medartis®

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 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 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 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

The instrumentation belonging to a specific system size is color-coded accordingly. Instruments intended for use with 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

MODUS Clip Case system: implants belonging to a specific system size are kept in a clip of the same color; information regarding screw diameter and thus indicating the system to which an implant belongs is organized in the implant trays according to the following color coding scheme:

System size	Color Code
MODUS 1.5	green
MODUS 2.0	blue

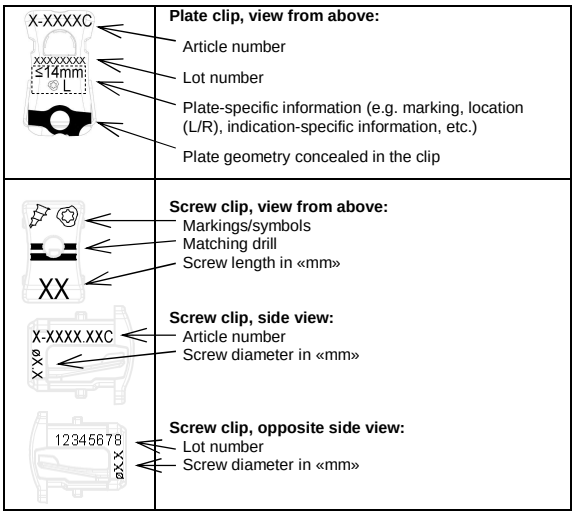
According to the color coding concept (MODUS product concept), implant plates and screws are always gold in color. Please see the table below for further color codings:

Implant plates gold	Rigid fixation plates
Implant plates green	Semi-rigid fixation plates
Implant plates blue	Semi-rigid fixation plates
Implant screws gold	Cortical screws (fixation) Lag screws
Implant screws green	SpeedTip screws (self-drilling) IMF SpeedTip screws (self-drilling) Cortical screws (self-drilling)
Implant screws blue	IMF screws (self-drilling)
Implant screws purple	Locking screws
Implant screws pink	Trilock cancellous screws (locking)
Implant screws silver	TriLock screws (locking) Locking cancellous screws

Markings/Symbols and Their Meanings:

	TriLock (locking)
	Self-drilling screws

Clip Labeling



Intended Use

The MODUS systems are used for the fixation of fractures, corrective osteotomies, bridging of load-bearing bone segments, and reconstructive procedures to the facial skeleton (skullcap, midface, and jaw).

Indications

The MODUS systems are subdivided into three modules according to their principal application in the three main anatomical regions of the facial skeleton:

MODUS Cranium plate and screw system is used for fixation of fractures, osteotomies and reconstructive procedures that require positional and functional stability in the upper midface and skullcap.

MODUS Midface plate and screw system is used for fixation of fractures, osteotomies and reconstructive procedures that require positional and functional stability in the midface, including maxillary osteotomies (Le Fort I, II, and III).

MODUS Mandible plate and screw system is used for the fixation of fractures, osteotomies and reconstructive procedures that require positional and functional stability in the mandible, including ramus and corpus osteotomies and genioplasties.

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

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 explantation of the implant

In consideration of patient's clinical condition and medical history, the treating physician shall ensure that the use of MODUS implants can be justified based on a patient-specific benefit/risk 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: plates in the clip must **only** be used with the screws in the clip; the screws in the clip must **only** be used with the matching drills (see article numbers in the applicable product brochure and labeling in the clip container)
- 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
- 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

- The sterilizing cases, instrument trays and implant containers 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. Twist drills may only be used for a maximum of ten times
- Use the indicated screwdriver for the respective system 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.
- The MODUS products have not been evaluated for safety and compatibility in the MR environment. The MODUS products have not been tested for heating or migration in the MR environment. Therefore, MR-assisted imaging techniques cannot be recommended.
- Implants can cause artifacts in various imaging procedures such as CT, MR

Multidirectional, Angular Stable TriLock Locking System

Correct locking (±15°) 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 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

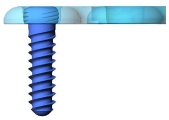


Fig. 1

Incorrect: UNLOCKED

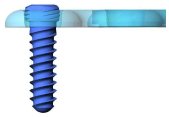


Fig. 2

Correct: LOCKED

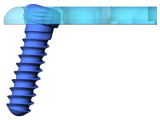


Fig. 3

Incorrect: UNLOCKED

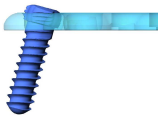


Fig. 4

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, 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.

