RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
ORTHOPEDIC IMPLANTS

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With the purchase of this implant, you are receiving a high-quality product whose proper handling and use are described below.

To keep risks and burden for the patient as low as possible, please read these instructions for use and keep them in a safe place.

PRODUCTS

These instructions for use contain basic instructions for the application and use of implants for the osteosynthesis.

The products may only be handled by trained medical personnel. Application and implantation may only be carried out by trained medical professionals.

The implants are **not** intended for the use on the central nervous and circulatory system and must not be used for this purpose.

These products are non-sterile, non-reusable (single use) medical devices. Before use, the implants must undergo reprocessing according to the instructions in these instructions for use.

Orthopedic implants including accessories:
- Drill wire, Steinmann pins
- K-wires
- Bone wires (Cerclage)

Drill wire tips:
- Trocar / Trocar knurled lengthwise
- Lancet / Lancet with hole
- Round / Flat
- Triangle / Square
- Partial / full thread
- Drill tip

PRODUCT DESCRIPTION

Orthopedic implants enable the orthopedic and trauma surgeons to precisely fixate bones. They support the treatment and healing process of bone fractures (osteosynthesis, correction of degenerative diseases). However, the implants are not suitable to replace normal body structures or to support the full body weight alone.

INTENDED PURPOSE

- **K-wires (drill wires)** are intended for closed repositioning and fixation of a fracture using a rotating drill wire (K-wire). These are procedures of surgical fracture treatment using one of the following methods:
  - Percutaneous intramedullary splinting (e.g., at the metacarpals) or percutaneous “pinning”
  - Fixating a fracture by inserting a K-wire, and if possible, by fixating the wire in the contralateral cortical bone
- **Steinmann pins** are intended for the extension treatment of bone fractures. Extension treatment is based on the use of a continuous longitudinal traction applied on the injured limb. Depending on the fracture to be treated, a drill wire is inserted diagonally through the bone, and longitudinal traction is applied with the aid of a metal clamp and a variable weight.
- **Bone wire (cerclage wire)** intended for fracture treatment by means of simple cerclage wiring as a stand-alone treatment. The soft wire is wrapped around the bone and tightened by twisting.

IMPLANT SELECTION

The following factors must be considered in fracture treatment:

Selection of the appropriate implant:
Selecting the appropriate implant is extremely important for a successful treatment. The appropriate implant size and shape increase the chances of success. The nature of the human bones and soft tissues sets a limitation on the characteristics of the size and strength of the implants. If a firm bone union is to be achieved the patient needs suitable external assistance. Physical strain and weight on the fracture site must be limited to prevent delayed healing and/or late sequelae.

Patient-related factors

a) Weight:
Overweight or obesity can adversely affect the implant and its stability. The limit of the load capacity must be specific to the area of application and purpose of the implant.

b) Occupation or activities:
Occupational activities where physical strain is exerted on the body pose a risk to the healing process. To ensure healing, immobilization is necessary.

c) Reduced mental capacity, mental illness or alcoholism:
There is a risk that patients might ignore certain necessary limitations and precautions leading to the failure of the product or other complications.

d) Degenerative diseases and nicotine intake:
At the time of the implantation, if the degenerative disease is advanced in such a way the expected useful lifetime of the implant might become significantly reduced. In this case, the products serve only as a means of delaying or temporarily alleviating the illness.

e) Foreign body reaction:
If there is some sensibility or allergic reaction towards the materials used in the implant to be expected appropriate tests must be carried out before implant selection and implantation.

INDICATIONS

Fixation of bones and bone fragments after successful repositioning

CONTRAINDICATIONS

- All concomitant diseases that might jeopardize or affect the fixation or the success of the surgery such as obesity or impairment of the blood circulation
- Poor bone quality or quantity might jeopardize or affect secure fixation of the implant
- Severe muscular, neurological or vascular diseases that might jeopardize or affect the procedure/surgery
- Allergic patients who are prone to allergic reactions towards the materials used in the implant
- Acute or chronic, local or systematic infections
- Nicotine intake that might jeopardize the success of the procedure/surgery due to a delayed bone//wound healing
- Mental conditions that impede the understanding and observance of the physician's instructions or the participation in a rehabilitation program (e.g., alcohol or drug consumption, Parkinson’s, Alzheimer’s)

POTENTIAL ADVERSE EVENTS

The adverse events listed below have been described in the literature:
- Implants becoming loose
- Wound infection (skin and deep wound infection)
- Vascular complications
- Pseudoarthrosis
- Damages to the nerves
- Inflammations
- Allergies to metal

CORRECT HANDLING

Implants must be treated with the care required for the handling of medical devices. If the shape of the implant has to be altered, the implant should not be bent excessively, bent against the original shape, notched or scratched. These manipulations, in combination with improper handling and application, might lead to surface defects and/or structural changes in the material and thus lead to product damage and/or failure.

