INSTRUCTIONS FOR USE (EN)
ORTHOPEDIC IMPLANTS

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

These instructions for use are valid for the RUDOLF Medical bone implants such as Kirschner wires, Steinmann pins and bone wire.
You are receiving a high-quality product whose proper handling and use are described below.

For professional use only: The instruments are intended for use by the professional users only (surgeons, operating room nurses, medical device reprocessing technicians).

Adequate training and knowledge of the materials, techniques and handling of complications is mandatory to perform surgical interventions in the area of osteosynthesis safely and successfully.

NON STERILE RUDOLF Medical bone implants are delivered non-sterile and must be cleaned, disinfected, and sterilized before use. Protective caps and transport packaging must be removed beforehand; those are not suitable for sterilization.

Be careful when handling sharp tips and cutting edges as there is a risk of injury.

SINGLE-USE PRODUCT

- The RUDOLF Medical bone implants are placed on the market as single-use products and are intended for single use only.
- These single-use products must not be reused, as they no longer function as intended after their first use.
- To ensure full traceability, the REF number (item or order number) and the LOT number (batch number) of the orthopedic implant used must be documented in the surgical report.

Detailed instructions for reprocessing can be found in the IFU D1494:

VISUAL INSPECTION OF THE PRODUCTS AFTER DELIVERY

Orthopedic implants are extremely susceptible to damage. Even small scratches or dents can cause internal stress that significantly reduces the strength of the implant. Therefore, they must be handled with the utmost care.

Check for:
- Before unpacking: Check the outer packaging for damage, including damage incurred during shipping, and condensation.
- Check to see if the contents match the information on the label.
- Check the products for external damage (e.g., discoloration, burrs, cracks, sharp edges, scratches, dents).

PRODUCT DESCRIPTION

- **Kirschner Wires and Steinmann Pins**
  Kirschner wires and Steinmann pins are semi-rigid wires of various diameters and lengths with different end configurations.

- **Bone wire**
  Bone wires are malleable wires and are supplied on 10-meter coils.

- The bone implants do not contain the following:
  - Tissue of human or animal origin
  - Medicinal components
  - Software

⚠ If the implants are used outside their intended purpose this can result in complications or harm to the patient; in some cases, the surgery must be redone. Orthopedic implants can only be used in procedures where the intended purpose of the implant is explicitly required and defined.

- **Materials used**

  The bone implants are manufactured from stainless steel according to DIN EN ISO 5832-1: implant steel 1.4441. The bone implants are suitable for MRI. However, artefacts are created.

INTENDED PURPOSE

Bone implants are used in osteosynthesis and for the correction of degenerative changes in the skeleton.

Patient population: There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

The choice of treatment is influenced by factors such as fracture type, comorbidities, biological age, and the overall physical and mental condition of the patient.

SURGICAL TECHNIQUES

Kirschner Wires and Steinmann Pins

Kirschner wires and Steinmann pins are used for open reduction and fixation of a fracture.

Procedures of surgical fracture treatment:

- Percutaneous intramedullary nailing, e.g., of the metacarpal bones
- Percutaneous “pinning” to stabilize a fracture by inserting a Kirschner wire, and, if possible, securing the wire in the opposite cortical bone, including the use of an external fixator

Bone wire

Bone wires are used to treat fractures by wrapping the wire around the bone. The soft wire is usually wrapped around the bone several times and tightened by twisting it.

INDICATIONS

- Bone fracture treatment
- 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

CONTRA-INDICATIONS

The medical devices are not intended for the use on the central nervous and circulatory system.

Medical conditions that preclude adequate implant support or hinder the healing process include, among others:

- Fractures of spine
- Impairment of blood supply
- Insufficient bone quality or quantity (osteoporosis)
- Extreme adiposity
- 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 tumors
- Systemic diseases and metabolic dysfunctions
- Severe deformities
- Serious falls
- Mental conditions that make participation in the rehabilitation program 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)
- Allergies or other reactions to the material used (see the “Risks / intolerances” section)
- Fusion of the proximal interphalangeal joint

⚠ WARNINGS AND PRECAUTIONS

Important notes for surgeons and operating room staff

- The bone implants must be used exclusively for their intended purpose in the corresponding medical specialties by sufficiently qualified personnel.
- The implants are intended for single use only. If the implant becomes deformed or damaged during implantation, it must not be implanted. In this case, a new implant must be used.
- Be careful when handling sharp tips and cutting edges as there is a risk of injury.
- The drill wires must not be cleaned while they are in a sterilization container (sterilization tube). However, for the sterilization process they are placed in the sterilization tubes.
- For patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices must be applied.
- RUDOLF Medical assumes no liability for damages or consequential damages resulting from improper use, handling, or improper reprocessing and sterilization.

