medicon®

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OPERATING INSTRUCTIONS

for the US market CE 0123 **Rx only**

MINI AND MICRO TITANIUM 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 pure titanium or Titanium alloy. Both materials are biocompatible, corrosion-proof and nontoxic in the biological environment. They allow imaging virtually free of artifacts.
- conventional x-ray radiography
- computer tomography
- MRI (Magnetic Resonance Imaging).

The surface is chemically passive and the material is antimagnetic.

Table of contents

1. GENERAL INFORMATION

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

2. INTENDED USE/INDICATIONS

For Mini Titanium Plate System: (K951690):
- Osteosynthesis of mandibular fractures, including simple fractures, multiple fractures, fractures of the mandibular angle, and fractures at the ascending ramus of the mandible;
- Osteosynthesis of maxillary, zygomatic arch, sphenoidal, temporofacila, orbital, and nasal skeleton fractures;
- Osteosynthesis of cranial fractures, including squamofrontal and parietofrontal fractures;
- Osteosynthesis of orthognathic osteotomies of mandible, maxilla, midface and cranium, including LEFORT I, II, and III osteotomies, sagittal split procedures of the mandible, and craniofacial osteotomies.

For MicroTitanium Plate System (K951688):
- Osteosynthesis of fractures, comminuted fractures and osteotomies in the maxillary region, midface, and cranial skeleton;
- Osteosynthesis of maxillary, zygomatic arch, sphenoidal, temporofacila, orbital, and nasal skeleton fractures;
- Osteosynthesis of cranial fractures, including squamofrontal and parietofrontal fractures;
- Osteosynthesis of orthognathic osteotomies of maxilla, midface and cranium, and craniofacial osteotomies.

3. CONTRAINDICATIONS

- Patients who are unable to follow the instructions for postoperative care. Such inability may be caused by psychological/mental or neurological conditions of the patient.
- Patients with unstable physical and/or mental health conditions.
- Patients with insufficient or poor-quality bone tissue, circulatory disorders or latent infections.
- Oversensitivity to materials and foreign-body reactions. Preimplantation tests must be carried out even if such oversensitivity or reactions are only suspected.
- Acute infections.

4. POSSIBLE SIDE EFFECTS AND COMPLICATIONS

- Insufficient adaptation of the implants can lead to bone union delay or failure.
- Complaints, pains, abnormal sensations or palpability of implants.
- Material/foreign-body sensitivity of the patient with allergic reactions.
- Stronger connective-tissue reaction in the fracture region or in the vicinity of the implant.
- Delayed or insufficient fracture healing leading to possible implant breakage.
- Inadequate healing.
- Insufficient bone formation, osteolysis, osteoporosis, reduced revascularization or infection, which can lead to loosening, bending, breakage or rupture of the implant.
- Breakage, bending, migration or loosening of the implant.
- Reduced bone density due to “stress shielding”.
- Loosening of the implant as a result of insufficient screw tightening.
- Osseous necrosis, osteoporosis, inhibited revascularizat on, boneresorption, and poor bone formation, which can cause premature loss of fixation leading to non-union.
- Extreme or repeated bending of the plates in the same place can result in plate breakage.
- Unstable comminuted fractures can lead to an increased connective tissue reaction in the fracture region.

This surgical procedure may cause not only the above-mentioned side effects and complications but also problems such as injuries to nerves, infections, pain etc., which are not necessarily caused by the implant.

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 re-used. 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 wthin 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. MRI COMPATIBILITY

The safety, compatibility, and heating of the implants in the MR environment have not been tested. The responsible physician is responsible to inform the patient that they carry an implant that has not been tested under MR conditions. It is then the responsibility of the patient to inform the treating physician prior to an MR examination.

7. Implant selection

The surgeon is responsible for the correct selection of implants.

The following aspects are critical for the correct selection of implants:
- bone defect to be treated / intended bone repositioning,
- body weight of the patient,
- general health condition, degree of activity of the patient.

