

# PM 1:1

## PM 1:1 Micro-Series



### Instruction

REF 2100064-081-ENG

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

#### Type

Dental straight handpiece, with internal spray, without light, direct ratio, locking ring.

#### Intended use

Product intended for professional use only. Use in dentistry for general dentistry work. Any use other than that for which this device is intended is prohibited and may prove dangerous.

#### Technical data

#### Classification

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

#### Type of coupling

PM 1:1, as per ISO Standard 3964, internal spray, without light.

PM 1:1 Micro-Series, only compatible with Bien-Air LED micromotors.

#### Transmission ratio

Direct drive, blue marker.

#### Motor speed

Max. 40.000 rpm.

#### Rotation speed

Max. 40.000 rpm.

#### Weight

PM 1:1 80 g

PM 1:1 Micro-Series 70 g

#### Length

PM 1:1 85 mm

PM 1:1 Micro-Series 76 mm

#### 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.

#### Using the handpiece

#### 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

Rotate the sleeve and remove the bur **fig. 2**. Fully insert the bur **fig. 3 step 1**. Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance **fig. 3 step 2**.

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

**⚠ Important** Each time a bur is inserted, check that the clamping sleeve is fully tightened by moving the bur back and forth **fig. 3 step 3**.

#### ⚠ 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.
- Always wear gloves or suitable protective clothing when checking and using this equipment.
- 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 above) this can cause a centrifugal force which may bend or break the bur.
- Do not exceed the maximum operating speed authorised by the bur manufacturer.
- Only use milling tools which are concentric and in perfect condition.

To ensure that your PM-micromotor unit functions with maximum efficiency, it must be cooled by an air supply of 8-10 standard litres/min. on the nose of the micromotor.

#### Maintenance

Separately clean, lubricate and sterilise the device before the treatment of each patient.

#### ⚠ Important

- **The instrument is delivered "non sterile".**
- Before using for the first time and **within a maximum of 30 minutes** after each treatment, clean, disinfect and lubricate the instrument, then sterilise. 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.**
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

#### Precautions for maintenance:

The universal precautions, in particular wearing of personal protective equipment (gloves, goggles, etc.), should be complied with by medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated. Pointed and sharp instruments should be handled with great caution.

#### Bur chuck mechanism (cutting tool)

- Carry out cleaning – disinfection – sterilisation without bur in the chuck mechanism.

#### Suitable detergent

#### For automatic cleaning-disinfection:

- Slightly alkaline enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments.

#### For manual cleaning-disinfection:

- **Spraynet**
- Detergent or detergent-disinfectant (pH 6- 9.5) recommended for cleaning-disinfection of dental or surgical instruments.
- Quaternary ammonium- and/or enzyme-based surfactants.
- **Do not use** detergents that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- Do not soak in physiological liquid (NaCl).

#### ⚠ Important

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

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.

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

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

#### Preparation

- Disconnect the drive motor attachment, rotate the sleeve, remove the bur and leave the sleeve loosened **fig. 2**.
- Clean the spray tubes (if fitted) with the Bien-Air Dental cleaning wire **fig. 6**.
- Perform manual pre-cleaning or pre-cleaning in a bath.

#### Manual pre-cleaning

Use the Spraynet cleaning product from Bien-Air Dental.

- Spray the interior and exterior of the instrument **fig. 4** 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 and disinfection

#### Manual cleaning-disinfection

Dip the instrument in a tank containing appropriate detergent and, using a soft-haired brush, clean and disinfected, clean the outside of the instrument in accordance with the detergent manufacturer's instructions (time, concentration, temperature, renewal, etc.).

#### Rinsing:

Rinse the inside and outside of the device with cold running water (< 35°C/<95°F) for about 30 sec.

#### Drying :

Spray the interior of the instrument with **Spraynet** product **fig. 4** 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. If necessary, clean with a dry paper towel.

or

#### Automatic cleaning-disinfection

**⚠ Attention** : only for devices engraved with 

#### Cleaner - disinfectant unit:

Use an approved cleaner-disinfectant unit 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.

#### Recommended temperatures for the devices:

#### Pre-wash

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

#### Wash

Water: 50 to 65°C (122 to 149°F) – Duration 5 mins.

#### Rinsing

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

#### Thermal disinfection

Water: 80 to 97°C (176 to 206.6°F) – Duration 5 mins.

#### Drying

Air: 65 to 75°C (149 to 167°F) – Duration 25 mins.

#### ⚠ Important:

Never rinse the devices to cool them.

#### ③ Lubrication, checks and conditioning process

#### Verifying cleanliness

Visually check the cleanliness of the instrument. If required, re-clean with a soft brush.

