Please read and follow these instructions completely!

1 Scope

These instructions for use apply to the following medical devices supplied by MK medical GmbH & Co. KG listed below.

Item Number	Description	Specification	Design
Non-Sterile: **KBddIIIxxxx**	Kirschner Wires / Drill wires made of Implant Steel	Material: Stainless steel (implant grade), type 1.4441 (X2CrNiMo18-15-3) according to ISO 5832-1 / AISI 316L Chem. composition (in % by mass): C: max. 0.03 Si: max. 1.00 Mn: max. 2.00 Cr: 17.0-19.0 Ni: 13.0-15.0 Mo: 2.25-3.00 S: max. 0.010 P: max. 0.025 N: max. 0.1 Cu: max. 0.5 Fe: rest Lengths (l): 50-600mm Diameter (d): 0.6-3.0mm	Design: Trocar (T), round (R), flat (F), lancet (L), lancet with hole (LB), 3-edge (3), 4-edge (4). Special design: Partially threaded (TGx, x = thread length in mm), Fully threaded (VG), Trocar longitudinal knurl (LR), Special eyelet (OE), Drill point (B).
Non-Sterile: **TKBddIIIxxxx**	Kirschner Wires / Drill wires made of Titanium	Material: Titanium alloy, type 3.7165 (Ti6AI4V ELI) according to DIN EN ISO 5832-3 / ASTM F136 Chem. composition (in% by mass): Fe: max. 0.3 C: max. 0.08 N: max. 0.05 O: max. 0.2 H: max. 0.015 Al: 5.50-6.75 V: 3,50-4,50 Ti: rest Lengths (l): 50-600mm Diameter (d): 0.8-3.0mm	

2 System Description

The Kirschner wires described in these instructions for use offer the surgeon in orthopedics and trauma surgery the possibility of fixing bones precisely. They support the treatment and healing process of bone fractures (osteosynthesis, correction of degenerative diseases). Fracture treatments using Kirschner wires represent classical fixation procedures, the principles of which are described in the textbooks of the Arbeitsgemeinschaft für Osteosynthesefragen [1], [2]. Kirschner wires are suitable for fixation as well as for supporting the retention of reduced fractures by intramedullary splinting, interfragmentary larding or splinting (e.g., in conjunction with cerclage wires).

The information in these Instructions for Use must always be observed but is not sufficient on its own for safe and effective use of the products. The implants described in these Instructions for Use should only be used by trained surgeons who are familiar with the basic principles of osteosynthesis and have been instructed in the techniques for implantation and handling of the implants.

3 Intended Use

3.1 Intended Use

Kirschner wires from MK medical GmbH & Co. KG are used for closed reduction and fixation of a fracture by means of a rotating drill wire (Kirschner wire) as well as for operative fracture treatment by:

- percutaneous intramedullary splinting
- percutaneous "cribbing", i.e., fixation of a fracture by inserting a Kirschner wire, if possible with fixation of the wire in the opposite cortex.

3.2 Indication

The products are intended for use in osteosynthesis as well as for the correction of degenerative diseases, especially in the following indications:

- Supracondylar humerus fractures in children
- Lateral articular head fractures of the humerus
- Metacarpal fractures
- Phalanx fractures
- Lateral, medial as well as distal radius fractures
- Isolated radial neck fractures
- Scaphoid fractures

3.2.1 Intended User Group

The products are designed only for qualified physicians in the field of trauma surgery and medical professionals (surgical assistants) with sufficient knowledge regarding the identification, selection, provision and aseptic handling of implants and instruments during surgical procedures.

3.2.2 Patient Target Group (s)

The products are intended for use in patients with the clinical pictures / pathological conditions mentioned in the indication.
There are no specific restrictions about age or etiology. No other patient-specific restrictions or contraindications.

3.3 Expected Clinical Benefits

The goal of treatment using Kirschner wires is an anatomically correct, functionally unrestricted reduction of a bone fracture and a complete, unrestricted restoration of the range of motion.

