Instruction for Use

Holding, Grasping Instruments

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1 Important Information

Read this Instruction for Use carefully before every application and keep it easily accessible for all users or the respective specialist staff.

Carefully read the warnings marked with this symbol. Improper use of the products may result in serious injuries to the patient, the users or third parties.

2 Scope

The instruments must be used according to their intended use in the medical fields and by respectively trained and qualified staff only. The treating physician and/or user is responsible for choosing the equipment for specific applications and/or operative use, for the appropriate training and information, and for the sufficient experience regarding the handling of the equipment.

3 Products / Intended use

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

Product family Forceps	
(Basic UDI-DI)	**Intended use**
Surgical soft-tissue manipulation forcep 404279662466BG	An open-surgery instrument designed to facilitate grasping and manipulation of soft-tissues
Ophthalmic soft-tissue manipulation forceps 404279662674BR	Instrument designed to facilitate the grasping, manipulation, or clamping of, and/or removal of foreign bodies from, ophthalmic soft-tissues
ENT forceps 404279639995CY	A surgical instrument designed to facilitate the grasping, holding, or manipulation of anatomical structures
Implant handling forceps 404279635079AR	Instrument with blades designed to grasp and manipulate surgical implants/devices (excluding sutures) during implantation
Dental articulation paper forceps 404279631813A7	Dental instrument designed for grasping and holding articulation paper during its application to a patient's oral cavity
Dental dressing forceps 404279631814A9	Dental instrument designed for grasping and holding a dental dressing during its application to a patient's oral cavity
Cilia forceps 404279663485BT	Surgical instrument designed to facilitate the grasping and removal of the cilia (eyelashes)
Product family Clamp atraumatic	
(Basic UDI-DI)	**Intended use**
Intestinal clamp 4042796108719Q	Instrument designed for the atraumatic grasping, compression, or support of the intestines during a surgical procedure
Rectal clamp 404279615671AH	Instrument designed for grasping or compression of the rectum and/or anal canal during a surgical procedure
Uterine clamp 404279616453AC	Instrument designed to grasp and/or manipulate the uterus during surgery.
Bronchus clamp 4042796108679Z	Instrument designed to be used for the temporary, atraumatic compression of the bronchus
Pylorus clamp 404279646599CA	Instrument intended for atraumatic compression of the pylorus (the lower muscular opening of the stomach) during a surgical procedure
Dissection forceps 404279615800A4	Instrument for grasping, manipulation, compression or joining of tissue during dissection and/or autopsy
Spermatic cord clamp 404279642468AW	Instrument designed for the temporary, atraumatic compression of the spermatic cord
Product family Clamps non-invasive	
(Basic UDI-DI)	**Intended use**
Surgical penile clamp 4042796109089N	Instrument wiht the intended to stop blood flow to the penis.
Umbilical cord clamp 404279610876A2	Instrument designed to temporarily compress the umbilical cord immediately after birth.
Towel clamp 404279634961BC	Instrument designed to hold together surgical towels and/or drapes, or for securing other devices such as cables/leads, during an operation
Surgical tubing clamp 4042796108759Y	Instrument intended to compress a tube used in association with a surgical intervention
Circumcision clamp 404279632648AP	Instrument designed 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 und vena cava inferior)	
(Basic UDI-DI)	**Intended use**
