

COUPLING LK 4HL WATER ADJ COUPLING LK 4HL

ENG Instructions for use



CE
0123

REF 2100272-0002/2020.06

Set supplied



REF 1600866-001



REF 1600902-001

Optional accessories



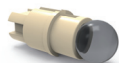
REF 1600036-006



REF 1501955-001



REF 1300155-001



REF 1501880-001




















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ENG Instructions for use

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Reference number.
	CE marking with the number of the notified body.		Serial number.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
	Electrical or electronic materials to be recycled.		Recyclable materials.
	Electrical 4-way fitting (4VLM).		Use rubber gloves.
	Light.		Water valve on coupling.
	360° rotating coupling.		After initial mechanical resistance, fully tighten in the direction indicated.
	Movement in the direction indicated.		Back and forth movement.
	Movement to the stop in the direction indicated.		Refer to the accompanying documents.
	Medical device.		

2 Identification & Intended Use

2.1 Identification

Accessories for medical devices made in Switzerland by Bien-Air Dental SA.

Type

Connection, as per ISO 9168 type 3. COUPLING LK rapid connection for dental turbines and 360° rotation for 4-way fitting.

Classification

Class IIa according to European Directive 93/42/EEC relating to medical devices.

This medical device accessory complies with the legislation in force.

2.2 Intended use

Product intended for professional use only.

For use in dentistry. Intended to be connected to compatible COUPLING LK dental turbines.

Any use of this medical device accessory outside of its intended use is prohibited and may prove dangerous.

3 Precautions for use

This medical device accessory must be used by a competent person, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and these instructions for use.

According to these measures, the user has the following obligations:

- To only use devices that are in perfect

working order. In the event of irregular operation, excessive vibrations, abnormal heating or other signs suggesting that the device is malfunctioning, work must be suspended immediately.

- In this case, contact a repair centre approved by Bien-Air Dental SA.
- make sure that this medical device accessory is used only for the purpose for which it is intended, protect yourself and patients and third parties from all danger and avoid contamination by the product.

WARNING

Install the device on an appropriate mounting to protect yourself, the patient or third parties against the risk of injury or infection.

CAUTION

To avoid adversely affecting the device's service life, ensure purified, dry compressed air is used.

Ensure the quality of the air and water being supplied through regular maintenance of the compressor and the filtration systems.

Note: *Using unfiltered hard water will speed up the blockage of the hoses, couplings and spray diffusers.*

CAUTION

The creepage distances and air clearances for this accessory comply with the requirements of the standard IEC 60601-1 (basic safety for medical electrical equipment).

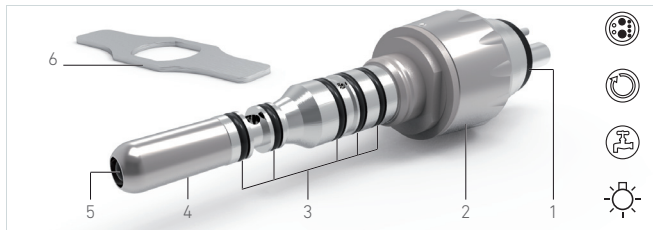


FIG. 1 (REF 1600866-001)

4 Description

4.1 Overview

FIG. 1

- (1) 4VLM flat seal
- (2) Spray dosage sleeve (REF 1600866-001 only).
- (3) O-rings
- (4) LED cover
- (5) LED
- (6) Chuck key

Note: In the interests of clarity, only the COUPLING LK 4HL WATER ADJ (REF 1600866-001) is described in these operating instructions. However, the explanations also apply to the COUPLING LK 4HL (REF 1600902-001).

4.2 Technical data

Note: The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim. For any further information, please contact Bien-Air Dental SA at the address shown on the back of the cover.

Standard coupling

The coupling-hose connection is a type 3 connection as per ISO standard 9168. Electrical 4-way (4VLM).

Dimensions (L x Ø): 70 x 18 mm

Weight: 34 g

Voltage (LED lighting)

3.5 VDC, 3.8 VDC max.

Input pressure

Settings according to turbine pressure.

Operating conditions

Refer to the operating conditions for the dental turbines.

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices.

4.3 Undesirable effects

There are no undesirable effects associated with this medical device accessory.

4.4 Transport and storage conditions

There are no special restrictions for this medical device accessory.

