Instructions for general use of bone or skeletal implants

CE 0483  

ORTHO MEDICAL GmbH · IMPLANTS

Important information / General

The raw material used for the production of an Ortho Medical GmbH implant comprises a Titan-6-aluminium-4-vanadium wrought alloy that complies with DIN ISO 5832-3. The material is non-magnetic and its surface is chemically passive.
Combinations of implants made of materials that meet the specifications of DIN ISO 5832-3 are unproblematic from a materials technology viewpoint. We only guarantee the safety and function of implants and implant combinations supplied by Ortho Medical GmbH.
Any intermediate dealers are responsible for safe repackaging that is sufficiently secured and prevents the product falling out.
The medical products law stipulates that customers are obliged to archive the enclosed or assignable documentation so that traceability can be guaranteed at all times.
Furthermore, incoming goods inspection is necessary to verify the main characteristics, even if we have subjected these products to final goods inspection.

Compatibility

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 in the product catalogue or on the product labels.
Before treatment, ensure that the necessary instruments are available and that these are suitable for combining with our implants.
No warranty is given for combinations with products made by other manufacturers.

Intended use / Application

Implants serve for the correction of degenerative skeletal changes and to support osteosynthesis, and are only able to fulfil their function when the following rules are complied with:

- Only surgically trained medical personnel are qualified to use and select suitable implants for the respective applications, as the implant must be gauged correctly for the respective bone defect, weight, degree of activity and comorbidities of the patient.
- The physician must inform the patient that they should not place their full body weight on the implant due to its limited strength, and that non-compliance with this warning can have serious consequences for the healing process of the patient.
- Furthermore, the physician is obliged to inform the patient about the advantages and disadvantages of the implant.

Indication

When selecting the implant and the operative method, the physician must also take comorbidities of the patient such as osteoporosis, obesity etc. into consideration. Implants are designed to encourage optimum wound and bone healing. Their use demands strict observance of the anatomical and biomechanical conditions and exact compliance with known and conventional surgical procedures. The physician is obliged to inform patients of the stress limits before surgery and instruct them on correct post-operative behaviour.

Contraindication

1.) Diseases that exclude sufficient implant support or negatively affect the healing process such as
Impairment of the blood supply
Inadequate bone quality or quantity
Extreme obesity
Previous infection
Twisting or pronounced inclination of the thigh
2.) Mental states that make participation in a rehabilitation programme impossible (Parkinson's disease, alcoholism, drug consumption etc.)
3.) Activities involving considerable physical exertion and pronounced impact in which the implants are exposed to shock and/or excessively high strain
4.) Allergies to one of the material components

Complications

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

1.) The implant can show signs of fatigue or break if it is moved forwards and backwards several times. Pressure points or similar can also have a considerably negative effect on the mechanical strength.
2.) Loosening or detachment of the implant components
3.) In the event of inadequate healing of the fracture, loss of the anatomical position can occur
4.) Superficial and deep infections can occur
5.) The operation itself and use of Kirschner wires can result in vascular disorders such as thrombophlebitis, pulmonary embolisms, haematomas and non-vascular necrosis of the femoral neck
6.) Limping due to shortening of the limb may occur
7.) Penetration of the Kirschner wires through the femoral head (mainly in connection with osteoporotic bones)
8.) Penetration of the screw through the joint (mainly in connection with low-angled plates or impeded motion of the screw as well as unsuitable attachment of the plate on the femur)
9.) Allergies, tissue and foreign body reactions can occur near the implants
10.) Injury to the main thigh epiphysis by a trauma during the operation of as a consequence of the unsuitable length or position of the traction bolt
11.) In the event of clavicle fractures, pseudarthrosis can infrequently occur. They are treated osteosynthetically with plates. Open fractures are treated surgically.
12.) In the event of acromial and sternal luxation, rib fractures or injury to the N. axillaris can occur.
13.) In the event of scapular fractures, restricted mobility may occur.

