4VLM HOSES

⚠ **Do not sterilize**

ENG INSTRUCTIONS FOR USE.

Other languages available on
https://dental.bienair.com/IFU

CE 0123 RX Only
REF 2100031-0002/2024-04

Devices

Ø11

HOSE 4VLM11 GREY
REF 1600097-001

Ø10

HOSE 4VLM GREY
REF 1600102-001

Optional accessories

10X

REF 1300876-010

6X

Spraynet®, cleaning spray 500 ml, box of 6 cans (BOX OF 6 CANS)
REF 1600036-006

Table of content

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Catalogue number.
	CE Marking with number of the notified body.		Consult instructions for use or consult electronic instructions for use.
	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.		Medical device.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		Authorized EC Representative in the European Community.
	Wear protective gloves.		Batch code.
	Data Matrix code for product information including UDI (Unique Device Identification). .		Temperature limit.
	Humidity limitation.		Atmospheric pressure limitation.
	Keep away from rain.		General symbol for recovery/ recyclable.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Recyclable electrical and electronic material.

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type:

Multi-purpose hoses, diameter either of 10 mm or 11 mm. 4-hole connector. For turbines, air motors and electric micromotors MC3, with or without light.

HOSE 4VLM11 GREY

With integral exhaust. Silicone sheath with electrical socket.

HOSE 4VLM GREY

Without integral exhaust. Silicone sheath with electrical socket.

Description:

Hoses are essential accessories meant to connect motors to the consoles/electrical drive motor board.

2.2 Intended use

Product intended for use in:

- General dentistry which includes restorative dentistry, dental prophylaxis and orthodontics treatments.
- Endodontics

2.3 Intended patient population

The intended patient population for the device includes any person visiting a dental practitioners' office to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.4 Intended User

Product intended for professional use only. Used by dentists and dental professionals.

2.5 Use Environment

Professional healthcare facility environment.

2.6 Intended Medical conditions

General dentistry which includes restorative dentistry, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health.

Endodontics procedure addresses root canal treatment.

2.7 Patient contra-indications and side effects

No specific patient contra indication, side effects nor warnings exist for the device when it is used as intended.

2.8 In case of accident

If an accident occurs, the device must not be used.

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.

⚠ **WARNING**

Any use other than that for which this device is intended is prohibited and may prove dangerous.

3 User and Patient Safety: Warnings and Precautions for use

This medical device must be used by professionals in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and these instructions for use.
In accordance with these provisions, the user is responsible for ensuring he or she only uses devices which are in perfect working order.

Electrical safety:

⚠ **WARNING**
Electrical safety in conformance with IEC 60601-1 can only be claimed when the device is used with Bien-Air Dental compatible devices (drive motors and motors). In addition, only medical power supply with 2 MOPP should be used.

Electromagnetic compatibility:

⚠ **WARNING**

- Electromagnetic compatibility can only be claimed when the device is used with Bien-Air Dental compatible devices (drive motors and motors).
- Since compliance with the international standard IEC60601-1-2 does not guarantee immunity against 5G worldwide (due to the different frequency bands used locally), avoid the presence of devices equipped with 5G broadband cellular networks in the clinical environment or ensure that the network functionality of these devices is disabled during the clinical procedure.

To prevent any risk of explosion, the warnings below must be observed:

⚠ **WARNING**
According to IEC 60601-1:2005 +A1 2012 / AnnexG, electrified devices (motors, control units, couplers and attachments), can be safely used in a medical environment in which potentially explosive or flammable mixtures of anaesthetic substances are delivered to the patient only if:

- The distance between the motor and the anaesthetic breathing circuit exceeds 25 cm.
- The motor is not used simultaneously to the administration of the anaesthetic substances to the patient.

To prevent any risk of infection, the warning below must be observed:

⚠ **WARNING**

- 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.). Pointed and sharp instruments should be handled with great care.

To prevent any material damage the cautions below must be observed:

⚠ **CAUTION**

- Do not use the hose to pull the unit or the cart. This misuse could damage the internal wires and/or the external sheath.
- It is essential to use dry, purified compressed air in the dental unit in order to ensure the long working life of the device. Maintain the quality of the air and the water by regular maintenance of the compressor and the filtration systems. The use of unfiltered hard water will lead to early blockage of the tubes and connectors.

