K-Wires and Steinmann Pins: Part No. OM 71-0XXX

**With the purchase of this implant, you will receive a high-quality product whose proper handling and use is described below. In order to minimize risks and unnecessary burdens for the user / patient, you must follow the instructions for use.**

**Usage:**

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.

**Possible complications:**

The following complications have been observed and therefore require the special attention of the treating specialist. The complications listed below should be communicated to the patient:
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 of the femoral neck.
Allergies, Tissue, or Foreign body reactions near the implants may occur.
Fracture does not heal.
Bone deformation and refracture.
Displacement of the implant.
Cardiovascular dysfunction.

**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.

**Indication:**

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. If there is insufficient knowledge to use our products, you must commission us with a user training in order to acquire the professional qualification to handle our products.

- 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.

**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.

**Check after receipt and before use:**

Implants are extremely sensitive to damage.

- 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 cannot accept returned implants that are NOT in their undamaged original packaging. If the packaging is improperly opened, the manufacturer does not assume any warranty.

**General handling:**

*Combination*

Material information is available upon request. Before beginning the treatment, make sure that the necessary instruments are available and suitable for combination with our implants.
Instrumentation for handling the implants:

Hand-Drill
Wire-Driver
Pin / Pin Extractor

**Notes and 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.

**Danger:**

When using small diameter partially threaded or fully threaded wires, they may break easily if used improperly. We cannot accept liability for this.

**Validation of cleaning:**

The cleaning procedure has been validated by a certified lab.

**Preparation for sterilization of the implants:**

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.
**The user is responsible for the sterility of the implants, implants are delivered non-sterile and are only pre-cleaned!**
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:**

For the cleaning / disinfection of the implants, a mechanical procedure (washer-disinfector) should be used. In accordance with the 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 RDGs meeting the general requirements for washer-disinfectors (RDG, part 1 of EN ISO 15883) should be used.
**Recommended procedure in the RDG:**
**Processing:**
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; 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.
**Neutralization:**
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.
**Intermediate rinsing:**
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.
**Thermal disinfection / final rinse:**
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.
**Drying:**
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.
**Function test, 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.

**Packaging:**
The products are packed non-sterile.
**Sterilization of the cleaned products under own responsibility of the user:**
For sterilization, only the following sterilization methods may be used; other sterilization methods are not allowed.
Steam sterilization
- Fractionated vacuum procedure[1, 2] (with sufficient product drying[3])
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)

[1] at least three vacuum steps
[2] The use of the less effective gravity displacement is only permitted if the fractionated vacuum procedure is not available. It requires significantly longer sterilization times and must be validated by the user for each specific product, device, procedure and parameter.
[3] The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.

- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

| Country | Fractionated vacuum procedure | Gravity displacement |
|---|---|---|
| Germany | at least 5 min[4] at 134 °C (273 °F) | not recommended[2] |
| USA | at least 4 min at 132 °C (270 °F), drying time at least 20 min[4] | not recommended[2] |
| France | at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min | not recommended[2] |
| other countries | at least 5 min[4] at 132 °C (270 °F) / 134 °C (273 °F) | not recommended[2] |

*Verification of the general suitability of the products for effective steam sterilization was provided by an independent,* governmentally *accredited and respected* (§ 15 (5) MPG) *test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.*
The flash sterilization procedure is generally not permitted.
Do not use dry head sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma 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.**
**Disposal:**
After implementation / termination of the product life, deliver the implants to a professional disposal or recycling system.
**Returns:**
Defective products must have undergone the entire reprocessing process prior to return. Acceptance of returns only if declared as "hygienically safe" (treated with disinfection procedure) or marked as "not decontaminated" and safely packed. For this purpose, a decontamination certificate is mandatory.
**Abuse and damage of implants:**
Personnel must have knowledge of the instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of the implants.
Training certificates must be kept for at least 10 years.

**Symbols used and their meaning:**

Product is delivered non-sterile.


Follow the instructions.


Attention, follow instructions.


For single use only.


Store dry.


Keep away from sunlight.


Do not use if the packaging is damaged.

Batch number.

Article- or order number.

Quantities.

European free market sign.


Manufacturer.


