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

1. GENERAL INFORMATION

for items under SRN-No. **DE-MF-000005592 Part # 03120-xx until 98000-xx and R440-xxxxx-xxx until R449-xxxxx-xxx**

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 projects 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	Article or Order Catalogue number		Symbol of Manufacturer (Name and address of manufacturer)
	Caution, observe the accompanying documentation!		Observe the Instructions for Use
LOT	Batch/Lot number	CE 0297	Community European, CE mark+number Notified Body
NON STERILE	Information about NON-sterile product	MD	Medical Device
UDI	UDI Code		

3. DESCRIPTION AND PRODUCT SPECIFIC INSTRUCTIONS

The products are medical devices with regard to national and international laws for products in human medicine.

4. INTENDED USE

Exclusively adequately qualified personnel may only use the instruments in order to fulfil their defined functions. The attending doctor or rather the user is responsible for the selection of instruments for certain utilization and accordingly to the surgical use, the adequate training and information and the sufficient experience for the handling with the instruments.

Scissors, Micro, Scissors, Eye, Scissors Plastic Surgery with and without carbide inserts Some Scissors by REDA can be used to sever tissue, organs, bones, bandaging materials and suture materials. Union Scissors can be used to cut bandage. The screw lock must be lubricated, the closing part of the scissors must be checked for breaks or other errors, cutting edges must be checked for integrity.

Rongeurs and Rongeurs, Other are used to prepare parts of the cartilage and bone. They are also used to sever fine bones. They are primarily used in orthopedics. The screw lock must be lubricated, the joint area must be checked for breaks, check whether all required screws are still present, cutting edges must be checked for integrity, the working ends must close in parallel, cutting test must be carried out using a carton, the instruments have to be cleaned.

Chisels, Bone and Mallets, Bone are used to prepare bones. He cutting edges must not have any nicks.

Bowls are used in surgery for covering fluids and for depositing surgical instruments.

Knives, Scalpel, Hemostatic and Knife Handles are used to sever tissue, vessels and organs. A sharp, even grinding of the blade is important for good cutting ability. The grinding is either hollow or flat.

Clamps, Skull are instruments used to grip, hold and clamp blood vessels, tissue, organs and medical supplies. They are classified as follows: Hard gripping clamps soft gripping clamps Atraumatic clamps Anatomical clamps surgical clamps. The box lock must be lubricated, the toothing must be checked for integrity, the joint area must be checked for breaks, working part must close correctly, the rest lock must lock in place and must not lose independently.

Needle holders and Needles, Suture are used to grip and hold surgical suture needles during an operation. In medicine, sutures are only inserted using a needle holder. The right choice of needle holder is important. The appropriate needle holder can be determined using the list on left hand side. Screw lock or box lock must be lubricated, joint area must be checked for breaks, Tungsten Carbide (TC) inserts must be checked for integrity and must be able to fit into one another, rest lock must lock in place and must not come loose independently

Pliers are used to remove bone wires and rods. The beaks are design with and without carbide inserts. Screw lock must be lubricated, joint area must be checked for breaks, Tungsten Carbide (TC) inserts must be checked for integrity.

Trocars are used in minimally invasive surgery, a sharp or blunt trocar is used to create access to a body cavity, and this is kept open with a tube. Various different instruments can be inserted into the body cavity through this tube.

Ophthalmic instruments are designed to prevent and potential eye damage, disease or injuries.

Forceps, Dressing, Forceps, Tissue and Hemostatic Forceps are used to hold and grip tissue, organs, medical supplies and materials. Forceps are divided into three main categories: Anatomical forceps Atraumatic forceps surgical forceps. Working ends must be checked for integrity, when forceps closed, the working ends must lie perfectly on top of each other, the spring part must be checked for cracks.

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. Working ends must be checked for integrity.

Wound Retractors are used to hold tissue, organs and bones and to spread the edges of wounds. Working ends must be checked for integrity.