Lubrication before each sterilisation, and at least twice a day. Only use the spray **Lubrifiuid**.

- Remove the bur before lubricating
- Place the instrument in a cloth so as to catch the debris and foreign matter expelled by the atomizer jet.
- Remove the protective cap and insert the nozzle into the back of the instrument sleeve.
- Spray for about 1 second **fig. 5**.

#### ⚠ Clamp operation inspection

- Fully insert the bur **fig. 7A step 1**. Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance **fig. 7A step 2**.

**⚠ Each time a bur is inserted**, check that the clamping sleeve is fully tightened by moving the bur back and forth **fig. 7B**.

- Hold the handpiece upright by the bur between your thumb and index finger **fig. 7C** and rotate the handpiece; the handpiece should rotate freely (more than 3 rotations).
- Rotate the sleeve and remove the bur to sterilise **fig. 7D**.

**⚠ Warning:** If the handpiece does not rotate freely, there is a **risk of burns to the patient**. In this case, return the handpiece to your usual supplier or directly to Bien-Air Dental for repair.

#### Packaging process

Wrap the instrument in approved packaging for steam sterilisation.

#### ④ Sterilisation

#### ⚠ Important

The quality of the sterilisation depends

**very much on the cleanliness of the device.**

Only perfectly clean devices may be sterilised.

**Do not use a sterilisation procedure other than the one described below.**

**Procedure:**

Fractionated pre-vacuum steam sterilisation, class B cycle according to EN13060. The procedure has been approved according to ISO 17664.

All Bien-Air Dental straight handpieces are sterilisable in an autoclave up to 135°C (273.2°F). Duration: 3 or 18 minutes, depending on the national requirements in force.

**Servicing**

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 106 kPa (7.3 to 15.3 psi).

**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.

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

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. Never lubricate the electric brush motor.

**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.

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.

**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.

Bien-Air Dental offers a 24-month guarantee for the glass-bar light conductors.

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.

