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Instructions for Use for Medartis MODUS Modular Distraction Osteogenesis System MDO 2.0

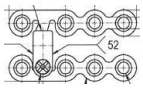
Introduction

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.

Product Description

The MODUS MDO 2.0 modular distraction osteogenesis system consists of distraction cylinders, flexible distraction extensions, distraction keys, adapter plates, implant screws and instruments.

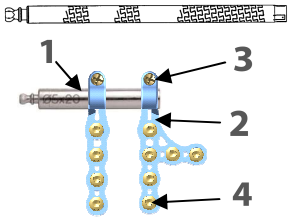
MODUS adapter plates 2.0
MODUS adapter plates are used with the distraction cylinders for various applications involving the mandibular bone structure. The plates are offered in various shapes and are designed to respect the anatomy of the mandible. They permit vector alignment by means of intra-operative bending, if necessary.



MODUS traction cylinders 2.0
MODUS distraction cylinders are used with the adapter plates and implant screws for gradual distraction osteogenesis and for mandibular osteotomies. The distraction cylinders are available in different distraction lengths.

MODUS flexible distraction extensions 2.0
MODUS flexible distraction extensions are used with the distraction cylinders when necessary.

MDO system ready for use, consisting of one distraction cylinder (1), two adapter plates with clamps (2), two locking screws (3) and ten implant screws (4).



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 MDO 2.0 implants are made of pure titanium (ASTM F67, ISO 5832-2) or titanium alloy (ASTM F136, ISO 5832-3).
Distraction cylinders and flexible distraction extensions are made of stainless steel (ASTM F138 and ASTM F139).
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 MDO 2.0	blue

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

Implant plates blue	Adapter plates, semi-rigid
Implant screws gold	Cortical screws (fixation)
Implant screws green	SpeedTip screws (self-drilling)

Intended Use

The MODUS MDO 2.0 modular distraction osteogenesis system is designed for use in unilateral or bilateral underdevelopment (hypoplasia or dysgnathia) or malformations of ramus, corpus or the whole mandible.

Indications

The MODUS MDO 2.0 modular distraction osteogenesis system is designed for use in unilateral or bilateral underdevelopment (hypoplasia or dysgnathia) or malformations of the ramus or body or of the whole mandible. This includes both congenital and acquired deformities such as:

Congenital malocclusions or malformations:
- Marked sagittal malformation of the mandible (mandibular retrognathism)
- Hemifacial microsomia (Pruzansky-Omens classification)
- Syndromes involving mandibular hypoplasia, microglossia or micrognathia (Hall classification), particularly Pierre Robin sequence and Hanhart syndrome
- Transverse mandibular underdevelopment

Acquired hypoplasia:
Abnormalities affecting the growth of the ascending ramus as a result of TMJ defects due to:
- Ankylosis
- Rheumatic lesions
- Segmental loss of bone substance after treatment of benign or malignant tumors that have healed with bone defects

Contraindications

- Acute or chronic infections or necrosis of the jaw at or near the implant site (dental infections, osteomyelitis, osteoradionecrosis, bisphosphonate-associated osteonecrosis of the jaw)
- Known allergies and/or hypersensitivity to foreign bodies
- Inadequate bone volume 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 (particularly with bone metabolism disorders) is inadvisable

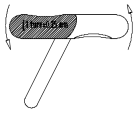
Possible Complications

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 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

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 components (adapter plates, implant screws, distraction cylinders and distraction extensions) are intended for single use and may not be reused under any circumstances; distraction keys may only be used on one patient
- The components must be visually inspected and their functionality checked before use. It is recommended that these checks should also include placing the extensions on the distraction cylinder so that they can be clearly felt to snap into place. After the flexible extensions have been assembled, the extension should be pulled in an axial direction to verify that it is securely seated on the distraction cylinder. The distraction function is checked by performing the distraction procedure over the entire length of the distraction cylinder, then subsequently resetting it.

- The distraction cylinder is activated with the distraction key (M-2300) or the flexible distraction key (M-2330). To open the distraction cylinder, turn the distraction key in the direction of the arrow, i.e. counterclockwise. One complete turn (360°) corresponds to a distraction length of 0.25 mm.



- 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 vertically aligned. 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
- Fixation using implants should be considered a temporary measure until complete bone healing and therefore cannot withstand substantial loads and stresses

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 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

The MODUS MDO 2.0 modular distraction osteogenesis system is a temporary implant and must be removed again after bones have healed adequately. The physician is responsible for follow-up care, including patient information.

It must be ensured prior to surgery that the desired distraction length is achievable with the selected components and that the selected angle setting can be performed.

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. They are not allowed to be reprocessed. 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.

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
- 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

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

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, check them 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 (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.

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℃/134℃	132℃/134℃
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)
The components (adapter plates, implant screws, distraction cylinders, distraction extensions, and distraction key) that were used in a patient and removed, have to be discarded. They are not allowed to be reprocessed. 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.

Production and Sales
Medartis AG
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4057 Basel/Switzerland

	Caution: Consult accompanying documents
	Article number / Order number
	Lot number
	Non-sterile
 Do not reuse	Do not reuse
 0197	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/.