In consideration of the individual fracture situation as well as the compliance of the patient, the surgeon shall ensure an adequate postoperative relief of the osteosynthesis in terms of adaption- or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved by the implants must be treated carefully until osseous healing is completed. The doctor's aftercare instructions have to be strictly observed by the patient in order to avoid adverse loads of the implants. Early load bearing can increase the risk of loosening, migration or breakage of the devices.

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, care, cleaning, disinfection and sterilization) 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.

Instructions Regarding Cleaning, Disinfection and Sterilization

All implants, instruments and containers in the MODUS systems are **NON-STERILE** when delivered and 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.
Implants that were used in a patient and removed, have to be discarded following the local requirements. They are not allowed to be reprocessed. Re-use may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, re-use of single-use devices 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 or user.

Implants that have come in 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 tray.
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 the FDA, or a CE mark)
- 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 and/or soft brushes (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 paper wipes 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 trays (steel or plastic) and implant trays made from aluminum or plastic 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 trays and then cleaned and disinfected separately.

Implant trays from the MODUS Clip Case system can undergo automated cleaning and disinfection when loaded. For manual cleaning, the clips must be removed from the system and then cleaned and disinfected separately. However, the implants must always be left in the clip and can also be cleaned and disinfected manually in this state.

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 trays completely and remove the lid, if necessary
- Empty the aluminum or plastic implant trays completely and remove the lid if necessary; for steel implant trays, the implants can be left in the tray but the lid must be removed during the rinsing process and rinsed separately
- Clip system: with implant trays from the Clip Case system, the implants must not be removed from the clips; keep the clips in the trays for pretreatment
- 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 trays should remain dismantled for the following cleaning and disinfection process.

Manual Cleaning and Disinfection
Clip system: the clips must be removed from the trays for manual cleaning and disinfection; implants must be left in the clip.

Manual Cleaning Process
- Place the (disassembled) products in the cleaning bath with enzymatic cleaning solution for 5 minutes (the products must be adequately covered and the individual components should not be in a position to damage each other)
- Clean with a soft plastic brush
- 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), e.g. cannulated drills, must be cleaned by inserting the dedicated cleaning stylet and rinsed using a suitable cannula and disposable syringe (rinse volume: 30 ml)
- Clean the products in the ultrasonic bath for 15 minutes using a suitable detergent
- 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 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 (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 (rinse 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

With the clip system, ensure that the implant trays have been properly sealed with their lid before automated cleaning.

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 disinfector, 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; ±35.6°F)*	10 min.*	Adding detergent*
Neutralization	Cold	2 min.	Neutralize with cold water
Rinsing	Cold	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
Rinsing	Device-specific	Device-specific	Rinse with demineralized and purified water
Dry	Device-specific	Device-specific	Drying process

* The information provided is based on the use of «Neodisher MediClean forte» by Dr. Weigert; times and temperatures may vary if a different detergent is used; follow the applicable information provided by the manufacturer.

When loading the disinfector, 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)
Before assigning the implants to the implant containers/trays, check them after cleaning and disinfection for damage and contaminants, and remove damaged and contaminated implants.
Clip system: the implants must not be removed from the clips. Once removed from the clip, implants must not be re-inserted into the clip and must be discarded.

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 (e.g. cannulated drills) 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 trays should be reassembled for the following sterilization process.
Clip system: the clips must be sorted into the implant trays for sterilization.

Sterilization
Medartis recommends sterilizing the products in the specially designed MODUS sterilization containers, implant containers and instrument trays.

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)
Implants that were used in a patient and removed, have to be discarded following the local requirements. They are not allowed to be reprocessed. Re-use may compromise the structural integrity of the implants and/or lead to device failure which may result in patient injury. Furthermore, re-use of single-use devices 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 or user.
Implants that have come in 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 tray.
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

	Caution: Consult accompanying documents
	Article number / Order number
	Lot number
	Non-sterile
	Do not reuse
	Marking for Risk Class I medical devices, sterile, I with measuring function, IIA and IIB
	Marking for Risk Class I medical devices, non-sterile and without measuring function

This document is subject to continuous revision. Please verify that the current printed version is identical to the one at www.medartis.com/meta/downloads/instructions-for-use/.