Y CE	Instrument for clamping a tube during a surgical procedure.
Circumcision clamps 404279632648AP CE	Instrument for the controlled removal of the foreskin of the penis during circumcision.
Product family Vascular clamps	
(*Excluded vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)	
(Basis UDI-DI)	Intended use
Vascular clips 404279615882AY CE 0123	Instrument for direct compression of a blood vessel* for temporary hemostasis.
Artery clamps 4042796108659V CE 0123	Instrument for atraumatic compression of an artery* for the purpose of temporary hemostasis.
Vascular clamps 404279615882AY CE 0123	Instrument for direct compression of a blood vessel* for temporary hemostasis.
Bulldog clamps 404279610868A3 CE 0123	Instrument for grasping, bringing together, compressing or holding an organ, tissue or vessel*.
Product family Clip applicators	
(Basis UDI-DI)	Intended use
Applicator for surgical clamps 404279635798BY CE 0123	Instrument for applying clamps to ligate blood vessels or similar tubular structures.
Applicator for aneurysm clips 404279632591AK CE 0123	Instrument for the application/insertion of aneurysm clips.
Product family snare instruments	

(Basis UDI-DI)	Intended use
Hemorrhoid gator 404279635157AL CE 0123	Instrument for attaching a ligature (e.g. latex rubber band) to internal hemorrhoids in order to cause them to die by stopping the blood circulation.
Endotherapy polypectomy ligator 404279636176AX CE 0123	Instrument for forming a ligature loop to prevent or stop bleeding after a polypectomy.
Product family pliers	
(Basis UDI-DI)	Intended use
Ear tongs 404279662467BJ CE 0123	Instrument for grasping and manipulating soft tissue/anatomical structures during ENT surgery.
Hammerhead tongs 404279635213A5 CE 0123	Instrument for trimming the tongs malleus (ossicle in the middle ear).
ENT forceps 404279639995CY CE 0123	Instrument for grasping, holding or manipulating anatomical structures during (ENT) procedures
Lung grasping forceps 404279611787A9 CE 0123	Instrument for atraumatic grasping, manipulation or support of the lung during a surgical procedure.
Kidney grasping forceps 404279616519AH CE 0123	Instrument for grasping and lifting a kidney during a surgical procedure.
Gallbladder forceps 4042796117829X CE 0123	Instrument for grasping and manipulating the gallbladder during a surgical procedure.
Swab forceps 404279634823AX CE 0123	Instrument for applying or handling dressing material on tissue during a surgical procedure.
Wire holding/wire twisting pliers 404279632874B2 CE 0123	Instrument for grasping, pulling and/or twisting wires during a surgical procedure.
Wire holding/wire bending pliers 404279632886B9 CE	Instrument for grasping, pulling and/or bending wires during a surgical procedure.
Surgical stone grasping forceps 404279635083AG CE 0123	Instrument for grasping and/or manipulating a kidney or gallstone during a surgical procedure.
Intestinal/tissue grasping forceps 404279611785A5 CE 0123	Instrument for atraumatic holding/gripping and/or compression of intestinal structures, tissues and certain organs during a surgical procedure.
Hemorrhoid clamp 4042796108709N CE 0123	Instrument for holding and compressing the hemorrhoidal tissue during a surgical procedure on the rectum.
Tendon grasping forceps 404279642597BA CE 0123	Instrument for interlacing, grasping, threading, holding or bringing together tendons during a surgical procedure.
Bone grasping forceps 404279646751BQ CE 0123	Instrument for grasping and holding a bone during a surgical procedure.

