Instructions for use
Cranio-Maxillo-System

Content

MANUFACTURER

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CMF System

IMPORTANT PRODUCT INFORMATION PLEASE READ CAREFULLY BEFORE EACH CLINICAL APPLICATION!

Dear customer!
With the purchase of this implant, you are receiving a high-quality product, the proper handling and use of which are described below. In order to minimize hazards for patients and users, we kindly ask you to carefully read and observe the instructions for use.
Attention

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

1. SCOPE OF APPLICATION

The scope of these instructions for use applies to the following products in our catalogs and brochures:

System:
System Ø 1.2 mm
System Ø 1.6 mm
System Ø 2.0 mm
System Ø 2,3 mm
System Ø 2,7 mm

2. INTENDED PURPOSE / INDICATION / MATERIAL

2.1 Intended purpose

The implants consist of solid material that is attached with screws to fractured craniofacial bone (including maxilla and mandible) to bridge and stabilize the fracture gap and shield against stress during bone healing; the material is neither chemically degradable nor resorbable by natural processes in the body. The product can also be used for craniofacial reconstruction or for fixation of the zygomatic bone or craniotomy flaps. The implants, as well as the accessories, must never be used outside of this intended purpose!

2.2 Indication

CMF plates, screws and meshes are indicated for use in trauma repair and reconstruction of the craniomaxillofacial skeleton:

- ✓ Trauma reconstruction in craniomaxillofacial surgery.
- ✓ Craniofacial reconstruction
- ✓ Fixation of the zygomatic bone or craniotomy flaps
- ✓ Orbital fractures
- ✓ Orbital floor fracture
- ✓ Medial orbital wall fractures
- ✓ Soft tissue regeneration

2.3 CONTRAINDICATIONS

Digimed Medizintechnik implants should not be used if any of the following conditions apply:

- ✓ Patients suffering from osteoporosis, limited or no revascularization, bone resorption or poor new bone formation.
- ✓ Fractures of severely atrophic maxillae or mandibles.
- ✓ Patients with manifested infection
- ✓ Patients with material intolerance to titanium
- ✓ Markedly uncooperative patients who, due to mental or neurological disorders, are unwilling or unable to follow the physician's instructions regarding follow-up care

2.4 Warnings

- ✓ The screws may only be used with the corresponding instruments:
- ✓ Implantation: Screwdriver Digimed Medical Technology see chapter Combination
- ✓ Explantation: Screwdriver Digimed Medical Technology see chapter Combination
- ✓ Make sure that the screws are firmly seated in the respective instrument. Ensure that there is sufficient axial pressure over the screws during implantation. Otherwise there is a risk of mechanical damage.
- ✓ excessive bending may cause damage to the implants and or premature failure of the plates and meshes
- ✓ multiple bending can cause damage to the implants and or premature failure of the plates and meshes
- ✓ inadequate adaptation of the implants to the local situation can lead to delayed, inadequate retention
- ✓ Reuse of implants is absolutely prohibited (single use).

Do not reuse

Failure to observe the restriction (single-use product) can have serious consequences for the patient
1. implant failure (e.g. fracture)
2. failure to heal

2.5 Possible complications/side effects

In many cases, complications are caused by the surgical procedure rather than the implant.

- ✓ Osteoporosis, limited or no revascularization, bone resorption, or poor new bone formation can lead to loosening, bending, cracking, or fracture of the implant; in addition, premature loss of fixation with the bone is possible, so that bone fragments cannot grow together.
- ✓ Mucosal or tissue reaction
- ✓ Skin rash
- ✓ loosening of the implant due to inadequate, improper fixation
- ✓ Possible nerve or blood vessel damage as a result of the surgical procedure
- ✓ Increased connective tissue reaction in the fracture area due to unstable comminuted fractures.
- ✓ Delayed, inadequate or absent osseous remodeling of the fracture can lead to implant failure.

The following side effects may occur after implantation:

- ✓ Exposure of meshes, plates and/or screws
- ✓ immediate or delayed infection (deep and/or superficial)
- ✓ increased response of fibrous tissue around the fracture site due to unstable comminuted fractures.