POSTOPERATIVE CARE:

- Physicians may have to inform their patients about the weight restrictions on the implant and provide instructions on postoperative behavioral adaptations and on gradual increase of physical loads. Failure to do so can generate malalignment, delayed bone healing, implant failure, infection, thrombophlebitis and/or wound hematoma.
- The physician makes the final decision on when to remove the implant. If possible and appropriate for the individual patient, we recommend removing the fixation products after the healing is complete. This particularly applies to young and active patients. The risk of a negative impact such as secondary infection, allergies, material fatigue fractures, implant failure and/or impaired blood circulation increases with the duration the implant remains in the body.

COMPATIBILITY

- It is not recommended to use RUDOLF Medical products in combination with products of other manufacturers because the design, materials, mechanics and constructions are not aligned with each other. RUDOLF Medical assumes no liability for any complications arising from the combination of components or the use of third-party medical devices.
- Unless described otherwise, a combination of different implant metals is not recommended. A combination of metals might lead to galvanic corrosion and the release of ions. This may cause an inflammatory response, metal sensitivity reactions and/or long-term systemic adverse events. In addition, the corrosion process can reduce the mechanical strength of the implant.

⚠ WARNINGS AND PRECAUTIONS

- Before using a RUDOLF Medical implant, we kindly ask the user to read these instructions for use and observe the recommendations, warnings and instructions.
- RUDOLF Medical cannot be held liable for any complications arising from the use of the implants/instruments that are outside the control of RUDOLF Medical, including but not limited to product selection and deviations in application/handling and surgical technique.
- The implants are single-use products and must not be reused. RUDOLF Medical assumes no liability in the case of non-compliance.
- Implants that have come into contact with blood, soft tissue, bone or body fluids must not be reused and must be disposed of according to respective guidelines about contaminated products. Contamination residues on the implants may lead to injuries or infections to the patient or user.
- Incorrectly selected, positioned or sized implants or incorrect fixation may lead to unusual stress that may negatively affect the life of the implants.
- The implants must be used only for the intended indication. These implants must not be used for other indications (off-label use).
- The patient should be regularly examined and tested for infection for the duration the implant remains implanted.
- These implants have been developed for temporary use and should be removed after full healing of the fracture.
- The implants must not be modified using a machine.
- Unless the implant is labelled as “MR Safe” or “MR Conditional”, there are hazards associated with the use of RUDOLF Medical products in an MRI environment. This includes but is not limited to:
  - Heating and/or migration of the implant
  - Artefacts created by the implant

  The RUDOLF Medical have not been tested for MRI compatibility.

SINGLE-USE PRODUCTS

- The implants are intended for single-use and must not be reused.
- The reuse or clinical reprocessing of single-use products may compromise the structural integrity of the device and lead to device failure, causing patient injury, illness or death. Furthermore, the reuse or clinical reprocessing of single-use devices increases the risk of contamination, e.g., through the transmission of pathogens from one patient to another. This can also lead to patient injury, illness or death.
- RUDOLF Medical advises against the clinical reprocessing of contaminated implants. Implants contaminated with blood, tissue and/or body fluids or substances must not be reused and must be disposed of in accordance with hospital guidelines and regulations. Even if components appear externally intact after use, minor defects and invisible material damage may cause material fatigue.

MATERIAL

Material	Material specification	Standard
Implant steel 1.4441	X2CrNiMo 18-15-3	DIN EN ISO 5832-1
Titanium 3.7165	Ti6Al4V (ELI)	DIN EN ISO 5832-3
Titanium 3.7025	Grade 1	DIN EN ISO 5832-2
Titanium 9.9367	Ti6AlNb7	DIN ISO 5832-11

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

- Before use, check the implants for visible damages such as cracks, breaks, damaged tips. Damaged implants must not be used.

