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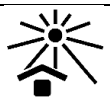
# 1 Symbol descriptions

| Symbol | Definition |
|---|---|
| CE / CE 0123 | CE-labelling |
|  | Attention |
|  | Validated Parameters |
|  | Manufacturer |
| LOT | Lot-description |
| REF | Reference code |
| Rx only | Medical device / FDA Prescription device |
| MD | Medical device |
|   | Non sterile |
|  | Keep away from sunlight |
|  | Dry storage required |
|   | (Electronic) instrucion for use |

# 2 Introduction

Our products are exclusively intended for professional use by appropriately trained and qualified personnel and may only be acquired by them.
By purchasing this instrument, you are now the owner of a high-quality product whose use and correct handling are described in the following. In order to minimize possible risks to patients and users, please observe these instructions carefully. Use, disinfection, cleaning and sterilization may only be performed by suitably trained specialist personnel.

# 3 Scope

The use of forceps and clamps is mainly in the following areas:

Approximators; Hemostatic Forceps; Sigmoid Hemostatic Forceps; Suture Clip Applying Forceps; Vein Clamps; Vessel Clips: The instrument is used in various procedures in vascular surgery. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bending Forceps; Tubing Clamps; Towel Forceps; Penis Seizing Forceps; Plaster Cast Instruments; Special Forceps; Sterilizing Forceps; Forceps, miscellaneous: The instrument is used in various procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Biopsie Punches The instrument is used in various procedures for histopathological examinations. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bronchus Clamps; Lung Grasping Forceps The instrument is used for procedures in thoracic surgery. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bulldog Clamps, atrauma; Titanium Bulldog Clamps; Hysterectomy Forceps; Kidney Pedicle Clamps; Kidney and Pankreas Clamps; Sponge Holding Forceps; Cotton Swab Forceps; Peritoneal Clamp Forceps; Multi-Purpose-Clamps; Polypus and Dressing Forceps; Nasal Polypus Forceps; Tissue Seizing Forceps with T/C jaws; Muscle grasping Forceps; Intestinal and Tissue Grasping Forceps; Capsule Forceps; Prostatic lobe forceps; Splinter Forceps; Clip Applying Forceps; Wire tightening-and twisting forceps; Wire tightener; Wire and Pin cutters; Wire seizing forceps with tungsten carbide inserts; Wire Cutting Pliers; Drill guide and protecting forceps; Flat nose pliers; Tendon seizing instrument; Bone Holding Clamps; Bone Cutting Forceps; Bone Rongeur Forceps; Scull-Cutting Forceps; Catheter Instroducing Instrument; Sinus Forceps; Clamp Forceps; Clamp Closing Forceps; Clamp holders; Grasping Forceps; Tissue- and Organ Grasping Forceps; Dissecting and Ligature Forceps, Muscle Forceps: The instrument is used in various surgical procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Intestinal and Stomach Clamp; Intestinal Clamp Forceps; Gastrointestinal Forceps: The instrument is used for surgical procedures in the area of the gastrointestinal tract. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bile Canal Clamps: The instrument is used during a surgical operation of the gallbladder. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Bile Stone Forceps; Kidney Stone Forceps; Lithotomy Forceps; Circumcision Instruments: The instrument is used for urological surgical procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Obstetrical Forceps; Catheter Instroducing Forceps; Tongue Holding Forceps: The instrument is used various invasive procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Tenaculum Forceps; Uterine Hermostasis Forceps; Ovarian Elevating Forceps; Placenta and Ovum Forceps; Uterine Elevating Forceps; Uterine Polypus Forceps: The instrument is used for surgical procedures and treatment in gynaecology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Haemorrhoidal grasping Forceps: The instrument is used for various procedures in rectal/abdominal surgery. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Cuticle- and Nail Instruments; Cuticle Nippers; Nail Nippers: The instrument is used for nail and foot care.

Bone Holding Forceps; Cartilage Seizing Forceps: The instrument is used in various surgical procedures in orthopaedics. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Septum Forceps; Nasal Forceps; Nasal Septum Forceps; Ear forceps; Goitre grasping forceps; Laryngeal Polypus Forceps; Ethmoid Forceps; Tonsil Seizing Forceps; Cartilage Crusher: The instrument is used during ENT procedures. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Occlusive Clamps: The instrument is used for various surgical procedures in the rectal area. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Vitrectomy grasping forceps; Eye forceps; Micro Forceps; Forceps ophthalmologic: The instrument is used for surgical procedures in ophthalmology. The procedure may only be carried out by suitably trained and qualified specialist personnel.

Tissue dissectors: The procedure may only be carried out by suitably trained and qualified specialist personnel.