In the course of market monitoring, further potential complications / side effects could be identified:

- ✓ Infections
- ✓ Dehiscence of soft tissue
- ✓ Breakage of plates, screws, meshes

2.6 Material

Implants made of titanium according to:

Screw	Titan Grade 5 - ELI (Ti6Al4V) gem. ASTM F136 oder ISO 5832-3
Plates	Titan Grade 5 - ELI (Ti6Al4V) gem. ASTM F136 oder ISO 5832-3
Meshes	Titan Grade 2 gem. ASTM F67 oder 5832-2

The surface of these implants is chemically passive, non-magnetic. These implants can be combined with the standardized material whose composition within the standard specified directional analysis according to the table above and the required specifications. These materials of titanium are biocompatible and prevent so-called chrome-nickel allergies in its properties!

2.7 Caution

Instruments, and in particular implants, may only be used by persons who have been specially trained or instructed for this purpose. Suitable instruments must be used for the application and explantation of the pins. (see "Instruments for insertion and explantation"). Explantation of the implants is recommended after patient recovery. The decision to leave the implants in the patient's body can be made by the physician on his or her own responsibility after evaluation by the physician.

3. MRT NOTE

Digimed Medizintechnik is a manufacturer of orthopedic implants made of titanium and titanium alloys. This type of non-ferromagnetic material does not pose any risk to the patient during magnetic resonance imaging (MRI) examination.

Various studies and test reports have shown that this titanium alloy can be safely used in an MRI environment according to ISO ISO 5832-3 and ISO5832-2 and can be considered "MRI Conditional" according to ASTM F2503. MRI Conditional is defined as an item that has been shown to present no known hazards in a specific MRI environment with specified conditions of use (ASTM F2503, 3.1.9).

Precautions: The above statement is based on non-clinical testing. The actual patient temperature rise depends on a variety of factors beyond SAR and timing of radiofrequency application. Therefore, it is recommended that special attention be paid to the following:

- ✓ It is recommended that patients undergoing MRI scanning be thoroughly monitored for perceived temperature and/or pain sensations.
- ✓ Patients with impaired thermoregulation or temperature sensation should be excluded from MRI scanning procedures.
- ✓ In general, it is recommended that a low field strength MRI system be used when conductive implants are present. The specific absorption rate (SAR) used should be reduced as much as possible.
- ✓ The use of the ventilation system can further help to reduce the temperature rise in the body.

The implants are made of a titanium that is not magnetic. For this reason, the systems have not been tested for heating, migration or image artifacts in the magnetic resonance environment. The safety of these systems in the magnetic resonance environment is unknown.

Note that - MRI techniques in the form of dedicated spin-echo sequences such as VAT, SEMAC (SEMAC-VAT - 2D), MSVAT-SPACE (3D), and MAVRIC should be used to optimize image quality and minimize artifacts.

4. APPLICATION & SAFETY INSTRUCTIONS

The products must be checked for defects, cracks, nicks or other damage before use. Damaged products must be sorted out.
The products are delivered in a non-sterile condition and must be completely cleaned, disinfected and sterilized by the user before first use.

5. COMBINATION PRODUCTS & ACCESSORIES

5.1 Correct selection of implants

The choice of implants is made taking into account the patient-specific characteristics, such as the type of fracture/injury or the need for bone augmentation and the condition of the patient's bone material. The implantation method must be selected according to the state of the art in the field.
Errors in implant selection can lead to premature clinical implant failure. The use of the correct components allows sufficient blood supply and results in stable fixation, whereas a wrong choice can lead to loosening, bending or fracture of the implant and/or bone, among others. In general, the implants are designed for temporary use. However, due to the use of pure titanium and titanium alloys, it is also possible to leave them in the operated area. However, this evaluation is the sole responsibility of the physician.

5.2 Tools

Plate cutting instruments are used to divide or shorten plates in the area of the webs. When cutting, make sure that the cut parts do not fling away, therefore do not point them at persons when cutting and cover them during the cutting process if necessary. The plate part to be used must be deburred after cutting to avoid friction conditions on the fabric. Drill/drilling aids: Always use the shortest possible drill bit to ensure the best possible concentricity. It should be checked whether the drill bit connection and the drilling aid are compatible. Basically, only work with drill bush or similar and at speeds of <= 1000 rpm. When drilling, ensure sufficient cooling with NaCl to minimize the heat load 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 indicated on the packaging.

