Instructions for Use for Medartis CMX MODUS 2 Mandible Plates, Guides and Bone Models

I. General Instructions

These instructions for use do not include all of the information necessary for use of the products. Additional, case-specific information can be found in the respective documents ("Case-specific Design Freeze Document", "Statement Custom-Made Devices"), which are supplied with each case and can be viewed online on the CMX Portal in the case overview. Information on the custom-made instruments (guides and/or models) can be found in the respective case documentation.

Additional information on the products (e.g. surgical techniques, instructions for handling of sterile products, instructions for reprocessing and maintenance, assembly/disassembly instructions, instruction for use for Medartis MODUS 2 plates, screws and instruments) can be found on the internet at www.medartis.com/documentation/instructions-for-use. They can also be requested from your local Medartis representative or the Medartis distribution partner. All instructions provided in this document and in the corresponding user information must be followed.

The individual parts of the system may only be accepted when the manufacturer's label and packaging are undamaged and unopened at the time of delivery. If this is not the case, the rejected goods must be returned to Medartis AG, Basel/Switzerland or to the relevant Medartis representative or distribution partner within ten working days.

The physician should always have an alternative to treatment available.

II. Scope

Implants, guides and bone models for the following MODUS 2 system are covered by these instructions for use:

- CMX MODUS 2 Mandible plates, guides and bone models

III. Product Description

Product Materials

Medartis implants and instruments are manufactured from biocompatible materials. All materials are standard implant and instrument materials for use in medical devices for orthopedics, traumatology, and general surgery.

Product	Material
CMX MODUS 2 Mandible plates	Pure titanium
CMX MODUS 2 Mandible guides and bone models	PA12 (Polyamide/Nylon 12)

Color Coding Concept

CMX MODUS 2 Mandible plates have their own color, corresponding to a specific implant technology:

Implant plates silver	TriLock plates (locking)

CMX MODUS 2 Mandible guides and bone models are not color coded.

The color coding concept of the MODUS 2 screws and instruments to be used is described in the "Instructions for Use for Medartis MODUS 2 Plates, Screws and Instruments". You can find the current version on the internet at www.medartis.com.

Intended Purpose and Indications

Plates

Intended Purpose
CMX MODUS 2 Mandible plates are intended for the positionally and functionally stable fixation of fractures and osteotomies and for reconstructive procedures in craniomaxillofacial surgery of a specific patient.

Indication
CMX MODUS 2 Mandible plates are indicated for reconstructive procedures and for bridging load-bearing bone segments in the mandible. This does not include the replacement of the condylar head.

Guides

Intended Purpose
CMX MODUS 2 Mandible guides are intended for use as surgical instruments for guiding purposes when marking, drilling or sawing the bone of a specific patient.

Bone Models

Intended Purpose
CMX MODUS 2 Mandible bone models are intended to illustrate preoperative and/or postoperative anatomical structures of a specific patient.

Risks About Which Your Patients Must Be Informed

Before using patient-specific products, inform your patients about the risks, contraindications and possible complications from the following sections ("Contraindications", "Side Effects / Possible Complications", "Warnings" and "Cautions"). Where appropriate, particular case-specific risks are listed in the "Case-specific Design Freeze Document" and/or the "Statement Custom-Made Devices".

Contraindications

- Preexisting or suspected infection at or near the surgical site
- Known allergies and/or hypersensitivity to product materials
- Inferior or insufficient bone quality to securely anchor the implant or the guide
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Blocking of growth plates with plates and screws

Intended User / Patient Target Group

The products may only be used by health care professionals, e.g. surgeons, radiologists, operating room staff, and individuals involved in preparation of the device, who hold the relevant qualifications.
Medartis, as the manufacturer, recommends that the user reads all available documents (e.g. surgical techniques, instructions for reprocessing and maintenance) before first use and contacts other users who have practical experience with this type of treatment. The user must be familiar with the state of the art and the instrument and implant function.
For specific patient target groups related to each system refer to the corresponding surgical technique of the system being used. Responsibility for proper selection of patients rests with the surgeon, based on the specific indications and contraindication of each system and on patient-related factors (e.g. activity, occupation, mental health, age, bone quality).