## 3.1 Intended Use

Approximators: A surgical device for the transient retention of vessels other than the arterial vessels pulmonary, ascending aorta, aortic arcus, descending aorta, aortic bifurcation, coronary arteries, common carotid artery, external carotid artery, internal carotid artery, cerebral arteries, brachiocephalic trunk, venae cordis, vena pulmonales, superior vena cava and inferior vena cava. It is a reusable instrument.

Eye forceps; Micro Forceps; Forceps ophthalmologic: A surgical ophthalmic instrument for transient holding, manipulating, compressing, pulling or connecting ocular tissue or surrounding tissue during a surgical procedure. It is a reusable instrument.

Circumcision Instruments: A surgical instrument for the controlled removal of the penis foreskin during circumcision. It is typically made of high quality stainless steel and may have various shapes, e.g. the bell clamp (bell-shaped clamp). The foreskin is pushed over the bell-shaped protective body and the glans are positioned therein. A screw mechanism is tightened so that the foreskin is compressed in an annular manner and fitted with e.g. a scalpel along the compression ring can be cut off. It is a reusable instrument intended for transient use.

Bending Forceps: A non- invasive instrument for bending wire that serves as an ossicular replacement in the ENT area. It is a reusable product.

Biopsie Punches: A surgical instrument for the general removal of biopsies of tumours and other tissues during surgical intervention for histopathologic investigation. It is typically made of high quality stainless steel and it is a long, inelastic instrument whose distal ends are furnished with two formed cutting shells with sharped edges, one of them fits exactly in the other one, or scissor-like shells with a raw edge, which offer the cut of the biopsy. These ones are controled due to a scissor-like ring handle on the proximal end. It is inserted over a man-made or a natural body opening in body cavities. The instrument is available in a large number of sizes. It is a reusable instrument intended for transient use.

Drill guide and protecting forceps: A surgical hand instrument in the form of a cannula for simultaneously placing and anchoring a rotating drill (i.e., a surgical twist drill) through hard tissue. Surrounding soft tissue is protected while the drill is in operation. It usually has ridges at the distal end to give a secure placement on the tissue surface. At the proximal end is a handle for holding and moving. The product is usually adjusted to the drill size and is made of stainless steel. It is a reusable instrument intended for transient use.

Bronchus Clamps: A surgical instrument for atraumatic compression of the bronchi. It is a reusable instrument intended for transient use.

Titanium Bulldog Clamps: A coarse toothed surgical instrument for grasping, squeezing, connecting or holding an organ, vessel or tissue. The instrument is made of titanium and is available in two versions: 1) a flat, tweezer-like design with legs that intersect between the jaw part and the gripping surfaces. When the user presses the gripping surface, the jaw part opens or closes. 2) A locking, scissor-like design with ring handles. Both versions are available with different mouth shapes: straight, bent or angled. It is a reusable instrument intended for transient use.

Bulldog Clamps; Bulldog Clamps, atrauma: A coarse toothed surgical instrument for grasping, squeezing, connecting or holding an organ, vessel or tissue. The instrument is usually made of stainless steel and is available in two versions: 1) a flat, tweezer-like design with legs that intersect between the jaw part and the gripping surfaces. When the user presses the gripping surface, the jaw part opens or closes. 2) A locking, scissor-like design with ring handles. Both versions are available with different mouth shapes: straight, bent or angled. It is a reusable instrument intended for transient use.

Intestinal and Stomach Clamp; Intestinal Clamp Forceps; Gastrointestinal Forceps, Muscle Forceps: A surgical instrument for atraumatically gripping, compressing, connecting or holding the intestine during gastrointestinal procedures. It is a reusable instrument intended for transient use.

Wire tightening-and twisting forceps; Wire tightener; Wire and Pin cutters; Wire seizing Forceps with tungsten carbide inserts; Wire Cutting Pliers: A surgical instrument with specially designed powerful jaws for transient holding, cocking and / or twisting wire introduced during a surgical procedure. It usually has a scissor-like design with ring handles, possibly with a lock and is made of stainless steel. It is available in different sizes and the working end can be made in different mouth shapes, e.g. typically short and wide with carbide inserts. Some may also be long, with side pins for attaching the wire. The jaw and trailer are usually heavily serrated. It is a reusable instrument.

Grasping Forceps: A surgical instrument consisting of two branches, which merge into two mouth parts over an end. The mouth parts are the actual working part of the forceps, which are used in different surgical treatments, therefore they are available in different shapes. It is a reusable instrument intended for transient use.

Flat nose pliers: A surgical instrument with specially designed sturdy handles and grasping mouth (usually parallel) for transient grasping and holding an object during a surgical procedure. It has a scissor-type design with curved handles and is made of stainless steel. It is available in different sizes and the jaw part is usually wide with a ridge. The branches are connected by a swivel joint or a double-pitch screw connection to allow greater force to be exerted. It is a reusable instrument.

