English EN

Kirschner Wire Instructions For Use

INTENDED USE

- The purpose of the products is the rapid and complete recovery of the damaged bone function. Osteosynthesis implants can not replace a broken bone, but temporarily take over the mechanical function by holding the fracture fragments in the anatomically correct position of the achieved reduction.

NOTES REGARDING THE OPERATION

- Of the utmost importance is the right choice of implant components. The appropriate implant type and size must be selected for the individual patient. The weight and degree of activity of the patient as well as the fracture to be treated should be considered. The use of the largest possible implant and correct positioning prevent bending, cracking, tear up and loosening of the implant. Also, the power transmission to the bone must be taken into account. In case of possible rotation or inclination of the implant after the application, the implant site must be additionally fixed until complete healing.
- Before starting treatment, make sure that the required instruments are available and suitable for combination with our implants. Different implant materials must not be combined. Fractures, deformations due to improper use or overuse of the implant must be avoided. Also sample components (if included) and additional implant sizes should be provided.
- To ensure complete traceability, the article and lot number of the implant used must be attached to the surgical report and documented in the implant card.

INDICATIONS

- The bone implants can never support the full load of the treated bone segment. The implants serve only for the healing promotion and do not represent substitute material for intact tissue and bone material. Therefore the physician must inform the patient about the load limits and prescribe a corresponding postoperative behavior. In general, the doctor must educate the patient about indications, contraindications, adverse reactions and postoperative treatment and record this information. After implantation, regular medical checks must be carried out.
    - Treatment of fractures alone or in combination with other methods of fixation (e.g., plaster casts, screwing, etc.)
    - Treatment of e.g. Finger, patella, olecranon fractures or fractures of the upper extremities in children.

CONTRAINDICATIONS

- For local bone tumors, the product may only be used under an individual examination and under the responsibility of the surgeon / user.
- In the case of systemic diseases and metabolic dysfunctions, the product may only be used under an individual examination and under the responsibility of the surgeon / user.
- Allergies to a material component of the implant; if such an allergy is suspected, appropriate tests must be carried out.
- If you have proven allergy to implant steel (such as the nickel component), do not use implants made from this material. In these cases, use titanium or titanium alloys.
- The products are not safe in the magnetic field (information according to DIN EN ISO 14630). The drill wires or artifacts can cause problems in the diagnosis.

POSSIBLE COMPLICATIONS

- The following complications have been observed and therefore require the special attention of the treating specialist:
    - Bend, break, loosen or loosen the implant.
    - In case of insufficient fusion of the fracture, a loss of anatomical position may occur.
    - Superficial and deep infections can occur.
    - The intervention and use of bone implants may lead to vascular diseases such as thrombophlebitis, pulmonary embolism, bruising, and non-vascular necrosis.
    - Allergies, Tissue u. Foreign body reactions near the implants may occur.
    - Fracture does not heal.
    - Bone deformation and refracture.
    - Displacement of the implant.
    - Cardiovascular dysfunction.

On the above mentioned complications should be noted to the patient.

INTENDED USER PROFILE

- Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. The physician's education, training and professional judgement are necessary to determine the most appropriate device and treatment option.
- Consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features must be read carefully.

WARNINGS

- Implants are NOT supplied STERILE.
- Implant has sharp cutting edges, careful handling!
- Implants must not be reused! Single use product.
- Explanted implants must be returned to the hospital for disposal.
- Patients with stainless steel implants should not come in contact with electromagnetic / magnetic fields.
- The components of the implant must be checked for cleanliness, dryness, freedom from damage and freedom from residues.
- The surgeon alone is responsible for the choice and use of the implant.

CAUTION

Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.

DISPOSAL

- After implementation / termination of the product life, deliver the implants to a professional disposal or recycling system.

Reprocessing Instructions

POINT-OF-USE AND CONTAINMENT

1) Before using the implant, the original packaging must be removed and a complete treatment (cleaning, sterilization) by qualified personnel carried out. The instructions for use of the sterilization equipment manufacturer must be observed.
2) The user is responsible for the sterility of the implants, implants are delivered non-sterile and are only precleaned!
3) Please avoid additional contamination of the implants during the application, otherwise a renewed cleaning and disinfection of the implants is necessary. In addition, observe the legal requirements of your country and the hygienic specifications of the practice or the hospital or clinic. This applies in particular to the various prion control / prevention guidelines.

