# ⚠Instructions for use

**for titanium bone implants**

**REF 12-xxx-xx/16-xxx-xx/20-xxx-xx/23-xxx-xx 27-xxx-xx**

**1. General**

**Please print out these instructions for use and keep them in a safe place for future reference.**
**Ensure that you always have the latest version of these instructions for use. You can find the latest versions on our website at https://g-imp.de/IFU**

**1.1 ADVERSE EVENTS**

**Report adverse events, such as malfunctions/patient injuries, immediately to your competent authority and to General Implants GmbH in accordance with the country-specific requirements. To report to General Implants GmbH, Germany, please use our website at:**
**https://general-implants.com/ccn/**
**Please also use this link if you have a complaint about one of our products.**

**2. Product description:**

**Plate–screw system 1.2 (profile height 0.6 mm):**

| Plate (Titanium Grade 2): | **Screw (Titanium Grade 5):** |
|---|---|
| • Mesh<br>• Triangular plate<br>• Double T<br>• Double Y<br>• Straight plate<br>• H plate<br>• T plate (wide and narrow)<br>• Y plate<br>• L plate<br>• Orbital<br>• Rectangular plate | Self-drilling: Thread 1.2 / Head 1.8 4-13 mm<br>Self-tapping: Thread 1.2 / Head 1.8 2-13 mm<br>Emergency self-drilling: Thread 1.4 / 3-9 mm |

Plate-screw system 1.6 (profile height 0.6 mm):

| Plate (Titanium Grade 2): | **Screw (Titanium Grade 5):** |
|---|---|
| • Mesh<br>• Bore hole plate<br>• Triangular plate<br>• Double T<br>• Double Y<br>• Straight plate<br>• Cross plate<br>• Neuro gap plates<br>• Neuro subtemporal plate<br>• Square plate<br>• T plate (wide and narrow)<br>• Y plate<br>• Z plate<br>• L plate<br>• Orbital<br>• Rectangular plate | Self-drilling, crossed slot, head diameter 3.50<br>Thread diameter 1.6, length 6-12 mm |
| | Self-drilling, crossed slot, OM head diameter 3.0, thread diameter 1.6, length 5 mm |
| | Self-drilling, standard crossed slot, Head diameter 2.55, thread diameter 1.6, length 3-15 mm |
| | Self-tapping, standard crossed slot Head diameter 2.55, thread diameter 1.6, length 3-15 mm |
| | Self-tapping, emergency crossed slot, head diameter 2.55, thread diameter 1.9 Length 3-9 mm |

Plate-screw system 2.0 (profile height 0.6-1.0 mm):

| **Plate (Titanium Grade 2):** | **Screw (Titanium Grade 5):** |
|---|---|
| • Mesh<br>• Bore hole plate<br>• Double T<br>• Double Y plate<br>• Straight plate<br>• L plate<br>• Orbital plate<br>• Rectangular plate<br>• T plate<br>• Y plate<br>• Double Y<br>• Z plate<br>• Cross plate<br>• Mandibular angle plate<br>• Mandibular plate | Self-drilling, crossed slot, thread diameter 2.0, length 8-14 mm |
| | Self-drilling, emergency crossed slot, thread diameter 2.3, length 5-11 mm |
| | Self-drilling, OM crossed slot, thread diameter 2.0, length 5-15 mm |
| | Self-drilling, standard crossed slot, thread diameter 2.0, length 4-17 mm |
| | Self-drilling, emergency crossed slot Thread diameter 2.3, length 5-7 mm |
| | Self-tapping, OM crossed slot, thread diameter 2.0, length 7-9 mm |
| | Self-tapping, standard crossed slot, thread diameter 2.0, length 4-21 mm |

Plate-screw system 2.3 (profile height 1.5mm):

| **Plate (Titanium Grade 2):** | **Screw (Titanium Grade 5):** |
|---|---|
| • C plate<br>• Straight plate<br>• Mandibular angle plate | Self-tapping<br>Emergency crossed slot<br>Thread diameter 2.7<br>Length 5-15 mm |
| | Self-tapping<br>Standard crossed slot<br>Thread diameter 2.3<br>Length 4-22 mm |