Intended Performance

The available clinical data confirms good clinical performance and safety outcomes of the CMX MODUS 2 Mandible plates, guides and bone models, when they are used according to the user information. This is in line with or superior to the state of the art.

IV. Side Effects / Possible Complications

In most cases, potential complications have a clinical source as opposed to arising from the implants/instruments. These include among other things:

- Loosening of the implant from insufficient fixation
- Hypersensitivity or allergic reactions
- Bone necrosis, osteoporosis, insufficient revascularization, bone resorption and poor bone formation that can cause premature loss of fixation
- Soft tissue irritation and/or nerve damage through surgical trauma
- Early or late infection, both superficial and deep
- Elevated fibrotic tissue reaction around the surgical area
- Poor accuracy of fit due to insufficient image data (e.g. old data, insufficient resolution)
- Complications in implant removal from improper explantation of the implant

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, or incorrectly combined implant components.

V. Warnings

- The products may only be used by medical personnel who hold relevant qualifications.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way. The physician should always have an alternative to treatment available.
- Medartis, as manufacturer, recommends that the user reads all available documents before first use and contacts other users who have practical experience with this type of treatment.
- The products are prescribed and designed specifically for the named patient only and may only be used for the treatment of the named patient. By approving the "Case-specific Design Freeze Document", the physician confirms that the custom-made product is linked to one specific patient only.
- Patient-specific products are to be used only for single use on the patient named in the "Statement Custom-Made Devices" and the indication specified there and are not to be reused under any circumstances.
- The designs of the custom-made products are based on medical image data of the patient mentioned in the "Statement Custom-Made Devices" and are therefore only applicable to this patient.
- Although the CMX MODUS 2 Mandible plates and guides are based on patient-specific anatomies, an optimal fit cannot always be guaranteed as this depends on the quality and currentness of the medical image data used.
- The CMX MODUS 2 Mandible guides and bone models are designed for short-term contact with tissue only (less than one hour). Under no circumstances may they be implanted in whole or in part.
- Do not drill or saw into the guide. Manipulation of the guide may cause abrasion, which should not be allowed to penetrate into the tissue. Thoroughly rinse the surgical site during and after drilling and sawing and aspirate any particles that may have formed.
- Do not drill or saw into the bone model, neither preoperatively nor intraoperatively. If manipulated, the bone model is no longer representative.
- CMX MODUS 2 Mandible guides and bone models may only be sterilized once.
- CMX MODUS 2 Mandible devices are supplied with the "Statement Custom-Made Devices". This must always be handed over to the patient.
- Note on compatibility: CMX MODUS 2 Mandible plates and guides are to be used exclusively with serial products of MODUS 2 Mandible (or with other products specifically listed in the "Case-specific Design Freeze Document"). MODUS 2 implants and instruments are not compatible with other MODUS systems in terms of color concept.

For application-specific warnings related to MODUS 2 Mandible, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VI. Cautions

- All of the system components have been developed and manufactured for a specific purpose and are therefore precisely adapted to each other. The user may not alter any of the components or replace them with an instrument or product from another manufacturer even if the size or shape is similar or exactly corresponds to that of the original product. The use of materials from other manufacturers, structural changes resulting from the use of third-party products and/or material impurities, as well as minor deviations or imprecise fit between the implants and instruments, or similar, can represent a risk for the user, patient or third parties.
- If the patient's anatomy has changed significantly since the medical image data were recorded, the guides shall no longer be used. Bone models are no longer

representative. Ideally, this should be clarified again before surgery. The physician should always have an alternative to treatment available.
- CMX MODUS 2 plates must not be cut or bent.
- Use the indicated screwdriver blade for the respective screw diameter. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction. If not, there is a greater risk of damage to the implant and screwdriver blade. When inserting the screw, ensure that a sufficient axial force is used between blade and screw. At the same time, the axial force should be in certain limits in order not to damage the bone structure.