14.) In the event of humerus fractures, pseudarthrosis may occur, for example as the result of insufficient osteosynthesis or conservative treatment of unstable fractures.
15.) Fractures of the distal humerus segment: As a result of impaired circulation in the elbow joint, a Volkmann's contracture can occur. For this reason it is necessary to observe the patient for symptoms of peripheral circulation impairment to enable suitable reaction if necessary. A frequent complication is stiffening of the joint. If joint stiffening occurs, a flexural position of more than 90° produces the least problems, as main activities can still be carried out.
16.) Olecranon fracture: As a result of the fracture, impairment of the bending and stretching capability as well as arthrosis or pseudarthrosis can occur.
17.) Fracture of the radial head: Possible complications are stiffening of the joint or secondary arthrosis.
18.) Diaphyseal lower arm fractures: Joint stiffening and pseudarthrosis as well as ischaemia are possible complications as well as restricted mobility in the event of axis misalignment of the radius.
19.) Pelvic fractures: Rupture of a blood vessel (Plexus sacralis, Plexus prostaticus) with massive retroperitoneal bleeding. Injury to the bladder and urethra, infrequently to the vagina and rectum.
20.) Acetabulum fractures: Possible complications include periarticular ossification, secondary arthrosis and necrosis of the femoral head. If necessary, endoprosthetic treatment should be considered for older patients.
21.) Femoral neck fracture: In 30 per cent of all cases, femoral neck necrosis occurs, in 15 per cent femoral neck pseudarthrosis, mainly in the event of femoral fractures with a steep fracture line. In the event of pseudarthrosis, intertrochanteric relocation osteotomy can produce positive healing results.
22.) Pertrochanteric fractures: In addition to specific procedural complications (also refer to Therapy), pseudarthrosis, thrombosis, embolisms and infection of the urogenital tract can occur.
23.) Fractures of the foot: Posttraumatic arthrosis and soft tissue injury can occur. If metatarsal head fractures heal in an incorrect position, this can result in pain under strain. Late complications can be posttraumatic arthrosis in the ankle joint and a flat or splay foot.
24.) Joint instability and posttraumatic arthrosis are possible complications.
25.) Fractures of the distal lower leg: Damage to the skin with tension bulla can occur as early or late complications in the form of posttraumatic arthrosis.
26.) Market observation has revealed that when distal femur plates are used for patients with endoprostheses, implant failure (breakage of the plate) can occur due to lack of cortical support combined with foreseeable negative bone healing. In such cases the patient must be comprehensively informed about potential risks and possible complications!

Surgical techniques

The correct selection of the implant components is absolutely essential. The respective implant type and size must be adapted to suit the individual patient. The use of the largest possible implants as well as correct positioning prevents bending, breakage or cracks and loosening of the implant.
The implants are subjected to higher strain caused by subtrochanteric or intertrochanteric fractures as well as osteotomy. To ensure the best possible fixation, the largest possible plate size must be used. The length which permits the use of a large number of Cortex Kirschner wires in intact the femur distally from the fracture line should be selected. The stipulated period without or with only very slight stress until the fracture has healed and is stable must be of sufficient duration.
In the event of subtrochanteric fractures and osteotomies, the implants are subjected to particularly high levels of stress, as the muscular forces do not act regularly, and the chances of healing are lowered considerably by implants which bend or even break. Additional cautionary measures and internal or external supports are necessary to stabilise the fracture and lower the strain on the implant to the minimum until x-rays determine that the bone fracture has firmly united.
The thread of the Kirschner wires should never be located in the line of the fracture. It is important to select the correct length of the Kirschner wires, as the Kirschner wires must be fully fixed in the bone to enable a telescopic motion in the event of absorption of the fracture surface.
Only implants of the same systems and the same materials may be combined.
The implants should never come into contact with objects, as the surface could be damaged. They should be neither machined nor changed in any way.
When the bone has healed, the metal implants can be either removed with a minor surgical procedure (second operation), in many cases even as an outpatient procedure. With children the material should always be removed when the bone has healed, as the bone still has to grow.
Removing the material from the bone is generally a low-risk procedure. As during any surgical procedure, however, risks cannot be fully excluded. Your doctor will inform you in detail of uncommon complications such as wound infections and haematoma before the operation.
In rare cases the operation may reveal that the bone has unexpectedly not grown together correctly. If this is the case, it may be necessary to leave the material intact or replace it.
When the material has been removed, the bone may be somewhat less resilient for some time, so that there is the risk of a new fracture occurring if the bone is subjected to excessive stress or strain.
A description of such a surgical procedure can never be exhaustive or include all risks and complications which may be involved. Scientific rules and scientific publications are decisive in this respect. Surgeons must observe the respective surgical techniques. They must familiarise themselves with the implants and their applications before use. The product brochures also contain relevant information. The experience and knowledge contained in relevant international literature must be observed in accordance with the respective situation. In the event of incorrect indication, surgical techniques and/or post-operative treatment, failure of the implant (dislocation, loosening, breakage) and non-union of the bone must be expected. If the surgical procedure is not atraumatic, the wound may not heal correctly, haematoma may form and the wound may become infected.

Magnetism

Although these implants are made of non-magnetic wrought titanium alloy, they can be unintentionally moved or heated during MRT tests due to the magnetic field.
It is therefore not recommended to use them in magnetic fields.

Notes and warnings

Implants are not designed to be reused. If they are subjected to additional stress after successful use it cannot be guaranteed that they are resilient to stress in a new application.
Reuse of the products can result in serious injury to the patient and even death!
There is a label on the packaging of the implant that shows the serial number which the physician must note on the surgical report of the patient to ensure seamless traceability of the implant.