3.4 Contraindication

3.4.1 Patient Contraindications

- Any concomitant diseases that may jeopardize / impair the fixation or the success of the intervention.
- Poor bone substance/structure, which endanger or impair the secure fixation of the implants
- Serious muscular, neurological or vascular diseases which endanger or impair the success of the intervention/surgery
- Allergic patients who are prone to allergic reactions due to the appropriate materials used for the implant
- Acute or chronic, local or systemic infections
- Nicotine consumption, which may jeopardize the success of the procedure / surgery due to delayed bone / wound healing.
- Mental conditions that make it impossible to understand and follow the doctor's instructions and/or participate in the rehabilitation program (e.g. alcohol or drug consumption, Parkinson's disease, Alzheimer's disease, etc.).

3.4.2 Product / Process Contraindications

- Due to an increased risk of complications (e.g. malpositioning), Kirschner wires should not be used for fixation of distal and medial clavicle fractures.

3.5 Risks from Intended Use

Phase	Risk	Possible Cause
During Treatment	Injury to surrounding tissue, nerves or vessels Puncture / injury by the implant during insertion / positioning	Non-compliance with the respective treatment principles
	Mechanical deformations or fractures of the implants	Excessive force application during implantation Selection of inadequately dimensioned implants for the respective procedure
After Treatment	Local irritations / infections	Use of incorrectly prepared implants Non-compliance with the principles of asepsis during implantation Allergic reactions of the patient caused by the materials used Potentially increased risk in case of fixation by means of free-lying technique (epicutaneous wire fixation), e.g. of metacarpal, phalanx or distal radius fractures.
	Implant loosening / migration with risk of loss of reduction	Non-compliance with the respective treatment principles - Inadequate reduction and fixation/positioning of the implants Insufficient postoperative immobilization Biomechanical overloading of the implants in-situ
	Superficial Skin Necrosis	Potentially increased risk with fixation using a countersunk technique (subcutaneous wire fixation).
	Postoperative pain, tissue or cartilage damage due to protrusion / protrusion of the Kirschner wire	Non-compliance with the respective treatment principles - Inadequate reduction and fixation/positioning of the implants Insufficient postoperative immobilization Potentially increased risk in the case of fixation using a countersunk technique (subcutaneous wire fixation)
	Mechanical deformations or fractures of the implants	Biomechanical overload of the implants in-situ
	Postoperative bleeding	Procedural risk

3.6 Side Effects

Product- and procedure-specific side effects may include angular deformities, decreased joint range of motion, and, in rare cases, pseudoarthroses or delayed healing.

3.7 General Warnings

Improper use of the implants described in these Instructions for Use may result in injury to bone, tissue, or organs, loss of reduction, re-fracture, pseudoarthrosis, delayed healing and local irritation or infection.

Kirschner wires from MK medical GmbH & Co. KG are intended exclusively for physicians specialized in the field of osteosynthesis who are familiar with the basic principles of fracture treatment, including diagnosis, preoperative planning, surgical procedure and postoperative care. Before use, the user must ensure that he/she has read and understood all instructions for use provided by MK medical GmbH & Co. KG, the user must ensure that he/she has read and understood all instructions for use, manuals and other information provided by MK medical GmbH & Co.

Kirschner wires from MK medical GmbH & Co. KG are intended for single use on one patient. Since the implant is subjected to strong mechanical stresses during insertion and use, multiple use is excluded.
Re-use of the implants can lead to functional failure and a lack of treatment success as well as serious injuries, up to irreversible, permanent impairments of the patient.

The following situations may decrease the likelihood of successful implant treatment:

- Alcohol or drug abuse
- Smoking
- Risk due to poorly controlled diabetes with fluctuating blood glucose levels
- Risk due to bone loss
- Risk due to material intolerance
- Risk due to polymorbidity

In patients with suspected hypersensitivity to the implant materials used or to one of the alloy components, an allergy test with corresponding material samples should be performed by the attending physician as part of the preliminary examinations.

The use of MK medical products in combination with products from other manufacturers is not recommended due to the mismatched designs, materials, mechanics and constructions. MK medical assumes no liability for any complications arising from the combination of components or the use of third-party medical products in combination. Unless otherwise described, the combined use of different implant metals is not recommended. The combined use of different metals can lead to galvanic corrosion and release of ions. This may cause inflammatory reactions, hypersensitivity reactions to metal, and/or long-term adverse systemic effects. In addition, the corrosion process may reduce the mechanical strength of the implant.