Bile Canal Clamps: A surgical instrument for transient holding and manipulating the gallbladder during a surgical operation. It is typically a scissors-like, self-retaining instrument with ring handles. It is made of stainless steel in different sizes. The end of work is usually grooved. The branches are interlocked to find additional adhesion to the gallbladder. It is a reusable instrument.

Bile Stone Forceps; Kidney Stone Forceps; Lithotomy Forceps: A surgical instrument for gripping or manipulating urological stones to remove them. The instrument has two handles that need to be permanently compressed during use. For stone removal, other products may be used. It is a reusable instrument intended for transient use.

Obstetrical Forceps: An obstetric instrument to help with difficult births. It usually has two curved blades which are individually inserted and then assembled together like a handle which is placed around the child's head to pull or rotate to facilitate passage through the birth canal. It is made of stainless steel. It is a reusable instrument intended for transient use.

Vessel Clips; Hemostatic Forceps; Sigmoid Hemostatic Forceps: A surgical device for achieving temporary haemostasis during surgery on vessels other than the blood vessels, arteriae pulmonales, ascending aorta, aortic arc, descending aorta, aortic bifurcation, coronary artery, common carotid artery, external carotid artery, internal carotid artery, arteriae cerebrales, truncus brachiocephalicus,

venae cordis, vena pulmonales, superior vena cava, and inferior vena cava. It is a reusable instrument intended for transient use.

Tissue- and Organ Grasping Forceps: A scissors-shaped, surgical instrument with ring handles whose working end is shaped as a ring, loop or ellipse to hold tissues or organs. It is a reusable instrument intended for transient use.

Plaster Cast Instruments: A large, non-invasive, scissor-type, hand-held instrument whose leaves, distal to the end, merge into different mouth shapes suitable for cutting thick layers of plaster or synthetic material used for a plaster cast for various body parts. The tip of one of the distal blades of the scissor-type cutting mechanism is typically rounded at its lower edge to prevent injury to the patient when cutting the cast. The product is usually made of stainless steel and usually has a spring mechanism that helps to open the mouth. It is a reusable product.

Tissue dissectors: A surgical hand instrument, usually in the form of spoon or rounded at the working end. It is used to separate soft tissue or body structures in interventions of general or plastic surgery. It usually has a handle that continues into a shaft that has a tip at the distal end. The tip may be pointed or flat, sharp or dull, angled or straight on the shaft. The instrument is made of high quality stainless steel and available in various shapes and dimensions. The instrument is reusable.

Tenaculum Forceps; Uterine Hermostasis Forceps: A surgical instrument used to grasp or manipulate the organ during an operation on the uterus. It is a reusable instrument intended for transient use.

Haemorrhoidal grasping Forceps: A scissors-type, surgical instrument with ring handles, with triangular, toothed jaw part at the working end. For transient use in rectal / abdominal surgery. The instrument is reusable after sterilization.

Cuticle- and Nail Instruments; Cuticle Nippers; Nail Nippers: A non-invasive instrument for cutting fingernails and toenails. It can be bent to match the natural curvature of human nails. The toenail models are usually made more robust to cut thick toenails. The instrument consists of two movable branches, with holes for fingers and thumbs in the handle, and cuts by closing the leaves over the nail. It is a reusable instrument.

Hysterectomy Forceps: A surgical instrument for transient grasping, pulling or pushing the uterus during a hysterectomy (removal of the uterus). It typically has a self-holding, scissor-type design with ring handles made of stainless steel. It is available in different sizes. The working end may be made in various designs, e.g. straight or bent. Some models may have an additional gripping tooth in their mouth. The mouth surfaces are roughly grooved, they can also be gerieft in the longitudinal direction in order to hold the organs better. The instrument is also known as a parametrium clamp or vaginal clamp. It is a reusable instrument.

Catheter Instroducing Instrument: A metallic, flexible stick, which is inserted transient into the lumen of a catheter or inserted into a cannula to effect a internal amplification for a temporary increase of the rigidity. With it, the manipulation and the introduction in the body is simplified for different procedures . It is a reusable instrument.

Catheter Instroducing Forceps: A hand-held instrument for gripping a tube ( a catheter or a endotracheal tube), who is inserted in or carried out of the trachea. It also serves for gripping a foreign body out of the trachea. Usually it is known as " Magill catheter introduction pliers" and has a scissor-like design with ring-shaped handles. It is made of stainless steel. It is deliverable in different types and the working end typically has snatching branches with narrow, round or S-shaped, open Mouth. The mouth areas are groved to improve a better hold. It is a reusable instrument intended for transient use.