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Rigid endoscopy grasping forceps 404279637100A5 CE 0123	Instrument for grasping tissue or foreign bodies during endotherapeutic procedures.
Tooth extraction forceps 404279635552AW CE	Bite forceps for extracting teeth.
Rubber dam clamp forceps 404279635851BB CE	Instrument for attaching and removing rubber dam clamps.
Tonsil forceps 404279615672AK CE	Instrument for gripping, grasping and manipulating the tonsils during an (ENT) procedure.
Tongue depressor forceps 4042796108619M CE	Instrument for easier grasping, blocking or manipulating the tongue.
Birth forceps 404279635082AE CE	Instrument to support the birth of a fetus during difficult vaginal births.
Cranioclast 404279632650AA CE	Instrument used to fragment the fetal head after perforation to facilitate delivery of a dead or abnormal fetus.
Uterine saculum 404279613998B6 CE 0123	Instrument with hook at the distal end for grasping and/or manipulating uterine tissue.
Gynecology forceps 404279632595AT CE	Instrument for grasping, pulling or compressing internal structures during a gynecological surgical procedure.
Hysterectomy forceps 404279635804B2 CE	Instrument for grasping, pulling or compressing the uterus during a hysterectomy.
Forceps for removing foreign bodies from the airway 4042796100588Q CE 0123	Instrument for removing foreign bodies or substances from the oropharynx, trachea or upper bronchi.
Intubation forceps 4042796312649S CE	Instrument for grasping a tube (e.g. catheter or endotracheal tube) in order to insert it into or remove it from the airways, or to pick up and remove foreign bodies from the airways.
Orthodontic forceps 4042796332099Y CE	Instrument for holding/bending/cutting metal strips or wires during orthodontic procedures.
Orthopaedic bending pliers 404279644795BW CE 0123	Instrument for bending orthopaedic products (e.g. bone plates).
Sterilizing tongs 404279611792A2 CE 0123	Instrument for gripping / handling sterile instruments or packaging.
Sterilisierklammer 404279611792A2 CE 0123	Product for holding instruments for fastening/protection during reprocessing.
Plaster crusher 404279646313AU CE 0123	Instrument for gripping and breaking up hardened plaster.

Surgical staple puller 404279616787BC CE 0123	Instrument for removing wound staples.
<b>Product family Fixing instruments</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Hand extension device 404279640633A7 CE	Product for attaching the hand.
ENT headrest 404279631920A9 CE	Instrument for fixing the skull during a surgical procedure.
Orthopaedic external fixator system 404279635647BA CE	Assembly of products for the stabilization of fractured bones with the exception of the spine to support treatment and promote healing.
<b>Product family Stripper</b> (*excluded vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Vein stripper 404279635377B4 CE 0123	Instrument for manual excision of a vein section*.
Tendon stripper 404279635380AR CE 0123	Instrument for excising a piece of ligament, tendon or fascia.
Intraluminal artery stripper 404279631729AH CE 0123	Instrument for performing an endarterectomy*.
<b>Eye magnet product family</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Eye magnet, currentless 404279646718BS CE	Instrument for removing metallic foreign bodies from the eye tissue.
<b>Product family scalp wound clip</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Scalp wound clip 404279646953C6 CE 0123	Staple for joining the edges of a scalp wound during a surgical procedure on the skull (non-implantable).
<b>Die band product family</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Die band tensioner, dental 404279645008AD CE	Instrument for tensioning a matrix band around a tooth.
<b>Product family rubber dam clamp</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Rubber dam clamp 404279615712A6 CE	Product for anchoring a rubber dam.
<b>Tray product family for dental impression material</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Tray for dental impression material 404279635850B9 CE	Product for holding the dental impression material for obtaining the tooth or gum impression.
<b>Blade crusher product family</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Blade breaker 404279644959C4 CE	Instrument for cutting pre-scored razor blades into extremely sharp segments.

<b>Product family bone holding clamp</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Bone holding clamp 404279634949BN CE 0123	Instrument for grasping and holding a bone or - when used in pairs on both sides of a fracture.
<b>Product family absorbent cotton carrier</b>	
<b>(Basis UDI-DI)</b>	
<b>Intended use</b>	
Absorbent cotton carrier 404279664011AH CE 0123	Instrument for holding an absorbent material such as a cotton ball.

#### 4 Contraindications

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

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

The products are contraindicated for all applications other than the techniques specified in the intended use / indication(s).

#### Product-specific contraindications

##### Stripper

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

- Thrombosis
- arterial circulatory disorders
- Pregnancy
- Primary or secondary lymphoedema

#### 5 Complications / side effects

##### General:

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

Further potential complications / side effects were identified in the course of market monitoring:

##### Treatment-related complications / side effects / risks

##### General

- Injuries to surrounding vessels and tissue
- Nerve injury

##### Clip applicators

- Post-bleeding
- Permanent epilepsy
- Vascular occlusion with stroke as a consequence

##### Snare instruments

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

##### Dental forceps

- Post-bleeding
- Hematomas

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- Injuries to surrounding vessels, nerves and tissue
- Wound healing disorders
- Infections
- Tooth damage to the neighboring teeth
- Fracture of tooth roots
- Ankylosis
- Dislocation (dislocation of the jaw)

### Birth forceps

- Bruising in the child
- Abrasions on the child's head
- Bruising on the child's head
- Nerve damage to the child
- Perineal tear in the mother
- Injuries to the bladder and ureter in the mother
- Injury to the pelvic floor in the mother
- Lowering of the pelvic floor in the mother