Note for Users and Patients:
Please report all serious incidents or near incidents that have occurred in connection with the product to MK medical GmbH & Co. KG using the contact details provided in these Instructions for Use and to the relevant competent authority in your country. For a list of relevant competent authorities, see: https://ec.europa.eu/health/md_sector/contact_en

3.8 Notes on MRI Compatibility

Kirschner wires from MK medical GmbH & Co. KG are made of non-ferromagnetic materials. Stainless steel alloys used are fully austenitic and thus, in principle, non-magnetic. Titanium alloys used are non-magnetic.

The products have not been evaluated for possible heating, migration or artifact formation in the MRI environment. Strong magnetic fields during MRI examinations can therefore lead to patient injury due to movement or heating of the implants as well as to impairment of the imaging.

4 Packaging and Storage

The implants of MK medical GmbH & Co. KG can be supplied in non-sterile form.

Non-sterile Delivery - one-time reprocessing (cleaning and sterilization) by the end user necessary! Please note information on suitable procedures in the following chapters

4.1 Non-Sterile Implants

Non-sterile implants are packaged individually, in units of 5 or 10 in PE bags and are identified by the following symbol on the primary packaging and outer packaging:

Implants supplied in a non-sterile state must be subjected to the one-time reprocessing procedure described below, consisting of machine reprocessing, disinfection, and sterilization (steam) before use. Use of the products in a non-sterilized state leads to a high risk of infection for the patient!

4.1.1 One-Time Reprocessing of Non-Sterile Implants

The manufacturer has ensured that the procedures specified below for the one-time reprocessing of implants supplied in non-sterile condition are effective and suitable for bringing the products into a ready-to-use condition. The reprocessor is responsible for ensuring that the reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results.
This normally requires routine checks of the validated reprocessing procedures. Likewise, any deviation from the procedures listed here (e.g., use of other process chemicals and deviation from the process parameters described) should be carefully evaluated by the reprocessor for effectiveness and possible adverse consequences.

Observe the legal regulations applicable in your country for the reprocessing of medical devices (e.g., www.rki.de).

For cleaning and disinfection, a mechanical process should be used whenever possible in a suitable washer-disinfector (WD) that meets the requirements according to the ISO 15883 series of standards. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available due to the significantly lower effectiveness and reproducibility and requires specific development and validation under the sole responsibility of the user.

4.1.2 Mechanical Cleaning Sequence

The procedure described below was validated using the WD type G 7835 CD (disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning and cleaning agent Neodisher Mediclean forte and neutralizer Neodisher Z (Dr. Weigert GmbH & Co. KG, Hamburg) from MK medical.

1. Pre-rinsing with cold water for 1 minute.
2. Cleaning with water 55°C ± 5°C and alkaline cleaning agent, "Neodisher Mediclean forte", 0.5%" for 5 minutes
3. Neutralizing with neutralizer "Neodisher Z" for 2 minutes
4. Rinsing with deionized water for at least 1 minute
5. Disinfecting 55°C ± 5°C for 5 minutes
6. Drying at 60°C ± 5°C for 30 minutes

4.1.3 Visual Inspection

After cleaning, the implants must be visually checked for cleanliness and integrity. Implants that are not clean must be cleaned again, and damaged implants must be sorted out and disposed of.

4.1.4 Packaging

The instruments must be packaged for sterilization in suitable sterilization packaging compatible with moist heat sterilization in accordance with EN ISO 11607-1. Care must be taken to ensure that the packaging has sufficient temperature resistance (min. 137°C) and is sufficiently dimensioned so that the seal is not under tension when the implant is wrapped. The validated sterilization procedure refers to double foil pouches.

4.1.5 Sterilization

The procedure described below was validated using autoclaves Tuttnauer type B 3870 (Tuttnauer, Breda, NL) from MK medical.

- 2 fractionated pre-vacuum phases
- Holding time: min. 5 minutes max. 7 minutes at 134°C
- Drying for at least 10 minutes

4.1.6 Storage

Reprocessed products must be stored clean and dry at room temperature, protected from recontamination, moisture and direct sunlight.