Clip Applying Forceps: A surgical instrument adapted for applying and removing of hemostatic clips for connecting blood vessels except than arteriae pulmonales, ascending aorta, aortic arc, descending aorta to aortic bifurcation, coronary artery, common carotid artery, external carotid artery, internal carotid artery, arteriae cerebrales, truncus brachiocephalicus, venae cordis, vena pulmonales, superior vena cava, and inferior vena cava. It is a reusable instrument intended for transient use.

Bone Holding Clamps; Bone Cutting Forceps; Bone Rongeur Forceps; Scull-Cutting Forceps: A surgical instrument with stable branches and teeth for gripping, cutting or crushing bones. It is a reusable instrument intended for transient use.

Bone Holding Forceps; Cartilage Seizing Forceps: A surgical instrument for gripping and holding bones during a surgical procedure. It is usually sturdily constructed and has a scissor-like design that can be self-holding or non-latching, with ring handles or curved shaft handles. The instrument is made of stainless steel and is available in different sizes. The working end may consist of a wide variety of jaw variants, e.g., curved serrated jaw, straight, serrated jaw, or profiled key-shaped jaw with grooves for extra grip of the bones. It is a reusable instrument intended for transient use.

Cartilage Crusher: A product through which the body's own material is broken up. This material can be used to seal a perforation of the nasal septum. It is a reusable instrument intended for transient use.

Lung Grasping Forceps: A surgical instrument for transient atraumatically holding, manipulating or supporting the lung during a surgical procedure. It is typically scissor-like, self-holding with ring handles and is made of stainless steel. It's available in a variety of sizes and the gripping end is shaped like oval rings or triangular loops, which can be toothed to find better hold on the lung tissue. It is a reusable instrument.

Multi-Purpose-Clamps; Polypus and Dressing Forceps; Nasal Polypus Forceps; Tissue Seizing Forceps with T/C jaws; Muscle grasping Forceps; Intestinal and Tissue Grasping Forceps; Capsule Forceps; Prostatic lobe forceps; Splinter Forceps; Dissecting and Ligature Forceps: A surgical instrument for atraumatically holding / gripping and / or squeezing intestinal tissue, tissue and some organs during a surgical procedure. It typically has two designs: 1) a self-holding, scissor-like design with ring handles; or 2) a large tweezer-like design with straight branches interlocking at the proximal end. It is available in different sizes. The working end may be made in various designs, e.g. ring-shaped, triangular, with parallel grooving or toothing to give grip, or inwardly bent profiles for grasping. The branches are typically wide and thin. It is made of stainless steel. It is a reusable instrument intended for transient use.

Kidney Pedicle Clamps; Kidney and Pankreas Clamps: A surgical instrument for gripping or lifting the kidneys during a surgical procedure. Usually it is scissor-like and is carried out self- locked, furnished with ring-shaped handles. It is made of stainless steel and is available in different sizes. The working end has gripping branches, which are formed as very big, grooved, oval rings or half open circles. It is a reusable instrument intended for transient use.

Ovarian Elevating Forceps: A surgical instrument used for general atraumatic grasping, pulling or compression of internal structures during a gynecological surgical procedure. It is usually designed like scissors with ring handles and is made of high quality stainless steel. It is available in various sizes, the working end may have a variety of leaf shapes, e.g. straight or bent. The leaves are usually flat in profile and thin, and rounded, so they do not hurt the internal organs. It is a reusable instrument intended for transient use.

Penis Seizing Forceps: A non-invasive instrument for grasping and holding the penis during a procedure. It is a reusable instrument.

Peritoneal Clamp Forceps: A surgical instrument for transient holding the peritoneum during a surgical procedure. It is a reusable instrument.

Placenta and Ovum Forceps; Uterine Elevating Forceps; Uterine Polypus Forceps: A surgical instrument used to grasp or manipulate the organ during an operation on the uterus. It is a reusable instrument intended for transient use.

Tubing Clamps: A non-invasive surgical instrument for squeezing a tube during surgery or intervention to stop flow. It is typically a locking scissor-type instrument with stainless steel ring handles. It is available in various sizes with strong, thick, wide mouth parts, so as not to damage the hoses. Some models have scored mouth surfaces. It is a reusable instrument.

Sponge Holding Forceps; Cotton Swab Forceps: A scissors-shaped, surgical instrument with ring handles, whose working end is shaped as a ring, loop or ellipse to hold swabs or bandages. It is a reusable instrument intended for transient use.

Tendon seizing instrument: A surgical instrument with a connected handle and two branches, usually serrated, for crossing, grasping, performing, holding or approaching sinews during surgery. It is a reusable instrument intended for transient use.