Manufacturing date

**Material Composition:**

[1] at least three vacuum steps
[2] The use of the less effective gravity displacement is only permitted if the fractionated vacuum procedure is not available. It requires significantly longer sterilization times and must be validated by the user for each specific product, device, procedure and parameter.
[3] The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.
[4] or 18 min (prion inactivation, not relevant for the USA)

| **Implant steel**<br>1.4441<br>DIN ISO 5832-1; ASTM F138<br>Tensile strength Rm: ≥ 1400 MPa | **Cobalt-Chromium-Alloy**<br>CoCr28Mo6<br>DIN ISO 5832-12; ASTM F1537<br>Alloy1<br>Tensile strength Rm: ≥ 1172 MPa | **Titanium-Alloy**<br>Ti 6-AI 4-V<br>DIN EN ISO 5832-3; ASTM F136<br>Tensile strength Rm: ≥ 860 MPa | **Nitinol**<br>NiTi#1<br>ASTM F2063<br>Tensile strength Rm: ≥ 1241 MPa |
|---|---|---|---|
| **chemische Zusammensetzung:** | **chemische Zusammensetzung:** | **chemische Zusammensetzung:** | **chemische Zusammensetzung:** |
| **C**<br>Carbon (Kohlenstoff) | **C**<br>Carbon (Kohlenstoff) | **N**<br>Nitrogen (Stickstoff) | **Ni**<br>Nickel (Nickel) |
| **Mn**<br>Manganese (Mangan) | **Cr**<br>Chromium (Chrom) | **C**<br>Carbon (Kohlenstoff) | **C**<br>Carbon (Kohlenstoff) |
| **P**<br>Phosphorous (Phosphor | **Mo**<br>Molybdenum (Molybdän) | **H**<br>Hydrogen (Wasserstoff) | **Co**<br>Cobalt (Kobalt) |
| **S**<br>Sulfur (Schwefel) | **Ni**<br>Nickel (Nickel) | **Fe**<br>Iron (Eisen) | **Cu**<br>Copper (Kupfer) |
| **Si**<br>Silicon (Silizium) | **Fe**<br>Iron (Eisen) | **O**<br>Oxygen (Sauerstoff) | **Cr**<br>Chromium (Chrom) |
| **Cr**<br>Chromium (Chrom) | **Si**<br>Silicon (Silizium) | **Al**<br>Aluminum (Aluminium) | **H**<br>Hydrogen (Wasserstoff) |
| **Ni**<br>Nickel (Nickel) | **Mn**<br>Manganese (Mangan) | **V**<br>Vanadium (Vanadium) | **Fe**<br>Iron (Eisen) |
| **Mo**<br>Molybdenum (Molybdän) | **N**<br>Nitrogen (Stickstoff) | **Ti**<br>Titanium (Titan) | **Nb**<br>Niobium (Niob) |
| **N**<br>Nitrogen (Stickstoff) | **Co**<br>Cobalt (Kobalt) | | **N**<br>Nitrogen (Stickstoff) |
| **Cu**<br>Copper (Kupfer) | | | **O**<br>Oxygen (Sauerstoff) |
| **Fe**<br>Iron (Eisen) | | | **Ti**<br>Titanium (Titan) |

Due to the size, labeling on the products themselves is not possible. For this reason, the labeling is carried out exclusively on the label or on the outer packaging, which must remain with the products until complete processing of all products of a lot. To ensure traceability, the specialist is obliged to include the identification, in particular the LOT number, in the implant card.

Revisions:

| REV. | SECTION | DESCRIPTION | DATE | AUTHORIZED BY |
|---|---|---|---|---|
| | All | Initial release to QMS | 4/8/2019 | Ron Dyches |
| A | All | Layout adjustments to reduce the number of pages | 6/16/2020 | Mardi Trone |
| B | Cleaning<br><br>Sterilization & footnotes<br><br>Addition of revision table | "For the cleaning…should be used"<br>"For sterilization…or plasma sterilization."<br>This table at the end of the document | 2/25/2021 | Mardi Trone |
| C | Possible complications<br><br><br>Indication<br>General handling<br><br>Danger<br><br>Validation of cleaning<br>Shelf life | Minor grammatical changes and note to mention complications to patient moved above the list<br>Removal of duplicate phrase<br>Updated to state material information is available upon request.<br>Updated verbiage to more clearly describe threaded wires<br>Reworded for clarity<br>This section removed as there is no shelf life | 10/11/2021 | Ron Dyches |