

Instruction of use

Osteosynthesis
implants made of TITANIUM



43-151-06T - 44-451-69T



AS Medizintechnik GmbH
Sattlerstraße 15
78532 Tuttlingen
Germany

Tel: +49/74 61/966 32-6
Fax: +49/74 61/966 32-88
www.AS-Medizintechnik.de
info@AS-Medizintechnik.de



Important Information / General

The raw material used by AS Medizintechnik GmbH for manufacturing an implant consists of titanium 6 aluminium 4 vanadium wrought alloy according to DIN ISO 5832-3. The material is non-magnetic and its surface is chemically inert.

Combinations of implants with other materials according to DIN ISO 5832-3 are in terms of materials unproblematic. We make only warranties regarding safety and features for implants and combinations of implants manufactured by AS Medizintechnik GmbH.

Possible intermediaries are responsible for a safe re-packaging which prevents implants from falling out.

According to Medical Devices Act, the customer is liable to archive the documentation supplied with the product or directly allocatable to the product in a way which guarantees the traceability at any time.

Furthermore the most relevant features should be tested on receipt, even in the event of a respective final inspection by us.

Compatibility

For metallurgical, mechanical and design reasons, never combine implants from different producers and different materials. Materials used are stated in the product catalogue or on the product labels.

Before starting treatment, make sure that the required set of instruments is available and is suitable to combinations with our implants.

We do not accept any liability for combinations with parts made by other companies.

Intended Use / Application

Implants are to serve the correction of degenerative skeletal changes and support osteosynthesis. In order to fulfil their functions the following provisions must be complied with:

- The selection and implementation of the most appropriate implants can only be performed by surgical trained medical qualified personnel, as the implant has to be adjusted to the bone deficiency, the weight, the level of activity and con-comitant diseases.
- The physician has to indicate to the patient, that due to its limited strength the implant may not be loaded with the entire body weight and that non-compliance with this instruction could result in serious consequences for the healing process for the patient.
- Furthermore the physician has the duty to inform the patient about the advantages and disadvantages of the implant.

Indication

Selecting the type of implant and surgical treatment the physician has also to consider the patient's concomitant diseases, osteoporosis, obesity, etc. Implants are designed for optimum healing of wounds and bones. The placement requires strict compliance of the anatomical and biomechanical conditions as well as the exact compliance of the known and usual surgery techniques. Pre-operatively, the physician has to inform the patient about the stress limits and using these to set up the respective post-operative behaviour.

Contra-Indication

1. Health conditions, which would exclude a sufficient treatment with implants or would affect the healing process, such as Interference of blood supply
2. Insufficient bone quality or -quantity / Extreme obesity / Prior infection / Distortion or inclination of thigh.
3. Mental conditions, which make it impossible to participate in an ambulatory rehabilitation programme (Parkinson's disease, alcoholism, drug consumption, etc.)
4. Heavy physical activities and those associated with hard shocks, where the implants are exposed to impact and other excessive strain.
5. Allergy to one of the material components.

Complications

The following complications had been variously observed and require therefore the special attention of the treating physician:

1. The implant can fatigue or break when moved back and forth several times. Pressure marks or the like can also reduce the mechanical strength significantly.
2. Loosening and releasing of the implant components
3. In the case of insufficient healing of the fracture a loss of the anatomical position can occur
4. Superficial and deep infections can occur
5. Vascular diseases such as thrombophlebitis, pulmonary embolism, haematoma and non-vascular necrosis of femoral neck can arise due to the surgery and use of Kirschner wires.
6. Limping caused by shortening of limbs can arise.
7. Penetration of Kirschner wires into the femoral head (usually combined with osteoporotic bones)
8. Penetration of screw into the joint (usually combined with low angled plates or an impairment of the sliding of the screw as well as inappropriate fixing of plates at the femur)
9. Allergies, tissue and foreign body reaction can arise in the environment of the implant.
10. Traumatic lesions of main epiphysis of thigh during the surgery or as a result of an unsuitable length or position of the traction bolt
11. Clavicular fractures seldom result in formation of pseudarthroses. There are treated with plating osteosynthesis. Open bridges are treated surgically.
12. In case of acromial and sternal dislocations fractures of ribs or injuries of the axillary nerve can occur.
13. In case of scapula fractures a restriction of mobility can occur.
14. In case of humerus fractures pseudarthroses can often occur; i.e. as a result of insufficient osteosynthesis or conservative treatment of instable fractures.
15. Fractures of the distal humerus segment: As a result of circulation disturbances in the elbow joint a Volkmann's-contraction can occur. Therefore, after reposition resp. surgery symptoms of peripheral circulation disturbances must be observed in order to take correspondent measures. A frequent complication is the stiffening of the joints. In case of joint stiffening a flexion position of more than 90° causes the least issues as the most important activities can be still performed.
16. Olecranon fracture: As a result of the fracture impairments of flexing and extending ability can occur as well as an arthrosis and pseudarthrosis.

