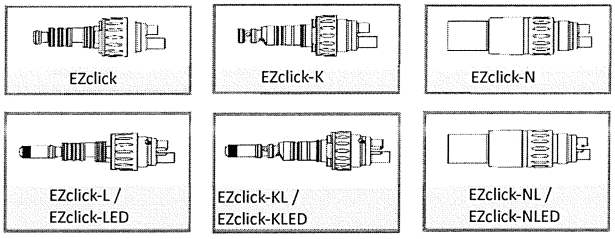
TTBIO

CE 2797

EZclick Couplings Instruction Manual

1. Product Description



Indications for Use: The EZclick series coupling attach the handpiece to the dental unit tubing to deliver water and air to the handpiece.

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

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

Indications: N/A

Contraindications: N/A

The clinical benefits of our coupling enable to transform the air supplied by a dental unit to drive the high speed handpiece.

2. Specifications

EZclick & EZclick-K & EZclick-N coupling

Standard 4-hole connection and anti-suction valve.

EZclick-L & EZclick-KL & EZclick-NL coupling

Standard 4-hole connection, anti-suction valve,
two electrical contacts and Xenon Bulb.
Xenon Bulb ideal voltage range: 3.4~3.6 Vd.c. (for Ezclick-L & EZclick-KL)
Xenon Bulb recommended voltage: 3.5 Vd.c. (for EZclick-L & EZclick-KL)
Xenon Bulb ideal voltage range: 3.0-3.5 Vd.c. (for EZclick-NL)
Xenon Bulb recommended voltage: 3.3 Vd.c. (for EZclick-NL)

EZclick-LED & EZclick-KLED & EZclick-NLED coupling

Standard 4-hole connection, anti-suction valve,
two electrical contacts and LED Bulb
LED Bulb ideal voltage range: 3.0-3.4 Vd.c. (for EZclick-LED & EZclick-KLED)
LED Bulb recommended voltage: 3.2 Vd.c. (for EZclick-LED & EZclick-KLED)
LED Bulb ideal voltage range: 3.0-3.4 Vd.c. (for EZclick-NLED)
LED Bulb recommended voltage: 3.2 Vd.c. (for EZclick-NLED)

Table of EZclick couplings and suitable handpieces

Handpiece	EZclick couplings
KAVO® LUX handpiece	EZclick-KL/ EZclick-KLED
KAVO® handpiece	EZclick-K
TTBIO LUX handpiece	EZclick-L/ EZclick-LED
TTBIO handpiece	EZclick
NSK Mach® LUX handpiece	EZclick-NL/ EZclick-NLED
NSK Mach® handpiece	EZclick-N

3. Safety Notes

1. Once EZclick couplings are damaged (i.e. deformed cause by hit) or improperly used (i.e. sterilized above suggested temperature), be sure not to continue using them.
2. Before operation, always make sure the product and its accessories meet the specified requirements.
3. It is the duty of the user to use only faultless tools, for the correct purpose, and protect patients and third parties from all dangers.
4. Please do not look directly into the lighting bulb, or it may hurt eyes when you use the EZclick coupling with light.

4. Installation

Connection to the hose

> Attach the EZclick couplings to the hose.
> Use fixed tool to fix the EZclick couplings
> Rotate the thread ferrule of the hose in a clockwise direction.
> Spray oil onto the O-rings. (for EZclick & EZclick-K series)

Removal from the hose

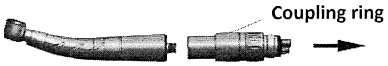
> Use fixed tool to remove the EZclick couplings
> Rotate the thread ferrule of the hose in an anti-clockwise direction.
> Separate the EZclick couplings from the hose

Connect the handpiece

Connect the handpiece exactly onto the EZclick coupling until it clicks audibly.

Removal from the handpiece (for EZclick-N series)

Pull back the EZclick coupling ring and remove from the handpiece.



Fixed Tool

1. EZclick-K series

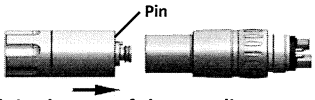
2. EZclick series

⚠ 1. Do not activate the coupling system during installation.
2. Please choose the correct connected interface of the fixed tool according to the different types.

3. EZclick-N series

(1) Connection to the coupling

Connect the fixed tool to the coupling. Ensure that the pin of the fixed tool is firmly inserted to the coupling hole until you hear the "Click" sound.

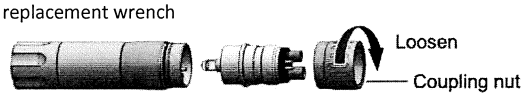


(2) Approach in the use of the coupling

> as a coupling wrench

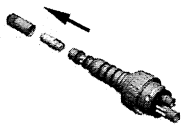
> as a protection-against-dust tool

> as a bulb replacement wrench



5. Trouble Shooting

Replacing the bulb (for EZzclick, EZclick-K series)



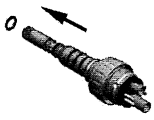
Unscrew the cap by turning it anti-clockwise.
Pull a bulb out of the coupling and insert a new one.
Screw the cap by turning it clockwise.

Replacing the bulb (for EZclick-N series)

Refer to Fixed Tool section.

⚠ 1. Note the position of two contact lugs in the couplings.
2. Do not touch the bulb immediately after operation.
3. The LED bulb must be inserted into the polar position in the correct orientation.
4. Inserted in the incorrect orientation may result in failure of lighting. If so, please rotate it 180° and re-insert the LED bulb.

Replacing the O-ring (for EZclick, EZclick-K series)



Press the sides of a defective O-ring between two fingers until a loop is formed and then slide the O-ring out of couplings and remove it.
Insert these new O-rings in the grooves and spray them with lubrication oil.

⚠ When sliding the O-ring, do not use any tools, such as tweezers, etc.

6. Cleaning and Disinfection

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

⚠ **Manual cleaning** is applicable.

⚠ Automated cleaning is **NOT** applicable.

1. Using a soft-bristled brush, rinse and brush the surfaces of the entire device under running tap-water (30±5°C).
2. Prepare a detergent solution using a mild enzymatic detergent (such as "METREX" EmPower Instrument Cleaner) with the ratio of 1 oz "METREX" EmPower Instrument Cleaner per gallon of warmed distilled water.
3. Using a lint-free cloth soaked in the detergent solution, wipe the devices thoroughly to remove any visible soil.
4. Use a soft bristled brush moistened with the detergent solution to clean any remaining debris from the coupling. Brush device for at least 1 minute and 30 seconds.

5. Rinse the coupling under running tap water for 30 seconds.
6. Using a lint-free cloth wipe the devices thoroughly to remove any visible liquid residues.

7. Sterilization

1. Before sterilization, the coupling 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 coupling 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 coupling into chemical sterilant, otherwise could damage the coupling 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 coupling after 250 reprocessing cycles.

8. Disposal

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

⚠ Dispose it according to the user manual provided by the original manufacturer to eliminate the biohazard and physical hazards.

9. Disclaimer

1. Information in this operation manual was carefully reviewed. We cannot assume any liability for damage arising from improper use of the hand piece or from use of this manual
2. Products are subject to change without notice.
3. This product is only for dental hand piece treatment and use for other purpose may damage the handpiece and cause severe consequence.
4. Please use the product correctly according to the instruction.

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NSK Mach® is the registered trademark of NAKANISHI INC. Japan.

10. 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.

11. 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.

12. 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)		Caution
	Instructions for use		Transportation and storage conditions (Temperature limit)
	Transportation and storage conditions (Humidity limitation)		Transportation and storage conditions (Atmospheric pressure limitation)

Dealer

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