



Carefully read the operating instructions before clinical application, and keep them safe and at hand. The instructions and notes contained therein must be followed.

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### 1. General Notes

The MEDICON implants are made of titanium or titanium alloy. Both materials are biocompatible, corrosion-resistant and non-toxic in a biological environment. The surface is chemically passive; the material is antimagnetic.



The MEDICON Mandibular Reconstruction and Fracture Plate Systems are supplied in non-sterile condition and must therefore be disinfected and sterilised before the single use. Please observe the following notes. These will ensure flawless and reliable functioning of the product.

### 2. Intended Use and Indications

The plate systems by MEDICON are intended for surgical interventions and may be used only by doctors and surgeons with sufficient training and experience in oral and maxillofacial surgery in hospitals and practices. The implants are single-use products and may be used only in combination with the specified MEDICON application instruments.

#### Mandibular reconstruction plate systems:

- 2.0 Reconstruction, 2.4 Reconstruction and 2.4 Reconstruction with locking)
  - Immediate replacement in case of mandibular bone loss
  - Primary and secondary functionally stable bridging of mandibular defects following ablative tumour surgery or trauma
  - Fixation of bone transplants

#### Mandibular fracture plate systems: (2.0 Fracture with locking and 2.4 Fracture)

- Treatment of simple and multiple mandibular fractures, including of the mandibular angles

The fracture plate system is intended as a support for normal bone healing but not for replacing normal body structures or for bearing the body weight in case of insufficient bone healing.

### 3. Contraindications

- Patients who are unable to comply with the instructions for postoperative care,
- for example due to psychological, mental or neurological problems
- Patients in unstable physical and/or mental condition
- Patients with inadequate or low-quality bone tissue, with perfusion problems or latent infections
- Material hypersensitivity, i.e. reaction of the patient to foreign bodies. Here appropriate tests are mandatory before implantation (even in case of mere suspicion!)
- Acute and manifest infections

### 4. Mögliche Nebenwirkungen und Komplikationen

- In case of insufficient adaptation of the implants, bone healing may be delayed or the bone may heal insufficiently or not at all
- Discomfort, pain, abnormal sensations due to the implant
- Material hypersensitivity of the patient due to foreign objects in the form of allergic reactions
- Elevated reaction of the connective tissue in the area of the fracture and/or the implant
- Delayed or insufficient fracture healing, which can result in breakage of the implant
- Insufficient healing
- Insufficient bone formation, osteolysis, osteomyelitis, osteoporosis, inhibited revascularisation or infection that may lead to loosening, bending, tearing or breaking of the implants and endanger the fixation or the healing of the bone
- Breaking, bending, migration or loosening of the implant
- Decrease in bone density due to stress shielding
- Implant loosening caused by insufficient tightening of the screws
- Bone necrosis, osteoporosis and bone resorption can lead to non-union formation

- Extreme and/or multiple bending of the plates at the same point may cause the plates to break
- Unstable comminuted fractures can lead to increased connective tissue reactions in the area of the fracture, which may present as deep or superficial early or late infections

In addition to the undesirable effects and complications already mentioned, the surgical procedure can lead to other problems such as nerve damage, infections, pain etc. that are not necessarily attributable to the implant.

### 5. Single-Use Product



Implants are intended and designed for single use on one patient only and may not be reused

An explanted implant must never be reused. Even if the implant appears to be intact or fully functional, there may be wear, minor defects and attrition due to overuse that are not visible to the naked eye.

As the impact of the forces and conditions inside the body on the stability, function and material quality of an explanted implant cannot be estimated, reimplantation would entail the risk of premature wear or failure and is therefore unacceptable. The user will be held liable if the operating instructions are not observed.

### 6. MR notes



#### Instruments

The use of medical devices in the vicinity of an MR poses a hazard. Individual medical devices must not be located near the equipment during the application of these procedures.

#### Implants

The implants are not MR-safe and have not been tested for MR safety. Therefore, use in an MR environment may pose a risk. It is recommended to inform patients and medical staff that the implants are not approved for use in MR devices.

