1. Product Description

Tiger 101 Design

- Connection (ISO 2-hole / 4-hole)
- Head size (T: Torque)
- Spray hole (Single, Triple)
- Press chucking mechanism

CE 2797

Intended purpose: The Tiger 101 series High Speed Handpieces are designed for removing carious material, reducing hard tooth structure, cavity preparation, and finishing tooth reparations/restorations.

Use environment/Intended user: This device is to be connected to dental unit and operated by qualified professional (dentist) in the clinic.

Patient population: Any patient (except babies). The user's discretion is required prior use.

Indications: Removing carious material, reducing hard tooth structure, cavity preparation, and finishing tooth preparations/restorations.

Contraindications: N/A

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

	Fixed Connection	
	Tiger 101 T2+	Tiger 101 T4+
Connection	Borden 2-hole	Midwest 4-hole
Spray Hole	Single	Triple
Rotating speed (rpm)	T：300,000 ~ 360,000	
Bur size-diameter / length (mm)	Ø1.59~1.60 /T(19~25) ISO 1797 Type3	
Drive air pressure (bar)	2.2 ~ 2.8	
Suggested drive air pressure (bar)	2.5	
Water flow rate (ml/min)	>50	
Water pressure (bar)	0.8 ~ 2.0	
Air pressure (bar)	1.0 ~ 3.0	
Transportation and Store Environment	Temperature: -10~50°C Humidity: 30~85% Atmospheric Pressure: 700~1,060hPa	

※ The ISO 2/4 holes is defined in accordance with ISO 9168:2009 ※ T: torque head

※ Air pressure must be higher than water pressure.

※ Pressure values are measured by multi gauge.

3. Safety Notes

1. Once handpiece is damage (i.e. deformed caused by hit) or improperly use (i.e. sterilized above suggested temperature), be sure not to continue using it.
2. Before operation, always make sure the product and its accessories meet the specified requirements (i.e. drive air pressure, chip air pressure, chip water pressure, illumination, vibration and noise), check the head cap is firmly tightened and water spray normally.
3. Please stop using it immediately whenever you have problems such as abnormal vibration, exceeding temperature, unusual noise or loose headcap, etc., then contact our dealer or us with proof of purchase.
4. Depressing the push button while the handpiece is in rotation may lead to overheating, causing burn injuries or product failure. Avoid the push button to contact with any oral tissue.
5. Be sure it is functioning correctly before using on a patient.
6. Read this Operation Manual before use to fully understand the product functions.
7. This device complies with relevant safety and performance standards and incorporates state-of-the-art risk controls. Nonetheless, not all risks can be completely eliminated. There is still a very low chance that residual risks will arise, including:
   - Device functional failures, loose parts, or misuse, potentially causing foreign body issues in patients or treatment delays.
   - Biocompatibility hazards, such as infections, allergic reactions, irritation, or inhalation hazards.
   - High temperature hazards, which could result in burn injuries.
   - Acoustic hazards, which could lead to hearing impairments.
8. Tiger 101 series handpieces are supplied as non-sterile to the user and require the user to clean and sterilize the device prior to its use.

4. Installation

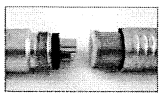
Fig.1

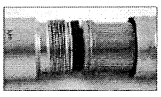
Fig.2

Fig.3

To install handpiece into ISO 2/4-hole hose(*), please follow the steps illustrated from Fig.1 to Fig.3.

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

5. Changing Bur

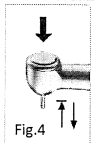
Fig.4

1. Follow the arrowhead direction show in Fig.4 to take off or install the bur.
2. Put on protective gloves to reduce the risk of interactive inflection, especially not to touch the used burs without proper protection.
3. 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.
4. Bur must be complied with ISO requirement. Burs not in good conditions such as being bent and damaged, or are deviated from ISO standards and in improper length may decrease the lifetime of the handpiece or even cause severe consequence such as injury to people.
5. Do not press the button while bur is rotating, otherwise it could harm internal parts.