The conditions of the storage shall be:

Temperature	Min. 5°C	Max. 25°C
Humidity	Min. 25% rH	Max. 75% rH
Protect from humidity		
Protect from direct sunlight		

5 Application Instructions

5.1 Preoperative Phase

Before use, the implants must be inspected by the user for visible damage such as cracks, fractures, or damaged tips. Damaged implants must not be used.

The selection of the right implant is of enormous importance for the success of the treatment. Correct dimensioning with regard to implant size and shape increases the chances of success. The size and strength of the implant are limited by the nature of human bone and soft tissue. If a firm connection of the bones is to be established, the patient needs appropriate external assistance. Physical stress and strain on the fracture site must be limited to prevent delayed healing and/or late effects.

5.2 Intraoperative Phase

Application principles for the surgical treatment of fractures according to the publications of the Working Group on Osteosynthesis (AO) must always be observed.

Keep the implants in the operating area protected from contamination (e.g. by covering them with sterile cloth).

The implants should always be inserted with the greatest possible care and as little force as necessary for correct positioning.

The implants must be handled with the care required when handling medical devices. If it is necessary to shape the implant, excessive bending, bending against the original shape, notching or scratching should be avoided. These manipulations, combined with improper handling and use, can lead to defects on the surface and/or to a structural change in the material and thus lead to impairment and/or failure of the products.

5.3 Postoperative Phase

While the implant is in situ, the patient should be monitored and tested for infection at regular intervals.

The physician must inform the patient about the load limits of the implant and give instructions for postoperative behavior and gradual load build-up. Failure to do so may result in malpositioning, delayed bone healing, implant failure, infection, thrombophlebitis and/or wound hematoma.

Implants are designed for temporary use and should be removed after bone healing has occurred.

The final decision on when to remove the implant is the responsibility of the treating physician. It is recommended, if possible and applicable for the individual patient, to remove the fixation products after the healing process is complete. This is especially true for young and active patients. The risk of adverse effects such as secondary infections, allergies, material fatigue fractures, implant failure and/or impaired blood circulation increases with the duration of the implant in the body.

6 Warranty Statement

MK medical GmbH & Co. KG is responsible for ensuring that each individual product has been manufactured, inspected and packaged with the greatest possible care. MK medical has no influence and no control over the correct, proper, and professional application. MK medical can also not be held responsible for complications or the failure of an application. MK medical individual products and sets are compatible with each other. The user is responsible for ensuring the compatibility of the products with each other before use.
MK medical employees are not authorized to modify the aforementioned conditions or to extend liability or to enter into additional product-related obligations.

7 Disposal

The packaging of the products can be disposed of via the applicable disposal system for plastics and paper or cardboard packaging.
Explanted products must be disposed of as biohazardous waste in accordance with the applicable standard of the medical facility.

8 Labeling and Symbols Used

Symbol	Explanation	Symbol	Explanation
MD	Medical device in the sense of the Medical Devices Regulation VO (EU) 2017/745, Article 2,1.		Manufacturer as defined in the Medical Devices Regulation VO (EU) 2017/745, Article 2.30.
UDI	Unique Device Identifier (UDI)		Note: Do not reuse!
	Date of manufacture		Note: protect from moisture
LOT	LOT number		Note: protect from direct sunlight
REF	Item number		Note: storage conditions
	Observe the Instructions for Use		Note: NOT STERILE
	Caution: Observe warning notices!	CE 0483	CE mark with identification number of the Notified Body mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, Germany

9 Literature

[1.] Texhammar, Rigmor, und Christopher Colton. AO-Instrumente und-Implantate: technisches Handbuch. Springer-Verlag, 2013.

[2.] Buckley, Richard E., Christopher G. Moran, and Theerachai Apivatthakakul. AO Principles of Fracture Management: Vol. 1: Principles, Vol. 2: Specific Fractures. Thieme Medical Publishers, Incorporated, 2017.

9.1 Brief report on safety and clinical performance

A summary report on safety and clinical performance in accordance with Regulation (EU) 2017/745, Art. 32 can be viewed at the following web address https://ec.europa.eu/tools/eudamed via Basic UDI-DI **42514627xKB00000xxUM**.

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