STEMA Medizintechnik GmbH

Bone Screws / Bone Plates

Instruction for Use

LEGAL DISCLAIMER

The products referenced herein are part of a comprehensive treatment concept and may only used in combination with the associated original products in accordance with the instructions and recommendations of STEMA Medizintechnik Due to not rec-ommended use of third-party products in combination with prod-ucts of STEMA Medizintechnik the warranty is expired and any other explicit or implied obligation of STEMA Medizintechnik will be declared void. The user of STEMA Medizintechnik products must determine whether the product is suitable for a particular patient under the given circumstances. STEMA Medizintechnik does not assume any liability neither express nor implied for di-rect or indirect damage, compensation for damages or any other damages caused by or in connection with errors in professional assessments or practice when using STEMA Medizintechnik prod-ucts. The user is also obliged to keep himself informed regarding the latest developments referring STEMA Medizintechnik prod-ucts and their application. In case of doubt STEMA Medizintech-nik must be consulted. The correct use of the products is the re-sponsibility of the user. STEMA Medizintechnik assumes no liabil-ity regarding damages resulting from the use of the product. We would like to point out that some of the products referenced in this instructions for use may not be licensed or approved for sale in all markets.

SOCPE OF APPLICATION OF THE INSTRUCTIONS FOR USE

This instructions for use is valid for bone screws and bone plates as well as the associated accessories, which will be introduced onto the market by STEMA Medizintechnik. A detailed list of all components can be viewed on the homepage (www.stema- mediz-intechnik.de) or in the product catalogue.

DESCRIPTION

Bone screws / - plates must only be incorpo-rated by experienced surgeons and oral-, maxil-lofacial and facial surgeons who have acquired the necessary knowledge through literature study as well as theoretical and practical training in the field of implantology. Therefore the choice of indication, the determination of a contraindication and the risk assessment are fundamentally subjected to the surgeon. These explanations are only to be viewed as guidelines and do not replace the implantological knowledge of the surgeon.

Bone Plates

The bone plates are implantable plates made of titanium which are fixed with screws to small fractured bone stumps in order to bridge and stabilize a traumarelated fracture cleft and to protect against exposure during the bone healing / reconstruction.

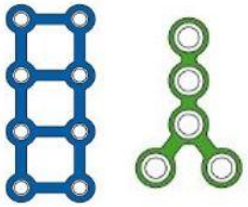

Figure 1: Extract from the product portfolio of bone plates

Bone Screws

The bone screws are small, non-sterile grub screws with head of titanium for orthopedic fixation of small, internal bone fractures, which are screwed into the bone, in order to anchor the bone plates to stabilize the small bone framents directly against one an-other or to attach the soft tissue to the bone.

Figure 2: Extract from the product portfolio of bone screws

Tools

The tools are to be used in conjunction with the bone screws and -plates to prepare the fixation sites, to adapt the bone plates and fix them with bone screws. The tools include drills, pliers, tweezers, screwdrivers and depth gauges.

Figure 3: Extract from product portfolio of tools (left depth gauge, middle pliers and right screwdriver)

Accessories

The accessories are used for storage, transport within the hospital, for sterilization and for making the instruments / tools available during and after surgical procedure.

4 Figure : Extract from the accessories product portfolio (surgery tray)

INTENDED USE

Bone Plates

Bone Plates are intended for the internal fixation of small bone fragments, which were damaged by trauma or require a reconstruction. The deformable drill hole cover plates are designed to cover trephination holes and to re-fix bony lid during intracranial operations.

Bone Screws

Bone screws are used to fix the bone plates in their final position and to fix small bone fragments.

Tools

The screwdrivers are adapted tools, which fit on the screw heads and with which a bone screw can be tightened / loosened / unscrewed by rotation during surigcal porcedures.

The depth gauge is used for precise determination of the length of the drilled cavity to determine, inter alia, the length of the bone screw.

The drills are used to mount a notch or to widen a pre-drilled hole in a bone, so that a bone srew can be screwed in.

The pliers serve as a surcial bending and cutting hand instrument for the correct adjustment of the bone plates.

