Instruction for Use
Nails
unsteril

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

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

REDA Implants are design for Osteosynthesis procedures and degenerative skeletal dislocations. In addition of this document, detailed information is available in our REDA Brochures or following literature:

- Knochenbruchbehandlung, Empfehlung des Gerhard-Küntscher-Kreises, V. Vécsei et al – Georg Thieme Verlag 1995
- FMT-Fachwissen Medizin-Technik, Folge 3: Instrumente in der Medizin, Knochenchirurgie, Klaus Witzer – MTD-Verlag Amtzell, 1991
- AO-Instrumente und Implantate, R. Texhammar, C. Colton – Springer-Verlag 1995

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 Number
	Caution, observe the accompanying documentation!
LOT	LOT number
NON STERILE	Information about NON-sterile product
	Symbol for Manufacturer
	Observe the Instructions for Use
CE	Community European (Free trade sign) CE

	Single use only
	Storage temperature range -20°C to 60°C
	protect from humidity

3. PRODUCT SPECIFIC INSTRUCTIONS

Our products may involve an individual implant or a number of implants where reusable or single use instruments are required, as well as other accessories required for implantation. The products are medical devices with regard to national and international laws for products in human medicine.

4. INTENDED USE

Nails are intended for single use only and are not designed to be reused. All components are delivered NON-STERILE and must be appropriately prepared before first use. All packaging must be removed before preparation**.**
The instruments may only be used for their intended purpose in the specified medical fields, with use being restricted to adequately trained and qualified personnel. The treating physician or user is responsible for selecting the right instrument(s) for the surgical task/application at hand as well as for their safe handling. This includes ensuring an adequate level of training, knowledge and experience.

5. INDICATION

Bone nails are used in bone fracture procedures to support the Osteosynthesis.

INTERLOCKING INTRAMEDULLARY NAIL

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated. In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures. In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

SUPRACONDYLAR NAIL

Indications for supracondylar nails include supracondylar fractures; bone lengthening and shortening. Devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

6. MATERIALS USED

Nails are made of stainless steel 1.4441 and 3.7164 TiAL6V4 according to ISO 5832-1 and ASTM F-138. which are austenitic Stainless Steel for implants, with high corrosion resistance.

7. CONTRAINDICATION

- Insufficient quantity or quality of bone, which would inhibit rigid fixation of the device.
- Ulcers in the area where the device is to be placed, or the use of radiation or chemotherapy.
- Extrem adipositis
- Previous history of infections.
- Arthrodesis
- Mental, physical or neurological conditions, which may impair the patient's ability to cooperate with the postoperative regimen.
- Compromised vascularity.
- Application for spine surgeries
- Osteoporosis

8. 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.

- Increased fibrous tissue response around the osteotomy area.
- Early or late infection, both deep and/or superficial.
- Nerve damage may occur as a result of the surgical intervention.
- Metal sensitivity reactions in patients have rarely been reported, and their significance awaits further clinical evaluation.
- Complications during implementation of screws without pre-drilling.
- Harm of soft tissue and bone by imprecisely positioning of the hole for the screw.

9. 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.

10. SPECIAL INFORMATION REGARDING DISPOSABLE PRODUCTS

When a product is marked as being a disposable product, re-usage, under consideration in this or in the product specific Instructions for Use, is not allowed. Initial proper usage depending on the type of product, leads to or respectively causes among others

- A product contamination that cannot be safely controlled
- Material fatigue and material change, i.e. plastics
- Non-detectable damages i.e. in the form of micro cracks
- Wear out of the functioning characteristics that are required for safe use of the product, i.e. screw head
- Missing or no longer complete functioning, i.e. by filters for sterilization containers

That excludes re-usage and among others can lead to the following dangers for the patient, user and third party:

- Life threatening infections
- Failure of the clinical treatment
- Interruption and repetition of operations
- Delayed recovery or prolonged treatment periods
- Permanent damage, disability or death of the patient
- Damage claims resulting therein and penal measures

After an implant has been implanted, it is not allowed in any case, to be used again. Also implants that are adapted but not yet implanted are not allowed to be used on another patient. Even when the implant seems not to be damaged, previous stress could have led to irregularities which shorten the life of the implant. The level of a permitted adaption cannot be defined by MONDEAL and lies solely at the discretion, the experience and the responsibility of the user. We take absolutely no responsibility and assume no liability for consequences and claims of any kind based on re-usage of a disposable product.

11. 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.

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

12.1 GENERAL PRINCIPLES

All products must be cleaned, disinfected and sterilized before each use. This also applies to initial use after delivery of products 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.
With regard to your responsibility for the sterility of the products, 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.

12.2 CLEANING AND DISINFECTION

Basic Principles

A mechanical method (RDG - cleaning and disinfection machines / disinfectors) should be used when possible to clean and disinfect bone plates and component. A manual method – even when using an ultrasonic bath – should only use 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.

12.3 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 5 min. at 134 °C or A_0 value > 3000) 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 implants.
- 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 implants (see chapter "Material Resistance").

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

Procedure:

1. Disassemble the products to the maximum extent possible.
2. Place the disassembled instruments in the RDG. Make sure that the products do not touch one another.
3. Start the program.
4. Take the instruments out of the RDG after program completion.
5. Check and package the products 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 products 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.

12.4 PACKAGING

Sort the cleaned and disinfected products 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 min. 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)

12.5 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 134 °C (273 °F; plus tolerance according to DIN EN ISO/ANSI AAMI ISO 17665)
- Sterilization time (exposure time at sterilization temperature) at least 5 min.[3] at 132 °C (270 °F) / 134 °C (273 °F)

2 The less effective gravitational method should only be used when the fractional vacuum/pre-vacuum method is unavailable.
3 Or 18 min. (prion inactivation)

Proof of the basic suitability of the products 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 is not permitted. Also do not use any hot air sterilization, no radiation sterilization, no formaldehyde or ethylene oxide sterilization and no plasma sterilization.

CAUTION: STERILIZATION IS NOT A SUBSTITUTE FOR CLEANLINESS.

13. CONTROL

Check all implants for damage and contamination and separate damaged and contaminated implants from one another.

14. STORAGE

After sterilization, the instruments must be stored in the sterilization package and kept dry and dust-free.

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 products, sterilization trays or sterilization containers with metal brushes or steel wool.

Products, sterilization trays and sterilization containers should never be exposed to temperatures above 137 °C (279 °F)

16. RECONDITIONING

Should an implant be taken out of the sterile packaging, respectively implant tray and, according to the previous description not used and not discarded due to other reasons, respectively sorted out, it can be prepared again. This is valid also for previously, once or twice prepared implants. Please pay attention in this regard Chapter 9, last paragraph with regard to Creutzfeldt-Jacob disease (CJK). By repeated preparation according to the requirements in the Instructions for Use, changes in color can occur. These are purely optical and do not represent any functional deficit. Notice should be taken that implants, if applicable, based on a color code within an implant system can become discolored and as a result be mixed up. You should use the implant in due time or it should be replaced. No measureable and according to our current knowledge, no material changes have occurred due to multiple preparations. 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.

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. 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

[1] AKI: Working Group Instrument Prepare

REDA INSTRUMENTE GMBH

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Reda Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen
(Germany)

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