### 7. Application and handling

#### Implant selection



The surgeon is responsible for correct selection and use of the implants.

The following aspects are critical for correct implant selection:

- Bone defect to be treated or bone repositioning, respectively
- Patient's body weight
- Physical condition and level of activity of the patient

Incorrect implant selection can result in premature loosening, bending or implant breakage and therefore loss of function. Only use of the correct components ensures sufficient blood supply to the bone and will result in optimally stable fixation, whereas an incorrect decision may lead to loosening, bending or breakage of the implant and/or bone. The success of an operation depends, among other things, on how the implants are handled.

The plates must be bent carefully, avoiding excessive deformation. Plates must not be bent to and from more than 2 to 3 times. Damage leads to reduction in product strength and premature fatigue of the implant. Implants and devices are developed and manufactured to be compatible with each other. Using products by other manufacturers with MEDICON products may lead to unforeseeable risks and/or danger of the material becoming contaminated, as well as the instrument and implant not being sufficiently compatible. Patients, users and/or third parties may be endangered as a result. The patient must be informed that due to the limited stability loading of the implant with the body weight should be avoided, and that non-compliance can endanger safe bone healing. The patient must be carefully monitored if there are actual changes in the fixation area. If bone healing fails to set in, or is delayed or inadequate, the possibility that the implant will bend, fail or break cannot be ruled out. Therefore adequate immobilisation of the fracture site must be ensured until the bone has grown together again firmly. The constant load change the implants are subject to may lead to fatigue breakage. The decision on whether the implants should remain in the body or be removed after complete healing is the responsibility of the surgeon and should be made after considering the risks and benefits of each approach. It cannot be ruled out that the implants may break, loosen, bend, migrate in the tissue and cause pain.

#### Use and handling of plates:

The plates must be adapted to the natural bone structure as precisely as possible. Use only the instruments and bending templates provided by MEDICON for adapting the plates. Bend the bending templates into the desired shape, then transfer this shape to the bone plates in order to avoid unnecessary bending of the plates. During the bending of the plate, cold straining of the material occurs, under which the titanium increases in hardness but simultaneously loses deformability. It is therefore essential to use as few bending steps as possible to achieve the desired shape of the implant.

Excessive bending can lead to post-operative breaking of the plates. Plates must not be bent to and from more than 2 to 3 times. Excessively forceful use of the

bending instruments can lead to visible implant damage (marks, deformed plate holes, etc.). In such cases, a new plate must be used and adapted more carefully. Deformed plate holes for screw insertion not only lead to increased risk of breakage in these locations, but also compromise the precise fixation of the screw head and the locking in the plate. Plates must therefore be bent carefully, and it is recommended that the intended bend protection screws be used with the locking plates. Deformed plates must always be checked for notches, deformed screw holes or other mechanical damage before being used on the patient. Damaged plates must be replaced. Always choose the plate that best suits the specific situation. Should it be necessary to shorten a plate, use only the instruments provided for this purpose. The plate must be cut between the screw holes. Ensure that the cut-off part of the plate is not catapulted towards the patient, the surgeons or others, to prevent putting them at risk. The cutting edges of a shortened plate must be deburred in order to prevent tissue injury or irritation. For plates that have compression holes, the compression technique can be used in addition to use of the standard screws. Only plates and screws from the same system may be used together.

- Plates from Reconstruction System 2.4 with the corresponding bone screws
- Plates from Reconstruction Locking System 2.4 with the corresponding locking screws
- Plates from Fracture Locking System 2.0 with the corresponding locking screws
- Plates from Fracture System 2.4 with the corresponding bone screws

The implants from Fracture Locking System 2.0 and the plates from Fracture System 2.4 are not suitable for reconstruction.

The locking screws must be inserted at an angle of 90° to the plate surface. Bending angles of more than 15° and small bending radii (< 30 mm) must be avoided, as they carry the risk of post-operative plate breakage. No primary straight plates may be used at the outer mandibular angle. Always use the intended angled plates or total plates.

