



## 1. Product Description



EVO 450 Design

- Omni-directional lighting system
- Stainless steel body and head
- Triple spray holes
- Push button
- Easy grip coating

※ Indications for Use: The EVO 450 series is the air-powered dental handpiece which is used by dental professionals for removal of carious tooth, cavities, crown preparation and as a surgical tool for impacted third molar removal and periodontal procedures.

The clinical benefits of our handpieces enable dentists to operate effectively in removing carious lesions and hard dental tissues, preparing cavity for restoration and finishing after treatment.

## 2. Specifications

Model	450K/KL	450N/NL	450M4
Connection	TTBIO® EZclick-K/ KaVo® MULTiflex®	TTBIO® EZclick-N/ NSK® PLT-CL®	Fixed backend
Rotating speed (rpm)	380,000 ~ 460,000		
Bur size (mm) (diameter / length)	Ø1.59~1.60 / 25		
Driving air pressure (bar)	2.6~3.0	2.0~2.2	
Recommended Driving Air Pressure (bar)	2.8	2.0	
Spray Volume (ml/min)	>50		
Water pressure (bar)	1.0~2.0		
Head size(mm)	Ø10.5×H12.35		
Light system	Glass rod	—	
Transportation and Store Environment	Temperature: -10-50°C Humidity: 10-85% Atmospheric Pressure: 700-1,060hPa		

L : light support

## 3. Safety Notes

- Once handpiece is damaged (ie deformed caused by hit) or improper use (ie sterilized above suggested temperature), be sure not to continue using it.
- Before operation, always make sure the product and its accessories meet the specified requirements (ie drive air pressure, chip air pressure, water pressure, illumination), check the head cap is firmly tightened, water spray normally. Also check for handpiece vibration, noise and overheating outside the patient's oral cavity. When abnormalities are in LED (dark, do not light on or flashing or so), contact dealer to repair.
- Make sure that the supply of cooling air is dry, clean and uncontaminated according to ISO 7494-2. (CAUTION: Contaminated and moist cooling air can cause malfunctions)
- Make sure air is not emitted in the direction of the bur.
- Routinely monitor dental unit water quality to ensure microbial counts are below the levels for drinking water recommended by your local agency. The U.S. Centers for Disease Control and Prevention (CDC) recommends a level of <500 CFU/ml of heterotrophic water bacteria.
- After each patient use, disinfect the tubing waterlines including the handpiece waterlines by flushing with cleaning water to prevent cross-contamination according to handpiece waterlines disinfection procedure of main dental unit.
- Please contact our dealer or us with proof of purchase, whenever you have problems such as abnormal vibration, exceeding temperature or unusual noise, etc.
- Avoid contact between the instrument head and soft tissue (risk of burning due to the press button heating up).
- Sure it is functioning correctly before using on a patient.
- Read this Operation Manual before use to fully understand the product functions.
- Patient population: Any patient (except babies). The user's discretion is required prior use.
- This device is to be connected to dental unit and operated by dentists in the clinic.

## 4. Installation

### 1. Quick Coupling :

To install or strip handpiece, please follow the steps illustrated from Fig. 1 to Fig. 3 (Please refer to the coupling manufacturers' instructions.)



Fig.1 Install EZclick connector



Fig.2 Rotate the connector to install



Fig.3 Strip Ezclick connector

### 2. Fixed backend :

To install handpiece into ISO hose(\*), please follow the steps illustrated from Fig.4 to Fig.6. Make sure the handpiece is connected to the hose tightly. If there is any leakage of water or air, please repeat this installation procedure.

\*The holes hose is defined in accordance with ISO 9168:2009



Fig.4



Fig.5

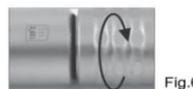


Fig.6

## 5. Changing Bur

- Follow the arrowhead direction show in Fig.7 to take off or install the bur.