Plate-screw system 2.7 (profile height 2.3-2.8 mm):

| **Plate (Titanium Grade 2):** | **Screw (Titanium Grade 5):** |
|---|---|
| • Condylar implant with ball<br>• Straight plate<br>• Mandibular angle plate, one-sided<br>• Mandibular angle plate, two-sided | Self-tapping<br>Emergency crossed slot<br>Thread diameter 3.0<br>Head diameter 3.9-4.0<br>Length 9-13 mm |
| | Self-tapping<br>Standard hexagonal and crossed slot<br>Thread diameter 2.7<br>Length 7-21 mm |

Quick-Lock System

| **Quick Lock System (clamping plates ø 12 mm, ø 16 mm, or ø 20 mm)** | |
|---|---|
| • Threaded pin (Titan Grade 5)<br>• Clamping plate round (Titan Grade 2)<br>• Clamping plate with prongs (Titan Grade 2)<br>• Knob (Titan Grade 2)<br>• Threaded sleeve (Titan Grade 5) | Clamp fixation |

**3. Material:** The implants are manufactured with implant titanium, a highly biocompatible material that has been in use for many years. This material meets the rigorous requirements of DIN EN ISO 5832-2 and DIN EN ISO 5832-3.

**4. Imaging:**
The material provides for artifact-free reproduction of x-ray and computer tomography images. Rebstock implants are not compatible with magnetic resonance tomography (MRT).

**5. Mechanical properties:**
All Rebstock implants are characterized by both high strength as well as above-average elasticity, thus guaranteeing excellent results under static as well as dynamic stresses. The implants are able to be adapted to the anatomical conditions of the bone using bending instruments.

**6. Design:**
Based on the manufacturer's ergonomic design of the product, there is no risk of injury to the surgeon while installing the implant or to the patient while wearing the implant when applied properly by qualified personnel.

**7.Intended use**
The Rebstock Mini Plate System are craniomaxillofacial (CMF) plate and screw systems for osteotomy, stabilization and rigid fixation in fractures and reconstructions.

**8.Indication:**

**Implants for CMF:**

Plate-screw system 1.2:
- Neurosurgical fractures of the frontal and maxillary sinus
- Oral and preprosthetic surgery
- Pediatric surgery

Plate-screw system 1.6:
- Craniotomy, cranioplasty
- Pediatric neurosurgery
- Cranial base defects and neurotrauma
- Midfacial trauma
- Fractures of the frontal and maxillary sinus, in the naso- and infra-orbital region
- Fixation of bone grafts, individual implants, and distractors

Plate-screw system 2.0:
- Midfacial trauma
- Mandibular fracture
- Fixation of bone grafts

Plate-screw system 2.3:
- Fractures of atrophic maxilla
- Unstable oblique and mandibular angle fractures and fractures with loss of bone substance
- Mandibular reconstruction with non-vascularized bone grafts (primary reconstruction)

Plate-screw system 2.7:
- Mandibular reconstruction with vascularized and non-vascularized bone grafts
- Bridging of continuity defects

Quick Lock System:
- Fixation of cranial bone flaps
- Fixation of cranial fractures

**8. Contraindication**

**Implants for CMF:**
- Non-removable and unstable fractures (excluding reconstruction plates).
- Fractures of a severe atrophic bone.
- Patients with manifest infection.
- Patients with metal allergy and foreign body hypersensitivity.
- Patients without adequate compliance who, due to their mental or neurological condition, are unwilling or unable to follow the follow-up instructions.
- Patients with impaired blood flow or insufficient bone quality or quantity.
- Patients with unstable physical and/or mental health

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**9. Potential adverse effects/complications**
In many cases, undesirable outcomes are not due to the implant, but instead due to the clinical circumstances:
- Implant loosening due to inadequate tightening of the screws.
- Pain, hypoesthesia
- Bending and breakage of the implant
- Osteonecrosis, osteoporosis, restricted revascularization, bone resorption and poor bone regeneration may result in the loosening, bending, cracking or breakage of the implant and premature loss of fixation to the bone, thus resulting in non-union.
- Non-union
- Malpositioning
- Limited mobility
- Connective tissue reactions due to unstable comminuted fracture
- Deep or superficial, early- or late-onset infection
- Nerve damage resulting from surgical trauma
- Metal hypersensitivity reactions
- Palpation of the implants
- Exposure of the implants
- Osteomyelitis

**9. Clinical Benefit**
The performance and safety of the investigated devices could be demonstrated based on the preclinical trials, evaluation of the PMS data and clinical standards. The devices to be evaluated are considered state of the art and are clinically established. Therefore, an acceptable device-related risk-benefit ratio is given.

