

Instructions for Use

medartis®



CE
0197

Angulated screwdriver
WSD-90

MANDIBLE-00000901_RevH

Instructions for Use for MODUS 90° Screwdriver

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WARNING!
(risk of injury)



ATTENTION!
(to prevent damage occurring)



General explanations,
no risk to persons or
objects



Do not dispose of with
domestic waste



UL Component
Recognition Mark
indicates compliance
with Canadian and U.S.
requirements



Caution:
According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices and intends to use or order the use of this medical device.

Symbols

on the medical device/packaging



CE marking
with identification number
of the Notified Body



Thermo washer
disinfectable



Catalogue number



Sterilizable up to the
stated temperature



Serial number



DataMatrix Code
for product information
including UDI (Unique
Device Identification)



Date of manufacture



Equipment number

1. Introduction

Customer satisfaction is the main priority our quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Instructions for Use. These explain how to use your medical device and guarantee a smooth and efficient operation.



Observe the safety notes.

Intended use

Surgical treatment of organic hard tissue.




Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user

We have based our development and design of the medical device on the physician target group.

Production according to EU directive

 The medical device meets the requirements of Directive 93/42/EEC.

0197

Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:


- > The medical device must be used in accordance with these Instructions for Use.
- > The medical device has no components that can be repaired by the user.
- > Modifications or repairs must only be undertaken by an authorized service partner (see page 47).

Skilled application

The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for Use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by us, invalidates all claims under warranty and any other claims.

 Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Safety notes



- > Before using the medical device for the first time, store it at room temperature for 24 hours.
- > The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- > The medical device should only be operated with sufficiently powerful drive motors.
- > The maximum permitted drive speed of 1750 rpm must not be exceeded.
- > Always ensure that you have the correct operating conditions.
- > Check the medical device for damage and loose parts each time before using (e.g. retaining clip).
- > Do not operate the medical device if it is damaged.
- > Only attach the medical device onto the motor when the motor is at a complete standstill.
- > Perform a test run prior to each use.
- > Avoid overheating at the treatment site.
- > Unintended use may result in the medical device getting hot (risk of burning)!
- > Always ensure that you have a second right angled screwdriver ready for use during the operation.

Hygiene and maintenance prior to initial use

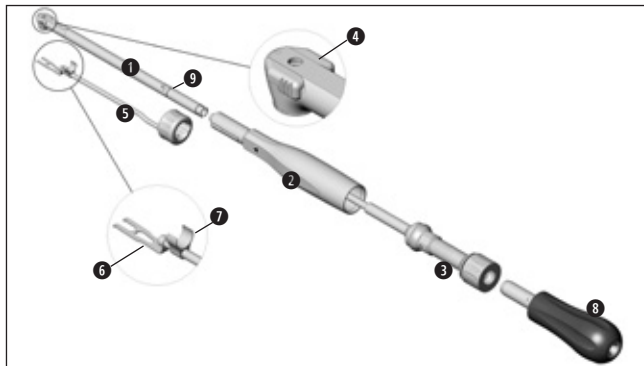


- > The medical device is not sterilized when delivered.
- > The packaging is non-sterilizable.



- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device and the turning attachment.

3. Product description WSD-90



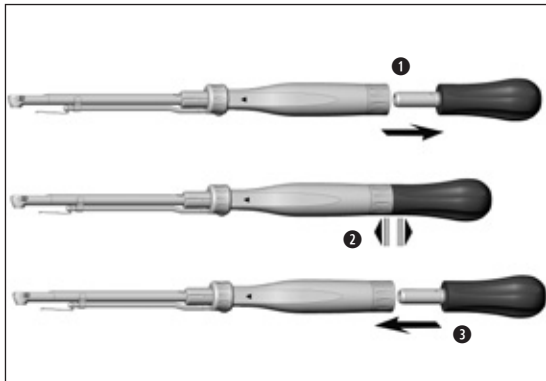
90° Screwdriver

- ① Head
- ② Sheath
- ③ Shaft
- ④ Tension clamp
- ⑤ Screwholding fork
- ⑥ Retaining clip
- ⑦ Clip
- ⑧ Rotation knob
- ⑨ Symbol description
- = Sheath open
- = Sheath locked

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Do not assemble or remove the medical device during operation!

1

Place the medical device on the motor or turning attachment.



