Instruction manual

for Bone Implants (risk class IIb) **ENGLISH**

Kirschner Wire, Steinmann Pin, Bone Wire, Cerclage Wire

CE 0297

REDA INSTRUMENTE GMBH

Product Group	Item numbers	Basis UDI-DI
Drill wires Kirschner Tonsilwire	34401-xxx until34411-xx	4063058000001223J
Kirschner wires with trocar:	ROT-440xx – ROT-440-310-30/T	4063058000001223J
Kirschner wires with lance:	ROT-442xx – ROT-442310-30/L	4063058000001223J
Cerclage wires:	34520-xx – 34520-15	40630580000015745SB
Steinmann pins:	ROT-417xx - ROT-421xx	40630580000015847SL

EUDAMED SRN: DE-MF-000005592

TABLE OF CONTENTS

1. Product description, intended use, feature 2
2. Intended Use 2
3. Target group, Indications and contraindications 3
3.1 st Target group 3
3.2 nd Indications 3
3.3 rd Contraindications 3
4. General information 3
4.1 st Packaging 3
4.2 nd Storage 3
4.3 rd Application / area of use 3
4.4 th Combination 4
4.5 th Modification 4
4.6 th Guarantee 4
4.7 th Materials used 4
4.8 th Inspection after receipt and before use 4
4.9 th Summary report on safety and clinical performance 5
5. Important information for doctors and operating theatre staff 5
5.1 st Risks / Intolerances 5
5.2 nd Complications 5
5.3 rd Further information 6
5.4 th Postoperative risks 6
5.5 th Removal of bone implants 6
6. Preparation (cleaning, disinfection and sterilisation) of products 6
6.1 st General principles 6
6.2 nd Preliminary treatment at the place of use 7
6.3 rd Cleaning and disinfection 7
6.3rd.1 Grundlæggende viden 7
6.3rd.2 Mechanical cleaning/disinfection (WD (washer-disinfector)) 7
6.3 rd.3 Manual cleaning and disinfection 8
6.4 th Checking 9
6.5 th Maintenance 9
6.6 th Packaging 9
6.7 th Sterilisation 9
6.8 th Transport and storage 10
6.9 th Material durability 10
6.10 th Reusability 10
7. Disposal and returns 10
8. Explanation of the symbols used 11
9. Applicable standards / guidelines 11
10. Manufacturer 12

All bone implants are non-sterile when supplied and must be cleaned, disinfected and sterilized before each use.

With the purchase of the above-mentioned medical devices, hereinafter referred to as bone implants, you will receive a product, the proper handling and use of which are described below. In order to keep the risks and unnecessary strains for the patient as low as possible, we ask you to follow the instructions for use carefully

1. PRODUCT DESCRIPTION, INTENDED USE, FEATURE

- **Kirschner Wire** (Ø 0.8 mm to 3.0 mm) / **Steinmann Pin** (Ø 3.2 mm to 10.0 mm)

is a semi-rigid wire with different end finishes. The length is freely selectable (from 5 to 600 mm).
They are used for closed repositioning and fixation of a fracture. Surgical fracture treatment procedures:

- Percutaneous intramedullary splinting e.g. on the metacarpal bones
- percutaneous "cribbing" as fixation of a fracture by insertion of a Kirschner wire, if possible with fixation of the wire in the opposite cortical bone.

- **Bone Wire** (Ø 0.2 mm to 2.0 mm)

is a malleable wire on rolls of 5 m or 10 m (implant steel).
Bone wires are used to treat a fracture by wire wrapping as a stand-alone procedure. The soft wire is usually passed around the bone several times and tensioned by twisting.

- **Steinmann** (Ø 3.2 mm to 6.0 mm)

Steinmann Pins are used for traction of larger bones. These pins are pushed through the skin rotating clockwise to engage the thread into the bone.

- **Cerclage Wire** (Ø 0.2 mm to 2.0 mm)

is a cut bone wire with one or two eyelets (also available without an eyelet). The length is freely selectable (from 10 to 1000 mm).
Cerclage wires are used to treat a fracture by wire wrapping as a stand-alone procedure. The soft wire is usually passed around the bone several times and tensioned by twisting.

The ready-cut wires with eyelets are used for folded cerclage. Here the wire ends are not twisted together, but the straight end is pulled through the eyelet, tensioned (with the wire tensioner), sharply bent over, cut off and pushed under the loop.

