



OPERATING INSTRUCTIONS

for the US market

CE 0123

Rx only



LOW PROFILE PLATE SYSTEM

Please read these instructions carefully before clinical application and keep them safe and close to hand. The instructions must be followed.

MEDICON implants are manufactured from titanium or titanium alloy. This material is biocompatible, corrosion-resistant and non-toxic in the biological environment. It enables virtually artifact-free imaging:

- conventional x-ray radiography
- computer tomography
- MRI (Magnetic Resonance Imaging).

The surface is chemically passive and the material is antimagnetic.

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1. GENERAL NOTES

The MEDICON plate systems are supplied unsterile and must be disinfected, cleaned and sterilised prior to use. Please observe the following instructions. This will guarantee that the implants will function faultlessly and reliably.

2. INTENDED USE/INDICATIONS (K951688):

- Osteosynthesis of fractures, comminuted fractures and osteotomies in the cranial skeleton;
- Osteosynthesis of cranial fractures, including squamofrontal and parietofrontal fractures;
- Osteosynthesis of orthognathic osteotomies of cranium.

3. CONTRAINDICATIONS

- Patients that are unable to follow the instructions for postoperative care. This may be caused e.g. by psychological/mental or neurological problems of the patient.
- Patients with inadequate bone tissue, or bone tissue of insufficient quality, and patients with circulatory disorders or latent infections.
- Extreme material sensitivity, i. e. foreign-body reaction of the patient. For this case, appropriate tests must be carried out under all circumstances prior to implantation (even when there is only a suspicion of such condition).
- Acute infections.

4. POSSIBLE SIDE EFFECTS AND COMPLICATIONS

- Complaints, pain, abnormal sensations or palpability of the implant.
- Extreme material sensitivity of the patient (foreign-body sensitivity) manifested by allergic reactions, etc.
- Heightened reaction of connective tissue in the region of the fracture and/or implant.
- Insufficient bone formation, osteolysis, osteomyelitis, osteoporosis, inhibited revascularization or infections that can result in loosening, bending, rupture or breakage of the implants.
- Delayed or insufficient fracture union, which can result in implant breakage.
- Bone necrosis.
- Inadequate healing.
- If the implants were not adapted properly, bone fusion can be delayed, or fusion is insufficient or does not occur at all.
- Breakage, bending, migration or loosening of the implant.
- Reduced bone density due to stress shielding.

Apart from the side effects and complications mentioned above, the surgical intervention can also lead to problems such as nerve injuries, infections, pain, etc., which are not directly attributable to the implant. The possible complications are often the result of incorrect selection of the patient, lack of exercise or inadequate repositioning of the bone fragments, rather than being caused by the implant itself. Extreme bending of the plates, or repeated bending at the same place, can lead to plate fractures. The implants can come loose if the screws are not tightened sufficiently.

5. SINGLE USE PRODUCT

Implants are designed and constructed for single use only on a single patient and may not be reused. An explanted implant must never be reused. Even if the implant appears undamaged or functionally intact, indications of wear, small defects, and invisible stresses may exist. Since it is unclear what effect the forces and conditions within the body may have had on the stability, function, and material properties of an explanted implant, reimplantation incurs an unacceptable risk of early wearout or failure. The user is liable for non-compliance with the instructions for use.

6. MAGNETIC RESONANCE (MRI) COMPATIBILITY

The safety, compatibility and heating of the implant in the MR environment has not been tested. The responsible physician must inform the patients that they carry an implant that has not been tested under MR conditions, and that

they must inform the treating physician about this prior to an MR examination. It is recommended that patients always carry the implant pass with them.

7. IMPLANT SELECTION

The surgeon is responsible for the correct selection of implants.

The following aspects are crucial for the correct selection of implants:

- Bone defect to be treated
- Body weight of the patient
- general health and degree of activity of the patient.