https://ec.europa.eu/tools/eudamed
''This is the Summary of Safety and Clinical Performance (SSCP) location after the launch of European Database on Medical Devices/ Eudamed''

**11 General warnings** ⚠

- Implants are exclusively intended for single use. Single-use products are not permitted to be reused as they will no longer function as intended and designed following initial use.
- The treating surgeon is responsible for proper patient selection, necessary training, implant selection and insertion based on suitable experience, and postoperative decision-making concerning whether to leave an implant in place or remove it.
- Delayed or impaired bone healing, subsequent bone resorption or injury may cause excessive stress on the implant, thus resulting in loosening, bending, cracking or breakage.
- The surgeon should discuss with the patient in detail the surgical outcome to be expected with the use of this product. Special emphasis must be placed on postoperative factors, such as proper nutrition and the need for periodic follow-ups.
- The selection of the right product is extremely important. The device must be implanted at the correct anatomical position in accordance with the current, recognized osteosynthesis technique (AOCMF). The use of an unsuitable device for an application may result in premature clinical failure of the implant.
- The patient must be advised to notify the surgeon immediately concerning any unusual change at the surgical site. The patient must be closely monitored if any change is detected at the fixation site.
- The surgeon should consider the possibility of clinical implant failure and discuss with the patient the measures necessary to promote healing.
- Excessive movement or stress may place inordinate strain on implants, resulting in loosening, bending, splintering or breakage.
- Delayed healing, impaired bone healing, subsequent bone resorption or injury may cause excessive stress on the implant, thus resulting in loosening, bending, cracking or breakage. Patients must receive a diet of pureed foods following surgery.
- The treating surgeon must consider therapeutic alternatives to titanium implants in patients with identified risk of titanium intolerance.
- The device must be handled and stored with care. Damage or scratches on the implant may have considerable negative impacts on the strength and fatigue resistance of the device.
- ⚠ All implants must be inspected for damage or discoloration before each clinical use. Damaged (scratched, bent, cracked, fractured) implants must be disposed of in accordance with internal procedures.
- Monitoring of implant placement under radiological observation
- Hospital personnel must convey the following information to patients concerning activities to be avoided and precautions to be taken, including:
  - Avoiding extreme physical activity (e.g. extreme sports, such as boxing) until the bone has completely healed because such activity may result in implant failure.
  - The patient must seek medical advice when accessing potentially harmful environments (electromagnetic fields).
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**12. Notes** ⚠

Implants are only permitted to be applied with corresponding tools (Rebstock blades) specially intended for this use. Combining implants and tools from different manufacturers poses the risk of inadequate fixation and technical complications. Rebstock assumes no liability whatsoever in such cases. Markings (specification of the system number) guarantee the correct combination of plates and screws. Combinations across systems are not permitted.

***12.1 Implant plates***

The desired shape of the bone plates should be achieved with as few bending procedures as possible using the bending instruments provided for this purpose. Major and repeated reshaping of the implants must be avoided because this may result in material fatigue or even postoperative failure. Nicks and dents also considerably reduce mechanical strength. Damaged or deformed screw holes may also result in implant failure because it may not be possible to position the screw head correctly. All plate holes must be filled with screws. Plate holes over a fracture line are never permitted to be filled with screws. Wherever standard plates are unable to be used, alternative plates should be selected or specially manufactured plates should be used that meet the patient's needs.

***12.2 Implant screws***

Implant screws are self-tapping, unless otherwise specified. As a result, a thread cutter is normally not necessary. It must be ensured that screwdriver alignment is precisely vertical to the screw and that sufficient axial pressure is applied. Otherwise, an increase in mechanical stress may result or the screwdriver could potentially slip. Once there is a noticeable increase in resistance while screwing in the screw, greater caution must be taken when tightening it in order to prevent damage to the bone, implant or instruments.

Emergency screws should only be used if it is not possible to seat standard screws precisely when tightening them.

