MX2-400 & B-MX2-400

⚠ **Do not sterilize**

ENG INSTRUCTIONS FOR USE.

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

CE 0123 Rx Only
REF 2100223-0004/2024.06

Devices

HOSE MX2 400 GREY
REF 1600700-001

HOSE B-MX2 GREY
REF 1600762-001

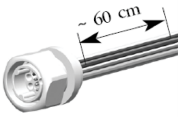
HOSE MX2 400 GREY 20.2x40
REF 1600809-001

Optional accessories

O-RING 3.20x0.60
REF 705.02.31-010

O-RING 4x0.6
REF 705.01.77-010

O-RING 1.5x0.75
REF 705.02.62-010



COUPLING SOCKET B B-MX2
REF 1600753-001

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

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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:

HOSE MX2 400 GREY

With rotating connector (± 200°)

HOSE B-MX2 400

With rotating connector (± 200°), bayonet connection to unit

HOSE MX2 400 GREY 20.2x40

With rotating connector (± 200°), bayonet, connection to unit with long fitting body

HOSE MX2 400 GREY 2.2m

With rotating connector (± 200°), 2.2 meter hose

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 of 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 treatments addresses root canal treatment.

2.7 Patient contra -indications and side effects

No specific patient contra- indication, side effects nor warning 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 unauthorised and may be 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) Motor connector

(2) Sheath

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.

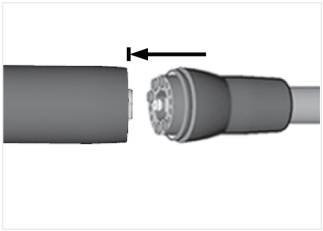

FIG. 2

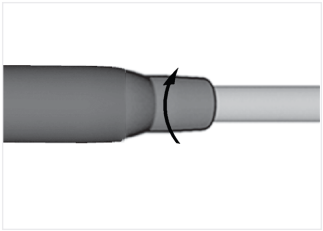

FIG. 3

4.2 Assembly and preparation

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

1. Check that the rear of the motor and the hose connector are clean and dry.
2. Position the motor and its proprietary hose as shown in **FIG. 2**. 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. 3**.

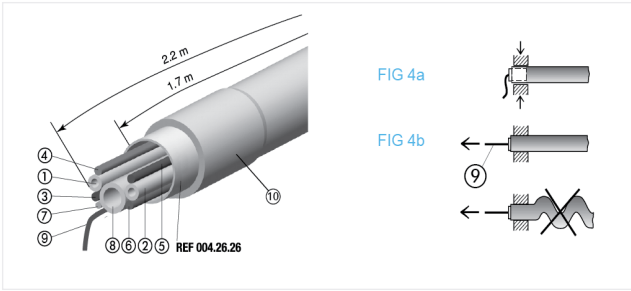

FIG. 4

4.3 Assembly MX2-400

FIG. 4

Preserve the initial alignment of the wires and tubes. Place the sheath (10) in the chucking zone FIG. 4a.

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. 4b.
The outer tube must not be wrinkled after installation. The resistance to traction is 60N maximum.

Description FIG. 4

1. Ø 1.5/2.5 mm green: waterspray
2. Ø 1.5/2.5 mm white: airspray
3. Phase A motor, blue
4. Phase B motor, red
5. Phase C motor, black
6. + light, brown
7. - light, orange
8. Ø 2.8/4.1 mm white: cooling motors
9. Securing cord
10. Sheath

4.4 Installing the socket in the unit

FIG. 5-8

- Drilling for the wall Ø 18 mm ± 0.2
- Machine a countersink for the catch FIG. 5.
- Tighten nut (150 Ncm maximum)
- Minimum wall thickness 1.5 mm
- Maximum wall thickness 6 mm
- Quick connector on unit side only for Ø 18 mm hole, with rotation prevention notch. Standard length 60 cm, REF 1600753-001.

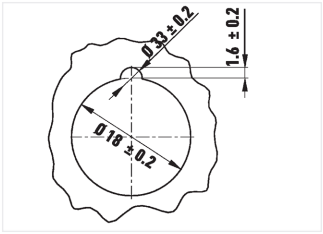

FIG. 5

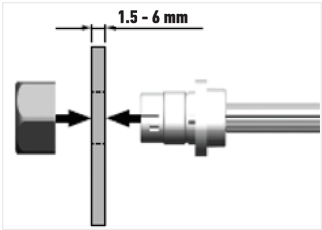

FIG. 6

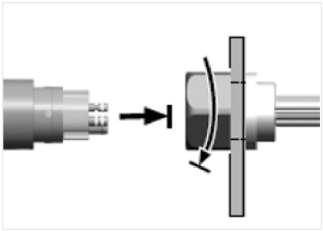

FIG. 7

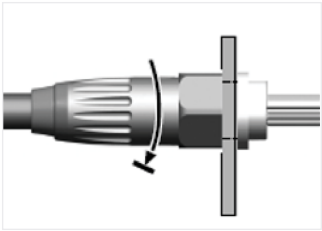

FIG. 8

4.5 Accessories

For rotating connectors (± 200°), FIG. 9 & 10: O-ring connections REF 705.02.62-010 and 705.01.77-010.

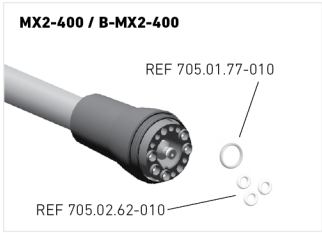

FIG. 9

FIG. 10

For bayonet connectors, FIG.11 : O-ring connections REF 705.02.31-010 and 705.02.62-010.

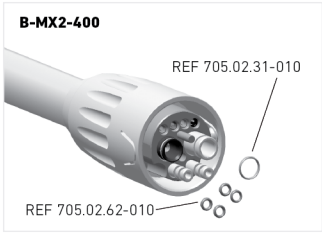

FIG. 11

4.6 Technical data

⚠ **CAUTION**

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

Standard length (REF 1600700-001, 1600762-001, 1600809-001)

1.70 m

Special length (REF 1600781-001)

2.20 m

Note : *See the technical data of the micromotor MOT MX2 (REF 1600677-001) for more information.*

4.7 Classification

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

4.8 Performances

No performances related to the hose alone. Refer to the IFU of the compatible micromotor MOT MX2 (REF 1600677-001).

4.9 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

ENG

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 disinfectant 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. The temperature must not exceed 55°C (131°F).

⚠ **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

⚠ **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
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
705.01.77-010	O-ring, Ø 4 x 0.6
705.02.31-010	O-ring, Ø 3.20 x 0.60
705.02.62-010	O-ring, Ø 1.5 x 0.75

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