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Sheath
(2) Reinforced part of the sheath
(3) Nut (coupling for turbine connection)
(4) Motor connector

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.
The original language of those instructions for use is English.
For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

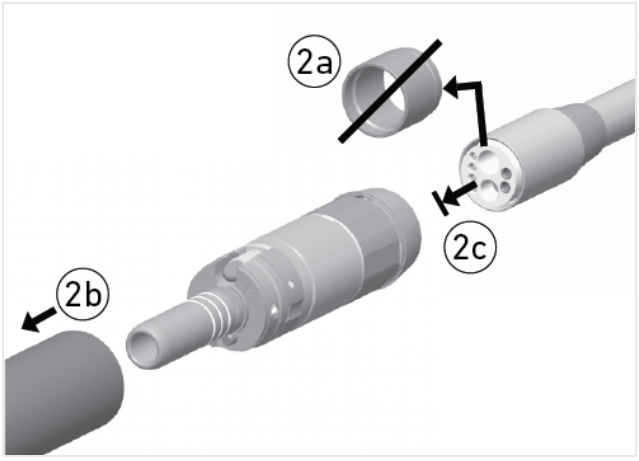


FIG. 2

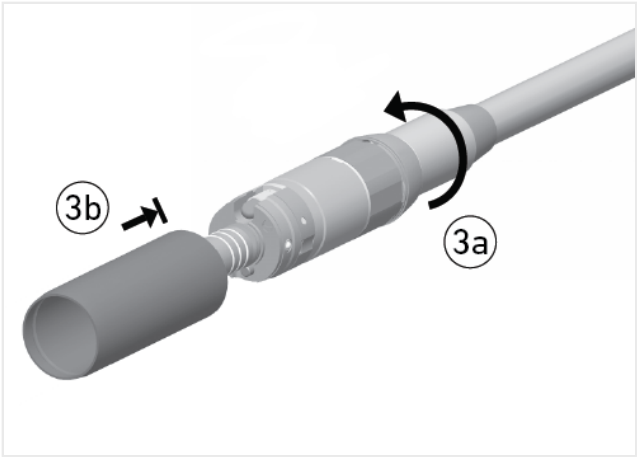


FIG. 3

4.2 Assembly and preparation

4.2.1 Motor coupling

Pictogram used			
	Move in the direction indicated.		Move fully to the stop, in the direction indicated.

1. To connect the motor to 4VLM Bien-Air Dental hoses, remove the nut (FIG. 2a) from the hose and remove the sleeve from the motor by pushing it forward (FIG. 2b).
2. Check that the rear of the motor and the joint on the hose are clean. Position the motor and its proprietary hose as shown in FIG. 2c. Rotate it to find the exact position and push it into the motor.
3. Holding the motor, fully screw the hose sleeve to the rear motor connection (FIG. 3a).
4. Replace the sterilizable sleeve by pushing it (FIG. 3b). Great care should be taken during this operation as to not damage the O-ring when replacing the sleeve.

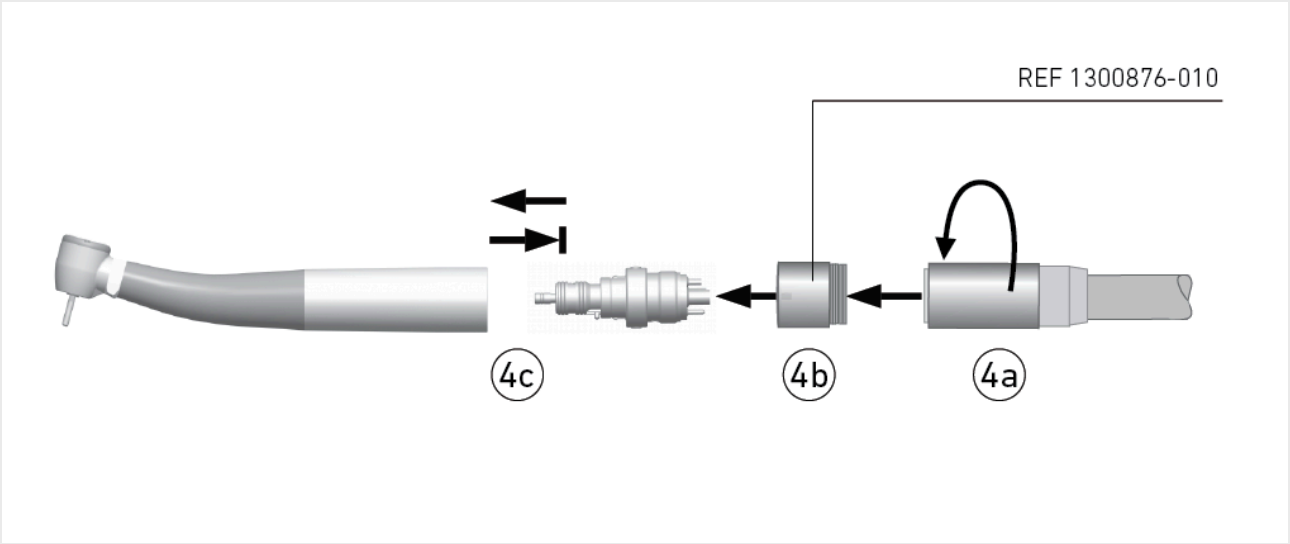


FIG. 4

4.2.2 Turbine coupling

1. Screw the 4 VLM Bien-Air Dental hose to the nut (FIG. 4a).
2. Push forward the hose with the screwed nut into the turbine coupling (FIG. 4b).
3. Push fully to the stop the turbine into Unifix quick-couplings 4-hole instruments for optic and non-optic (FIG. 4c).

