MICROMOTOR MX2

ENG INSTRUCTIONS FOR USE.

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

CE 0123 Rx Only
REF 2100199-0009/2024.02

Packaging content (REF)

MC MX2
REF 1600677-001

O-RING 8.1x0.73
REF 1300967-003

Optional accessories

HOSE MX2 400 GREY
REF 1600700-001

HOSE MX2 400 GREY 20.2x40
REF 1600809-001

HOSE B-MX2 GREY
REF 1600762-001

O-RING 8.1x0.73
REF 1300967-010

FLOWMETER
REF 1600307-001

MAINT SPRAYNET® (BOX OF 6 CANS)
REF 1600036-006

Table of contents

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Catalogue number.
	CE Marking with number of the notified body.		Serial number.
	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.		Lamp; lighting, illumination.
	Electrical security. Applied part type B.		Sterilizable in a steam sterilizer (autoclave) at the specified temperature.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Consult instructions for use or consult electronic instructions for use.
	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.
	Recyclable electrical and electronic material.		

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type:

Brushless, sterilizable, electric micromotor with internal spray and LED light.

Description:

Bien-Air Dental micromotors are designed to transform electricity into mechanic rotation to drive dental straight hand-pieces and contra-angles.

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 until repairs have been completed by a qualified, authorized and trained technician in a repair center.

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 can only be claimed when the device is used with Bien-Air Dental compatible drive motors and hoses.

- Always refer to the dental unit or console instruction for use to confirm compatibility with the device and electrical safety compliance.
- When used with Bien-Air dental medical devices, the device is compliant with standard IEC 60601-1 for which the following requirements apply:
  - Protection against electrical shock
  - Ingress of liquids
  - Protection against excessive temperatures and other safety hazards.

Electromagnetic compatibility:

⚠ **WARNING**

- Electromagnetic compatibility can only be claimed when the device is used with Bien-Air Dental compatible drive motors and hoses.
- Always refer to the dental unit or console instruction for use to confirm compatibility with the device and electromagnetic compliance.
- Since compliance with the international standard IEC 60601-1-2 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.
- Magnetic disturbance can occur from other electromedical devices, refer to the dental unit or console instruction for use for EMC specifications.

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

⚠ **WARNING**

- The device is supplied not sterile. To avoid any infection, respect the cleaning, sterilization and maintenance procedure detailed in section 5.
- 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.
- Rest the device on a cleanable support.

To prevent any risk of motor overheating, the cautions below must be observed:

⚠ **CAUTION**

- The motor needs to be connected to the dental unit air cooling system to avoid overheating and/or auto-limitation of the speed via the electronic board safety control.
- Always ensure that the micromotor hose is

not bent and that both the hose and the motor are in good condition.

To prevent any risk of injury and/or material damage the cautions below must be observed:

⚠ **CAUTION**

- In the event of excessive vibrations, abnormal heating, unusual noise 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.
- Never connect an instrument on a running micromotor.
- Do not spray any lubricant or cleaning solution into the motor.
- Never rinse the device to cool them.
- 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.

3.1 Installation

⚠ **WARNING**

The micromotor can only be used with Bien-Air Dental or compatible electronic devices. To conform with IEC 60601-1 safety requirement, only medical device power supply with two MOPP should be used.

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Motor nose

(2) Motor body

(3) Hose/motor connection

Nota : *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.

