REDA INSTRUMENTE GMBH	**Instruction for use** **Re-usable instruments**	**Reda Instrumente GmbH** **Gänsäcker 34** **78532 Tuttlingen** (Germany) Tel. +49(0) 7462/9445 0 Fax. +49 (0) 7462/9445 20 Email: info@reda-instrumente.de

Instruction for use for Reusable medical devices

for items under SRN-No. DE-MF-000005592

Part 03120-xx until 98000-xx Link for IFU: www.reda-instrumente.de/IFU

Part R030-05xxx-248 - R030-05xxx-262 and R490-xxxxxx-xx

1. GENERAL INFORMATION

It is absolutely essential that all conditions contained in these instructions are met and all special information taken into account. Otherwise, these products may not be clinically used. In addition, any instructions for use specific to the products must be carefully followed. Should uncertainties, disagreements or questions arise, please contact us before (re)using or preparing the products.

These Instructions for Use do not replace the training, care and best available technology for the user. Therefore, we assume that the statutory provisions, standards and recommendations (e.g. from RKI or AKI) are known (see "Standards/References) and therefore, we restrict ourselves to the instructions and information for each product to be followed by the user, which are of importance for our products. The reasons for these instructions and risks that result from non-observance are listed in the statutory provisions and recommendations. Any serious incident that has occurred in relation to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and / or patient is established..

READ ALL APPLICABLE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE PREPARING OR USING A PRODUCT FOR THE FIRST TIME.

2. INFORMATION AND SYMBOLS ON LABELS

REF	Item or Ref-Number	LOT	Icon for Batch/ LOT number
	ATTENTION! Important hint.	NON STERILE	NON-steril product
	Manufacturer		Storage temperature from -20°C to 60°C
	Protect from moisture	CE 0297	CE mark and identification number of the notified body DQS Medical Products GmbH August-Schanz-Strasse 21 60433 Frankfurt, Germany
	Follow the instructions		Protect from sunlight
	Distributor	#	Icon for model number
MD	Icon for medical device		Model number
UDI	Icon for UDI code follows	QTY	Quantity

3. DESCRIPTION AND PRODUCT SPECIFIC INSTRUCTIONS

The products are medical devices with regard to national and international laws for products in human medicine
Our medical devices can be a single instrument or a set of instruments. These are instruments that are intended for repeated use.

4. INTENDED USE

The products are cutting, grasping, holding, clamping and all class IR reusable instruments (knife holders, knife blades, other knives, scissors, punches, cutting pliers, forceps, specula, Biopsy punches, curettes, clamps, needle holder, chisels and files and more (see below), which are used for skin incisions during operations, preparation processes or the cutting of tissue parts, with a locking device for tissues, needles, organs and medical supplies during operations and dissection procedures, as well as surgical aids will. In detail

The **knife holder** is a surgical instrument for sharply cutting through tissue, which is only functional in combination with a knife blade. After use, the solid scalpel handle is fed into the reprocessing process and - unlike the knife blade - reused.

A **knife blade** is a surgical instrument for sharply cutting through tissue, which is only functional in combination with the knife handle. These knife blades are sterile, disposable material. Before use, it must be sterile and securely attached to the knife handle according to the instructions for use. After use, it must be safely removed according to the instructions for use and safely disposed of in the needle disposal container.

Other knives, such as the **meniscus knife** (SMILLIE, NEFF) or the **amputation knife** consist of a handle and a blade. These are often reusable instruments and must always be sharpened. Finer reusable knives are also used in dental surgery (**gum knife, gingivectomy knife - GOLDMAN-FOX, KIRKLAND, ORBAN, wax knife**).
Reusable knives are also used in microsurgery and are therefore of a finer nature (KOOS, YASARGIL), **Ophthalmology knives** e.g. GRAEFE knife, KNAPP, BERENS, CASTROVIEJO, GRAEFE, Ziegler, DEAN, JAEGER, cornea knife TOOK, goniotomy knife SCHEIE, keratoplasty knife PAUFIQUE

In ENT or oral and maxillofacial surgery, the handles for the scalpel blade can be bayonet-shaped or elbow-bent in order to make an incision in a confined space and not obstruct the view with the operator's hand. There are also reusable knives (paracentesis, tonsils, septum, e.g. SEXTON ear knife, SCHUKNECHT, SICHELMESSER, TABB, PLESTER, ROSEN, JOSEPH, FREERINGALS, FREER, MASING, CONVERSE, BALLENGER swing knife, ring knife, cleft palate knife, tonsil knife - FISCHER, ABRAHAM, CANFIELD). These must be precisely checked during reprocessing and, if necessary, sent for grinding.
In gynaecology: mostly long handle and large blade, e.g. fibroid knife - SEGOND
Plaster knife allows precise modelling, cutting, scraping and shaping (GRITMANN, FAHNESTOCK).

Scissors can be used for sharp cutting, forcing apart (dissection) and for cutting off various materials.
Depending on the depth of the body, the handles are long, curved, angled, the cutting blades are curved in different ways and sharpened in different ways. Short scissor models are needed on the surface, in depth the working parts need to be longer. Some scissors are characterized by a golden handle - the hard metal blades have a special precision cut that does not wear out so quickly.
The working part of a pair of scissors is straight, curved or angled according to their application. The bend can be to the right or left, up or down.
The names of the scissors result from the field of application or correspond to the inventor.

Dissecting scissors: usually have rounded blades for tissue preparation and are therefore finer than surgical scissors and have different shapes.

Scissors according to **Mayo** are straight or angled to the side.

Scissors according to **Deaver** are available in different designs: pointed or blunt, straight or curved and can therefore be used in many different ways.

LEXER scissors are blunt/blunt and straight or curved. They are therefore well suited for dilating the cervix if it cannot be opened any further using Hegar pins.

Weller dissecting scissors are long scissors with short blades and are therefore well suited for deep dissection.

Ragnell scissors are blunt-blunt and have a typical blade design.

Metzenbaum scissors have a typical relationship between blade length and branch length. They are available in straight and up-curved form.

Baby-Metzenbaum scissors can be described like Metzenbaum scissors, but for use in infant and pediatric surgery, as they are much finer in design.

SANVENERO scissors are pointed/pointed and very fine and can therefore be used in plastic surgery in particular.

