

Directions for Use



Push Button Contra-angles
8:1 (TUL-8M), 16:1 (TUL-16M), 1:1 (TUL-1)

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1. Symbols

in the Directions for Use



CAUTION!
(to prevent
damage occurring)



WARNING!
(risk of injury)



General explanations,
without risk to
persons or objects



Do not dispose of with
domestic waste

Symbols

on the contra-angle / packaging

REF

Catalog number



Thermo washer
disinfectable

HIBC

Data structure in
accordance with
Health Industry Bar Code

SN

Serial number



Sterilizable up to the
stated temperature



Date of manufacture



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

R_x_{only}

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 who intends to use or order the use of this medical device.

2. Introduction

This contra-angle has been developed, manufactured, and subjected to final inspection according to legal regulations, quality, and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Directions for Use. These explain how to use your contra-angle and guarantee a smooth and efficient operation.



Observe the safety notes.

Intended use

TUL-1: For endodontic procedures, for removing carious material, reducing hard tooth structure, cavity preparations, finishing tooth preparations and restorations, and polishing teeth.

TUL-8M/TUL-16MT: Mechanical root canal preparation with suitable endodontic rotary files.



Misuse may damage the handpiece 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 contra-angle on the dentists target group.

Device labeling statement

U.S. Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

Responsibility of the manufacturer

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

- > The contra-angle must be used in accordance with these Directions for Use.
- > The contra-angle has no components that can be repaired by the user.
- > Modifications or repairs must only be undertaken by an authorized service partner (p. 37).

Skilled application

The contra-angle 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 Directions for Use.

The contra-angle 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 Dentsply Tulsa, invalidates all claims under warranty and any other claims.

3. Safety notes



- > Before using the contra-angle for the first time, store it at room temperature for 24 hours.
- > The operation of the contra-angle 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).
- > Always ensure the correct operating conditions and cooling function.
- > Check the contra-angle for damage and loose parts each time before use (e.g., push-button).
- > Do not operate the contra-angle if it is damaged.
- > Only attach the contra-angle onto the motor when the motor is at a complete standstill.
- > Do not activate the push-button of the contra-angle during operation. This leads to detachment of the root canal instrument and/or makes the contra-angle hot.
- > Perform a test run each time before using. (p. 15)
- > Do not touch the soft tissue with the contra-angle head (risk of burning due to the push-button heating up)!

Hygiene and maintenance prior to initial use



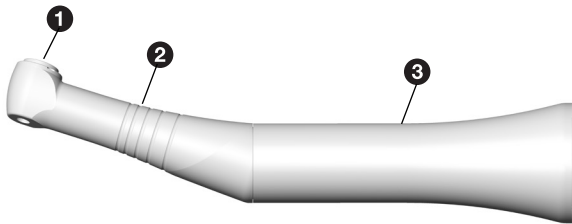
- > The contra-angle is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



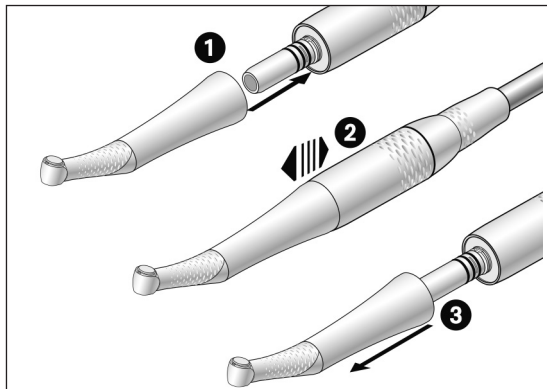
- > Clean, disinfect and lubricate the contra-angle.
- > Sterilize the contra-angle.

4. Product description

TUL-8M, TUL-16M, TUL-1



- ① push button
- ② grip profile
- ③ sheath



Do not assemble / remove the contra-angle during operation!

- ❶ Fit the contra-angle handpiece onto the motor until it snaps into place.



