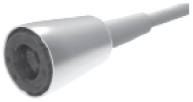
Cables for micromotors
MX-i
MX-I LED 3RD GEN
MX-i LED

ENG INSTRUCTIONS FOR USE.

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

CE 0123 RX Only
REF 2100163-0010/2024-01

Packaging content (REF)



CABLE MX-i LED
REF 1601069-001

CABLE MX-I LED 3RD GEN
REF 1601009-001

Optional accessories

6X

MAINT SPRAYNET®
(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.		Batch code.
	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.		Thermo washer disinfectable.
	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 limitation.
	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:

CABLE MX-i LED and MX LED 3M

Cable intended for use with MX-i LED and MX-i micromotors

CABLE MX-I LED 3RD GEN

Cable intended for use with an MX-I LED 3rd GEN micromotor

Description:

Cables are essential accessories meant to connect motors to the Bien-Air proprietary consoles or to unit/chairs.

2.2 Intended use

CABLE MX-I LED 3RD GEN

Product intended for use in implantology.

CABLE MX-i and MX LED 3M

Product intended for use in Implantology, Periodontology and Oral surgery.

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

- Dental implantology is the treatment to replace one or more missing teeth.
- Oral surgery treatments include impacted teeth extraction, wisdom teeth extraction, non- salvageable decayed teeth extraction, Guided and not-guided bone regeneration, apicoectomy, osteotomy, sequestrectomy and hemisection.
- The main periodontology treatments include gingivitis and periodontis.

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 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 product is intended is unauthorized 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 (consoles, drive motor boards and motors).

Electromagnetic compatibility:

⚠ **WARNING**

- Electromagnetic compatibility in conformance with IEC 60601-1-2 can only be claimed when the device is used with Bien-Air Dental compatible devices (consoles, drive motor boards 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 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.

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.

Note : The original language of those instructions for use is English.

Note : For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

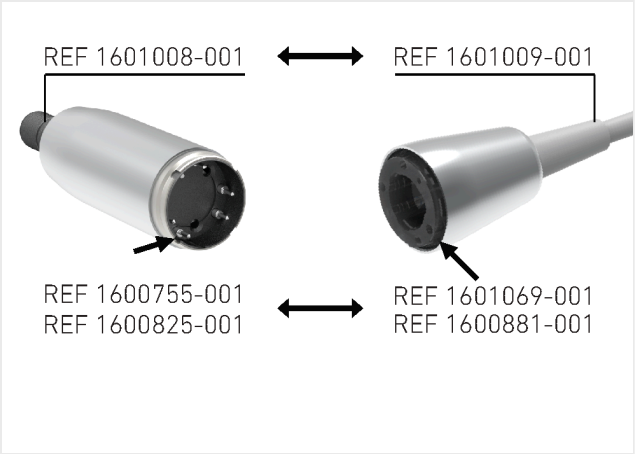


FIG. 2

FIG. 3

FIG. 4

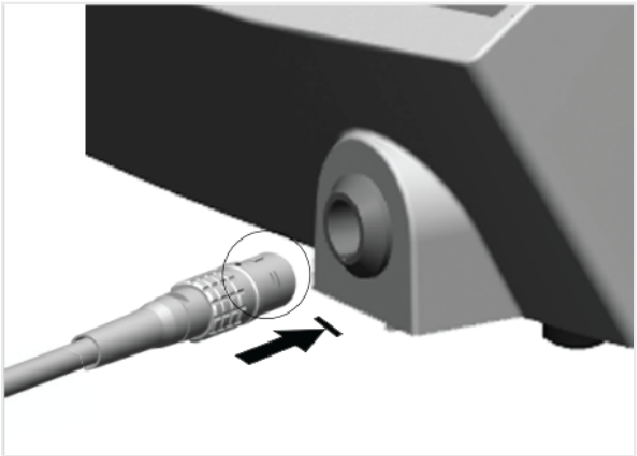
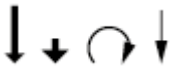
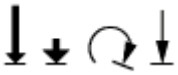


FIG. 5

4.1 Assembly and preparation

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

1. The motors MOT MX-i REF 1600825-001 & MOT MX-i LED REF 1600755-001 are assembled with the power cable REF 1601069-001 and REF.1600881-001. FIG. 2.
2. The motor MOT MX-i LED 3RD GEN REF 1601008-001 is assembled with the power cable REF 1601009-001 as described in FIG. 2. Check that the rear of the motor and the cable connector are clean and dry.
3. Position the motor and its proprietary cable as shown in FIG. 2 (The locator must be in front of the hole). Rotate it to find the exact position and push in the motor. FIG. 3.
4. Holding the motor fully screw the cable sleeve to the rear motor connection. FIG. 4.
5. Check the cleanliness and the dryness of the pin on the cable. Position the cable correctly and plug the cable in the unit. Press the pin in until you feel the locking 'click'. FIG. 5.