***12.3 Tools***

Plate cutting instruments are used to segment or shorten plates in the region of the bars. When cutting, it must be ensured that the segments are not flung out; as a result, do not cut toward the patient or other persons and consider draping the site while cutting. The plate segment to be used must be deburred after cutting in order to prevent friction damage to the tissue.
Drills/Drilling aids: Always use the shortest drill possible in order to ensure the best possible concentricity. Check to ensure that the drill port and drill are compatible. Always use a drill sleeve or similar and only work at speeds of <= 1000 rpm. Ensure adequate cooling with NaCl while drilling in order to minimize thermal stress on the bone. This is the only way to minimize the risk of bone demineralization. The manufacturer recommends using drills only once.
Depth gauge: Measurement of the screw length with the implant plate. The value displayed on the depth gauge corresponds to the screw length as specified on the package.



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***12.4 Implant removal***

According to the "Vereinigung Orthopädischer Implantathersteller" [an association of orthopedic implant manufacturers], the function of the implants ends with the conclusion of the healing process.
In principle, only the physician can decide whether and when an implant should be removed based on the stress that is expected to be exerted by the patient. However, the earliest an implant may be removed is after a clinically and radiologically acceptable outcome is established. At the start of metal removal, a sharp hook must be used to completely remove any tissue residues from the screw head. The screwdriver (Rebstock blade) must be selected based on the screw head. Insert the screwdriver as deeply as possible into the screw head along the axis of the screw shank. It may be possible to optimally seat the screwdriver in the screw by gently tapping the handle with a hammer, as necessary. Then manually turn the screwdriver counterclockwise while gently applying counter-pressure. If removal in this manner is not possible, then a metal removal set intended for this purpose must be used. The instructions in the metal removal set must be followed.

**13. Residual risk** ⚠

Rebstock provides no guarantee concerning whether its products are suitable for a certain procedure. **This is solely to be determined by a trained professional**. We assume no liability for any incidental or consequential damages. Rebstock also assumes no liability in proven cases where these instructions for use were not followed.

**14. as delivered**

The implants are supplied sterile or non-sterile. The sterile variants can be identified by an "S" in the article number. Respective symbols are also included in the labels.

| | Labeling | Article number |
|---|---|---|
| **Non-sterile implants** | NON STERILE | REF 50-30-XXX/50-31-XXX/50-32-XXX/50-33-XXX/50-34-XXX/50-35-XXX/50-36-XXX |
| **Sterile implants** | STERILE R | |

If you have purchased a non-sterile implant, please follow the instructions in chapter 13.1, including all sub-chapters.
If you have purchased a sterile implant, please follow the instructions in chapter 13.2, including all sub-chapters.

**14.1 Non-sterile implants** NON STERILE

***14.1.1 Notes and warnings***

⚠Before use, the implant must be removed from the original packaging and completely processed (cleaned, disinfected, sterilized) by qualified personnel.
In order to ensure complete traceability, the article number and lot number on the package label must always be tracked to the end use and documented in the operative report.
In order to prevent potential damage/distortions, handle implants carefully, do not bring them into contact with hard objects, and do not "drop" them improperly.

⚠Do not use damaged products.
Do not use cleaning agents containing chlorine or fluorine or corrosive disinfectants - risk of corrosion! Sterilization with chemical additives is not permitted. Contaminated implants must be disposed of properly and are not permitted to be reprocessed or sterilized.
When used as indicated, the system may become contaminated with unconventional transmissible agents, such as vCJD, especially through contact with lymphatic tissue. If contamination with
unconventional transmissible agents is suspected, Rebstock recommends the incineration of the affected products in accordance with proper disposal methods.

***14.1.2 Restrictions regarding reprocessing***.

⚠Implants are single-use products, i.e. intended to be used only once, and are not permitted to be reused following surgical removal. Dispose of used implants in accordance with hospital-waste disposal procedures. The reuse of implants may compromise the design and/or materials with potential negative impacts on safety, performance and/or conformity with the specifications in the accompanying documentation. Repeated processing and sterilization of products has no negative impacts on their performance or quality. Discolored products must be disposed of properly.

***14.3.3 Storage and transport***

Implants must be stored in their original packaging in a clean, dry place until they are processed. Take special care not to store them in the immediate vicinity of any chemicals. In order to ensure the safe use of the product, make sure that the outer packaging remains undamaged. Implants are also only permitted to be transported in the original packaging!

***14.1.4 Preparation for decontamination***

⚠Note: Implants are only permitted to be processed by suitably trained and skilled personnel who are able to assess any occurring risks with the corresponding impacts. Implants must be removed from the original packaging prior to cleaning.

