Please read and follow these instructions completely!

1 Scope

These instructions for use apply to the following medical products supplied by newbox medical GmbH.

Product group	Basis-UDI	Product list
TD02_K-Wires, sterile	4059216KW1C6	TD02_1.1_K-Wires_Product List, sterile
TD02_K-Wires, non-sterile	4059216KW0C4	TD02_1.1_K-Wires_Product List, non-sterile

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 cribbing 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 Purpose

Kirschner wires of newbox medical GmbH
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 insertion of 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 and for the correction of degenerative diseases, particularly 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 / user group

The products are designed only for qualified physicians in the field of trauma surgery as well as medical professionals (surgical assistants) with sufficient knowledge regarding the identification, selection, deployment 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 age or etiology restrictions. No other patient-specific restrictions or contraindications

3.3 Expected clinical benefit

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 conditions that may jeopardize / interfere with fixation or the success of the procedure.
- Poor bone substance/structure, which jeopardizes or impairs the secure fixation of the implants
- Serious muscular, neurological, or vascular diseases that jeopardize or interfere with the success of the procedure/surgery
- Allergy patients who are prone to allergic reactions due to the corresponding materials used for the implant.
- Acute or chronic, local or systemic infections
- 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 use, Parkinson's disease, Alzheimer's disease, etc.).

3.4.2 Product / process side 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 caused by the implant during insertion / positioning	Non-compliance with the respective treatment principles

Phase	Risk	Possible cause
	Mechanical deformations or fractures of the implants	Excessive force during implantation Selection of implants that are inadequately dimensioned for the respective procedure
After the Treatment	local irritations / irritations as well as infections	Application of incorrectly prepared implants Non-compliance with principles of asepsis during implantation. Allergic reactions of the patient caused by the materials used Potentially increased risk with fixation using exposed 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 No sufficient postoperative immobilization Biomechanical overload 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 No sufficient postoperative immobilization Potentially increased risk with fixation using a countersunk technique (subcutaneous wire fixation).
	Mechanical deformations or fractures of the implants	Biomechanical overload of the implants in-situ
	Post-bleeding	Process-related risk

3.6 Side effects

Product- and procedure-specific side effects may include angular deformities, decreased joint range of motion, and, in rare cases, pseudoarthrosis 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 newbox medical Gm 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 acquired and understood all instructions for use, manuals and other information accompanying the product provided by newbox medical GmbH

Kirschner wires from newbox medical GmbH 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.
Reuse of the implants can lead to functional failure and a lack of treatment success as well as serious injury, even non-reversible, permanent impairment of the patient.

The following situations may reduce the probability of success of the implant treatment:

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

In patients with suspected hypersensitivity to the implant materials used or to one of the alloy components, allergy testing with appropriate material samples should be performed by the treating physician as part of the preliminary examinations

The use of newbox medical products in combination with products from other manufacturers is not recommended due to the mismatched designs, materials, mechanics and constructions. newbox medical assumes no liability for any complications arising from combining components or using 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 may 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 newbox medical GmbH using the contact details provided in these instructions for use and to the relevant competent authority in your country. For a list of competent authorities, see: https://ec.europa.eu/health/md_sector/contact_en

3.8 Notes on MRI compatibility

Kirschner wires from newbox medical GmbH 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 may therefore lead to patient injury due to movement or heating of the implants as well as to impairment of the imaging.

4 Packing and storage

newbox medical GmbH implants can be supplied in both sterile and non-sterile form.

To avoid confusion between sterile and non-sterile implants, pay attention to the following symbols on the product labeling in addition to the different packaging configuration:



Sterile delivery - no sterilization required by the end user



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 Sterile implants

Sterile implants have been sterilized by gamma irradiation and are identified by the following symbol on the primary packaging and outer packaging:



The primary packaging consists of a double sterile package in which the inner pouch represents the sterile barrier in each case, whose protective effect against the medical device against microbial contamination has been validated by the manufacturer over the specified shelf life.

Implants marked with the symbol STERILE R are supplied in a ready-to-use condition. Do not carry out any reprocessing and/or sterilization of the products! newbox medical GmbH accepts no liability for implants that have been sterilized by the user.

The implants must be stored in their intact sealed original packaging in a dry place at room temperature.
Only remove the products from the sterile packaging immediately before use.