Incorrect implant selection can lead to premature implant loss and loosening, deformations or fractures of the implants. Among other factors, the success of the intervention depends on how the implants are handled. The plates must be bent carefully and cautiously, avoiding repeated and extensive deformation. Damage and scratches reduce the stability of the product and result in early fatigue of the implant material. A product that has already been used may, under no circumstances, be used a second time.

Even if the product appears to be undamaged from a macroscopic point of view, prior strain on the product may have resulted in quality loss and a reduced product life.

In cases of failed, delayed or insufficient fracture union, the incidence of implant bending, implant failure or implant breakage cannot be excluded. Therefore, immobilization of the fracture site must be ensured until there is solid bone fusion. Incessant load changes on the implant can result in fatigue fractures.

The implants and instruments are adapted to each other. Any use of implants and instruments from other manufacturers in combination with MEDICON products entails unpredictable risks, since the products are not adapted to each other. To avoid risks, only such MEDICON products that are designated for combination with each other may be combined with each other. Prior to applying the product, the surgeon must thoroughly discuss the intended surgical result with the patient. In such discussions, special attention must be given to the postoperative aspects and aftercare, which may become necessary.

The patient must be informed that, due to the limited stability of the fixation, the fixation site must not be put under the full body weight. The patient must also be informed the non-observance of this advice can put at risk any safe bone union. The patient must be instructed to inform, without delay, the operating surgeon of unusual changes at the operating site. The patient must be monitored carefully if there is a manifest change in the fixation region.

The surgeon must consider possible consequences, e.g. implant failure, and discuss with the patient any necessary measures for further healing.

The implants can be removed as soon as the fracture has fully healed. An implant left in the body after complete healing may act as a load-bearing element and can contribute to an increased risk of re-fracturing in active patients.

For this reason, too, we accept liability for the implants only up to complete healing. We will not accept liability for any damage or injuries caused by implants that were not removed after complete healing of the treated fracture.

The surgeon is responsible for deciding whether the implants shall remain in the body after complete healing of the fracture or whether they shall be removed. For his decision, the surgeon has to weigh risks and advantages of leaving the implants in the body. It cannot be excluded that implants break, loosen, corrode, migrate in tissue and cause pain.

The implants are provided with labels. These labels carry a "Lot Number". We recommend transferring this "Lot Number" to the patient records as this number allows tracing the production history of the implant back to the raw material

8. APPLICATION/HANDLING OF PLATES

The plates have to be adapted to the natural or planned bone contours as precisely as possible. For adapting the plates use the instruments provided for this purpose by the manufacturer. During the plate bending procedure, there occur cold stresses, under which the titanium hardens while, at the same time, its ductility is decreased. Therefore it is absolutely necessary to achieve the required plate shape in as few bending steps as possible. Excessive bending can lead to postoperative plate breakage.

Overly aggressive application of the bending instruments can result in visible damage to the implant. When such damage has occurred, a new plate must be selected and adapted more cautiously.

Deformed plate holes for the screws entail not only an increased risk of breakage at the location of the holes; they also compromise the precise seating of the screw head in the plate. Therefore the plates must be bent carefully under all circumstances. Deformed plates must be inspected for notches, deformed screw holes and other mechanical damage prior to application.

Always select the plates that provide the closest fit to the specific situation and indication. If a plate needs to be shortened, only use the instruments supplied for this purpose. The plate must be cut between the screw holes. Care must be taken that the portion of the plate that is cut off is not flung towards the patient or towards third parties during the cutting procedure. The edges of a shortened plate must be deburred to prevent tissue injuries or irritations.

9. APPLICATION/HANDLING OF SCREWS

Self-tapping screws do not require pre-cutting of threads. To apply the drill holes, only use the respective drill designated by MEDICON for the specific screw so that the correct drill hole diameter for the screw is obtained. Only use drill bits with sharp cutting edges.

During drilling, there is a risk of heat damage to the bone. Therefore, only work at low drill speed and always ensure sufficient cooling during the drilling procedure.

Excessive application of force during the drilling procedure can lead to drill breakage, endangering the patient, the surgeon and third parties. If, due to a failed drilling effort or a slack drill hole, the screw cannot be anchored firmly in the bone, the emergency screws intended for this purpose must be used.

