Instructions for use

ORTHO MEDICAL GmbH · IMPLANTS

CE 0483

For drill wires, Steinmann pins and bone marrow pins, bone wire

In purchasing this implant you have acquired a high quality product, the correct handling and use of which is described below. To minimise risks and unnecessary stress and strain for the patient, please read and follow these instructions for use carefully.

Intended use / indication

Implants supplied by Ortho Medical serve for osteosynthesis and for the correction of degenerative skeletal changes.

Detailed information on the respective indications is contained in various specialist reference works:

- Knochenbruchbehandlung, Empfehlung des Gerhard-Küntscher-Kreises, V. Vécsei et al – Georg Thieme Verlag
- FMT-Fachwissen Medizin-Technik, Folge 3: Instrumente in der Medizin, Knochenchirurgie, Klaus Witzer – MTD-Verlag Amtzell
- AO-Instrumente, R. Texhammar, C. Colton – Springer-Verlag

They should only be used by experienced, surgically qualified medical personnel who have been instructed in the various procedures within the framework of generally recognised training programmes and only in compliance with the relevant literature (see above).
It is particularly important that the physician determines the extent of the injury/changes that require operative intervention and specifies the suitable therapeutic procedures and the correct implants. In addition, the physician must determine the correct time and surgical treatment for the patient, especially in the case of comorbidities and complex multiple injuries. Complications that may arise due to incorrect indications, implant handling, surgical techniques or asepsis are the responsibility of the surgeon and the manufacturer cannot be held liable in such cases.

The bone implants can never bear the full load of the treated bone segment. The implants serve solely for promoting healing and are not suitable for the replacement of intact tissue and bone matter. For this reason the physician must inform the patient about the limits of stress and strain and specify correct post-operative behaviour. The physician must generally inform the patient about indications, contraindications, unwanted side effects and post-operative treatment and note that the patient has been instructed accordingly. The patient must be given regular medical checks after implantation.

Contraindications:

- Medical conditions that exclude sufficient implant support or negatively affect the healing process such as
  - Impairment of the blood supply
  - Inadequate bone quality or quantity (osteoporosis)
  - Extreme obesity
  - Acute and chronic, local or systematic infections
  - Twisting or pronounced inclination of the thigh
  - Muscular, neurological or vascular ailments that endanger the affected extremity
  - Local bone tumours
  - Systemic diseases and metabolic functional diseases
  - Serious deformities
  - Serious falls
- Mental states that make participation in a rehabilitation programme impossible (Parkinson's disease, alcoholism, drug consumption etc.)
- 3. Other
  - Activities involving considerable physical exertion and pronounced impact in which the implants are exposed to shock and/or excessively high strain (e.g. heavy manual labour etc.)
  - Allergies to one of the material components of the implant; if such an allergy is suspected, corresponding tests must be made.

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Employed materials

The implants are made of materials that meet the requirements of the harmonised European standards:
DIN ISO 5832-1 Wrought stainless steel
DIN ISO 5832-2 Unalloyed titanium
DIN ISO 5832-3 Wrought titanium 6-aluminium 4-vanadium alloy
.
In the event of a proven allergy against steel implants, do not use any implants made of this material. In these cases use titanium or titanium alloy.

General instructions for use

Combinations

For metallurgical, mechanical and design-related reasons, it is prohibited to use combinations of implants from different manufacturers as well as of different materials. Material specifications are listed on the batch documents or on the product labels.
Before treatment, ensure that the necessary instruments are available and that these are suitable for combining with our implants.

Modification

Modification of the implants is only permitted with the suitable instruments in accordance with literature references.