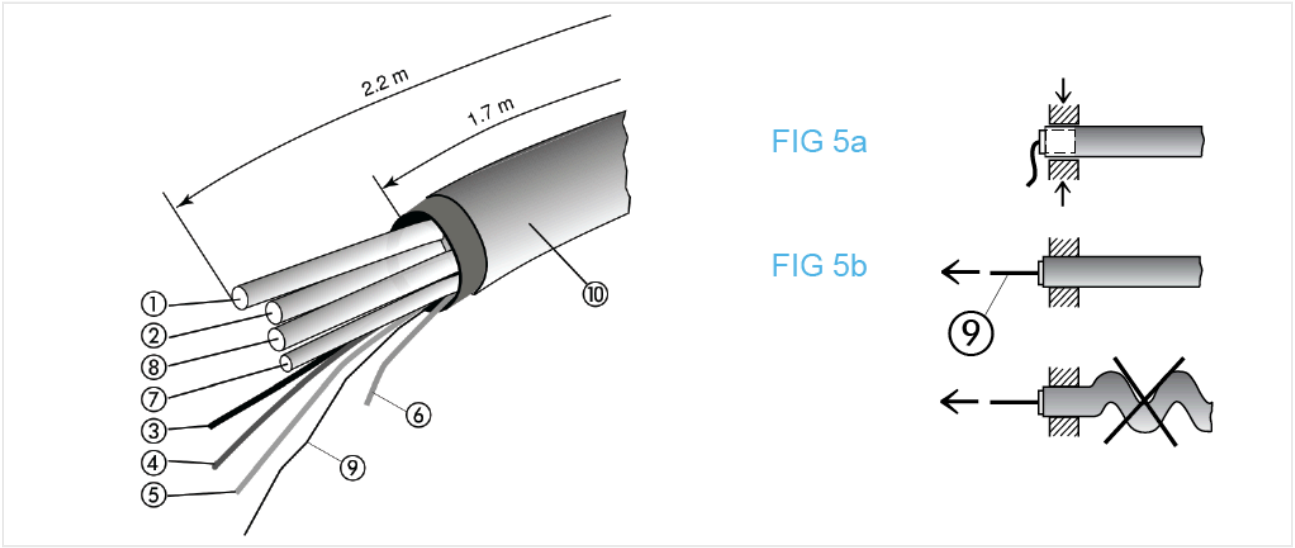


FIG. 5

4.3 Assembly

FIG. 5

Preserve the initial alignment of the wires and tubes. Place the metal reinforcement ring (REF 004.26.26) in the chucking zone (FIG. 5a).

The securing cord must be attached to the chassis of the unit or table-top device to avoid any traction on the wires and tubes (FIG. 5b).
The outer tube must not be wrinkled after installation. The resistance to traction is 60N maximum.

Description FIG. 5

1. Ø 1.5/2.5 mm green: waterspray
2. Ø 1.5/2.5 mm white: airspray
3. (+) red: motor
4. (0V) black: motor
5. (+) brown: bulb
6. (0V) blue: bulb
7. Ø 2.8/4.1 mm white: cooling MC3 or drive turbines
8. Red: return air
9. Securing cord
10. Metal reinforcement of the sheath

