Instructions for use and sterilisation instructions

Orthopaedic Implants

(drill wires)

dimeda®
SURGICAL INSTRUMENTS

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1. Intended use – important information for the surgeon

General instructions on the use of orthopaedic and osteosynthesis implants and instruments from DIMEDA Instrumente GmbH (hereinafter referred to as DIMEDA).

Purchasing this implant provides you with a high quality product whose proper handling and use are described below.

To minimise risks and unnecessary strain on the patient, please read carefully and save these instructions for use.

The products are disposable medical devices (single-use products).

The products are single-use products ( )

Read these instructions in full and observe them

Item name: Orthopaedic implants incl. accessories drill wires, Kirschner Wire, fixation wires, Steinmann pins, intramedullary pins, K-wires, bone wires and cerclage wires

Dimensions/specifications: See table

Our drill wire tips are available in the following models and with the following points: angled trocar, lancet, round, flat, knurled, eyelet, drill tips, bayonet, with olive, with thread

Item no.	Item name	UMDNS code	Dimensions	Material
33.xxx.xx	K-wires/drill wires	16 – 104	L = 50 – 600 mm Ø 0,7 – 3,0 mm	Ti6Al4V (ELI) 3.7165 1.4441
33.xxx.xx	Steinmann pins	16 – 078	L = 50 – 600 mm Ø 3,2 – 5,0 mm	Ti6Al4V (ELI) 3.7165 1.4441
33.xxx.xx	Bone wire (cerclage)	16 – 104	L = 10 m Ø 0,2 – 2,0 mm	Ti6Al4V (ELI) 3.7165 1.4441

The item is identified by a label on the outer packaging; the product itself is marked by etching or laser if the product size permits.

Before using an DIMEDA implant or instrument, the surgeon (user) must carefully read the following instructions for use and the recommendations, warnings, and instructions. Please also note the additionally available product-specific information (e.g., product literature, brochures and surgical instructions). They must be carefully read before use as well, and the recommendations, warnings and instructions must be followed. DIMEDA cannot be held liable for complications arising due to the use of the implants/ instruments that are outside of the control of DIMEDA, including but not limited to product selection and deviations from use/handling and surgical technique.

2. Product description

Surgical/orthopaedic implants offer orthopaedic and trauma surgeons a means for fixing bones precisely. They also play a general supportive role in treatment, the healing of bone fractures and reconstructive surgery (osteosynthesis and correction of degenerative diseases). However, implants are not suitable for replacing normal body structures or bearing the body`s weight (see product-specific instructions).

3. Implant selection

The following factors must be considered in fracture treatment:

1. Selection of the correct implant

Choosing the proper implant is extremely important. 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. No partially weight-bearing or non-weight-bearing product can be expected to withstand the full, unsupported weight of the body. If a strong bone union is to be achieved, the patient requires adequate external assistance. Likewise, the patient must restrict physical activities that could place stress upon the implant or prevent immobilisation of the fracture site and hence delay healing.

2. Patient-related factors

a) Weight
Overweight or obese patients can place so much stress on the product that it will fail. This may even reverse the effects of the procedure.

b) Occupation or activities
Occupational activities pose a risk if they are associated with the application of considerable force and hence physical loads on the body. They can lead to product failure and therefore potentially undo the actual achievements of surgery.

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) Certain 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 selecting or implanting the material.

4. Indications

The indications are evident from the product used, the respective surgical instructions and/or the product brochure.

5. Contraindications

- All concomitant diseases that may pose a risk for the success of surgery or negatively affect it
- Poor bone substance or structure 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 anaphylactic shock or soft tissue 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
- Additional product-specific contraindications are found in the respective surgical instructions and/or product brochures

6. Correct handling

Correct handling of the implant is extremely important. 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 use, may lead to surface defects and/or structural changes in the material and ultimately to product failure.

7. Required postoperative care

Doctors should 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.

8. Compatibility

DIMEDA guarantees the compatibility of its original implants and/or instruments. The product-specific applications as described by DIMEDA must be followed. DIMEDA does not recommend the combination of DIMEDA products with those of other manufacturers since their designs, materials, mechanics and construction are not harmonised. DIMEDA assumes no liability for any complications arising from mixing components or from using third-party instruments.