Rib retractors are used to spread the sternum during a heart operation. Working ends must be checked for integrity.

Speculum is a medical examination instrument, which is primarily used in gynecology. Mainly for **Vaginal** examination but some items examine also ear, nose and human throat. Screw caps must be lubricated, blade must be checked for burrs and damage, the lever must be checked for smooth operation, joint area must be checked for breaks or other damage, working ends must be checked for mobility. **Rectal** instruments are used in various diagnostic procedures in anus and rectum. (Colorectal surgery, Heamorrhoidal, Rectal Biopsy).

Dilators are surgical instruments used to induce dilation, that is, to expand an opening or passage such as the urethra.

Bougie used for introduction into the urethra, usually for calibrating or dilating constricted areas.

Curettes are surgical instruments with circular cutting loop, ring, or scoop with sharpened edges, attached to a rod-shaped handle, used for curettage.

Hooks, Probes and Punches 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. Punches are designed for cutting and dissecting tissue or opening and enlargement of the bony sinus.

Reusable **Sterilization Containers** for medical devices and **Container Systems** as wire baskets and filters, are used for steam sterilization procedures to autoclave surgical instruments in high temperature. Please follow instructions of IFU-TD01-02 (separated IFU)

Elevators are an Essential part of Oral Surgical procedures as they are used in multiple purposes like reflection of mucoperiosteum, 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.

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.

Picks for Middle Ear are surgical instruments to be used for shape middle ear fluid and for examination.

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).

Titanium instruments are dependent on the above-mentioned purpose and reduce trauma to sensitive vessels and arteries.

5. MATERIALS USED

Surgical instruments are made of stainless steel according to ISO 7153-1 and EN 10088-3, and of Ti6Al4V alloy in accordance with ISO 5832-3/ASTM F136 and biocompatible, autoclavable, non-metallic materials on an individual basis.

6. POSSIBLE ADVERSE EFFECTS

In most cases, possible complications are not directly related to the use of the instruments, but are more likely attributed to the incorrect selection of the patient, inadequate training.

1. Metal sensitivity reactions in patients have rarely been reported, and their significance awaits further clinical evaluation.
2. Increased fibrous tissue response around the osteotomy area.
3. Early or late infection, both deep and/or superficial.
4. Nerve damage may occur as a result of the surgical intervention.

7. CONTRAINDICATIONS

The circumstances listed below may reduce the chances of a successful outcome:

1. Insufficient quantity or quality of bone, which would inhibit rigid fixation of the device.
2. Compromised vascularity.
3. Previous history of infections.
4. Ulcers in the area where the device is to be placed, or the use of radiation or chemotherapy.
5. Mental, physical or neurological conditions, which may impair the patient's ability to cooperate with the postoperative regimen

8. GENERAL WARNINGS AND PRECAUTIONS FOR USE

The products are supplied NON-STERILE. Sterile packaged products are labeled accordingly.
Check the identity, completeness, intactness and function upon receipt of the products before making them available for use.
Check instruments for breakage, cracks, deformations, damage and functional ability before each use. Particular attention should be paid to areas such as blades, tips, box locks, locks, ratchets and all moveable parts. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted.
The surgeon and all other persons involved in the use of the products are responsible in regards to their field of activity to have appropriate product knowledge based on the current technology standard. This ensures proper use of the product and prevents health or safety risks to patients, users or third parties.
Additional sources of information for the products may include applicable product catalogs, videos, technical specifications, instructions from medical product advisors, working committees, seminars, specialized courses, publications, etc. Appropriate product training, including proper handling, is required before clinical use.
The indications on the use of the products represent a group of standard instructions that can be adjusted to the particular needs and situations that may arise according to the ability, experience and diagnosis made by a legally qualified medical user. Responsibility for proper selection of patients, adequate training, rests with the surgeon.
The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient. Particular attention should be given to a postoperative discussion and the necessity for periodic medical follow-up.
The correct selection of the product is extremely important. This can be determined by evaluating the patient's functional demands and anatomy. See also other general scientific documents with detailed indications regarding the selection of instruments.