Incorrect implant selection can lead to premature implant loss and cause loosen-ing, deformations and fractures of the implants. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, or fracturing of the product and/or bone.

The success of an operation also depends on how the implants are handled. The plates must be bent carefully and cautiously, avoiding repeated and excessive bending. Scratches and other damage can reduce the stability of the product and result in early fatigue of the implant. Medicon implants and instruments have been designed for being used together.

Using implants or instruments from other manufacturers in conjunction with Medicon products entails unpredictable risks since the products will not be matched to each other. To avoid such risks, only Medicon products that are intended for combination with each other may be used together. Prior to applying the products, the surgeon must thoroughly discuss with the patient the intended outcome of the operation.

In such discussions, special attention must be paid to postoperative care measures that may become necessary. The patient must be informed that, due to its limited stability, the fixation must not put under the load of the full body weight. The patient must also be informed that non-observance of this advice can put at risk any safe bone union. The patient must be instructed to inform the surgeon immediately if they notice unusual changes in the situs. 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. In cases of failed, delayed or insufficient bone 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. The incessant load changes, to which the implant will be subjected, can lead to fatigue fractures. The implants can be removed once the fracture has healed completely.

An implant left in the body after complete healing may act as a load-baring element and can contribute to an increased risk of re-fracturing in active patients. For this reason, we accept liability for the implants only until healing is complete. We will not accept liability for any damage or injuries caused by implants that were not removed as soon as healing of the treated fracture was complete. 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 will break, loosen, corrode, migrate through 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 AND HANDLING OF PLATES

The plates need to be adapted to the natural or planned bone contours as precisely as possible. Only use the instruments provided by the manufacturer for the purpose of adapting the plates. During the plate bending procedure the plates are subjected to cold stresses, under which the titanium hardens and 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. The plates must not be bent back and forth more than 2 – 3 times. Overaggressive 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 holes; they also compromise the precise seating of the screw head in the plate. Therefore the plates must be bent cautiously. Adapted plates must be inspected for notches, deformed screw holes and other mechanical damage before they are applied to the patient. 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. When shortening a plate, 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 cut edges of a shortened plate must be deburred to prevent tissue injuries or irritations. Bending templates must not be implanted under any circumstances.

9. APPLICATION AND HANDLING OF SCREWS

Self-tapping screws do not require pre-cutting of threads. To apply the drill holes, only use the drills designated by Medicon for the respective 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 the 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. Use the emergency screws intended for this purpose if, due to a failed drilling effort or a worn drill hole, the original screw cannot be anchored firmly in the bone.

To ensure that the screwdriver blade is firmly seated in the screw head, axial pressure must be applied when the screwdriver is inserted into the screw head. This ensures the correct axial alignment of screw and screwdriver, and prevents slipping of the screwdriver blade and damage to the screw head. Application of excessive force when tightening the screws can lead to intraoperative screw breakage. 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, every screw and plate connection must be checked for stability. 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-drilling screws

It is normally not necessary to drill a pilot hole for self-drilling screws. Still, in dense and hard bones, e.g. at the calvarium or in the mandible, it may be necessary to prepare drill holes. Self-drilling screws are unsuitable for small bone fragments as the axial pressure on them can lead to fragment shifts or screw breakage.

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 Enzol® enzymatic detergent at 1oz. per gallon warm tap water.
- Immerse the tray to soak for 1 minute into Enzol® 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 distillated 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 Enzol® 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 distillated 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	Enzol 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. Dur-ing 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 Dis-infection Device (CDD):	Steris Genfore washer/disinfector
Cleaning agent	Enzol® enzymatic
Neutralizer:	Valsure® Neutral detergent
Ultrasonic bath:	Bronson sonicator
Sterilizer:	Steris AMSCO LV250
Wrapping:	Kimguard 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 0123	CE label according to directive 93/42/EEC
	Warning
	Single use product
	Manufacturer
	Non-sterile
LOT	Batch code
REF	Catalogue number
Rx only	Prescription use only (US Federal Law)

Distributor in the US for product information and complaints:

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