Instructions for Use 1/2 2023-08-21
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MORITA

CP4-LD <with LED> Coupling
CP4-W-LD <with LED and Spray Control> Coupling

INSTRUCTIONS FOR USE

This instrument is a connection part (coupling) to connect the TWINPOWER TURBINE 4H series and ISO 9168 Type 3(C) tube, and does not have any performance or availability by itself.
In order to utilize the instrument's functions fully and ensure its safe and effective use, read this manual thoroughly before using the instrument and pay close attention to the operating procedures and precautions. Keep this manual at hand for quick reference. For instructions concerning the non-light equipped models, simply ignore the instructions for use of the light.

The user (e.g., healthcare facility, hospital, clinic, etc.) is responsible for supervising the use and maintenance of medical devices. This instrument must not be used by anyone other than a dentist, doctor or other legally qualified professional.
This instrument must not be used for any purpose other than the provision of dental treatment.
Federal law restricts this device to sale by or on the order of a dentist (for U.S.A.).

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the instructions they accompany:

⚠WARNING This warns the user of the possibility of serious injury or death to the patient, damage or complete destruction of the instrument or other valuable property, and fire.

⚠CAUTION This warns the user of the possibility of slight or moderate injury to the patient.

Disclaimer

J. MORITA MFG. CORP. will not be responsible for the following matters, even during the warranty period.
1. Malfunction or damage resulting from repairs made by personnel not authorized by J. MORITA MFG. CORP.
2. Any unauthorized modifications to its products
3. Malfunction or damage resulting from maintenance or repairs carried out using parts or components other than those specified by J. MORITA MFG. CORP.
4. Malfunction of or damage to Morita products caused by products made by other manufacturers unless they were supplied by J. MORITA MFG. CORP.
5. Malfunction or damage resulting from failure to observe the safety precautions or operating procedures described in these Operating Instructions
6. Malfunction or damage resulting from ambient conditions that do not conform to the operating conditions specified in these Operating Instructions, such as an improper electrical power supply or installation environment
7. Malfunction or damage resulting from a natural disaster, such as a fire, earthquake, flood or lightning

J. MORITA MFG. CORP. maintains supplies of service parts for 10 years after discontinuation of their production. For the duration of this period, we will supply replacement parts and be able to repair the product.

In Case of Accident
If an accident occurs, this device must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

For customers who use this device in the EU:
If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

Standards and Procedures for the Disposal of Medical Devices
When disposing of this device, it should fall into the category of infectious waste.
The dentist or doctor must confirm that the device is uncontaminated, and must then have it disposed of by a healthcare facility or an agent licensed and qualified to handle standard industrial waste and industrial waste requiring special treatment.

Technical Specifications

Use this instrument with dental treatment units that conform to IEC 60601-1.

Type	CP4-LD	CP4-W-LD
Spray Control	No	Yes
Light Source	LED	
Joint	ISO 9168 Type 3(C)	
Input Voltage	AC 2.5 - 10 V / DC 2.5 - 15 V (for coupling contacts)	
IP Code	IPX0	

⚠CAUTION
- Be sure to follow the input voltage. If it exceeds specifications, the LED lamp could burn out immediately.
- Some functions of a dental treatment unit, such as the light intensity and afterglow setting, may not work properly.
- The LED may flicker when it turns on and off depending on the dental treatment unit's light control system.
- This coupling cannot be connected to a tube that does not have light capability.

Operating, Transport and Storage Environments

Operating Temperature: +10 °C to +40 °C (+50 °F to +104 °F), Humidity: 30% to 75% (without condensation), Atmospheric Pressure: 70 kPa to 106 kPa

Transport and Storage Temperature: -10 °C to +70 °C (+14 °F to +158 °F), Humidity: 10% to 85% (without condensation), Atmospheric Pressure: 70 kPa to 106 kPa

* Do not expose the coupling to direct sunlight for an extended period of time.
* The useful life of the coupling is 4 years from the date of installation provided it is regularly and properly inspected and maintained.

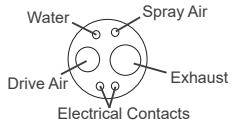
Accompanying Items

Wrench
Cord No. 5011831 (1)

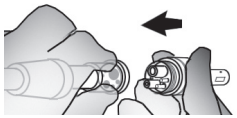
O-ring Set
Cord No. 5811835 (1)
(Large × 4, Small × 1)

Before Use

Check the following items:
- Connection end of the tube matches the coupling.
- The input voltage is correct (see Technical Specifications).