To ensure that the screwdriver blade is firmly seated in the screw head, axial force must be applied when inserting the screwdriver into the screw head. This ensures the correct axial alignment of screw and screwdriver, and prevents slipping of, or damage to the screw head or the screwdriver blade. Application of excessive force in tightening the screws can lead to screw breakage during the intervention. Wear of the screwdriver blade will impair the firm connection between blade and screw. Whenever such wear is detected, the screwdriver blade must be replaced by a new blade.

Once the implantation has been completed, the secure connection between every screw and plate must be checked. If necessary re-tighten the screws. Prior to implant removal, all screw heads must be cleaned carefully, using a scalpel or another suitable instrument, so that the screwdriver can be optimally seated in the screw head.

9.1 Self-tapping screws

When using self-drilling screws, you are usually not required to drill a hole. If the bone is very dense and hard, it may be necessary to drill holes, e.g. on the calvarium or mandible.

10. INSTRUMENTS

The instruments intended for application of the system are subject to wear and tear and mechanical strains even when used normally, but even more so when applied with excessive force.

To prevent failure of, or mechanical damage to the instruments during the operation, prior to each use the instruments must be inspected to make certain they are mechanically intact, not deformed, and fully functional. Do not use instruments that were found to be damaged, deformed or not fully functional.

11. DECONTAMINATION, CLEANING AND STERILIZATION

The following vCJD (Creutzfeld-Jakob-Disease) prion specific protective measure is indicated when processing instruments.

In the event of diagnosis of a definite or probable case of vCJD:

If it is not possible to use disposable products, the instrument used, which has been contaminated or where contamination cannot be ruled out, must be disposed of as incinerated waste.

If prion contamination is suspected:

In the event of suspected prion contamination, incineration of the instrument is recommended according to the vCJD task force final report.

If vCJD is excluded:

Continue to use after instrument processing is completed. Otherwise, the instrument, which has been contaminated or where contamination cannot be ruled out, must be disposed of as incinerated waste.

In the case of a non-identifiable vCJD illness:

Even if nothing is known about the presence of a prion disease, two processing procedures should be used with at least partial efficacy against prions – e.g. mechanical alkaline cleaning combined with steam sterilization. If mechanical alkaline cleaning or another cleaning procedure with proven efficacy against prions is not used and the medical devices in question are in contact with risk tissues (CNS, eyes, lymphatic tissue), the RKI recommends a prolonged sterilization time of 18 minutes at 134 °C/273 °F.

Note: Please observe the relevant national regulations concerning the reprocessing of the products for patients with CJD or suspected CJD or possible variants of CJD.

Instruments made of stainless steel must not be placed in physiological saline solution (NaCl solution) as prolonged contact leads to corrosion such as pitting and stress corrosion cracking. Only cleaned and disinfected implants may be sterilized.

Location of use

Implants that have been contaminated by blood and/or secretions or are suspected to be contaminated must not be placed back in the storage tray and reprocessed.

They have to be disposed in a suitable container. Instruments that have been contaminated by blood and/or secretions or are suspected to be contaminated must not be cleaned in the implant/instrument storage tray.

They have to be cleaned separately and after proper cleaning they can be placed in the implant/instrument storage tray.

Preparation for decontamination

Before manual/machine cleaning the instruments have to be taken out of the implant/instrument storage tray. The screwdriver blade has to be removed from the screwdriver handle. Place the lid back onto the implant/instrument storage tray.

The implant/instrument storage tray must be placed in instrument holders suitable for machine cleaning. The instrument holders (e.g. wire basket) must allow subsequent cleaning in a sonication unit or in the cleaning and disinfection device (CDD) where they are not impeded by acoustic or rinsing shadows.