General information on hygiene and processing

Information:

- Implants that are supplied directly from the factory must be processed before use. The transport packaging, protective caps etc. are not suitable for sterilisation.
- Only approved products (RKI, DGHN, VHA, etc.) may be used.
- Both alkaline and pH-neutral cleaning agents may be used
- Water quality in compliance with DIN EN 285 Annex B
- Only adequate and validated processes that are suitable for the respective equipment and products may be employed for cleaning/disinfection/sterilisation
- The manufacturer's specifications and recommendations must always be complied with
- Due to the product design and the employed materials it is not possible to specify a defined maximum limit of executable processing cycles. The service life of the medical products is determined by their function and careful handling.
- Defective products must have undergone the full recycling process before being returned for repair.

Preparation at the site of use:

Immediately after use, remove coarse dirt from the instruments. Do not use fixing products or hot water (>40 °C) as this can result in fixation of residues that can negatively affect the cleaning results.

Preparation before cleaning

Products must be cleaned and sterilised separately and individually in accordance with the following processing steps.

Cleaning

Manual cleaning:

- Products must be rinsed in running tap water (>40 °C) until all visible contamination has been removed.
- If necessary, a soft brush should be used to remove visible contaminants
- Immerse the instruments in an enzymatic cleaning agent (if an ultrasound bath is used, ultrasound processes of three minutes and ultrasound frequencies of 35 KHz are effective).
- Follow the instructions of the cleaning agent manufacturer
- Rinse the instrument under running tap water (>40 °C)

Machine cleaning

Place the products into a tray on the rack trolleys and start the cleaning process

- 1 minutes pre-rinsing with cold water
- Emptying
- 3 minutes pre-rinsing with cold water
- Emptying
- 5 minutes washing at 55 °C with an 0.5% alkaline cleaning agent
- Emptying
- 3 minutes neutralisation with warm tap water (>40 °C) and neutraliser
- Emptying
- 2 minutes intermediate rinsing with warm tap water (>40 °C)
- Emptying

Special specifications of the cleaning machine manufacturer must be complied with

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Disinfection

Manual disinfection

Place the products in cold water for at least five minutes. Clean the products in cold water with a soft brush until no more residues are visible. A water jet must be used for pressure cleaning of the thread for at least 10 seconds (pulsed setting). Place the products in an ultrasound bath for 15 minutes at 40 °C with an 0.5 % enzymatic cleaning agent and clean with ultrasound. After chemical disinfection and cleaning, always rinse thoroughly with clear, running water. Manually remove any dirt residues that may still be attached (do not use any metal brushes or abrasive agents!) To prevent water stains, a final rinse with fully demineralised water is recommended. The instruments must then be dried immediately.

Always follow the instructions of the disinfection cleaning agent manufacturer. Ensure that the cleaning agent can reach all internal and external parts of the product. Clean the product with distilled water after the contact period to remove the cleaning agent.

Machine disinfection

Carry out thermal machine disinfection in compliance with the national requirements regarding the A0 value (see ISO 15883).

Drying

Manual drying with a lint-free cloth
Drying the outside of the product with the drying cycle of the washer/disinfector. If necessary, dry manually with a lint-free cloth.
Dry cavities in products with sterile compressed air

Inspection, maintenance and testing

Before use, implants must be checked for discolouration, notches, cracks and other damage that could be caused by incorrect sterilisation and/or storage.
Should any of these be detected on the implant, it should never be used or fitted before being inspected once more by our company.
Visual assessment to ensure cleanliness; care and function test according to the instructions for use. If necessary, repeat the reprocessing process until the instrument is visibly clean.

Packaging

Standard-compliant packaging of the instruments for sterilisation in compliance with ISO 11607 and EN 868

Sterilisation

- Steam sterilisation is recommended.
- Other sterilisation methods and flash sterilisation are not permitted.
- Steam sterilisation at 134° C for five minutes at a pressure of 2.3 bar (in compliance with DIN EN ISO 17665-1; ANSI AAMI ISO 11134)

The products can be resterilised with the described methods.

- Cleaning in a machine/thermal disinfection are preferred methods
- Correct instrument handling and storage
- A0 value (duration/temperature) in accordance with the product classification in accordance with the RKI2 directive
- Only use suitable chemicals in the correct dosage in compliance with the specifications of the cleaning agent manufacturer.
- The material can be damaged by unsuitable water, cleaning agents or methods.

Cleaning and sterilisation may only be carried out by qualified specialists. If processing is incorrect, there is the risk that the implant is damaged and can no longer be used.

Storage

Storage of the sterilised instruments in a dry, clean and dust-free environment at moderate temperatures of 5° C to 40° C.

Disposal

After successful disinfection, defective or extracted implants must be disposed of correctly.

Graphic symbols/marking

The symbols provided for marking in compliance with DIN EN 980 have the following meanings:

Not for reuse

Comply with instructions for use

CE mark with ID number of the stated authority

Article number

Batch number

Indication of a non-sterile product

Manufacturer:
Ortho Medical GmbH
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