Always check the expiration date before using the product. The implant must not be used after the expiry date has passed

Always check the integrity of the sterile packaging before using the product.
Do not use the implants in case of:

- Damaged sterile packaging, in particular damage to or irregularities in the sealing seam
- Moisture inside the packaging (e.g. damp spots on the underside or condensation inside the packaging.

4.2 Non-sterile implants

Non-sterile implants are packed individually, in units of 5 or 10 in PE bags and are marked 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!

4.2.1 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 actually 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 as well as deviation from the described process parameters) 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.

4.2.2 Sequence mechanical cleaning

The procedure described below was validated using the WD type G 7835 CD (thermal 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 newbox medical GmbH

1. Pre-rinse with cold water for 1 minute
2. Cleaning with water 55°C ± 5°C and alkaline cleaner "Neodisher Mediclean forte, 0.5%" for 5 minutes
3. Neutralize with neutralizer "Neodiher Z" for 2 minutes
4. Rinse with deionized water for at least 1 minute
5. Thermal disinfection 55°C for 5 minutes
6. Drying at 60°C ± 5°C for 30 minutes

Final GLP-Report 1403.0639 Automatic Reprocessing Validation

4.2.3 Visual inspection

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

4.2.4 Packing

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.

4.2.5 Sterilization

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

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

Final GLP Report 1403.1209 Sterility validation

4.2.6 Storage

Storage of non-sterile products must be clean and dry at room temperature, protected from recontamination, moisture and direct sunlight.

The sterile products must be stored in accordance with the instructions on the label.
The specifications for the storage conditions here in detail:

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

In the case of sterile products, the shelf life of the sterile goods (guarantee of sterility with proper handling and storage) is limited. The expiration date marked by the hourglass (see primary or secondary label) must be observed. Expired sterile products may no longer be used as sterile products.

5 Application instructions

5.1 Preoperative phase

Before use, the implants must be inspected by the user for visible damage such as cracks, fractures, 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 in terms of 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 adequate 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 Arbeitskreis für Osteosynthesefragen (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 shaping of the implant is necessary, 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 a structural change in the material, resulting in 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.

The 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 fully completed. 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 Declaration of warranty

newbox medical GmbH is responsible for ensuring that each individual product has been manufactured, inspected and packaged with the greatest possible care. newbox medical has no influence or control over the correct proper and professional application, newbox medical can also not be held responsible for complications or the failure of an application. newbox 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.
newbox medical employees are not authorized to modify the foregoing terms or to extend liability or to incur additional product-related obligations.

7 Disposal

The packaging of the products (sterile and non-sterile) can be disposed of via the applicable disposal system for plastics and paper or cardboard packaging.
Explanted devices must be disposed of as Biohazardous Waste via the applicable medical facility standard.

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)	YYYY-MM	Expiration date
	Date of manufacture		Note: do not reuse!
LOT	LOT number		Note: Do not resterilize!
REF	Item number		Note: protect from moisture
	Observe operating instructions		Note: protect from direct sunlight
	Attention: Observe warning notices!		Note: do not use if sterile packaging is damaged
NON STERILE	Note: NOT STERILE		Note: Storage conditions
STERILE R	Note: Sterilized by irradiation	CE 1304	CE mark with identification number of the Notified Body SIQ Ljubljana Mašera - Spasićeva ulica 10 1000 LJUBLJANA Slovenia
Rx Only	This medical device may only be used by qualified healthcare personnel or under their instruction.	IFU indicator	The instructions for use are available in electronic form: www.newbox-medical.com/ifu A printed version can be provided upon request.

9 Literature

[1.] Texhammar, Rigmor, and Christopher Colton. AO instruments and implants: technical manual. 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 Safety and clinical performance summary report

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

10. Materials

Materials	Characterization	Kind of body contact
Medical grade stainless steel 1.4441 (X2CrNiMo 18-15-3	DIN EN ISO 5832-1 ASTM F138	Direct contact
Titanium 3.7165 (Ti6Al4V (ELI)	DIN EN ISO 5832-3 ASTM F136	Direct contact

newbox medical GmbH
Euler Street 14-16
48155 Münster
Telefon: +49(0) 251 – 97 824 29-0
Telefax: +49(0) 251 – 97 824 29-9
E-Mail: service@newbox-medical.com


eIFU indicator