Patient

- To ensure full traceability, the REF number (item or order number) and the LOT number (batch number) of the orthopedic implant used must be documented in the surgical report.
- **Implant selection:**
  - The user is responsible for selecting the bone implant suitable for the specific application or surgical procedure, for receiving adequate training and information, and for having sufficient experience in handling the bone implants.
  - For implants with a deliberately roughened surface (e.g., threads or knurling), the increased diameter must be taken into account.
  - Before use, the diameter of the implant must be checked using a suitable measuring device or template. Selecting an implant that is too thin for the indication poses a risk of fracture.
  - It is the user's responsibility to assess the extent of the injuries or changes requiring surgical treatment and to select the appropriate implants.
  - The appropriate implant type and size must be tailored to the patient. The patient's weight and activity level must be taken into account, as well as the fracture to be treated.
  - Using the largest possible bone implant and ensuring proper positioning prevents bending, breaking, cracking, and loosening of the bone implant. This also minimizes the force transmitted to the bone.
  - Selecting the wrong implant can lead to implant failure.
  - Before a surgery, it must be determined whether the patient might have an unusually sensitive reaction or a potential allergy to the implant material.
- **Postoperative risks and care:**
  - The bone implants can never bear the full load of the treated bone segment. The patient must be informed of the load limits. Appropriate postoperative behavior must be prescribed.
  - In general, the patient must be informed about indications, contra-indications, adverse side effects, and postoperative care. This must be documented.
  - After implantation, regular medical follow-up should take place.
  - Early weight-bearing increases the stress on the implant and can lead to fracture, bending, or loosening of the implant. In patients who are exposed to heavy loads or who suffer from delayed healing or delayed bone union this requires special attention. Weight-bearing can then be considered if the fracture is stable with good bone-to-bone contact. Full weight-bearing before complete fracture healing is contraindicated.

Implants

- Before each procedure, the implant must be inspected by trained medical personnel. If the implant shows signs of damage or deformation, particularly at the sharp tips, it must not be used. See the "VISUAL INSPECTION OF THE PRODUCTS AFTER DELIVERY" section above.
- It is absolutely essential that the user, surgeon, and operating room staff are familiar with the appropriate surgical technique for the instruments and implants being used.
- Modifications of the bone implants must only be performed by trained users using the appropriate instruments. Before beginning treatment, ensure that the necessary instruments are available and suitable for the use with our bone implants. Material fatigue must be avoided.
- **Compatibility**:
  - **Application instruments and implants:**
    - Depending on the surgical technique, various application instruments are used to insert the implants, such as a drill with an appropriate chuck, wire cutting pliers, bone-holding forceps, or external fixators (e.g., the Böhler traction bow). The user must verify the selection and combination of these application instruments prior to clinical use.
  - **Combining the implants with other implants:**
    - Depending on the type of fracture treatment, these bone implants are used in combination with other medical devices—such as external fixators, plates, or screws—as part of a comprehensive fracture treatment plan. The treating physician selects the appropriate combination based on the type of fracture, the required stability, and the individual patient factors.
    - ⚠ When different implants are combined observe the following: For example, if a bone wire is additionally secured to the bone with a bone plate, the bone wire and bone plate must not be damaged in the process. In the case of the bone wire, there is a risk that the bone wire's original properties will be adversely affected.
    - For metallurgical, mechanical, and design reasons, implants made of different materials must not be combined.

- **Handling:**
  - Drill wires with partial or full threads, as well as those with drill tips, might break if used improperly. We as the manufacturer assume no liability for such damage.
  - Appropriate drilling devices with a three-jaw chuck must be used when implanting these wires.
  - The bone implants must not come into contact with objects that could damage the implant surface.
  - The bone implants must not be mechanically modified or manipulated in any way, unless the design and surgical technique expressly require this. In the latter case, the modification must be performed using the appropriate instruments.
  - Bending the bone implants must be done with care. Extreme deformation of the bone implant must be avoided at all costs.
  - Repeated bending back and forth leads to fatigue or fracture of the bone implant. Notches and pressure marks also significantly reduce mechanical strength.
  - Surgical technique: The rules of art and science, as well as scientific publications, are authoritative.

