Instructions For Use

Please read these instructions in full and observe them.

1. Intended use – important information for the user

These instructions for use contain general instructions on the application and use of osteosynthesis implants from Dimeda Instrumente GmbH.
Purchasing this implant provides you with a high quality product whose appropriate and correct handling are described below.
To minimise risks and unnecessary strain on the patient, please carefully read and save these instructions for use.
⚠ The products are non-sterile disposable medical devices (single-use products ⊗). Before use, the implants must be reprocessed in accordance with the specifications defined in these IFU.

Item name: Orthopaedic implants incl. accessories:
- Drill wires, Steinmann pins,
- Intramedullary pins
- K-wires
- Bone wires (cerclage)

Dimensions/specifications: See table below

Item number	Item name	UMDNS code	Dimensions
33.xxx.xx	K-wires / drill wires made of implant steel	16-104	L=50-600mm D=0.6-3.0 mm
33.xxx.xx	Steinmann pins made of implant steel	16-078	L=50-600mm D=3.2-6.0mm
33.xxx.xx	Bone soft wire (cerclage) made of implant steel	16-104	L=10m D=0.2-2.0mm

Material:

Material	Material specification	Standard
Implant steel 1.4441	X2CrNiMo 18-15-3	DIN ISO 5832-1

Before using an Dimeda implant, the user must carefully read the following instructions for use and comply with its recommendations, warnings and instructions.
Dimeda cannot be held liable for complications arising due to the use of implants/instruments outside of the control of Dimeda, including but not limited to product selection and deviations from use/handling and surgical technique.

⚠ The implants are **not** intended for use on the central nervous/circulatory system and must not be used for this purpose.

2. Product description

Orthopaedic implants offer orthopaedic and trauma surgeons a means for fixing bones precisely. They play a supportive role in the treatment and healing of bone fractures (osteosynthesis and correction of degenerative diseases). However, implants are not suitable for replacing normal body structures or bearing the whole body weight.

3. Intended purpose

- K-wires (drill wires)
  intended for use in the closed reduction and fixation of fractures by means of a rotating drill wire (K-wire). This includes surgical fracture treatment by means of percutaneous intramedullary splints (e.g., at the metacarpals) or percutaneous “pinning”, fracture fixation by K-wire insertion, if possible with fixation of the wire in the contralateral cortical bone.
- Steinmann pins
  intended for use in the extension treatment of fractures. Extension treatment is based on applying continuous longitudinal traction to the injured limb. Depending on the fracture to be treated, a drill wire must be applied transversely through the bone, and longitudinal traction is applied with the aid of a metal clamp and a variable weight.
- Bone wire (cerclage wire)
  intended for fracture care by means of simple cerclage wiring as stand-alone treatment. The bone is encircled by the soft wire, and tension is applied by twisting.
- Intramedullary pins
  intended for treating shaft fractures and some metaphyseal and epiphyseal fractures.

4. Implant selection

The following factors must be considered in fracture treatment:

Selection of the correct implant:

Choosing the proper implant is extremely important for successful treatment. The potential for success is increased by selecting the proper implant size and shape. The characteristics of human bone and soft tissue pose restrictions on the size and strength of implants. If a strong bone union is to be achieved, the patient requires adequate external assistance. Physical strain and load on the fracture site must be limited to prevent delayed healing and/or late sequelae.

Patient-related factors

a) Weight:
Patient overweight or obesity can adversely affect the implant and its stability. The load limits must be considered individually depending on the implant site and purpose.

b) Occupation or activities:
Occupational activities pose a risk to the healing process if they are associated with the application of considerable force and hence physical loads on the body. In that case, immobilisation is necessary to ensure healing.

c) Senility, mental illness or alcoholism:
There is a risk of affected patients ignoring certain necessary limitations and precautions, leading to the failure of the product or other complications.

d) Degenerative diseases and nicotine use:
In some cases, degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant. In that case, the products serve only as a means of delaying or temporarily alleviating the disease.

e) Sensitivity to foreign bodies:
Where sensitivity or allergy to the materials used in the implant is suspected, appropriate tests must be conducted prior to implant selection and placement.