#### Use and handling of screws:

All screws are self-tapping. Therefore, drilling a threaded hole is usually not required. In cases of compact spongiosa and in close proximity to an osseous gap, we recommend drilling a threaded hole anyway before inserting the screw. Use only the drills specified by MEDICON to drill holes so that the correct hole diameter required for the screws can be achieved. Use only drill bits with sharp cutting edges. There is a risk of heat damage to the bone during drilling. Therefore always ensure sufficient cooling during the drilling process, and use low drilling speeds. Excessive force during the drilling process can result in fracture of the tool, which can be dangerous for the surgeon, patient and third parties.

If the screw cannot be securely anchored in the bone due to an incorrect or worn-out drill hole, the emergency screws intended for such circumstances are to be used. The screw-driver must be inserted into the screw head with axial pressure to ensure that the blade sits tightly on the head. This guarantees correct longitudinal alignment of screw and screwdriver and prevents slipping of or damage to the screw head or the blade. If excessive force is used during fixing of the screws, the screws may break during surgery, or the screw heads may tear off. Wear and tear effects to the screwdriver blade impair the firm connection between the blade and screw. In this case, replace the blade with a new one.

The screws are self-retaining on the screwdriver blade. Excessive tightening of the locking screws may cause the threads to pull out. In such a case, the defective locking screw and / or the locking plate is to be replaced with a new one. The damaged locking screw and / or locking plate may not be used further. Upon completion of the implantation, the secure connection between all screws and plates must be checked. If necessary, re-tighten the screws. Before removing the implant, all screw heads must be thoroughly cleaned with a scalpel or other suitable instrument so that the screwdriver sits perfectly on the screw head. The locking screws must always be inserted in a right angle to the splinting plate to ensure a tight connection between plate and screws and to avoid damage to the thread. Always use the drill guide for the corresponding locking system to precisely place the drill hole.

#### Use and handling of instruments:

The MEDICON instruments intended for application of the system are subject to wear and mechanical stresses even when used normally, but especially if used too forcefully. In order to prevent failure or mechanical damage to the instruments during surgery, they must be checked before each use to ensure that they are mechanically intact, that there are no deformations, and that the parts are fully functioning. Instruments that are damaged in this manner must not be used.

### 8. Pre-Operative and post-operative behaviour

#### Pre-operatively:

Before using the products, the surgeon must thoroughly discuss the desired operation result with the patient. Particular attention must be paid to post-operative behaviour and potentially required follow-up care.

#### Post-operatively:

The patient must be instructed to immediately inform the surgeon about any unusual changes at the operation site. The surgeon must consider possible consequences such as implant failure, and discuss required measures for further healing with the patient.

An implant that remains in the body after complete healing can act as a load support and contribute to an increased risk of re-fracture. The decision on whether the implants should remain in the body or be removed after complete healing is the responsibility of the surgeon and should be made after considering the risks and benefits of each approach.

A "LOT" number (batch number) is indicated on the label of the packaging. To ensure 100% traceability, we recommend noting down the "LOT" number in the patient records.

#### Disposal:

Observe the applicable national laws when disposing of the MEDICON system and accessories!

### 9. Decontamination, cleaning and sterilisation



Cleaning solutions to which hydrogen peroxide has been added and/or very alkaline washing solutions can cause colour changes. This may cause the cording function to be lost. Only cleaned and disinfected implants may be sterilised.

#### Place of use:



Implants contaminated with blood and/or secretions must not be placed back into the implant storage tray. They must be disposed of.

#### Preparation for decontamination:

The implant storage tray must be appropriately placed on a washer-proof instrument carrier for rinsing. The instrument carriers (for example wire mesh trays) must be such that subsequent cleaning in the washer-disinfector (WD) is not impaired by "rinsing shadows" or "sound shadows" that may render any areas inaccessible to ultrasound or rinsing.

#### Pre-cleaning:

Always use fresh and previously unused cleaning solution for manual pre-cleaning in the ultrasonic bath to prevent cross-contamination.

