

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

Product Materials

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


Color Coding Concept

The instrument set that belongs to a specific system size is color-coded. Instruments that do not belong to a specific system are not color-coded.

system	color code
MODUS 0.9/ 1.2	red
MODUS Mesh	red- green- blue
MODUS Neuro 1.5	green
MODUS Bone Fixation Set 1.2	red
MODUS Bone Fixation Set 1.5	green
MODUS 1.5	green
MODUS OSS 2.0	blue
MODUS IMF 2.0	blue
MODUS 2.0	blue
MODUS Trauma 2.0	blue
MODUS Reco 2.5	purple
MODUS Trauma 2.5	purple
MODUS TriLock 2.0/2.3/2.5	blue- brown- purple

According to the color system (MODUS product system), the implant plates and screws are gold. The meaning of the other color codes can be found in the table below:

Gold implant plates	Fixation plates
Green implant plates	Fixation plates, malleable
Blue implant plates	Fixation plates, malleable
Gold implant screws	Cortical screws (fixation) Lag screws
Green implant screws	SpeedTip screws (self-drilling) IMF SpeedTip screws (self-drilling) Cortical screws (self-drilling)
Blue implant screws	IMF screws (self-drilling)
Purple implant screws	Locking screws
Pink implant screws	TriLock cancellous screws (locking)
Silver implant screws	TriLock screws (locking) Locking cancellous screws

TriLock plates (locking) are marked with the following symbol: 

Intended Use

The MODUS osteosynthesis systems are used to fix fractures, for displacement osteotomies, and for bridging load-bearing bone segments and reconstructions in the area of the facial skull (cranium, midface and jaw).

Indications

The different MODUS osteosynthesis systems are used for the entire facial skull (cranium, midface and jaw) for osteotomies, fractures and reconstructions that require positional and functional stability.

Contraindications

- Pre-existing or suspected infections at or near the implantation site
- Known allergies and/or hypersensitivity to foreign bodies
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at-risk groups is inadvisable

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 from surgical trauma
- Early or late infection, both superficial and deep
- Elevated fibrotic tissue reaction around the surgical field
- Complications in implant removal from improper explantation of the implant

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
- 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 to (e.g. from improper cutting or bending) 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 can cause the plate to break during postoperative treatment
- 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. Utilized 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 implant and instrument or the like can represent a risk for the user, the patient or to third parties
- The sterilizing and implant containers as well as the instrument trays 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 to not exceed a maximum drilling speed of 1'000 revolutions per minute to avoid overheating the bone. Twist drills may only be used a maximum of ten times
- Use the indicated screwdriver for the respective system size. Make sure that the screwdriver/screw head connection is precisely vertically aligned. If not, there is a greater risk for the implant and screwdriver blade to get damaged. When inserting the screw, ensure that a sufficient axial force is used between blade and screw whereas the axial force should be in certain limits in order not to damage the bone structure

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 surface (Fig. 1 and 3). However, if the screw head can still be seen or felt (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. 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

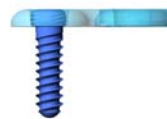


Fig. 1



Fig. 2

Correct: LOCKED

Incorrect: UNLOCKED

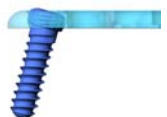


Fig. 3

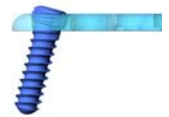


Fig. 4

Instructions for Selecting the Appropriate MODUS 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 and practice of the surgical procedure

Implants are generally designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place.

Additional Information

Additional information on the products (e.g. the surgical technique, care, cleaning and sterilization) can be requested from your local Medartis branch or your distribution partner. In addition, all relevant information can be found on the internet at www.medartis.com.

Instructions Regarding Cleaning, Disinfection and Sterilization

All implants, instruments and containers in the MODUS systems are delivered **NON-STERILE** and must be cleaned, disinfected and sterilized before each use. This also holds true for the first use after the delivery (cleaning and disinfection after removing the protective transport packaging, sterilization after placing in the sterilizing container). Implants which have come in contact with the blood or other bodily fluids of a patient must be discarded. Thorough cleaning and disinfection are essential for effective sterilization. It is the responsibility of hospital practice 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 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.

Pretreatment

Remove major contaminants in the operating room before returning the instruments to the tray. It is preferable to remove contaminants using a dry method. If contaminants are removed using a wet method, place the instruments in a prepared solution directly after they have been used. The instruments must be disassembled and opened as much as possible. All products (including flutes, holes, lumens, etc.) must be sufficiently covered with solution. The instruments must not be placed in the solution for more than 15 minutes since the instruments/containers may otherwise corrode.