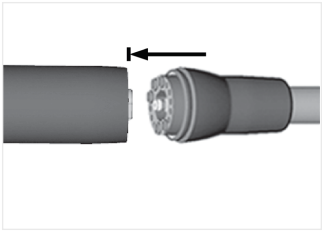

FIG. 2

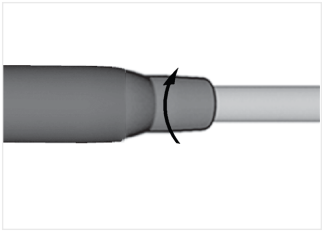

FIG. 3

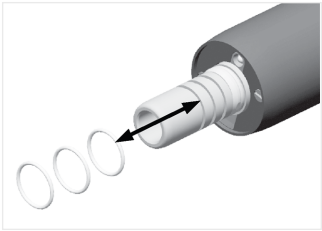

FIG. 4

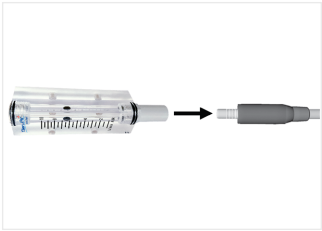

FIG. 5

4.2 Assembly and preparation

1. Check that the rear of the motor and the hose connector are clean and dry.
2. Connect the motor to the proprietary hose (with connector type MX2) as shown in FIG. 2.
3. Rotate it to find the exact position and push it into the motor.
4. Holding the motor fully screw the hose sleeve to the rear motor connection FIG. 3.
5. Place the flowmeter on the nose attachment then activate the cooling air and measure the airflow. The value is measured in the middle of the flowmeter's ball according to standard JIS B7551. FIG. 5.
6. If the cooling airflow is not in the range of 10 normliter/min (+/-10%), tune the air pressure to meet this requirement.

Changing the seals manually (no tool required) FIG. 4

- Do not lubricate the O-ring.
- Use proprietary O-ring only.
- Check that the O-rings are neither broken nor scratched after mounting them.

4.3 Technical data

Technical data	
Recommended air flow (measured at the motor nose)	10 Nl/min (+/-10%)
Air pressure range	2.5 -5 bar
Coupling	Nose in accordance with ISO 3964*
Operating times	No limitations for the user. Operating times are electronically imposed by Bien-Air control boards, as a function of the applied torque.
Rotation speed range	100 — 40'000 rpm
Direction of rotation	Clockwise and anticlockwise
Luminous intensity	LED, variable from 20 klux to 24 klux**

**Compatible with handpieces dimensions "short", "middle" and "long".*
***Measured in combination with REF1601138-001 CA 1:5L NOVA MS*

4.4 Classification

Class IIa in accordance with European Medical Regulation (EU) 2017/745.
Class II type B device in accordance with IEC 60601-1 standard.

4.5 Performances

Performances	
Give speed and torque as preset	Electronically controlled
Speed value accuracy	+- 5%

4.6 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

FIG. 6

5 Maintenance and servicing

5.1 Maintenance - General information

Clean and sterilize the device prior to first use.
Within a maximum of 30 minutes after each treatment, clean the motor. Observing this procedure eliminates any blood or saliva residues.

⚠ **WARNING**

Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.

⚠ **CAUTION**

Do not spray any lubricant or cleaning solution into the motor. FIG. 6.

5.1.1 Suitable maintenance products

Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. Using other products or parts may cause faults during operation and/or void the warranty.

- Spraynet®
- Alkaline detergent or detergent disinfectant (pH 8-11) recommended for cleaning-disinfection of dental or surgical instruments. Disinfectant products composed either of didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product. (e.g. neodisher® Mediclean) are also allowable.

5.1.2 Precautions for maintenance

- Within a maximum of 30 minutes after each treatment, clean and disinfect the motor. Observing this procedure eliminates any blood or saliva residues.
- Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. Using other products or parts may cause faults during operation and/or void the warranty.

⚠ **CAUTION**

- Use detergents that are pH 8-11, are neither corrosive nor contain chlorine, acetone and/or aldehydes.
- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Do not submerge in a cleaning bath.
- Clean using manual cleaning (**do not use an ultrasonic cleaner or a washer-disinfectant unit**).
- If the sterilization is required by national directives, use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system. As with all instruments, following each sterilization cycle, including drying, remove the device to avoid an excessive exposure to heat which can result in corrosion.

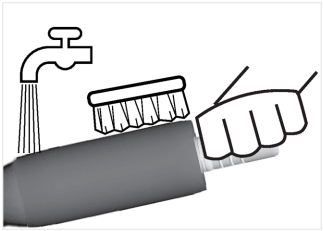

FIG. 7

5.2 Cleaning

⚠ **CAUTION**

- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Do not submerge in a cleaning bath.
- Do not use in a washer-disinfectant unit, nor ultrasonic cleaner.
- Do not spray any cleaning solution into the motor.
- Always ensure that the motor contacts are kept clean.

