

Instructions for use

medartis®



CE
0197

Angulated screwdriver
WSD-90

MANDIBLE-00000901 RevG

Instructions for Use for MODUS 90° Screwdriver

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Contents

Symbols	3 – 4
1. Introduction	5 – 7
2. Before use – safety notes	8 – 9
3. Product description WSD-90	10
4. Operation	11 – 17
Assembly/removal , rotating instruments, changing the rotating instrument, use of the screwholding fork and the retaining clip, test run	
5. Hygiene and maintenance	18 – 33
General, pre-disinfection, disassembly, manual cleaning, manual disinfection, mechanical cleaning and disinfection, reassembly, oil service, sterilization	
6. Accessories	34
7. Technical data	35 – 36
8. Recycling and disposal	37 – 38
Explanation of warranty terms	39
Authorized service partners	40

MANDIBLE-00000901_RevG

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Symbols

Symbols in the instructions for use



WARNING!
(risk of injury)



ATTENTION!
(to prevent damage
occurring)



General explanations,
no risk to persons or
objects



Do not dispose of with
domestic waste

Caution:

According to the federal law of the USA, the sale of this device is only permitted by or on instruction of a dentist, a doctor or another medical practitioner who is licensed to work in the state in which they are practising and in which they want to use or arrange the use of this device.

MANDIBLE-00000901_RevG

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Symbols

Symbols on the 90° screwdriver



Identification number of notified body

REF Catalogue number

EN Equipment number



Thermo washer disinfectable

SN Serial number



Sterilizable up to the stated temperature



Date of manufacture

1. Introduction

Customer satisfaction is the main priority of our quality policy. This product 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

Please read the instructions for use booklet before using this product for the first time. This explains to you how to use your product and guarantees smooth, efficient and safe operation.

Intended use

Surgical treatment of dental hard tissue.

Misuse can damage the 90° screwdriver and involves risk and danger to the patient, user and third parties.

Qualifications of the user

Only suitably qualified medical, technical and specialist trained staff may use the 90° screwdriver. We have based our development and design of the 90° screwdriver on the "physician" target group.



0197

Production according to EU directive

The 90° screwdriver is a medical product according to EU Directive 93/42/EEC.



Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the 90° screwdriver when the following directions are complied with:

- > The 90° screwdriver must be used in compliance with these instructions for use.
- > The 90° screwdriver contains no parts which are repairable by the user. Modifications or repairs must only be undertaken by an authorized service partner (see page 40).

Skilled application

The 90° screwdriver is intended only for skilled application in surgery according to its purpose of use in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance with these instructions for use. The 90° screwdriver should only 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. poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by us for the WSD-90, invalidate all claims under warranty and any other claims.

Service

If you observe any problems, contact an authorized service partner immediately (see page 40). Repair and maintenance work must only be carried out by an authorized service partner.

2. Before use – safety notes



- > The operation of the 90° screwdriver is permitted only on drive units which comply with the medical device directives.
- > The screwdriver should only be operated with sufficiently powerful drive motors (see page 35).
- > The maximum permitted drive speed of 1750 rpm must not be exceeded.
- > Always ensure that you have the correct operating conditions.
- > Check the 90° screwdriver for damage and loose parts prior to use (e.g. retaining clip).
- > Do not operate the 90° screwdriver if it is damaged.
- > Only fit the 90° screwdriver when the motor is at a complete standstill.
- > Never touch the rotary instrument when it is still rotating.
- > Carry out a test run prior to each use.
- > Avoid overheating at the treatment site.
- > Unintended use may result in the 90° screwdriver getting hot (risk of burning)!
- > During surgery, we recommend to have two angled screwdrivers ready for use.

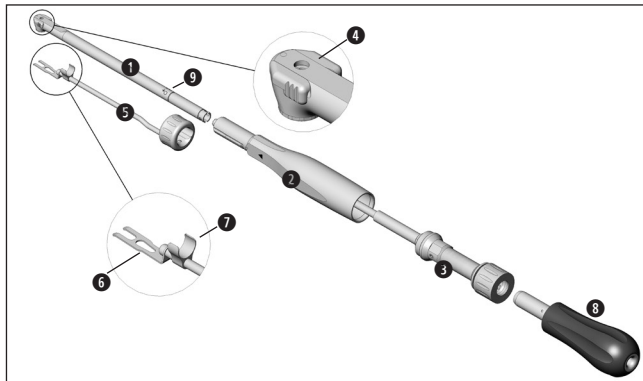
Hygiene and maintenance prior to initial use

- > Oil service prior to initial use.
- > Sterilize the 90° screwdriver and the rotation knob.

