

Instructions for Use for Medartis MODUS 2 Plates, Screws and Instruments

Introduction

These instructions for use are for a product line of Medartis AG, Hochbergerstrasse 60E, 4057 Basel/Switzerland Phone +41 61 633 34 34, Fax +41 61 633 34 00, www.medartis.com. All instructions provided in this document must be followed.

Notes Regarding the Delivered Goods

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 Territory Consultant or distribution partner within ten working days. Implants are intended for single use only and are not designed to be reused. All components that are delivered **NON-STERILE** must be appropriately prepared before first use. All packaging must be removed before preparation.

Product Materials

All MODUS 2 implants are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (ASTM F136, ISO 5832-3). All of the titanium materials used are biocompatible, corrosion-resistant and non-toxic in a biological environment. The instruments are made of stainless steel, PEEK, aluminum or titanium.

Color Coding Concept




All MODUS 2 screws, associated drills and screwdriver blades are color-coded.

Screw Diameter	Color Code
1.2	Red
1.5	Green
1.8	Yellow
2.0	Blue
2.3	Brown
2.5	Purple

Implants have an individual color:

Implant plates gold	Rigid fixation plates
Implant plates blue	Semi-rigid fixation plates
Implant plates silver	TriLock plates (locking)
Implant screws gold	Cortical screws (fixation) Lag screws
Implant screws green	SpeedTip screws (self-drilling) SpeedTip TriLock screws (self-drilling and locking) IMF SpeedTip screws (self-drilling)
Implant screws silver	TriLock screws (locking)

Markings/Symbols and Their Meanings

	TriLock (locking)		HexaDrive
	Self-drilling screws		

Intended Use

The MODUS 2 osteosynthesis systems are intended for oral and craniomaxillofacial surgery.

Indications

MODUS 2 Midface is indicated for midfacial trauma repair, fixation of maxillary osteotomies and reconstructive procedures in the midface.

MODUS 2 Orthognathics is indicated for maxillary (LeFort I, II and III) and mandibular (ramus and corpus) osteotomies and genioplasties as part of orthognathic surgery and for fixation of maxillary and mandibular traumas.

MODUS 2 Mandible is indicated for mandibular trauma repair, fixation of mandibular osteotomies, reconstructive procedures and bridging of load-bearing bone segments in the mandible.

MODUS 2 IMF is indicated for temporary perioperative fixation and/or stabilization of occlusion.

Contraindications

- Pre-existing or suspected infection at or near the implantation site.
- Known allergies and/or hypersensitivity to implant materials.
- Inferior or insufficient bone quality to securely anchor the implant.
- Patients who are incapacitated and/or uncooperative during the treatment phase.
- Blocking of cranial sutures/growth plates with plates and screws.
- Not intended for use in direct contact with the dura mater and the central nervous system.
- The IMF screws cannot be used in unstable fractures.

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 to metal 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.
- Complications in implant removal from improper explanation of the implant.

In consideration of patient's clinical condition and medical history, the treating physician shall ensure that the use of MODUS2 implants is appropriate for the individual case based on a patient-specific risk/benefit assessment.

Warnings and Precautionary Measures

- The products may only be used by medical personnel who hold relevant qualifications.
- 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.
- Compatibility information: MODUS 2 implants and instruments are not compatible with other MODUS systems in terms of color concept.
- 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.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way!
- All of the implant components are intended for single use and may not be reused under any circumstances.
- Necessary care must be observed for storage and use of the products:
 - Damages (e.g. from improper cutting or bending) to and/or scratches on the instruments/implants can substantially impair the strength of the product and lead to premature breakage.
 - Repeatedly bending the plate in opposite directions may cause the plate to break during postoperative treatment.
- The implant containers and instrument cases shall not be vigorously shaken or tipped over since the individual components may become damaged or fall out.
- Unless otherwise expressly stated on the label, the instruments can be reused.
- Twist drills: It is recommended not to exceed a maximum drilling speed of 1'000 revolutions per minute to avoid overheating the bone. Reusable, non-sterile packed twist drills and reamers may only be used for a maximum of ten times. Sterile packed twist drills and reamers are for single use only, and may not be reused under any circumstances.
- Use the indicated screwdriver for the respective screw size. 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.
- Implants can cause artifacts in various imaging procedures such as MR.

Information on MR-Marking



Conditionally MR safe

Non-clinical tests under worst case conditions show that all Medartis implants are MR conditional.

Magnetically Induced Torque and Displacement According to ASTM F2213-06 and ASTM F2052-06e1

Non-clinical tests in a 3T MRI system under worst conditions have shown that no relevant torque and displacement of Medartis products were observed at a maximum spatial gradient of 12 T/m.

Image Artifacts According to ASTM F2119-07

Non-clinical tests in a 1.5T MRI system showed image artifacts extended up to 29 mm away from the implant during a gradient echo pulse sequence.