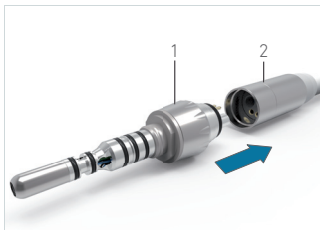


FIG. 2

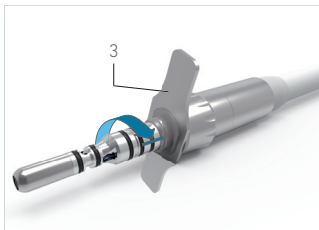


FIG. 3

4.5 Environmental protection and disposal



The disposal and/or recycling of materials must be performed in accordance with the legislation in force.



The LK coupling and its accessories must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards.

Users should send devices to their distributors or directly contact an approved body responsible for processing and recovering this type of equipment (European directive 2012/19/EU).

5 Set-up

5.1 Installing the coupling on the hose

⚠ WARNING

Do not connect or disconnect the hose until the dental unit has completely stopped (refer to the manufacturer's instructions).

⚠ CAUTION

Only use 4-way electrified hoses.

FIG. 2

A. Connect the coupling (1) to the hose (2).

FIG. 3

B. Hold the hose and tighten the coupling fully using the chuck key (3).

Note : After assembling the coupling on the hose, if no water flows:

- adjust the flow rate if the coupling allows this (see section 6.1 "Adjusting the flow rate", page 6).
- ensure that the hose is correctly connected to the dental unit.
- send the coupling to an approved repair centre.

Note : After assembling the coupling on the hose, if the LED does not work, see section 7.4.3 "LED repair", page 9.

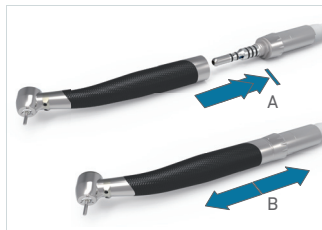


FIG. 4

5.2 Installing the turbine

FIG. 4

A. Insert the turbine fully on the Bien-Air LK coupling. The turbine is fully engaged after the initial mechanical resistance is overcome.

B. Check that the turbine is fully engaged by moving it back and forth.

⚠ CAUTION

Never connect or disconnect the turbine unless the bur has completely stopped.

⚠ CAUTION

Only connect turbines that are compatible with the MULTIflex®. Refer to the manufacturer's instructions.

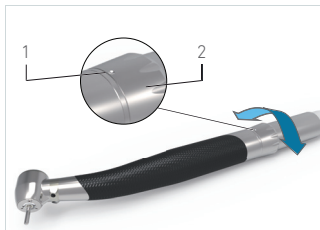


FIG. 5

6 Operation

If the dental unit pedal is activated, the coupling is operational even if no turbine is connected.

6.1 Adjusting the flow rate

Note: Only for coupling REF 1600866-001

FIG. 5

A. The flow rate is adjusted by turning the sleeve (2) left or right.

Note: The coupling is supplied in the open position (maximum flow rate) (1).

6.2 Changing the performance

⚠ CAUTION

Precautions to be taken when changing the performance.

The Bien-Air LK coupling is equipped with a non-return valve that prevents contaminated water from flowing back into the turbine.

If the turbine is blocked, contact Bien-Air Dental SA at the address shown on the back of the cover.

During use, if the LED stops working:

- replace the LED (see section 7.4.2 "Replacing the LED", page 9).
- send the coupling to an approved repair centre.

During use, if the water stops flowing or the flow rate drops too low:

- adjust the flow rate if the coupling allows this (1600866-001), see section 6.1 "Adjusting the flow rate", page 6.
- unblock the sprays on the turbine used (refer to the manufacturer's instructions).
- send the coupling to an approved repair centre.

7 Cleaning and servicing

7.1 Maintenance

CAUTION

Only use original Bien-Air Dental maintenance products and parts. The use of other products or parts may void the warranty.

7.1.1 Precautions for maintenance

CAUTION

Medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated must comply with universal precautions, in particular the wearing of personal protective equipment (gloves, goggles, etc.).

CAUTION

Do not sterilise in an autoclave.

CAUTION

Do not wash in a washer-disinfector or immerse in an ultrasonic cleaner.

7.2 Manual cleaning/ disinfecting

Clean and disinfect the device between patients.

Suitable maintenance products:

- Detergent or detergent-disinfect (pH 6 - 9.5) recommended for cleaning-disinfection of dental or surgical instruments. Surface-active quaternary enzymatic/ammonium detergent.
- Do not use detergents that are corrosive or contain chlorine, acetone, aldehydes or bleach.



FIG. 6

7.2.1 Cleaning

FIG. 6

A. Carefully clean the outside of the coupling using a clean cloth sprayed with Spraynet® or a suitable detergent between patients.

7.2.2 Disinfection

A. Disinfect using a suitable product on a clean cloth or wipes.

Products not to be used

Disinfectants containing acetone, chlorine or bleach.