2

Verify full engagement.

or

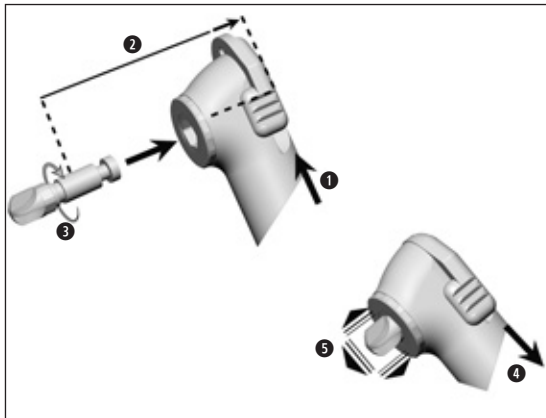
3

Remove the medical device.

Rotary instrument (bur and screwdriver blade)



- > Only use rotary instruments which are in perfect condition and pay attention to the direction of rotation of rotating instruments. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when the medical device is stationary.
- > Only use the screwdriver blade with the turning attachment.
- > Never touch the rotary instrument while it is still rotating.
- > Never touch the tension clamp of the medical device during use. This leads to detachment of the rotary instrument and/or overheating of the medical device.



Changing the rotary instrument

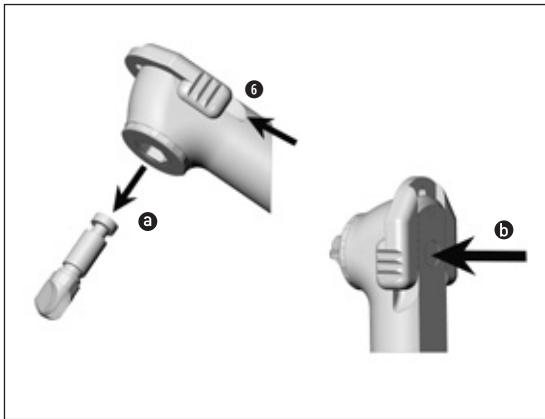
- 1 Push the tension clamp forwards in the axial direction.
- 2 Then insert the tool into the head until limit stop
- 3 Turn the tool in order to make sure that it is fully inserted.
- 4 Pull the tension clamp completely backwards in the axial direction until it engages.



- 5 Verify full engagement.



The tension clamp should engage without force being exerted. If the tension clamp does not engage, check steps 2 and 3.



Changing the rotary instrument

6 To remove the tool, push the tension clamp forwards.

a Remove the tool.

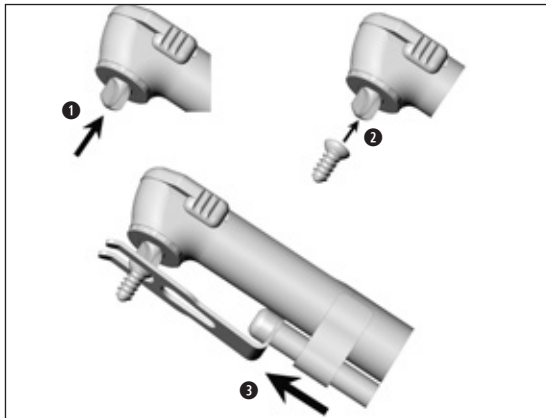
or

b Remove the tool by pressing with a pair of tweezers.

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Use of the screwholding fork and the retaining clip

- 1 Insert the screwdriver blade.
- 2 Guide the screw onto the screwdriver blade.
- 3 Push the bolt retainer forwards until the screw is held by the retaining clip.



The retaining clip of the screw holding fork only provides a secure hold for screws measuring $\geq \varnothing 2.0$ mm



Use of the screwholding fork and the retaining clip

- 4 After inserting the first few threads, pull the screwholding fork backwards.
- 5 Tighten the screw until secure.



In the rear position, the screwholding fork can be turned 90° to the left or right.

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Test run



Do not hold the medical device at eye level.

- > Insert the rotary instrument.
- > Operate the medical device.



In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating) stop the medical device immediately and contact an authorized service partner.



- > Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



- > Wear protective clothing, safety glasses, face mask and gloves.



- > Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

Cleaning agents and disinfectants



- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- > Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- > Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).



The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.



The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

- > Send worn or damaged medical devices and/or medical devices with material changes to an authorized service partner.



Processing cycles

- > We recommend a regular service for the medical device after 500 processing cycles or one year.



Clean the medical device immediately after every treatment, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

- > Operate the medical device for at least 10 seconds at idle speed.



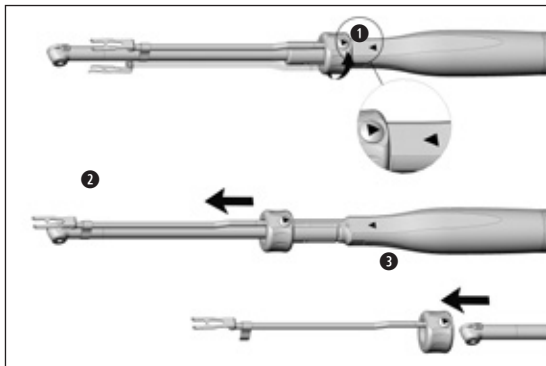
- > Wipe the entire surface of the medical device with disinfectant.