5. Indications

Fixation of bones and bone fragments following successful reduction.

6. Contraindications

- All concomitant diseases that may pose a risk to fixation or the success of surgery or negatively affect them, such as obesity, impairment of the circulation, etc.
- Poor bone quality or quantity that poses a risk for or adversely affects the secure fixation of implants
- Severe muscular, neurological or vascular disease that poses a risk for or adversely affects the success of the procedure/surgery
- Allergy patients who are susceptible to developing reactions when coming into contact with materials used in the implant
- Acute or chronic, local or systematic infections
- Nicotine use that may pose a risk for the success of the procedure/surgery due to delayed bone/wound healing
- Mental conditions that make it impossible to understand and follow physician instructions and/or to participate in the rehabilitation program (e.g., alcohol or drug use, Parkinson's disease, Alzheimer's disease, etc.)

7. Potential adverse effects

The adverse effects listed below have been described in the literature:

- Loosening of implants
- Wound infection (skin and deep wound infection)
- Vascular complications
- Nonunions
- Nerve damage
- Inflammations
- Metal allergies

8. Correct handling

Implants must be treated with the care required when handling medical devices. If the shape of the implant has to be altered, it should not be bent excessively, bent backward, notched or scratched. These manipulations, in combination with improper handling and application, may lead to surface defects and/or structural changes in the material and to product damage and/or failure.

9. Postoperative care:

Doctors must inform their patients about the load restrictions of the implant and give instructions on postoperative behaviour and on gradually increasing physical loads. Failure to do so can generate malalignment, delayed bone healing, implant failure, infection, thrombophlebitis and/or wound haematoma.
The doctor takes the final decision on when to remove the implant. If possible and appropriate for the individual patient, we recommend removing fixation products after healing is complete. This particularly applies to young and active patients. The risk of negative effects, such as secondary infection, allergies, material fatigue fractures, implant failure and/or impaired blood circulation, increases with the length of time the implant remains in the body.

10. Compatibility:

Dimeda does not recommend the combination of Dimeda products with those of other manufacturers since the designs, materials, mechanics and construction are not mutually harmonised. Dimeda assumes no liability for any complications arising from combining components or from using third-party medical devices in combination.
Unless described otherwise, mixing different implant metals is not recommended. Mixing of metals may lead to galvanic corrosion and the release of ions. This may cause inflammatory response, metal sensitivity reactions and/or long-term adverse systemic effects. In addition, the corrosion process can reduce the mechanical strength of the implant.

⚠ ***Warning:***

- The implants are intended for single use. They must not be reused after being used once. Dimeda assumes no liability in case of non-compliance.
- Implants that have come into contact with blood, soft tissue, bone or body fluids must not be reused and must be disposed of following the disposal guidelines for contaminated products. Contamination residues on the implants may lead to patient or user injuries or infections.
- Before use, the user must check the implants for visible damage such as cracks, fractures or damaged tips. Damaged implants must not be placed.
- The products must be handled exclusively by trained medical staff. They must be used and implanted exclusively by appropriately trained doctors.
- Incorrectly selected, positioned or sized implants or incorrect fixation may lead to unusual stress that may negatively affect the life of the implants.
- The implants must be used exclusively for the intended indication. These implants must not be used for other indications (off-label use).

⚠ ***Precautions:***

- The patient should be regularly monitored and tested for infection for as long as the implant remains in the body.
- These implants have been developed for temporary use and should be removed after complete healing of the fracture.
- The implants must not be machined or modified.
- Unless the implant is labelled as “MR Safe” or “MR Conditional”, there are hazards associated with the use of Dimeda products in an MRI environment. This includes but is not limited to:
    - Heating and/or migration of the implant

- Artefacts created by the implant

Dimeda implants have not been tested for MRI compatibility.