⚠ CAUTION

Never immerse in cleaning-disinfecting solutions.

Do not submerge in physiological liquid (NaCl).

Do not immerse in an ultrasonic cleaner.

7.3 Lubrication and checks

7.3.1 Lubrication

⚠ CAUTION

Do not lubricate the Bien-Air LK coupling.

7.3.2 Checks

If leaks are observed, immediately stop the coupling and contact Bien-Air Dental SA at the address shown on the back of the cover.

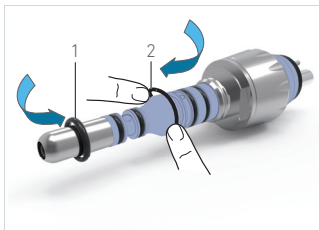


FIG. 7

7.4 Servicing

Never dismantle the device. For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental directly.

Note: Bien-Air Dental invites users to have their dynamic devices checked or serviced at least once a year.

7.4.1 Replacing the O-rings and flat seal

⚠ CAUTION

Replace any damaged seals immediately. Do not use a sharp or pointed tool.

Replacing O-rings (Kit, REF 1501955-001)

FIG. 7

A. Press with your thumb and index finger to form a loop (2) and remove the seals.

B. Insert the new seals (1).

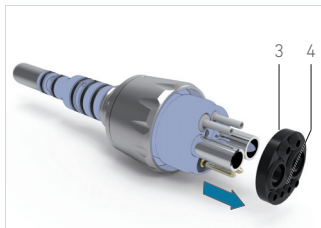


FIG. 8

Replacing the flat seal (REF 1300155-001)

FIG. 8

- A.** Press with your thumb or index finger and remove the seal (3) by sliding it along the connectors.
- B.** Fully insert the new flat seal (3) around the entire circumference.

Note: When fitting the new flat seal, pay attention to the side with the ridges (FIG. 8, 4).

7.4.2 Replacing the LED

⚠ WARNING

The LED may be very hot. Allow the LED to cool.

FIG. 9

- A.** Remove the turbine.
- B.** Unscrew the cover (1).
- C.** Remove the LED (3).
- D.** Insert the new LED. Pay attention to the position of the contact surfaces.

⚠ CAUTION

The glass of the LED (2) may be damaged by excessive pressure.

- E.** Wipe the glass of the LED (2) with a clean cloth.
- F.** Screw the cover (1) onto the LK coupling.

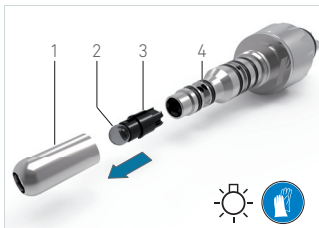


FIG. 9

- G.** Check the coupling's lighting function.

7.4.3 LED repair

FIG. 9

After assembling the coupling on the hose, if the LED does not work:

- turn it over by unscrewing the cover (1) then carefully remove it and turn the LED (3) 180°.
- ensure that the hose is correctly connected electrically to the dental unit.
- send the coupling to an approved repair centre.

8 General information, warranty conditions and references

8.1 Notation

- **A, B, C**, etc.
Text preceded by a letter indicates a procedure to be carried out in steps.
- **(1), (2), (3)**, etc.
Text preceded by a number indicates that the text is used alongside an illustration.

8.2 Trademarks

MULTiflex® is a registered trademark of KaVo Dental GmbH.

8.3 Warranty conditions

Bien-Air Dental grants the user a warranty covering any operating fault, or material or manufacturing defect. The warranty period is 12 months for this medical device accessory, starting from the invoice date.

In the event of a justified claim, Bien-Air Dental or its authorised representative will fulfil the company's obligations under this warranty by repairing or replacing the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, are excluded.

Bien-Air Dental SA shall not be held liable for damage or injury and the consequences thereof, resulting from:

- excessive wear.
- inappropriate use.

- failure to follow the servicing, assembly or maintenance instructions.
- unusual chemical, electrical or electrolytic influences.
- faulty air, water or electrical connections.

CAUTION

The warranty does not cover the LED.

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorised by Bien-Air Dental SA.

Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

8.4 References

8.4.1 Set supplied (see cover)

REF	Legend
1600866-001	COUPLING LK 4HL WATER ADJ
1600902-001	COUPLING LK 4HL
1000028-001	Chuck key

8.4.2 Optional accessories (see cover)

REF	Legend
1501955-001	O-ring kit
1300155-001	4VLM flat seal
1501880-001	LED for COUPLING LK
1600036-006	Spraynet, 500 ml cleaning spray, box of 6

NOTES

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NOTES

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Warranty

12

Months

 **Bien-Air Dental SA**

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