***14.1.5 Reprocessing***

If automated reprocessing is an option, then automated reprocessing should be given priority over manual reprocessing because this is the best way to achieve a standardized process. Regardless of whether reprocessing is automated or manual, thorough testing should be conducted to determine the cleaning agents and methods to be used for each product.

***14.1.5.1 Preparation***

Avoid contact between products wherever possible (movement during washing may cause damage and impede cleaning). Do not overload washing machines.
The washing machine must be loaded with cleaning and rinsing agents, as recommended by the manufacturer. Rebstock recommends the exclusive use of VAH-listed cleaning agents and disinfectants.

***14.1.5.2 (Combined) automated cleaning, disinfection, and drying***

Pre-cleaning:

1. Rinse the products under running tap water (potable water quality) for at least 1 minute.
2. Use a soft brush to clean the products in a freshly prepared 2% neutral pH enzymatic cleaning bath (neodisher MediZym) for at least 2 minutes.
3. Use a pressure gun (or similar) to thoroughly flush the products with water (> 2 min).
4. Cleaning in the ultrasonic bath:
   - Place in 2% neutral pH enzymatic cleaning solution (neodisher MediZym)
   - Sonication time of 10 min
   - Temperature of 40°C-45°C and
   - Frequency of 35 kHz

Follow the cleaning agent manufacturer's instructions here.

5. Use a pressure gun (or similar) to thoroughly flush the products with water (> 2 min).
6. Visual inspection
7. Automated cleaning

Conformity with the following cleaning phases is required in accordance with EN ISO 15883:

| Step | Description | T [C°] | t [min] | Water quality | Medium |
|---|---|---|---|---|---|
| 7.1 | Pre-rinse | < 25 | 2 | Drinking Water | -- |
| 7.2 | Cleaning I | 45±3 | 7 | Deionised water | Neutral enzymatic pH between 7 and 9 (0.5% neodisher MediZym) |
| 7.3 | Rinsing | 40±3 | 2 | Deionised water | -- |
| 7.4 | Thermal disinfection | 94 | 10 | Deionised water | -- |
| 7.5 | Drying | 90 | 40 | -- | -- |

*TW = potable water quality, VE = demineralized water*

***14.1.5.3 Manual cleaning, disinfection and drying***

1. Rinse the products under running tap water (potable water quality) for at least 1 minute.
2. Placement in immersion bath:
   - Place in 2% neutral pH enzymatic cleaning solution (neodisher MediZym)
   - At least 20 minutes
3. Use a pressure gun (or similar) to thoroughly flush the products with water (> 2 min).
4. Use a soft brush to clean the products in a freshly prepared 2% neutral pH enzymatic cleaning bath (neodisher MediZym) for at least 2 minutes.
   Cleaning:
5. Use a pressure gun (or similar) to thoroughly flush the products with water (> 2 min).
6. Cleaning in the ultrasonic bath:
   - Place in 2% neutral pH enzymatic cleaning solution (neodisher MediZym)
   - Sonication time of 10 min
   - Temperature of 40°C-45°C and
   - Frequency of 35 kHz

   Follow the cleaning agent manufacturer's instructions here.
7. Use a pressure gun (or similar) to thoroughly flush the products with water (> 2 min).
8. Visual inspection

Disinfection:

9. Immerse products in an RKI- or VAH-listed disinfectant. Follow the disinfectant manufacturer's instructions here. It must be ensured that the disinfectant actually reaches all areas of the product. Always prepare the solution with cold water (max. room temperature).
   The following immersion bath procedure has been validated:
   - Bomix® plus disinfectant
   - Concentration 1%
   - Immersion time 15 min
10. Rinse of products (complete rinse of interior, exterior, and voids) in demineralized water >15 sec

Drying:

11. Manual drying with lint-free disposable cloth. In order to minimize water residues in voids as much as possible, we recommend blowing out voids with sterile, oil-free compressed air.

***14.1.6 Inspection, servicing, testing, maintenance***

The product must be inspected to ensure that it is completely operable prior to use:
If visible damages, such as nicks, cracks, bends, fractures, deformities or surface changes (discolorations), should occur during the transport, storage or processing of the products and/or if the sterilization packaging has been opened or damaged, then the implant is not permitted to be used. Explanted products are never permitted to be reused. Even if such implants are classified as usable following an initial superficial inspection, the interior material may have signs of fatigue.