4.2 Technical data

Length:

2 m for cable MX-i LED REF. 1601069-001 and cable MX-I LED 3RD GEN REF. 1601009-001
3m for cable MX LED 3M REF. 160881-001

Note : See the technical data of the MX-i micromotors (MOT MX-i REF 1600825-001; MOT MX-I LED 3RD GEN REF 1601008-001; MOT MX-i LED REF 1600755-001) for more information.

4.3 Classification

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

4.4 Performances

No performances related to the cable alone. Refer to the IFU of the compatible micromotor.

4.5 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

Clean, disinfect, dry and sterilize the device prior to first use.
Within a maximum of 30 minutes after each treatment, clean the cable.

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

ENG

Suitable maintenance products:

Only use original Bien-Air Dental SA maintenance products mentioned below 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.

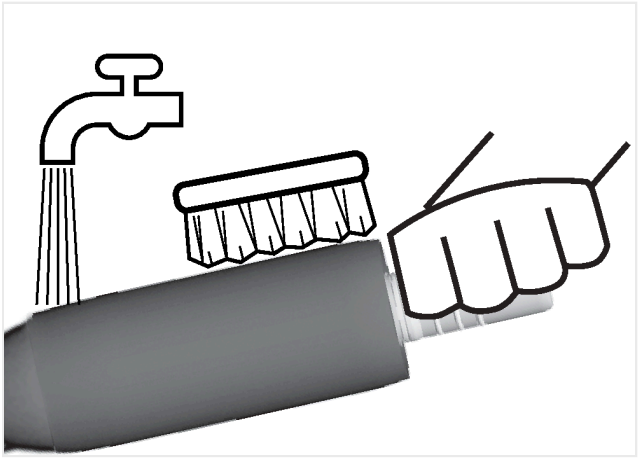


FIG. 6

5.2 Cleaning and disinfection

⚠ **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 clean in a washer-disinfectant unit, nor ultrasonic cleaner.
- Always ensure that the cable contacts are kept clean.

The external surface of the cable must be cleaned to remove impurities as follows FIG. 6:

1. Disconnect the power cable from the console and it is recommended to unscrew the cable from the motor.
2. With the aid of a smooth flexible brush, clean the external surface of the cable using recommended cleaning products.
3. Rinse the cable with cold running water.
4. Dry the external surface of the cable with low linting textile moistened with Spraynet®.

Note : Automatic cleaning-disinfection can replace the above steps 2. if the automatic cleaner/ disinfector does not provide efficient drying, follow the above step 4.

Washer-disinfector:

Carry out automatic cleaning- disinfection using an approved washer-disinfector which complies with ISO standard 15883-1.

Detergent and washing cycle:

Use an alkaline or detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

Recommended specifications for the thermo-disinfection cycle:

Phase	Parameters
Pre-cleaning	<45°C (113°F); ≥ 2 minutes
Cleaning	55°C — 65°C (131°F — 149°F); ≥ 5 minutes
Neutralization	≥ 2 minutes
Rinsing	Tap water, ≤30°C (86°F), ≥ 2 minutes cold water
Thermal Disinfection	Demineralized water, 90°C — 95°C (194°F — 203°F), 5 — 10 minutes
Drying	18— 22 minutes

⚠ **CAUTION**
Never rinse the devices to cool them.

⚠ **CAUTION**
If an automatic washer is used at the place of the washer/thermo-disinfector, respect the previous program for the Pre-cleaning, Cleaning, Neutralization and Rinsing phases. If the local tap water has a pH outside the range of 6.5-8.5 or if it contains more than 100 mg/l chloride (Cl-ion), do not dry the device inside the automatic washer but dry it manually with low linting textiles.

⚠ **CAUTION**
If automatic cleaner/disinfector does not provide efficient drying and/or if traces of humidity remain after drying, dry the external surface of the device with low linting textile impregnated with Spraynet®.

5.3 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 device 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.

5.3.1 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 device 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.

5.4 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.

5.5 Servicing

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

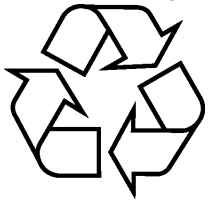
⚠ **CAUTION**
Never disassemble the device. For all modification and repair, contact your regular supplier or Bien-Air Dental service centre.

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	

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.

7.2 References

REF	Legend
1601009-001	MX-I LED 3RD GEN cable, 2 meters length, welded, compatible with MX-I 3RD GEN electric micromotor REF. 1601008-001
1601069-001	MX-i LED cable, 2 meters length, welded, compatible with MX-i LED and MX-i LED electric micromotor REF. 1600755-001 and REF. 1600825-001
16000881-001	MX LED 3M cable, 3 meters length, welded, compatible with MX-i LED and MX-i LED electric micromotor REF. 1600755-001 and REF. 1600825-001
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans

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

Other addresses available at
www.bienair.com

EC REP Bien-Air Europe Sàrl
19-21 rue du 8 mai 1945
94110 Arcueil
France