Risks / intolerances:

- After the implantation of metal implants, an inflammatory reaction of varying severity can occur. Other symptoms could be: localized or generalized eczema, impaired wound healing, and pain.
- If a patient has a confirmed allergy to nickel, cobalt, or chromium, implants made of implant-grade steel (material number 1.4441 according to DIN EN ISO 5832-1) must not be used.
- Inadequate cleaning and sterilization can lead to infections in the patient.
- Improper reprocessing procedures can lead to surface discoloration or corrosion of the implant.
- Improper application during implantation or excessive stress on the implant during and after the implantation can lead to fractures or deformation of the implant. This can cause harm to the patient.
- The physician must carefully weigh any potential risks posed by external electrical and electromagnetic influences (radiation, magnetic fields) in connection with diagnostic and therapeutic procedures (e.g., X-rays, MRI) prior to the examination.

Complications:

The following complications have been observed in various cases and therefore require special attention from the treating physician:

- Bending, breaking, loosening or detachment of the implant
- If the fracture does not heal properly, secondary dislocation of the fracture can occur.
- Superficial and deep infections
- The procedure and the use of bone implants can result in vascular injuries caused by implantation or migration, such as thrombophlebitis, pulmonary embolism, hematomas, and non-vascular necrosis of the femoral neck.
- Allergies, tissue and foreign body reactions can occur near the bone implants.
- Delayed or incomplete fracture healing
- Bone deformity and refracture
- Displacement of the bone implant
- Cardiovascular dysfunction
- Nerve injuries caused by implantation or migration
- CRPS (complex regional pain syndrome) resulting from trauma
- Dysesthesia
- Pseudoarthrosis
- Pin-site infection: infections at the implant entry sites
- Reoperation/symptomatic implant removal: the need for reoperation or premature implant removal
- Postoperative arthritis: particularly in fractures near joints

⚠ REPORTING SERIOUS INCIDENTS

All serious incidents related to the product must be reported to the manufacturer and to the competent authority of the country in which the user and/or patient is located.

GENERAL NOTES ON THE IMPLANTATION AND REMOVAL OF THE BONE IMPLANTS

In general, the insertion techniques and usage of Kirschner wires, Steinmann nails, and bone wire during surgery are highly dependent on the specific medical indication and are guided by the current recommendations from both national and international professional associations. This in turn means that the explanation is also highly dependent on the individual situation.

Given the variability in surgical techniques and the evolving nature of medical guidelines, it is impractical and impossible for a medical device manufacturer to provide exhaustive instructions for every possible scenario. Instead, it is the responsibility of the medical professionals to apply their expertise and adhere to the latest guidelines and standards of care when using these devices. This ensures that the procedures are tailored to the individual need of the patient and the specific clinical context, thereby optimizing patient outcomes.

Furthermore, the implementation of controls for insertion depth, such as scales or markings, is also subject to the professional judgment of the surgeon, who must consider the unique anatomical and clinical circumstances of each case.

Implanting the bone implants

- The choice of surgical procedure depends on the patient's general condition, severity of the fracture, bone quality, closed or open soft tissue injuries, concomitant injuries, the patient's motivation and compliance, the expected functional load as well as surgeon’s preference.
- The placement of the implant is monitored and verified radiologically in accordance with the current state of the art.
- The Kirschner wire or Steinmann pin is inserted mechanically using a surgical drill. To do this, the wire is clamped into the appropriate holder (e.g., a three-jaw chuck). Contraindications are the same as those for osteosynthesis. The insertion depth is monitored radiologically using a mobile X-ray image intensifier (C-arm) (typically involving bicortical bone fixation).
- In some surgical procedures involving Steinmann pins, a Böhler traction bow is used.
- Bone wire is wrapped around the bone.

Removal of the bone implants

- Wire removal can be performed once the goal of the surgery has been achieved, i.e., once the fracture has healed. If the wires become loose, prompt removal is necessary; otherwise, the wires can pierce the skin from the inside, break, or migrate, thereby damaging tendons, nerves, and/or blood vessels. If left in the body for too long, the wires become difficult or impossible to remove.
- Given the wide variety of possible locations where an implant can be placed in a patient, it is impossible to provide exhaustive instructions for removing a specific implant. Common instruments used to remove implants include flat-nose pliers and the wire-holding forceps.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary Safety and Clinical Performance Report (SSCP; Basic UDI-DI 4049356TD-010GR) is available on the RUDOLF Medical website until the corresponding feature is implemented in the European Database on Medical Devices (EUDAMED): https://ifu.rudolf-med.com/150/.

MATERIAL STANDARD

- DIN EN ISO 5832-1 Implants for surgery - Metallic materials - Part 1: Wrought stainless steel

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 the Medical Device Regulation (EU) 2017/745 (MDR) with the ID of the notified body
	Keep dry
	Keep away from sunlight
MD	Medical Device