stomdevice

MC2 & Isolite hoses

⚠ Do not sterilize



ENG INSTRUCTIONS FOR USE.

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

CE 0123 Rx Only
REF 2100017-0002/2022.10

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Devices (REF)



HOSE ISOLITE/MC2 GREY
REF 1600120-001



HOSE ISOLITE/MC2 COILED BLACK
REF 1600315-001



HOSE ISOLITE SWIVEL GREY
REF 1600298-001



HOSE ISOLITE WATER ADJ GREY
REF 1600134-001



HOSE ISOLITE SWIVEL GREY
REF 1600132-001

Optional accessories



10X

O-RING 2.5x1.5
REF 7050208-010



6X

MAINT SPRAYNET® IBOX OF 6 CANS
REF 1600036-006

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1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.	REF	Catalogue number.
CE 0123	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.	MD	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.	EC REP	Authorized EC Representative in the European Community.
	Wear protective gloves.	LOT	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.

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2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type:

HOSE ISOLITE/MC2 GREY

Grey hose with fixed connector.

HOSE ISOLITE/MC2 COILED BLACK

Black coiled hose with fixed connector.

HOSE ISOLITE/MC2 SWIVEL GREY

Grey hose with revolving connector.

HOSE ISOLITE WATER ADJ GREY

Grey hose with ring to adjust water spray flow.

HOSE ISOLITE SWIVEL GREY

Grey swivel hose with revolving connector.

Those hoses are intended to be used with motors ISOLITE LK & ISOLITE LED (from this point on referred to as MC2 motor type).

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.

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.

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.

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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.

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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.

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FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Sheath

(2) Reinforced part of the sheath

(3) 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.

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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. Connect (without the split ring) the motor to the proprietary hose 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).

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FIG. 4

Changing the O-ring:

FIG. 4

O-ring connections REF 705.02.08-010.

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FIG. 5

4.3 Assembly

FIG. 5

Preserve the initial alignment of the wires and tubes. Insert the hose in the Dental unit fixation placing the reinforced part of the hose (10) in the chucking zone (FIG. 5a).

The securing cord (9) 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 air spray (small white) with "A" or (blue)
2. Ø 1.5/2.5 mm water spray (small white) with "W" or (green)
3. Ø 1.5/2.5 mm motor cooling (small white) or (transparent) Ø2.8/4.1 mm
4. (+) red: motor
5. Black: motor
6. (+) brown: bulb
7. (0V) blue: bulb
8. Back-up ring
9. Securing cord
10. Metal reinforcement of the sheath

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FIG. 6

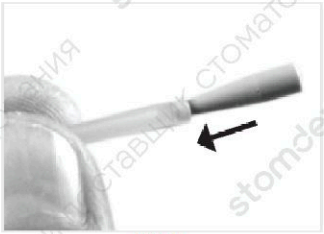


FIG. 7

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

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4.4 Technical data

⚠ CAUTION

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

Standard length

1.7 or 2 m

Special length

3 m

Note : *See the technical data of the micromotor MOT ISOLITE LED (REF 1600681-001) or of the micromotor MOT ISOLITE LK (1600078-001) 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 ISOLITE LED (REF 1600681-001) or MOT ISOLITE LK (1600078-001).

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

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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.

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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).

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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
1600120-001	HOSE ISOLITE/MC2 GREY
1600315-001	HOSE ISOLITE/MC2 COILED BLACK
1600298-001	HOSE ISOLITE/MC2 SWIVEL GREY
1600134-001	HOSE ISOLITE WATER ADJ GREY
1600132-001	HOSE ISOLITE SWIVEL GREY
705.0208-010	O-RING 2.5x1.5
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans

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