***14.1.7 Packaging (for sterilization)***

The implants should be packaged in a suitable container or suitable sterilization packaging (ISO 11607 Part 1,2 and EN 868) prior to sterilization. The sterilization packaging depends on the sterilization procedure and the transport and storage conditions. The packaging has a considerable impact on sterilization outcomes. The packaging must be selected to ensure that the implants fit completely in the packaging.

***14.1.8 Sterilization***

Steam sterilization in accordance with DIN EN ISO 17665-1:
Temperature: 134°C/273°F, pressure 3 bar; hold time ≥ 5 min
Drying period 10 min. Repeat drying, as necessary, if products are not sufficiently dry.

Allow implant to thoroughly cool following removal from the sterilizer. Sterilization systems have differing design and performance characteristics; as a result, cycle parameters should always be based on the manufacturer's instructions for the corresponding sterilization system and loading configuration in use.

Carefully follow the operating instructions and sterilizer manufacturer's recommendations! The sterilization process should be periodically tested and validated.

***14.1.9 Storage***

Store the sterilized implants in sterile goods packaging in a clean and dry place. Take special care not to store them in the immediate vicinity of any chemicals. Only packaged implants are permitted to be transported. In order to ensure the safe use of the product, always make sure that the sterilization packaging remains undamaged.

Use a sterilization indicator for the packaging and document the sterilization and expiration date on the packaging. Do not use implants past the expiration date!

***14.1.10 Additional information***

Additional instructions for the processing of medical products:
- Internet: http://www.rki.de
- Internet: http://www.a-k-i.org
- Hygiene requirements for the reprocessing of medical devices. Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)] concerning the "Hygiene requirements for the reprocessing of medical products"

***14.1.11 Residual risk for reprocessing***

The manufacturer has validated that the instructions listed above are suitable for the preparation and use of implants. The processor is responsible for ensuring that the processing that is actually performed achieves the desired results with the equipment, materials, and personnel in use within the processing facility. To do so, validations and routine monitoring are normally required. Any deviation by the processor from the provided instructions must be carefully evaluated for efficacy and potential negative impacts.

| **14.1.12 Symbol explanation, non-sterile implants** | |
|---|---|
| CE 0483 | CE mark with ID number of notified body<br>mdc - medical device certification GmbH; Kriegerstraße 9; 70191 Stuttgart Germany; |
| | Manufacturer |
| LOT | Lot code |
| REF | Article number |
| NON STERILE | Non-sterile |
| | Do not reuse. |
| | Follow instructions for use. |
| | Attention |
| | Store in a dry place. |
| | Symbol for "Do Not Use if Package is Damaged" |
| | Symbol for "Keep Away from Sunlight" |
| | Symbol for "Date of Manufacture" |
| MD | Symbol for "Medical Device" |
| MR | Symbol for "MR Unsafe" |

**14.2 Sterile implants** STERILE R

***14.2.1 Notes and warnings***

The sterile barrier can only be guaranteed if the packaging is not damaged. If the sterile packaging has been opened, torn or is damaged, the implants must be considered as non-sterile and may not be used.

If the expiry date has been exceeded, the implants must be considered as non-sterile and may not be used.

***14.2.2 Limitation of use***

⚠Implants are single-use products, i.e. intended to be used only once, and are not permitted to be reused following surgical removal. Dispose of used implants in accordance with hospital-waste disposal procedures. The reuse of implants may compromise the design and/or materials with potential negative impacts on safety, performance and/or conformity with the specifications in the accompanying documentation.

***14.2.3 Storage***

Store the sterile implants in a clean and dry place. Take special care not to store them in the immediate vicinity of any chemicals. Only packaged implants are permitted to be transported. In order to ensure the safe use of the product, always make sure that the sterilization packaging remains undamaged.

| **14.2.4. Symbol explanation, sterile implants** | |
|---|---|
| CE 0483 | CE mark with ID number of notified body<br>mdc - medical device certification GmbH; Kriegerstraße 9; 70191 Stuttgart Germany; |
| | Manufacturer |
| LOT | Batch code |
| REF | Catalogue number |
| | Do not re-use |
| | Consult instruction for use |
| | Caution |
| | Keep dry |
| | Use-By Date |
| STERILE R | Sterilized using irradiation |
| | Do not use if packaging is damaged and consult instructions for use |
| | Do not resterilize |



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| | |
|---|---|
| | Use-By Date |
| | Date of Manufacture |
| | Keep dry |
| | Keep away from sunlight |
| | Temperature limit +10°C - 35°C |
| | Humidity limitation 25 - 75 %. |
| MD | Medical Device |
| | Double sterile barrier system |
| MR | MR unsave |

## Surgical technique for traumatic injury repair and reconstruction

**Expose and reduce fracture:**
Expose the fracture or osteotomy site following completion of preoperative planning. In the case of traumatic injuries, reduce the fracture, as necessary.