- > Remove the rotary instrument.

- > Remove the medical device.



Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.



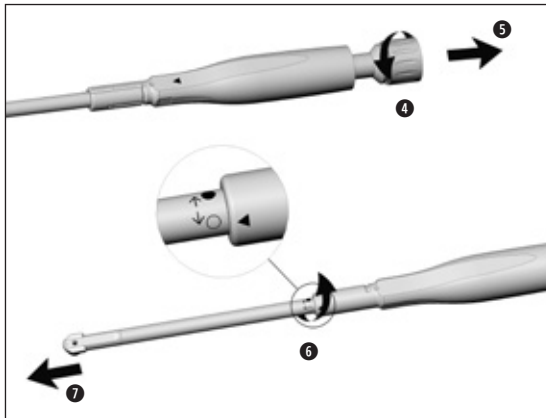
Disassembly of the medical device

- 1 Turn the screwholding fork into the unlocking position.
- 2 Push the screwholding fork forwards until the clip releases.
- 3 Remove the screwholding fork in a forwards direction.

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- 4 Screw on the shaft.
- 5 Remove the shaft from the sheath.
- 6 Loosen the head from the sheath by turning it from »●« to »○«.
- 7 Remove the sheath from the head.



Do not place the medical device in liquid disinfectant or in an ultrasonic bath.

- > **Clean the medical device under running tap water (< 35°C / < 95°F).**
- > **Rinse and brush off all internal and external surfaces.**
- > **Move moving parts back and forth several times.**
- > **Remove any liquid residues using compressed air.**



> Medartis recommends wiping down with disinfectant.



Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the disinfectants "mikrozid® AF wipes" (Schülke & Mayr GmbH, Norderstedt) and "CaviWipes™" (Metrex).



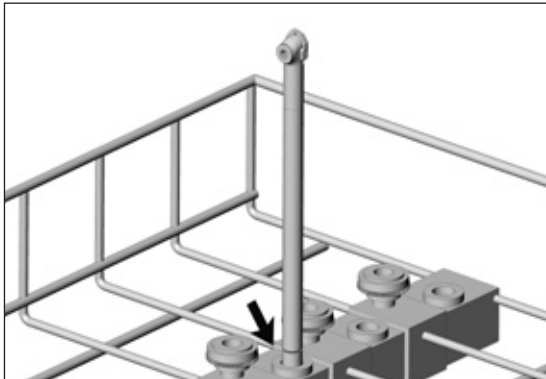
Medartis recommends automated cleaning and disinfection using a washer-disinfector (WD).

- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.



Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg).

- > Cleaning at 55°C (131°F) – 5 minutes
- > Disinfection at 93°C (200°F) – 5 minutes



Ensure that the disassemble angled screwdriver is placed in the WD correctly.



- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove any liquid residues using compressed air.
- > The medical device is designed for sterilization in the corresponding instrument tray.
Please observe the instructions for Use provided.

Inspection



- > Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
- > Reprocess any medical devices that are still soiled.
- > Sterilize the reassembled medical device following cleaning, disinfection and lubrication.



Reassembling the medical device



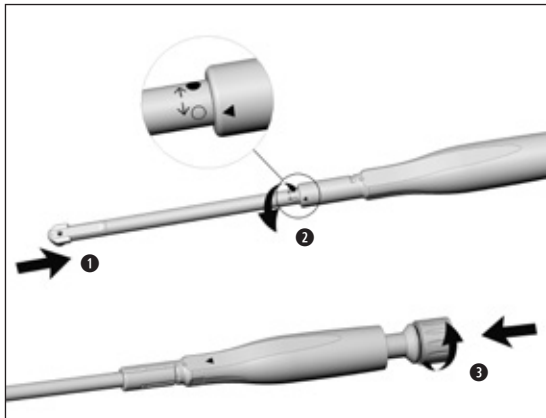
Reassemble the medical device following cleaning and disinfection.

- > Type and EN numbers must be identical.