Careful handling and storage of the products is required. The patient must be instructed on proper postoperative hygiene procedures and should be advised to report any unusual changes in the operated site to the surgeon. The surgeon should evaluate the possibility of subsequent clinical failure and discuss the need for any measures deemed necessary to aid healing with the patient.
After contact with or use on patients with Creutzfeldt - Jakob disease (CJD) or its variants, we decline all responsibility. In this regard, take notice that the unused instruments in the trays could have also been contaminated.
Preparation and reuse even according to the RKI Guidelines rests solely on one's own responsibility.

9. RETURNS

All returns of products to us is only allowed after a visible disinfection/sterilization has been performed (respective packaging with sterilization indicator, decontamination certificate etc.).
The corresponding hygiene and company regulations are to be adhered to.

10. PREPARATION, CLEANING, DISINFECTION, MAINTENANCE AND STERILIZATION OF INSTRUMENTS

10.1 General Principles

All instruments must be cleaned, disinfected and sterilized before each use. This also applies to initial use after delivery of instruments in particular, which are supplied non-sterile (cleaning and disinfection after removal of the protective transportation packaging; sterilization after packaging). Sterile packaged products are labeled accordingly upon delivery. Effective cleaning and disinfection is an absolute requirement for an efficient sterilization.
Please pay particular attention that contaminated instruments are separated and not placed back into the instrument tray once used to prevent increased contamination of the filled instrument tray. Clean/disinfect reusable contaminated instruments, sort them again into the instrument tray and then sterilize the fully filled and previously cleaned/disinfected instrument tray.
With regard to your responsibility for the sterility of the instruments, please ensure, as a matter of principle, that only adequate methods validated based on the device and product, are used for cleaning/disinfection and sterilization, that the devices used (RDG, sterilizer) are regularly maintained and checked, and that the validated parameters are observed during each cycle.
Please also follow the statutory provisions valid in your country and the hygiene regulations of the medical practice or hospital. This particularly applies to the various specifications with regard to effective prion inactivation.

10.2 Cleaning and Disinfection

Basic Principles

A mechanical method (RDG - cleaning and disinfection machines / disinfectors) should be used when possible to clean and disinfect instruments. A manual method – even when using an ultrasonic bath – should only used if a mechanical method is unavailable due to the much lower effectiveness and reproducibility of the manual method[1].

[1] The use of a manual cleaning and disinfection method must be verified by the user by means of an additional product and procedure specific validation.

Pre-treatment is required in both cases.

10.3 Pre-treatment

General contamination must be removed from the product directly after use (recommendation within a maximum of 2 hours).
To maximize cleaning and disinfection efficiency, products consisting of several components that can be disassembled should be disassembled according to the product specific Instructions for Use and the instructions in the section "Special Instructions" as the case may be (replaceable parts, accessories, adapters, interchangeable inserts, etc.).
Use running water or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood contamination), exhibit proven effectiveness (e.g. VAH/DGHM or FDA approval or CE mark), be suitable for the disinfection of instruments and be compatible with the instruments (see chapter "Material Resistance").
Only use a soft brush or a soft clean towel intended for this purpose to manually remove impurities, i.e. never use metal brushes or steel wool. Please note that the disinfectant used for pre-treatment is intended for personal safety only and cannot replace the disinfection step to be performed after a successful cleaning.

Mechanical Cleaning/Disinfection (RDG)

In selecting the RDG, ensure that:

- The RDG exhibits proven effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO 15883).
- A proven program for thermal disinfection is used (minimum of 1 minute at 90 °C or A_0 value of 600) if possible (for chemical disinfection, risk of disinfectant residues on the instruments).
- The program used for the instruments is suitable and contains adequate rinse cycles.
- That the water suitable for rinsing (e.g. Aqua purificata/Aqua purficita valde) is used, and furthermore that the air used for drying is filtered and therefore not decrease the hygiene status at this point.
- The RDG is regularly maintained and tested.

