Directions for use
AO Angle Stable Bone Plates [EN]

Content

MANUFACTURER

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AO angle-stable bone plates

IMPORTANT PRODUCT INFORMATION BEFORE EACH CLINICAL APPLICATION PLEASE READ CAREFULLY!

Dear Customer!

With the purchase of this implant, you will receive a high-quality product, the proper handling and use of which are described below. In order to keep hazards for patients and users as low as possible, we ask you to read and observe the instructions for use carefully.

Attention

Please read the information in these instructions for use carefully. Improper handling and care, as well as misused use, can lead to premature wear and risks for patients and users. Please also note the imprints on the packaging.

1 General

1. *Manufacturers and producers of bone plates guarantee the quality of the construction and material of the product.*
2. *For the success of an operation using bone plates are crucial:*
   - *Correct selection of the patient suitable for the operation*
   - *Comprehensive information of the patient about the existing risks*
   - *Perfect surgical technique with correct use of special surgical instruments*
   - *Severe asepsis, preferably cleanroom conditions*
3. *Complications that could arise due to incorrect indication, surgical technique or asepsis are the responsibility of the surgeon and can not be blamed on either the producer or manufacturer of the bone plates and screws.*

The above-mentioned implants are only used to promote healing and do not represent a substitute material for intact tissue and bone material. The anatomy of human bone sets certain limits in terms of size and thickness of bone plates. A full weight load before complete fracture healing is contraindicated. In patients who are exposed to heavy loads or who suffer from a delay in healing or the growth of the bone, the implants can bend, break or cause bone fractures.

1.1 Construction and material

The implants are designed according to the latest findings in implantation technology and the state of the art. However, their safety and functionality can only be guaranteed if the instructions of the surgical instructions and the instructions for use are taken into account and followed. Detailed information is described in the available literature. The implants have undergone EMC testing and fully meet the requirements. No impairments on function, safety and performance are to be expected and are therefore also suitable for MRI.

1.2 Compatibility

The angle-stable bone plates are available in many shapes and sizes and are made of various materials indicated on the label. At the same time, only components made of the same material may be used. The angle-stable bone plate implants are not compatible with components of other systems and must not be mixed. As accessories for the angle-stable bone plates, bone screws are used, which can be found under the item Accessories.

2 Purpose

In the case of angle-stable bone plates (T-plates, radius plates, reconstruction plates, third-tube plates, distal and proximal humerus plates, clavicula plates, olekranon plates, distal, proximal tibia plates, metaphysiseal plates, distal fibula plates and calcaneal plates. DHS/DCS plates, straight plates, distal buttress plates, distal femoral plates) is a fixation system that can only be used in combination with the appropriate locking screws. This is used for open surgical fracture restoration and is attached directly to the fractured bone to bridge or splint the fracture gap. This dispenses with interfragmentary compression and pressing of the force carrier on the bones, which ensures significantly better periosteal blood circulation.
The right selection of components (screws, plates) is extremely important. The appropriate type and size should be selected for the patient based on injury, weight, fracture size, number of fragments, etc.
The goal of fracture treatment is always the complete anatomical and functional restoration of the bone.

Angle-stable small fragment bone plates

Angle-stable small fragment plates are offered in different variants and hole numbers. They are mainly used in the area of the upper arm and elbow, on the lower and thighs in mono-, bicondylar, supracondylar debris fractures and pseudoarthrosis. The angle-stable plates are used for smaller bones.
The fractures are fixed, stabilized and repositioned by means of angle-stable small fragment plates and locking screws. This creates a high stability of the fracture between the bone tissue and the locking screw as well as the angle-stable bone plate.

DHS and DCS supracondylar plates

DHS plates are used and applied for sub-, pertrochantary and intertrochantary and basilar fractures and especially for femoral neck fractures. The DHS plates are available at different angles and can therefore be easily adapted to the anatomical conditions. The DCS supracondylar plates as well as the normal DCS plates are used for proximal femoral fractures and subtrochantary fractures. Furthermore, they are used for extra-articular fractures of the distal femur. Fixation and stabilization of the fracture is achieved.

