Dimeda Instrumente GmbH
Gänsäcker 54 + 58
78532 Tuttlingen
Germany

Tel. +49 (0) 7462-94613
Fax +49 (0)7462-946133
info@dimeda.de
www.dimeda.de

CE 0123

Instructions for use

for Titanium bone implants

REF 36.9xx.xx/36.8xx.xx/36.5xx.xx

1. General

With the acquisition of these implants, you have received high-quality products manufactured for the treatment of bone fractures, deformities or osteotomies. Proper handling by surgically trained medical specialists is the basic prerequisite to minimize patient discomfort as much as possible; as a result, the instructions for use must be followed carefully.

2. Product description:

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

Plate (Titanium Grade 2):	Screw (Titanium Grade 5):	Instruments
• Mesh (36.965.51-36.965.56) • Triangular plate (36.962.22) • Double T (36.958.09) • Double Y (36.962.06-36.962.09) • Straight plate (36.952.04-36.952.24) • H Platte (36.962.20-36.962.21) • T plate (wide and narrow) (36.958.05-36.962.19) • Y Platte (36.951.06) • L Platte (36.954.05-36.955.08) • Orbital (36.931.08) • Rectangular plate (36.963.90-36.964.04	Self-drilling: Thread 1.2 / Head 1.8 4-13 mm (36.855.03-36.855.13) Self-tapping: Thread 1.2 / Head 1.8 2-13 mm (36.858.02-36.858.13) Emergency self-drilling: Thread 1.4 / 3-9 mm (36.859.03-36.859.09)	• Plate cutting pliers TC, 16,0cm (33.545.16) • Flat nose pliers, serrated, 14,5cm (36.545.13) • Plate bending pliers, 12,0cm (36.820.12) • Depth gauge 15,0cm until 50,0cm (36.824.05) • Plate and screw holding forceps, TITANIUM, 15,0cm (36.972.15) • Screw-driver, self-retaining, 15,0cm for TITANIUM Cross head screws , Ø 1,2mm (36.984.31) • Screwdriver handle for Dental coupling (36.984.40) • Screwdriver blade for Ø 1,2mm Titanium cross head screws (36.984.42) • Twist drill Ø 1,0x46mm / 1,0x50mm / 1,0x30mm / 1,0x34mm / (36.984.51-53)

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

Plate(Titanium Grade 2):	Screw (Titanium Grade 5):	Instruments
• Mesh (36.867.10-36.965.58) • Bohrlochplatte (36.995.11-36.996.18) • Triangular plate (36.994.03) • Double T (36.993.11-36.993.16) • Double Y (36.993.07-36.993.36) • Straight plate (36.990.02-36.990.54) • Cross plate (36.994.14) • NeurospaltenPlate(36.995.70-36.995.74) • Neuro-Sub-temporale Platte (36.995.76-36.995.80) • T plate(breit und schmal) (36.993.04-36.993.56) • Y Platte (36.993.15-36.993.45) • Z Platte (36.996.46-36.997.46) • L Platte (36.991.04-36.992.74) • Orbital • (36.994.04-36.994.10) • Rectangular plate (36.995.22-36.995.65)	Self-drilling, crossed slot, head diameter 3.50 Thread diameter 1.6, length 6-12 mm (36.851.56-36.851.62) Self-drilling, crossed slot, head diameter 2,55, thread diameter 1.6, length 3-15 mm (36.851.33-36.851.45) Self-drilling, standard crossed slot, Head diameter 2.55, thread diameter 1.6, length 3-19 mm (36.850.03-36.850.19) Self-tapping, emergency crossed slot, head diameter 2.55, thread diameter 1.9 Length 3-9 mm (36.851.03-36.851.09)	• Plate cutting pliers TC, 16,0cm (33.545.16) • Flat nose pliers, serrated, 14,5cm (36.545.13) • Plate bending pliers, 12,0cm (36.820.12) • Depth gauge 15,0cm until 50,0cm (36.824.05) • Plate and screw holding forceps, TITANIUM, 15,0cm (36.972.15) • Screw-driver, self-retaining, 16,0cm for TITANIUM Cross head screws, Ø 1,7mm (36.828.81) • Screwdriver handle for Ø 1,7-2,3mm Screwdriver blade (36.828.15) • Screw driver 18cm, turnable self-retaining, for Titanium cross head screws Ø 1,6mm (36.828.60) • Screwdriver handle for Ø 1,6-2,7mm for Screwdriver blade (36.828.40/41) • Screwdriver blade for Ø 1,6mm Titanium cross head screws (36.828.17) • Twist drill Ø 1,3x50mm / 1,3x31mm / 1,3x34mm / (36.829.05-18)