Septum Forceps; Nasal Forceps; Nasal Septum Forceps; Ear forceps; Goitre grasping forceps; Laryngeal Polypus Forceps: A general surgical instrument for transient gripping, holding or manipulating anatomical structures during an ENT procedure at e.g. the bronchi, esophagus, trachea, larynx, pharynx, nose, or ear. It usually has two main designs: 1) a locking, scissor-type design with ring handles and a working end with different mouth designs, e.g. straight, angled, or curved with teeth or ridges to improve retention, and 2) a tweezer-like design (may also be a micro-fine instrument) with two connected legs with toothed jaw. It is made of stainless steel. It is a reusable product.

Ethmoid Forceps: A surgical instrument for removal of tissue or bone specimen during ear, nose and throat (ENT) procedures. The instrument can be equipped with a ring handle or pistol grip. The ring handles or pistol grips have extended shafts provided with punch-like or mechanical locking mechanisms at the distal end. It is a reusable instrument intended for transient use.

Sinus Forceps; Clamp Forceps; Clamp Closing Forceps; Clamp holders: A scissors-type surgical instrument with ring handles. The leaves are serrated and either straight or curved. The serrated area has a central, non-toothed area in its length to prevent injury to the surrounding vessels. It is a reusable instrument intended for transient use.

Special Forceps: An instrument with carbide metal insert to remove flexTIP- tips. It has a scissor-type design with isolated ring handles. It is a reusable instrument.

Sterilizing Forceps: A scissors-type, non-invasive instrument with ring handles whose leaves at the end of the joint form open circles, loops or ellipses specially designed to grip and apply sterile instruments or implants directly from a sterilizer. This is a reusable instrument.

Tonsil Seizing Forceps: A surgical instrument for transient grasping, securing and manipulating the tonsils during an ENT procedure, usually during an almond removal. It typically has a scissor-type, self-retaining design with ring handles and is made of stainless steel. It is available in different sizes. The working end is typically gripping with curved blades of various designs and / or ending in oval rings or narrow serrated triangles. The leaves are usually coarsely toothed to better grip the tonsillar tissue. It is a reusable instrument.

Towel Forceps: A non-insvasive instrument for holding wipes and other products, e.g. Cables, guides that must be securely attached near the surgical field, e.g. Towels covering the operating table. The instrument is typically made of stainless steel and may have different designs. It may, for example, have two branches crossed at the end with ring handles, or it may be a one-piece, A-shaped, end-connected instrument, the working end may be pointed, truncated, fenestrated or differently ridged. The instrument is commonly known as a cloth clamp or cloth clip. It is a reusable instrument.

Vein Clamps: A surgical device for applying atraumatic pressure to a vein except the venae cordis, vena pulmonary, superior vena cava, and inferior vena cava. For clamps used for a specific surgical purpose. It is a reusable instrument intended for transient use.

Occlusive Clamps: A surgical instrument for atraumatically gripping, squeezing, connecting or holding the rectum or rectal canal. It is a reusable instrument intended for transient use.

Vitrectomy grasping forceps: A surgical eye instrument for removing foreign bodies or the vitreous body from the eye. It is a reusable instrument intended for transient use.

Suture Clip Applying Forceps: A surgical instrument adapted for use of hemostatic clips for connecting blood vessels except than arteriae pulmonales, ascending aorta, aortic arc, descending aorta to aortic bifurcation, coronary artery, common carotid artery, external carotid artery, internal

carotid artery, arteriae cerebrales, truncus brachiocephalicus, venae cordis, vena pulmonales, superior vena cava, and inferior vena cava. It is a reusable instrument intended for transient use.

Tongue Holding Forceps: A instrument for grasping, holding or manipulating the tongue during a surgical procedure. It usually has a self-retaining, scissor-like design with ring handles. The working end is different, e.g. straight, angled or curved with large, oval-fenced, cross-scored mouth surfaces for a better grip. Some models may have replaceable, grooved rubber inserts in the jaw part. The instrument is made of stainless steel. It is a reusable instrument intended for transient use.

Forceps, miscellaneous: A surgical instrument for holding / gripping and / or squeezing tissue during a surgical procedure. It typically has two designs: 1) a self-holding, scissor-like design with ring handles; or 2) a large tweezer-like design with straight branches interlocking at the proximal end. It is available in different sizes. The working end may be made in various designs, e.g. ring-shaped, triangular, with parallel grooving or toothing to give grip, or inwardly bent profiles for grasping. The branches are typically wide and thin. It is made of stainless steel. It is a reusable instrument intended for transient use.

## 3.2 Contraindications

No contraindications are known.