For application-specific cautions related to MODUS 2 Mandible, it is mandatory to consult the surgical technique (www.medartis.com/documentation/instructions-for-use) of the corresponding product system being used.

VII. Instructions for Selecting Compatible MODUS 2 Serial Products

CMX MODUS 2 Mandible plates and guides can only be used in conjunction with MODUS 2 screws and instruments.
In principle, the CMX MODUS 2 Mandible plates and guides are compatible with 2.0, 2.3 and 2.5 screws. To bridge bone defects, the plates must be fixated with 2.5 TriLock screws. MODUS 2 screws, compatible drills and screwdriver blades are color coded.

Screw Diameters	Color Code
2.0	Blue
2.3	Brown
2.5	Purple

VIII. General Important Information

Clinical Benefits

In consideration of the patient's clinical condition and medical history, the treating physician shall ensure that the use of CMX MODUS 2 Mandible plates, guides and bone models can be justified based on a patient-specific benefit/risk assessment. Based on the clinical evaluation and risk analysis, all residual risks are deemed acceptable when weighed against the benefits to the patient based on current knowledge/the state of the art.

Selecting the Appropriate Implants

Medartis, as the manufacturer, does not recommend a specific surgical procedure for a specific patient. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case. The follow-up treatment as well as the decision of whether to retain or explant the implant is the responsibility of the user.
The treating physician must beforehand become thoroughly familiarized with the procedure, for example by:
- Carefully studying all the product documentation
- Carefully reviewing the current professional literature
- Consulting with colleagues experienced in this field and with the use of this system
- Practice in handling the system, practice of the surgical procedure and postoperative treatment

Generally, implants are designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place. They are not designed for long-term bone replacement. Where they are mechanically supporting the osteosynthesis, the regular operating period of the implants is expected to be between 30 days and 6 months.

Removal of Implants

In the case of complications, it might be necessary to remove the implants. For removal use the indicated screwdriver. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction.

Postoperative Care

Taking into account the individual fracture conditions and patient compliance, it is important to ensure adequate postoperative relief of the osteosynthesis in terms of adaptation or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved with the implants must be treated with care until the bone has fully healed. Patients must strictly observe follow-up instructions given by their physicians to avoid detrimental strain on the implants. Early load bearing can increase the risk of loosening, migration or breakage of the implants

Information on MR-Marking

MR Conditional

Non-clinical testing has demonstrated that all current Medartis implants are conditionally MR safe in accordance with the ASTM F2503-20 standard definition. A patient with this device can be safely scanned in a MR system meeting the following conditions. Failure to follow these conditions may result in injury. The MRI safety information was issued in May 2022.

Parameter	Notes
Item Name / Identification	Medartis MODUS 2
Item Manufacturer	Medartis AG
Location of MRI Safety Information	www.medartis.com/documentation/instructions-for-use
Static Magnetic Field Strength	3.0 T
Type of Nuclei	Hydrogen
Static Magnetic Field (B0) Orientation	Horizontal
Magnet Type	Cylindrical-bore
Maximum Spatial Field Gradient	19.5 T/m (1950 gauss/cm)
RF Excitation	Circularly polarized (CP)
RF Transmit Coil Type	Integrated whole body transmit coil
RF Receive Coil Type	Any receive only coil may be used.
RF Power	Normal operating mode (including FPO:B)
Maximum Whole-Body SAR	Whole-body SAR ≤ 2 W/kg **Note:** During non-clinical testing, the Medartis implants produced a maximal temperature rise of 26.5 ± 1.8°F (14.7 ± 1.0°C) at 1.5T for a measured wbSAR of 2.12 ± 0.81 W/kg and a maximal temperature rise of 9.9 ± 1.8°F (5.5 ± 1.0°C) at 3T for a measured wbSAR of 2.05 ± 0.88 W/kg both after 15 minutes of continuous scanning. Under the scan conditions defined above, the Medartis implants are expected to produce a maximum temperature rise of less than 11.7°F (6.5°C) (when adding uncertainties) at 3T after 15 minutes, and 7.2°F (4°C) after 7 minutes of continuous scanning.
Scan Duration and Wait Time	Scan for up to 30 minutes. Wait 30 minutes before the next imaging session.
Patient Characteristics	During the MRI scan, it is recommended to visually and audibly monitor the patient, including verbal communication. Patients with uncompromised thermoregulation and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat-induced physiological stress).
MR Image Artifact	MR image quality may be compromised if the imaging area of interest is in the exact same area of the implant. Some manipulation of scan parameters may be required to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 29 mm from the device when imaged with a gradient echo at 1.5T.