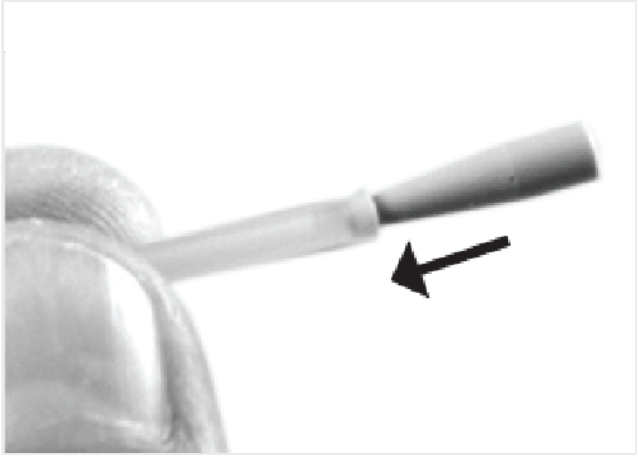


FIG. 6

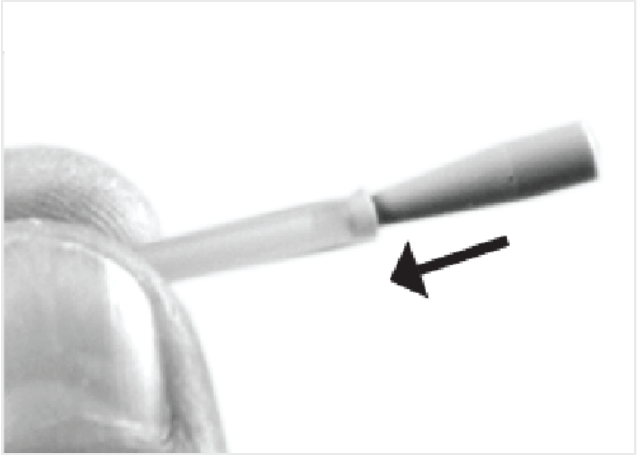


FIG. 7

1. The conical piece provided can be useful for connecting the cooling tube to the unit tube (FIG. 6 & FIG. 7).

4.4 Technical data

⚠ **CAUTION**
These hoses are not suitable for pressure higher than 5 bar (500 kPa, 72 psi).

Standard length

1.70 m

Special length

3 m

Note : See the technical data of the micromotor MOT MC3 (REF 1600680-001), MOT MC3 LK (1600077-001) or MOT MC3 IR (REF 1600071-001) for more information.

4.5 Classification

Class IIa in accordance with the European Medical Regulation (EU) 2017/745.

4.6 Performances

No performances related to the hose alone. Refer to the IFU of the compatible micromotor MOT MC3 (REF 1600680-001), MOT MC3 LK (1600077-001) or MOT MC3 IR (REF 1600071-001).

4.7 Operating conditions

Operating conditions		
	Temperature range:	+10°C — +35°C (+50°F — +95°F)
	Relative humidity range:	30% — 80%
	Air pressure range:	700 hPa — 1060 hPa

5 Maintenance and servicing

5.1 Maintenance – General information

⚠ **CAUTION**

- Non-sterilizable.
- Never submerge the hose in disinfectant solutions (the connectors should never be completely submerged).
- Do not use an ultrasonic cleaner.

5.2 Cleaning

Clean with a clean cloth moistened with either tap water, sterile demineralized (deionized) water or any appropriate product for dissolving protein and blood residues.

5.3 Rinsing

Remove the product residues with a clean cloth soaked either in tap water or in sterile demineralized (deionized) water.

5.4 Drying

Spray the exterior of the hose with Spraynet then remove its excess with a non-woven cloth. Do not use products containing acetone, chlorine or bleach.

5.5 Packing and storage

Storage conditions		
	Temperature range:	0°C — +40°C (+32°F — +104°F)
	Relative humidity range:	10% — 80%
	Air pressure range:	650 hPa — 1060 hPa
	Keep away from rain	

The device must be stored in a dry and dust free environment.

⚠ **CAUTION**

If the medical device has been stored refrigerated, allow it to warm up to room temperature prior to its

use.

5.6 Servicing

Bien-Air Dental SA recommends that the user change the hose every two years.

⚠ **CAUTION**

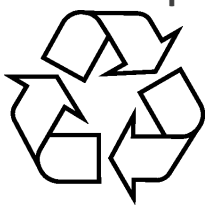
Never disassemble the device. For any inquiry, contact your regular supplier or Bien-Air Dental service centre.

6 Transport & disposal

6.1 Transport

Transport conditions		
	Temperature range:	-20°C — +50°C (-4°F — +122°F)
	Relative humidity range:	5% — 80%
	Air pressure range:	650 hPa — 1060 hPa
	Keep away from rain	

6.2 Disposal



The disposal of this device must be performed in accordance with the legislation in force.

This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the device to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2012/19/ EU).

7 General information

7.1 Terms of guarantee

Bien-Air Dental SA grants the operator a guarantee covering all functional defects, material or production faults.

The warranty period is:

- 12 months from the date of invoicing.

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

Any other claims of any kind whatsoever, particularly claims for damage or injury and the consequences thereof resulting from:

- Excessive wear and tear
- Infrequent or improper use
- Failure to observe the servicing, assembly or maintenance instructions
- Damage caused by unusual chemical, electrical or electrolytic influences
- Faulty air, water or electrical connections

Are excluded.

⚠ **CAUTION**

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized 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 References

REF	Legend
1600097-001	4VLM Ø 11, with integral exhaust, 4-hole connector with electrical socket. Grey silicone hosee
1600102-001	4VLM Ø 10, 4-hole connector with electrical socket. Grey silicone hose
1300876-010	Intermediate nut
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans

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