Angle-stable large fragment bone plates

The large fragment contains different types of angle-stable bone plates. These would be: DHS/DCS plates, straight plates, proximal Tibia L/T plates, distal/proximal tibia plates, distal buttress plates, distal femoral plates and metaphysiseal plates. Large fragment plates are used in lower leg neck fractures as well as in femur and tibial fractures as well as in ankle fractures for fixation, stabilization and repositioning. Depending on the type of fracture, several angle-stable large fragment plates or combinations with other bone plates are to be used.

Angle-stable reconstruction of bone plates

Reconstruction plates can be easily modeled in 3 levels due to their shape and are therefore easily adaptable to any anatomical condition. Distal humerus fractures and proximal ulna fractures can be optimally supplied. Due to the angle-stable reconstruction plates, complicated drigenomenal fractures can be easily repositioned due to small interfragmentary displacements between the two bone tissues. Callus formation is promoted by the well anatomically formable angle-stable reconstruction plate. Furthermore, the low compression between the bone tissue and the angle-stable bone plate accelerates the blood circulation of the healing process.

3 Indications

3.1 General indications

- *Deformity correction*
- *Bone deformities*
- *Arthrodesis*
- *Open fracture fixation*
- *Post-traumatic joint contracture*
- *Periprosthetic fractures*
- *Periarticular fractures*
- *Pathological fractures*
- *Fractures with vascular and nerve injuries*
- *Fractures with compartment syndrome*
- *Open fractures*
- *Corrective osteotomies*
- *multifragmentary shaft fractures*

3.2 Product-specific indications

T-plates, radius plates	- *Fixation of complex intra- and extra-articular fractures* - *Fractures of the distal radius and other small bones* - *distal radius fracture*
Reconstruction plates	- *Fractures in the pelvic and hip area* - *Fractures of the distal humerus, clavicle or calcaneus*
Third tube plates	- *Fractures of smaller bones such as fibula, humerus, ulna.*
Humerus plate, distal and proximal	- *Fractures of the distal, proximal humerus*
Clavicula plate	- *Clavicle fractures*
Olekranon plate	- *Fractures of smaller bones such as olekranon and ulna*
Tibia plate, distal, proximal	- *Fractures of the tibia, the tibias*
Tibial L-plate / T-plate	- *proximal, distal tibial fractures* - *metaphysis fractures* - *intraarticular fractures* - *periprostine fractures* - *proximal humeral fractures* - *Corrective osteotomy*
Metaphysisal plate	- *extra-articular fractures of the metaphyseal area, which can extend into the shaft area* - *Fractures of the distal tibia, distal / proximal humerus, distal fibula*
Fibula plate	- *Fractures of the fibula, the fibula detention*

Calcaneus plate	- *Calcaneal fractures*
DHS/DCS Plate	- *Femoral neck fractures* - *supracondylar fractures*
straight plate	- *Fractures of smaller bones such as ulna, radius and humerus* - *Fractures of larger bones such as humerus, tibia, femur* - *periprosthetic fractures*
Femur plate	- *Supporting multi-fragment fractures*

4 Contraindication

Warning:
Before the fracture supply with bone plates, the following contraindications should be observed:
•Insufficient bone substance (e.B. severe osteoarthritis)
•patients with metal allergies or hypersensitivity reactions
•patients with circulatory disorders and coagulation disorders
•Large physical and severe vibration activities in which the implants are subjected to blows and/or excessive stress (e.B. heavy physical work, etc.).
•patient who is mentally unable to understand and follow the doctor's instructions
•patient with acute chronic infection
•wound healing disorders caused by type 2 diabetes mellitus (macroangiopathy)