- Put on protective gloves to reduce the risk of interactive inflection, especially not to touch the used burs without proper protection.
- Make sure bur is tightly secured before operation according to ISO 1797, otherwise risks of injury to doctors, patients or the third party may occur.
- Do not press the button while bur is rotating, otherwise it could harm internal parts.
- Do not use standard length or short shank burs with these handpieces, they can come out and injure the patient or be swallowed.
- The water stream is designed to be delivered to the tip of a 25mm bur only. Using a bur of another size may risks overheating the cutting area.

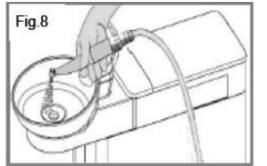


## 6. Replacement of Rotor

- Please contact local dealers and let the technicians replace the rotor.
- Do not use unsuitable rotors or spare parts, otherwise could damage the handpiece and result in severe consequence during treatment.

## 7. Cleaning for dental unit tubing

- Internal cleaning waterlines must be conducted through the main dental unit by connecting to handpiece connector and follow the instruction for handpiece and hose waterlines disinfection of the main dental unit. (It is recommended to use Waterline Maintenance Tablets for main dental unit, it is the simple way to maintaining clean dental unit waterlines.)
- Do not remove attached handpiece from the connecting cable during internal waterlines cleaning and disinfection procedure.
- Hold the handpiece over the cuspidor or over a waterproof container on main dental unit with sufficient capacity and press the purging key on the main dental unit. Setting time to clean and disinfect the waterlines base on manual instruction of main dental unit. (Fig.8)



## 8. Cleaning for dental handpiece

Evidence of the medical device's basic suitability for effective manual cleaning and automated cleaning were provided by an independent test laboratory.

### Manual cleaning OR Automated cleaning

Handpiece with thermal disinfection mark may be cleaned by a washer-disinfector which comply with EN ISO 15883-1.

### 8.1 Manual cleaning

- If included, remove the cutter or grinder.
- Using a soft-bristled brush, brush the external surfaces of the entire device under running (30±5°C) utility (tap) water.
- If spray nozzle is blocked with debris clean the spray nozzle with the nozzle cleaner needle. (See Fig.9)
- Prepare a detergent bath using a mild enzymatic detergent (such as Enzol®) per the vendor's recommendation of 1 oz/gal using warm tap water.
- Using a lint-free cloth soaked in the detergent solution, wipe the devices thoroughly to remove any visible soil.
- Use a soft bristled brush moistened with the prepared detergent to clean any remaining debris from the EVO 450 series handpiece. Brush device for 1 minute and 30 seconds.
- Rinse the EVO 450 series handpiece under running tap water for 30 seconds.
- Dry the EVO 450 series handpiece with a lint-free cloth.



### 8.2 Automated cleaning

- If included, remove the cutter or grinder.
- If spray nozzle is blocked with debris clean the spray nozzle with the nozzle cleaner needle. (See Fig.9)
- TTBIO recommends to place the handpiece in a cassette or container prior to wash in "Miele G7883" washer-disinfector, by switching the preprogrammed mode to "Vario TD". The recommended cleaning agent is alkaline detergent, such as "neodisher® mediclean" and the neutralizing agent is acid neutralizer, such as "neodisher® Z".

※ Operate washer-disinfector according to user manual provided by the original manufacturer.

The automated cleaning will be processed by pressing one "Vario TD" button and the preprogrammed procedures and parameters set by "Miele G7883" are shown as below:

Pre-wash	Main wash	Rinse	Rinse	Final rinse	Drying
Cold water	Cold water; 55°C for 5 minutes (Default); Alkaline detergent (neodisher® mediclean is recommended)	Hot water; Acid neutralizer (neodisher® Z is recommended)	Hot water	Deionized Water; 93°C for 5 minutes (Default)	10 minutes (Default)

- Dry the handpiece with a lint-free cloth. If any visible soil is still found, please repeat step 3.