Blepharoplasty scissors (Greenberg-PAR, KAYE) are very delicate in their design and smaller overall than normal dissecting scissors; they have slightly rounded, blunt blades so as not to injure the eye.

JOSEPH scissors are pointed/pointed and very fine and can therefore be used primarily in plastic surgery.

Iris Scissors: The iris scissors are used, for example, to cut and remove sutures. The dissecting scissors can also be used for smaller cuts at the edge of the wound or for surgical interventions, e.g. on the eye.
Scissors with pointed or blunt ends, straight or curved. More eye scissors: WESTCOTT, NOYES, WECKER, BARRAQUER

Bulldog clamps are artery and vessel clamps that can be kept closed at all times by spring force. Their jaws are serrated so that the vessel closure is as safe and gentle as possible, e.g. bulldog clamp according to de Bakey (narrow, fine, straight or curved with the DeBakey serration), bulldog clamp according to Glover (straight or curved, barrel pressure adjustable by screws).

Backhaus clamps They are used to fix sterile drapes. The Backhaus drape clamp is a pointed, traumatic clamp that is used to fix drapes in the operating room.

Pentoneum Clamps They are used to grasp and hold the peritoneum during laparotomies and prevent the peritoneum from sliding back. A lateral bend is possible. e.g.: Peritoneum clamp according to Mikulicz/Baby- Mikulicz (removed, tooth 1 to 1, 1 to 2); Peritoneum clamp according to Schindler (completely curved, 1 to 1)

Dissecting clamps They are used for blunt severing of tissue and can be used to tie off vessels, e.g. Overholt dissecting clamps, Baby-Overholt, Mixter, Geissendoerfer, Rumel They are short, slightly curved and have cross-grooved, anatomical jaws. This means that tissue structures can be bluntly separated from one another or tied off after severing

Bowel clamps They are used to hold the intestine and prevent ingesta from passing through elastic pressure. They are long-gripping, elastically springy, usually longitudinally grooved and have jaws that are curved to varying degrees. To protect them, the jaws should be covered with fabric. The blood flow can be interrupted briefly without crushing the vessel walls. E.g.: Doyen intestinal clamp, Hartmann intestinal clamp (slanted grooved jaw), Kocher intestinal clamp (straight or curved jaw), Baby-Kocher intestinal clamp (soft, elastic jaw)

Artery clamps Grasping and holding bleeding vessels, before or after transection for primary hemostasis or before the intended ligation. Does not have atraumatic jaw surfaces - the closed jaw surface is equipped with teeth and is 1.5-3 mm long. Use only for its intended purpose. For example, anatomical artery clamp according to Péan (grooved jaws, slightly curved - it grips firmly, but does not destroy the surface of the material due to anatomical grooves. This is used to clamp coarse tissue that should not be damaged by surgical teeth. Similar clamps are Spencer or Crile, hard-grip clamp according to Rochester-Pean (grooved jaws, hook). Other examples of artery clamps are the Rochester-Ochsner (hard-grip clamp with 2 to 1 teeth), according to Kocher-Ochsner (hard-grip, clamp with cross-grooved jaws, and 2 to 1 teeth), artery clamp according to Kelly, mosquito clamps (smaller, more delicate version of the artery clamps, with toothed or untoothed jaws, addition Baby = particularly delicate), Halstead-Mosquito (1 to 2 teeth), Halstead-Mosquito-Baby ,Baby Mosquito (1 tooth).

Forceps are gripping aids. They grasp the tissue that is to be cut, prepared or sewn. They are also used to grasp, remove or place other materials. Atraumatic designs prevent tissue from being crushed. The primary intended use of **hemostatic forceps** is **hemostasis**—controlling bleeding by physically constricting blood vessels

Needle holders are instruments for grasping, holding and guiding surgical sewing needles during sutures.
Needle case / box is used for the safe disposal and processing of used, sharp, or pointed medical devices.

Retractors are needed to keep the surgical area open. They are designed depending on which layer needs to be kept aside.

Retractor holder Used to securely clamp/fix a retractor. It is used for open surgery.

Spatulas Used for scraping, crushing, holding away, picking up and transporting. They differ in shape, material and size depending on the area of application.

Spreader / rubber dam clamps Using a grid system or tension, they allow the wound to be spread with varying degrees of force depending on the area of application and keep the access path passively open after locking/inserting.

Specula The term speculum covers all instruments that are grooved or tube-shaped. They are inserted into natural body openings (rectum speculum, nasal speculum, vaginal speculum) in order to be able to look at them, examine them or operate on them. They come in different sizes.

Dilators Are used to stretch and/or widen narrowing of hollow organs and body cavities. Lacrimal dilators used for widening of narrowed or blocked lacrimal puncta and lacrimal ducts.

Mouth gags They are used to keep the mouth open during a medical examination/operation. These are usually for fixing.

Catheters A catheter is an instrument with one or more lumens that can be inserted into hollow organs or body cavities for diagnostic or therapeutic purposes. They can be used to probe, empty, fill or flush hollow organs.

Bone lever This blunt instrument can be used to lift bone fragments or narrow bones in order to reposition them or to lift a depressed bone.

Bowls are used in surgery for covering fluids and for depositing surgical instruments. Cotton wool **boxes** for storing cotton wool, cotton swabs and other accessories.

Cotton Applicators used for applying medications or solutions to specific areas, cleaning wounds, and collecting samples for testing

Elevators are handheld instruments used across multiple medical specialties to lift, loosen, or separate tissue, bone, mobilizing teeth, removal of teeth and removal of roots. In most cases they are used to loosen firm teeth before application of forceps to extract the tooth out of the socket. They are categorized into tissue (periosteal) elevators and dental luxating elevators.

A **surgical awl** is provided for orthopaedic applications that include creating or enlarging holes in bone. The **awl** has a shaft and a cutting tip that has a working end and an opposite attachment end, which mechanically locks in place into a recess formed in the end of the shaft opposite the handle. A surgical **extractor** for removing objects from a body including, for example, kidney stones and gall stones. The extractor includes a handle at an proximal end of the extractor with a slider for operation. A trephine handle is a surgical instrument designed to hold and manipulate a trephine blade to cut out circular pieces of tissue.

