Instructions for Use for Medartis MODUS Orthodontic Anchorage System

Introduction
These instructions for use are for a product line of Medartis AG, Hochbergerstrasse 60E, 4057 Basel/Switzerland.

Product Description
The MODUS Orthodontic Anchorage System is made up of:

<table>
<thead>
<tr>
<th>Article no.</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-4694</td>
<td>2.0 TriLock palate plate, 3 hole, 11.3</td>
</tr>
<tr>
<td>M-5247.xx</td>
<td>2.0 TriLock SpeedTip screw (locking, self-drilling)</td>
</tr>
<tr>
<td>M-5265.xx</td>
<td>2.5 TriLock screw (locking) + emergency screw</td>
</tr>
<tr>
<td>M-4696</td>
<td>Adaption sleeve for palate plate</td>
</tr>
<tr>
<td>M-4695</td>
<td>Guide sleeve for silicone imprint</td>
</tr>
<tr>
<td>M-4697</td>
<td>Dummy pin for plaster model</td>
</tr>
<tr>
<td>M-2046</td>
<td>2.0–2.5 Screwdriver handle and 2.0 screwdriver blade HD6, 84 mm</td>
</tr>
<tr>
<td>M-2663</td>
<td></td>
</tr>
<tr>
<td>M-2178</td>
<td>Plate holding &amp; positioning instrument, pins</td>
</tr>
</tbody>
</table>

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 distributor partner within ten working days.

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 2.0 | blue

Please see the table below for the meaning of the color codes for the plate and the screws:

- **Implant plates** blue: Semi-rigid fixation plates
- **Implant screws** green: TriLock SpeedTip screws (locking, self-drilling)
- **Implant screws** silver: TriLock screws (locking) + emergency screw

Intended Use
The MODUS Orthodontic Anchorage System acts as the anchor point for orthodontic treatments.

Indications
The MODUS Orthodontic Anchorage System is inserted intraorally. It acts as the anchor point for orthodontic treatments in adults and adolescents over 12 years of age. The system is inserted temporarily and is removed once the treatment is complete. Possible indications include:

- Molar distalization
- Anchorage of molars
- Dental class II correction in adults
- Resolving crowding without extracting teeth

Contraindications
Pre-existing or suspected infection 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
Patients with primary dentition or mixed dentition
The treatment of at-risk groups is inadvisable (e.g., pregnant women, smokers)

Possible Complications
In most cases, potential complications have a clinical source as opposed to arising from the implant/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.
- The 2.0 TriLock palate plate must be removed once the treatment is complete.
- When preparing the silicone impression, it is essential that the guide sleeve is actually inserted in the silicone impression and does not remain in the patient (choke hazard).
- Before inserting the implant in the patient’s mouth, check that the plate is securely and firmly seated on the positioning and holding instrument and that the screw is securely attached to the screwdriver blade to prevent a choking hazard.
- 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:
  o 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.
  o 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.
- When using twist drills it is recommended not to exceed a maximum drilling speed of 1000 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.

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 head should 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.
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 user is responsible for deciding when to remove the implant and for follow-up treatment.

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

Pretreatment prior to Cleaning, Disinfection and Sterilization

Pretreatment is required in both cases.

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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. canulated 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 applicable information provided by the manufacturer.

Steam Sterilization

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Fractionated and Dynamic Prevacuum Process</th>
<th>Flow and Gravitation Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>≥ 4 min.</td>
<td>≥ 15 min.</td>
</tr>
<tr>
<td>Temperature</td>
<td>132°C/134°C</td>
<td>132°C/134°C</td>
</tr>
<tr>
<td>Drying time</td>
<td>≥ 20 - 30 min.</td>
<td>≥ 20 - 30 min.</td>
</tr>
</tbody>
</table>

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. 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.