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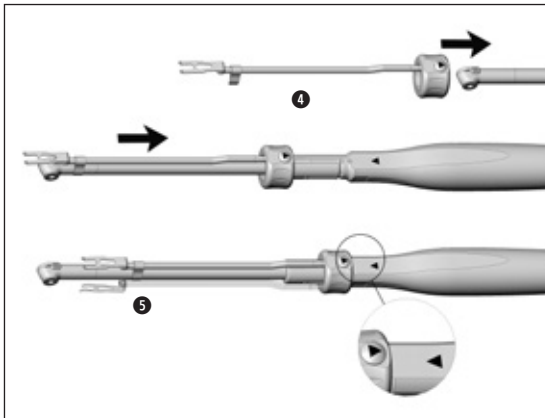
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Reassemble the medical device

- 1 Insert the head into the sheath until limit stop.
- 2 Pay attention to the symbols and turn from »○« to »●« until it locks.
- 3 Push the shaft into the sheath and screw this tightly in place.



Reassemble the medical device

- 4 Push the screwholding fork until it audibly engages.
- 5 Pay attention to the positioning and tighten the clip.

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Lubrication



- > Lubricate the dry medical device immediately after cleaning and/or disinfection.

Recommended lubrication cycles

- > Essential after every internal cleaning
- > Before each sterilization

Only with W&H Service Oil F1, MD-400

- > Follow the instructions on the oil spray can and on the packaging.

Test after lubrication



- > Direct the medical device downwards.
- > Operate the medical device so that excess oil can escape.
- > Remove any oil that has escaped.



Pack the medical device and the accessories in sterilization packages that meet the following requirements:

- > The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
- > The sterilization package must be large enough for the sterilization goods.
- > The filled sterilization package must not be under tension.



Medartis recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST79.



- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
- > The program selected must be suitable for the medical device.

Recommended sterilization procedures

- > Steam sterilization (type B, N)
- > Sterilization time at least 3 minutes at 134°C (273°F), 4 minutes at 132°C (270°F), 30 minutes at 121°C (250°F)
- > Maximum sterilization temperature 135°C (275°F)



Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)) and the CertoClav MultiControl MC2-S09S273 gravitation sterilizer (CertoClav GmbH, Traun).

- »Dynamic-air-removal prevacuum cycle« (type B): temperature 134°C (273°F) – 3 minutes*
temperature 132°C (270°F) – 4 minutes*/**
- »Gravity-displacement cycle« (type N): temperature 121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665

** ANSI/AAMI ST55, ANSI/AAMI ST79



- > Store sterile goods dust-free and dry.
- > The shelf life of the sterile goods depends on the storage conditions and type of packaging.

6. Servicing

Repairs and returns

In the event of operating malfunctions immediately contact an authorized service partner.

Repairs and maintenance work must only be undertaken by an authorized service partner.



> Ensure that the medical device has been completely processed before returning it.

7. Accessories and spare parts



Only use original Medartis accessories and spare parts or accessories approved by Medartis.

Supplier – Medartis AG:

M-2440	90° Screwdriver, Complete
M-2441	90° Screwdriver
M-2442	Screwholding Fork for 90° Screwdriver
M-2443	Rotation Knob for 90° Screwdriver

Supplier – W&H:

1094011	Service Oil F1
02038200	Spray cap

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8. Technical data

Transmission ratio		1.75:1
Motor connection according to standard		ISO 3964
Chuck system Note: only use tools approved for the angled screwdriver! *	[mm]	Ø 2.35 W&H special chuck system
Drive speed	[rpm]	1,750
Max. torque on tool */**	[Ncm]	120
Drive torque at stable speed	[Ncm]	at least 3

rpm (revolutions per minute)



- * For tools which are not approved for use in the angled screwdriver by the manufacturer, the user must choose the correct operating conditions in order to ensure that there is no risk to the user, the patient or third parties.
- ** We recommend using the M-2438 torque head in order to protect the gear mechanism.

Temperature information



- Temperature of the medical device on the operator side: maximum 55°C (131°F)
Temperature of the medical device on the patient side: maximum 50°C (122°F)
Temperature of the working part (rotary instrument): maximum 41°C (105.8°F)

Ambient conditions

- Temperature during storage and transport: -40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport: 8% to 80% (relative), non-condensing
Temperature during operation: +10°C to +35°C (+50°F to +95°F)
Humidity during operation: 15% to 80% (relative), non-condensing

9. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.

- > Medical device
- > Packaging

Explanation of warranty terms

This product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for Use have been followed.

As the manufacturer, Medartis is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase.

We accept no responsibility for damage caused by improper handling or by repairs carried out by third parties not authorized to do so by Medartis.

Claims under warranty – accompanied by proof of purchase – must be sent Medartis. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12 months warranty

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Authorized service partners

For service requests, please contact your sales representative or the responsible Medartis branch in your country. Medartis works in collaboration with service partners authorised by W&H.

Visit the Medartis website at www.medartis.com.

You can find the contact details for your local partner on the 'Location' page.

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Subject to alterations

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