A **gauze packer** (also known as a packing instrument or uterine packer) is a specialized medical tool designed to assist healthcare professionals in placing ribbon gauze into deep wounds, narrow cavities, or surgical sites to absorb fluits.
Middle Ear Picks: Middle ear picks are surgical instruments used to manipulate tissue, clear fluids, and perform examinations within the middle ear cavity.
Surgical spoons or **Spatulas** are used for scraping or debriding tissue. A surgical spoon, curette, spatula or excavator can be used to remove pathologic tissue.

Drill Guides, Hand Drills, Surgical Centric and eccentric drill guides (in conjunction with compression plates) ensure a low-strain seat of the bone screw in the bone plate and thus, make maximum axial compression possible (for compression techniques).

Bougie used for introduction into the urethra, usually for calibrating or dilating constricted areas.
Curets are surgical instruments with circular cutting loop, ring, or scoop with sharpened edges, attached to a rod shaped handle, used for curettage.
Hooks (Hooklet) and Probes are surgical instruments to be used for lifting and retracting tissues. The **Uterine Sound** is **used** to gauge the depth and position of the **uterine** cavity. Surgical **needles** are essential instruments used in various medical and surgical procedures. They facilitate the process of suturing tissues together, ensuring correct healing and functionality. Surgical needles can be classified based on their shape, type of point, and intended application.

Spreader, Rip and Spreaders, Plaster are surgical instruments, which are used to keep an operating area open. Unlike tissue retractors, wound spreaders are self-holding instruments. This is mostly achieved using a rest lock.

Abdominal retractors are surgical instruments, which are used to keep an operating area open. Unlike tissue retractors, abdominal blades are self-holding instruments. This is mostly achieved using a rest lock.

Wound Retractors are used to hold tissue, organs and bones and to spread the edges of wounds.

Ophthalmic scissors are short and either pointed/pointed or blunt/blunt – straight or curved. They are used for operations on the eye.

AEBLI eye scissors are blunt and suitable for operations on the eye.
KILNER dissecting scissors are blunt/blunt, straight or curved. These are suitable for fine preparations.

BONN scissors have a very delicate cutting blade, which is pointed or pointed-blunt. They are usually used to cut through very fine suture material.

REYNOLDS dissecting scissors are available pointed, straight or curved.

COTTLE, Bulldog scissors are curved scissors with a short blade and are used in rhinoplasty surgeries.

STEVENS scissors are straight or curved pointed/pointed or blunt/blunt. They are small and delicate. These scissors can be used in both plastic surgery and ENT. Due to the narrow, short blade, tendons can be shortened, separated or split very precisely.

PERWITZSCHKY scissors are salivary duct scissors that are curved and have a spherical button on the upper blade. It serves to widen the salivary duct.

Strabismus scissors are blunt/blunt-straight or curved and are mainly used in ophthalmology.

LANDOLT scissors are **curved on the flat**. They are primarily used in ophthalmology, for example, during strabismus (squint)

HEYMANN, FOMON and COTTLE nose scissors are angled scissors which are usually used for operations in the nasal cavities.

DEAN tonsil scissors are serrated or smooth and are used in ENT for operations on the tonsils.

BOETTCHER tonsil scissors are specially designed to prepare tonsils. A tip of the scissor blade is round or has a button so as not to injure nearby tissue.

Vascular scissors (POTTS-DEMARTEL with knob, DIETRICH, DE BAKEY, POTTS-SMITH, FAVALORO, KELLY, SCHMIEDEN-TAY- LOR, KLINKENBERG-LOTH) are angled to the right or left at the working ends. The angle is specified in degrees: 25, 45, 60, 90 and 125 degrees. They are usually slightly bent upwards like a beak. They are used, for example, to open smaller vessels.

Ligature scissors (SPENCER, NORTHBENT, LITTAUER) A hook is notched at the tip of the lower blade. The opposite scissor blade is used to cut the thread. The pointed hook can easily be slid under a thread, making it easier to pull threads. The curvature of the hook prevents the thread or thin surgical wire from slipping out of the scissors when cutting. In this way you can cut without having to pull the thread and the surrounding tissue too hard. Ligature scissors are mainly used for atraumatic suture pulling.

Gallbladder scissors (THOREK, SATINSKY) are S-shaped, have long branches, short blades and a blunt/blunt tip. They will be used to open/expand the gallbladder duct.

Neurosurgical scissors have long branches and short, curved or straight branches that enable delicate working methods. They are used in neurosurgery and vascular surgery (STRULLY, TOENNIS-ADSON, DANDY, OLIVECRONA)**.**

Parametric scissors have long branches and long, curved, rounded blades and are used in gynaecology, e.g. hysterectomy**.**

Gynecological scissors (such as SIMS, SIEBOLD, WERTHEIM, DOYEN, DUBOIS) are usually curved and gently angled. They have curved cutting blades, with the covering blade being slightly longer.

Episiotomy scissors (WALDMANN, BRAUN-STADLER) These scissors are used in the delivery room - they are used to perform the episiotomy (siotomy). The slightly curved scissor blades allow the perineum to be cut even from an angled position.

Umbilical cord scissors (mod. USA, BUSCH, Schumacher) are powerful scissors for clamping and cutting the umbilical cord.

Cartilage scissors (MARTIN, McIndoe Cartilage) are serrated and designed to cut through cartilage and other types of connective and supporting tissue**.**

Rectum scissors (CRAFOORD) are strongly curved, have long branches and short blades and blunt/blunt tips. They find their application in proctology.

Intestinal scissors (FERGUSSON) have a button-shaped rounded edge at the tip of the blade. This allows the intestinal wall to be lifted so that an incision can then be made. The intestinal scissors are very powerful models.

Nail splitting scissors (SYSTRUNK) have strong branches and short, pointed blades so that ingrown nails can be split easily with little effort.

Sternum scissors are sharply angled, have fine teeth and are used to transect the sternum during anterior thoracotomy.

Enucleation scissors: In surgery, these scissors are used to remove a delimited, encapsulated area of tissue. The surrounding tissue is not removed any further.

Rib shears are crescent-shaped and are used to cut through ribs (GLUCK, STILLE, CORYLLOS, BETHUNE, SAUERBRUCH, GIERTZ- STILLE, BRUNNER).

Facelift scissors (GORNEY, REES, KAYE, FREEMANN, PECK-JOSEPH, BEUSE, GORNEY- FREEMANN) are characterized by longer branches and shorter cutting blades in order to be able to carefully and widely prepare through a small surgical access.