**Select and prepare implant:**
Select a plate that is suitable for the indication. The top of the plate must be facing out. Shorten, as necessary.

⚠The surgeon must take the size and shape of the fracture into account when determining the number of screws necessary for stable fixation of the construct. Protect soft tissue against sharp plate edges. Instrument tips may be sharp; as a result, handle them with care and dispose of sharps in a sharps container.

**Contour plate:**
Contour the plate to the patient's anatomy using the plate cutter and bending forceps. Check to ensure that the plate is passively adapted to the bone.

⚠If contouring is unavoidable, make sure that the device is not bent at the screw hole. Avoid sharp angles, repeated bending, and bending in the opposite direction while contouring the implant because this will increase the risk of implant failure. Remove sharp edges to protect against soft tissue injury.

**Position plate:**
Set the plate over the fracture or osteotomy site.

⚠ Check to ensure that the placement of the plate and spiral drill and the length of the screws provide for suitable clearance from nerves, teeth, tooth roots, and other critical structures.

**Pre-drilling and screw placement:**
Pre-drilling is recommended in the case of complex fractures of the midfacial and mandibular regions with thick cortical bone. If pre-drilling of the drill holes is desired, drill the first hole, insert the first screw near the fracture or osteotomy site, and tighten it completely. Insert the second screw on the opposite side of the fracture or osteotomy site and then all other screws, using the technique described above. When inserting the screw at an angle, check to ensure that the screw is securely seated in the plate hole and that the profile of the construct has not enlarged considerably.

⚠Before drilling, check to ensure that the length and diameter of the spiral drill match the selected screw. Do not exceed a spiral drill speed of 1,800 rpm, especially in dense, hard bone. A higher spiral drill speed may result in thermal necrosis of the bone, soft tissue burns,
An oversized drill hole that may result in reduced pull-out resistance, increased risk of stripping the screws in the bone, suboptimal fixation, and/or
the need for emergency screws. Avoid damaging the plate threads with the drill. Always irrigate and apply suction while drilling in order to prevent thermal damage to the bone and ensure that the spiral drill is concentrically aligned in the plate hole. Irrigation removes debris that may potentially result during implantation. Be careful while drilling in order to avoid damaging, catching or tearing the patient's soft tissue and vital structures, nerves, and tooth roots. The surgeon must take the size and shape of the fracture into account when determining the number of screws necessary for stable fixation of the construct. Check the screw length prior to implantation. Tighten screws in a controlled manner. Applying excessive torque to the screw may result in screw/plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace it with an emergency screw.

## Orbital plate surgical technique

**Select plate:**
Select the plate in a shape and thickness that is suitable for the bone anatomy of the patient and the treatment goal.

**Adapt plate to bone:**
Use the plate cutter and bending forceps to cut and contour the plate to the patient's anatomy, as necessary. Ensure that the plate is flush with the bone.

⚠ Check to ensure that the placement of the plate and spiral drill and the length of the screws provide for suitable clearance from nerves, the edge of the bone, and other critical structures. Instrument tips may be sharp; as a result, handle them with care and dispose of sharps in a sharps container. If contouring is unavoidable, make sure that the device is not bent at the screw hole. Avoid sharp angles, repeated bending, and bending in the opposite direction while contouring the implant because this will increase the risk of implant failure. Avoid contouring the implant in situ because this may result in malpositioning of the implant and/or a posterior cantilever effect. Remove sharp edges to protect against soft tissue injury.

**Drill screw hole:**
If pre-drilling of the screw holes is desired, use a spiral drill of suitable length to ensure adequate clearance from nerves and critical structures.

⚠ Do not exceed a spiral drill speed of 1,800 rpm, especially in dense, hard bone. A higher spiral drill speed may result in thermal necrosis of the bone, soft tissue burns, an oversized drill hole that may result in reduced pull-out resistance, increased risk of stripping the screws in the bone, suboptimal fixation, and/or the need for emergency screws. Avoid damaging the plate threads with the drill. Always rinse while drilling in order to prevent thermal damage to the bone. Always irrigate and apply suction while drilling to remove debris that may potentially result during implantation.