Radio-Frequency Induced Heating According to ASTM F2182-11a

Electromagnetic and thermal simulations combined with non-clinical tests demonstrated maximum temperature rises of 13.1°C (1.5T) and 4.2°C (3T) after 15 minutes of continuous scanning (Normal Operating Mode, whole body specific absorption rate (SAR) of 2.1 W/kg)

Since the above test results were obtained through non-clinical tests, the actual in vivo temperature increase will depend on a variety of factors beyond the SAR and scan duration. Therefore, 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.

Multidirectional, Angular Stable TriLock Locking System

Correct locking ($\pm 15^\circ$) of the TriLock screws in the plate

Visual inspection of the screw head projection provides an indicator of correct locking. Correct locking has occurred only when the screw head has locked flush with the plate contour (Fig. 1 and 3). However, if there is still a noticeable protrusion (Fig. 2 and 4), the screw head has not completely entered the plate and reached the locking position. In this case the screw has to be retightened to obtain full penetration and proper locking. In case of poor bone quality a slight axial pressure might be necessary to achieve proper locking. Due to the system characteristics, a screw head protrusion of around 0.2 mm exists when using plates with 1.0 mm thickness.

Do not overtighten the screw, otherwise the locking function cannot be guaranteed anymore.

Correct: LOCKED

Incorrect: UNLOCKED

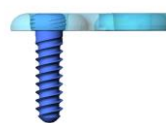


Fig. 1

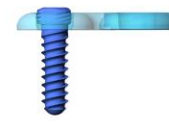


Fig. 2

Correct: LOCKED

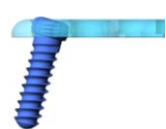


Fig. 3

Incorrect: UNLOCKED

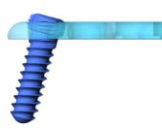


Fig. 4

Instructions for Selecting the Appropriate MODUS 2 Products

Medartis, as 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 should 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.

Taking into account the individual fracture conditions and patient compliance, it is important for the surgeon 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.

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.

Additional Information

Additional information on the products (e.g. the surgical technique, handling instructions for sterile plates, screws and instruments, care, cleaning, disinfection and sterilization of non sterile products) can be requested from your local Medartis Territory Consultant or distribution partner. In addition, all relevant information can be found on the internet at www.medartis.com.

Single-Use Device



Do not reuse

The product is intended for one single application in a single patient. Application of an already used device may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.

Sterile Packaged Products



The product has been subjected to a validated irradiation sterilization process and is supplied in sterile packaging. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use any product where the sterile packaging has been opened or damaged and do not remove them from the packaging until immediately before use. Once the sterile packaging has been opened, the product cannot be resterilized. Sterility of the device must be ensured at all times. The device is for single-use only and may not be reused under any circumstances. Reuse or reprocessing (e.g. cleaning and reesterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury.

Sterile packaged twist drills:

Single-use, sterile packaged cutting tools such as twist drills are intended for single-use and must not be reused. Reuse or reprocessing (e.g. cleaning and reesterilization) may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury. All single-use cutting tools have to be discarded after the operation following the local requirements.

Non-Sterile Products



Instructions Regarding Cleaning, Disinfection and Sterilization of Non-Sterile Products

All implants, instruments and containers in the MODUS 2 systems that are delivered **NON-STERILE** must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery (after removal of the protective transport packaging).

Thorough cleaning and disinfection are essential for effective sterilization. All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, have to be discarded following the local requirements. Application of an already used device may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, application of an implant that has already been used may create a risk of contamination e.g. due to the trans-

mission of infectious material from one patient to another. This could result in injury of the patient or user.

Implants that have not come into direct contact with a patient may be reprocessed. Implants that have come into direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the implant module.

It is your responsibility to ensure that the implants and instruments 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 for each cycle.

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.

Basic Instructions

If possible, use an automated procedure (disinfector) for cleaning and disinfecting. Do not use a manual procedure – even with an ultrasonic bath – due to the significantly reduced efficiency and potential damage.

Pretreatment is required in both cases.

Choosing Detergents, Disinfectants and Equipment

Observe the following aspects when choosing detergents, disinfectants and equipment for all steps:

- They must be suitable for their intended use (e.g. cleaning, disinfection or ultrasonic cleaning).
- The detergents and disinfectants must be aldehyde-free (otherwise blood residues may dry and attach firmly to surfaces).
- The disinfectant used must have a proven effectiveness (such as approval by VAH/DGHM or a CE marking).
- The detergents and disinfectants must be suitable and compatible for use with the products.
- The manufacturers' instructions, such as those regarding concentration, exposure time and temperature, must be followed.