Unless stated 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 product is intended for single use. It must not be reused
- Implants that have come into contact with blood, soft tissue, bone or body fluids must not be reused and must be disposed of by hospital staff following the disposal guidelines for contaminated products. Contamination residues on the implants may lead to patient or user injuries or infections.
- Previously implanted implants must not be reused due to the very high risk of material fatigue fracture and infection. DIMEDA assumes no liability in case of non-compliance
- Implants or instruments must not be used if damage has been identified during use or implantation
- DIMEDA implants and containers must be used exclusively since they ensure the safety of proper and secure implantation.
- 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 tested for infection so 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 (see above)
- The implants must not and do not need to be machined or modified
- Unless the implant is labelled as “MR Safe” or “MR Conditional”, there are several hazards associated with the use of DIMEDA products in combination with MRI. 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. For further information, please refer to the corresponding surgical instructions or product brochures.

9. Miscellaneous information / Creutzfeldt-Jakob disease

In patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or potential related infections, the applicable national regulations regarding instrument reprocessing apply.

10. 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

11. Single-use products

Products intended for single use must not be reused (see product-specific instructions for use and explanation of symbols).

The reuse or clinical reprocessing (e.g., cleaning and resterilisation) of single-use products may compromise the structural integrity of the device and/or 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 could also result in patient or user 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 should not be reused under any circumstances 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. Sterile implants

DIMEDA products supplied in sterile condition are labelled “STERILE” (see interpretation of symbols). The products must be removed from their packaging in an aseptic manner. If the package seal is damaged or if the packaging is improperly opened, the manufacturer does not guarantee the sterility of the products and assumes no liability.

13. Non-sterile implants

DIMEDA products supplied in non-sterile condition must be cleaned and steam-sterilised prior to surgical use. Before cleaning, the original packaging must be completely removed. Clean products before the first and every other use and before returning them for maintenance and repair. Before steam-sterilisation, place the products into a validated packaging system (sterilisation wrap or sterilisation container).

The first and most important step in decontaminating all reusable instruments is thorough (manual and/or mechanical) cleaning and rinsing. Thorough cleaning is a complex process whose success depends on various interrelated factors: Water quality, quantity and type of cleaning agent, cleaning method (manual, ultrasonic bath, washer-disinfector), sufficient rinsing and drying, proper product preparation, time, temperature and thoroughness of the individual responsible for cleaning.

Residues, organic matter and/or a large number of microorganisms may reduce the effectiveness of the sterilisation process.

DIMEDA recommends a cleaning agent with pH 7-9.5. Depending on the specific cleaning agent, those with a higher pH may attack the surfaces of aluminium, titanium, their alloys, synthetics or composites. Above pH 11, the surface of stainless steel can be adversely affected as well.

14. Mechanical cleaning

1. General information

We recommend the following cleaning/sterilisation methods (alternatively RKI procedures).

For thermostable medical devices, mechanical reprocessing with thermal disinfection followed by steam-sterilisation is preferable to other methods.

The reprocessing of medical devices typically involves the following:

- Preparation (pre-treatment, collection, pre-cleaning and disassembly if necessary)
- Cleaning, disinfection, rinsing, drying if applicable
- Visual inspection for cleanliness and immaculate condition of the material
- Care and maintenance if applicable
- Functional testing
- Labelling
- Packaging if applicable
- Sterilisation, release and packaging

2. Preparation measures (pre-treatment, collection, pre-cleaning and disassembly if applicable)

The first steps for successful reprocessing are taken at the site of use. Instruments must be properly disposed of after use. Instrument trays must not be overfilled.

Disposal containers should be kept closed to prevent drying out.Wherever possible, dry disposal until reprocessing should be preferred.Long intervals (over 5 hours) until reprocessing should be avoided.Major soiling must be removed under running water before placement into the washer-disinfector (WD).

When using wet disposal, it is advisable to immerse the instruments in a combined detergent and disinfectant that has no protein-fixing effect. (Manufacturer information must be followed.)

Dried-on residues are particularly problematic in instruments because contaminant residues are difficult to remove in small lumina and may lead to joint malfunction.

Therefore, such instruments must be reprocessed immediately after use.

- Major soiling should be removed at the site of use
- Set down jointed or hinged instruments in an open position
- Instruments consisting of multiple parts must be disassembled
- Instrument disposal must prevent the access of unauthorised third parties as well as reuse
- Instruments with cavities (cannulas, drill sleeves, etc.) must be flushed with water at the site of use
- Microinstruments must be placed on a separate tray

3. Pre-cleaning

After each use, all blood and other residues must be removed from instruments using a cleaning agent. For this purpose, use only soft-bristled brushes and sponges. Jaws and lumina, for instance, and areas where soiling and residues can easily collect must be cleaned with particular care.