For the fixation of fragments under a plate, for rotation-stable fragment fixation during intramedullary nailing.

The bone implants do not contain any

- tissue of human or animal origin
- Components of medicinal products
- Software

⚠ If used outside its intended purpose, complications or harm to the patient may occur and re-operation may be necessary.

2. INTENDED USE

Bone implants by **REDA Instrumente GmbH** are used in osteosynthesis and for the correction of degenerative changes in the skeleton.

The bone implants may only be used for their intended purpose in the medical fields by appropriately trained and qualified personnel. The treating practitioner or the user is responsible for the selection of the bone implant for specific applications or operative use, the appropriate training and information and sufficient experience for the handling of the bone implant. **REDA Instrumente GmbH** as the manufacturer and seller of the products, assumes no liability for damage or consequential damage resulting from improper use or handling or from improper preparation and sterilisation. The products must be inspected for damage before each use.

The doctor must determine the extent of the injuries/changes that require surgical treatment and determine the correct implants. In addition, the doctor must determine the right time and the right surgical therapeutic procedure for the patient, especially in the case of concomitant diseases and complex multiple injuries. Complications that may arise due to incorrect indication, handling of the implant, surgical technique or asepsis are the responsibility of the surgeon and cannot be blamed on the manufacturer of the bone implants.

The bone implants can never bear the full load of the treated bone segment. The bone implants only serve to promote healing and are not a substitute for intact tissue and bone material. The doctor must inform the patient about the load limits and prescribe appropriate post-operative behaviour. In general, the doctor must inform the patient about indications, contraindications, undesirable side effects and postoperative treatment and record this information. Regular medical check-ups should be carried out after implantation.

3. TARGET GROUP, INDICATIONS AND CONTRAINDICATIONS

3.1 st TARGET GROUP

There is no restriction of the patient target group.

3.2 nd INDICATIONS

- Bone fracture treatment, recommendation of the Gerhard-Küntscher-Kreis, V. Vécsei et al - Georg Thieme Verlag
- Repositioning and fixation of metaphyseal fractures
- Diaphyseal fractures and dislocations of the hand and foot bones
- Temporary arthrodesis of small joints
- Temporary intraoperative fixation of fracture fragments
- Fractures of the musculoskeletal system
- Closed / open fracture

Detailed information on the indication can be found in a variety of specialist literature:

- Bone fracture treatment, recommendation of the Gerhard-Küntscher-Kreis, V. Vécsei et al - Georg Thieme Verlag
- FMT-Fachwissen Medizin-Technik (medical technology expertise), Episode 3: Instruments in Medicine, Bone Surgery, Klaus Witzer-MTD Publishers Amtzell
- AO-Instruments, R. Texhammar, C. Colton – Springer Publishers

3.3 rd CONTRAINDICATIONS

Health conditions that preclude sufficient implant support or inhibit the healing process, e.g.:

- Fractures of spine
- Impairment of blood supply
- insufficient bone quality or quantity (osteoporosis)
- extreme obesity
- Acute and chronic, local or systemic infections
- Deep and superficial infections
- Twisting or strong inclination of the fracture
- Muscle, nerve or vascular diseases that endanger the affected extremity
- Local bone tumours
- Systemic diseases and metabolic dysfunctions
- severe deformities
- serious falls
- Mental conditions that make participation in the rehabilitation programme impossible (Parkinson's disease, alcoholism, drug use, etc.)
- great physical activities and those involving strong vibrations, where the implants are subjected to blows and/or excessive loads (e.g. heavy physical work, etc.);
- Allergies or other reactions to the material used

Indications and contraindications are determined by current medical practice.

4. GENERAL INFORMATION

4.1 st PACKAGING

Delivery is generally non-sterile.

The packaging is solely transport packaging and is not suitable for sterilisation.

4.2 nd STORAGE

The bone implants must be stored in a clean, dry environment in their packaging or in a protective container. Protect areas that may cause injury (e.g. tips and cutting edges).

⚠ Take special care that there are no aggressive chemicals in the immediate vicinity of the storage location.

4.3 rd APPLICATION / AREA OF USE

Before starting treatment, make sure that the required instruments are available and suitable for combination with our bone implants.

