

# PM 1:1 External spray

**Bien-Air**<sup>®</sup>  
Dental



## Instruction

REF 2100046-ENG/08.11



### English

**Medical devices entirely made in Switzerland by Bien-Air Dental SA.**

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

### Intended use

Product intended for professional use only. Use in dentistry for general dentistry work.

### Technical data and assembly

**Classification**  
Class IIa in accordance with European Directive 93/42 /EEC concerning medical devices.

**Type of coupling**  
The most commonly used coupling in the world as per ISO Standard 3964.

**Drive**  
The PM 1:1 can be fitted onto an ISO 3964 - compliant coupling motor.

**Transmission ratio**  
Blue instrument sleeve direct ratio.

**Motor speed**  
max. 40 000 rpm

**Rotation speed**  
max. 40 000 rpm

**Bur**  
Diameter of shaft 2,35 mm type 2, in accordance with ISO 1797, max. length 44,5 mm code 4, in accordance with ISO 6360/1, fig 1.

**Changing the bur**  
Turn the ring completely in the direction of arrow, insert the tool until the stop:

A: unlocking fig. 2  
B: locking fig. 3

Exert traction on the tool to check that it is correctly in place.

Always wear gloves or suitable protective clothing when checking and using this equipment.

**Important**  
The device must not be started without a bur inserted into the chuck.

**Never mount an instrument on a rotating motor.**  
Never adjust the clamping/ unclamping ring while the instrument is rotating, since this could damage the mechanism or destroy the motor.

**PM 1:1 Spray**  
The spray tube, connects the hand-piece to the motor. The socket, which holds the spray tube, is detachable. A socket without tube, see option and fig. 5, can be fitted.

### Maintenance

The instrument is delivered "non sterile". Before first use, lubricate and sterilise the instrument. Please comply with these instructions.

- ⚠ Important**
- After each surgical intervention, the instrument should be cleaned, disinfected and lubricated **as soon as possible (within max. 2 hours)**, then sterilized. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
  - Only instruments bearing a pictogram **can be placed in the washer/disinfectant unit.**
  - Do not immerse in an ultrasonic bath.
  - The sleeves and clipped tubes follow the same procedure as the instrument.

- ⚠ Bur chuck mechanism (cutting tool)**
- Never close the chuck mechanism without the bur in place, or it may get damaged.
  - Never start running this rotary instrument without a bur in the chuck mechanism.
  - Perform the cleaning - disinfection - sterilisation process with the chuck mechanism open and without a bur installed.

- ⚠ Detergent**
- Use a PH-neutral to alkaline (max. pH11), enzyme-based detergent specifically designed for the cleaning and disinfection of dental instruments.
  - Do not use detergents which are corrosive or which contain chlorine, acetone or Javel water.

Only use maintenance products and components from Bien-Air Dental. The use of other products and components can void the guarantee.

Check that the steriliser and the water that is used are clean. After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion.

⚠ In the event of prolonged disuse, the instrument must be stored in a dry environment. Lubricate and sterilise the instrument before reuse.

**⚠ Important**  
**After cleaning and disinfecting/sterilising the instrument and before using it, operate at moderate speed, with a bur in the chuck, for 10 to 15 seconds to circulate lubricant and remove excess.**

### 1 Pre-disinfection (at place of operation)

- Preparation**
- Disconnect the instrument from the drive motor, withdraw the bur and leave the chuck mechanism in its open position (fig. 2)
  - Clean the spray tubes (if fitted) with the Bien-Air wire cleaning (fig. 4) and remove the sleeve and the clipped irrigation tube (if fitted) from the instrument (fig. 5).
  - Perform manual pre-cleaning or pre-cleaning in a bath.

- Manual pre-cleaning**  
Use the **Spraynet** cleaning product from Bien-Air.
- Spray the interior and exterior of the instrument (fig. 6) to remove residue and clean all surfaces carefully.
  - Wipe down the external surfaces with an absorbent paper towel.
  - Perform a manual or automatic cleaning-disinfection process.

or

- Pre-cleaning by bath**  
⚠ Attention: Pre-cleaning by bath **must be followed** by automatic cleaning-disinfection.
- Immerse the instrument completely in a cleaning bath containing a sufficient amount of detergent.
  - As it leaves the bath, rinse the interior and exterior of the instrument under cold running water.
  - Dry the interior and exterior of the instrument to remove all traces of detergent and rinsing water immediately to prevent any adverse impact on the internal components, e.g. which might cause them to seize.
  - Perform an automatic cleaning-disinfection process.