Note the following:
- Do not scan patients with impaired thermo regulation, temperature or pain sensation.
- Reduce the SAR as much as possible as reducing the SAR strongly reduces the temperature increase caused by RF heating.
- Use an external cooling/ventilation system to help reduce the body temperature.

IX. Cleaning, Disinfection and Sterilization of Non-Sterile Products

The supplied plates, guides and bone models are custom-made devices and are intended for SINGLE USE ONLY on a SPECIFIC PATIENT and are not designed to be reused. All components are delivered NON-STERILE and must be cleaned, disinfected and sterilized befor first use. All packaging must be removed before preparation.
Thorough cleaning and disinfection are essential for effective sterilization.

CMX MODUS 2 Mandible plates, guides and bone models should be wrapped in sterilization paper or packed in double bags approved for steam sterilization and sterilized according to the state-of-the-art and approved methods.

Due to the high temperatures during the cleaning, disinfection and sterilization steps, the guides and bone models must not be stacked or subjected to other loads. Otherwise, the high temperature during the sterilization process in combination with the load can lead to a deformation of the products.

It is your responsibility to ensure that the products are completely sterile when used, to use device- and product-specific procedures for cleaning/disinfection and sterilization that are sufficiently validated, to regularly service and inspect the employed devices (disinfector, sterilizer), and to ensure that the validated and/or manufacturer's recommended parameters are maintained.
The statutory regulations applicable in your country and the hospital's hygiene requirements must also be observed. This applies in particular to the various instructions for effectively deactivating prions.

After use, the products must be disposed according to local guidelines.

Detailed instructions for processing of medical devices are described in the brochure "Instructions for Cleaning, Disinfection, Sterilization, Inspection and Maintenance of Medartis Products" and can be downloaded from www.medartis.com/documentation/instructions-for-use.

X. Complaints and Adverse Events

Any complaint or adverse event that has occurred in relation to the device should be reported to the manufacturer and the respective national competent authority of the state in which the user and/or patient is established.

XI. References

The following user documentation on the products is additionally available online and can be found under the following link www.medartis.com/documentation/instructions-for-use:
- Surgical techniques
- Instructions for Use for Medartis MODUS 2 Plates, Screws and Instruments
- Instructions for handling of sterile plates, screws, staples and instruments
- Instructions for cleaning, disinfection, sterilization, inspection and maintenance
- Assembly/disassembly instructions

For additional information contact your local Medartis representative or the Medartis distribution partner or the manufacturer directly under the given address.

XII. Symbols

	Consult instructions for use
	Article number / Reference number
	Lot number/ Batch code
	Non-sterile
 Do not reuse	Single-use product. Do not reuse The product is intended for one single application in a single patient. Application of an already used product may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.
	Do not use if packaging is damaged
	Medical device
 YYYY-MM-DD	Manufacturer Date of manufacture
	MR Conditional
	Authorized representative in the European Community / European Union
	Importer
	TriLock (locking technology)

This document is subject to continuous revision. Please verify that the current printed version is the same as the online version in your case overview in the CMX Portal (cmx.medartis.com).

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Disclaimer: This information is intended to demonstrate the Medartis portfolio of medical devices. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. Medartis is not giving any medical advice.
The devices may not be available in all countries due to registration and/or medical practices. For further questions, please contact your Medartis representative (www.medartis.com).