4.4th COMBINATION

Implants made of different materials must not be combined for metallurgical, mechanical and design reasons. Material details are given in the batch certificate.

4.5th MODIFICATION

Alteration of the bone implants may only be carried out with suitable instruments by trained users. Material fatigue must be avoided.

4.6th GUARANTEE

The products are made of high-quality materials and are inspected carefully before delivery. If any errors should still occur, please contact our customer service.

⚠ Defective products must have gone through the entire reprocessing process before being returned.

4.7th MATERIALS USED

The bone implants are made of materials that meet the requirements of the harmonised European standards:

- ISO 5832-1 Stainless steel

Chemical composition										
C %	**Si %**	**Mn %**	**Ni %**	**Cr %**	**Cu %**	**Mo %**	**P %**	**S %**	**N %**	**Fe**
max. 0.03	**max. 1.0**	**max. 2.00**	**13.00-15.00**	**17.00-19.00**	**max. 0.50**	**2.25 - 3.50**	**max. 0.025**	**max. 0.01**	**max. 0.10**	**Balance**

All performance and safety characteristics required by the EN ISO 5832-x standards are met, including grain size and degree of micro-purity, which relate to the microstructure. This is confirmed on the corresponding material certificates.

The material assignment can be derived from the item number:

Product	Item number	Material
Kirschner Wire Steinmann Pin	ROT-440xx - ROT-442310-30/L	Implant steel (ISO 5832-1)
Cerclage Wire	34520-xx – 34520-15	Implant steel (ISO 5832-1)

Product	Item number	Material
Steinmann Pin	ROT-417xx - ROT-421xx	Implant steel (ISO 5832-1)

4.8th INSPECTION AFTER RECEIPT AND BEFORE USE

Bone implants are extremely sensitive to damage. Even small scratches or impact dents can cause internal stresses that significantly reduce strength. It is therefore advisable to handle them with extreme care.

- Before unpacking: Inspect the outer packaging for damage/transport damage and condensation.
- Check that the label matches the contents.
- Visual inspection of the bone implant for damage (discolouration, cracks, nicks, burrs or other damage).

Returns may only be made in protected packaging.

4.9th SUMMARY REPORT ON SAFETY AND CLINICAL PERFORMANCE

The Summary Safety and Clinical Performance Report (SSCP) is available in the European Medical Devices Database (Eudamed). The URL of the public Eudamed website is: https://ec.europa.eu/tools/eudamed.

5. IMPORTANT INFORMATION FOR DOCTORS AND OPERATING THEATRE STAFF ⚠

The products are <u>not</u> suitable for use / application on the central nervous or circulatory system[1]!

- The correct choice of implant is of utmost importance. The corresponding implant type as well as the size must be adapted to the individual patient. The patient's weight and level of activity must be taken into account, as well as the fracture that is to be treated. Using the largest possible bone implant and correct positioning prevents bending, breaking, cracking and loosening of the bone implant. This also keeps the transmission of force to the bone low. **Choosing the wrong implant can lead to implant failure.**
- The user, surgeon and operating theatre staff must be familiar with the appropriate surgical technique for the instruments and implants used. The surgeon is solely responsible for the choice and application of the implant.
- Bone implants may only be used in procedures intended for this purpose, where the intended use of the implant is explicitly required and defined.
- Before each operation, it is necessary to check whether the patient is exceptionally sensitive, or possibly allergic to the implant material.
- Drill wires with partial or full thread as well as with drill tips, can break if used improperly. The manufacturer accepts no liability for this.
- Use appropriate drilling equipment with three-jaw chuck for the application of the wires.
- Trained professionals are obliged to inspect the implant before each application / intervention. If there are any damages or deformations, mainly at the tips and sheaths, the implant must not be used. (see also chapter 6.4).
- Different instruments and/or implants may be used if they have already been successfully tested for the corresponding application.
- For implants with deliberately roughened surfaces (e.g. thread or knurl), the increased diameter must be taken into account where necessary (e.g. for combined use with other instruments or implants).
- Before use, check the diameter of the implant with a suitable measuring device or a measuring template. There is a risk of fracture if the implants are too thin.