Cavities must be thoroughly flushed and pre-cleaned using a water jet pistol (or similar).

The solutions used in manual cleaning must be mixed in accordance with manufacturer instructions (concentration and exposure time).

Pre-cleaning in an ultrasonic bath facilitates the removal of contaminants.

Manual cleaning method for implants

- Prepare a clean, freshly-prepared cleaning solution consisting of warm, demineralised water (DI/PURW) and cleaning agents
- Gently manually clean the implants in this solution
- Thoroughly rinse the implants with DI/PURW water
- Dry the implants with a clean, soft, lint-free cloth and/or clean compressed air

ATTENTION: Delicate instruments such as optics or motor systems must not be cleaned in an ultrasonic bath. (Follow instrument and manufacturer instructions).

4. Mechanical reprocessing in washer-disinfectors (WD)

Only WDs that meet the general requirements for washer-disinfectors should be used (WD, Part 1 of EN ISO 15883).

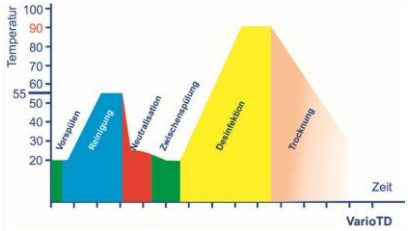
In mechanical reprocessing, several points must be particularly considered:

- Effective mechanical cleaning requires that trays, inserts, holders, etc., are properly loaded to ensure proper rinsing. Jointed instruments must be placed in an open position
- To ensure that fluids can easily flow around the instruments, trays must not be overloaded
- When placing large-surface instruments on the tray, ensure that they do not negatively affect the cleaning of other instruments due to “dead zones”
- Instruments with cavities must be fully flushed on the inside as well. For this purpose, inserts with flushing devices that are especially designed for the respective instruments must be used
- Depending on their mechanical sensitivity, instruments must be placed and stored in such a way as to prevent damage
- The cleaned items must be removed from the machine immediately after the program is finished since leaving them in the closed machine may cause corrosion due to residual moisture

To achieve optimal cleaning results, process parameters such as the dosing quantity and temperature must be set according to the instructions of the cleaning agent manufacturer.

After cleaning, the instruments must be visually checked for cleanliness. Instruments that are not clean must be recleaned (perform manual pre-cleaning again if necessary).

We recommend the Miele “Vario TD” cleaning and disinfection program.



Pre-rinsing

Cold water without additive to remove the coarse dirt load and foam-forming substances.

Cleaning

Cleaning must be performed at about 55°C for at least 5 minutes. For the mechanical cleaning of thermostable and thermolabile instruments, we recommend an alkaline cleaner such as Neodisher® MediClean forte, 0.5%. If the water contains elevated chloride concentrations, the instruments may be exposed to pitting corrosion and stress corrosion. The use of alkaline cleaners or the use of demineralised water can minimise such corrosion.

Neutralisation

The addition of an acid-based neutralisation agent such as Neodisher® Z facilitates rinsing off alkaline cleaning agents. Even with neutral cleaners, the use of a neutraliser is recommended to prevent the formation of deposits in case of unfavourable water quality, such as water with high salt content.

Intermediate flushing

Water without additive

Thermal disinfection / final rinsing

As a measure of disinfecting capability, the A0 concept has been introduced (EN ISO 15883-1, Annex A). It determines the temperature-time relation as a function of microbiological contamination and the intended purpose of the medical devices. An A0 value of 3000 should be reached (e.g., A0 3000 = 90°C and 5 minutes exposure time).

Drying

Sufficient drying must be ensured by the washer-disinfector or other suitable measures. In case of residual moisture, additional drying can be achieved in a drying chamber at 60°C. However, the drying time depends on the loading level and the cleaned items.

15. Manual cleaning

In thermostable medical devices, mechanical reprocessing with thermal disinfection followed by steam sterilisation is preferable to other procedures.

The products should be disinfected and cleaned immediately after use if possible. Contaminants should not start drying on the products as this will additionally complicate disinfection and cleaning

The following points must be considered:

- The solutions used in manual cleaning must be mixed according to manufacturer instructions
- A suitable brush should be used for the cleaning of cannulas, blind holes and hollow bodies to ensure that all places are reached.