## 9. Lubrication and Maintenance

- Be sure to lubricate the handpiece prior to sterilization.
- Servicing with the Maxima XTEND Spray.
- To lubricate EVO 450 series handpiece, put Spray Nozzle into nozzle of the lubrication oil can (Fig.10). Connect handpiece with the nozzle (Fig.11) and inject lubrication oil for 2~3 seconds.
- To lubricate handpiece chucks, put Shaft Spray Nozzle into nozzle of the lubrication oil can and inject lubrication oil into the chuck (Fig.12) for 1 second. It's recommended to lubricate chuck at least once a week and then proceeds step 2.
- To lubricate 5H/M4 series handpiece, put Spindle Nozzle into nozzle of the lubrication oil can and inject the oil into drive air tube for 2~3 seconds (Fig.13).

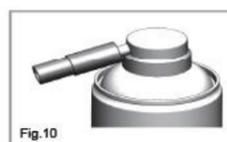


Fig.10



Fig.11

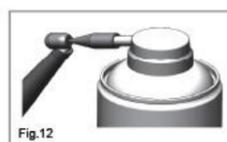


Fig.12



Fig.13

⚠ Never use dental handpiece lubricant that is not legally marketed; any unspecified oil not intended for lubricating handpieces could shorten the lifetime and harm human body.

## 10. Sterilization

- Before sterilization, the handpiece must be placed into a legally marketed disposable sterilization pouch made by a combination of plastic film and material which can allow penetration of steam (e.g. paper).
- Sterilization must be in compliance with ISO 17665-1 (choose **ONE** from the following methods):
  - Gravity-displacement steam sterilization: place in autoclave in accordance with: ANSI/AAMI ST55 at 132°C for 15 minutes and drying duration is 30 minutes.
  - Dynamic-air-removal Steam Sterilization: place in autoclave in accordance with EN13060 at 134°C for 4 minutes and drying duration is 15 minutes.
- Always perform complete drying process and remove the handpiece from steam sterilizer once the sterilization cycle is completed as the user manual of sterilizer manufacturer.
- Chemical sterilization is **NOT** applicable. **DO NOT** immerse the entire handpiece or cartridge/rotor into chemical sterilant, otherwise could damage the handpiece or harm the users or patients (e.g. allergic contact dermatitis, asthma, mucosal damage and so forth).

 We recommend a regular service for the TT BIO handpiece after 250 reprocessing cycles.

## 11. Disposal

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

- Medical device
- Packaging

## 12. Disclaimer

- Information in this operation manual has been carefully reviewed. We will not take any liability for any damage arising from improper use of the handpiece or misuse of this manual.
- Products are subject to change without notice.
- Please refer to the bar code on the packing box for manufacturing and expiry date.
- The product can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.

KaVo® & MULTiflex® are the registered trademarks of Kaltenbach & Voigt GmbH CO., Germany.  
NSK® & PLT-CL® are the registered trademarks of NAKANISHI INC. Japan.

 U.S. Federal law restricts this device to sale by or on the order of a licensed dentist.

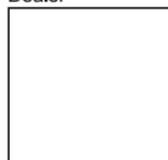
## 13. Quality and Service

- All of our products have passed strict QC procedures before delivery.
- Please note that improper use or not using the recommended parts and accessories or modifying our products without our approval may shorten the lifetime of the product or cause damage.
- Please contact us or dealers with proof of purchase for consultation whenever you have any questions.
- Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority.
- eIFU use the ref on <https://www.ttbio.com/download.php>.

## 14. Symbol

	Manufacturer		Caution
	CE mark (European Conformity)		Serial number
	Authorized representative in the European Community		Sterilizable up to the temperature specified
	Data Matrix Code for product information including UDI (Unique Device Identification)		Washer-disinfector for thermal disinfection

Dealer



Manufactured by  
TTBIO CORP.  
2F., NO.7, 6TH ROAD INDUSTRY PARK  
TAICHUNG, TAIWAN 40755  
TEL: 886-4-23595958  
E-mail: info@ttbio.com  
Website: www.ttbio.com

  
CMC MEDICAL DEVICES &  
DRUGS S.L.  
C/ Horacio Lengo N18.  
CP29006, Málaga Spain

OJL0473EU1 V1.2  
2022.05