Accessories

The containers are used to hold the surgical tools during sterilization and subsequent storage.

INDICATION

Bone implants are subject to various mechanical stresses during use. Depending on the indication, the bone implants must also take up a function of the repositioned fracture / osteotomy. Specially if used in maxillofacial surgery the implants are subjected to high loads. For these reasons the implnat system, consisting of bone plate (s) and bone screw (s) must be selected according to the clinic. The various systems show different indications. The decision for the indciated implant system is in the responsibility of the treating surgeon respectively the oral- and maxillofacial surgeon.

Micro System, Titanium, 1.2 mm

The Micro System is designed for use with the following indications:

- neurosurigical fractures of the frontal and maxillary oral sinus
- preprosthetic surgery;
- pediatric surgery.

Medium System, Titanium, 1.6 mm

The Medium System is designed for use with fhe following indications:

- craniotomy and surgery;
- pediatric neurosurgery;
- skull base defects;
- neurotrauma;
- midface trauma;
- fractures of the frontal and maxillary sinuses in the naso and infraorbital regions;
- fixation of bone grafts, individual implants and distractors.

Mini System, Titanium, 2.0 mm

The Mini System is designed for use with the following indications:

- midface trauma;
- mandibular fractures;
- fixation of bone transplants.

Mandibular Fracture System, Titanium, 2.3 mm

The Mandibular Fracture System is designed for use with the following indications:

- fractures of atrophic jaws;
- unstable oblique, jaw angles and defective fractures;
- mandibular reconstruction with non-vascular bone grafts (primary reconstruction).

Mandibular Reconstruction System, Titanium, 2.7 mm

The Mandibular Reconstruction System is designed for use with the following indications:

- mandibular reconstruction with vascularized and non-vascularized bone transplants;
- bridging of continuity defects.

CONTRAINDICATION

No use outside of facial (craniomaxillofacial) and hand surgery.
Auto-pilot screws shouldn’t be used for very small and thin bone fragments, as these fragments may shift due to the axial pressure during the insertion.
Osteoporosis, missing revascularization, bone resorption or poor new bone formation can lead to loosening, bending or fracturing of the implant or the premature loss of fixation with the bone so that the bone does not grow together.

Informationen about the product

Precautions when using bone plates

Due to the cold deformation that takes place during the bending process the hardness of titanium increases and the bendability decreases. Therefore it is vital, that the requested shape of the implant is achieved with as few bending maneuvers as possible. Excessive bending may lead to a plate breakage postooperatively. The interaction between extreme angles and small bending radii must be avoided, as there is a risk, that microscopically visible damage occurs to the implant postoperatively. (Cracks, deformed screw holes, etc.) In these cases the implant must be replaced by a new one that has been bent with the utmost caution.

Deformed screw holes not ony mean an increased risk of the implant breaking in this area, they also affect precise placement of the screw head in the plate.

The shortened bone plate segment should be deburred after cutting, to avoid injury or irritation of the soft tissue.

Precautions to be taken when using deformable wellbore cover plates.

The deformable borehole cover plates are provided with a positioning aid, which must be removed before the surgical site is closed. The positioning aid is not intended for implantation.

The deformable borehole cover plates can be manually shaped into the required form, i.e. without bending instruments.

Precautions when using bone screws

Auto-Pilot screws are self-drilling, so there is no need to use a drill prior to inserting the screw. These exceptions include (but not exclusively) the drilling into the dense cranial bone. In these cases it may be necessary to use a drill. Square-Fit screws are self-tapping, so that the application of a thread cutter prior to insertion is not needed.

Regardless of the mounting gemoetry of the screw head (slot, cross slot, square, hexagon, etc.) it must be ensured that the connection screwdriver / screw head is exactly vertically aligned. Otherwise there is an increased risk of damage due to meachanical action for the implant and screwdriver.

When inserting the bone screw, the screwdriver must be sunk with sufficient axial pressure. This ensures axial alignment and a good contact between the screwdriver and screw.