  Remove blood and other residues with a soft-bristled brush (natural bristles or synthetic bristles, no metal) and a mild neutral cleaner or alkaline cleaner (not for aluminium). **Never** use metal brushes or metal sponges for manual cleaning
- To ensure proper function of the devices, ensure that all moveable parts are thoroughly cleaned
- Joints and connections must be cleaned in closed and open condition
- Disassemble products to the extent possible for reprocessing
- The products must be placed on supports suitable for cleaning, e.g., sterilisation baskets or mesh baskets

Recommendation: Bode manual instrument cleaning Bodedex forte (pH-neutral cleaner) Use according to manufacturer information

Ultrasound treatment

- For cleaning in an ultrasonic bath, the disassembled, open products must be placed on sterilisation trays or mesh baskets designed for cleaning

- The products must be completely immersed in the solution
- Since warm water without additives does not achieve satisfactory cleaning results, a suitable cleaning agent must be added to the water. Follow manufacturer instructions regarding the concentration
- The temperature of the cleaning solutions in the ultrasonic bath must be selected according to the instructions of the cleaning agent manufacturer. Excessive soiling adversely affects cleaning results. Therefore, the cleaning solution must be replaced at regular intervals according to the manufacturer's instructions
- The exposure times must be selected following the instructions of the manufacturer of the applied cleaning agent. In general, instruments cleaned by ultrasound must undergo a rinsing step. After ultrasound treatment, the products should be checked for loosened parts (screws, etc.). To prevent water spots, rinsing is performed with demineralised or distilled water

Unless otherwise specified by the manufacturer of the ultrasonic bath, the following parameters should be set: Frequency 25-40 kHz, time 3-5 minutes, temperature 40-60°C.

Chemical disinfection

- The solutions for chemical disinfection must be used as specified by the manufacturer of the applied solvent
- The working dilutions of the chemical agents must be prepared with pure water. The addition of further cleaning agents is not permissible
- When using chemical agents, the manufacturer information (exposure time and concentration) must be closely followed
- Disinfectant solutions must be prepared fresh daily. If they are used multiple times, the following problems may arise:
    - rising concentration due to evaporation (risk of corrosion) or excessive contamination levels (corrosion and reduced effectiveness)
- After disinfection, rinsing with sufficiently clear, running water is generally required. To prevent water spots, demineralised water is used
- The devices must be sufficiently dried immediately after completion of the cleaning and rinsing steps

Recommendation: Korsolex® Endo-Disinfectant Disinfectant for chemothermal reprocessing. Use according to manufacturer information.

16. Packaging

After cleaning and disinfection, the instruments and implants must be placed in packaging and trays suitable for sterilisation. The applicable standards must be observed.

17. (Steam) sterilisation

Recommended sterilisation method: Steam-sterilisation with fractionated vacuum

- Recommended temperature: 134° to 137° C
- Holding time: min. 5 minutes max. 7 minutes
- Fractionation/pre-vacuum = yes (minimum of 2 pre-vacuum levels)

The instructions (instructions for use) of the steriliser manufacturer must be followed.

Standards: DIN EN ISO 17665-1, DIN EN 554, DIN/EN 285

18. Inspection and maintenance

- Allow products to cool to room temperature
- Check individual parts in disassembled condition for damage or deformation
- The products must be assembled to test the function

19. Symbols used in the instructions for use and packaging / label / sterile

Symbol	Explanation
	Observe instructions for use
	For single use only
	Attention!
	Manufacturing date
	Do not use product if packaging is damaged

Symbol	Explanation
	Manufacturer
	Use by date
	Batch name
	Product is supplied sterile (sterilised by irradiation)
	Protect from heat and direct sunlight

20. Symbols used in the instructions for use and packaging / label / non-sterile

Symbol	Explanation
	Observe instructions for use
	For single use only
	Attention!
	Manufacturing date

Symbol	Explanation
	Manufacturer
	Batch name
	Product is supplied non-sterile

21. Storage

Stored at room temperature. There are no special requirements regarding the storage of the product.

22. Guarantee policy

DIMEDA Instrumente GmbH is responsible only for each individual product being produced, inspected and packaged with the utmost care. Since DIMEDA has no influence or control over indications and/or applications, DIMEDA cannot be held responsible for complications or failure of an application. DIMEDA sets and individual products are mutually compatible. Nevertheless, users should verify the mutual compatibility of the products before use. This particularly applies if the user mixes DIMEDA products with products from other manufacturers. DIMEDA employees are not authorised to change the above conditions or extend liability or enter into additional product-related commitments.

23. Bibliography

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("Instrument reprocessing done properly")
AKI (Arbeitskreis Instrumentenaufbereitung)

"Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten"
("Hygiene requirements for the reprocessing of medical devices")
RKI (Robert Koch Institut)

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