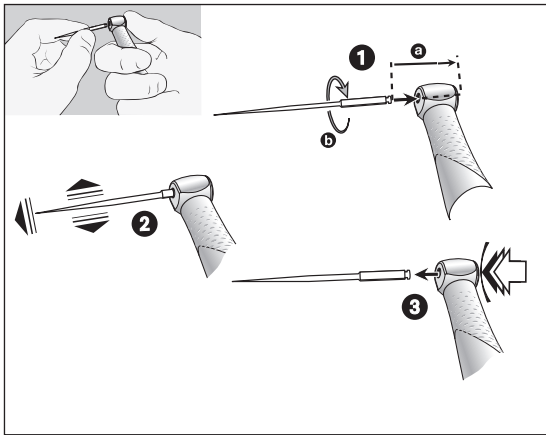
- ❷ Check the secure hold on the motor.

- ❸ Remove the the contra-angle by pulling in an axial direction.

Root canal instrument



- > Use only root canal instruments in perfect condition and follow the manufacturer's instructions.
- > Only insert the root canal instrument when the contra-angle is stationary.
- > Never touch the rotary instrument while it is still rotating.
- > Do not activate the push-button of the contra-angle during operation. This leads to detachment of the rotary instrument and/or makes the contra-angle hot.
- > We recommend the use of a rubber dam.



Changing the root canal instrument

- 1 Insert root canal instrument until the limit stop (a) and turn until it engages (b).



- 2 Verify full engagement.

- 3 Remove the root canal instrument by pushing the push button.

Test run



Do not hold the contra-angle at eye level!

- > Insert the root canal instrument.
- > Start the contra-angle.



In the event of operating malfunctions (e.g. vibrations, unusual noise, overheating) **stop the contra-angle immediately** and please call 800-662-1202 (see contact information on p. 37).



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 contra-angles 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, for example: the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).



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



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

- > Send worn or damaged contra-angles and/or contra-angles with material changes to Tulsa Dental. Beforehand, please call 800-662-1202.



Processing cycles

- > We recommend a regular service for the Tulsa contra-angle after 1,000 processing cycles or one year. Please call 800-662-1202.

See contact information on page 37.



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

- > Operate the contra-angle for at least 10 seconds at idle speed.
- > Ensure that all outlets are rinsed out.



- > Wipe the entire surface of the contra-angle with disinfectant.
- > Remove the root canal instrument.
- > Remove the contra-angle.



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



Do not place the contra-angle in liquid disinfectant or in an ultrasonic bath.

- > Clean the contra-angle under running tap water (< 95°F / 35°C).
- > Rinse and brush off all surfaces.
- > Remove any liquid residues using compressed air.



We recommend automated cleaning and lubrication with W&H Assistina 3x3.
> Follow the instructions in the Assistina Directions for Use.



> We recommend wiping down with disinfectant.



Evidence of the contra-angle's basic suitability for effective manual disinfection was provided by an independent test laboratory using the »mikrozid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).



We recommend 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 contra-angle'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 131°F (55°C) – 5 minutes
- > Disinfection at 200°F (93°C) – 5 minutes



- > Ensure that the contra-angle is completely dry internally and externally after cleaning and disinfection.
- > Remove any liquid residues using compressed air.

Inspection



- > Check the contra-angle after cleaning and disinfection for damage, visible residual soiling, and surface changes.
- > Reprocess any contra-angles that are still soiled.
- > Sterilize the contra-angle following cleaning, disinfection and lubrication.

Lubrication



> Lubricate the dry contra-angle immediately after cleaning and/or disinfection before sterilization.

Recommended lubrication cycles

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

or

- > After 30 minutes of use or at least once daily
- > Chucking system once a week

With W&H Service Oil F1, MD-400

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

or

With W&H Assistina

- > Follow the instructions in the Assistina Directions for Use.

Testing after lubrication



- > Direct the contra-angle downwards.
- > Operate the contra-angle so that excess oil can escape.