### 2 Cleaning-disinfection

- Manual cleaning-disinfection**  
**Cleaning and disinfection:**  
Clean and disinfect the interior and the exterior of the instrument with a suitable detergent.  
**Rinsing:**  
Rinse the interior and exterior of the instrument under cold running water.  
**Drying:**  
Spray the exterior and interior of the instrument with **Spraynet** product (fig. 6) immediately to remove all traces of detergent and rinsing water to prevent any adverse impact on the internal components, e.g. which might cause them to seize.

or

- Automatic cleaning-disinfection**  
⚠ Note: only for engraved instruments
- Cleaner - disinfectant:**  
Use an approved cleaner-disinfectant with a suitable amount and type of detergent.  
**Washing cycle:**  
Select the specified washing cycle for these instruments which should be compatible with the detergent manufacturer's instructions.  
**Temperatures recommended for these instruments:**  
Water: cold to max 95°C (203°F)  
Air: Max. ambient temperature of 100°C (212°F)

### 3 Lubrication, inspections and conditioning process

- Check for cleanliness**  
Visually inspect the cleanliness of the instrument, the sleeve and the clipped tube (if fitted).
- Lubrication**  
Use **Lubrifiuid** lubricant spray from Bien-Air.
- Place the instrument in a cloth to collect all surplus lubricant.
  - Insert the spray tip in the back of the instrument handle (fig. 7).
  - Operate the spray for 1 second.
  - Reinstall the sleeve or the clipped tube (fig. 5).

- Clamp operation inspection**
- Insert a bur in the chuck mechanism of the instrument (fig. 3).
  - Check that the bur remains in position when traction is applied.
  - Remove the bur and leave the chuck mechanism in its open position (fig. 2).

**Conditioning process**  
immediately wrap the instrument in approved packaging for steam sterilisation.

### 4 Sterilisation

**Procedure:**  
With steam after fractioned initial vacuum phase, Class B cycle acc. to EN13060.

Type 2 / ISO 1797  
Code 4 / ISO 6360/1

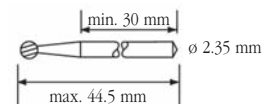


fig. 1

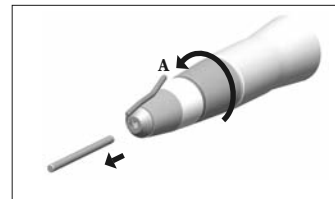


fig. 2

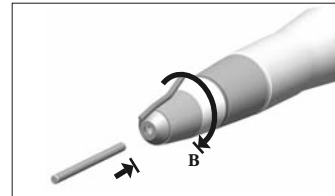


fig. 3

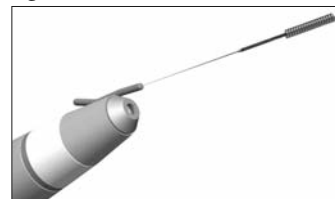


fig. 4

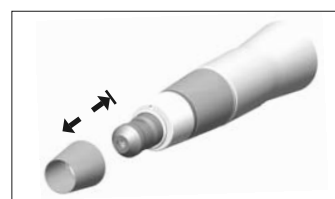


fig. 5

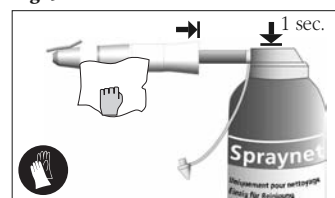


fig. 6

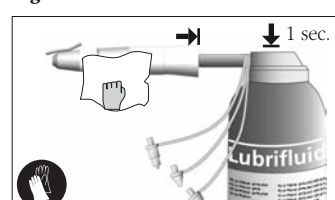


fig. 7

The procedure has been validated according to ISO 17664. Nominal temperature: 134°C (273°F). Duration: 3 or 18 min., according to the national guidelines in force.

**Overhaul**  
Never disassemble the device. For any modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental directly. Bien-Air Dental asks the user to have its dynamic instruments checked or inspected at least once a year.

**Transport and storage conditions**  
Temperature between -40°C (-40°F) and 70°C (158°F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 1 06 kPa (7.3 to 15.3 psi).