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Manual Cleaning

Implant tray

- Rinse the articles under cold running tap water to remove visible soil.
- Use a soft bristled brush and lumen brush to aid in removal of visible soil while rinsing.
- Using a syringe, flush hard to reach areas while rinsing
- Prepare Enzo[®] enzymatic detergent at 1oz. per gallon warm tap water.
- Immerse the tray to soak for 1 minute into Enzo[®] enzymatic detergent
- Following the soak time, brush the implant tray with a soft bristled brush and lumen brush for a minimum of 1 minute to remove soil residuals.
- Using a syringe, flush hard to reach areas with the detergent solution.
- Remove the implant tray from the enzymatic detergent solution and rinse under running tap water to remove detergent residuals.
- Prepare a neutral detergent Valsure[®] neutral in a sonication unit at ¼ oz. per gallon of warm (37 – 40 °C/98.6 – 104 °F) tap water. Immerse in the sonicator and actuate.
- Allow the implant tray to sonicate for 10 minutes
- Remove the implant tray from the sonicator and rinse them under cold distilled water to remove detergent residuals.
- Dry the implant tray completely using medical compressed air and disposable, lint-free cloths.

Instruments

- Rinse instruments under cold running tap water for at least one minute to remove visible soil and actuate movable parts while rinsing. Use a soft bristled brush and lumen brush to aid in removal of soil while rinsing and actuate movable parts while brushing. Use a syringe to flush the lumen (internal spaces, threads, and holes) with rinse water.
- Prepare Enzo[®] enzymatic detergent at 1 oz. per gallon of warm tap water and immerse instruments to soak for at least one minute.
- Following the soak time, brush the instruments with a soft bristled brush and lumen brush for a minimum of one minute to remove soil residuals.
- Using a syringe, flush internal spaces, threads, and holes with the enzymatic detergent solution
- Remove the instruments from the enzymatic detergent solution and rinse under running tap water to remove detergent residuals
- Prepare a neutral detergent Valsure[®] neutral in a sonication unit at ¼ oz. per gallon of warm (37 – 40 °C/98.6 – 104 °F) tap water. Immerse in the sonicator and actuate.
- Using a syringe, flush the lumen (internal spaces, threads, and holes) with the detergent solution and then allow the instruments to sonicate for at least 10 minutes
- Remove the instruments from the sonicator and rinse them under cold distilled water to remove detergent residuals.
- Dry the instruments completely using medical compressed air and disposable, lint-free cloths.

Machine Cleaning

Implant Tray and Instruments

- Rinse the articles under cold running tap water to remove visible soil.
- Use a soft bristled brush and lumen brush to aid in removal of visible soil while rinsing
- Using a syringe, flush hard to reach areas while rinsing
- Prepare a neutral detergent Valsure[®] Neutral in a sonication unit at ¼ oz. per gallon of warm (37 – 40 °C/98.6 – 104 °F) tap water. Immerse in the sonicator and actuate.
- Using a syringe, flush hard to reach areas with the detergent solution and then allow the implant tray and instruments to sonicate for 10 minutes
- Transfer the implant tray and the instruments in the washer for reprocessing and choose the following cycle parameters:

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Enzo enzymatic 1 oz/gallon
Wash 1	02:00	65.5 °C/150 °F	ValSure neutral ¼ oz/gallon
Rinse 1	00:15	Distilled water	N/A
Drying	06:00	98.8 °C/210 °F	N/A

Dry the implant tray and instruments completely using medical compressed air and disposable, lint-free cloths.

Maintenance, Inspection, and Testing

After cleaning the implants and instruments must be macroscopically clean; free from visible residues and soiling. Inspection is performed visually. Insufficiently cleaned implants and instruments must be cleaned again and then adequately rinsed and dried. Deformed or damaged implants and instruments must be removed and disposed of, as they can no longer be guaranteed to be safe to use.

Packaging

The implant tray must be placed in a suitable sterile barrier system. The sterile barrier system must meet the following criteria:

- The implant and instrument trays may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.

The packaging for terminally sterilized medical devices should fulfill the following requirements:

- AAMI/ANSI/ISO 11607
- Suitable for steam sterilization (temperature resistance up to at least 141 °C/286 °F, sufficient steam permeability)
- Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- Sterilization equipment and sterilization wrapping must match both the wrap contents and the employed sterilization method.