> Oil service page 30

> Sterilization page 32

3. Product description WSD-90



90° Screwdriver

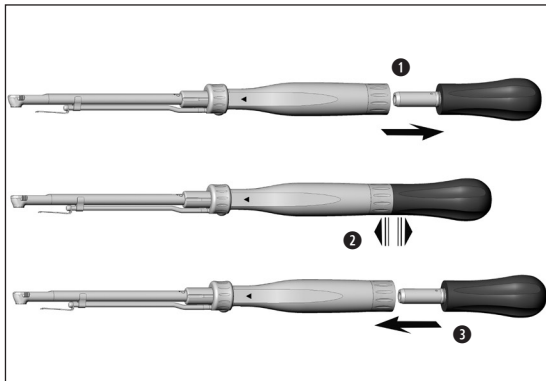
- ① Head
- ② Sheath
- ③ Shaft
- ④ Tension clamp
- ⑤ Screwholding fork
- ⑥ Retaining clip
- ⑦ Clip
- ⑧ Rotation knob
- ⑨ Symbol description
 - = Sheath open
 - = Sheath locked

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4. Operation



Assembly/removal



Do not assemble/remove
during operation!



- 1 Place the 90° screwdriver on the motor or rotation knob.
- 2 Check that the connection to the motor or rotation knob is secure.
- 3 Remove the 90° screwdriver using axial tension or by pressing the unlocking button.

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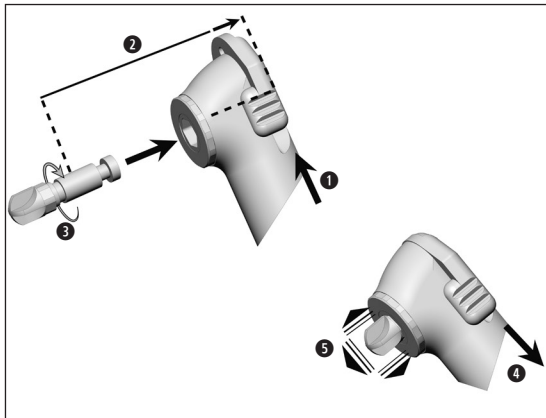
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Rotating instruments (bur and screwdriver blade)

- > Only use rotary instruments which are in perfect condition and pay attention to the direction of rotation of rotating instruments. Observe the manufacturer's recommendations.
- > Insert the rotary instrument only when the 90° screwdriver is stationary.
- > Only use the screwdriver blade with the rotation knob.
- > Never touch rotary instruments which are still rotating.
- > Never touch the tension clip of the 90° screwdriver during use. This leads to detachment of the rotary instrument and/or overheating of the 90° screwdriver.



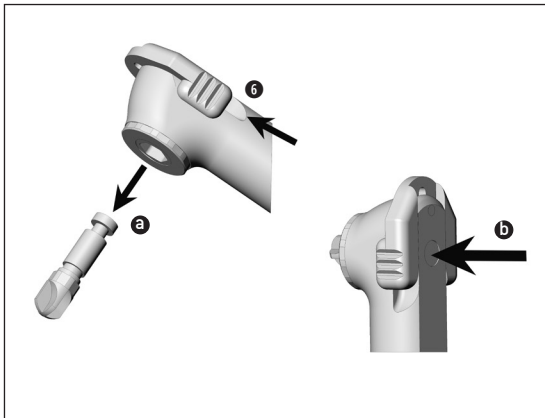
Changing the rotary instrument

- ➊ Push the tension clamp forwards in an axial direction.
 - ➋ Then insert the tool into the head until it reaches the stop.
 - ➌ Turn the tool in order to make sure that it is fully inserted.
 - ➍ Pull the tension clamp completely backwards in the axial direction until it engages.
-  The tension clamp should engage without force being exerted. If the tension clamp does not engage, check steps 2 and 3.
- ➎ Check that the tool is secure by applying axial tension.

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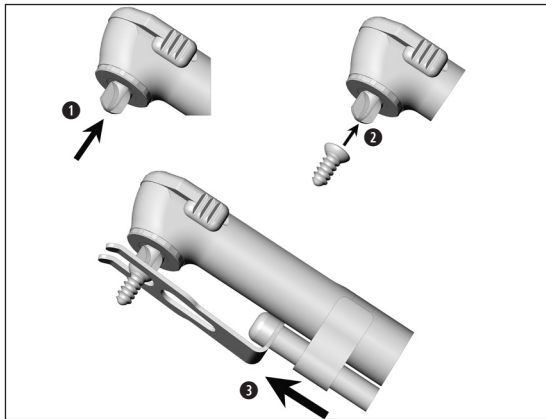
Changing the rotary instrument

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.