Micro scissors (MICRO SPRING SCISSORS Type VANNAS, REDA, HEPP-SCHEIDEL, GOMEL) are particularly delicate and correspondingly sensitive to incorrect stress or improper use. The instruments are flattened in the handles and have a profile on the outside, which makes them safe to handle. If the jaws are round, turning them during use is very easy, without the need for a second hand. The scissors have a spring mechanism. They are available with and without a button.

Micro ear scissors have a tubular shaft. They have very small, fine blades (BELLUCCI, SHEA, WULLSTEIN).

Thread scissors (SPENCER; NORTHBENT; LITTAUER; O`BRIEN, HEATH, WAGNER) are specially designed for the precise cutting of surgical threads. Since the thread scissors are made of stainless steel, they can be used particularly hygienically. Due to the different lengths and variants of the thread scissors, curved and straight, they can be used appropriately depending on the material.

Gum scissors (GOLDMAN-FOX) have a high cutting performance and a good grip. The serrated cutting edge prevents tissue and thread from slipping off.
The leaves are curved or straight and the tip is pointed/tapered. Also available as supercut scissors:
The Super-Cut scissors are characterized by a special grind on one side of the cutting edge and micro-serration on the other. Some of the "Supercut" scissors are available with black handles, which have a Ti-AlN coating.

Gum scissors (QUINBY, LOCKLIN, CHADWICK)- The cutting blades are short, more curved and have sharp tips (dental instrument)

Crown scissors: Are mostly used to undo intermaxillary lacing or wiring in patients who may be at risk of aspiration. Crown scissors are ideal for marking and bending the wire.

More scissors in dentistry - BEEBEE crown scissors

Wire cutters (UNIVERSAL TC) with hard metal inserts (TC). These differ in they usually last 30 times longer and remain sharp over many sterilization cycles. For cutting through fine wire material.

Plaster and bandage scissors have cutting blades that are angled upwards, the lower blade of which has a thickened, blunt tip so as not to injure the patient when checking or removing bandages, etc
e.g. REDA-EXCENTER, KNOWLES, LORENZ, UNIVERSAL bandage scissors.
Special scissors can be found primarily when applying bandages and in special operations**.**

Bandage scissors according to **Lister** are bent and blunt. Next Bandage Scissors- SMITH US ARMY is used for cutting gauze.

Plaster scissors (ESMARCH, SEUTIN, BRUNS, STILLE) have cutting blades angled upwards, the lower blade of which has a thickened, blunt tip. Thus, injuries when working the cast on the patient are reduced.
Bandage cutting scissors are used to cut through gauze and cellulose. A punch is used to remove tissue and bone and is used in general surgery. Thanks to its long, narrow shaft and the angled branches, it is very easy to work through small body openings/surgical accesses. They are used, for example, in knee joint arthroscopy to smooth a torn meniscus there.
This means that the jaw parts cut the cartilage tissue between them when the rings are pressed together. There are many different types of jaw parts, which are directed up or down, to the right or left in different graduations. There are also left-hand and right-hand versions.
Pliers with sharp jaws/blades such as gouge pliers, pinching pliers, Nasal grasping forceps, laminectomy forceps, rongeur, pituitary forceps, wire clippers, wire cutters.
Cutting bone forceps usually do not have rings, but branches that are grooved on the outside to prevent the hand using the force from slipping off. Other forceps used for cutting, such as nasal grasping forceps, laminectomy forceps, have rings that the surgeon can reach into. Since bones are hard in structure, these instruments must be adapted to the strength and size of the bone. They have a sharp, spoon-shaped jaw, according to the task, a locking mechanism that is usually offered without a lock, sometimes with a double translation so that it does not take up too much space in the situs, and two jaws. Two ground cutting edges meet in the jaw part and cut through strong cortical structures. The working part can be straight, curved or bent at right angles, depending on the shape and location of the bone. Pinching pliers and wire cutters have the same structure, but these have a larger gear ratio, depending on the material to be cut through. They have jaws with sharp cutting edges. As already mentioned, nasal grasping forceps and laminectomy forceps have a handle consisting of two rings, a long shaft (different lengths depending on the surgical area) and a jaw part. There are many different types of jaw parts, which are directed up or down, to the right or left in different graduations. There are also left-hand and right-hand versions. If bones are to be severed, saws or bone scissors are used. These cutting instruments are referred to as bone splinter forceps because they can also be used to remove splintered bone parts. Two ground cutting edges meet in the jaw part and cut through strong cortical structures. As with the Luer, for example, the working part can have different variations. The **handle for a wire saw** is intended to provide a secure, comfortable grip to control the saw during cutting
A biopsy forceps is a medical instrument for taking tissue samples (biopsy) in medicine and veterinary medicine. It consists of two scissor-like handles which, when pressed together, close the jaws (notches) on the head and thus sharply sever the tissue located between them. Biopsy forceps are available in different designs - for example forceps according to Tischler, Eppendorfer, Kevorkian or Burke. They differ in the shape of the pliers heads. Biopsy forceps are also available for use in the working channel of an endoscope and thus for taking tissue samples in minimally invasive procedures.
A **proctoscope** may be performed to diagnose problems or conditions affecting the rectum or anus, such as: Tumors, rectal polyps, sources of inflammation and bleeding. Hemorrhoids. **Anoscopes** have the same indication but can be useful in evaluating for anal cancer.
Curettes have a long shaft and a handle that can be found either in the middle or at one end. They either have two different spoon-like working ends (blunt or ground) or one (blunt or ground). They are available in different sizes and lengths and in different angles (e.g. slightly curved) and are used for scratching or scraping.
Curettes are used in gynecology to scrape the lining of the uterus. It is important to know whether the scraping is being performed on a non-pregnant or on a pregnant uterus, as this will determine whether sharp or blunt curettes are used.