6. Replacement of Rotor

1. Please contact local dealers and let the technicians replace the rotor.
2. 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

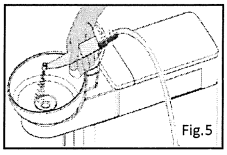
Fig.5

1. 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.)
2. Do not remove attached handpiece from the connecting cable during internal waterlines cleaning and disinfection procedure.
3. 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.5)

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 <u>OR</u> 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

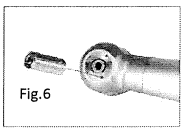
Fig.6

1. If included, remove the cutter or grinder.
2. Using a soft-bristled brush, brush the external surfaces of the entire device under running (30±5°C) utility (tap) water.
3. If spray nozzle is blocked with debris clean the spray nozzle with the nozzle cleaner needle. (See Fig.6)
4. 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.
5. Using a lint-free cloth soaked in the detergent solution, wipe the devices thoroughly to remove any visible soil.
6. Use a soft bristled brush moistened with the prepared detergent to clean any remaining debris from the Tiger 101 series handpiece. Brush device for 1 minute and 30 seconds.
7. Rinse the Tiger 101 series handpiece under running tap water for 30 seconds.
8. Dry the Tiger 101 series handpiece with a lint-free cloth.

8.2 Automated cleaning

1. If included, remove the cutter or grinder.
2. If spray nozzle is blocked with debris clean the spray nozzle with the nozzle cleaner needle. (See Fig.6)
3. 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 forte" 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 forte is recommended)	Hot water; Acid neutralizer (neodisher® Z is recommended)	Hot water	Deionized Water; 93°C for 5 minutes (Default)	10 minutes (Default)

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

9. Lubrication and Maintenance

Fig.7

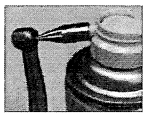
Fig.8

1. Use dental handpiece lubrication oil for maintenance, any unspecified oil not intended for lubricating handpieces could shorten the lifetime and harm human body.
2. To lubricate Tiger 101 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.7).
3. Be sure to lubricate the handpieces prior to sterilization and run the handpieces for 20~30 seconds to emit residual oil and dirt.
4. To lubricate handpiece chucks, put Spindle Nozzle into nozzle of the lubrication oil can and inject lubrication oil into the chuck (Fig.8) for 1 second. It's recommended to lubricate chuck at least once a week and then proceeds step 2.
5. After unpacking and prior to first use, be sure to lubricate with oil and run the handpieces in low rotation speed for 30 seconds and in full speed for 20~30 seconds to emit residual oil.

10. Sterilization

1. 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).
2. Sterilization must be in compliance with ISO 17665-1 (choose **ONE** from the following methods):
   i. 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.
   ii. Dynamic-air-removal steam sterilization: place in autoclave in accordance with EN13060 at 134°C for 4 minutes and drying duration is 15 minutes.
3. 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.
4. 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 TTBIO handpiece after 250 reprocessing cycles.

11. Disposal

Follow your local and national laws, directives, standards and guidelines for disposal.
-Medical device
-Packaging

⚠ Remove the dental bur from the handpiece, and dispose it according to the user manual provided by the original manufacturer to eliminate the biohazard and physical hazards.

12. Disclaimer

1. 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.
2. Products are subject to change without notice.
3. Please refer to the bar code on the packing box for manufacturing.
4. 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.

13. Reporting

Any serious incident and adverse event (e.g. bur detached accidentally and poor clamping) caused by device deficiency must be reported to the manufacturer, the authorized representative and the local competent authorities.

14. Quality and Service

1. All of our products have passed strict QC procedures before delivery.
2. 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.
3. Please contact us or dealers with proof of purchase for consultation whenever you have any questions.
4. eIFU use the ref on https://www.ttbio.com/download.php.

15. Symbol

	Manufacturer		Date of manufacture
CE 2797	CE mark (European Conformity)	SN	Serial number
EC REP	Authorized representative in the European Community	135°C	Sterilizable up to the temperature specified
	Data Matrix Code for product information including UDI (Unique Device Identification)		Washer-disinfector for thermal disinfection
	Instructions for use		Caution
	Transportation and storage conditions (Temperature limit)		Transportation and storage conditions (Humidity limitation)
	Transportation and storage conditions (Atmospheric pressure limitation)		

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

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

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