REPROCESSING INSTRUCTIONS

Reprocessing the products

- RUDOLF Medical implants are supplied non-sterile and must be cleaned, disinfected and sterilized prior to the surgical procedure.
- Before reprocessing, the implants must be removed from the original packaging. The products are not intended to be sterilized in their original packaging.
- RUDOLF Medical recommends automated reprocessing using a standardized cleaning program in a washer/disinfector according to ISO 15883-2.
- Manual reprocessing is not validated because the implants are not suitable for it due to their design (thread, holes, drill tip etc.).

Validated automated reprocessing procedure

The validated automated reprocessing procedure comprises:

a) Automated cleaning, disinfection and drying in a washer/disinfector (WD)
b) Visual inspection
c) Packaging
d) Validated sterilization method

Transportation

- Safe storage and transport of the products to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.

Automated cleaning, disinfection and drying in a WD

- The validated cleaning and disinfection method is the Miele standard program “DES-VAR-TD” of the Miele G7835 CD washer/disinfector.
- The instructions of the WD manufacturer regarding appropriate operation and loading as well as maintenance of the WD must be closely observed.
- Literature: „Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten“ by the Robert Koch Institute (Hygiene requirements for the reprocessing of medical devices)

Process

Process	Reagents	Time / Min.	T / °C
Pre-cleaning	Cold water	1	cold
Cleaning	Water 55° C ± 5° C and alkaline detergent Neodisher Mediclean forte, 0.5%	5	55° C ± 5° C
Neutralization	Neutralizer Neodisher Z	2	--
Rinsing	Deionized water	At least 1	--
Thermal disinfection*	--	5	>90°C
Drying	--	30	60° C ± 5° C

- * Carry out an automated thermal disinfection taking into consideration the national requirements regarding the A0 value in ISO 15883-1 (A0 = 3000).

Visual inspection

- After cleaning, the implants must be visually inspected for cleanliness and damage. Implants that are still not clean must be cleaned and disinfected again. Damaged implants must be taken out of circulation and disposed of accordingly.

Packaging

- The products must be packaged for sterilization according to ISO 11607-1. The validated sterilization method applies to double-layer sterilization bags.

STERILIZATION

Validated sterilization method

The validated sterilization method was performed using to the autoclave Tuttnauer Type B 3870 EHS.

Sterilization:

- 2 fractionated pre-vacuum phases
- Holding time: minimum 5 minutes, maximum 7 minutes at 132 - 137°C
- Drying for at least 10 minutes

The operating and maintenance instructions of the machine's manufacturer must be closely observed.

STORAGE

- Store the sterilized products in a clean and dry environment at room temperature and protected from humidity and direct sunlight.

ADDITIONAL NOTES

- If the specified chemical agents and machines are not available, the user needs to validate their process.

DISPOSAL

- Only after the products have been cleaned and disinfected properly, they can be disposed of accordingly.
- Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
- Dispose of the product in an environmentally friendly manner according to the applicable hospital guidelines.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS

- Never carry out repairs yourself. Service and repairs should only be carried out by appropriately instructed and qualified persons. If you have any questions, contact RUDOLF Medical or your medical technology department.
- Contaminated defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

RETURNS

- Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint. Repairs must not be carried out by the user.
- Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

PROBLEMS / EVENTS

- The user should report any problems with RUDOLF Medical products to the respective distributor.
- In the event of serious incidents with the products, the user must report this to RUDOLF Medical as the manufacturer and the competent authority of the member state in which the user resides.

WARRANTY

- The instruments are made of high-quality materials and are subjected to a strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical.
- RUDOLF Medical is responsible for ensuring that each product is manufactured, inspected, and packaged with the utmost care.
- Since RUDOLF Medical has no influence and no control over the proper application and handling RUDOLF Medical cannot be held responsible for complications or the failure of the treatment.
- Individual RUDOLF Medical products and sets are compatible with each other. Before use, the user is responsible for ensuring the compatibility of the products with each other.

SYMBOLS

	Consult instructions for use.
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	Do not re-use
CE 0297	CE marking according to EG directive 93/42/EEC with the ID of the notified body
	Keep dry
	Keep away from sunlight
UDI	Unique Device Identifier
MD	Medical Device