5 Complications / Side effects

- *delayed or absent healing of the fracture*
- *Deformity*
- *Bone infections*
- *considerable, sometimes permanent movement restrictions of adjacent joints*
- *Pain or discomfort due to the insertion of the implant (angle-stable bone plates and bone screws)*
- *Primary as well as secondary, superficial and/or deep infection / sepsis*
- *Hematomas and reduced wound healing*
- *Edema or swelling, possible compartment syndrome*
- *Allergic reactions to the implant material*
- *Clinical failure due to e.B incorrect assembly technique of angle-stable bone plates and screws with the consequence of fixation loss; Excessive movement at the fracture site: failure of angle-stable bone plates and screws*
- *Loosening or breaking of screws and bone plates, including unintentional injury to the patient or surgical staff by the pointed screw end*
- *Re-operation: one component or the entire device must be replaced*
- *Excessive surgical bleeding or muscle-tendon injury*
- *intrinsic risks associated with anesthesia*
- *Pseudarthrosis*
- *Fracture of the regenerated bone fracture or through a hole after metal removal (plates, screws)*
- *abnormal growth joint: development in patients who are not adult*
- *Loss of bone mass due to "stress shielding"*
- *Bone sequestration secondary: too fast drilling of the bone cortex, with heat build-up and bone necrosis*
- *Thrombosis, thrombophlebitis, pulmonary embolism, bruising and nonvascular necrosis*
- *In case of insufficient fusion of the fracture, a loss of anatomical layers may occur*
- *Penetration of the screws through the bone (usually in conjunction with osteoporotic bone).*
- *Penetration of the screw through the joint (usually in connection with small-angle plates or an impairment of the sliding of the screw as well as unsuitable plate fixation)*
- *Injuries to the growth joints due to trauma during surgery or as a result of the length or location of a bone screw.*

6 Conditions that can affect the success of the operation

- *Of utmost importance is the correct selection of implant components - the corresponding implant type as well as the size. Implants must be adapted to the individual patient. The use of the largest possible implant as well as the correct positioning prevent the bending, breaking, cracking and loosening of the implant.*
- *Care must be taken to ensure that the forces to be transmitted by the implants are kept low by appropriate choice of biomechanics.*
- *In the case of fractures and osteotomies, the implants are exposed to increased loads. The period with only very little load until the fracture grows together stably must be chosen for a sufficiently long time.*
- *In some fractures and osteotomies, the implants are exposed to particularly high loads, as the muscle forces do not act evenly, so the chance of healing is greatly reduced by bending or even breaking implants. Additional precautions as well as internal and external support agents are required to increase the stability of the fracture and to reduce the load on the implant to a minimum until a solid fusion of the fracture is determined by X-ray examinations.*
- *The thread of the bone screw must not come to rest in the fracture line. The correct selection of the screw length is important because the screws must be completely fixed in the bone in order to allow telescopic movement in the event of resorption of the fracture surface.*
- *Only implants made of the same systems and the same materials may be used together. (see surgical techniques)*
- *The implants must not come into contact with objects that could damage their surface. They may not be mechanically processed or altered in any other way, unless the design and surgical technique expressly provide for this.*
- *Surgical technique: The rules of art and science as well as scientific publications are decisive. A surgical description can never be complete and may include all the risks and complications to be considered. Information regarding the surgical technique is available on request. During the procedure, the surgeon must familiarize himself with the implants, instruments and corresponding techniques.*

7 Postoperative follow-up inspection

- *Postoperative instructions to patients as well as proper nursing care are of great importance, an earlier weight load increases the stress on the implant and can lead to breakage, bending or loosening. Early loading may be considered if there is a stable fracture with good bone-bone contact.*
- *The final decision to remove the implant is made by the surgeon. The implants should be removed when they are no longer needed as an aid to healing and such a step is possible and practical for the patient.*

8 Duration of use

The duration of use is limited to a maximum of two years.

9 Preparation

Preparation according to DIN EN ISO 17664
The implants and instruments are delivered sterile and must be prepared (cleaned, disinfected, repackaged) and sterilized before use. When unpacking the implant, it is identical to the name on the packaging (Art. No. / LOT # and size). The packaging used by is a transport packaging.Digimed Medizintechnik
The preparation may only be carried out by medical professionals. The machine preparation must be qualified and validated by the user. The cleaning and disinfection tomatoes must fully meet the requirements of DIN 15883-1. The bone plates may only be processed and sterilized once!
The bone plates are not recyclable!