Vascular clamp 404279615882AY	Instrument designed to directly compress a blood vessel (vein or artery) to create a temporary haemostasis (arrest or prevention of bleeding)
Artery clamp 4042796L07080102UC	Instrument designed for the temporary, atraumatic compression of an artery for haemostasis (arrest or prevention of bleeding) during a procedure.
Vascular clamp 404279615882AY	Instrument designed to directly compress a blood vessel (vein or artery) to create a temporary haemostasis (arrest or prevention of bleeding)
Bulldog clamp 404279610868A3	Instrument with heavily serrated jaws at the working end designed to grasp, join, compress or support an organ, vessel or tissue
Product family Clip Applicator	
(Basic UDI-DI)	**Intended use**
Open-surgery ligation clip applier 404279635798BY	Instrument designed to apply small atraumatic clips (not included) for the ligation of blood vessels
Applikator für Aneurysma-Clips 404279632591AK	Instrument designed for the application/insertion of aneurysm clips
Product family Snare Instruments	
(Basic UDI-DI)	**Intended use**
Haemorrhoid ligator 4042796G030301W5	Instrument designed to deploy a ligature (e.g., a latex rubber band) to internal haemorrhoids for their removal through blood flow occlusion
Polypectomy endoscopic ligator 404279636176AX	Instrument used to form a ligature loop to prevent or stop bleeding after polypectomy
Product family Forceps	
(Basic UDI-DI)	**Intended use**
Surgical soft-tissue manipulation forceps 404279662467BJ	Instrument designed to facilitate grasping and manipulation of soft-tissues/anatomical structures
Middle ear malleus nipper 404279635213A5	Instrument used to cut the malleus (hammer-shaped lateral bone in the middle ear)
ENT forceps 404279639995CY	Instrument designed to facilitate the grasping, holding, or manipulation of anatomical structures
Lung forceps 404279611787A9	Instrument designed to atraumatically grasp, manipulate, or support the lung during a surgical intervention
Kidney forceps 404279616519AH	Instrument designed for grasping and elevating a kidney during a surgical intervention
Gallbladder forceps 4042796117829X	Instrument used for grasping and manipulating the gallbladder during a surgical intervention
Dressing forceps 404279634823AX	Instrument designed to apply or manipulate a dressing on tissue during a surgical intervention
Wire holding/twisting Forceps 404279632874B2	Instrument to grip, tighten, and/or twist wires during a surgical intervention
Wire holding/twisting forceps 404279632886B9	Instrument to grip, tighten and/or twist wires that are being applied to the patient during a surgical intervention
Open-surgery stone-retrieval forceps 404279635083AG	Instrument designed to grasp and/or manipulate a calculus (i.e., a kidney or gallbladder stone) during an open surgical procedure
Intestinal forceps 404279611785A5	Instrument for holding/grasping and/or compression of intestinal structures, tissues, and some organs during a surgical procedure
Haemorrhoid clamp 4042796108709N	Instrument designed for the temporary, atraumatic holding and compression of haemorrhoidal tissue during rectal surgery
Tendon forceps 404279642597BA	Instrument designed for interlacing, seizing, passing, holding, or approximating a tendon during surgery
Bone holding forceps 404279646751BQ	Instrument designed to grasp and hold a bone during an open surgical procedure
Rigid endoscopic grasping forceps 404279637100A5	Instrument used in endotherapeutic procedures to grasp tissue (usually atraumatically) or foreign bodies
Tooth extraction forceps 404279635552AW	Instrument designed for the extraction of teeth
Rubber dam clamp forceps 404279635851BB	Dental instrument used for the insertion and removal of rubber dam clamps
Tonsil forceps 404279615672AK	Instrument grasping, and manipulating the tonsils during an ear/nose/throat