In the final phase of the screw insertion the underside of the screw head is in contact with the bone or with the imaginary recess in the plate intended for the srew head. At this moment a significant in-crease in resistance can be felt. The screw must now be tightened carefully to avoid the risk of mechanical damage of the screw, screwdriver or drill hole in the bone.

If the self-drilling Auto-Pilot screws are difficult to insert into the bone, insertion can be facilitated by drilling a pilot hole.

Possible Complications

Possible complications are in most cases not directly related to the application of the implant but rather influenced by the wrong selection of the patient caused by inadequate training as well as by imprecise fracture reduction and implant placement.

1. Osteoporosis, missing revascularization, bone resorption or poor bone formation may cause loosening, bending or fracturing of the implants or lead to premature fixation loss with the bone so that the bone does not grow together.

2. Due to an insufficient adaptation of the implant, the bone fragments in the fracture area are possibly delayed, insufficient or not at all comined.

3. Increased connective tissue reaction in the fracture area due to unstable fractures.

4. Early or late deep- and/or surface infection.

5. As a result of surgical procedure nerve damage is possible.

6. Hypersensitivity to metals after the surgical insertion of the implant has become known in extremely rare cases.

WARNINGS

The treating surgeon bears the responsibility for the correct selection of the patients, the required training and experience in the selection and placement of implants as well as in the decision to leave implants postoperatively or to remove them again. The surgeon should discuss extensively the expected operative result with the patient in particluar with regard to possible physical limitations of the product. Particular attentions should be paid to the postoperative consultation and the need for regular medical controls. The correct selection of the product is extremely important. The product must be implanted in the correct anatomical position in accordance with the recognised standards for internal fixation. Errors in the selection of the implant may lead to premature implant failure. The use of the right component enables a sufficient blood supply and results in a stable fixation, whereas a wrong decision can lead to loosening, bending or fracturing of the implant and/or bone. The product must be carefully handled and stored. Damage or scrathes on the implant may siginficantly impair the strength and fatigue resistance of the product. After having used the product once, it must not be reused. Even if the product appears to be undamaged, previous loads may have led to irregularities that shorten the life of the product. The patient should be instructed to inform his surgeon immediately of any unusual changes in the surgery area. The patient should be monitored permanently if there is a change in the fixation area noticed. The surgeon should evaluate the possibility of a resulting clinical implant failure and discuss with the patient the necessary measures that contribute to further healing. The implants are intended to perform their func-tion only until the bone has healed (usually 6-10 weeks). A delayed healing phase, a failure of the bone connection or subsequent bone resorption or trauma may overload the implant and lead to loosening, bending or fracturing of the implant. In more spongy bones do no further rotation is allowed after reaching the desired truning depth.

There is a risk that the thread cut into the bone will be overturned and the primary stability will suffer.

General

There is no 100% guarantee of success for implants. Failure to comply with the stated limitations of use and work steps can lead to malfunctions.

The insertion of implants can cause bone loss as well as biological or mechancial failure, for example fatigue fracture of the implant.

Due to imporper procedure, damage to the implant or bone loss may occur. The bone plates and -screws must only be used by surgeons trained with the system (maxillofacial) surgery, as the applications requires special knowledge and skills.

The components of the system are only given to (oral and maxillofacial) surgeons or on their behalf. This is to ensure that the special knowledge is available to enable safe application.

Regarding insertion only tools of STEMA Medizintechnik must be used. The use of thrid-party components and instruments can impair the function and security of the system. When using third-party components, no guarantee and no replacement is provided.

The instruments are intended for specific bone plates and screws. The association is indicated by colour markings (Table 1). Use for other implants or other diameters may lead to mechanical failure of system components, tissue damage or unsatisfactory aesthetic results.