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17. Fractures of the radial head: More complications can be a joint stiffening or secondary arthrosis.
18. Diaphyseal forearm fractures: Joint stiffness and pseudarthrosis as well as ischemia are possible complications; also restriction of mobility because of axialmisalignment of the radius.
19. Pelvic fractures: Rupture of a blood vessel (plexus sacralis, plexus prostaticus) with massive retroperitoneal bleeding. Damaging the bladder and urethra, more seldom of vagina and rectum.
20. Acetabular fractures: All possible complications go along with periarticular ossifications, secondary arthrosis and necrosis of the femoral head. If necessary, consider at the same time an endoprosthesis treatment for elder patients.
21. Femoral head fractures: 30 % of the cases will develop a necrosis of the femoral head, 15 % develop a femoral neck-pseudarthrosis, mostly at femoral neck fractures with steep fracture lines. In case of pseudarthroses an intertrochanteric re-arrangement osteotomy can result in complete healing.
22. Pertrochanteric fractures: Besides the procedure-oriented complications (see therapies) pseudarthroses, thrombo-embolisms and infections of urogenital tract can occur.
23. Fractures of foot: Post-traumatic arthrosis and soft tissue damage can occur. If fractures of metatarsal heads heal in the wrong position, so this can result in stress-induced pain. As a late complication post-traumatic arthrosis in the lower ankle joint and flat or splay foot can occur.
24. Instability of the joint and post-traumatic arthrosis are possible complications.
25. Fractures of distal lower leg: Skin damages with dermolysis can occur as arthrosis – at an early stage, post-traumatic or as late complication.
26. On the basis of market observations it can be determined that failure of implant (breach of plate) can occur at application of distal femur plates for patients with endoprotheses due to absent cortical support in connection with expected bad bone healing. Pursuant to the existing situation the patient has to be exactly informed about the potential risks and possible complications!

Surgical Technique

The right choice of implant components is most important. The corresponding implant type as well as the size must be adjusted to the individual patient. The use of the largest possible implant as well as the right positioning prevents bending, breaking, crack forming and loosening of the implant. In case of subtrochanteric or fractmental trochanteric fractures as well as osteotomies, the implants are subject to higher mechanical stresses. The largest possible plate size must be used to achieve the highest level of fixation. The length should be selected in a way that a large number of Kirschner wires can be inserted into the intact femur distal to the fracture line. The time period without or with very less stress must be long enough up until the fracture is stable after healing.

In case of subtrochanteric fractures and osteotomies, the implants are subjected to particularly high stresses because of the muscular forces do not work evenly; therefore the healing chances are very reduced by bending or even breaking implants. Additional precautions as well as internal or external supporting elements are necessary to increase the stability of the fracture and to minimise the stress upon the implant up until a solid healing of the fracture has been verified by x-ray examination.

The thread of Kirschner wires must not be inherent in the fracture line. The right selection of length of Kirschner wires is important because of the Kirschner wires must be completely fixed in the bone to enable a telescopic movement in case of an absorption of the fracture surface.

Only implants of same systems and same materials may be used together.

The implants may not come into contact with other objects as the surface could be damaged. They may not mechanically worked or otherwise altered. When the bone have healed, the metal implants can be removed by a small surgical procedure (second surgery), often even on an outpatient basis. In the case of children, the material should be always removed after the bone has healed because the bone has still to grow.

The material removing from the bone is normally a very low-risk procedure. As in any surgical intervention, risks can't be excluded for one hundred percent. Your physician will inform you comprehensively about rare complications as i. e. wound infections and haematoma prior to operation. In rare cases, during the surgery is found that the bone hasn't healed optimal contrary to expectations. Then, it's possible that the material has to be left or newly fixed. After the removal of the material, the bone is eventually less resistant for some time; therefore the risk for a renewed fracture because of excessive stress is increased.

A surgery description can never be complete and contain all risks and complications that have to be considered. Scientific laws as well as scientific publications are substanceially. The surgeon must follow the appropriate surgery techniques. He has to get familiar with the implants and their use before surgery. Notes are can also be found in the product brochures. The given knowledge and experience of relevant international publications shall be complied with in accordance as circumstances require. In case of wrong medical indication, wrong surgery techniques and/or wrong post-treatment, implant failure (dislocation, loosening, fracture) and absent bone healing have to be expected. In case of no atraumatic surgery, disorders of wound healing, formation of haematoma, or wound infection are possible.

Magnetism

Although these implants are made of non-magnetic wrought titanium alloy, they could be moved and warmed by the magnetic field of an MRT in an unwanted manner.

Application under magnetic fields is therefore not recommended.

Information and Warnings

Implants are not designed for re-utilisation. By means of a new stress after inserting the implant it is not guaranteed that a new implantation will bear the stress.

A repeated application of the product can result in severe injuries or in the death of the patient!

On the packaging of the implant there is a label with a serial number, which must be noted in the surgery report for the patient in order to ensure the seamless traceability of the implant.