For **cleaning materials and accessories**, both for precleaning and manual cleaning, observe the following:

- Use only clean, lint-free cloths (e.g. Peform classic from Schülke & Mayr) and/or soft brushes (e.g. Justman Brush from VWR International). Never use metal brushes or steel wool.
- When necessary, use materials and accessories such as cleaning stylets, syringes, cannulas and bottle brushes for cannulated products or products with a lumen.

For **drying accessories**, Medartis recommends lint-free disposable wipes (e.g. Perform classic from Schülke & Mayr) or medical compressed air.

For **water quality**, Medartis recommends that demineralized and purified water (e.g. Aqua purificata) is used for cleaning, disinfection and subsequent rinsing steps.

Medartis instrument cases are intended for the sterilization, transportation and storage of products. They are not intended for cleaning and disinfection when loaded. The products must be removed from the cases and then cleaned and disinfected separately.

Implant cases made of steel can undergo automated cleaning and disinfection when loaded. For manual cleaning, the implants must be removed from the system and then cleaned and disinfected separately.

Remove major contaminants in the operating room before segregating dirty instruments. Preferably use dry preparation for the transportation to the cleaning/sterilization department. If a wet preparation method is used, place the instruments in a prepared solution directly after usage. The instruments must be disassembled and opened as much as possible. All products (including grooves, holes, lumens, etc.) must be sufficiently covered with solution. To avoid damage to the materials, do not leave them in the solution for longer than directed.

Pretreatment Prior to Cleaning, Disinfection and Sterilization

Pretreatment process

- Disassemble and open the instruments as far as possible. When doing so, follow the assembly and disassembly instructions, which can be found at www.medartis.com.
- Empty the instrument cases completely and remove the lid, if necessary.
- For implant cases, the implants can be left in the case.
- Clean products and individual parts under running water using soft brushes (shift moveable parts back and forth, use cleaning wire, syringes and cannulas for cannulated products; for larger lumina, use a bottle brush if necessary).
- Visually inspect the products and repeat pretreatment as required until visible contamination is no longer evident.

The disassembled instruments and cases should remain dismantled for the following cleaning and disinfection process.

Manual Cleaning and Disinfection

Manual Cleaning Process

- Place the (disassembled) products in the cleaning bath with enzymatic cleaning solution for 5 minutes (e.g. CIDEZYME® Enzymatic Detergent Solution, 1.6 % v/v). The products must be adequately covered and the individual components should not be in a position to damage each other. Follow the enzymatic cleaner manufacturer's instructions for use for correct exposure time, temperature and concentration.
- Clean with a soft plastic brush (e.g. Justman Brush from VWR International).
- Shift moveable parts back and forth several times.
- Clean large lumina with a bottle brush.
- Cannulated products (with cavities whose diameter is less than or equal to 1/6 of the device's length), must be cleaned by inserting the dedicated cleaning stylet and rinsed using a suitable cannula and disposable syringe (rinsing volume: 30 ml).
- Clean the products in the ultrasonic bath for 15 minutes using a suitable detergent (e.g. CIDEZYME® Enzymatic Detergent Solution, 1.6 % v/v). Follow the enzymatic detergent manufacturer's instructions for use for correct exposure time, temperature and concentration.
- Rinse with cold ($T < 40^{\circ}\text{C}$) or warm ($T > 40^{\circ}\text{C}$) water for at least one minute (lumina and cannulated products must also be rinsed inside using syringes and suitable cannulas); hand-held water jets can also be used.
- Visually inspect the products and repeat the cleaning process as required until visible contamination is no longer evident.
- Inspect the products (see the section «Inspection»).

Manual Disinfection Process

- Place the (disassembled), cleaned and inspected products in the disinfection bath for 15 minutes (e.g. CIDEX® OPA Solution). The products must be adequately covered and the individual components should not be in a position to damage each other).
- Shift moveable parts back and forth several times.
- Large lumina must also be filled on the inside.
- Cannulated products (with cavities whose diameter is less than or equal to 1/6 of the device's length), e.g. cannulated drills, must be filled with disinfectant and rinsed using a syringe and suitable cannula (rinsing volume: 30 ml).
- Rinse with water for at least one minute (lumina and cannulated products must also be rinsed inside using syringes and suitable cannulas); hand-held water jets can also be used.
- Visually inspect the products and repeat the cleaning and disinfection process as required until visible contamination is no longer evident.
- The products must be completely dried directly afterwards (it is recommendable to dry them using medical compressed air).
- Inspect the products (see the section «Inspection») and service them (see the section «Product Care»).
- Pack the products preferably immediately or if necessary after giving them additional time to dry.

Automated Cleaning and Disinfection

For automated cleaning and disinfection instruments have to be removed from the cases. Instruments have to be opened and disassembled!

Implant cases can undergo automated cleaning and disinfection when loaded. Make sure the implant cases have been properly sealed with their lid prior to automated cleaning/disinfection.

