PM 1:1

External spray

ENG INSTRUCTIONS FOR USE.

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

CE 0123 Rx Only
REF 2100046-0003/2022.09

Packaging content (REF)

PM 1:1 EXT SPRAY

REF 1600052-001

Optional accessories

SLEEVE CONE PM 1:1 EXT SPRAY

REF 1500003-001

RING WITH SPRAY TUBE

REF 1500552-001

PACK OF 10 DISPOSABLE STERILE IRRIGATION LINES

REF 1500984-010

MAINT SPRAYNET® (BOX OF 6 CANS)

REF 1600036-006

MAINT LUBRIFLUID® (BOX OF 6 CANS)

REF 1600064-006

MAINT AQUACARE (BOX OF 6 CANS)

REF 1600617-006

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.		Thermo washer disinfectable.
	Data Matrix code for product information including UDI (Unique Device Identification).		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.

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type:

Straight handpiece PM 1:1, external irrigation, without light, direct ratio, interchangeable nose with or without irrigation tube.

Description:

Bien-Air Dental contra-angle and straight handpieces are designed to transmit and apply the mechanical energy produced by an electric or air micromotor.

2.2 Intended use

Product intended for use in general dentistry which includes restorative dentistry and dental prophylaxis as well as in oral and maxillofacial 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, dental professionals and oral surgeon.

2.5 Use environment

Professional healthcare facility environment.

2.6 Intended medical conditions

- General dentistry which includes restorative dentistry, dental prophylaxis, and addresses the maintenance or reestablishment of dental health.
- 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.
- Maxillofacial surgery includes procedures such as Orthognathic surgery, genioplasty and rhinoplasty.

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 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 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.

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

⚠ **WARNING**

- Rest the device on a cleanable support to avoid risks of infection for yourself, the patient or third parties.
- 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.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6. Sterilization before first use is mandatory.
- When disposing of the device, the user must return it sterilized to their dealer or contact an authorized body for the treatment and recovery of this type of equipment.
- While performing surgical treatment, the handpiece must not receive pressurised cooling air from the unit, to prevent contamination of the area being treated.

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

⚠ **WARNING**

- The device is intended for professional use only.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.
- 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 center approved by Bien-Air Dental SA.
- Never insert or remove a device while the micromotor is rotating.
- Do not touch the dental bur while it is rotating.
- Never rotate the locking ring while the PM (straight handpiece) is in operation.
- Each time a bur is inserted, check that the bur is fully inserted to the stop and rotates freely. If it is blocked, contact your usual supplier or Bien-Air Dental SA for repair.
- Always check that the bur is locked by gently pushing and pulling the bur.
- Always check that the or locking ring is fully tightened, passing the initial mechanical resistance to meet the abutment.
- Follow the guidelines for use, according to the bur manufacturer's instructions. Never use a bur if the shaft is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or third parties.

- Comply with maximum lengths by always inserting the bur as far as possible into the locking mechanism. If a bur is operated at high speeds when incorrectly mounted (i.e. not fully inserted into the locking mechanism, or being longer than the values specified in section 4.2) a centrifugal force may be exerted which may bend or break the bur.
- **Good practices of use** (e.g. for removing metal bridges, adjusting ceramic crowns or other milling operations on hard materials) **should always be followed**. They include but are not limited to: following the recommendation of the cutting- tool/bur manufacturer, checking the integrity of the bur and adapting the clinical protocol in order to avoid any risk of excessive vibration and damage to the device's integrity.
- Always ensure that the coolant supply provided by the motor is sufficient and adequate.

To prevent any risk of contra-angle/handpiece overheating, the cautions below must be observed:

⚠ **CAUTION**

- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.

To prevent any risk of device malfunction the caution below must be observed:

⚠ **CAUTION**

- Before performing any clinical application, always test your device to ensure its proper operation.
- Only use original Bien-Air Dental SA devices and accessories or those recommended by Bien-Air Dental SA.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.

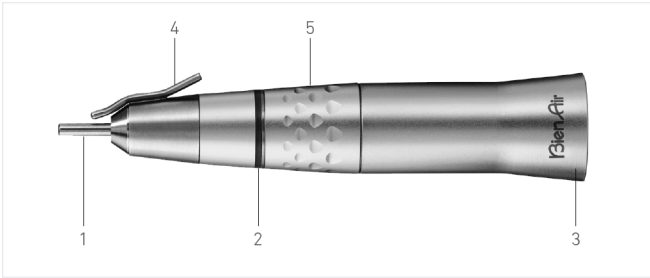

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Bur (not supplied)

(2) Transmission ratio

(3) Micromotor connection

(4) Irrigation tube

(5) Locking ring

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.

