

Micromotors MCX LED & MCX

Instruction

REF 2100231-0003/2014.05/ENG



English

Medical devices entirely made in Switzerland by Bien-Air Dental SA.

Identification

Brushless electric micromotor. The most commonly used coupling in the world as per ISO Standard 3964. Sterilisable motors.

Description MCX LED

With internal spray and light with LED light.

Description MCX

With internal spray without light.

USA Caution: Federal law restricts this device to sale by or on the order of a dentist.

Intended use

Product intended for professional use only. Use in dentistry for prophylaxis, general dentistry and endodontics work.

The device is not designed for use in an explosive atmosphere (anaesthetic gas).

The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorised and may be dangerous. The medical device meets all the current legal requirements.

Technical data

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices. This medical device is in compliance with the legislation in force.

Electrical safety

According to IEC 60601-1 standard (General safety for Medical Electrical Equipment), the device shall be classified as a class II type B device. Associated terminology is defined in sections 3.14 (3.13 if Class I) & 3.132 of the same standard. The following requirements as specified in IEC 60601-1 apply:

- Protection against electrical shock
- Ingress of liquids
- Protection against excessive temperatures and other safety hazards

Electromagnetic compatibility

Corresponds to the electromagnetic compatibility in accordance with IEC 60601-1-2. Declaration by the manufacturer regarding electromagnetic compatibility.

Hose Junction fig. 1

Hose with connector type MCX. Brushless type, 3-phase. Effective power according to the type of electronic power supply used. Synchronous motor with permanent magnets. Body of chromium and nickel-plated brass. Stainless steel nose.

Rphase

0.9 Ohm
(included hose MCX resistance).

Lphase

60 µH

Torque constant

5.20 mNm/A rms

Permanent

1.25 A rms

I max.

5 A rms [10s]

Cooling

Through compressed air from the unit. Place the flowmeter on the connector and set 10 to normliter/min. fig. 2.

Air consumption output

10 NL/min.

Dimensions

Ø 21 x 64 mm (0.82 x 2.51 inches) including the nose attachment.

Coupling

Nose in accordance with ISO 3964, with internal spray and light.

Weight

76 g (2.68 oz) without the cable.

Operating times

According to the type of electronics used.

Noise level

In accordance with ISO 11498, less than 53 dBA at 45 cm (17.72 in).

Recommended rotation speed

From 1.000 to 40.000 rpm.

Direction of rotation

Clockwise and anticlockwise.

Torque

Depending on the type of electronic controller used.

Light MCX LED

LED, variable from 10 klux to 38 klux.

Assembly

⚠ Important

Never connect an instrument on a running micromotor.

Changing the seals, fig. 3

Disposal

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 2002/96/EC).

Maintenance

⚠ Important

- The instrument is delivered "non sterile".
- Before using for the first time and within a maximum of 30 minutes after each treatment, clean, disinfect the attachment, then sterilise. Observing this procedure eliminates any blood, saliva or saline solution residues.
- Do not immerse in an ultrasonic bath.

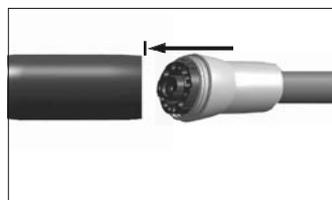


fig. 1a

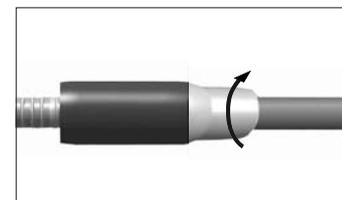


fig. 1b



fig. 2



fig. 3

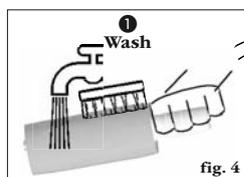


fig. 4

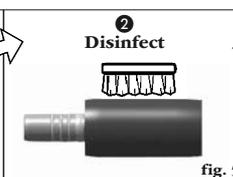


fig. 5



fig. 6



fig. 7

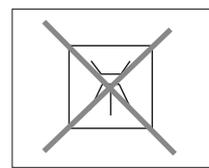


fig. 8

- Do not clean in a washer-disinfectant unit fig. 8.
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

In the event of prolonged disuse, the instrument must be stored in a dry environment. Clean and sterilise the instrument before reuse.