In selecting the detergent system used, ensure that:

- It is generally suitable for cleaning the instruments.
- If no thermal disinfection is used, a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval or CE mark) and the disinfectant is compatible with the detergent is used and
- The chemicals used are compatible with the instruments (see chapter "Material Resistance").

The detergent and disinfectant concentrations specified by the manufacturer must be strictly followed.

Procedure:

1. Disassemble the instruments to the maximum extent possible.
2. Place the disassembled instruments in the RDG. Make sure that the instruments do not touch one another.
3. If products with narrow lumens or cavities cannot be connected, they must be placed in the RDG to allow water and disinfectant to drain.
4. Time/temperature bands meeting the requirements of an acceptable A_0 value > 600. Start the program.
5. Take the instruments out of the RDG after program completion.
6. Check and package the instruments if possible immediately after removal from the RDG (see Chapters "Control", "Maintenance" and "Packaging" and if necessary after an additional final drying process in a clean area).

Proof of basic suitability of the instruments for an effective mechanical cleaning and disinfection has been furnished by an independent accredited test laboratory using the "RDG G 7836 CD" (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the detergent "Neodisher mediclean forte" (Dr. Weigert GmbH & Co. KG, Hamburg). The method described above was considered.

11. INSPECTION AND TESTING PRIOR TO REUSE

Before each use, the instruments must be thoroughly inspected for damage such as fractures, cracks or deformation, as well as for functional reliability. Special attention must be paid to cutting edges, tips, joints, box locks, ratchets and all movable parts. If wear, corrosion, deformation, porosity or other damage is detected, the instrument must be immediately withdrawn from service. Due to their alloy, stainless steel instruments typically develop a passive film in the form of a protective layer. However, this film does not protect them well against chemical attack by chloride ions and aggressive media and liquids! Therefore, in addition to the instrument manufacturer's endeavors to select the right materials and process them carefully, the user must make an important contribution by ensuring proper instrument processing along with adequate and regular care.

12. PACKAGING AND TRANSPORTATION

Sort the cleaned and disinfected instruments into the sterilization trays and package them in single use sterilization packaging (single and double packaging) and/or sterilization containers that meet the following requirements:

- In compliance with DIN EN 868/ANSI AAMI ISO 11607 and EN 868-2 until -10.
- Suitable for steam sterilization (temperature resistant up to max. 137 °C (279 °F), sufficient vapor permeability)
- Sufficient protection of instruments or sterilization packaging from mechanical damage
- Regular maintenance according to manufacturer specifications (sterilization containers)
- Protect from mechanical damage. Handle with care, do not throw or drop.

13. STERILIZATION

Only the sterilization methods listed below are to be used for sterilization; no other sterilization methods are permitted.

Steam sterilization

- Fractional vacuum method/pre-vacuum method or gravitational method[2] (with sufficient drying of product)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO/ANSI AAMI ISO 17665 (valid commissioning and product specific performance assessment)
- Maximum sterilization temperature 137 °C (279 °F) includes tolerance according to DIN EN ISO/ANSI AAMI ISO 17665
  Sterilization time (exposure time at sterilization temperature) 3 minutes[3] at min. 132 °C (270 °F) to max. 137 °C (279 °F)

[2] The less effective gravitational method should only be used when the fractional vacuum/pre-vacuum method is unavailable.
[3] max. 3.5 minutes or 18 min. (prion inactivation)

Proof of the basic suitability of the instruments for an effective steam sterilization has been furnished by an independent accredited test laboratory using the steam sterilizer "Systec V-150, Systec Labor- Systemtechnik, Wettenberg" using the fractional vacuum method and gravitational method. The method described above was considered.
The rapid sterilization method is generally not permitted. Also do not use any hot air sterilization, no radiation sterilization, no formaldehyde or ethylene oxide sterilization and no plasma sterilization.