The above recommendations must also be followed when choosing detergents and disinfectants for this process.

For automated cleaning, ensure that the products have been rinsed thoroughly and that there is no remaining foam.

When selecting the disinfectant, make sure:

- That the cleaning process includes the following phases in accordance with EN ISO 15883:

Phase	Temperature	Duration	Action
Cleaning	55°C (±2°C) (131°F; ±3.6°F)*	10 min.*	Adding detergent*
Neutralization	Cold (T < 40°C/104°F)	2 min.	Neutralize with cold water
Rinsing	Cold (T < 40°C/104°F)	1 min.	Rinse with cold water
Thermal disinfection (Ao value > 3'000)	≥ 90°C (194°F)	5 min.	With demineralized and purified water; do not add additional detergent
Dry	Device-specific (T < 141°C/286°F)	Device-specific	Drying process

* The information provided refers to the use of «Neodisher MediClean forte» by Dr. Weigert; the validation was performed with a concentration of 0.2 % at 50°C; if a different detergent is used, exposure times, concentrations and temperatures may vary, the relevant manufacturer's instructions must be observed.

When loading the disinfectant, use the loading layouts provided by the manufacturer; also follow the detailed information provided in «Instructions for Cleaning, Disinfection and Sterilization» at www.medartis.com.

Inspection (Implants and Instruments)

Check implants and instruments after cleaning and disinfection for damage and contaminants, and remove damaged and contaminated implants.

After the instruments are cleaned and disinfected, check them all for damage (e.g. corrosion, damage to surfaces, chipping, etc.), contaminants and function. Remove damaged instruments. In addition, instruments with lumina have to be checked for free passage without obstructions, cutting instruments must be checked for sharpness and rotating instruments must be checked for bending. Instruments that are still soiled must be cleaned and disinfected again. You can find further details at www.medartis.com in «Instructions for Cleaning, Disinfection and Sterilization».

Product Care

Carefully apply maintenance products (paraffin-based/white oil-based, biocompatible, steam-sterilizable and steam-permeable) to the articulations, closures or threads and sliding surfaces. Do not use maintenance products containing silicone.

The disassembled instruments and cases should be reassembled for the following sterilization process.

Sterilization

Medartis recommends sterilizing the products in the designated MODUS 2 implant containers and instrument cases.

If the total weight of the loaded module is over 10 kg, the module must not be sterilized in a sterilization container; rather, wrap it in sterilization paper and sterilize it according to state of the art techniques and using approved methods.

Steam Sterilization

All **NON-STERILE** products can be sterilized in an autoclave (EN 13060 and EN 285). For both initial and subsequent sterilization, the following parameters were validated by Medartis in accordance with the requirements of the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79:

Procedure	Fractionated and Dynamic Prevacuum Process	Flow and Gravitation Processes
Exposure time	≥ 4 min	≥ 15 min.
Temperature	132°C/134°C	132°C/134°C
Drying time	> 20 – 30 min.	> 20 – 30 min.

Medartis recommends that sterilization is performed in accordance with the above validated processes. If the user utilizes other processes (e.g. flash sterilization), these must be validated by the user.

The ultimate responsibility for validation of sterilization techniques and equipment lies with the user.

Outside the USA: the sterilization time can be extended to 18 minutes to meet the recommendations of the WHO and the Robert Koch Institut (RKI). Medartis products are designed for these sterilization cycles.

Do not use hot-air sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile products such as plasma or peroxide sterilization for Medartis products.

After sterilization, the products must be stored in a dry and dust-free environment.

Reusability (Implants and Instruments)

All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, have to be discarded following the local requirements. Application of an already used device may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, application of an implant that has already been used may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury of the patient user.






Implants that have not come into direct contact with a patient may be reprocessed. Implants that have come into direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the corresponding implant module. The instruments can be reused if corresponding precautions are observed and if they are undamaged and uncontaminated.






No liability is assumed by the manufacturer in case of non-observance.

Medartis recommends: if products come in contact with pathogens that are difficult to identify such as variations of Creutzfeldt-Jakob's disease (confirmed or suspected pathogen), they must be discarded.

Manufacturer

Medartis AG
Hochbergerstrasse 60E
4057 Basel/Switzerland

	Consult instructions for use
	Article number / Order number
	Lot number
	Non-sterile
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Sterilized using irradiation
	Use by date
	Manufacturer
	Date of manufacture
	Medical device

	Importer
	Authorized representative
	Applies only to EC risk class IIa and IIb medical devices
	Applies only to EC risk class I medical devices
	Conditionally MR safe

This document is subject to continuous revision. Please verify that the current printed version is identical to the one at www.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). This information contains CE-marked products.

For US only: Federal law restricts this device to sale by or on the order of a physician.