- Place the implant storage tray in the ultrasonic bath and treat with ultrasound for 15 minutes at 40 °C (104 °F) using 0.5 % alkaline cleaner (Neodisher® Medi-Clean forte).
- Remove the implant storage tray and thoroughly rinse it with cold water.

A high level of contamination in the cleaning basin will impair the cleaning effect and promote corrosion. The cleaning solution must be regularly replaced, depending on the conditions of use. The decisive criterion is optically recognisable contamination. In any case, the bath must be changed frequently, at least once a day. The national guidelines have to be observed.

#### Automated cleaning:

To prevent cross-contamination during machine processing, always clean and disinfect the implant cassette containing the implants to be reprocessed in the washer-disinfector (WD) in an individual run, separate from instruments contaminated with blood or secretion. The WD must comply with the requirements according to DIN EN ISO 15883-1.

- Prewashing: 3 minute with softened cold water, without additives
- Emptying
- Cleaning: with softened water, heating to 55 °C (131 °F) and 5 minutes washing and cleaning, addition of the cleaning agent at 45 °C (113 °F), alkaline cleaning agent (Neodisher® MediClean forte), dosage 0.5 %.
- Emptying
- Neutralisation: 3 minutes with warm water (>40 °C (104 °F)) with addition of neutraliser, dosage 1 ml/l
- Emptying
- Final rinse: 2 minutes with warm, fully demineralised water (>40 °C) (without any other additives)
- Emptying

#### Disinfection:

Thermal disinfection A0 value 3000:  
– Fully demineralised water, thermal disinfection is carried out at temperatures >80 °C (>176 °F) with a corresponding application time according to the A0 concept of standard DIN EN ISO 15883-1 and guideline DGHK, DGSV and Akl  
(e.g. A0 3000 = 90 °C (194 °F) and 5 minutes application time).  
– The operator is responsible for the A0 value to be implemented.

#### Drying:

Sufficient drying must be ensured by the WD (e.g. 60 °C (140 °F), 30 minutes). The instruments must be removed from the WD immediately after completion of



the cleaning and disinfection programme. If required, use of pressurised air for drying is recommended due to its good and quick effect (RKI recommendation).

#### Manual cleaning:

- Rinse the instruments for at least one minute with cold tap water to remove visible contaminants, and move the movable parts while rinsing the instrument. Use a soft bristle brush and lumen brush to remove contaminants during the rinsing process, and move the movable parts during the rinsing. Use a syringe to rinse the lumina (interior spaces, threads and holes) with rinsing water.
- Prepare enzyme cleaner Enzo® with 1 ounce per gallon of tap water and soak the instruments in it for at least one minute.
- Brush off the instruments after the soaking process using a soft bristle brush and lumen brush for at least one minute to remove residual contaminants.
- Use a syringe to clean interior spaces, threads and holes using the enzyme cleaner solution.
- Remove the instruments from the enzyme cleaner solution and rinse them under tap water to remove cleaning solution residues.
- Prepare the neutral cleaner Valsure® Neutral in an ultrasound unit using ¼ ounce per gallon of hot water (37 to 40 °C (99 to 104 °F)). Immerse the instruments into the ultrasound unit and actuate them.
- Use a syringe to rinse the lumina (interior spaces, threads, holes) using a cleaning solution, and treat the instruments with ultrasound for at least 10 minutes.
- Remove the instruments from the ultrasound unit and rinse them under cold demineralised water to remove cleaning solution residues.
- Fully dry the instruments using pressurised air and a lint-free disposable cloth.

#### Maintenance, control and inspection:

Following cleaning/disinfection, the implants must be macroscopically clean, i.e. free from visible dirt and residues. The inspection is performed visually. Insufficiently cleaned im-plants must be cleaned again and then rinsed and dried sufficiently. Deformed or damaged implants must be sorted out and disposed of, as safe use cannot be guaranteed.

#### Packaging:

The implant storage tray is to be inserted into a suitable sterile barrier system. The sterile barrier system must meet the following requirements:

- DIN EN 868
- DIN EN ISO 11607
- suitable for steam sterilisation (steam permeability)
- sufficient temperature resistance up to 138 °C (281 °F)
- Sterilisation accessories and sterilisation packaging must be adapted to the package con-
- tent as well as to the sterilisation procedure to be applied.