5.1st RISKS / INTOLERANCES

- An inflammatory reaction of varying severity can set in after the insertion of metal implants. Further symptoms may include: Local or generalised eczema, wound healing disorders, pain.
- If you have a proven allergy to nickel, cobalt and chromium, do not use implants made of material containing these substances (e.g. implant steel 1.4441).
- Inadequate cleaning and sterilisation can lead to infections in the patient
- Incorrect reprocessing procedures can lead to surface discolouration or corrosion on the implant
- Improper use during implantation or overloading of the implant during and after implantation can lead to fracture or deformation of the implant. This could possibly harm the patient.
- Possible risks from external electrical and electromagnetic influences (radiation, magnetic fields) in connection with diagnostic and therapeutic procedures (e.g. X-ray, MRI) must be carefully assessed by the doctor before the examination. According to the manufacturer, the bone wires are not suitable for MRI.

5.2nd COMPLICATIONS

The following complications have been observed in various cases and therefore require the special attention of the doctor in charge:

- Bending, breaking, loosening or detaching of the implant
- In case of insufficient regrowth of the fracture, loss of anatomical position may occur

[1] "Central nervous system" means the brain, meninges and spinal cord (Directive (EU) 2017/745, Annex VIII, Chapter I (2.7)

Central circulatory system' means the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior* (Directive (EU) 2017/745, Annex VIII, Chap. I (2.6)

- Superficial and deep infections can occur
- Vascular diseases such as thrombophlebitis, pulmonary embolism, haematomas and non-vascular necrosis of the femoral neck may occur as a result of the procedure and the use of bone implants
- Allergies, tissue and foreign body reactions can occur in the vicinity of the bone implants
- Fracture does not heal
- Bone deformation and re-fracturing
- Displacement of the bone implant
- cardiovascular dysfunction

5.3rd FURTHER INFORMATION

- Before starting treatment, make sure that the required instruments are available and suitable for combination with our bone implants.
- The bone implants must not come into contact with objects that could damage their surface. They must not be processed mechanically or altered in any other way unless the design and surgical technique expressly provide for this. In the latter case, the modification must be carried out with the appropriate instruments according to the literature references. The bending of bone implants must be done carefully. Extreme deformation of the bone implant must be avoided under all circumstances.
- Repeated bending back and forth leads to fatigue or fracture of the bone implant. Scoring and pressure marks also significantly reduce the mechanical strength.
- Surgical technique: the principles of art and science as well as scientific publications are valid. A surgery description can never be complete and include all risks and complications to be considered. Before the procedure, the surgeon must familiarise himself with the implants, instruments and corresponding techniques.
- To ensure complete traceability, the article number and batch number (lot number) of the bone implant used must be documented in the surgical report.
- All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

5.4th POSTOPERATIVE RISKS

- The bone implants can never bear the full load of the treated bone segment. The doctor must therefore inform the patient about the load limits and prescribe appropriate post-operative behaviour.
- Early weight bearing increases the stress on the implant and can lead to fracture, bending or loosening. In patients who are exposed to heavy loads or who suffer from a delay in healing or in the coalescence of the bone, this should be given special attention. Loading may be considered if there is a stable fracture with good bone-on-bone contact. Full weight bearing before complete fracture healing is contraindicated.
- Post-operative instructions to the patient, proper nursing care and regular medical checks are of great importance.

5.5th REMOVAL OF BONE IMPLANTS

Wire removal can be undertaken when the aim of the operation has been achieved, i.e. that the fracture has healed, for example. If the wires become loose, they must be removed as soon as possible, otherwise the wires can spike, break or migrate through the skin from the inside, damaging tendons, nerves and/or vessels. If they remain in the body too long, it becomes difficult or impossible to remove the wires.

➔ The final decision to remove the bone implant is made by the surgeon.

6. PREPARATION (CLEANING, DISINFECTION AND STERILISATION) OF PRODUCTS

⚠ Staff should be aware of this instruction and recommendation to ensure safe and effective preparation and to prevent damage to or misuse of the bone implants.

6.1st GENERAL PRINCIPLES

All bone implants must be cleaned, disinfected and sterilised before each use; this applies in particular to the first use after delivery, as all instruments are delivered non-sterile by the manufacturer (cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation.

As part of your responsibility for the sterility of the bone implants, please observe the following during use,

- that, as a matter of principle, only sufficiently device and product specific validated procedures are used for cleaning/disinfection and sterilisation,
- that the equipment used (WD, steriliser, etc.) is regularly maintained, checked and calibrated, and
- that the validated parameters are adhered to in each cycle.