	(ENT) surgical intervention, typically during tonsillectomy
Tongue forceps 4042796108619M	Instrument to facilitate the grasping, holding, or manipulation of the tongue during a surgical procedure
Obstetrical forceps, reusable 404279635082AE	Instrument intended specifically to assist the birth of the foetus during difficult vaginal births
Cranioclast 404279632650AA	Instrument is used for crushing the foetal head after perforation to facilitate the delivery of a dead or anomalous (abnormal) foetus
Uterine tenaculum 404279613998B6	instrument with hooks used for grasping and/or manipulating uterine tissue during a surgical intervention
Gynaecological grasping forceps 404279632595AT	Instrument intended to be used for the general grasping, pulling, or compression of internal structures
Hysterectomy forceps 404279635804B2	Instrument intended for the grasping, pulling or compression of the uterus during a hysterectomy
Airway obstruction forceps 4042796100588Q	Instrument to remove an airflow-obstructing object or material in the oropharynx, trachea, or upper bronchi to prevent patient asphyxiation
Airway tube forceps 4042796312649S	Instrument used for grasping a tube [e.g., a catheter or an endotracheal (ET) tube] for its insertion and/or extraction into/from the airways
Orthodontic Forceps 4042796332099Y	Instrument designed to hold small objects or to bend or to cut metal strips or wire used in orthodontic procedures
Manual orthopaedic bender 404279644795BW	Instrument designed to bend orthopaedic devices, typically those for implantation (e.g., orthopaedic rods, bone fixation plates)
Sterilizer transfer forceps 404279611792A2	Instrument designed to grasp and handle sterile instruments, packages, or implants, especially directly from a sterilizer
Sterilizing clip 404279611792A2	Product for holding instruments for fixation / protection during reprocessing
Cast breaker 404279646313AU	Instrument with strong, curved blades used to grasp and break apart hardened plaster
Surgical staple remover 404279616787BC	Instrument intended to be used to remove surgical staples
Product family Fixation Instruments	
(Basic UDI-DI)	**Intended use**
Hand traction plate 404279640633A7	Product for fixing the hand
ENT headrest 404279631920A9	To support and stabilize the head of a recumbent patient during an ear/nose/throat (ENT) procedure
External orthopaedic fixation system 404279635647BA	Devices designed to stabilize fractured bones, other than those in the vertebral column, to promote treatment and healing
Product family Stripper (*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 und vena cava inferior)	
(Basic UDI-DI)	**Intended use**
Vein stripper 404279635377B4	Instrument designed to manually excise (strip by stab avulsion)
Tendon stripper 404279635380AR	Instrument designed to excise a length of ligament, tendon or fascia for use as a living graft
Intraluminal artery stripper 404279631729AH	Instrument designed to perform an endarterectomy
Product family Eye Magnet	
(Basic UDI-DI)	**Intended use**
Eye magnet 404279646718BS	Instrument designed to generate a magnetic field intended to locate and remove metallic foreign bodies
Product family Scalp wound clip	
(Basic UDI-DI)	**Intended use**
Scalp wound clip 404279646953C6	Clamp used to unite the edges of a scalp wound during a surgical procedure on the skull (non-implantable)
Product family Matrix band	
(Basic UDI-DI)	**Intended use**
Dental matrix band tensioner 404279645008AD	Instrument designed for tightening a matrix band around a tooth that is being prepared for a dental restoration
Dental matrix band 404279616195AD	Strong material or a short tube that is used to form a mould around a tooth for the insertion of restorative materials
Product family Rubber dam clamp	
(Basic UDI-DI)	**Intended use**
Rubber dam clamp 404279615712A6	Device which is used to anchor a rubber dam down to the cervical region of an exposed tooth
Product family Impression tray	
(Basic UDI-DI)	**Intended use**
Dental impression tray 404279635850B9	A horseshoe-shaped receptacle made of metal or plastic designed to carry dental impression material to the mouth
Product family Razor blade breaker	
(Basic UDI-DI)	**Intended use**
Razor Blade breaker 404279644959C4	Instrument specially designed to be used to break, breakable razor blades into shards of extremely sharp segments
Product family Bone Approximation Clamp	
(Basic UDI-DI)	**Intended use**
Bone approximation clamp 404279634949BN	Instrument designed to grip segment of a fractured bone during orthopaedic surgery
Product family Absorbent Tip applicator/Swab	
(Basic UDI-DI)	**Intended use**
Cotton carrier 404279664011AH	An absorbent material such as a cotton pledget for cleaning or applying a substance (e.g., medication) to a superficial wound or body orifice, and to take specimens from a patient