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 screwholding fork 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.

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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 90° screwdriver at eye level.

- > Attach the 90° screwdriver to the motor.
- > Insert the rotary instrument.
- > Start the motor.
- > If you observe problems (e.g. vibrations, unusual noise, overheating), stop the 90° screwdriver immediately and contact an authorized service partner (see page 40).

5. Hygiene and maintenance



- > Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.
- > The 90° screwdriver can be prepared manually or mechanically.



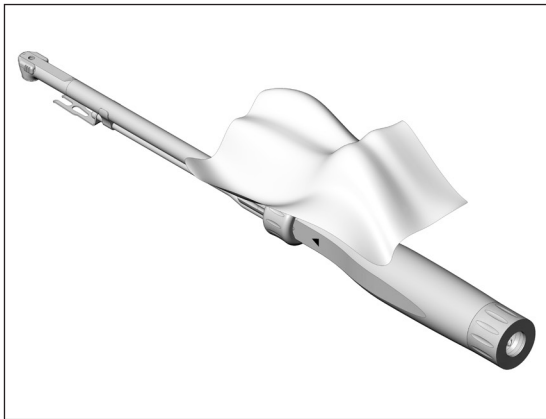
- > Wear protective clothing.
- > Remove the 90° screwdriver from the motor or rotation knob.
- > Remove the rotary instrument.
- > Clean and disinfect the 90° screwdriver and the accessories **immediately after every treatment** to rinse out any liquids that may have entered (e.g. blood, saliva, etc.) and prevent seizing up of the internal parts.
- > Sterilize the 90° screwdriver following manual or mechanical cleaning, disinfection and oil service.



- > Reassemble the dismantled 90° screwdriver after manual cleaning and disinfection (the type respectively the EN number on the sheath, head and shaft must match).



- > Sterilize the 90° screwdriver following manual or mechanical cleaning, disinfection and oil service.



Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.

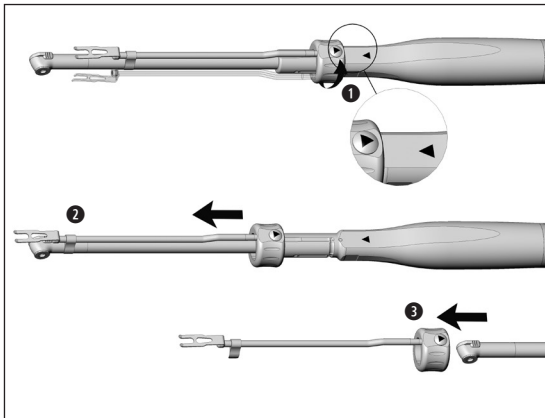


Only use disinfectants that have no protein-fixing effects.

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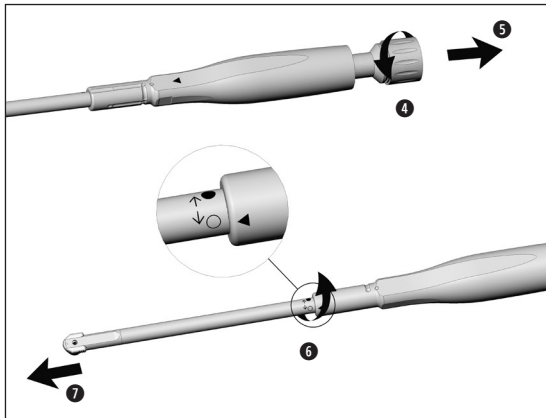
Disassembly of the 90° screwdriver

- 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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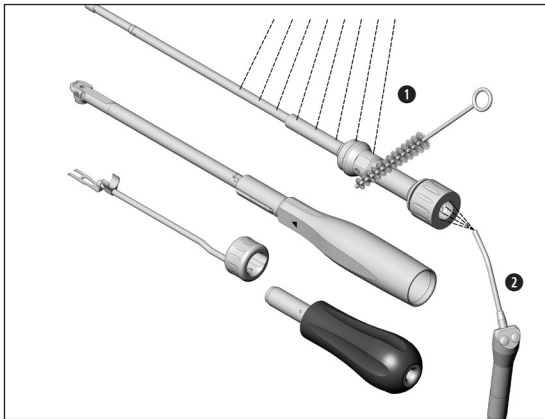


- ④ Screw on the shaft.
- ⑤ Remove the shaft from the sheath.
- ⑥ Loosen the head from the sheath by turning it from “●” to “○”.
- ⑦ Remove the sheath from the head.