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

Plate(Titanium Grade 2):	Screw (Titanium Grade 5):	Instruments
• Mesh (36.867.10-36.965.56) • Double T (36.875.66-36.879.64) • Double Y plate (36.865.06-36.890.07) • Straight plate (36.860.04-36.898.40) • L plate (36.874.04-36.898.19) • Orbital plate (36.868.14-36.901.22) • Rectangular plate (36.866.22-36.879.22) • T plate (36.865.04-36.899.10) • Y plate (36.861.05-36.899.08) • Z plate (36.892.04-36.892.54) • KreuZ plate (36.866.04)	Self-drilling, crossed slot, thread diameter 2.0, length 6-14 mm 36.853.56-36.853.64) Self-drilling, emergency crossed slot, thread diameter 2.3, length 5-11 mm (36.853.05-36.853.16) Self-drilling, OM crossed slot, thread diameter 2.0, length 4-17 mm (36.853.24-36.853.37) Self-drilling, emergency crossed slot Thread diameter 2.3, length 5-7 mm (36.853.45-36.853.47) Self-tapping, standard crossed slot, thread diameter 2.0, length 4-21 mm (36.852.04-36.852.21)	• Plate cutting pliers TC, 18,0cm (33.545.18) • Flat nose pliers, serrated, 14,5cm (36.545.13) • Plate bending pliers, 12,0cm (36.820.12) • Depth gauge 15,0cm until 50,0cm (36.824.05) • Plate and screw holding forceps, TITANIUM, 15,0cm (36.972.15) • Screwdriver, self-retaining, 16,0cm for TITANIUM Cross head screws Screwn, Ø 1,7mm (36.828.81) • Screwdriver handle for Ø 1,7-2,3mm Screwdriver blade (36.828.15) • Screwdriver 18cm, turnable self-retaining, for Titanium cross head screws Ø 2,0mm (36.828.11) • Screwdriver handle for Ø 1,6-2,7mm for Screwdriver blade (36.828.40/41) • Screwdriver blade for Ø 2,0 & 2,3mm Titanium cross head screws (36.828.53) • Holding sleeve for Screwdriver blade (36.828.52) • Twist drill Ø 1,5x50mm / 1,5x70mm / 1,5x105mm / (36.830.50/36.831.30-40) • Transbuccal drill guide (36.827.00/36.829.00)

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

Plate(Titanium Grade 2):	Screw (Titanium Grade 5):	Instruments
• C-Platte (36.573.02-36.573.10) • Straight plate (36.574.02-36.579.02) • KieferwinkeL plate (36.572.02-36.573.08)	Self-tapping Emergency crossed slot Thread diameter 2.7 Length 5-15 mm (36.581.05-36.581.15) Self-tapping Standard crossed slot Thread diameter 2.3 Length 4-22 mm (36.580.04-36.580.22)	• Plate cutting pliers TC, 22,5cm (33.545.22) • Flat nose pliers, serrated, 14,5cm (36.545.13) • Plate bending pliers, 15,0cm (36.820.15) • Depth gauge 15,0cm until 50,0cm (36.824.05) • Plate and screw holding forceps, TITANIUM, 15,0cm (36.972.15) • Screwdriver handle for Ø 1,7-2,3mm Screwdriver blade (36.828.15) • Screwdriver handle for Ø 1,6-2,7mm for Screwdriver blade (36.828.40/41) • Screwdriver blade for Ø 2,0 u. 2,3mm Titanium cross head screws (36.828.53) • Twist drill Ø 1,8x98mm / 1,3x58mm / (36.832.25/26)