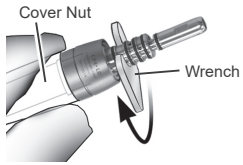


1.Connect Coupling



Line up the projections on the coupling with the indentations in the tube and then tighten up the cover nut.

⚠CAUTION
- Before connection, make sure the tube connector is clean and free of debris.



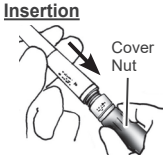
Hold the cover nut and tighten the coupling securely with the wrench provided.

⚠CAUTION
- Make sure the coupling is properly secured. Otherwise, it could result in air or water leakage, or damage the handpiece and dental treatment unit.

* Before using right after purchase, or if handpiece insertion/removal becomes tight, apply a small amount of the MORITA MULTI SPRAY to the O-rings of the instrument.

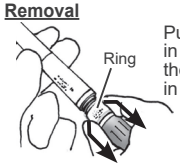
2.Handpiece Connection

Insertion



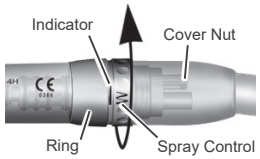
Hold the cover nut, and slide the handpiece straight onto the coupling until it clicks securely into place.

Removal



Push down the ring in the direction of the arrows as shown in the illustration.

3.Spray Adjustment (CP4-W-LD)



Turning the dial in the direction indicated by the arrow in the illustration will gradually reduce the amount of spray and then reach 0. For maximum spray, continue the turning the dial until the "W" matches up with the indicator. (See illustration.)

⚠WARNING
- Hold the cover nut to adjust the amount of spray. The handpiece could come off its connection and injure someone if it is held by the ring part.
- Do not operate the TWINPOWER TURBINE handpiece without emitting the water spray. Otherwise, this could burn the tooth.

⚠CAUTION
- If the coupling is not tightened up enough with the wrench, the connection part get loose and air or water may leak when turning the spray control dial.

4.Reprocessing

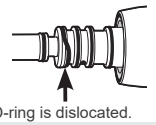
Hygiene Plan Guidebook

A reference guidebook of hygiene information about our products is available. Scan the following QR code and visit our website.

In order to view PDF documents, you will need the free Adobe Acrobat Reader distributed by Adobe Inc. Download the latest version via the Adobe website. PDF documents may not be displayed correctly using previous versions.

Dampen a piece of cleaning wipe with disinfectant, and then wipe the outer surface.

Disinfectants Approved by J. MORITA MFG. CORP.
FD 333 forte
Ethanol (70 vol% to 80 vol%)



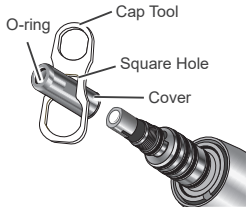
Allow to stand for a period of time to take effect, and then wipe off with a clean cloth or paper towel.

Make sure that there are no fibers from cleaning cloth or paper towel, O-ring dislocation, or any loose connection of the lamp cover or the tube connector.

⚠CAUTION
- For procedures required before removing the handpiece, refer to the accompanying Instructions for Use for each handpiece.
- For the duration of the disinfection activity, follow the instructions of each disinfectant manufacturer.
- Do not use highly corrosive disinfectants. This may damage the device.
- This device is not capable of being cleaned and disinfected with an autoclave or washer-disinfector.
- (For USA) Do not use isopropyl alcohol.

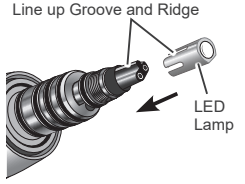
5.LED Lamp Replacement

* Use the LED lamp that is specially designed for this coupling.



Turn the dental treatment unit's main switch off. Remove the cover using the square hole in the cap tool.

⚠CAUTION
- Before replacing the LED lamp, always make sure the cover is not too hot. Otherwise, you could get burned.
- Do not lose the O-ring in the end of the cover.



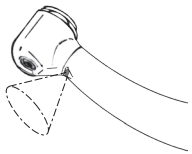
Take the LED lamp out of its socket and install a new one.

Line up the groove in the LED lamp with the ridge in the socket and push the LED lamp straight in all the way.

Screw the cover back on with your fingers and then tighten it up with the square hole in the cap tool.

⚠WARNING
- Make sure the cover is properly tightened up. If it is loose, the handpiece cannot be connected to the coupling securely and air pressure could cause the tube to suddenly disconnect, and this could injure the patient.

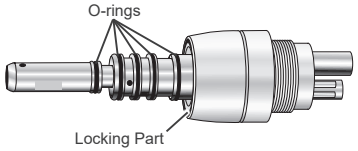
⚠CAUTION
- If the O-ring in the end of the cover is lost or damaged, the light may not be bright enough or it may malfunction.