Corner files are used for fine work in the nail fold, smoothing and rounding off nail edges and nail corners as well as for treating ingrown toenails and fingernails. Corner files are available in straight, curved, coarse, fine and extra fine versions.
Chisels and gouges are sharp instruments and are used to cut through bone or split off a portion.
Flat-shaped chisels are often also called osteotomes and are used to split off bone parts.
If the blade is straight, one speaks of a so-called flat chisel, hollow in shape of a gouge.
The blades can be sharpened on one or both sides, straight or curved, and the blade can also have a split tip for special applications.
The size of the chisel is adapted to the bone which would be separate adapted. As a rule, chisels / osteotomes and gouges have a strong, rectangular plastic handle so that the hammer has a large contact surface.
A **ruler** is a common measuring tool used to measure and draw straight lines. It is typically a long, flat, and narrow strip made of materials of metal. Rulers are marked with units of measurement, such as inches or centimeters, along their length, allowing for precise measurement and drawing

Dorsey bowl grasper, ear forceps, ear polyps forceps, finger ring saw forceps, fixation forceps, flat noise pliers, Frohn cotton carrier, gall duct forceps, Gerald tissue forceps, Glover multi purpose vascular clamp, goiter seizing forceps Lahey, Guyon atraumatic forceps, haemorrhoidal forceps, Hemostatic forceps, holder, Kristeller, Hunt forceps, Hysterectomy forceps, Serpentine grasper, intestinal forceps, Kalt needle holder, Kelly forceps, Kidney stone forceps Randall, Kocher-Nippon arterial forceps, Lambert-key anastomosic clamps, Landolt forceps, Landolt Pituitary rongeur, Leland-Jones peripheral vascular clamp, ligature carrier, ligature forceps, lobe grasping forceps Millin, ligature catcher, Micro laryngeal cup forceps, micro tying forceps, micro-needle holder, Parametrium forceps, Mixter clamp, muscule forceps and nail extracting forceps are also part of this instruction manual.

Mallet/Hammer: Reflex hammer: The classic reflex hammer is used to examine the nervous system. The doctor strikes specific nerves with a precise movement of the wrist to test their reflexes. The mallet: Surgeons use this during joint replacement surgery (e.g. hip or knee implants) to drive artificial components precisely and securely into the bone.
Working on bones: During spinal surgery or when treating fractures, it helps to position instruments or pins in a controlled manner

5. INDICATION

Knife holder: Is a surgical instrument for sharply cutting through tissue, which is only functional in combination with a knife blade. These are used in general surgery.
Knife blade: The blade is clamped in a knife holder. These are used in general surgery.
Other knives: These instruments separate different materials with sharp edges. Possible materials are tissue, skin, thread and sutures/dressing material, plaster of paris and bone. Depending on the application, the instruments differ in shape and size.
Percussion hammer: used primarily in neurological examinations to assess reflexes, nerve and muscle function, and for percussion.
Impact hammer: A medical bone hammer (surgical hammer or impact instrument) is used in orthopaedics, trauma surgery, oral and maxillofacial surgery and neurosurgery to apply targeted mechanical force to other surgical instruments.

Scissors: Scissors can be used for sharp cutting, forcing apart (dissection) and for cutting off various materials**.**

Punch: Used to remove tissue and bone. Application in general surgery.

Forceps: Used to remove tissue/bone/cartilage tissue or to cut Kirschner wires or similar. Depending on the area of application, the pliers differ in shape and size. Application in general surgery. Hemostatic forceps are indicated in surgical procedures for Occlusion of Blood Vessels, Tissue Retraction and Dissection and Holding Sutures.

Bone Curette: Bone curettes are intended for scraping, debriding, or removing bone tissue, fibrous growth, or cartilage, as well as for harvesting small cancellous bone grafts during orthopedic, trauma, dental, or neurosurgical procedures..

Corner files: Corner files are used for fine work in the nail fold, smoothing and rounding off nail edges and nail corners and for treating ingrown toenails and fingernails. Corner files are available in straight, curved, coarse, fine and extra fine versions

Chisels: Chisels and gouges are sharp instruments and are used to cut through bone or split off a part.

Mallet/Hammer:

6. MATERIAL USED

Surgical instruments are made of stainless steel according to ISO 7153-1.

7. INTENDED PATIENT GROUP

- The cutting and grasping instruments can be used throughout a person's entire life cycle.
- The cutting and grasping instruments can be used on female, male and various people of both sexes, taking into account the indication, product-specific indication, contraindications.
- The patient's anatomy and physiology are evaluated by the user, taking into account the indications, product-specific indications, contraindications, and notes to be taken into account, which can be found in the instructions for use. With regard to the psychological stress in the contraindications, we would like to point out that patients who are not mentally able to understand and follow the doctor's instructions are not permitted to use cutting instruments.

8. USER

The application should only be carried out by practiced, surgically trained medical personnel who have been instructed in the relevant procedures within the framework of generally recognized training courses and taking into account the relevant literature..

9. CONTRAINDICATIONS

1. Local infection due to poor soft tissue conditions in the area of the osteotomy
2. Increased fibrous tissue around the surgical site.
3. Early or late deep and/or surface infection.
4. Nerve damage is possible as a result of surgical intervention.
5. Application failure due to insufficient pre-load healing period
6. Do not use in combination with high-frequency surgical instruments

In most cases, any complications that may occur are not directly related to the use of an instrument, but rather are caused by the wrong selection of the patient, inadequate training and imprecise handling. If the forces are too great, unwanted injuries to the tissue or the bones can lead to impairments or even cause the instruments to break. Careful use of the instruments is therefore absolutely necessary. In order to rule out complications caused by damage to the instruments, the material used must always be checked before use.

10. WARNINGS AND PRECAUTIONS

- The surgical instruments are not suitable for implantation.
- The surgical instruments are delivered NON-STERILE! The packaging is a transport packaging. The packaged products are labeled according to the "non-sterile" symbol (ISO 15223-1). Upon receipt of the products, check the identity, completeness, intactness and function.
- After each treatment and before each use of surgical instruments, they must be checked for breaks, cracks, deformation, damage and functionality (100%). Areas such as cutting edges, points, ends, locks, detents and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out and properly disposed of in accordance with country-specific disposal guidelines.
- The doctor treating you and all other people involved in handling the products are responsible within the scope of their area of activity for having appropriate product knowledge based on the latest technology standards. This enables the products to be handled correctly and prevents health or safety risks for the patient, user or third parties.
- The corresponding product catalogues, videos, technical specifications, instructions from medical product advisors, working groups, seminars, specialist courses, publications, etc. serve as sources of information for the products. Appropriate product training - including the handling of the products - must be carried out prior to clinical use
- The indications for use for the products represent a set of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The attending physician is responsible for the correct selection of the patient, the assessment of the indication and the selection of the surgical instrument.
- The doctor treating you should discuss in detail with the patient the treatment result to be expected from using the products. Particular attention should be paid to a postoperative review and the need for regular medical follow-up.
- Surgical instruments must be handled and stored with care. Damage or scratches on the surface of surgical instruments can significantly affect the strength and fatigue resistance of a product.

