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Instructions for Use for MODUS 90° Screwdriver

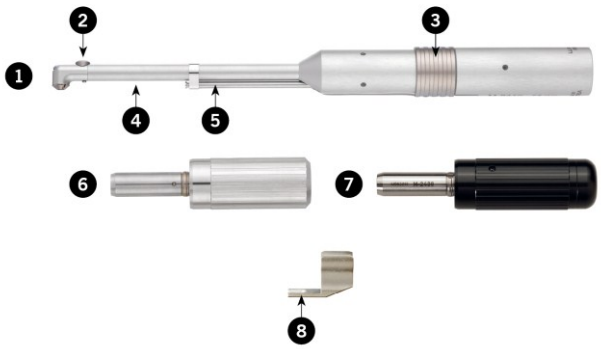
Introduction

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.

Description of the MODUS 90° Screwdriver

The MODUS 90° Screwdriver consists of the following parts:

1 = Screwdriver (M-2410) **2** = Sliding button (M-2414); **3** = Slider; **4** = Neck;
5 = Push rod; **6** = Rotation knob (M-2430); **7** = Torque-limiting knob (M-2438)
8 = Screwholding fork (M-2412)



The MODUS 90° Screwdriver is designed for intraoral drilling and screw insertion as described in the section entitled "Intended Use".
The MODUS 90° Screwdriver is comprised of interchangeable twist drills and screwdriver blades with a dental shaft end as well as a screwholding fork that holds the screw securely during insertion. Optionally, self-holding blades can also be used without the screwholding fork.

MODUS 90° Screwdriver (M-2410) with screw secured with screw holding fork:

MODUS 90° Screwdriver with screw on self-holding blade:

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.
All components are delivered **NON-STERILE** and must be appropriately prepared before first use.
All packaging must be removed before preparation.

Product Materials

The 90° Screwdriver is made from stainless steel and aluminum. The neck is made from brass (plated with nickel and chrome).

Intended Use

The MODUS 90° Screwdriver was developed for pre-drilling and for the insertion of implant screws via intraoral access. It is designed for use with MODUS screws together with 1.5/2.0 cross-drive screwdriver blades, HexaDrive 4 (HD4) and HexaDrive 6 (HD6) (including TriLock screws). Failure to use the screwdriver as intended may damage the hand piece and result in risks and hazards for users and/or the patient.

Indications

The MODUS 90° Screwdriver can be used for intraoral access for the following purposes:
- Osteosyntheses in area of the mandibular angle
- Sagittal split osteotomies
- Distractions
- Screw and plate removal

Contraindications

There are no known product-specific contraindications.

Potential complications with the MODUS 90° Screwdriver

- If the screwholding fork is not retracted after a few turns during the screw insertion process, the MODUS 90° Screwdriver may become wedged together with the plate. In this case, releasing the screwholding fork will be extremely difficult
- Incorrect cleaning and/or care may possibly result in the drive seizing
- When loosening the sliding button for the cleaning process, lifting the button with too much force (bending the spring too far) may result in damage to the sliding button and a loss of functionality

Warnings and Precautionary Measures

- The products may only be used by medical personnel who hold relevant qualifications
- Medartis, as a private label manufacturer, recommends that the user carefully 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 components of the screwdriver 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 a 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 can represent a risk for the user, the patient or to third parties
- Unless otherwise expressly stated on the label, the screwdriver can be reused
- Medartis recommends that the maximum initial speed in the handset for pre-drilling should not exceed 1'700 revolutions per minute . This corresponds to an initial speed at the drill of approximately 1'000 revolutions per minute (translation ratio: 1.66:1)
- The maximum permissible torque for the drive in the screwdriver is 100 Ncm to avoid a risk of damage
- The screwdriver may only be operated on drive units that are compliant with the guidelines for medical devices
- Always ensure that the operating conditions are correct
- Before each use, inspect the screwdriver for damage and loose parts (e.g. the sliding button, screwholding fork)

Instruction for Selecting the Appropriate Product

This medical device is intended solely for use by medical professionals. The operating surgeon is responsible for the correct patient selection and proper use of the MODUS 90° Screwdriver. Medartis, as a private label manufacturer, does not recommend a specific surgical procedure for a specific patient.
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

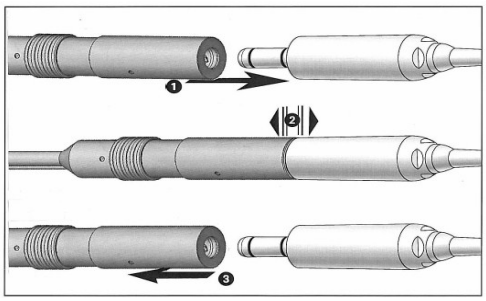
Additional Information

Additional information on the product 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.