### ENT headrest

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

### Extension units

- Drill channel infection
- Dislocation
- Bore canal osteomyelitis

### Tendon stripper

- 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's disease)
- Special consequences: Restriction of movement in the ankle and/or ankle joint, renewed instability, pain persistence, intra-articular scarring (arthrofibrosis), osteoarthritis
- Nerve injury
- Cyclops
- Infections
- Thromboses
- Removal of seam buttons

### Vein stripper

- Nerve damage
- Post-bleeding
- Swelling of the legs due to accumulation of lymph fluid
- Pain in the first few days
- Injury to vessels (mostly side branch veins)
- Bruising, hardening and bruising
- Infections
- Wound healing disorders
- Thrombosis

### Eye magnet

- Infections
- Retinal detachment

### Wound clamps

- Infections
- Scarring
- Chronic wound healing disorder

### Matrix band / rubber dam clamp

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

### Tray for dental impression material

- Tooth injuries

### Bone holding clamp

- Joint stiffening
- Tendon bonding
- Atrophy of muscles, ligaments and cartilage due to inactivity
- Compartment syndrome
- Fat clot formation

- Failure of fracture healing with formation of a false joint (pseudarthrosis)
- Death of a piece of bone (bone necrosis)
- Infections of the periosteum or bone
- Bleeding during or after the operation
- Blood clot formation
- Bruise with possible need for surgical removal
- Nerve injury
- Infection of the surgical site
- unaesthetic scarring
- Anaesthetic incidents
- allergic reaction to materials used (latex, medication)

### Absorbent cotton carrier

- Infections
- Scarring
- Chronic wound healing disorder

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

Further potential complications / side effects were identified in the course of market monitoring:

#### Tweezers

- Breakage
- Remaining remnants
- Injury to the surrounding area (tissue)

#### Clamps, atraumatic

- Breakage
- Remaining remnants
- Injury to the surrounding area (tissue)

## 6 Precautions and warnings

### ⚠ Attention!

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

### ⚠ Material incompatibility.

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

### ⚠ Functional impairment

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

### ⚠ Operating conditions

Correct maintenance and care of the products is essential to ensure safe operation of the aforementioned products. Furthermore, a functional and visual inspection should be carried out before each use. For this reason, please refer to the relevant sections in these instructions for use.

### ⚠ Combination with other products

If 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), parts from other manufacturers must not be used! We also recommend purchasing other accessories (e.g. care products) from Dimeda Instrumente GmbH.

### ⚠ Storage

There are no specific requirements for the storage of the products. However, 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 on patients suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) or suspected cases of the disease, the requirements specified in the corresponding annex of 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 that have been used on this patient group must be disposed of safely by incineration (European Waste Catalog EWC 18 01 03). Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but not an

inactivating effect on TSE pathogens. Of the available sterilization methods, only steam sterilization (in particular 134° C, 18 min) has been shown to have a limited effect.

### ⚠ Pointed / sharp instruments

Care must 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

Dimeda Instrumente GmbH is not liable for consequential damage caused by 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 carried out by unauthorized personnel of the manufacturer. These exclusions of liability also apply to warranty services.

## 9 Sterility

### ⚠ Delivery condition

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

## 10 Preparation

### ⚠ Warnings

- Frequent reprocessing impairs the quality of the products.
- Urban water to be used must comply with Directive (EU) 2020/2184 on the quality of water intended for human consumption.
- The cleaning agents and disinfectants used for validation are specified in these reprocessing instructions. If an alternative cleaning agent and disinfectant (RK1 or VAH listed) is used, the responsibility lies with the reprocessor.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be carried out by qualified medical personnel. Automated reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.
- Sterilization must be qualified and validated by the user. The autoclaves must fully comply with the requirements of DIN EN ISO 17665.

### ⚠ Place of use

The first steps of proper reprocessing begin in the operating room. If possible, coarse soiling and residues should be removed before the instruments are put away. To do this, the instruments should be rinsed under cold tap water (< 40°C). If this procedure is not sufficient to remove the obvious soiling, a soft plastic brush can be used to remove soiling. Wherever possible, dry disposal is preferable, as prolonged immersion of medical devices in solutions can lead to material damage (e.g. corrosion). Drying of residues must be avoided! Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided with both types of disposal (<60 minutes).

### ⚠ Transportation

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

### Preparation for decontamination

If possible, the products must be disassembled before the subsequent reprocessing steps or fed to the subsequent reprocessing steps in an open state. Avoid rinsing shadows. The products must

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be processed in suitable sieve baskets or rinsing trays (select size according to product). The products should be placed at a minimum distance from each other in the cleaning basket. Avoid overlapping in order to prevent damage to the products during the cleaning process.