Complications:

The following complications have been observed in various cases and therefore require the special attention of the physician:

- Bending, breaking, loosening or detachment of the implant components
- In the event of inadequate healing of the fracture, the anatomical position can be lost
- Superficial and deep infections can occur
- The operation itself and use of bone implants can result in vascular disorders such as thrombophlebitis, pulmonary embolisms, haematoma and non-vascular necrosis of the femoral neck
- Allergies, tissue and foreign body reactions can occur near the implants
- Fracture does not heal
- Bone deformation and re-fracture
- Shifting of the implant
- Cardiovascular dysfunction

Instructions for the operation:

- Before each operation it must be determined whether the patient is unusually sensitive or possibly allergic to the material of which the implant is made
- The correct selection of the implant components is absolutely essential. The respective implant type and size must be suitable for the individual patient. The weight and degree of physical activity of the patient as well as the fracture that requires treatment must be taken into account. The use of the largest possible implants as well as correct positioning prevents bending, breakage of cracks and loosening of the implant. The transmission of force to the bone also remains low.
- Before treatment, ensure that the necessary instruments are available and that these are suitable for combining with our implants. Sample components (if included in the scope of supply) and additional implant sizes should be kept available.
- The implants should never come into contact with objects that could damage their surface. They may not be machined nor modified in any way, unless the design and surgical techniques expressly demand such changes. In the latter case, modifications must be made with suitable instruments in compliance with literature references. If wires, plates and pins are bent with sufficient care, the implant is not damaged. Extreme deformation of the implant must always be avoided.

CAUTION: Bending forwards and backwards several times results in fatigue and even breakage of the implant. Notches and pressure points also have a very negative effect on the mechanical strength.

- Surgical techniques: Scientific rules and scientific publications are decisive in this respect. A description of such a surgical procedure can never be exhaustive or include all risks and complications which may be involved. Information on surgical techniques and procedures is available upon request. Before the operation, surgeons must familiarise themselves with the implants, instruments and the corresponding techniques
- To guarantee seamless traceability, the article and lot number of the employed implants must be appended to the operation report

Notes and warnings:

- Implants are NOT STERILE when they are supplied.
- Implants cannot be reused! >> Single use product!
- Removed implants must be disposed of in the hospital waste system
- Patients with stainless steel implants should not come into contact with electromagnetic / magnetic fields.
- The components of the implant must be examined to ensure that they are clean and dry and free from damage and residues
- The operating surgeon is solely responsible for selection and use of the implants.

Caution: When using **partially and fully threaded wires** with small diameters, they can easily break if used incorrectly. We cannot accept any liability in this respect.

Post-operative medical check-ups:

- Post-operative instructions to the patient, adequate medical care and regular check-ups are very important. The bone implants can never bear the full load of the treated bone segment. For this reason the physician must inform the patient about the limits of stress and strain and specify correct post-operative behaviour. Premature weight-bearing strain increases the stress on the implant and can result in breakage, bending or loosening. Early strain can be considered if the fracture is stable and there is positive bone to bone contact. Subjecting the fracture to full body weight before it is fully healed is contraindicated. In patients who are exposed to heavy strain or who suffer from delayed healing or union of the bone, the implants can bend or break or cause bone splitting
- The final decision to remove the implant must be made by the surgeon. The implants should be removed if they are no longer required for healing and such a step is feasible and practical for the patient.

Inspection after receipt and before use

Implants are very sensitive to damage. Even the smallest scratches or dents caused by knocks can cause internal tension
that considerably reduces their strength. For this reason they must be handled with extreme care.

- Before unpacking the implants, check the packaging for damage/transport damage as well as condensation
- Only remove outer packaging and protective caps immediately before use
- Check that the information on the label corresponds with the contents of the packaging
- Visual inspection of the implant for damage (discolouration, cracks, notches, burrs or other damage)

The manufacturer or supplier cannot accept any returned implants that are NOT in their undamaged, original packaging. If the packaging has been opened incorrectly, the manufacturer does not accept any liability.

Preparing for sterilisation of the implants

Before the implant is used it must be removed from the original packaging and once more cleaned and sterilised by qualified personnel. Always observe the instructions for use of the sterilisation device manufacturer.

The user is responsible for the sterility of the implants; they are not sterile when supplied and only pre-cleaned!!

Please avoid any additional contamination of the implants during use; otherwise the implants must be re-cleaned and disinfected.