4 Contraindication

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 and 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 when using RF, RF or laser devices simultaneously.

The products are contraindicated for all other uses except for the techniques mentioned in the intended purpose / 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 lymphedema

5 Complications / Side effect

⚠ 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 discontinued immediately and the necessary steps taken.

- Breakage of the instruments
- Injury to vessels, tissue, nerves
- infections
- Perforation of tissue, vessels, and cavities
- After bleeding
- Necroses
- Thromboses

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

⚠ Treatment-related complications / side effects / risks

General

- Injury to surrounding vessels and tissues
- Injury to nerves

Clip applicators

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

Snare Instruments

- After bleeding
- infections
- Postoperative pain
- Anal/rectal stenosis
- Incontinence
- Wound healing disorders
- Rectal perforation
- Urinary retention
- Recurrence rate

Dental forceps

- After bleeding
- Hematomas
- Injuries to surrounding vessels, nerves and tissue
- Wound healing disorders
- infections
- Damage to the adjacent teeth
- Fracture of tooth roots
- Ankylosis
- Luxation (dislocation of the jaw)

Obstetrical forceps

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

ENT head support:

- Abrasions
- Nerve lesion
- nerve damage
- Hematoma or edema formation
- Soft tissue damage
- Tissue damage

- Circulatory disturbances
- Eye damage

Extension units

- Burr canal infection
- Dislocation
- Burr canal osteomyelitis

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's disease)
- Specific sequelae: Restricted motion in OSG and/or USG, renewed instability, persistence of pain, intra-articular scarring (arthrofibrosis), arthrosis
- Nerve injury
- Cyclops
- Infections
- Thromboses
- Removal of suture buttons

Vein stripper

- Nerve damage
- After bleeding
- Swelling of the legs due to accumulation of lymphatic fluid
- Heavy in the first days
- Injury of vessels (mostly side branch veins)
- Bruises, indurations and bruises
- Infections
- Wound healing disorders
- Thrombosis

Eye magnet

- Infections
- Retinal detachment

Scalp wound clip

- Infections
- Scarring
- Chronic wound healing

Matrix band / rubber dam clamp

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

Impression tray

- Dental injuries

Bone approximation clamp

- Joint stiffening
- Tendon adhesion
- Atrophy of muscles, ligaments and cartilage due to inactivity
- compartment syndrome
- Fat clot formation
- Failure of the fracture to heal with formation of a false joint (pseudarthrosis)
- Death of a bone piece (bone necrosis)
- Infections of the periosteum or bone
- Bleeding during or after surgery
- Blood clot formation
- Hemorrhage with possible need for surgical evacuation
- Injury to nerves
- infection of the surgical area
- unaesthetic scarring
- anesthesia incidents
- allergic reaction to used materials (latex, medication)

Absorbent tip applicator/swab

- Infections
- Scarring
- Chronic wound healing

⚠ Product-related complications / side effects / risks

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

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

Clamps atraumatic:

- Breakage
- Remaining pieces
- 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 improper use can lead to premature wear of the instruments.

⚠ Material intolerance

Under no circumstances must the instruments be used if the user or specialist staff become aware of the patient being intolerant to the material.

⚠ Functional Impairment

Surgical instruments corrode and become impaired in their functionality if they come into contact with aggressive substances. It is therefore necessary to observe the storage and sterilization instructions.

⚠ Operating Conditions

The aforementioned products require correct maintenance and care in order to guarantee that the products operate safely. In addition to this, functionality testing and a visual check should be performed prior to each application. For this reason, please pay attention to the respective chapters in this Instruction for Use.

⚠ Combination with other products

Should the products be reassembled after disassembly, individual parts must not be replaced with parts from other manufacturers! If the intended purpose of the product entails certain parts being exchanged (e.g. different attachments), no parts from different manufacturers must be used! We recommend to also purchase other accessories (e.g. detergents) at Dimeda nstrumente GmbH.