Observe the legal regulations that apply in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements (e.g. in Germany according to Annex 7 of the KRINKO RKI BfArM recommendation on preparation) with regard to effective prion inactivation (not applicable to the USA).

Preparation may only be carried out by trained personnel in the central sterilisation department of the clinic or in the preparation room of the doctor's practice. The clinic or doctor's practice is also responsible for the selection and use of the necessary protective equipment and hygiene measures.

⚠ The use of non-sterile / contaminated instruments can lead to infections in the patient. There may be complications and delays in the healing process.

6.2 nd PRELIMINARY TREATMENT AT THE PLACE OF USE

N/A - the bone implants are intended for single use only. Remove coarse soiling from explanted implants with disposable/paper towels. See chapter 7 for further procedure.

⚠ Explanted, soiled implants must not be placed in the sterilisation tray to avoid contamination of the contents of the sterilisation tray..

6.3 rd CLEANING AND DISINFECTION

6.3rd.1 BASICS

Thorough cleaning before disinfection or sterilisation is particularly important. If a medical device is not sterile, the disinfection or sterilisation process may be compromised. If medical devices are not reprocessed correctly or effectively, there is a risk of transmission of infectious agents. Similarly, other effects may occur, e.g. corrosion and/or malfunction of the medical device.

A mechanical process (washer-disinfector) should be used for cleaning and disinfection if possible. A manual procedure - also using an ultrasonic bath - should only be used if a mechanical procedure is not available or if country-specific requirements apply (e.g. in Germany a mechanical procedure is mandatory for critical B-products) due to the significantly lower effectiveness and reproducibility.

When selecting the cleaning agent to be used it must be ensured

- that this is generally suitable for cleaning implants made of metals and plastics,
- that the cleaning agent is suitable for ultrasonic cleaning (no foam development),

The concentrations, temperatures and exposure times as well as the instructions for rinsing given by the manufacturer of the cleaning agent or detergent and disinfectant must be strictly observed. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[2] and for drying only a soft, clean and lint-free cloth and/or filtered air.

⚠ Take care with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can get stuck.

6.3rd.2 MECHANICAL CLEANING/DISINFECTION (WD (WASHER-DISINFECTOR))

When selecting the WD it must be ensured

- that the device basically complies with the requirements of the DIN EN ISO 15883 series of standards and has a tested efficacy (e.g. DGHM or FDA approval/clearance/registration or CE marking)
- that a tested thermal disinfection programme is used (with chemical disinfection there is a risk of disinfectant residue on the products),
- that the programme used is suitable for the products and contains sufficient rinse cycles (at least three depleting steps after cleaning or neutralisation, if applicable) to effectively prevent detergent residues),
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water is used (e.g. purified water/highly purified water)[1],
- that the air used for drying is suitable for medical purposes, and
- that the unit is regularly checked and maintained.

When selecting the cleaning agent to be used it must be ensured

- that this is generally suitable for cleaning implants made of metals and plastics,
- that - if thermal disinfection is not used - a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE mark) is also used and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the products (see chapter 6.9 'Material resistance').

[2] If you consider a lower water quality to be sufficient in the light of national recommendations (e.g. in Germany KRINKO/RKI/BfArM recommendation on treatment), this is your sole responsibility.

The concentrations, temperatures and exposure times as well as the instructions for rinsing given by the manufacturer of the cleaning agent or detergent and disinfectant must be strictly observed.

Sequence:

1. Place the products in a suitable cleaning sieve/trolley in the WD. Ensure that the products are not touching one another during this time.
2. Close the equipment and start the programme:

Recommended parameters:

Programme step	Medium / Concentration	Temperature	Exposure time
Pre-rinsing	Mains water	Not thermoregulated(Setting 10°C)	≥ 1 min
Cleaning	Requirements of the manufacturer of the cleaning agent	55°C	≥ 5 min (or requirement of the manufacturer of the cleaning agent
Neutralising (optional)	Requirements of the manufacturer of the cleaning agent	Not thermoregulated (Setting 10°C)	≥ 2 min
Rinsing	Mains water	Not thermoregulated(Setting 10°C)	≥ 1 min
Thermal disinfection	N/A	A0 value ≥ 3000 (for older units - min. 5 minutes at 90 °C / 194 °F)	
Drying	N/A	100°C	25 min

3. Remove the products after the programme has finished.
4. Check and pack the products as soon as possible after removal (see Chapter 6.4 ff 'Checking', 'Maintenance' and 'Packing'), if necessary after additional post-drying in a clean place.