Pack the contra-angle 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.



We recommend 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 contra-angle.

Recommended sterilization procedures

- > Fractionated pre-vacuum process (type B)
- or
- > Gravity displacement process (type N)
- > Sterilization time at least 30 minutes at 250°F (121°C) or at least 3 minutes at 273°F (134°C)
- > Maximum sterilization temperature 275°F (135°C)



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

- > Fractionated pre-vacuum process (type B): temperature 273°F (134°C) – 3 minutes*
- > Gravity displacement process (type N): temperature 250°F (121°C) – 30 minutes**

* according to EN 13060, EN 285, ISO 17665 / ** according to 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.

7. Servicing

Repairs and returns

In the event of operating malfunctions immediately contact your authorized service partner. (p. 37)

Repairs and maintenance work must only be undertaken by an authorized service partner. (p. 37)



> Ensure that the contra-angle has been completely processed before returning it.

8. Accessories and spare parts



Use only original accessories and spare parts or accessories approved by Dentsply Tulsa Specialties.

Suppliers: W&H partners

000301xx	W&H Assistina 301 plus
19922000	W&H Assistina 3x2 (MB-200)
19923000	W&H Assistina 3x3 (MB-300)
30310000	W&H Assistina TWIN (MB-302)
10940021	Service Oil F1, MD-400 (6 pcs)
02038200	Spray adaptor

9. Technical data

Contra-angles	TUL-1	TUL-8M	TUL-16M
Transmission ratio	1:1	8:1	16:1
Motor coupling according to standard	ISO 3964	ISO 3964	ISO 3964
Recommended root canal instruments* EN ISO 1797-1:1995	for contra angle burs Ø 2.35 mm	nickel-titanium files for root canal preparation Ø 2.35 mm	nickel-titanium files for root canal preparation Ø 2.35 mm
min. chuck length (mm)	engaging	engaging	engaging
max. rated motor speed (rpm)	30,000	30,000	30,000

* In choosing the correct operating conditions, the user must ensure that there is no risk to the user, the patient or third parties. Always follow the instructions of the manufacturer of the root canal instruments (e.g. in terms of speed, chuck length, described application).

Temperature information

Temperature of the contra-angle on the operator side:

maximum 131°F (55°C)

Temperature of the contra-angle on the patient side:

maximum 122°F (50°C)

Temperature of the working part (rotary instrument):

maximum 105,8°F (41°C)

Ambient conditions

Temperature during storage and transport:

-40°F to +158°F (-40°C to +70°C)

Humidity during storage and transport:

8% to 80% (relative), non-condensing

Temperature during operation:

+50°F to +95°F (+10°C to +35°C)

Humidity during operation:

15% to 80% (relative), non-condensing

10. Disposal



Ensure that the parts are not contaminated on disposal.

Instrument disposal



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

- > contra-angle
- > Packaging

11. Contact information

All service, in and out of warranty period, will be performed by W&H Impex Inc. If product requires service while under warranty, please call Dentsply Tulsa Dental Specialties Customer Service to make arrangements, 800-662-1202.

If out of warranty, contact W&H Impex Inc. at:

For service/repair please contact:

In warranty contact:

Dentsply Tulsa Dental Specialties at +1 800 662 1202

For any complaints after warranty contact:

W&H Impex Inc., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada

t + 1 519 944 6739, + 1 800 265 6277, f + 1 519 974 6121, E-Mail: service.ca@wh.com

W&H Impex Inc., 33091 W Jefferson Ave. Brownstown, MI-48173, USA

t + 1 519 944 6739, + 1 800 265 6277, f + 1 519 974 6121, E-Mail: service.us@wh.com

dentsplysirona.com



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USA

Phone: 1-800-662-1202
Fax: 1-800-597-2779
tulsacustserv@dentsplysirona.com
dentsplysirona.com

Limited one-year warranty

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