### Pre-cleaning

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

### Preparation

#### Automatic preparation

(Miele Disinfector G7835 CD according to ISO 15883):

- 1 minute pre-cleaning
- Water drainage
- 4 minutes pre-cleaning
- Water drainage
- 6 minutes cleaning with an alkaline cleaner (0.5 % Neodisher Mediclean) at 58°C +/- 1°C
- Water drainage
- 3 minutes neutralization (0.1 % NeodisherZ) with cold water
- Water drainage
- 2 minutes cleaning with cold water low in germs and endotoxins (max. 10 germs/ml and max. 0.25 endotoxin units/ml)

#### Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the A<sub>0</sub> value; e.g. A<sub>0</sub> value >3000: With 5 minutes at >92°C

#### Automatic drying

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

### 11 Sterilization

(Type B autoclave from Tuttnauer in accordance with DIN EN 13060)

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

Please observe chapter 12 before packing!

Sterilization must be carried out using a fractionated pre-vacuum process with the following parameters:

- 134°C,
- At least 5 minutes holding time
- 3 pre-vacuum cycles
- Drying in a vacuum for at least 20 minutes

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

#### Additional information

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results.

This generally requires validation and routine monitoring of the process and the equipment used.

### 12 Maintenance-inspection-testing

Cool the instruments down to room temperature!

#### Visual inspection (before assembly):

Check the surface of the instruments or individual components before assembly. Particular attention must be paid to checking joints (end piece), profiles, grooves and other structures that are difficult to access:

- Is there any residual dirt or residue? If yes, manual post-cleaning and complete mechanical cleaning and disinfection again.
- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the labeling on the instrument no longer legible?

If so, the instrument in question must be labeled 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 standard). EU standard) manually.
- 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 immerse instruments completely in the care product!

#### Function test

During the functional test, 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 smooth movement of handles, gait with as little play as possible
- Flawless cutting function for scissors
- Holding and spring pressure in order (punches, gouge cutters, etc.)
- Patency of lumen
- No other signs of wear, e.g. on seals, insulation or coatings

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

### 13 Service life of the products

The useful life of the products depends on their function, careful reprocessing in accordance with these instructions and careful handling of the instruments. It is therefore not possible to set a general limit on the number of reprocessing cycles. The user can recognize the end of the service life with regard to the functionality or identity of the products by the possible faults and limiting properties of the products specified under maintenance, inspection and testing, and biocompatibility can only be guaranteed up to 350 reprocessing cycles. After that, the products should be disposed of.

### 14 Service and repair

#### Service and repair

Do not carry out any repairs or modifications to the product yourself. Only authorized personnel of the manufacturer are responsible and intended for this. If you have any complaints, claims or comments regarding our products, please contact us.

#### Return transportation

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

### 15 Packaging, storage and disposal

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 kept in individual packaging, boxes or protective containers. Please handle the instruments with the utmost care during transportation, storage and reprocessing. The maintenance of the sterile condition after the sterilization process must be ensured by the user or the specialist personnel designated for this purpose.

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws. The manufacturer does not provide specific instructions for this.

### 16 Reporting obligations

Product defects that have occurred during proper use of our products should be reported directly to us as the manufacturer or to your specialist dealer. Defects in which patients, users or third parties have been harmed by the products (so-called reportable incidents) must be reported immediately to the manufacturer and, if applicable, to your competent authority. Incidents must be reported as soon as they occur so that important reporting deadlines can be met.

The affected products must be discarded, reconditioned and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.

After receiving your notification, we will inform you within a reasonable period of time about the further measures required.

### 17 Additional information

Further information on the reprocessing of medical devices:








- Internet: <http://www.rki.de>
- Internet: <http://www.a-k-i.org>
- Hygiene requirements for 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 "Hygiene requirements for the reprocessing of medical devices"
- DIN 96298-4 Functional check in the preparation process

### 18 Applicable documents

You can find instructions on how to properly dismantle the listed products on our homepage: <https://www.dimedada.de/demontageanleitung/>

- Disassembly instructions for instruments

### 19 Description of symbols used

	Attention!
	Follow the instructions for use
	Item number
	Batch designation
	CE mark, if applicable with identification number of the notified body.
	Indication for non-sterile product
	Name and address of the manufacturer


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<b>MD</b>	Medical device
<b>UDI</b>	Unique Device Identification, code for identifying a product
<b>SRN</b>	Registration number of the manufacturer in the EUDAMED database