- The patient must be instructed in proper postoperative hygiene and should be instructed to promptly inform the treating physician of any unusual changes in the surgical site. The patient should be monitored continuously if a change in the surgical area is noticed.
- After contact with or application to patients with Creutzfeldt-Jakob disease (CJD) or its variants, we reject any responsibility for the application! In this context, please note that you may also have contaminated the unused instruments in the trays. Instruments contaminated with CJD must be handled according to RKI guidelines.

11. CHECK BEFORE USE

All instruments must be checked visually for damage, wear and tear and contamination before use. Articulated instruments should be checked for ease of movement (avoid too much play). All instruments must be checked for function. In the case of sets, it must be checked whether all the associated components are present. The functional tests must be carried out in accordance with DIN 96298-1, -2, -3and -4.

12. PREPARATION, CLEANING, DISINFECTION, MAINTENANCE AND STERILIZATION OFINSTRUMENTS

I. Basic Warnings and Precautions

Instruments made of stainless steel must not be placed in a physiological saline solution (NaCl solution), since prolonged contact leads to corrosion such as pitting and stress corrosion cracking.

WARNINGS Only cleaned and disinfected instruments may be sterilized.

Limitation of reprocessing Frequent reprocessing has little impact on these instruments. End of life is usually determined by wear and damage from use.

Please note the instructions for use.

The products are delivered NON-STERILE! The packaged products are marked accordingly.

Upon receipt of the products, check the identity, completeness, intactness and function.

Before instruments are used, they must be checked for breaks, cracks, deformation, damage and functionality. Areas such as cutting edges, tips, ends, locks, detents and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

The attending doctor and all other persons involved in handling the products are responsible within the scope of their area of activity for having appropriate product knowledge based on the latest technology standards. This enables the products to be handled correctly and prevents health or safety risks for patients, users or third parties.

The relevant product catalogues, videos, technical specifications, instructions from medical product consultants, working groups, seminars, specialist courses, publications etc. serve as sources of information for the products. Appropriate product training - including how to use the products - must be carried out prior to clinical use

The indications for use for the products represent a set of standard information that can be adapted to individual needs and situations that arise according to the ability, experience and diagnosis of a legally qualified medical user. The attending physician is responsible for the correct selection of the patient, the assessment of the indication and the selection of the instrument.

The attending physician should discuss in detail with the patient the treatment result to be expected from the use of the products. Particular attention should be paid to postoperative consultation and the need for regular medical follow-up.

The products must be handled and stored with care. Damage or scratches to instruments can significantly affect the strength and fatigue resistance of a product.

The patient must be instructed in proper postoperative hygiene and should be instructed to promptly inform the treating physician of any unusual changes in the surgical site. The patient should be monitored continuously if a change in the surgical area is noticed

After contact with or use on patients with Creutzfeldt-Jakob disease (CJD) or its variants, we reject any responsibility for the use! In this context, please note that you may also have contaminated the unused instruments in the trays.

Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the doctor's practice or hospital.

II. Cleaning and desinfection by machine

1. Immediately after use, coarse soiling should be removed from the instruments with a disposable cloth/paper.
2. No fixing agents or warm water (>40°C) may be used, as this leads to the fixation of residues and can affect the cleaning success.
3. The instruments must be sent to the reprocessing process immediately.
4. Preferably dry disposal.
5. Transport in closed disposal containers

Preparation for decontamination:

Instruments with joints must be opened for processing. The instruments must be placed on machine-suitable instrument holders so that they can be washed. The instrument holders (e.g. wire mesh bowls) must be designed in such a way that the subsequent cleaning in the ultrasound or in the cleaning and disinfection device (RDG) is not impeded by sound or rinsing shadows.

pre-cleaning:

1. Soaking the instruments in cold water for 5 minutes;
2. Brush (plastic brushes) the instruments under cold water until all visible dirt has been removed;
3. Internal cavities, threads and bores are each rinsed with the water pressure gun for 10 seconds and brushed again;
   National guidelines must be observed.

Cleaning: by machine with cleaning and disinfection device

With regard to the responsibilities for the professional cleaning and disinfection of the cutting surgical instruments from the manufacturer Redainstrumente GmbH lie with the operator and the product user. The country-specific guidelines must be observed. The aseptic regulations for the respective country-specific guidelines must also be observed.

The following information must be observed:

- The cleaning and disinfecting medium used must be suitable for cleaning/disinfecting surgical instruments made of high-alloy steel and titanium alloys, which is non-foaming and highly alkaline. Only approved cleaning and disinfection media according to

(RKI, FDA DGHM, DGSV, DGKH) may be used.

- In order to be able to prepare the surgical instruments optimally, the holder or the surgical instruments should be placed in such a way that the bores, threaded holes or other indentations can be rinsed completely and thoroughly.
- The manufacturer, reprocessing and sterilization validation takes place individually packed and not in trays.
- The system manufacturer's instructions relating to mechanical processing must be observed.
- Loading of the receiving baskets or immersion tank screens of the processing machine must be carried out in accordance with the manufacturer's instructions.
- Automated reprocessing may only be carried out with deionized water (DI water) in accordance with EN 285:2015 +A1:2021 Annex B.
- The cold water specification corresponds to the drinking water supply (Drinking Water Regulation of April 10, 2022).