9.1 Cleaning and disinfection: MANUAL PREPARATION NOT POSSIBLE!

The manual preparation of bone plates is not possible!

9.2 Cleaning and disinfection: Mechanical treatment

With regard to the responsibilities for the professional cleaning and disinfection of the manufacturer's implants lie with the operator and product user. The country-specific guidelines must be observed. The aseptic regulations for the respective country-specific guidelines must also be observed Digimed Medizintechnik.

The following information must be observed:

- *The cleaning and disinfection medium used must be applicable for the cleaning/disinfection of implants made of high-alloy steel as well as titanium alloys and pure titanium, which is non-foaming, plasicitrating (highly alkaline). Only approved cleaning and disinfection media according to (RKI, FDA DGHM, DGSV, DGKH) may be used.*
- *In order to be able to prepare the implants optimally, the receptacle or implants should be placed in such a way that the holes, threaded holes, clamping sliding holes can be completely and thoroughly rinsed.*
- *The manufacturer' preparation and sterilization validation is carried out individually packaged and not in trays!*
- *The instructions of the plant manufacturer with regard to mechanical processing must be observed.*
- *Loading of the receiving baskets or plunge pool screens of the processing machine shall be carried out in accordance with the manufacturer's instructions.*
- *Mechanical treatment may only be carried out with fully desalinated water (demineralized water) in accordance with EN 285 Annex B*
- *Cold water specification corresponds to the drinking water supply (TrinkwV of 20.12.2019)*

Step 1: 1. Pre-rinse with cold water
Time: 2 minutes Temperature: 18 to 21°C

Step 2: 2. Pre-rinse with cold water
Time: 4 minutes Temperature: 18 to 21°C

Step 3: Cleaning with 0.5% alkaline cleaner
Time: 5 minutes Temperature: 55 to 58°C Medium: 0.5% alkal. Cleaner Neodisher®

Step 4: Neutralization with 0.1% neutralizer
Time: 3 minutes Temperature: 38 to 40°C Medium: 0.1% neutralizer

Step 5: Rinse with demineralised water
Time: 2 x 2 minutes Temperature: 40 to 45°C Medium: DEM- Water

With intermediate emptying

Step 6: Final rinse with demineralized water and thermal disinfection
Time: 5 minutes Temperature: 90 to 95°C Medium: DEM- Water

Disinfection: (Mechanical treatment)

- *The disinfection of the mechanical treatment is carried out with regard to the A0 value (ISO 15883- 1+2) and consideration of the national requirements.*
- *A0= 3000 value = 90°C temperature at 5 minutes holding time*
- *(worstcase validation performed at 55°C at 5 minutes holding time)*
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Step 7: Drying
Time: 20 to 30 minutes Temperature: 80 to 85°C
(worst case validation performed at 60°C at 30-35 minutes)

9.3 Packaging according to DIN EN ISO 11607-1

Sort the cleaned and disinfected implants individually and pack them in disposable sterilization packaging (single packaging) that meets the following requirements:

- *According to DIN EN ISO 11607-1*
- *Suitable for steam sterilization (temperature resistance up to at least 137°C (279°F), sufficient vapor permeability)*
- *Sufficient protection of implants or sterilization packaging against mechanical damage*

9.4 Sterilisation

As a recommended sterilization method, the "steam sterilization with saturated steam with fractional vacuum" is carried out in accordance with EN ISO 13060 and DIN EN ISO 17665-1 as well as taking into account the country-specific requirements.

- *There must be 3 pre-vacuum phases with at least 65 millibar pressure,*
- *A sterilization temperature of at least 134°C (maximum 138°C).*
- *Holding time of at least 5 minutes (max. 10 minutes)*
- *The drying time must be at least 10 minutes (maximum 15 minutes)*

10 Storage and treatment of bone plate implants

Implants are extremely sensitive to damage. Even small scratches or impact dents can cause internal tensions, which greatly reduce the strength. Extremely careful treatment is therefore indicated.