General Basics of Hygiene and Processing

Information:

- Implant straight from the factory must be processed before their first application. The transporting packages, protection covers, etc. are not suitable for sterilisation.

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- Use only approved agents (RKI, DGHN, VHA, etc.)
- Alkaline as well as neutral cleaners may be used.
- Water quality according to DIN EN 285 attachment B
- Use only sufficiently validated equipment and product specific processes are used for cleaning / disinfection / sterilisation.
- Follow manufacturer's notes and recommendations.
- Pursuant to product design and the used material no defined limit of maximum practicable processing cycles can be determined. The durability of the medical products is determined by their function and the considerate handling.
- Defect products must undergo the complete reprocessing treatment before shipped to repair.

Preparations at Location of Placement:

Remove coarse dirt from the instruments directly after use. Do not use fixating detergent or hot water (>40°C) as this can cause the fixation of residues which may influence the result of the cleaning process.

Preparations before Cleaning

Products must as far as possible be separated and individually cleaned and sterilised as priority matter for the following preparation procedure steps:

Cleaning

Manuel Cleaning:

- Products must be rinsed under current town water (>40°C) until all visible contaminations are removed.
- If required a smooth brush should be applied in order to remove all visible contaminations.
- Immerse the instruments into an enzymatic cleaning agent (when using a supersonic bath, supersonic processes of 3 minutes and supersonic frequency of 35 kHz are effective).
- Follow the instructions for use from the manufacturer of the cleaning agents.
- Rinse instrument under current town water (>40°C).

Mechanical Cleaning

Place products into a strainer tray on the infeed carriage and start the cleaning process

- Pre-rinse with cold water for 1 minutes
- Draining
- Pre-rinse with cold water for 3 minutes
- Draining
- 5 minutes washing at 55°C with 0.5 % alkaline cleaner
- Draining
- 3 minutes neutralisation with warm water tap water (>40°C) and neutraliser
- Draining
- 2 minutes intermediate rinsing with warm tap water (>40°C)
- Draining

Follow specific requirements of the cleaning machine's manufacturer.

Disinfection

Manuel Disinfection

Insert products into cold water for minimum 5 Minutes. Clean products with a smooth brush under cold water until no residues are visible. Pressure wash thread courses with a water pistol for minimum 10 sec. (pulsed procedure). Insert products into supersonic bath at 40°C for 15. Min. with 0.5 % enzymatic cleaner and treat with ultrasound.

After chemical disinfection and cleaning always rinse sufficiently with clear, running water. In doing so any adhered particles are removed manually (use no metal brush and no abrasive cleaners. A final rinse with demineralised water is recommended to avoid water spots. Subsequently the instruments must be dried immediately.

Follow the manufacturer's instructions for the disinfection cleaner. Make sure that the cleaner can reach every part inside and outside of the product. Clean the product after the contact time with distilled water in order to remove the cleaner.

Mechanical Disinfection

Perform mechanical thermal disinfection taking account of the national requirements regarding the A0-value (see ISO 15883).

Drying

Manuel drying with lint-free cloth.

Drying of the outer surface of the product by using the drying cycle of the cleaning-/disinfections machine. If necessary an additional manual drying by means of a lint-free cloth can be performed. Dry hollow spaces of products with sterile pressure air.

Control, Maintenance and Inspection

Implants must be inspected before implantation for discolourations, nicks cracks or other damage, which might be caused by inappropriate sterilisation and/or storage.

Should one of the above mentioned features visible at the implant it must under no circumstances be used resp implanted prior to a new inspection by us.

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Visual examination for cleanliness; Care and function testing according to user manual. If required, repeat preparation procedure until instrument is visually clean.

Packaging

Standardised packaging of instruments for sterilisation according to ISO 11607 und En 868.

Sterilisation

- As sterilisation method the steam sterilisation is recommended
- Other sterilisation methods and flash sterilization are not permissible.
- Use steam sterilisation with 134° C, 5 minutes long with a pressure of 2.3 bars (according to DIN EN ISO 17665-1; ANSI AAMI ISO 11134)

The products are not designed for re-sterilization with the mentioned procedure.

- Apply preferably mechanic cleaning / thermal disinfection.
- Appropriate handling and tray.
- A0-value (duration / temperature) according to the assessment of products by means of RKI2 policy
- Only appropriate chemicals in correct dosage according to instructions of cleaning agent's manufacturer may be used.
- The material could be damaged by inappropriate water, cleaning agents or procedures.

The cleaning and sterilization may only performed by qualified staff. Improper preparation procedure would result in a danger to damage to implant and cannot be applied any more.

Storage

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

Disposal

Defect or explanted instruments which had been successfully disinfected must be disposed in the proper way.

Graphical Symbols / Labelling

The Symbols provided by the marking and labelling according to DIN EN 980 have the following meanings:



Not for re-use



Follow the instructions for use



CE marking with ID number of the location mentioned



Product number



Batch number



Information on non-sterile product.



Manufacturer:
AS Medizintechnik GmbH
Sattlerstrasse 15
78532 Tuttlingen / Germany

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