Put the handpiece back on its coupling, and turn on the main switch of the dental treatment unit. Step on the foot pedal and make sure the lamp lights up.

⚠WARNING
- Do not let the light strike anyone directly in the eye; this might impair one's vision.

6. O-ring Replacement



Replace the O-rings if air or water starts leaking from the connection. After replacement, apply a small amount of the MORITA MULTI SPRAY to the O-rings of the instrument.

⚠WARNING

- Replace all five O-rings at the same time and make sure that there is no debris or broken pieces of the old O-rings. If something remains at the locking part, the tube could detach suddenly due to air pressure and cause physical injury.

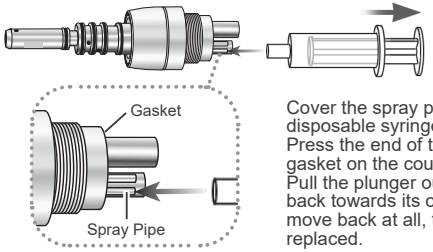
⚠CAUTION

- Using any kind of lubricant other than the MORITA MULTI SPRAY could cause the O-rings to swell up and make it hard to put the handpiece on and take it off.

7. Replace One-way Spray Valve

Inspect One-way Valve

* If the one-way valve is defective, cutting debris and contaminated matter could get inside the tube. Inspect the one-way valve at least once a month.

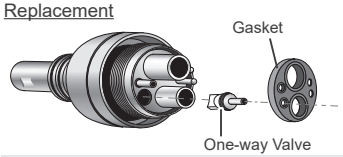


Cover the spray pipe with the end of a plastic disposable syringe with the needle removed. Press the end of the syringe flush against the gasket on the coupling so that it is air tight. Pull the plunger out slightly and see if it sucked back towards its original position. If it does not move back at all, the one-way valve must be replaced.

⚠CAUTION

- The end of the syringe must be pressed firmly against the gasket so that air cannot leak into the syringe. Otherwise the plunger will not go back even if the one-way valve is working normally.

Replacement



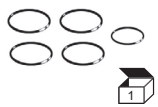
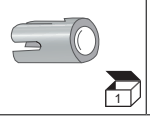
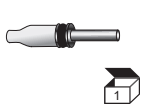
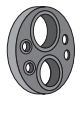
Take off the gasket with a needle. Take out the one-way valve. Slide a new valve into place. Put the gasket back on in its original position.

⚠CAUTION

- Do not damage the part of the gasket that bunches up against the spray pipe as it is required to make an effective seal.
- If the gasket is not put on right, the coupling could malfunction.

8. Replacement Parts

Replace parts as necessary based on the degree of wear and length of use.
Order parts from your local dealer or J. MORITA OFFICE.

O-ring set	LED Lamp	One-way Valve	Gasket
Code No. 5811835	Code No. 5011575	Code No. 5811837	Code No. 5811838
			

EMD (Electromagnetic Disturbances)

The Coupling (Model:CP4-LD, CP4-W-LD, hereafter "this device") conforms to IEC 60601-1-2 Edition 4.1, the relevant international standard for electromagnetic disturbances (EMD).

[Use environment]
The use environment of this device is the Professional healthcare facility environment.

⚠WARNING

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by us could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CP4-LD, CP4-W-LD, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

[Compliance for each EMISSIONS and IMMUNITY standards]

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1 Class B	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2[*1]	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3[*1]	N/A	

[*1] : The test is not applicable since the EUT does not have AC power input ports.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m(r.m.s.) Select from 50 Hz, 60 Hz as required	30 A/m(r.m.s.) 50 Hz and 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz 2.1 kHz, 65 A/m 13.56 MHz 50 kHz, 7.5 A/m	134.2 kHz 2.1 kHz, 65 A/m 13.56 MHz 50 kHz, 7.5 A/m	The proximity magnetic field should be at a level characteristic of magnetic fields emitted from RFID, IH (Induction Heating), etc.
Note : r.m.s. (root mean square)			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V ISM bands between[(c)] 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V ISM bands between[(c)] 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	3 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930 MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	Recommended separation distances $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the compliance level in V/m and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[(a)], should be less than the compliance level in each frequency range[(b)]. Interference may occur in the vicinity of equipment marked with the following symbol:
Note : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[(a)] Field strengths from fixed transmitters, such as base stations for ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating this device.
[(b)] Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.
[(c)] The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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The authority granted to the authorized representative, Medical Technology Promedt Consulting GmbH, by J. MORITA MFG. CORP. is solely limited to the work of the authorized representative with the requirements of the European Directive 93/42/EEC for product registration and incident report.

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