- *Implants must be stored unopened in their original packaging;*
- *Protective caps may only be removed immediately before use;*
- *For selection and implantation, only the specific surgical instruments are*
- *and to use;*
- *Implants must not be labelled or come into contact with metallic or other hard objects (e.B table top). If this is the case, such components may not be implanted. They must be returned to the supplier for inspection;*
- *Implants may not be mechanically processed or otherwise altered, unless construction and surgical technique expressly provide for this. In case of doubt, a*
- *obtain a written recommendation from the manufacturer;*
- *Under no circumstances should implant: Implants that are obviously damaged, scratched, improperly treated or unauthorised. As well as implants that have already been used once*
- *have been used.*
- *The implant packaging delivered by is a transport packaging, which is not approved for sterilization!Digimed Medizintechnik*
- *After sterilization, the sterile packaging must be checked for damage.*
- *Sterilization by means of hot air procedures must not be used.*

11 Disposal

After successful disinfection, defective or explanted implants must be disposed of professionally. The legal country-specific disposal guidelines are for medical devices.

12 Medical staff

The user group is limited to trained specialists who have already received instruction on the application, handling and handling of the bone plates. Furthermore, the respective user must ensure before use that he has carefully read and understood the instructions and also takes them into account.

13 Accessories

In the table below you can see the compatibility between the bone plates and bone screws.

Bone plate:	*Compatible with:*
DCS Supracondylar Plates 95° *DHS plates 135°*	*DHS Pull Screw* *DHS Compression Screw* *4.5 mm Titanium Kortical Screw*
5.0 mm Narrow plate *5.0 mm wide plate* *5.0 mm wide plate ws curved* *Distal Buttress Femur Plate* *T-plate angle stable* *Prox.Tibia plate lateral* *Prox.Tibia plate medial* *Distal Tibia Plate* *Prox.Tibia plate posteromed* *Distal Femur Plate* *5.0 MM Metaphyseal Plate*	*5.0 MM locking screw self-tapping* - *Standard* - *PolyAXIAL* *4.5 mm Titanium Kortical Screw*
3.5 MM Tibia plate distal medial *3.5 mm metaphyseal plate straight* *3.5 MM Tibia plate distal anterolateral* *3.5 mm fibula plate distal* *3.5 MM Clavikula Hook Plate* *3.5 MM Humerus Plate Proximal*	*4.0 mm Spongiosa screw* *3.5 MM locking screw self-tapping* - *Standard* - *PolyAXIAL* *3.7 MM locking screw* - *Standard* - *PolyAXIAL* *2.7 MM locking screw self-tapping* - *Standard* - *PolyAXIAL*
3.5 MM T-plate *3.5 MM T-plate 90°* *3.5 MM radius plate volar* *3.5 MM Radius Plate* *3.5 MM Narrow plate* *3.5 MM reconstruction plate combination holes* *3.5 MM reconstruction plate bent* *3.5 MM third tube plate* *3.5 mm Calcaneus plate type B*	*3.5 mm kortical screw self-tapping* *3.5 MM locking screw ss* - *Standard* - *PolyAXIAL* *3.7 MM locking screw SS; PA* *3.5 mm kortical screw ss* *4.0 mm Spongiosa screw* *3.5 mm kortical screw self-tapping*

3.5 MM Humerus Plate Proximal	*3.5 MM locking screw self-tapping* - *Standard* - *PolyAXIAL* *3.7 MM locking screw self-tapping, polyaxial* *3.5 mm Kortikalis screw ss* *4.0 mm Spongiosa screw*
3.5 MM reconstruction plate	*3.5 MM locking screw self-tapping* - *Standard* - *PolyAXIAL* *3.7 MM locking screw self-tapping, polyaxial* *2.7 MM locking screw self-tapping* - *Standard* - *PolyAXIAL*

14 SYMBOL EXPLANATIONS

The CE marking with notified body identification number applies exclusively to implantable devices. The conformity assessment procedure for the insertion instruments (screwdrivers, bending pliers, etc.) was carried out under sole responsibility. These instruments shall be marked with CE without the notified body identification number.


Manufacturer


Follow the instructions for use

Unsterile

CE marking with notified body number


Do not reuse

Batch description


Attention

Order number