Commencing Operation

Medartis recommends working with two MODUS 90° Screwdrivers (one set up for drilling and one for screw insertion).

Installation and Removal
- When using with the power drive, do not install or remove during operation!
- Fit the screwdriver with the power drive or rotation knob (1)
- Check that it is seated firmly on the power drive or rotation knob (2)
- Remove the screwdriver by pulling it off or, if applicable for your power drive, by pressing the release button (3)



Instructions for the Use of Drills
- Only use Medartis twist drills with dental shaft end
- Only use twist drills that are completely free of defects
  - When drilling with a power drive, only attach the drill when the screwdriver is not in operation
  - Never touch drills while running or in the process of stopping
  - Never operate the sliding button while the screwdriver is in use. This will result in the drill being released

- ***Fitting the twist drill***
  - Open sliding button
  - Insert twist drill until it stops (slightly rotating the drill if necessary)
  - Close sliding button



- ***Attaching to a power drive***
  - For the purpose of drilling, the MODUS 90° Screwdriver can be fitted to a power drive with a standard ISO 3964 connection
  - Remove the rotation knob and connect the drive coupling to the MODUS 90° Screwdriver

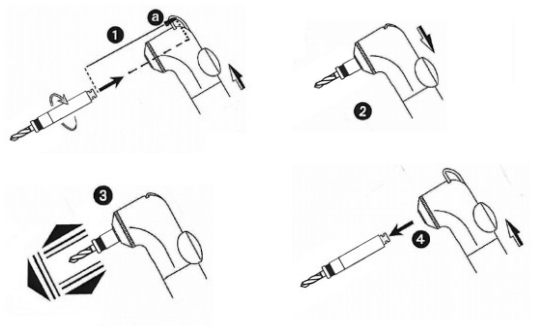
- ***Trial***
  Start the screwdriver (maximum initial speed: 1'700 revolutions per minute). If the screwdriver is not functioning properly (e.g. vibration, unusual noises, heating up or similar), contact your relevant Medartis branch or distribution partner

- ***Drilling***
  Drill to the desired depth (recommended initial drill speed: < 1'000 revolutions per minute)

Instructions on the Use of Screwdriver Blades
- Only use Medartis screwdriver blades with dental shaft end
- Only use screwdriver blades that are completely free of defects
- The screwdriver is designed for manual insertion of implant screws using the appropriate screwdriver blades. Using a power drive for the insertion of implant screws may cause undesirable side effects or have a negative impact on the outcome of the surgery
- Inserting the screwdriver blade:
  - Open sliding button
  - Insert screwdriver blade until it stops (slightly rotating the blade if necessary)
  - Close sliding button

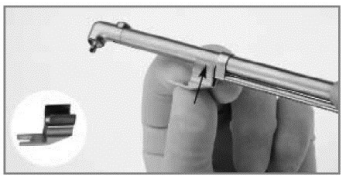


Instructions for Changing Twist Drills/Screwdriver Blades
- Slide the sliding button axially forward until it stops and then insert the instrument (screwdriver blade or twist drill) into the head until it stops (a). Twist the instrument to ensure that it is fully inserted (❶)
- Pull the sliding button all the way back in an axial direction until it catches (❷)
- Pull to check that the instrument is securely seated (❸)
- To remove the instrument, pull the sliding button forwards again and pull the instrument out (❹)

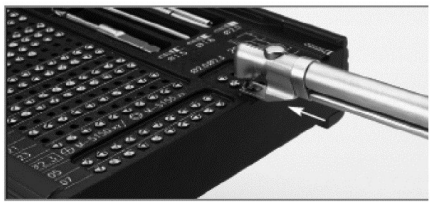
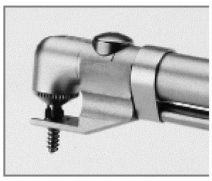


Instructions for Use of the Screwholding Fork
- Fitting the screwholding fork:
  - The screwholding fork must be fitted if a non-self holding screwdriver blade is used
  - Fit screwholding fork from below perpendicular to the longitudinal axis of the instrument onto the neck. In doing this, ensure that the front attachment of the push rod comes to rest beneath the screwholding fork
    The small ring must engage with the notch on the inside of the screwholding fork
  - Couple the rotation knob and insert the screwdriver blade
  - Advance the blade toward the head of the implant screw; place the blade on the screw and push the slider forward until the screw holding fork is holding the implant screw
  - Withdraw the slider after the first few turns of the screw in order to release the screw, then insert the screw completely
  - If the screwholding fork is not retracted after a few turns during the screw insertion process, the MODUS 90° Screwdriver may become wedged together with the plate. In this case, releasing the screwholding fork will be extremely difficult

- **Removing the Screwholding Fork**
  To remove, pull the screwholding fork downwards in a direction perpendicular to the longitudinal axis of the instrument



Instructions for Picking Up Screws
Only MODUS screws together with 1.5/2.0 cross-drive screwdriver blades, HexaDrive 4 (HD4) and HexaDrive 6 (HD6) (including TriLock screws) can be used.