Proof of the basic suitability of the products for effective machine cleaning and disinfection was provided by an independent, officially accredited and recognised test laboratory using the WD G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning and cleaning agent Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg).

6.3 rd.3 MANUAL CLEANING AND DISINFECTION

Care should be taken when selecting the cleaning agents and disinfectants to be used,

- that this is generally suitable for the cleaning and/or disinfection of medical products made ofmetals,
- that the cleaning agent is suitable for ultrasonic cleaning (no foam development),
- that a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE mark) is also used and that this is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the products (see chapter 6.9 'Materialresistance').

If possible, combined detergents/disinfectants should only be used in cases of very low contamination (no visible contamination).

During manual cleaning and disinfection with a possible risk of injury and infection, further occupational health and safety measures (e.g. protective clothing, safety goggles, gloves; room air filtration) must be observed according to national regulations (e.g. in Germany TRBA 250).

The concentrations, temperatures and soaking times as well as the instructions for rinsing given by the manufacturer of the cleaning agent or detergent and disinfectant must be strictly observed.

Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water is used (e.g. purified water/highly purified water)[3]

For drying, use only a soft, clean and lint-free cloth and/or filtered air. The use of medical compressed air is recommended.

⚠ Take care with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can get stuck

[3] If you consider a lower water quality to be sufficient in the light of national recommendations (e.g. in Germany KRINKO/RKI/BfArM recommendation for processing), this is your sole responsibility

Cleaning procedure:

1. Prepare the cleaning solution according to the manufacturer's instructions
2. Place the products in a sufficiently large pre-cleaning bath (e.g. an ultrasonic bath that has not yet been activated) for the specified exposure time (≥ 20 min) so that the products are completely covered. Ensure that the products are not touching one another during this time. Support the cleaning by completely brushing all surfaces with a soft brush
3. Then remove the products from the cleaning bath and rinse them thoroughly under running mains water (≥ 1 min).
4. Check the products (see Chapter 6.4 'Checking'). In case of visible dirt residues, repeat the aforementioned steps.

Disinfection procedure:

5. Prepare the disinfectant solution in an ultrasonic bath according to the manufacturer's instructions.
6. Place the cleaned and checked products in the bath for the specified exposure time (in accordance with the manufacturer's instructions) so that the products are completely covered. Ensure that the products are not touching one another during this time.
7. Start the ultrasound after the exposure time (≥ 5 min)
8. Then remove the products from the disinfection bath and rinse them thoroughly under running mains water (≥ 1 min).
9. Dry the products with a lint-free cloth and/or filtered air (see above).
10. Pack the products as soon as possible after removal (see Chapter 6.6 'Packing') if necessary after additional post-drying in a clean place.

Proof of the basic suitability of the products for effective machine cleaning and disinfection was provided by an independent, officially accredited and recognised test laboratory using the pre-cleaning and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt).

6.4 th CHECKING

After cleaning or cleaning/disinfection, check all products for corrosion, damaged surfaces, chipping, soiling and discolouration and replace affected products. On visual inspection (normal vision or vision corrected to normal), no soiling (e.g. incrustations, coatings) should be visible. Products that are still soiled must be cleaned and disinfected again. Safe sterilisation only occurs with clean medical devices.

6.5 th MAINTENANCE

No maintenance required

6.6 th PACKAGING

Sort the cleaned and disinfected products into the corresponding sterilisation tray.

Pack the products or the sterilisation trays in sterilisation containers or very large products in single-use sterilisation packaging (single or double packaging) that meet the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- Suitable for steam sterilisation (temperature resistance up to at least 138 °C (280 °F) sufficient vapour permeability)
- adequate protection of the products or sterilisation packaging against mechanical damage
- regular maintenance according to the manufacturer's specifications (sterilisation container)
- a maximum weight of 10 kg per package/content of the sterilisation container must not be exceeded.