**Secure plate to bone:**
Stabilize the implant with screws inserted into the plate via selected screw holes. Insert screws of suitable diameter and length and use them to secure the plate to the bone. Perform a test for unrestricted lateral and medial movement of the eyeball.

⚠The surgeon must take the size and shape of the fracture into account when determining the number of screws necessary for stable fixation of the construct. Check the screw length prior to implantation. Tighten screws in a controlled manner. Applying excessive torque to the screw may result in screw/plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace it with an emergency screw.

## Mandibular plate system surgical technique

**Visualize and reduce fracture:**
Visualize the fracture or osteotomy site following completion of preoperative planning. Reduce fractures, as necessary.

**Select and adapt implants:**
Select the suitable plate based on the indication. The top of the plate is facing out. Shorten plate using cutter and debur, as necessary.

⚠Determine suitable screw size and screw type. It is recommended to use screws with the same color-coding as the selected plate. After the implant has been inserted, dispose of any fragments or modified segments in approved sharps containers.

**Select and adapt implants:**
Use bending instruments to contour the plate to the bony anatomy.

⚠For stable fixation, at least two screws
per segment are necessary. At least four screws per segment must be included in the case of reconstruction plates in combination with locking screws for bridging a defect. At least three locking screws per segment are necessary in the case of limited bone length or poor bone quality. The plate must be adapted to the anatomy with special care when using non-locking screws. Avoid reverse bends as this may weaken the plate and lead to premature implant failure. Avoid sharp bends. Sharp bends include a single out-of-plane bend of 30 degrees between two adjacent holes.

**Position plate:**
Set the plate over the fracture or osteotomy site. Use the holding forceps to do so, if desired.

⚠Avoid placing the holes over the nerve or tooth root. If the plate requires placement over nerve or tooth root, drill monocortically using the appropriate drill bit with stop. In order to facilitate the insertion of self-drilling screws in dense cortical bone, it may be necessary to pre-drill the screw holes with a spiral drill.

**Drill the first hole:**
Create a stab incision and pass the cannula with obturator carefully through the soft tissue over the fracture site. Then remove the obturator. Create a stab incision and pass the cannula with obturator carefully through the soft tissue over the fracture site. Then remove the obturator. Pass the drill sleeve through the cannula. Position the tip of the cannula on the plate at the hole intended for the first screw. If the drill sleeve with thread is used, rotate the drill sleeve clockwise to engage the threads into the plate. Use a spiral drill with suitable diameter to drill directly through the drill sleeve. To achieve optimal angular stability with locking screws, the hole must be drilled at a right angle to the plate hole. However, a certain amount of
variation is possible here.

⚠Do not exceed a spiral drill speed of 1,800 rpm, especially in dense, hard bone. Higher drill speeds may result in:

- Thermal necrosis of the bone
- Soft tissue burns
- An oversized drill hole that may result in reduced pull-out resistance, increased risk of stripping the screws in the bone, suboptimal fixation, and/or the need for emergency screws.

Avoid damaging the plate threads with the drill. Always irrigate while drilling in order to prevent thermal damage to the bone. Irrigate and apply suction while drilling to remove debris that may potentially result during implantation or removal.

**Measure screw length:**
Use depth gauge to determine suitable screw length.

**Insert screw:**
Insert a locking or non-locking screw of suitable length through the plate and tighten until secure.
Tighten screws in a controlled manner.

⚠Applying excessive torque to the screw may result in screw/plate deformation or bone stripping.

**Drill and insert remaining screws:**
Insert the second screw on the opposite side of the fracture or osteotomy site, using the technique described above. Insert all remaining screws alternating from one side of the mandible to the other. Securely tighten all screws unless resection is to follow. Apply additional fixation, as necessary.

## Bone resection surgical technique

**Resect mandible:**
Once the plate is properly in place, remove the plate and screws, taking note of each screw's placement in the process. Resect the mandible.

**Replace implants:**
Place the plate back onto the mandible in its original position. Reinsert each corresponding screw. Check to ensure that all screws are securely seated in the plate.

**Apply bone graft:**
Secure bone graft with the screws.

⚠Plate failure may occur if a plate is required to bear the entire functional load for an extended period. It is necessary to implant a bone graft immediately or at a later date to adequately support the construct.



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