# 4 Warning

| | |
|---|---|
|  | Medical products are delivered in a non-sterile condition and must be cleaned, disinfected and sterilized prior to their initial use. |
|  | The use of faulty instruments is in principle forbidden and they have to go through the whole cleaning process before return. |
|  | Please take into consideration that through higher power a bigger damage of the tissue can result: f.e. on forceps: the power at the end of the jaw is higher than at the tip of the jaw |
|  | Please observe the additional information enclosed with the products. |
|  | Remove all protective sleeves and films prior to first using or preparation for use. |
|  | The safe combination of different products or of products with implants must be reviewed prior to clinical application by the user. |
|  | Avoid improper throwing or dropping of instruments |
|  | Avoid mechanical overstressing of the instrument beyond the structural design, this can lead to breakage and deformation! |
|  | A visual inspection of the instrument for damage and contamination must be carried out before each use! |
|  | To prevent all contact corrosion, instruments with damaged surfaces must be separated immediately. |
|  | If the products are used on patients with transmissible spongiform encephalopathy or HIV infection, we decline any responsibility for their reuse. |
|  | After ophthalmical use, please pay attention to water quality during treatment (according to the specifications of AAMI TIR34 and the recommendations of the Rober-Koch-Institute on preparation of medical devices)! |
|  | Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |

# 5 Handling

The type of treatment must be determined in each individual case by the surgeon in cooperation with the internist and the anaesthetist.
For operational use in various surgical disciplines must be done by appropriately trained and qualified personnel.

# 6 Preparation

The person in charge of preparatory treatment is responsible for ensuring that the treatment is duly carried out using the relevant equipment, materials and personnel in the treatment facility and so achieves the desired result. This necessitates validation and routine monitoring of the process used. We urge you to take note of the national regulations dealing with instrument preparation.

The validated parameters refer to reusable surgical instruments. The validated parameters should also be observed for the other products described, unless a different procedure is explicitly described.

## 6.1 Reutilization restrictions

Frequent repeat preparatory treatment has minimal effects on the product. The end of the product life is normally determined by wear and damage due to use

## 6.2 Information on instrument preparation

- Use cleaning and/or disinfection agents with a pH-value within 9-10. Please observe manufacturer instructions regarding dosage, exposure time and renewal of solutions.
- Do **not** use hard brushes (e.g. metal brushes or metal sponges) or coarse abrasive cleaners.
- Never leave instruments in cleaning or disinfection agents for longer than the specified time.
- Only used demineralized water for rinsing.
- Rinse and dry carefully through channels and pipes.
- Sensitive instruments must be cleaned in a storage or clamping fixture.
- Observe manufacturer instructions of cleaning – and sterilizing equipment.

## 6.3 Preparation at the place of use

Directly after using remove coarse dirt of the instruments and rinse out the working cannulas. Do not use fixing agents or hot water (> 40°C), as this results in residues becoming fixed and can affect the success of the subsequent cleaning operation
Dismantle and/or open instruments as far as possible. Within short time after use the instruments clean the instruments for reducing a drying of the residues.
This enables an easier cleaning. If instruments come into contact with corroding medicines or cleaning agents, wash these up with water immediately after use.

Longer drying times, e.g. for dry disposal are not validated and therefore not recommended.


The drying time during validation was 1 hour.

## 6.4 Ultrasound bath (optional)

All instruments must be opened, dismantled and any cavities rinsed through.
Place instruments in the screen basket in such a way that overlaps and contact between instruments are avoided. Add cleaning agent to the water and adjust the temperature of the solution in line with the cleaning agent manufacturer's instructions.
The cleaning in the ultrasound bath should be at 35-40 kHz, 5 minutes at least.


To validate cleaning in an ultrasonic bath, the test items were ultrasonically treated in Neodisher Mediclean forte 0,5 % for 5 minutes.

Subsequently rinse instruments including all cavities before cleaning and disinfection.

Medicine products which are possessing a bad ultrasound transmission, e.g. soft material are not usable for the ultrasound bath.

## 6.5 Manual cleaning

| | |
|---|---|
| ⚠ | Since mechanical processes can be standardizied, reproduced and therefore validated, mechanical cleaning/disinfection should be preferred to manual processes.<br>Manual cleaning and disinfection process ist not validated and therefore needs to be validated additionally by the end user. |

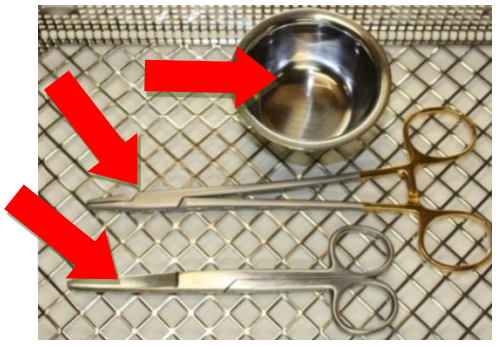
## 6.6 Mechanical cleaning

On the basis of international standards (EN ISO 15883) and national directives, only validated machine cleaning and disinfection methods may be used. For the mechanical cleaning we recommend a standard programme for surgical instruments, f.e. instruments from Miele.