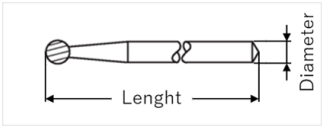

FIG. 2

ENG

4.2 Technical data

Technical data	PM 1:1 EXT SPRAY
Motor coupling compatibility	Coupling according to ISO 3964 - MS & MICRO-SERIES can be coupled to short and extra short Motor coupling - Other CA & PM can be coupled with all coupling type
Lightning	"L" letter means lightning CA & PM without L letter means no lightning
Transmission ratio according to ISO14457	Speed direct ratio 1:1 (blue color)
Motor max speed	40'000 rpm
Tool max speed	40'000 rpm
Irrigation type	External irrigation KM = Kirschner-Meyer

Cutting tool compatibility	
Shaft diameter ISO 1797-1	2.35 mm (Type 2)
Shaft length ISO 1797-1	≥ 30 mm
Cutting tool diameter ISO 6360-1	≤ 4 mm
Total length ISO 6360-1	≤ 44.5 mm (Code 4)

4.3 Classification

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

4.4 Performances

Performances	
Irrigation flow 5 levels*	25 - 110 ml/min
Speed & torque transmission ratio	1:1 +- 10%

**In combination with Chiropro peristaltic pumps.*

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

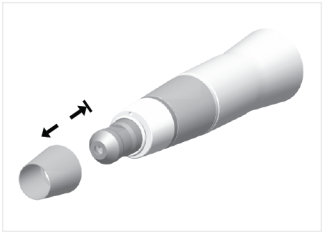

FIG. 3

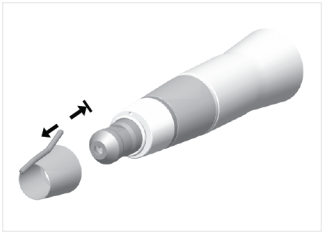

FIG. 4

5 Operation

Pictogram used			
	To-and-fro movement.		Move in the direction indicated.
	After initial mechanical resistance, fully tighten in the direction indicated.		Move fully to the stop, in direction indicated.

Irrigation / detachable noses

Both with and without irrigation tube noses (see the section "optional accessories" or FIG. 3 & FIG. 4 can be connected to the handpiece. The irrigation tube cannot be detached from its nose and is not meant to be bent by the user. A sterile external irrigation line should be connected to the irrigation tube.

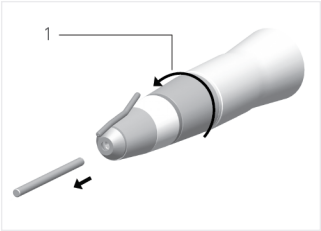

FIG. 5

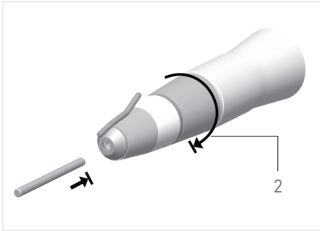

FIG. 6

Changing the bur

Turn the locking ring completely in the direction of the arrow, insert the new cutting tool until the stop:

1. Unlocking FIG. 5.

2. Locking FIG. 6.

Once locked in, exert traction on the tool to check that it is correctly in place.

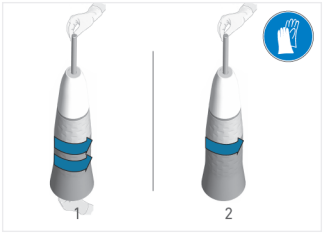

FIG. 7

Bur locking operation check:
FIG. 7

Hold the handpiece upright by the bur between your thumb and index finger and rotate the handpiece; the handpiece should rotate freely (more than 3 rotations).

6 Maintenance and servicing

6.1 Maintenance - General information

Clean, dry, lubricate and sterilize the device prior to first use.
Within a maximum of 30 minutes after each treatment, clean, disinfect and lubricate the instrument. Observing this procedure eliminates any blood or saliva residues and prevents the transmission system from being blocked.
Before surgical treatment, the handpiece must be sterilized.

The following procedure applies to both the handpiece and the nose.