Machine processing cycle
Step 1: 1. Pre-rinse with cold water
Time: 2 minutes Temperature: 18 to 21°C

Step 2: 2nd pre-rinse with cold water
Time: 4 minutes Temperature: 18 to 21°C

Step 3: Cleaning with 0.5% alkaline cleaner
Time: 5 minutes Temperature: 55 to 58°C Medium: 0.5% alkaline detergent Neodisher®

Step 4: Neutralization with 0.1% neutralizer
Time: 3 minutes Temperature: 38 to 40°C Medium: 0.1% neutralizer

Step 5: Intermediate rinsing with deionized water
Time: 2 x 2 minutes Temperature: 40 to 45°C Medium: deionized water
With intermediate emptying

Step 6: Final rinse with deionized water and thermal disinfection
Time: 5 minutes Temperature: 90 to 95°C Medium: deionized water

Disinfection:
The disinfection of the machine reprocessing takes place with regard to the A0 value (ISO 15883-1+2) and consideration of the national requirements. A0= 3000 value = 90°C temperature with 5 minutes holding time (worst case validation carried out with 55°C with 5 minutes holding time)
The following points must be observed for chemical disinfection:

- The solutions used in chemical disinfection must be used in accordance with the manufacturer's instructions for the solvent used.
- The working dilutions of the chemical agents are to be prepared with pure water. The addition of other cleaning agents is not permitted.
- When using chemical agents, the manufacturer's instructions (exposure time and concentration) must be observed. Recommendation: Korsolex® Endo-Disinfectant, disinfectant for chemo-thermal treatment. Application according to the manufacturer's instructions.

Drying:
Step 7: Drying
Time: 30 minutes Temperature: 80 to 85°C
(worst case validation carried out at 60°C for 30 minutes)
Adequate drying must be ensured by the RDG. The surgical instruments must be removed from the RDG immediately after the end of the cleaning and disinfection program. If necessary, the use of compressed air for drying is recommended due to its good and rapid effect (RKI recommendation).

III. Cleaning and desinfection manually

The cleaning and disinfecting agents used must always be suitable for the manual cleaning or disinfection of instruments and must be compatible. The disinfectant must have a tested effectiveness. When choosing the disinfectant and method, the relevant lists and recommendations of the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology (DGHM) must be observed.

Pre-cleaning:
1. Soaking the instruments in cold water for 5 minutes;
2. Brush (plastic brushes) the instruments under cold water until all visible dirt has been removed;
3. Internal cavities, threads and bores have to be rinsed with the water pressure gun for 10 seconds and brushed again;

Manual cleaning
1. Place instruments in an ultrasonic bath at 40°C with 0.5% enzymatic cleaner for 15 min and sonicate.
2. Remove instruments and rinse with cold water.
3. Brush (plastic brushes) the instruments under cold water for 1 minute. Internal cavities, threads and bores have to be rinsed with the water pressure gun for 10 seconds and brushed again. To avoid the risk of insulation damage or corrosion, do not use a metal brush, steel wool or other cleaning devices containing metal.
4. Dry instruments with an absorbent, soft and lint-free cloth. Dry the lumen and channels with compressed air.

A high level of dirt in the ultrasonic tank impairs the cleaning effect and increases the risk of corrosion. Depending on the conditions of use, the cleaning solution must be renewed regularly. The criterion is a visually recognizable contamination. In any case, frequent bath changes, at least once a day, are required.

Manual/chemical disinfection:
1. Place instruments in a bath with a listed disinfectant (e.g. 3% Korsolex® plus for 15 minutes)
2. The instruments must be completely covered with the solution; Cavities must be rinsed with the disinfectant.
3. The exposure times, temperatures and concentrations specified by the cleaning agent or disinfectant manufacturer must be observed;
4. Remove instruments and rinse with cold deionized water for at least 2 minutes;

Optical control:
5. Repeat the cleaning process if there is still visible contamination on the instrument;

Freshly prepared ready-to-use solutions must be used every day. If there is a lot of dirt, the working solution must be changed more often. The national guidelines must be observed.

Drying:
Manual drying with compressed air and using a lint-free cloth. The use of compressed air for drying is recommended in this regard due to its good and rapid effect (RKI recommendation).

Maintenance, control and testing:
After cleaning / disinfection, the instruments must be macroscopically clean, this means free from visible dirt and residues. The check is carried out visually. All instruments with lumen (cannulas) must be checked for continuity. Insufficiently cleaned instruments must be cleaned again and then adequately rinsed and dried. Instruments with moving parts (e.g. joints and ends) must have cooled down before the function test and oiled with sterilizable, vapour-permeable instrument care oil. Instruments that have a notch may only be closed up to the first notch (risk of stress cracking). Defective instruments (hairline cracks, deformation or wear) must be replaced because they no longer function, or no longer fulfill the requirements in a sufficiently safe way. Corroded instruments must also be removed, as they can cause corrosion on intact instruments through foreign rust transfer.

Packaging to DIN EN ISO 11607:
After cleaning and disinfection, the products must be placed in packaging and sieves suitable for sterilization. The relevant standards must be observed. Sort the cleaned and disinfected implants individually and pack them in disposable sterilization packaging or add them to a container that meets the following requirements:

- According to DIN EN ISO 11607 / ANSI AAMI ST79 / TIR12:2010 and EN 868-2 to -10
- Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), adequate steam permeability)
- Adequate protection of the surgical instruments or sterilization packaging against mechanical damage.
- regularly maintained according to the manufacturer's specifications (sterilization container)

Sterilization accessories and sterilization packaging must match both the contents of the packaging and the sterilization process used.

Sterilisation
The recommended sterilization method is "steam sterilization with saturated steam with fractionated vacuum" in accordance with EN 13060:2014 +A1:2018 and DIN EN ISO 17665-1, taking country-specific requirements into account.

- There must be 3 pre-vacuum phases with at least 65 millibar pressure,
- A sterilization temperature of at least 132°C (maximum 138°C).
- Holding time of at least 3 minutes (max. 10 minutes)
- The drying time must be at least 10 minutes (maximum 15 minutes).

Warnings:
The information (instructions for use) of the sterilizer manufacturer must be observed.
Allow products to cool to room temperature.
All surgical instruments must not be exposed to temperatures higher than 137 °C (279 °F)!
Storage:
Reprocessed sterile instruments must be stored in a suitable reusable sterilization container in a dry, dust-free, low-germ, dark and cool room free from vermin. In order to avoid the formation of condensate, major temperature fluctuations should be avoided during storage. No chemicals may be stored together with instruments. Walls, floors and ceilings of the storage room should be smooth, easy to clean and disinfect. Shelves must have a ground clearance of at least 30 cm. The permissible on-site storage time depends on the type of sterile barrier system used and the storage conditions. The permissible storage period is to be determined by the operator.