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

Plate(Titanium Grade 2):	Screw (Titanium Grade 5):	Instruments
• Gelenkkopf Aufsatz mit Kugel • Straight plate (36.590.11-36.590.12) • KieferwinkeL plate einseitig (36.553.08-36.559.14) • KieferwinkeL plate beidseitig (36.560.17-36.561.19)	Self-tapping Emergency crossed slot Thread diameter 3.0 Head diameter 3.9-4.0 Length 9-13 mm (36.593.07-36.594.13) Self-tapping Standard hexagonal and crossed slot Thread diameter 2.7 Length 7-21 mm (36.591.07-36.592.21)	• Depth gauge 15,0cm until 50,0cm (36.824.05) • Plate and screw holding forceps, TITANIUM, 15,0cm (36.972.15) • Screwdriver handle for Ø 1,6-2,7mm for Screwdriver blade (36.828.40/41) • Screwdriver blade for Ø 2,7mm Cross head / hexagon titanium screws (36.853.00/01) • Twist drill Ø 2,0x105mm / 2,0x85mm / (36.832.20/22) • Bending iron (33.643.01/02) • Bolt cutter (33.556.57) Plate bending pliers (33.652.22/ 36.656.18/ 36.820.28)

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. Dimeda implants are not compatible with magnetic resonance tomography (MRT).

5. Mechanical properties:
All Dimeda 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 Dimeda Miniplate System involves craniomaxillofacial (CMF) plate and screw systems for osteotomy, stabilization, and rigid fixation of 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

8. Contraindication

Implants for CMF:
- Non-reducible and unstable fractures (with the exception of reconstruction plates)
- Fractures of a severely atrophic bone
- Patients with active infections
- Patients with metal allergies and sensitivity to foreign bodies
- Patients with inadequate compliance that are unwilling or unable to follow aftercare instructions due to their mental or neurological condition
- Patients with restricted circulation or inadequate bone quality or quantity
- Patients who are physically and/or mentally unstable

.

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

10 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).

11. Notes ⚠
Implants are only permitted to be applied with corresponding tools (Dimeda blades) specially intended for this use. Combining implants and tools from different manufacturers poses the risk of inadequate fixation and technical complications. Dimeda 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.

11.1 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.

11.2 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.

11.3 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.

11.4 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 (Dimeda 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.

12. Residual risk ⚠

Dimeda 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. Dimeda also assumes no liability in proven cases where these instructions for use were not followed.

13 Reprocessing acc. DIN EN ISO 17664

13.1 Notes and warnings

⚠All implants are supplied non-sterile.

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, Dimeda recommends the incineration of the affected products in accordance with proper disposal methods.

*13.1.**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.

13.3 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!

13.4 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.

13.5 Cleaning

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

13.5.1 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. Dimeda recommends the exclusive use of VAH-listed cleaning agents and disinfectants.

13.5.2 (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	TW	--
7.2	Cleaning I	45±3	7	VE	Neutral enzymatic pH between 7 and 9 (0.5% neodisher MediZym)
7.3	Rinsing	40±3	2	VE	--
7.4	Thermal disinfection	94	10	VE	--
7.5	Drying	90	40	--	--

TW = potable water quality, VE = demineralized water

13.5.3 Manual cleaning and disinfection process

Cleaning:

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.

13.6 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.

13.7 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.

13.8 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.

13.9 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!

13.10 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"

13.1.11 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. Symbol explanation	
CE 0123	CE mark with ID number of notified body TÜV Süd Product Service GmbH; Ridler-Straße 65; 80339 München; Germany
	Manufacturer
LOT	Lot code
REF	Article number
NON STERILE	Non-sterile
	Do not reuse.
	Follow instructions for use.
	Attention
	Keep dry
	Date of manufacture
MD	Medical Device

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.