The external surface of the motor must be cleaned to remove impurities as follows FIG. 7:

- Hold the motor by the nose under tap water at 15°C - 38°C (59°F - 100°F) provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.
- With the aid of a smooth flexible brush, clean the external surface of the motor using recommended cleaning products.
- Do not allow water to seep in the motor either by the nose or by the hose connector.
- Dry the external surface of the motor with low linting textile moistened with Spraynet®.

5.3 Disinfection

Carefully rub the external surfaces of the motor, for approximately one minute, with a smooth flexible brush impregnated with a detergent or disinfectant solution **FIG. 7**.

The motor must be rinsed as follows FIG. 6

- Hold the motor by the nose under tap water at 15°C-38°C (59°F-100°F), as shown in the diagram below, provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.
- Avoid allowing water to penetrate the motor either by the nose or by the hose connector.
- Dry the motor with non-woven compress.

5.4 Sterilization

⚠ **CAUTION**

- The quality of the sterilization is highly dependent on how clean the device is. Only perfectly clean devices may be sterilized.
- To improve the effectiveness of the sterilization, make sure the motor is completely dry.
- Do not use a sterilization procedure other than the one described below.
- Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.
- If the sterilization is required by national directives, use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system. As with all instruments, following each sterilization cycle, including drying, remove the device to avoid an excessive exposure to heat which can result in corrosion.

5.4.1 Procedure

1. Pack the device in a packaging approved for steam sterilization.
2. Sterilize using steam, following dynamic air removal cycle (ANSI/AAMI ST79, Section 2.19), i.e. air removal via forced evacuation (ISO 17665-1, ISO/TS 17665-2) at 135°C (275°F), for 3 minutes or at 132°C (269.6°F) for 4 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C (275°F) for 18 minutes.

The instrument sustains more than 1000 sterilisations.

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C (278.6°F), i.e. the nominal temperature of the autoclave is set at 134°C (273.2°F), 135°C (275°F) or 135.5°C (275°F) taking into account the uncertainty of the sterilizer with regard to temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278.6 °F) is in accordance with national requirements for moist heat sterilization and does not exceed 30 minutes.
- The absolute pressure in the chamber of the sterilizer is comprised in the interval 0.07 bar to 3.17 bar (1 psia to 46 psia).
- The rate of change of temperature does not exceed 15°C/min (59°F/min) for increasing temperature and -35°C/min (-31°F/min) for decreasing temperature.
- The rate of change of pressure does not exceed 0.45 bar/min (6.6 psia/min) for increasing pressure and -1.7 bar/min (-25 psia/min) for decreasing pressure.
- No chemical or physical reagents are added to the water steam.

5.5 Lubrification

⚠ **CAUTION**

Do not spray any lubricant or cleaning-lubricant solution into the motor FIG. 8.

5.6 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 inside the sterilization pouch in a dry and dust free environment. The temperature must not exceed 55°C (131°F). If the device will not be used for 7 days or more after the sterilization, extract the device from the sterilization pouch and store it in the original package. If the device is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, dry and sterilize the device before using it.

⚠ **CAUTION**

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

⚠ **CAUTION**

Comply with the expiration date of the sterilization pouch which depends on the storage conditions and type of packaging.

5.7 Servicing

Bien-Air Dental SA recommends that the user has his or her dynamic devices checked or serviced after 5000 processing cycles or 5 years.

⚠ **CAUTION**

Never disassemble the device. For all modification and repair, 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	

ENG

6.2 Disposal

The disposal and/or recycling of materials 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:

- 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 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

⚠ **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.

7.2 References

REF	Legend
1600677-001	MX2 Micromotor
1600700-001	MX2 hose
1600809-001	MX2 hose, 20.2 x 40
1600762-001	MX2 hose. Bayonet connection to unit
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans
1300967-010	O-RING 8.1x0.73
1600307-001	Flowmeter, for micromotors

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REF 2100199-0009/2024.02