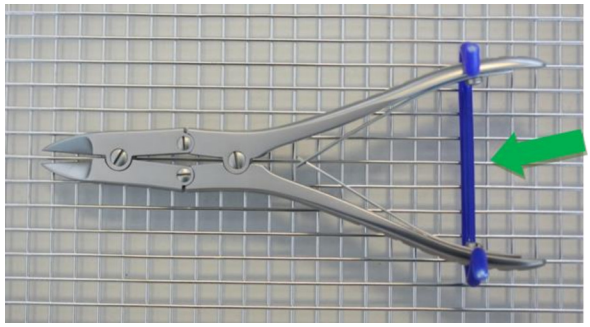
Only completely deminieralized water should be used for cleaning, neutralisation and rinsing, in accordance with the „Guidance Complied by the DGKH (Germany Society for Hospital Hygiene), DGSV (German Society for Sterile Supply) and AKI (Working Group on Instrument Reprocessing) for the Validation and Routine Monitoring of Automated Cleaning and Thermal Disinfection Processes for Medical Devices as well as Advice on Selecting Washer-Disinfectors“ (which refers to DIN EN ISO 15883-1 Point 6.4.2)

Flexible (complex) instruments with invisible surfaces have to be pre-cleaned manually before mechanical cleaning.
We recommend for all push shafts, -and pipe shafts instruments and instruments whose surfaces are on top of each others during the cleaning (f.e. bone forceps and gouge forceps) a manually pre-cleaning for an optimal cleaning result without residues
Observe the following by loading:

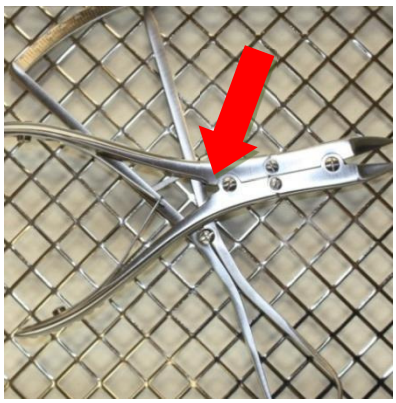
- Place the dismantled/opened instruments securely in the tray.
- Instruments with openings and gaps have to be faced down with the opened side so that they can be cleaned and no water of the cleaning process is collecting inside them. If available use balanced devices for rinsing

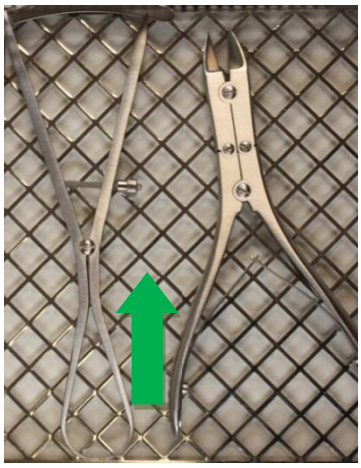


- Place the instruments with joints in an opened position into the cleaning, -and disinfection machine. If necessary use retaining clips.



- Do not overload trays, avoid creating any overlaps.





Preliminary rinsing (cold, if applicable fully demineralized water without additives) is followed by chemical. The chemical cleaning should take place at **40°C -60°C** for at **least 5 minutes**.

We recommend products with a **pH-value within 9-10,** e.g. Neodisher MediClean forte from Dr. Weigert. The cleaning agents used should be selected depending on the material and properties of the instruments and in accordance to national regulations: If there is a high chloride concentration in the water, pitting and tension crack corrosion can occur on the instruments. The occurrence of this type of
corrosion is minimized by using alkaline cleaning agents and demineralized water. By adding an acid-based neutralization medium, the rinsing off of alkaline cleaning agent residues is facilitated during the first intermediate rinsing process (warm or cold water).

In order to prevent the formation of deposits, it is advisable to use neutral cleaners where the water quality is unfavourable. After the second intermediate rinsing process, thermal disinfection takes place.
The thermal disinfection should take place at temperatures of between **80 and 95°C**, with an **exposure time as outlined in EN ISO 15883**.

After the finishing of the programme take the good out of the machine because corrosion can arise if the instrument remains in the machine.

| Parameters used for the validation of preparation | |
|---|---|
| **Pre-rinsing** | 1 minute with cold tap water |
| **Cleaning** | Temperature: 55 °C |
| | Soaking Time: 5 minutes (worst case) |
| | Neodischer Mediclean forte 0,4% (worst case) |
| **Neutralization** | Temperature: cold DI water |
| | Soaking Time: 2 minutes |
| | Neodisher Z 0,1% |
| **Post-rinsing** | 2 minutes with cold DI water |
| **Disinfection** | Temperature: 90 °C ($A_0$ 3000) |
| | Soaking Time: 5 minutes |

## 6.7 Drying

Ensure adequate drying by the cleaning and disinfection device or using other suitable measures.