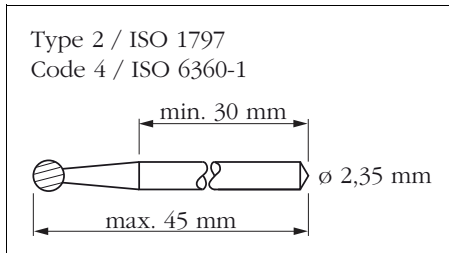


fig. 1

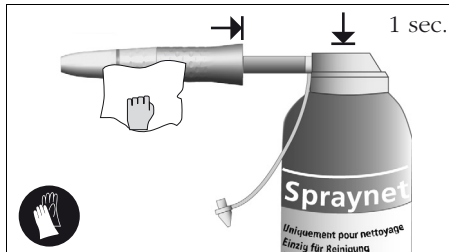


fig. 4

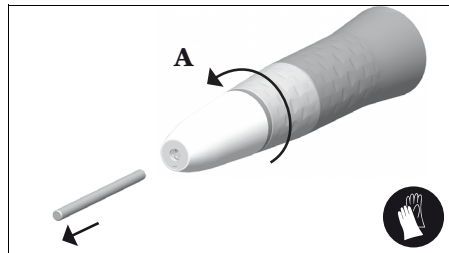


fig. 2

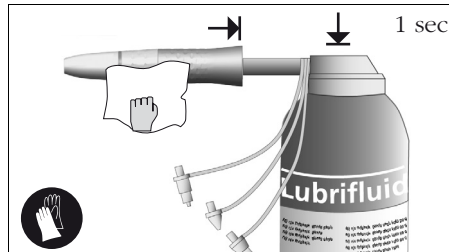


fig. 5

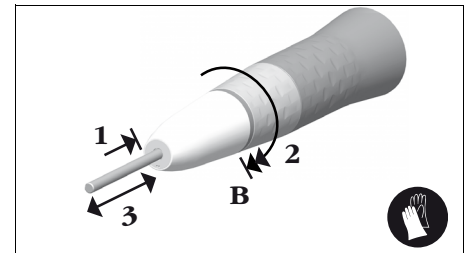


fig. 3

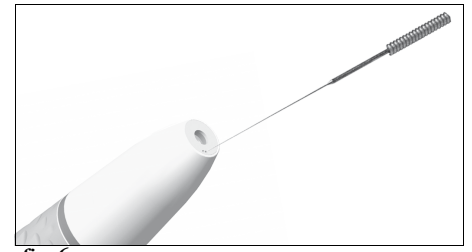


fig. 6

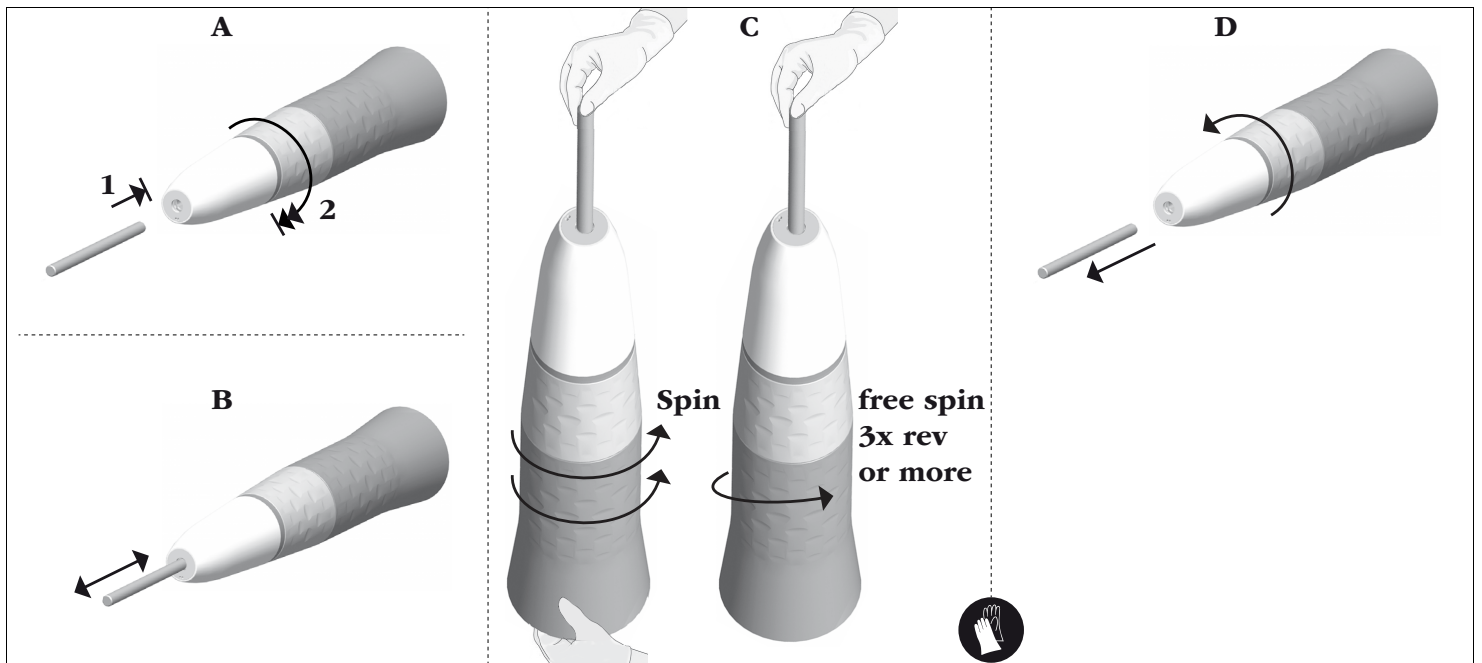


fig. 7

**Set supplied**



**PM 1:1**  
REF 1600383-001



**PM 1:1 Micro-Series**  
REF 1600693-001

**Optional accessories**



REF 1000001-010



REF 1600036-006



REF 1600064-006

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 1600383-001 PM 1:1 / REF 1600693-001 PM 1:1 Micro-Series

| REF         | Legend   |
|-------------|--|
| 1600383-001 | Straight handpiece PM 1:1, direct ratio, without light, locking ring, bur Ø 2.35 mm              |
| 1600693-001 | Straight handpiece PM 1:1 Micro-Series, direct ratio, without light, locking ring, bur Ø 2.35 mm |
| 1000001-010 | Wire probe, box of 10 wires  |
| 1600036-006 | Spraynet, cleaning spray 500 ml, box of 6 cans   |
| 1600064-006 | Lubrifiuid, lubricant 500 ml, box of 6 cans  |

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

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

In these instructions, "Device" corresponds to the product described in the heading "Type". For example, turbine, contra-angle, handpiece, micromotor, tube, electronics, connectors, station etc.

**Symbols**

|  |   |  |  |
|--|---|--|--|
|  | Manufacturer.   |  | Attention!   |
|  | Wear rubber gloves.   |  | Move in the direction indicated.   |
|  | Machine washable.   |  | Move fully to the stop, in the direction indicated.                            |
|  | Sterilisable in an autoclave up to the specified temperature. |  | After initial mechanical resistance, fully tighten in the direction indicated. |
|  | CE Marking with number of the notified body.                  |  | To-and-fro movement.   |

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