⚠ Storage

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

⚠ Creutzfeldt Jakob Disease

With regard to the reprocessing of medical devices that have been used on patients or suspected patients suffering from or suspected of suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), the requirements specified in the corresponding appendix of the guidelines for hospital hygiene and infection prevention and the requirements specified by publications in the Federal Health Gazette must be adhered to. The medical devices that were used on this group of patients must be disposed of by incineration (European Waste Catalogue EAK 18 01 03) without risk. Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but no inactivating effect on TSE pathogens. Of the sterilization methods available, only steam sterilization (especially 134°C, 18 minutes) has been shown to have a limited effect.

⚠ Pointed / sharp instruments

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

7 Combination products & accessories

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

8 Liability and Warranty

As a manufacturer, Dimeda Instrumente GmbH is not liable for consequential damage resulting from improper use or handling. This particularly applies to use which is not compliant with the defined intended use, or non-compliance with the instructions on preparation and sterilization. This also applies to repairs or changes to the product which are not carried out by authorized staff of the manufacturer. These disclaimers also apply to warranty services.

9 Sterility

⚠ State upon Delivery

Medical products are delivered in a non-sterile condition and need to be prepared and sterilized by the user prior to the first application and any subsequent application according to the following instructions.

10 Reprocessing

⚠ Warnings

- Frequent reprocessing impairs the quality of the products.
- City 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 treatment instruction specifies the detergents and disinfectants used for validation. If an alternative detergent and disinfectant (RKI or VAH listed) is used, the responsibility rests with the reprocessor
- Reassemble disassembled products before sterilization.
- Reprocessing may only be performed by qualified medical personnel. Machine reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.

⚠ Use Site

The first steps of a proper reprocessing take place in the operating theatre. Coarse contaminations must be removed prior to storing the instruments if possible. For this purpose, 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.

Whenever possible, dry removal (moistened, closed system) should be the method of choice. A drying of any residues should be avoided! Wherever possible, dry disposal is to be preferred, since with wet disposal the prolonged lying of the medical devices in solutions can lead to material damage (e.g. corrosion). Long periods of waiting until the reprocessing, for instance overnight or over the weekend, must be avoided with both types of removal (<60 minutes).

⚠ Transport

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

Preparing the Decontamination

The products must be disassembled prior to the following reprocessing steps and/or must be exposed to the following reprocessing steps in an open condition, where possible. Rinse residue must be avoided. The products must be reprocessed in appropriate screen baskets or rinsing shields (choose size according to product). The products must be positioned in the cleaning basket at a minimum clearance from one another. Avoid overlapping so that the damaging of the products during the cleaning process can be excluded.

Pre-cleaning

1. Pre-clean products completely under cold water (city water drinking water quality <40°C) with a soft brush.
2. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 60 sec using a water pressure gun.

3. Soak 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. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 30 sec using a water pressure gun.

Cleaning/disinfection

Automated cleaning and/or disinfection process

(Miele Disinfector G7835 CD as per ISO 15883):

- 1 Pre-clean for 1 minute
- Drain water
- Pre-clean for 4 minutes
- Drain water
- Clean for 6 minutes at 58°C +/- 1°C using 0.5 % alkaline detergent (0,5 % Neodisher Mediclean forte)
- Drain water
- 3 minutes Neutralization (0.1 % NeodisherZ) with cold water
- Drain water
- Clean for 2 minutes with FD water <40°C.

Automated Disinfection

Automated thermal disinfection in a cleaning and disinfection device taking into consideration the national requirements for the A0 value; for instance, A0 value 3000:
< 5 minutes at >95˚C.

Automated Drying

Automated drying in accordance with the drying operation of the cleaning and disinfection device for at least 30 minutes at 92°C +/- 2°C.

11 Sterilization

(Typ B Autoclave by Tuttmauer as per DIN EN 13060

Sterilization of products with a fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into consideration the respective national requirements. The sterilization of the products must be conducted in suitable sterilization packaging according to DIN EN ISO 11607-1 and EN 868.

The sterilization must be completed using a fractionated pre-vacuum method with the following parameters:

- 134°C,
- 5 minutes hold time
- 3 pre-vacuum cycles
- Drying in vacuum for least 20 minutes

The Instruction for Use of the manufacturer of the autoclave and the recommended directions for maximum loading with goods to be sterilized must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with requirements.