Precautions of use

The standard precautions in particular wearing individual protection equipment (gloves, glasses...), must be complied with by healthcare personnel working with contaminated or potentially contaminated medical instruments. Pointed and sharp instruments should be handled with great caution.

Check that the steriliser and the water that is used are clean. After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion.

We recommend that the motor is cleaned and sterilised as described below before the initial first use and subsequently after each treatment.

1 Cleaning

The external surface of the motor must be cleaned to remove impurities as follows fig. 4.

- Hold the motor by the nose under running water (< 25°C) as shown in the diagram below
- With the aid of a soft bristled brush, clean the external surface of the motor.
- Avoid allowing water to enter internally into the motor either by the the nose or hose connector.

2 Disinfection

Carefully rub the external surfaces of the motor, for approximately one minute, with a soft bristle brush

impregnated with a detergent or disinfectant solution fig. 5.

The motor must be rinsed as follows fig. 4

- Hold the motor by the nose under running water (< 25°C) as shown in the diagram below
- Avoid allowing water to enter internally into the motor either by the the nose or hose connector.

Suitable detergents

- Detergent or detergent-disinfectant (pH 6-9.5) recommended for cleaning-disinfection of dental or surgical instruments.
- Quaternary ammonium- and/or enzyme-based surfactants.
- Do not use solutions that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- Do not soak in physiological liquid (NaCl).

3 Sterilisation

Do not use a sterilisation procedure other than the one described below.

Procedure: Fractionated pre-vacuum steam sterilisation, Class B cycle acc. to EN13060. The procedure has been validated according to ISO 17664. All Bien-Air Dental straight handpieces are sterilisable in an autoclave up to 135°C (273.2°F). Duration: 3 or 18 min., depending to the national requirements in force.

Important

The quality of the sterilisation depends very much on the cleanliness of the device. Only perfectly clean devices may be sterilised fig. 6. The instrument will function in excess of 500 sterilisations.

4 Lubrication

⚠ Important

The Bien-Air Dental micromotors MCX LED and MCX are maintenance free.

Do not spray any lubricant or cleaning solution into the motor fig. 7!

Service

Never disassemble the device. For all modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental directly. Bien-Air Dental asks the user to have its dynamic instruments checked or inspected at least once a year.

Transportation and storage conditions

Temperature between -40°C (-40°F) and 70°C (158°F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 106 kPa (7.3 to 15.3 psi).

Information

The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

Other precautions for use

The device must be used by a qualified professional in compliance with the current legal provisions concerning workplace safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

Rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.

- To ensure the lifetime of the instrument, it is essential to maintain the quality of the cooling air and water utilised.

The compressed air should be dry and purified and the compressor should be regularly maintained.

To avoid the tubing and connectors from blocking, the water should be filtered and purified to avoid impurities and build-up of high levels of calcium deposits.

Guarantee

Terms of guarantee

Bien-Air Dental grants the operator a guarantee covering all functional defects, material or production faults. The device is covered by this guarantee for 36 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 whatever nature, in particular in the form of a claim for damages and interest, are excluded.

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

- excessive wear and tear
- improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible "fibre optic" type conductors, or any parts made of synthetic materials.

The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorised by Bien-Air Dental.

Claims under the terms of the guarantee will be considered only on presentation, together with the product, of the invoice or the consignment note, on which the date of purchase, the product reference and the Serial No. should be clearly indicated.

List of Bien-Air Dental SA registered trade mark products @:

Aquilon®	Eolia®	Lubrifiuid®	Prestilina®
Bora®	Gyro®	Lubrimed®	Spraynet®
Boralina®	Gyrolina®	MX®	
ChiroPro®	Isolite®	PowerCare®	

In these instructions, "Device" corresponds to the product described in the heading "Identification". For example, turbine, contra-angle, handpiece, micromotor, tube, electronics, connectors, station etc.