Due to chemical resistance of the **"Ferrozell"** material, undesirable material changes on the surface can occur if a cleaning and disinfecting alkaline agent is used.
It is recommended to use a neutral, enzymatic cleaner in order to preserve the material properties of components made of **"Ferrozell".**
Instruments with Ferrozell handles must not be exposed to temperatures higher than 134 °C (273 °F).

CAUTION: STERILIZATION IS NOT A SUBSTITUTE FOR CLEANLINESS.

14. STORAGE

After sterilization, the instruments must be stored in the sterilization package or in safe containers and kept dry and dust-free. The constant temperature is essential. It is recommended that the temperature range is between 18-25 ° C. Protect from mechanical damage. Handle with care, do not throw or drop.

15. 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).

Please be noted that special Instructions and handling care needs to be accounted for all **Aluminium** Instruments:

- **Do not** use alkaline cleaners > ph 7 for aluminium instruments!!
- **Do not** clean Aluminum instruments in an ultrasonic unit!, Clean by hand or in some automated washers
- Anodized aluminum instruments **should not** be sterilized with stainless steel instruments, it may cause an adverse chemical reaction.
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16. REUSABILITY-LIFETIME

The instruments can, by the respective thoroughness and providing that they are not damaged and fully functional, be prepared again and reused. The life cycle is limited due to damage and normal wear; these products are to be separated after preparation from the others. Please consider the limits from Chapter 9, last paragraph regarding Creutzfeldt-Jacob disease (CJK).

Using a validated procedure, Reda Instrumente GmbH has set a maximum number of uses and reprocessing cycles for reusable instruments of 100 cycles, but REDA does not define 100 cycles as maximum number of usage or preparation cycles of reusable instruments. The 100 cycles only refer to the validated procedure. The life cycle is dependent upon many factors including the type and length of usage, as well as handling, storage and transport of the instruments. Thorough examination and function testing before the next use is the best possible way to detect non-functioning instruments and sort them out.
We would like to point out that also through the accumulation of detergent residuals, the biological compatibility of the instruments can no longer given. This lies in the observation obligation of the user.

We assume no liability resulting from failure to observe these guidelines.

17. WARRANTY

Safety Instructions: Responsibility for proper cleaning, disinfection and sterilization of products is the sole responsibility of the operator / product user. National regulations including limitations must be carefully followed.
REDA supplies tested products free of defects to their customers. All our products are designed and manufactured to meet the highest quality demands.
REDA as the manufacturer of the products excludes any warranty claims and assumes no liability for direct or consequential damage as a result of:

- Misuse
- Improper use, application or handling
- Improper preparation and sterilization
- Improper maintenance and repair
- Failure to observe the Instructions for Use

18. 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 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)

19. STANDARDS - REFERENCES

- AKI[1] - "Proper Maintenance of Instruments" Guide
- RKI[2] - Recommendation: "Hygiene Requirements with regard to the Preparation of Medical Products"
- DIN EN 285 Large steam sterilizers
- DIN EN 13060 Small steam sterilizers
- DIN EN ISO 15883-1-3 Washer-Disinfectors
- DIN EN ISO/ ANSI AAMI ISO 11607 and EN 868-2 until -10 Packaging materials
- DIN EN ISO 17664/ ANSI AAMI ST81 Sterilization - Manufacturer's Information
- DIN EN ISO 17665-1 Sterilization process – Moist heat
- MDR 2017/745 Chapter III/23 ff. Labeling and IFU
- HTM 01-01 Management and decontamination of surgical instruments used in acute care Part C and Part D

[1] AKI: Working Group Instrument Preparation
[2] RKI: Robert-Koch-Institute

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