CLEANING

4) For the cleaning / disinfection of the implants, a mechanical procedure (washer-disinfector) should be used. In accordance with the Robert Koch Institute (RKI) guidelines "Hygiene requirements for the reprocessing of medical devices", a manual procedure is not recommended due to its significantly lower efficacy. The wire mesh trays must not be overloaded so that the implants are well-rinsed and no rinsing shadows can form. The implants must be stored or stored according to their mechanical sensitivity so that damage is excluded. Only equipment meeting the general requirements for washer-disinfectors (EN ISO 15883) should be used.
5) Perform cleaning at 55 ° C ± 2 ° C for at least 5 minutes. For the automatic cleaning of our drill wires we recommend the alkaline cleaner Neodisher ® MediClean forte, or equivalent; 0.5% in the machine. When elevated levels of chloride are present in the water, pitting and stress corrosion cracking may occur at the implant. By using alkaline cleaners or the use of demineralized water such corrosion can be minimized.
6) In principle, the conditioner must check whether neutralization is required. If so, the rinsing of alkaline detergent residues is facilitated by the addition of an acid-based neutralizer. Even with the use of neutral cleaners is in unfavorable water quality, e.g. In case of high salt content, it is recommended to use a neutralizer to prevent the formation of deposits. It is recommended to perform neutralization with Neodisher® Z. If not, check if the neutralizer does not contain any residual levels of process chemicals in the final rinse water below the values specified by the manufacturer of the process chemicals and if the pH of the last rinse water is in the neutral range.

7) For the intermediate rinse, we recommend the following values:
   — Total hardness: < 3°dH (< 0,5 mmol CaO/l)
   — Evaporation residue: < 500 mg/l
   — Chlorid content: < 100 mg/l
   — pH-value: 5 – 8.
8) Perform thermal disinfection at 92 ° C ± 2 ° C for at least 5 min (A0 value> 3000).
   The use of demineralized water for final rinse results in a machine-free preparation to a stain-free preparation material. For the final rinse, the quality of the desalinated water should be 95% and specified according to relevant recommendations with a conductance of 15 µS / cm. Optimal, however, is a value below 5 µS / cm.
9) Sufficient drying must be ensured by the washer-disinfector or by other suitable means. Dry at 55 - 60 ° C for approx. 30 min. If residual moisture is still present, it can be dried in a drying oven at 60 ° C. However, the drying time depends on the treatment and the items to be washed. Implants should be packed in a suitable container or sterilization packaging prior to sterilization (EN868 part 1 - 10). The sterilization packaging depends on the sterilization procedure, the transport and the storage. The packaging has a considerable influence on the sterilization result. The packaging should be chosen so that the implants fit into the packaging. Use a sterilization indicator for the packaging and note the sterilization and expiry date on the packaging.

FUNCTIONAL TESTING, MAINTENANCE

- Before starting treatment, make sure that the required instruments are available and suitable for combination with our implants. Different implant materials must not be combined. Fractures, deformations due to improper use or overuse of the implant must be avoided. Also sample components (if included) and additional implant sizes should be provided.
- To ensure complete traceability, the article and lot number of the implant used must be attached to the surgical report and documented in the implant card.
- Implants are extremely sensitive to damage. Even small scratches or impact dents can cause internal stresses that significantly reduce the strength. An extremely careful treatment is therefore indicated.
    - Before unpacking, inspect the outer packaging for damage / transport damage and condensate.
    - Outer packaging and protective caps may only be removed immediately before use.
    - Check if the label matches the content.
    - Optical inspection of the implant for damage (discoloration, cracks, nicks, burr or other damage).
    - The manufacturer or supplier can not accept returned implants that are NOT in their undamaged original packaging. If the packaging is improperly opened, the manufacturer does not assume any warranty.

PACKAGING

- The products are packaged non-sterile
- The bone implants are marketed as "disposable products". The product shelf life is 3 years from the date of manufacture.

STERILIZATION

- STERILIZER: Steam autoclave with fractionated pre-vacuum:
- Temperature: 134 ° C, with a holding time of at least> 5 to a maximum of 20 minutes and subsequent drying.
- Sterilize all implants before use.
- Recommended sterilization method: Steam sterilization with fractionated vacuum.
- Recommended temperature: 134 °C.
- Recommended pressure: 3 bar.
- Holding time ≥ 5 min.
- For sterilization, the instructions of the device manufacturer for the recommended use must be strictly observed.
- **Preparation and sterilization according to DIN EN ISO 17664**

STORAGE

- The bone implants should be stored in a clean, dry environment and in there packaging or in a protective container with individual compartments. Protect the areas of the cutting edges with appropriate tubes and protective caps. Take special care that there are no chemicals in the immediate vicinity of the storage location. Storage of sterilized implants in a dry, clean and dust-free environment at moderate temperatures of 5 ° C to 40 ° C.

CONTACT

- **Notice to Patient and User**: Any serious incident that has occurred in relation to the medical devices should be reported to the manufacturer.

AVALIGN German Specialty Instruments
626 Cooper Court
Schaumburg, IL 60173; USA
Tel: +1 877 289 1096
product.questions@avalign.com

Label Glossary

Symbol	Title and Translations	Symbol	Title and Translations
	Manufacturer and Date of Manufacture		Consult Instructions for Use
	Lot Number / Batch Code		Caution
	Catalogue Number		Federal Law (USA) restricts this device to sale by or on the order of a physician