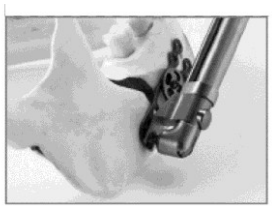
Non Self-Holding Blades
- Fit screwdriver blade at a 90° angle to the head of the screw and slide the screwholding fork over the sliding collar until it stops
- If available, use the loading module in the container
- Screw is secured with screwholding fork


Self-Holding Blades
- Fit screwdriver blade at a 90° angle to the screw head and pick up the screw by briefly applying gentle pressure
- The screw is securely held in the blade

Instructions for Us of the MODUS 90° Screwdriver for Screw Insertion/Extraction
The screwdriver has two available rotation knobs, one without and one with a torque-limiting knob. Both are screwed on/removed from the screwdriver in the same manner.
To protect the drive, Medartis recommends the use of the rotation knob with the torque-limiting knob.

- Push rotation knob until it clicks into place

- Screw insertion: Rotate to the right (clockwise)
- Screw extraction: Rotate to the left (counterclockwise)



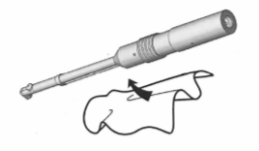

As soon as the screw is fixed in the bone with its first screw threads, the screwholding fork must be retracted over the sliding collar. Only then can the screw be fully inserted without obstruction

Instructions Regarding Cleaning, Disinfection and Sterilization

All instruments 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, lubrication and sterilization). Thorough cleaning and disinfection are essential for effective sterilization.
As part of your responsibility for ensuring instrument sterility, please always ensure during use that only adequate and suitable product-specific procedures are used for cleaning and disinfection and that only sterilization procedures that have undergone adequate equipment and product-specific validation are employed. Also ensure that the equipment used (sterilizer) is regularly serviced and inspected, and that the validated parameters are met during 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.

- The screwdriver may only be prepared manually
- Remove the rotating instrument
- Remove the screwdriver from the power drive
- Clean the screwdriver and accessories **immediately after treatment** (within 2 hours) in order to rinse out any penetrating fluids (such as blood, saliva, etc.) and to prevent the internal parts from seizing
- Sterilize the screwdriver after manual cleaning and disinfection, as well as lubrication

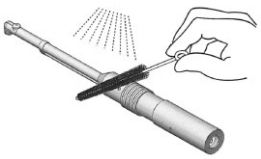
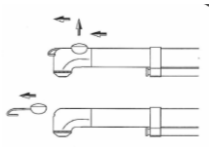
Preliminary Disinfection
In case of stronger contamination, pre-clean with disinfection wipes (see "Disinfection" for instructions regarding disinfectants).



Manual Cleaning

- Dismantle the instrument as far as possible (screwdriver, rotation knob and screwholding fork)
- Rinse off and brush off the screwdriver, screw holding fork and rotation knob using demineralized water (< 38 °C)
- Push the sliding button forwards, gently lift the sliding button from the neck and pull the sliding button forwards and away from the screwdriver head
- If necessary, clean the exposed head area once more using a nylon brush
- Clean the sliding button for 5 minutes in an ultrasound bath (see below for general information regarding ultrasound)

Never clean the whole screwdriver using ultrasound!

⚠ Warning:
lifting the sliding button with too much force (bending the spring too far) may result in damage and a loss of functionality

Ultrasound Cleaning and Disinfection

Ultrasound is particularly suited for the cleaning of instruments made from stainless steel and hard plastics. Mechanically sensitive instruments can be cleaned and disinfected gently and thoroughly with the aid of ultrasound.
Ultrasound cleaning is used

- as mechanical support for manual cleaning processes
- to remove stubborn spots or after machine cleaning
- as a supportive cleaning measure for mechanical preparatory procedures

When performing ultrasound cleaning, please note the following:

- the ultrasound bath must be prepared according to the manufacturer's instructions and refreshed each day; depending on the usage conditions, changing the bath more frequently may be advantageous
- warm water is recommended for filling the bath
- a suitable cleaning agent or combined disinfectant/cleaning agent must be added
- when using agents of this type, the concentration, temperature and ultrasound application time must be appropriately set according to the manufacturer's instructions