6.7 th STERILISATION

⚠ Bone and cerclage wires: Cable ties that hold the reels or wires together must be removed before sterilisation

The sterilisation procedure listed below is recommended for sterilisation. The flash sterilisation procedure is generally not permitted. Also, do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

Steam sterilisation

- Steam steriliser in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- fractionated vacuum process[4] (with sufficient product drying[5])

[4] at least three vacuum steps

[5] The actual drying time required depends directly on parameters that are the sole responsibility of the user (load configuration and density, steriliser condition, ...) and must therefore be determined by the user. Nevertheless, drying times of 20 min are not to be compromised.

- Sterilisation time (exposure time at the sterilisation temperature):

Country	fractionated vacuum process
Germany	At least 5 minutes[6] at 134 °C / 273 °F)
USA	min. 4 minutes at 132 °C / 270 °F), Drying time at least 20 min[6]
France	min. 5 minutes at 134 °C / 273 °F) if required for prion activation: Sterilisation time 18 minutes
other countries	min. 5 minutes[6] at 132 °C (270 °F) / 134 °C (273 °F)

- Maximum sterilisation temperature 134 °C (273 °F); plus tolerance according to DIN EN ISO 17665

Proof of the basic suitability of the products for effective steam sterilisation was provided by an independent, officially accredited and recognised test laboratory using the HST 6x6x6 steam steriliser (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum process. Typical conditions in clinics and medical practices were taken into account, as well as the procedure described above.

6.8 th TRANSPORT AND STORAGE

Transport and storage must not adversely affect the properties of the reprocessed medical device. When storing reprocessed medical devices, the information provided by the manufacturer of the medical device and the manufacturer of the packaging material must be taken into account (MPBetreibV). Reprocessed medical devices that are sterile for use always require packaging and must be stored at room temperature in a dust-protected, clean, dry and vermin-free environment.

The storage period depends on the quality of the packaging material, the tightness of the sealing seams and the storage conditions

6.9 th MATERIAL DURABILITY

When selecting cleaning agents and disinfectants, make sure that they do not contain the following ingredients:

- organic, mineral and oxidising acids (minimum permissible pH value 5.5)
- Lyes/strong alkalis (neutral/enzymatic (max. permissible pH value 8.5) or alkaline cleaner (max. permissible pH value 11)
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidising agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- aromatic/halogenatedhydrocarbons

Never clean products, sterilisation trays or sterilisation containers with metal brushes or steel wool.

All products, sterilisation trays and sterilisation containers must only be exposed to temperatures not higher than 134 °C (273 °F).

6.10 th REUSABILITY

The bone implants by **REDA Instrumente GmbH** are traded as '**Single use'** products.

Bone implants are intended for single use only. Single-use products must not be reused because, according to their design, they no longer function as intended after the first use.

Repeated use of the bone implant can lead to overloading and breaking of the implant due to wear or bending.

If the bone implant is not used after reprocessing, it can be stored again and reprocessed when required again.

7. DISPOSAL AND RETURNS

Expired or explanted bone implants must be disposed of in the hospital / practice. To prevent infections and microbiological hazards, products to be disposed of must go through the entire reprocessing process.

Rejected, used bone implants must also undergo the entire reprocessing process and be labelled as "hygienically safe" before being returned. The return shipment must be made in suitable and secure packaging.

[6] or extended sterilisation time (e.g. 18 minutes) for prion activation according to national requirements (not relevant for USA)

8. EXPLANATION OF THE SYMBOLS USED

NON STERILE	Product is supplied non-sterile		Follow the instructions for use
	Attention, observe instructions		For single use only
LOT	Batch number	REF	Item and/or order number
QTY	Quantity in packaging	CE 0297	European free circulation mark with number of the notified body
	Manufacturer		Manufacture date
	Store in a dry place	MD	Medical Device

9. APPLICABLE STANDARDS / GUIDELINES

- AKI guide "Instrument reprocessing done right”
- Hygiene requirements for the reprocessing of medical devices"
  (Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)).
- DIN EN 285 Large steam sterilisers
- DIN EN 13060 Small steam sterilisers
- DIN EN ISO 15883-1-3 Cleaning and disinfection devices
- DIN EN 868 Packaging material
- DIN EN ISO 17664 Sterilisation – Information from the manufacturer
- MDR 2017/745 Chapter III/23 followed „Kennzeichnung und Gebrauchsanweisung“

10. MANUFACTURER

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⚠ All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

INSTRUMENTE GMBH

REDA Instrumente GmbH assumes no liability, if this instruction manual is violated!