Drying was omitted in the validation (worst case condition).

# 7 Maintenance, inspection

After cooling to room temperature, the instruments must be visually inspected for protein residues and other contamination, paying particular attention to cavities, blocks, inclusions, pipes, and other inaccessible areas. Instruments which are not free of residues must be returned for a complete retreatment process.

Carry out the functional check mentioned above. Instruments with stains, which are blunt, bent, no longer function or which are otherwise damaged must be segregated!
To help identify faulty instruments that need to be sorted out, we recommend the brochure "Instrument Reprocessing" from the Working Group “Instrumenten Aufbereitung”. This includes in particular Chapter 8 " Checks and Care" and Chapter 12 " Surface Changes: Deposits, Discoloration, Corrosion, Aging, Swelling and Stress Cracks".

## 7.1 Functional check

A newly purchased product must be subjected to a thorough visual and function check after its delivery and before each use.
Products must be checked for irregularities. Paying attention to cracks, fractures and the occurrence of corrosion.

If there are joints, the instruments should be oiled with a care product before the functional test. We recommend a medical white oil based on paraffin oil.
Check instruments with joints for ease of movement. Carry out a function check in accordance with the intended application of the instrument.

Essential tests for instruments with serration, jaw and ratchetare are among others:

- Correct opening and closing (smooth movement, complete)
- Intact serration (bent, broken off)
- The jaws must close properly when the instrument (e.g. ring pliers) is engaged in the last lock
- No throwing the jaws over (cross bite)
- Lock must hold with first enganged tooth

Defective products must not be used and must have undergone the complete preparatory treatment process again before being returned.

# 8 Sterilization

Prior to sterilization, products must undergo cleaning and disinfection, be rinsed off without residue using demineralized water and subsequently dried. HEBUmedical recommends using a validated steam sterilization process (e.g. sterilizer in compliance with EN 285 and validated in accordance with DIN EN ISO 17665-1).

The validated parameters refer to reusable surgical instruments. The validated parameters should also be observed for the other products described, unless a different procedure is explicitly described.

On using the fractionated vacuum method, **sterilization** must be performed with at least **134°C (USA 132° C)** with a **minimum dwell period of 3 minutes.** Vacuum drying must then be carried out for at least 20 minutes.

| **Parameters used for the validation of steam sterilization** | |
|---|---|
| **Prevacuum** | 3 times |
| **Sterilization temperature** | 132 °C |
| **Sterilization time** | 1,5 minutes (half cycle method) |
| **Drying time** | 20 minutes |

The vapour must be free of ingredients, recommended limiting values of feed water and vapour condensate are determined through EN 285.

Other sterilization processes are compatible but not validatet from HEBUmedical.

When loading, observe the recommended total weight. After the sterilization, check the sterile product packaging for damage, and inspect the sterilization indicators

## 8.1 Packaging

Compliant packaging of products for sterilization in line with ISO 11607. Packaging used must be suitable for the instruments and protect them from microbiological contamination during storage. The seal must not be under tension. HEBUmedical recommends container or hospital common sterilization paper/film packagings for sterilized packaging.

During validation the instruments were packaged in hospital common sterilization packagings (paper/film packagings) and steam sterilized.

# 9 Lifetime

The steam sterilization procedure was validated by laboratory tests. The products were sterile validated at a pre-vacuum of at least 5min duration and a temperature of 134°C for a lifetime of 50 cycles.
You can continue to use the instruments at your own responsibility over this cycle value if the tests described in chapter 7 have been successfully completed.

# 10 Storage

Store products in a dry, clean and dust-free environment at moderate temperatures from 5°C to 40°C. Protect from the effects of the sun's rays and artificial light.

# 11 Warranty / Repair

Our products are manufactured from high-grade materials and carefully checked prior to dispatch. However, even if used properly in accordance with their intended purpose they are subject to a greater or lesser degree of wear depending on their intensity of use.
This wear is technically induced and unavoidable.
Should faults occur independently of wear, please contact our customer services. Defective products should no longer be used.
They must undergo the complete preparatory treatment process before being returned.

# 12 Manufacturer and servicing address

Should you require the instructions for use in paper form, please use the contact details below. The instructions for use in paper form will be made available to you within seven calendar days of receipt of the request.
Alternatively, you can print out the electronic instructions for use yourself.

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GAIN021V006 / 21.07.2022