#### Sterilisation:

For sterilisation, the following sterilisation procedure is to be used, taking into account all applicable national requirements:

- Fractionated vacuum procedure, triply fractionated and with sufficient product drying
- Steam steriliser validated according to DIN EN 13060 or DIN EN 285, respectively, and according to DIN EN ISO 17665-1.
- Sterilisation time and temperature: At least 5 minutes hold time at 134 °C (273 °F)

Reaching an SAL (Sterility Assurance Level) of 10<sup>-6</sup> is indispensable.

#### Storage:

Reprocessed sterile implants are to be stored in dry, dust-protected, low-germ, dark and cool rooms, free of vermin, in an appropriate reusable sterilisation container. To prevent condensation, extreme temperature fluctuations should be avoided during storage. No chemicals may be stored together with implants. Walls, floors and ceilings of the storage room should be smooth and easy to clean and disinfect. Shelves must have a ground clearance of at least 30 cm (12"). The permissible on-site storage period depends on the type of sterile barrier system used and on the storage conditions. The permissible storage period is to be specified by the operator.

#### Additional information on reprocessing:

A validated machine cleaning and disinfection procedure is always to be preferred to manual cleaning because of the greater safety of the process. Thorough cleaning also helps to maintain value and is a prerequisite for successful sterilisation. Please take note of the following points regarding automated processing:

- For effective automated processing, load the wire mesh baskets in such a way that they can easily be mechanically rinsed. Mesh baskets must not be over-loaded
- Avoid "rinsing shadows" cast by large instruments

The times and temperatures stated in these reprocessing instructions are minimum requirements that must be adhered to. Should any reduction be needed for procedural rea-sons, this must be validated by the operator. Exceeding the specified times and temperatures is generally possible. However, this will lead to increased stress on the material, which can cause premature wear. We accept no responsibility for use of other sterilisation procedures.

#### Information on validation of the processing procedure:

The validation was carried out with the following devices, materials and chemicals: Washer-disinfector (WD):

Type Mieta Disinfector G 7735 CD  
 Trolleyforsurgical instruments  
 neodisher® MediClean forte  
 Dr. Weigert GmbH & Co. KG  
 neodisher® Z  
 Dr. Weigert GmbH & Co. KG  
 Sonorex DIGITEC DT 156 BH  
 MMM Vaculab 969 S 3000  
 MMM Selectomat S 3000  
 Stiefenhofer KS 666-2ED  
 H+P Varioclav 400E

#### Note:

The person processing the products is responsible for ensuring that the processing actu-ally performed with the equipment, materials and staff at the reprocessing facility achieves the desired results.

Validation and routine monitoring of the process are normally required for this. If the devices, materials and chemicals described above are not available, it is up to the persons processing the instrument to have their procedures appropriately validated. Please observe the notes and regulations of the relevant national laws and standards. MEDICON eG reserves the right to make changes to these instructions due to new findings.

#### 10. Liability

In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version is authoritative. The information in these operating instructions applies only to the product with which the operating instructions are supplied.

Only the latest revision of the operating instructions applies. Due to constant technical development, the contents of these MEDICON operating instructions are updated regularly. The version date is printed into each current edition of the operating instructions. MEDICON eG assumes no liability for damage caused by improper use, care or maintenance, or non-compliance with the restrictions for use and other guidelines in the operating instructions. MEDICON eG assumes no liability for defects in case of changes or repairs to the product without prior written consent from MEDICON eG either, nor in case of repairs not carried out by workshops authorised by MEDICON eG or by the MEDICON Repair Service. Please contact MEDICON eG if you have any further questions regarding the implants or instruments.

#### 11. Description of symbols and icons

	Observe the operating instructions
	Caution
	CE label acc. to Directive 93/42/EEC
	Manufacturer
	Do not reuse
	MR Unsafe
<b>Rx only</b>	Subject to medical prescription (US federal law)
	Production lot number, batch
	Item number
	Non-sterile