Table 1: Colour coding of the system

Colour	System
blue	MICRO SYSTEM, TITANIUM, 1.2 MM
red	MANDIBULAR FRACTURE SYSTEM, TITANIUM, 2.3 MM
green	MEDIUM SYSTEM, TITANIUM, 1.6 MM
yellow	MINI SYSTEM, TITANIUM, 2.0 MM
	MANDIBULAR RECONSTRUCTION SYSTEM, TITANIUM, 2.7 MM

Prior to Surgery

Prior to the surgical procedure, a careful patial tenanamnese must be taken and if necessary a third-party anamnesis can be taken by the family physician to clarify whether,

a) an aggravated implantation due to the anatomic situation,
b) a serious surgical problem or general risk, or,
c) an impaired wound healing and/or osseointegration could occur.

During the Surgery

All instruments and devices used during the procedure must be in good condition, and it must be ensured that the implants or other components are not damaged by the instrument.

After the implant has been inserted the surgeon's assessment of bone quality and primaary stability decides when the implant can be loaded.

Should a fracture of the implant occurs during insertion due to an excessive load on the material, it must be removed again.

After the Surgery

To ensure an optimal treatment result regular comprehensive follow-up appointments should be arranged with the patient and the patient should be informed about the avoidance of high physical stress.

SURGICAL PROCEDURE

At every stage make sure that the sterility of the product and the sterile respectively sterilized product components are not impaired.

Operation

Placement and Fixation

After exposing the implantation site, the drilling hole cover plate must be gripped on the positioning aid placed above the prepared trephination site and attached loosely with a screw to the planned bone cover. The cover plate is turned to the side to create space for osteotomy. The bone cover shall be drilled out and lifted. Upon completion of the cranial surgery the bone lid has to be reposi-tioned and the cover plate has to be rotated to the final position. It is attached with further screws. The positioning aid is removed only after the cover plate has been completely fixed.

SUTURE CLOSURE

Subsequently, a tension-free seam closure is guided through, which is removed after 10-14 days. The final decision on the removal of suture closure is in the responsibility of the treating surgeon and must be made on the basis of the expertise and the individually assessed condition of the suture and the entire patient. If a suture dehiscence occurs, a surgical revison must be carried out promptly.

MATERIALS

Table 2 shows the materials of the individual system parts.

Table 2: Materials of the individual system parts

System Part	Material
bone plates	Titan Grade 2
bone screws	Titan Grade 5 (Ti6Al4V-Eli)
screwdrivers	Stahl (1.4021)
depth gauges	Stahl (1.4021)
drills	Stahl (1.4021)
pliers	Stahl (1.4021)

CLEANING AND STERILIZING INSTRUCTIONS

All products according to table 1 are delivered non-sterile and must be cleaned and sterilised before use. The reprocessing steps can be found in the reprocessing instructions for the accessories and the bone screws and plates (on the following pages).

Warning: The bone plates and – screws are only intended for single use and must not be reprocessed after use.

MRI-SAFETY INFORMATION

The product bone screws / -plates have not been tested regarding safety and compatability in MR environment. It has not been tested for warming, migration or image artifacts. The safety of the MR environment is therefore unknown. Scanning a patient with this product may injure the patient.

According to current available scientific literature, it can be expected, that titanium as material reflects the state-of- the-art. Furthermore current findings suggest that only marginally effects are expected. The individual decision regarding application of the magnetic resonance examination is however the responsibility of the radiologist.

HANDLING AND STORAGE

The product must be stored in a dry place in the original packaging. Improper storage may influence the product feature and lead to failure of the supply. .

DISPOSAL

The disposal of these products must be carried out in accord-ance with the local applicable regulations and environmental regulations. Each contamination level has to be considered.

Reprocessing for the Accessories of Bone Srews and Bone Plates

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SOCPE OF APPLICATION OF THE INSTRUCTIONS FOR USE

This instruction for use is valid for all instruments and implants of STEMA Medizintechnik with regard to the bone screws and -plates, which may be reprocessed (reusable instruments) according to their intended use and labeling.

SAFETY INSTRUCTIONS

For reasons of hygiene and health protection all reusable medical devices sold by STEMA Medizintechnik must be cleaned, disinfected and sterilized before/after each use on the patient. This applies also to the initial use after receipt of the product which are delivered non-sterile and must be sterilized.