Workflow

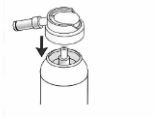
1. Dismantle the instruments and open the joint instruments as much as possible (if this has not already been done)
2. Place the dismantled instruments in the appropriate container in the ultrasound bath. When doing this, ensure that:
   - the instruments are completely covered with cleaning solution
   - instruments with a large area must be positioned in such a way as to avoid ultrasound shadows or ultrasound dead zones
   - do not overload the sieve trays
   - to maximize cleaning performance, different materials and surface qualities should not be mixed

If the ultrasound unit does not have a rinsing and drying chamber, follow steps 3 and 4:

3. The products must be rinsed under sterile or low microbial count (max. 10 microbes/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water) until all residues have been removed
4. The products must then be dried with a lint-free cloth or with medical-grade compressed air. Drying using compressed air is particularly gentle and effective, and is therefore preferable to any other drying method, e.g. using a cloth

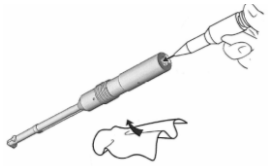
Pressure Rinsing the Screwdriver

- Once the sliding retaining spring has been removed, subject the screwdriver to a pressure rinse with W&H Service Oil MD-400
- Follow the instructions listed below, as well as the operating instructions for the oil spray can
- For the rinse process, wrap the screwdriver head with a clean cloth to catch the oil discharged from the head
- Insert the spray nozzle of the oil spray can into the grip of the screwdriver and spray for approximately 2 seconds
- In certain positions, the screwdriver is leak tight. In these positions, pressure rinsing is not possible. Couple the rotation knob and turn the drive 90°. In this new position, the pressure rinse can be completed successfully
- After the rinse process, wait 2 - 3 seconds before removing the spray nozzle from the instrument again so that the pressure built up inside the instrument can subside
- Repeat the pressure rinse until clean oil is discharged from the head
- Between rinse procedures, couple the rotation knob and use this to turn the drive a few more times to loosen any contamination in the drive
- Note: for technical reasons, opening the drive is not permitted. This can only be done by trained service personnel. For service and repairs, please send the instrument to your nearest Medartis branch or distribution partner



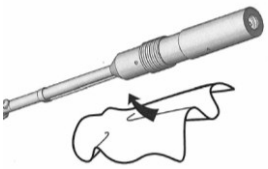

Drying After the Pressure Rinse

- Place the sliding retaining spring back on the head from the front, attach the rotation knob and verify that the drive operates freely
- Remove the rotation knob again
- Remove any excess oil,
  - inside:
    by carefully blowing out with compressed air (there must be no more oil discharged from the head)
  - outside:
    by wiping off with cellulose or a soft cloth
- Store the screwdriver with the head downward



Disinfection

- Disinfection with surface disinfectants (wiping disinfection is recommmended!)
- Only use surface disinfectants which do not contain chlorine and are certified by officially recognized institutions
- Use a disinfectant with proven effectiveness (such as VAH/DGHM or FDA approval or a CE marking)
- Follow the manufacturer's instructions for the use of the surface disinfectant!



Checks
After cleaning or cleaning and disinfection, check the screwdriver for corrosion, damage to surfaces, chipping, contaminants and function. Damaged screwdrivers may need to be removed. Screwdrivers which are still dirty must be cleaned and disinfected again.

Lubricating the Screwdriver
The correct lubrication is essential to ensure long service life of the product.
- Lubrication must be performed according to the instructions provided above ("Pressure rinsing the screwdriver"), as well as in accordance with the directions in the operating instructions for the oil spray can
- Perform lubrication with W&H Service Oil F1, MD-400
- Recommended care cycles: before each sterilization (spray into the instrument's coupling tube)

Note on Packaging for Sterilization
Place the screwdriver, rotation knob and screwholding fork (separated from each other) in EN 868-5 compliant sterile device pouches and weld the seam to seal.

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

Steam Sterilization
All **NON-STERILE** products can be steam sterilized in an autoclave (EN 13060). 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	> 3 min.	> 3 min.
Temperature	134°C (273°F) (+3°C) (37.4°F)	134°C (273°F) (+3°C) (37.4°F)
Drying time	> 20 min. - 30 min.	> 20 min. - 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, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization or substitute procedures for sterilizing thermolabile goods such as plasma or peroxide sterilization.
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 for obtaining the corresponding information.

After sterilization, the MODUS 90° Screwdriver must be stored in a dry environment.

Private Label Manufacturing and Sales Company
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/.