REF	Legend
1600751-001	Micromotor MCX LED, with internal spray and LED
1600780-001	Micromotor MCX, with internal spray without light
1600756-001	MCX hose, grey silicone
1600756-0	MCX hose, special length
1600824-001	B-MCX hose, grey silicone, bayonet connection to unit
1600824-0	B-MCX hose, special length
1300967-010	O-Ring for the motor MCX LED and MCX
1501566-001	Electronic DMCX
1600307-001	Flow-meter for micromotors MCX LED and MCX

Symbols

- Manufacturer.
- CE Marking with number of the notified body.
- Attention.
- Light.
- Wear rubber gloves.
- Sterilisable at the specified temperature.
- Recyclable electrical and electronic materials.
- Electrical security. Applied part type B.
- Move in the direction indicated.
- Move fully to the stop, in the direction indicated.

This product may be covered by one or more of the following patents:

EP Europe: 745358 / 688539 / 948294 / 1145688 / 1563800 / 1563801 / 1675523 / 1753360 **DE Germany:** 29616023.7
DK Denmark: 9600315 **FR France:** 2722972 **CH Switzerland:** 693922 **CN China:** 100528099 / 100522100 / 100522099 / 100553584 **JP Japan:** 3892485 / 4298933 / 7000419 **US United-States:** 5453008 / 6033220 / 6319003 / 7214060 / 7448870
RU Russia: 2361540 / 2361541 / 2372046

REF 1600751-001 MOT MCX LED / REF 1600780-001 MOT MCX

Set supplied

MCX LED



REF 1600751-001



REF 1300967-010

MCX



REF 1600780-001



REF 1300967-010

Optional accessories



REF 1600756-001



REF 1600824-001



REF 1300967-010



REF 1501566-001



REF 1600307-001

Bien-Air Dental SA
 Länggasse 60
 Case postale
 2500 Biemme 6, Switzerland
 Tel. +41 (0)32 344 64 64
 Fax +41 (0)32 344 64 91
 office@bienair.com

Bien-Air Deutschland GmbH
 Jechtinger Strasse 11
 79111 Freiburg, Deutschland
 Tel. +49 (0)761 45 57 40
 Fax +49 (0)761 47 47 28
 ba-d@bienair.com

Bien-Air España, SA
 Entença, 169 Bajos
 08029 Barcelona, España
 Tel. +34 934 25 30 40
 Fax +34 934 23 98 60
 ba-e@bienair.com

Bien-Air USA, Inc.
 Medical Technologies
 5 Corporate Park
 Suite 160
 Irvine, CA 92606 USA
 Phone 1-800-433-BIEN
 Phone 949-477-6050
 Fax 949-477-6051
 ba-usa@bienair.com

Bien-Air France Sàrl
 55-57, avenue Jean Lolive
 93508 Pantin Cedex, France
 Tel. +33 (0)1 41 83 60 70
 Fax +33 (0)1 48 96 07 40
 ba-f@bienair.com

Bien-Air Italia s.r.l.
 Via Vaina 3
 20122 Milano, Italia
 Tel. +39 (02) 58 32 12 51/52/54
 Fax +39 (02) 58 32 12 53
 ba-i@bienair.com

Bien-Air UK Ltd
 Arundel House
 Unit 1 - Ground Floor
 Amberley Court, Whitworth Road
 Crawley, West Sussex,
 RH11 7XL, England
 Telephone +44 (0)1293 550200
 Fax: +44 (0)1293 520481
 ba-uk@bienair.com

Bien-Air Asia Ltd.
 Nishi-Ikebukuro
 Daiichi-Seimei Bldg. 10F
 2-40-12 Ikebukuro, Toshimaku
 Tokyo, 171-0014, Japan
 ビエン・エア・アジア株式会社
 〒171-0014
 東京都豊島区池袋2-40-12
 西池袋第一生命ビルディング10F
 Tel. +81 (3) 5954-7661
 Fax +81 (3) 5954-7660
 ba-asia@bienair.com

Beijing Bien-Air
 Medical Instrument
 Technology Service Co. Ltd.
 Room 907, The Exchange Beijing,
 No 118 Jian Guo Lu Yi,
 Chao Yang District,
 Beijing 100022, China
 北京彼岸医疗器械
 技术有限公司
 北京市朝阳区建国路
 乙118号招商局中心
 京汇大厦2106室
 Tel. +86 10 6567 0651
 Fax +86 10 6567 8047
 ba-beijing@bienair.com