Sterilization

Cycle type	Temperature	Exposure Time	Dry time
Pre-vacuum (steam)	132 °C/270 °F	4 minutes	30 minutes
Pre-vacuum (steam)	134 °C/273 °F	18 minutes	30 minutes

It is essential to attain a sterility assurance level of 10⁻⁶.

Storage

After sterilization, the medical devices must be stored in the sterilization packaging in a dry, dark, cool, and semi-sterile place, protected from dust and free from vermin. To avoid the development of condensation, major temperature fluctuations should be avoided during storage. Chemicals must not be stored together with implants and instruments. The walls, floors, and ceilings of the storage room should be smooth and easy to clean and disinfect. Shelves must be at least 30 cm off the floor. The duration of storage permitted depends on the type of sterile barrier system employed and the storage conditions. This storage period must be established by the operating authority. Sterile packaging should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Disposal

National regulations have to be considered when disposing the products, its components and its packaging.

Further information on reprocessing

Validated machine cleaning and disinfection is always preferred over manual cleaning because of the greater certainty of the method. Good cleaning helps to preserve value and is a precondition of successful sterilization. During machine processing, the following points should be noted:

- Correct loading of the storage trays for rinsing is a precondition for effective machine processing. Storage trays must not be overloaded.
- Rinsing shadows due to large instruments must be avoided.

The times and temperatures specified in these reprocessing instructions are minimum requirements and must not be less than those stated here. If they are to be reduced for technical reasons, this must be validated by the operating authority. Exceeding the stated times and temperatures is always possible but leads to increased stress on the material, which may result in premature ageing of the implants and instruments. The use of other sterilization methods is outside our responsibility.

Information on validation processing

Validation was performed with the following equipment, materials, and chemicals:

Manual / Machine cleaning and sterilization

Cleaning and Disinfection Device (CDD): Steris Genfore washer/disinfector
 Cleaning agent: Enzo[®] enzymatic
 Neutralizer: Valsure[®] Neutral detergent
 Ultrasonic bath: Bronson sonicator
 Sterilizer: Steris AMSCO LV250
 Wrapping: Kinguard KC600
 Additional equipment: Lumen brushes, soft-bristled brushes, syringes

Note

The user is responsible for the actual processing achieving the desired results with the equipment, materials, and staff employed in the processing facility. Usually, this requires validation and routine monitoring of the method. If the previously described equipment, materials, and chemicals are not available, it is the responsibility of the user to validate his method accordingly. Please note the instructions and regulations of the relevant national regulations and standards and any instructions for use accompanying the medical device. Please note that all instruments sent to the Medicon Repair Service (MRS) for repair must be cleaned and sterilized prior to dispatch. Medicon eG reserves the right to modify these instructions whenever new information is obtained.

12. LIABILITY

In the event of discrepancies between the english and the german version of these instructions for use only the German version shall be applicable. Only the latest revision of the instructions for use applies. Due to constant technical development the contents of these MEDICON instructions for use are

updated regularly. Please use the MEDICON extranet www.medicon.de/extranet to ensure that you are using the current version. The current version date is printed on each edition of the instructions for use.

MEDICON eG assumes no liability for damages caused by improper use, care or maintenance or non-compliance with the restrictions for use, non-observance of post-operative instructions and other guidelines in the instructions for use. The liability for defects by MEDICON eG is also not applicable in case of changes or repairs to the product without prior written consent from MEDICON eG as well as in case of repairs which were not carried out by workshops authorised by MEDICON eG or the Medicon Repair Service (MRS).

Caution: for USA, federal law restricts this device to purchase by or on behalf of a physician or hospital.

13. SIGNS AND SYMBOLS

- Consult Instructions for Use
- CE label according to directive 93/42/EEC
- Warning
- Single use product
- Manufacturer
- Non-sterile
- Batch code
- Catalogue number
- Rx only** Prescription use only (US Federal Law)

Distributor in the US for product information and complaints:

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