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Manual cleaning internal and external

- 1 Rinse under demineralized water ($< 38\text{ }^{\circ}\text{C}$) with the aid of a brush
- 2 Remove any liquid residues (absorbent cloth, blow dry with compressed air).



Do not place the 90° screwdriver in disinfectant solution or in an ultrasonic bath.

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Manual disinfection



Medartis recommends disinfection by wiping.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



After manual cleaning, disinfection and oil service you must carry out a final sterilization (wrapped) in the class B or S steam sterilizer (as per EN 13060).

Mechanical cleaning and disinfection internal and external



The 90° screwdriver can be cleaned and disinfected in a thermo washer disinfectant.

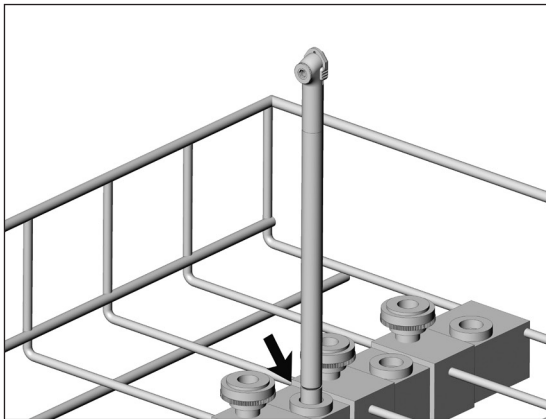


Medartis recommends processing in the thermo washer disinfectant.

- > Follow the manufacturer's recommendations for devices and cleaning and rinsing agents.



- > Ensure that the 90° screwdriver is completely dry, both inside and out, following thermo washer disinfection. Remove any liquid residues with compressed air.
- > Oil the dry 90° screwdriver immediately after thermosinfection.



Machine cleaning in the thermo washer disinfector

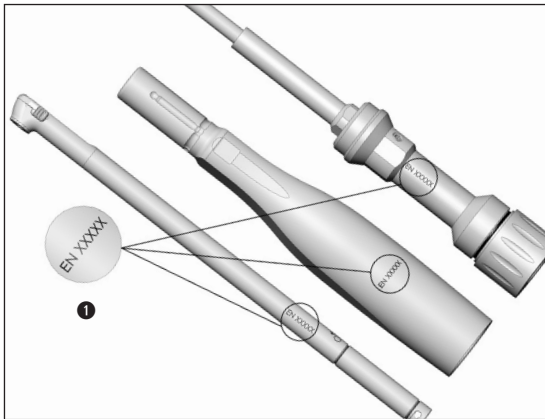


Ensure that the dismantled 90° screwdriver is placed in the thermo washer disinfector correctly.

MANDIBLE-00000901_RevG

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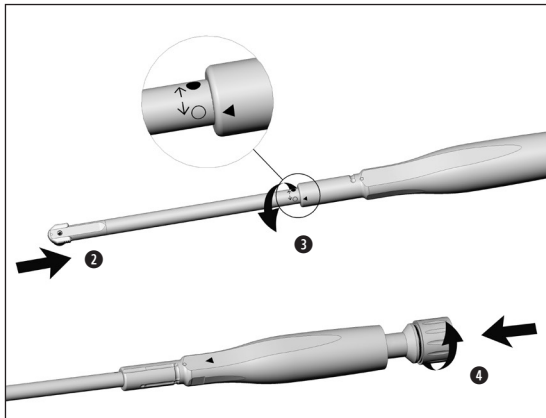
Assembling the 90° screwdriver

- 1 Check that the type respectively the EN number on the sheath, head and shaft match.

MANDIBLE-00000901_RevG

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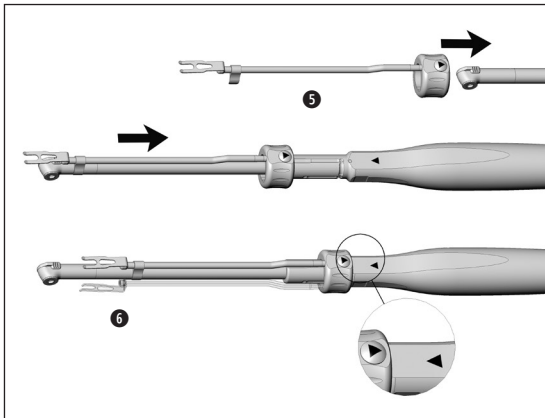
Assembling the 90° screwdriver

- ② Insert the head into the sheath until it engages.
- ③ Pay attention to the symbols and turn from “○” to “●” until it locks.
- ④ Push the shaft into the sheath and screw this tightly in place.