5.3 Color coding of screws & drills

The identification of the screws and drills is done by color coding, which is displayed by the system. The following color codes correspond to the same diameter:

Blue	System Ø 1.2 mm
Green	System Ø 1.6 mm
Gold	System Ø 2.0 mm
Purple	System Ø 2,3 mm
Gold	System Ø 2,7 mm

5.4 Instruments for insertion and explantation

# Twist drill Ø 1,0 mm for System Ø 1,2 mm	# Screwdriver 95-120-72
# Twist drill Ø 1,3 mm for System Ø 1,7 mm	# Screwdriver 95-120-81
# Twist drill Ø 1,5 mm for System Ø 2,0 mm	# Screwdriver 95-120-13
# Twist drill Ø 1,8 mm for System Ø 2,3 mm	# Screwdriver 95-120-25
# Twist drill Ø 2,0 mm for System Ø 2,7 mm	# Screwdriver 95-120-25

Digimed implants must never be combined with products, components and instruments from other manufacturers. Combinations with products from other manufacturers can have a negative influence on the result of the procedure and are not permitted, as the components used may not be compatible with each other. It is recommended to use only Digimed instruments and accessories for the application.

6. EXCLUSION OF RE-USABILITY

Once inserted, implants must not be reused under any circumstances. The products are intended for single use only. Failure to observe the restriction (single-use product) can have serious consequences for the patient

1. implant failure (e.g. fracture)
2. failure to heal

7. REPROCESSING

In principle, implants themselves may only be inserted once. Once an application has been completed, the implant may not be used again.

If implants are prepared for use and not used clinically, i.e. not implanted and not contaminated in the operating area with e.g. blood, tissue (contact with patients), they may generally be used again after reprocessing and sterilization. However, this does not apply

- ✓ if the color anodization (color coding) of the implants has changed in such a way that correct assignment to the corresponding drills is no longer guaranteed.

After treatment of a patient infected with Creutzfeldt-Jakob disease, the accessories and the instruments for insertion/use must not be reused or reprocessed. The products must be disposed of.

8. PREPARATION AND TRANSPORT

All system components are supplied non-sterile. It is therefore mandatory that they be cleaned and sterilized before use on the patient. In the case of reusable instruments, this applies to each reuse.

Transport the implants / instruments in a closed container to the reprocessing site to avoid damage to the implants / instruments and contamination of the environment.

9. CLEANING & DISINFECTION

9.1 Basics

If possible, a mechanical process (washer-disinfector) should be used for cleaning and disinfection. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available or in accordance with country-specific requirements (e.g. in Germany, a mechanical process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility.

Pretreatment must be carried out in both cases.

9.2 Pretreatment

The implants can be brushed under the water surface (tap water) until they are visually clean.

9.3 General information on machine cleaning/disinfection with a (RDG)

When selecting the WD, make sure,

- that the washer-disinfector basically has a tested effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking according to DIN EN ISO 15883),
- that, if possible, a tested program for thermal disinfection (A0 value > 3000 or - for older devices - at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, there is a risk of disinfectant residues on the products),
- that the program used is suitable for the products and contains sufficient rinsing cycles (at least three depleting steps after cleaning (or neutralization, if used) or conductivity control is recommended to effectively prevent detergent residues)),
- that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,
- the air used for drying is filtered (oil-free, low in germs and particles), and
- that the WD is regularly maintained, checked and calibrated.

When selecting the cleaning agent system to be used, make sure,

- that it is suitable for cleaning invasive medical devices made of metals and plastics,
- that - if thermal disinfection is not used - a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the products

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as specifications for post-rinsing, must be strictly adhered to.

Procedure:

1. place the products in the WD. Make sure that the products do not touch each other.
2. Start the program.
3. Remove the products from the washer-disinfector at the end of the program.
4. Check and pack the products as soon as possible after removal.

9.4 Cleaning & disinfection

Proof of the basic suitability of the products for effective machine cleaning and disinfection was provided by an independent, officially accredited and recognized (§ 15 (5) MPG) test laboratory using the cleaning agent Neodisher Mediclean Forte 0.4 % (v/v). The procedure described below was taken into account.