More information on reprocessing:
A validated mechanical cleaning and disinfection process is always preferable to manual cleaning due to the higher level of safety in the process. Good cleaning also serves to preserve the value and is a prerequisite for successful sterilization. The following points must be observed for machine reprocessing:

- For effective automated reprocessing, the sieve trays must be loaded properly for washing. Sieve bowls must not be overloaded.
- Rinsing shadows caused by large instruments must be avoided.
- Depending on their mechanical sensitivity, the instruments must be laid down or stored in such a way that damage is impossible. The times and temperatures specified in these instructions for reprocessing are minimum requirements that must not be undercut. If a lower deviation is required for procedural reasons, this must be validated by the operator. Exceeding the specified times and temperatures is possible in principle, but will lead to increased stress on the material, which can lead to premature aging of the instruments.

Information on the validation of the processing
The validation was performed with the following devices, materials and chemicals:
cleaning and Disinfection device: Type Miele PG 8536
Cleaning agent: neodisher® MediClean forte, Dr. Weigert GmbH & Co. KG

Neutralizer:	neodisher® Z, Dr. Weigert GmbH & Co. KG
Cleaning brushes:	Plastic / nylon bristles
Ultrasonic bath:	Sonorex HW-FG
Sterilizers:	MMM Autoclace Selectomat premium line 18 StE
Basic cleaning:	neodisher® IR, Dr. Weigert GmbH & Co. KG

IV. Material Resistance

When selecting the detergent and disinfectant, please ensure that they do not contain the following components:

- Organic, mineral and oxidizing acids
- Strong lye solutions (pH > 11 not permitted, mildly alkaline cleaners recommended)
- Organic solvents (alcohols, acetone, etc.), benzines
- Halogenated hydrocarbons, chlorine, iodine
- Ammonia

Never clean instruments, sterilization trays or sterilization containers with metal brushes or steel wool.
Instruments, sterilization trays and sterilization containers should never be exposed to temperatures above 137 °C (279 °F).

13. FOLLOW-UP INSPECTION / INSPECTION

After cleaning or cleaning/disinfecting, check all instruments for corrosion, damaged surfaces, chips and dirt and discard damaged instruments (for numerical restrictions on reuse, see chapter 16 "Reusability/Lifetime"). Instruments that are still dirty must be cleaned and disinfected again.

14. PACKAGING

After cleaning and disinfection, the products must be placed in packaging and sieves suitable for sterilization. The relevant standards must be observed. Sort the cleaned and disinfected implants individually and pack them in disposable sterilization packaging or add them to a container that meets the following requirements:

- According to DIN EN ISO 11607 / ANSI AAMI ST79 / TIR12:2010 and EN 868-2 to -10
- Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), adequate steam permeability)
- Adequate protection of the surgical instruments or sterilization packaging against mechanical damage.
- regularly maintained according to the manufacturer's specifications (sterilization container)

Sterilization accessories and sterilization packaging must match both the contents of the packaging and the sterilization process used.

15. STORAGE

After sterilization, the instruments must be stored dry and dust-free in the sterilization packaging. Store the instruments so that they are protected against mechanical damage. Use outer packaging to protect against dust and moisture. Do not place heavy objects on the instruments to avoid damage. Avoid storage temperatures below 3°C

16. REUSABILITY/ LIFETIME

With due care and provided they are undamaged and fully functional, the instruments can be reprocessed and reused. Lifetime is limited by damage and normal wear and tear; these products are to be sorted out after processing. However, please note the restrictions regarding Creutzfeldt-Jakob disease (CJD).
Reda Instrumente GmbH has validated the integrity of these instruments for **up to 100 cycles** under standard conditions. Since the effective service life is influenced by specific handling and sterilization parameters, the user may continue clinical use beyond this reference point if the instrument remains in peak functional condition following a documented inspection. The service life depends on many factors including the type and duration of use, as well as handling, storage and transport of the instruments. Careful inspection and functional testing before next use is the best way to identify and discard a non-functional instrument.
We would like to point out that the biological compatibility of the instruments can also no longer be guaranteed if detergent residues accumulate. This is the user's duty to monitor.
The medical devices can be reused after they have been reprocessed to meet essential safety and performance requirements.

Please note that any deviation from these instructions, including the use of cleaners/detergents not specified in these instructions, requires an evaluation of the product-specific effectiveness and suitability in the actual cycle being run. Any liability is excluded in the event of disregard.

17. DISPOSAL

- Mark defective instruments
- Dispose of sharp and pointed medical products in such a way that the risk of injury to personnel is minimized
- Place cables and hoses on top of the instruments or dispose of them separately
- Articulated instruments open to approx. 90 °
- Instruments must be decontaminated
- Instruments that do not fit on disposal sieves must be disposed of in suitable closed containers or closed in soft packaging (this must be tightly closed and free from contamination on the outside)

18. RETURNS

Any return of products may only be sent back to us after disinfection/sterilization has been carried out and is clearly visible (corresponding packaging with sterile indicators, decontamination certificate, etc.).
The corresponding hygiene and workplace regulations must be observed. Do not attempt to repair defective instruments yourself!

19. WARRANTY

Safety note: The operator / product user is responsible for the proper disinfection and sterilization of products. National regulations, including

restrictions on this, must be observed.

REDA only delivers tested products to his customers. All of our products are designed and manufactured to meet the highest quality standards.

REDA, as the distributor and manufacturer of the products, excludes any warranty claims and assumes no liability for direct damage or consequential damage caused by:

- misuse
- improper use, application or handling
- Improper preparation and sterilization
- improper maintenance and repair
- Non-observance of the instructions for use

20. STANDARDS/ REFERENCES

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- EN 285 Large steam sterilizers
- EN 13060 small steam sterilizers
- EN ISO 11135 Sterilization of health care products - ethylene oxide
- EN ISO 11607 packaging for medical devices to be sterilized in the final packaging
- EN ISO 15883-1-3 Washer-Disinfectors
- EN ISO/ANSI AAMI ISO 11607 und EN 868-2 to -10 Packagingmaterials
- EN ISO 17664-1 / ANSI AAMI ST81 Sterilization- Manufacturerßs Information
- EN ISO 17665-1 Sterilization process- Moistheat
- ISO 7153-1 Stainless Steel
- ISO 5832-3 Wrought titanium 6-aluminium 4-vanadium alloy
- ISO 15223-1 Symbols
- DIN 96298-1 to -4 functgional tests
- MDR 2017/745 Chapter III/23 ff. Labeling and IFU

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