11. Single-use products

Products intended for single use must not be reused.
The reuse or clinical reprocessing of single-use products may compromise the structural integrity of the device and lead to device failure, causing patient injury, illness or death. Furthermore, the reuse or clinical reprocessing of single-use devices increases the risk of contamination, e.g., due to the transmission of pathogens from one patient to another. This can also lead to patient injury, illness or death.
Dimeda advises against the clinical reprocessing of contaminated implants. Dimeda devices contaminated by blood, tissue and/or body fluids or substances must not be reused and must be disposed of in accordance with hospital guidelines and protocol. Even if components appear externally intact after use, minor defects and invisible material damage may cause material fatigue.

12. Device reprocessing

Dimeda products are supplied in non-sterile condition and must be cleaned, disinfected and steam sterilised prior to surgical use.
Before reprocessing, the implants must be removed from the original packaging; the products are not intended to be sterilised in their original packaging.

Dimeda recommends machine reprocessing with a standard cleaning program using a washer-disinfector in accordance with ISO 15883-2.
Manual reprocessing methods are unsuitable due to the implant design (threads, holes, drill tips, etc.) and have therefore not been validated.

13. Validated machine reprocessing methods

Validated machine reprocessing methods include:

a) Machine cleaning, disinfection and drying in the washer-disinfector
b) Visual check
c) Packaging
d) Validated sterilisation method

a) Machine cleaning, disinfection and drying in the washer-disinfector

The validated cleaning and disinfection method refers to the Miele standard program “DES-VAR-TD” in the Miele G7835 CD washer-disinfector.

The specifications of the washer-disinfector manufacturer regarding appropriate and professional operation and loading as well as maintenance of the washer-disinfector must be strictly observed.

Procedure:

- Prerinsing with cold water for 1 minute
- Cleaning using water and the alkaline cleaner “Neodisher Mediclean forte, 0.5%” for 5 minutes at 55°C ± 5°C

- Neutralisation with the “Neodisher Z” neutraliser for 2 minutes
- Rinsing with deionised water for at least 1 minute
- Thermal disinfection at 55°C for 5 minutes
- Drying at 60°C ± 5°C for 30 minutes

b) Visual inspection

After cleaning, the implants must be visually inspected for cleanliness and damage. Implants that are not clean must be cleaned again, and damaged implants must be separated out and discarded.

c) Packaging

The instruments must be packaged for sterilisation in accordance with 11607-1. The validated sterilisation method applies to double foil bags.

d) Validated sterilisation method

The validated sterilisation method applies to the autoclave Tuttnauer Type B 3870 EHS.

Sterilisation:

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

The unit manufacturer’s operating instructions as well as instructions for use and maintenance must be strictly followed.

14. Symbols for labelling

Symbol	Explanation	Symbol	Explanation
	Observe instructions for use		Manufacturer
	For single use only		Batch name
	Attention!		Product is supplied non-sterile
	Manufacturing date		Protect from heat and direct sunlight

15. Storage

Must be stored at room temperature in a clean and dry location and protected from humidity and direct sunlight.

16. Guarantee policy

Dimeda Instrumente GmbH is responsible for each individual product being produced, inspected and packaged with the utmost care. Since ***Dimeda*** has no influence or control over correct and professional application, ***Dimeda*** cannot be held responsible for complications or the failure of an application. ***Dimeda*** sets and individual products are mutually compatible. Users are responsible for verifying the mutual compatibility of the products before use.
Dimeda employees are not authorised to change the above conditions or extend liability or enter into additional product-related commitments.

17. Bibliography

"Hygiene requirements for the reprocessing of medical devices", RKI (Robert Koch Institute)

For additional information, please contact:

Dimeda Instrumente GmbH
Gänsäcker 54 + 58
78532 Tuttlingen
Germany
info@dimeda.de
Tel.: +49 7462 94 61 – 13
Fax: +49 7462 94 61 – 33
www.dimeda.de

Notified body:
CE 0123
TÜV-Süd Product Service GmbH
Ridlerstraße 65
80339 München, Germany
meineanfrage@tuev-sued.de
+49 89 50084747
www.tuev-sued.de

Last revised: April 2019
Instructions for use for orthopaedic implants (Revision 12)