Cleaning

Step	Parameters	
Pre-rinse	Rinsing temperature	Cold Water
	Reaction time	60 s
Cleaning	Cleaning temperature	55°
	Reaction time	600 s
	Cleaning agent	Neodischer Medclean Forte
	Concentration	0,70 %
Rinse	Rinsing temperature	Cold deionized water
	Reaction time	120 s

Disinfection

Step	Parameters	
Thermal disinfection	Disinfection temperature	93° C (Ao 3000)
	Reaction time	300 s
Drying	Drying temperature	100° C
	Drying time	20 min

10. FUNCTION TEST AND PACKAGING

The products must be checked for cleanliness and functionality after reprocessing and before sterilization. If necessary, the reprocessing process must be repeated until the product is visually clean.
Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) that meet the following requirements (material/process):

- ✓ DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- ✓ suitable for steam sterilization (temperature resistance up to min. 137 °C (280 °F) sufficient steam permeability)
- ✓ sufficient protection of the products or sterilization packaging against mechanical damage
- ✓ regular maintenance according to the manufacturer's instructions (sterilization container)
- ✓ a maximum weight of 10 kg per package/content of the sterilization container must not be exceeded

11. STERILIZATION

Only the sterilization methods listed below may be used for sterilization; other sterilization methods are not permitted.

11.1 Steam sterilization:

fractionated vacuum process (with sufficient product drying)
Steam sterilizer according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
validated according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
maximum sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)
Sterilization time (exposure time at sterilization temperature):

Country	fractionated vacuum process
Germany	at least 5 min at 134 °C (273 °F)
USA	at least 4 min at 132 °C (270 °F), Drying time at least 20 min
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation Sterilization time 18 min
other countries	at least 5 min at 132 °C (270 °F) / 134 °C (273 °F)

Proof of the fundamental suitability of the products for effective steam sterilization was provided by an independent, officially accredited and recognized (§ 15 (5) MPG) test laboratory using the steam sterilizer (Lautenschläger ZentraCert) and employing the fractionated vacuum process. Typical conditions in clinics and medical practices as well as the procedure described above were taken into account.

12. STORAGE

Store the implants in a dry, clean and dust-free environment. No shelf life or functional limitation is given for implants supplied non-sterile after manufacture, if properly stored.

13. REPAIRS & SERVICE

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer is responsible and intended for this. If you have any complaints, claims or information regarding our products, please contact us.

14. HANDLING

The system components must be handled and stored carefully. Damage or scratches to the implant can significantly affect the strength and fatigue resistance of the product.

15. DISCLAIMERS & WARRANTY

The products are made of high quality materials and are subjected to quality control before delivery. However, should any defects occur, please contact our service department. However, we cannot guarantee that the products are suitable for the respective operation. This must be determined by the user himself. We cannot accept any liability for accidental or resulting damage.

Any product liability expires

- ✓ in case of damage due to improper storage, handling, cleaning and / or sterilization
- ✓ in the event of incorrect cleaning and sterilization
- ✓ in case of non-observance of these instructions for use

DIGIMED ACCEPTS NO LIABILITY IF IT CAN BE PROVEN THAT THESE INSTRUCTIONS FOR USE HAVE BEEN VIOLATED.

16. Serious incidents

Any serious incident occurring in relation to the medical device shall be reported to the manufacturer and the competent authority in the Member State where the user and/or the patient is located.

17. INFORMATION

DIN EN ISO 13485:2016 requires all parties involved in distribution to ensure the traceability of implants:
Chapter 7.5.3.2.2 Specific requirements for active implantable medical devices and implantable medical devices.
In establishing traceability records, the organization shall include all components and materials used, as well as conditions of the working environment when these could cause the medical device to fail to meet its specified requirements.
The organization shall require that its agents or sales representatives maintain records of medical device delivery for traceability purposes and that such records are available for inspection.
Records must be maintained of the name and address of the recipient of the shipping package.

Due to the small size of the implants, there is no direct marking on the product. For traceability purposes, the user must ensure that the product label is stored in the patient's file.

18. SYMBOL EXPLANATIONS

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

	Manufacturer`s		Instruction for use
	Non-sterile		CE marking with number of notified body
	Do not reuse		Batch designation
	Attention		Order number
	Medical device		