Manual Cleaning and Disinfection

Observe the following when choosing cleansers and disinfectants:

- They must be suitable for cleaning and disinfection
- The cleanser - if applicable - must be suitable for ultrasonic cleaning (no foam development)
- Use a disinfectant with proven effectiveness (such as VAH/DGHM or FDA approval or a CE marking)
- The employed chemicals must be compatible

Manual Cleaning Process

- Disassemble and open the instruments as much as possible
- Place the products in the cleaning bath (the products must be completely covered, the specified exposure time must be observed, and the individual components may not touch each other)
- Ultrasonic cleaning may be used and/or with careful brushing using a soft brush
- Rinse at least twice thoroughly under flowing water (demineralized, at least drinking water quality in terms of the bacterial level)
- Inspect the products (see the section "Inspection")

Manual Disinfection Process

- Place the disassembled, cleaned and inspected products in the disinfection bath (the products must be completely covered, the specified exposure time must be observed, and the individual components may not touch each other)
- Rinse at least twice thoroughly under flowing water (demineralized, at least drinking water quality in terms of the bacterial level)
- The products must be completely dried directly afterwards (it is recommendable to dry them using compressed air)
- Inspect the products (see the section, "Inspection") and prepare them (see the section, "Product Care")
- Pack the products preferably immediately after they have dried

Ultrasonic (Re)Preparation of Instruments and Containers

The ultrasonic bath must be prepared according to the manufacturer's instructions. Follow the manufacturer's recommendations for medical devices for the ultrasonic treatment including the instrument rinsing and drying procedures. If the ultrasonic device does not have a rinsing and drying chamber, the products must be thoroughly rinsed with water and then dried with a disposable paper towel and/or medical compressed air.

Automated Cleaning and Disinfection

When selecting the disinfector, make sure:

- That the effectiveness of the disinfector is proven (such as approval by VAH/DGHM or the FDA, or a CE mark).
- That the cleaning process includes the following phases in accordance with EN ISO 15883:

Phase	Temperature	Duration	Action
Cleaning	Preheat to 93°C (199.4°F)	Device-specific	The cleanser is dispersed and suspended
Thermal disinfection (A ₂ value > 3000)	93°C (199.4°F)	10 min.	Do not add additional cleanser
Rinsing	-	Device-specific	Rinse with demineralized water

Inspection (Implants and Instruments)

Before assigning the implants to the implant containers, check them for damages and contaminants, and remove damaged and contaminated implants.

After they are cleaned or cleaned and disinfected, check all the instruments for corrosion, damage to surfaces, chipping, contaminants and function. Remove damaged instruments. Instruments that are still dirty must be cleaned and disinfected again.

Product Care

Carefully apply maintenance products (paraffin-based/white oil-based, biocompatible, steam-sterilizable and steam-permeable) to the articulations, ends or threads and sliding surfaces of the instruments.

Do not use silicone-containing products for maintenance.

Sterilization

As manufacturer, Medartis recommends sterilizing in the specially designed MODUS sterilizing containers, instrument trays and implant containers.

Only use the following sterilization methods. Other sterilization methods are not allowed.

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 verified by the manufacturer in accordance with the requirements of the current sterilization standard:

Procedure	Fractionated Vacuum Procedure	Flow Procedure
Exposure time	≥ 5 min	≥ 15 min.
Temperature	134°C (273°F)	134°C (273°F)
Drying time	> 20 - 30 min.	> 15 - 30 min.

Medartis recommends using the fractionated vacuum procedure for sterilization with an exposure time of ≥ 18 minutes.

Steam sterilization with the gravitation procedure needs to be verified by additional product-, sterilizer- and process-specific validation.

In addition, do not use hot-air sterilization, irradiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile goods such as plasma or peroxide sterilization for MODUS implants, instruments, implant containers, instrument trays and sterilizing containers.



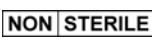



Flash sterilization is not recommended. If this procedure is used, observe the respective country-specific laws, standards, guidelines and instructions. The user is responsible for reviewing these requirements and procuring the related information. After sterilization, the products must be stored in a dry environment.

Reusability (Implants and Instruments)

The implants may only be brought into contact with a patient once. Implants which have come into contact with the blood or bodily fluids of a patient must not be reused. 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. 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. Those products must not be reused.

Manufacturer and Distributor

Medartis AG
Hochbergerstrasse 60E
4057 Basel/Switzerland

	Caution: Consult accompanying documents
	Batch number
	Non-sterile
	Do not reuse
	Manufacturer: Medartis AG, 4057 Basel/Switzerland
	Marking for risk Class I medical devices, non-sterile and without measuring function