⚠ **WARNING**

- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.
- The irrigation tube must be cleaned, disinfected and, if required by country-specific directives or by a surgical procedure, sterilized.

6.1.1 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®
- Aquacare
- 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. 8

6.2 Cleaning

⚠ **CAUTION**

- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Clean using manual cleaning or automated washer/disinfector only (do not use ultrasonic cleaner).
- Carry out the cleaning, disinfection and sterilization processes without a bur in the chuck mechanism.

Preparation:

- Disconnect the drive motor attachment, rotate the locking ring, remove the bur and leave the locking ring loosened FIG. 5.
- Disconnect the irrigation line, remove the detachable nose.

Remove dirt / deposits:

FIG. 8.

1. Clean the exterior and interior of the device under tap water between 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.
2. After selecting the appropriate nozzle, perform preliminary cleaning of the device by using the product Aquacare. Spray the inside and the outside of the device and inside the irrigation tube.

FIG. 9

6.3 Disinfection

Manual cleaning and disinfection

1. Dip the device in a bath containing a cleaning and disinfectant product (e.g. didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product which are allowable chemical agents). Follow the concentration and duration recommended by the fabricant of the disinfection product.
2. Brush the device with a smooth, flexible brush (e.g. soft- bristled toothbrush). DO NOT USE a wire brush.
3. **Optional:** perform additional cleaning and disinfection of the external surfaces with non- woven wipes impregnated with a disinfection product (e.g. didecyldimethylammonium chloride).
4. Rinse the device twice with running tap water (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.
5. After selecting the appropriate nozzle, spray inside the device with Spraynet® (FIG. 9).
6. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

Automatic disinfection:

Note : *Automatic cleaning-disinfection can replace the previous steps 4 et 6.*

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 motor with low linting textile impregnated with Spraynet®.

FIG. 10

6.4 Lubrication

Verifying cleanliness:

Visually inspect the device to ensure it is clean. Repeat the cleaning and disinfection procedure if necessary.

Lubrication:

Lubricate before each sterilization or at least twice a day. Only the Lubrifluid® spray must be used.

FIG. 10

1. Place the device in a sterile, non-woven cloth to collect the excess of lubricant.
2. Select the appropriate nozzle.
3. Insert the nozzle of the Lubrifluid® can in the rear of the device's handle.
4. Activate the spray for 1 second and clean the excess oil on the exterior with a sterile, non-woven compress.

Note : *If, during the test run of the handpiece before the clinical treatment, an excess of lubricant is ejected from the handpiece, prolongate the test run until the ejection stops. Then, modify the lubrication procedure, by reducing the quantity of lubricant inserted before sterilization or operate the handpiece for 2 seconds after lubrication and before sterilization.*

6.5 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 handpiece and the attachment are completely dry before and after the sterilization.
- 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.
- As with all instruments, following each sterilization cycle, including drying, remove the device to avoid excess exposure to heat which can result in corrosion.

6.5.1 Procedure

1. Pack the sleeve 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 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 between 132°C - 135.5°C (269.6°F – 275.9°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.

6.6 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.

6.7 Servicing

Bien-Air Dental SA recommends a regular service for the handpiece after 4000 processing cycles or five years.

⚠ CAUTION

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

7 Transport & disposal

7.1 Transport

There are no particular transport conditions required.

7.2 Disposal

The disposal and/or recycling of materials must be performed in accordance with the legislation in force.

The handpiece must be recycled. In order to avoid any risk of contamination, the user must return the device sterilized to their dealer or contact an authorized body for the treatment and recovery of this type of equipment.

8 General information

8.1 Terms of guarantee

Bien-Air Dental SA grants the operator a guarantee covering all functional defects, material or production faults.

The warranty period is:

- 24 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.

All other claims of any kind whatsoever, particularly claims for damages, are excluded.

Bien-Air Dental SA cannot be held liable 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 or water 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.

8.2 References

REF	Legend
1600052-001	Straight handpiece PM 1:1, direct ratio, 1 external irrigation tube on removable nose and 1 nose without irrigation tube.
031.16.42-010	Irrigation tube
1500984-010	Pack of 10 irrigation lines
1500552-001	Detachable nose with irrigation tube for PM 1:1
1500003-001	Detachable nose without irrigation tube for PM 1:1
1600064-006	Lubrifluid®, lubricant 500 ml, box of 6 cans
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans
1600617-006	Aquacare, cleaning spray 500 ml, box of 6 cans

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