The health regulations of the individual national and international legal provisions of dental-/medical practices, the hospitals and the dental laboratories must be observed.

For cleaning, disinfection and sterilization only devices may be used which show a validated method. The following parameters for clean-ing and sterilization must be strictly adhered to as they have been subjected to a validated process. In implementing the reprocessing with different parameters, the cleanliness of the product cannot be guaranteed.

CLEANING AND STERILIZING INSTRUCTIONS

Eeach reprocessing must be carried out by trained personnel in a room specially equipped for this purpose (with a clean and unclean zone)

Successful sterilization is preceded by efficient cleaning and disinfec-tion. Before / after each use on the patient the instruments must be cleaned, disinfected and sterilized. Contaminated/used instruments must be separated from the (still) clean instruments.

Dirty/used instruments must be separated from the (still) clean instruments during use. These are not to be put back into the tray. After successful cleaning and disinfection, the instruments are put back into the tray and then sterilised as a set.

Manual pre-cleaning

1. Place immediately after use all components to be cleaned in a liquid instrument cleaner for 30 minutes (e.g. INSTRU PLUS liquid cleaner for instruments and endoscopes from Dr. Schuhmacher, concnetration 5mg/L). If the components can be dismanteled, they must be disassembled into their individual parts beforehand.
2. Remove any ohter visible residues with a Nylon instrument brush. Cavities, penetrations and constrictions must be treated twice.
3. Rinse all components under cold, running water (drinking water quality).
4. Visual inspections of the purity of all parts. Magnifying glasses can be used as a support.

Repeat steps 1 to 4 if residues are still visible on the components.

Mechanical cleaning and disinfection

1. Place all components in an appropriately approved (small) parts holder in the washer-disinfector (according to ISO 15883). Previously disassembled components must be reassembled.

All products must be arranged so that they can be directly hit by the spray.

2. The cleaning and desinfection must be started using the Vario TD programme and a cleaning agent for mechanical cleaning (e.g. neodisher MediClean Dental von Dr. Weigert) Other cleaning programmes are not covered as part of the validation.
3. Dry the instruments with compressed air. Pay attention to hard-to reach areas such as e.g feedthroughs.

4. Visual inspection of purity and integrity of all components. Magnifiying glasses can be addes for support.

Repeat steps 1 to 4 if residues are still visible on the components.

Packaging and Sterilisation

All non-sterile components must not be sterilised in their original packaging.

1. Assemble the tray with the appropriate components and close it.
2. The tray (if applicable, the individual components that are not to be sorted into the tray) is packed in a sterile bag according to ISO 11607-1 and sealed with a sealing machine.

Make sure that the products in the sterile bag are not under tension. This could lead to damage to the sterile barrier and thus to loss of sterility.

3. Sterilisation is carried out with a class B small steam steriliser with fractional pre-vacuum in accordance with ISO 13060. Sterilisation parameters other than those mentioned below are not covered by the validation. Therefore, no guarantee can be given that the status "sterile" will be achieved.

Temperature	Pressure	Holding time	Drying time
134°C ± 1%	3 Bar ± 5%	≥ 3 Min.	≥ 5 Min.

4. The labeling of the prepared, packaged components must contain the following information:
   - ***a.*** designation of the product(s), if not recognisable plus size information
   - ***b.*** deails of the release
   - ***c.*** release decision
   - ***d.*** sterilisation cyle and sterilisation date
   - ***e.*** expiry date and sterile storage period

It is recommended that sterilisation is carried out before use on the patient.

DISPOSAL

Products that show a loss of function and/ or corrosion spots must be immediately withdrawn from use and not longer used on patients.

Defective products must be disposed of in accordance with the local regulations and environmental requirements, taking into account the level of contamination.

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EXPLANATION OF SYMBOPLS

Do not reuse

Attention: observe accompanying documents

Observe instructions for use

Batch-Code (see protective packaging)

Item number (see protective packaging)

Quanity (piece) (see protective packaging)

CE-mark for class IIb products

CE-mark for class I prodcuts

non-sterile

STEMA IFU Bone Srews / -Plates
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