Always observe the applicable statutory requirements of your country and the hygiene regulations of the surgery, hospital or clinic. This applies in particular to the various regulations for preventing/combating prions.

1. Cleaning: (Machine cleaning recommended)

Preparation of thermally stable medical products in machines with thermal disinfection and subsequent steam sterilisation is preferable to other methods.

Machine cleaning

The sterilisation trays should not be overloaded to ensure that the instruments are fully exposed.
The instruments must be positioned and stored so that they cannot be damaged. Only washing and disinfection equipment may be used that satisfy the general requirements (described in Washers and Disinfectors, Part 1 of EN ISO 15883).

Recommended procedures in washing and disinfection equipment:

Pre-rinsing

Cold water without additives to remove coarse dirt and foaming substances.

Cleaning

Clean at 55 °C ± 2 °C for at least five minutes For cleaning thermostable and thermolabile instruments we recommend the alkaline cleaning agent Neodisher ® MediClean forte; 0.5% solution in the machine.
If the water contains high levels of chloride, pitting corrosion and stress corrosion can occur on the instruments. Such corrosion can be prevented by the use of alkaline cleaning agents or fully demineralised water.

Neutralisation

Addition of an acid-based neutralisation agent improves the removal of alkaline cleaning agent residues. The use of a neutraliser is also recommended when using neutral cleaning agents if the water quality requires this, for example, if it contains high levels of mineral salts, to prevent the formation of residue layers. Neutralisation with Neodisher ® Z in cold water with an 0.1% concentration is recommended.

Intermediate rinsing

Deionised water without additives

Thermal disinfection/final rinsing

Carry out thermal disinfection at 92 °C ± 2 °C for at least five minutes (A0 value of >3000).

Drying

Sufficient drying must be ensured by the washing and disinfection equipment or other suitable measures. Dry for approx. 30 minutes at 55-60 °C. Should there still be traces of moisture, subsequent drying in a drying cabinet at 60 °C is possible. However, the drying time depends on the loaded material and quantity.

The implants should be packed in a suitable container or sterilisation packaging before sterilisation (EN 868, Parts 1-10). The sterilisation packaging depends on the sterilisation, transport and storage methods. The packaging has a considerable influence on the sterilisation results. Packaging must be selected so that the implants fit into the packaging.

Use a sterilisation indicator for packaging and note the sterilisation and use by date on the packaging.

We recommend commissioning an authorised company with packaging and sterilisation, for example:

- **Puracon GmbH for implant packaging**
- **BBF Sterilisationsservice GmbH for product sterilisation**

Sterilisation / autoclaving of the washed products under the responsibility of the user

STERILISER: Steam autoclave with fractioned pre-vacuum:
Temperature: 134° Celsius, with a holding time of at least 5 up to 20 minutes with subsequent drying.

Always sterilise all instruments before use.

Recommended sterilisation method:	Steam sterilisation with a fractionated vacuum
Recommended temperature:	134 °C
Recommended pressure:	3 bar
Holding time:	≥ 5 minutes

During sterilisation, always carefully observe the instructions of the equipment manufacturer for the recommended application.

Correct implant disposal

The removed implants must be disposed of so that injury and contamination of persons is excluded. The products must be cleaned and sterilised again before disposal.

Misuse of and damage to the implants

Personnel should be familiar with instructions and recommendations to ensure safe and effective processing and to prevent damage to or misuse of the implants.

Meaning of symbols

NON STERILE	The product is not sterile when supplied		Comply with instructions for use
	Caution, observe the instructions		Only for single use

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Applicable STANDARDS / References

- AKI Guide "Proper reprocessing of instruments"
- RKI recommendation: "Hygiene requirements for reprocessing of medical devices".
- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 13060 Small steam sterilizers
- DIN EN ISO 15883-1-3 Washer/disinfectors
- DIN EN 868 Packaging
- DIN EN ISO 17664 Sterilisation – information of the manufacturer

Ortho Medical GmbH does not accept any liability for non-compliance with these instructions for use.

Manufacturer and service address			
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