**Information**  
The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide.

They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

#### Other precautions for use

The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorised and may be dangerous. The medical device meets all the current legal requirements.

Excess material from products used for maintenance (lubricants, cleaning products and disinfectants) originating from CA or PM may penetrate into the electric brush motor and interfere with its functioning. It is essential to follow the maintenance instructions accompanying each product.

#### Recommendations

It is essential to use dry, purified compressed air 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, connectors and spray cones.

The device must not be used in the presence of open lesions, injury to the soft tissues or recent extractions. The exhaust air could propel infected material into the wounds and cause infections and risk of embolism.

Adhere to the Instructions for Use, in accordance with the instructions of the bur manufacturer. Never use a bur with an incorrect diameter, as there is a risk of this becoming detached during the treatment and causing injury to yourself, to your patient and to third parties.

Rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.

#### Guarantee

##### Terms of guarantee

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

The device is covered by this guarantee for 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 whatever nature, in particular in the form of a claim for damages and interest, are excluded.

Bien-Air Dental shall not be held responsible for damage or injury and the consequences thereof, resulting from:

- excessive wear and tear
- improper use

- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible "fibre optic" type conductors, or any parts made of synthetic materials.

The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorised by Bien-Air Dental.

Claims under the terms of the guarantee will be considered only on presentation, together with the product, of the invoice or the consignment note, on which the date of purchase, the product reference and the Serial No. should be clearly indicated.

REF	Legend
1600052-001	Straight handpiece PM 1:1, direct ratio, 1 external spray on removable sleeve and 1 sleeve without spray.
031.16.42	Spray tube
1500552-001	Nose cone with spray tube for PM 1:1
1500003-001	Nose cone without spray tube for PM 1:1
1000001-010	Wire probe, box of 10 wires
1600064-006	Lubrifluid, lubricant 500 ml, box of 6 cans
1600036-006	Spraynet, cleaning spray 500 ml, box of 6 cans

#### Symbols

- Manufacturer.
- CE Marking with number of the notified body.
- Wear rubber gloves.
- Attention.
- Machine washable.
- Move in the direction indicated.
- Move fully to the stop, in the direction indicated.

#### List of Bien-Air Dental SA registered trade mark products ®:

- |           |           |             |             |
|-----------|-----------|-------------|-------------|
| Aquilon®  | Eolia®    | Lubrifluid® | Prestilina® |
| Bora®     | Gyro®     | Lubrimed®   | Spraynet®   |
| Boralina® | Gyrolina® | MX®         |             |
| ChiroPro® | Isolite®  | PowerCare®  |             |

This product may be covered by one or more of the following patents:

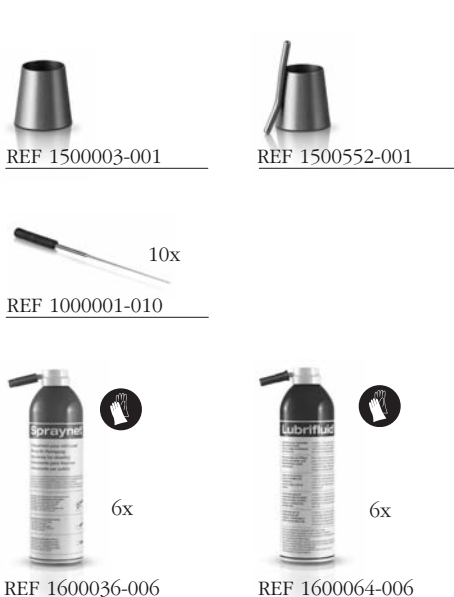
- EP Europe:** 745358 / 688539 / 948294 / 1145688 / 1563800 / 1563801 / 1675523 / 1753360
- DE Germany:** 29616023.7
- DK Denmark:** 9600315
- FR France:** 2722972
- CH Switzerland:** 693922
- CN China:** 100528099 / 100522100 / 100522099 / 100553584
- JP Japan:** 3892485 / 4298933 / 7000419
- US United-States:** 5453008 / 6033220 / 6319003 / 7214060 / 7448870
- RU Russia:** 2361540 / 2361541 / 2372046

REF 1600052-001 PM 1:1 EXT SPRAY

#### a Set supplied



#### b Optional accessories



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