⚠ Additional Information

The reprocessor is responsible for ensuring that the actual reprocessing, including the used equipment, materials and the staff involved in the reprocessing facility, achieves the desired results. This typically requires the validation and routine monitoring of the method and the equipment used.

12 Maintenance-Control-Inspection

Cool down the instruments to room temperature!

Visual inspection (before assembly):

Check the surface of the instruments or the individual components before assembly. Pay particular attention to checking joints (final part), profiles, grooves and other structures that are difficult to access:

- Is there any residual soiling or residue?

If so, manual re-cleaning and renewed complete mechanical cleaning and disinfection.

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

If so, the instrument in question must be marked and immediately sorted out and replaced.

Assembly and maintenance

- Assemble the disassembled instruments in a functionally correct manner.
- Treat moving parts, such as joints, threads and sliding surfaces, manually with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standard). EU standard)
- Distribute the oil in the joint by opening and closing 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 check, pay particular attention to the following aspects and possible malfunctions:

- No damage, such as broken tips, bent or loose parts (screws)
- Proper closure of jaws
- Correct and safe function of detents and locks
- Easy and even movement of handles, as backlash-free as possible
- Proper cutting function of shears
- Re- and spring pressure in order (punches, gouge forceps etc.)
- Continuity of lum
- 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 excluded from further use without fail.

13 Lifespan of the Products

The service life of the products results from their function, gentle reprocessing in accordance with these instructions and careful handling when handling the instruments. Therefore, a limit to the number of reprocessing cycles cannot be set across the board. Nevertheless, 100 reprocessing cycles were simulated, which showed no impairment of functionality, biocompatibility and identification of the products. The user recognizes the end of the usage cycle by the possible defects and limiting properties of the products indicated under maintenance, inspection and testing.

14 Service and Repair

⚠ Service and Repair

Do not carry out any repairs or changes to the product yourself. Authorized staff of the manufacturer are solely responsible for such work. Should you wish to make complaints or queries, or offer us any advice regarding our products, please feel free to contact us

⚠ Returns

Defective or non-compliant products must go through the entire reprocessing process before being sent back for repairs/service.

15 Packaging, Storage and Disposal

Standard packaging of the products for sterilization according to ISO 11607 and EN 868.

Store sterile products in a dry, clean, and dust-free environment, secured against damage, at moderate temperatures.

The medical products of the manufacturer should be stored and kept in single packaging, boxes or protective containers. Please handle the instruments with care during transportation, storage and reprocessing. The user and/or specialist staff intended for this is responsible for ensuring that the sterile state is maintained after the sterilization.

The disposal of the products, packaging as well as the accessories must be performed in accordance with current rules and laws. No specific instruction regarding this matter is provided by the manufacturer.

16 Reporting obligations

Product defects which have occurred during proper use of our products should be reported directly to us as the manufacturer or to your supervising 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 necessary, to your competent, responsible authority. This reporting of incidents must take place immediately after they occur so that important reporting deadlines can be met.
The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your servicing dealer will be pleased to help you with this.
After receipt of your notification, we will inform you within a reasonable time frame about the further measures required.

17 Additional information

If the chemicals and machines described here are not available, and if the reprocessing process cannot be carried out as described, it is the user's responsibility 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
- 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 control in the reprocessing process

18 Other applicable documents

Instructions for the proper disassembly of the listed products can be found on our homepage:
www.dimeda.de/ifu

- Disassembly instructions for instruments

19 Description of Symbols Used

⚠	Attention!
	Observe the Instruction fo Use
REF	Item number
LOT	Lot designation
CE xxxx	CE labeling, if necessary m identification number of the notified body.
	Indication of a non-sterile product
	Name and address of the manufacturer
	Manufacturing date
MD	Medical device
UDI	Unique Device Identification, code for identifying a product
SRN	Registration number of the manufacturer in the EUDAMED database