MANDIBLE-00000901_RevG

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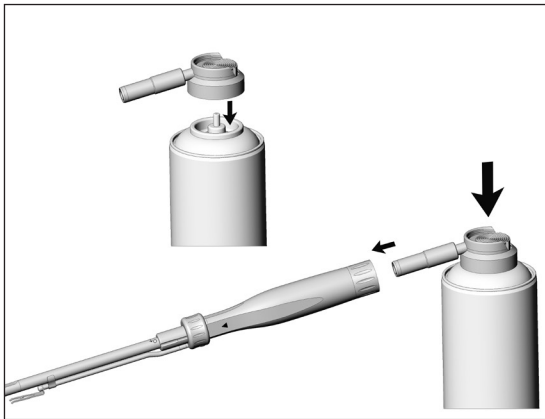
Assembling the 90° screwdriver

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

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Oil service

With Service Oil F1 or another oil approved for handpieces/contra-angles

- > Follow the instructions in the manufacturers instructions for use.

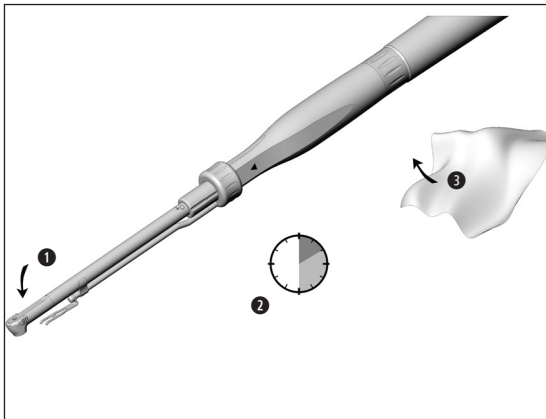
Recommended lubrication cycles

- > Essential after internal cleaning
- > Before each sterilization

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Test run following oil service

- ❶ Position the 90° screwdriver with the head pointing downwards.
 - ❷ Let the 90° screwdriver run for 30 seconds in order to remove excess oil. Start at the minimum speed and increase to maximum speed within 5-10 seconds.
- > Repeat the entire hygiene and maintenance process if dirt emerges.
- ❸ Wipe the 90° screwdriver with gauze or a soft cloth.

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Sterilization and storage



We recommend sterilization according to EN 13060, class B.

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect and lubricate prior to sterilization.
- > The 90° screwdriver is designed for sterilization in the corresponding instrument tray. Please observe the instructions for use provided.
- > If the 90° screwdriver is to be sterilized individually, wrap the 90° screwdriver and accessories in sterile goods packaging according to EN 868-5.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods in a dust-free and dry condition.



The standard ISO 7785-2/ISO 14457 stipulates a durability of at least 250 sterilization cycles.

In the case of the Medartis 90° screwdriver, we recommend you carry out a regular service after 500 sterilization cycles or one year.

Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.
Sterilization holding time of a minimum of 3 minutes at 134°C.

or

- > Steam sterilization class S with sterilizers in accordance with EN 13060.
The sterilizer manufacturer must give express approval for the sterilization of handpieces/contra-angles.
Sterilization holding time of a minimum of 3 minutes at 134°C.

6. Accessories

Only use original Medartis accessories and replacement parts or WSD-90 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

7. Technical data

Transmission ratio		1.75:1
Motor connection according to standard		ISO 3964
Chuck system Note: only use tools approved for the 90° screwdriver! *	[mm]	Ø 2.35 W&H special chuck system
Max. speed	[min ⁻¹]	1,750
Max. torque on tool *	[Ncm]	120
Drive torque at stable speed	[Ncm]	at least 3

min⁻¹ (revolutions per minute)

* For tools which are not approved for use in the 90° 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.

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Temperature details

Temperature of the 90° screwdriver on the operator's side:	max. 55 °C
Temperature of the 90° screwdriver on the patient's side:	max. 50 °C
Temperature of the working part (rotating instruments):	max. 41 °C

Physical characteristics

Temperature during storage and transport:	-40 °C to +70 °C
Air humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Ambient temperature during operation:	+10 °C to +35 °C
Air humidity during operation:	15 % to 80 % (relative), non-condensing



There are no further transportation requirements.

8. Recycling and disposal

Recycling

We consider that we have a special duty towards the environment. The 90° screwdriver along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the 90° screwdriver

-  > Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.
-  > Upon disposal, ensure that the parts are not contaminated.

Disposal of the packaging material



Follow your country-specific laws, directives, standards and guidelines for disposal.

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. In this way, you will contribute to the recycling of raw materials and the avoidance of waste.

Explanation of warranty terms

This product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee 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 to Medartis. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12-month 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.

Manufacturer

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Subject to alterations



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