

# Black Pearl Eco 3V & 4V

## Instruction

REF 2100026-0001/ENG



### English

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

### Type

Turbine type of hand piece. Supplied from the unit by hose via a specific connection.

### Description Black Pearl

Push-button grip, ball bearing, 1 spray.

### 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.

#### Coupling

Black Pearl Eco are attached with 3 or 4-hole couplings, fig. 1-2.

#### Rotation speed

Up to 310,000 rpm

#### Weight

Black Pearl Eco 3V: 51 g  
Black Pearl Eco 4V: 55 g

#### Air consumption output

Black Pearl Eco 3V: 32 normlitter/min on average  
Black Pearl Eco 4V: 29 normlitter/min on average

#### Water spray rate

150 ml/min to 200 kPa (29 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.

### Using

#### Required air pressure

Adjust the existing air pressure setting from 2.5 bar with the help of the Bien-Air Dental pressure gauge located between hose and connector, fig. 1-2.

Inspect the instrument for any obvious signs of damage either before each utilisation or if the instrument receives a shock. In the case of damage or shock, the instrument should then be returned for control to a Bien-Air Dental authorised service center.

#### ⚠ Important

A damaged instrument risks to malfunction resulting in an abnormal level of temperature.

#### ⚠ Important

The device must not be started without a bur inserted into the chuck. To avoid overheating of the

push-button, which could cause burns, it should not be pressed inadvertently while the instrument is rotating. Soft tissues (tongue, cheeks, lips etc.) must be protected by deflection with a retractor or a dental mirror.

#### Electrical safety

According to IEC 60601-1 standard (General safety for Medical Electrical Equipment), the device shall be classified as a class II type BF device. Associated terminology is defined in section 2.1.7 & 2.2.5 of the same document.

The following regulations as specified in IEC 60601-1 must be observed:

- "Protection against electrical shock".
- "Ingress of liquids".
- "Protection against excessive temperatures and other safety hazard".

#### Bur

Diameter of shaft 1.59 to 1.60 mm, type 3 in accordance with ISO 1797, max. length 21 mm (0.82 in), code 4-5 in accordance with ISO 6360-1.

#### Changing the bur

Push-button grip:

Press the push-button and, at the same time, withdraw the bur. To fit a new bur, press the pushbutton and insert the bur firmly home fig. 3.

#### Safety

Check that the tool stays in position with manual tension. Always wear gloves or suitable protective clothing when checking and using this equipment.

#### Seals replacement

Black Pearl Eco 3V: Remove the seal according to fig. 4 / Black Pearl Eco 4V: Remove the seal according to fig. 5

Removing seal, place it on the tubes and remount the attachment fig. 1-2.

### Maintenance

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

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

Can be sterilised (autoclavable): the turbine itself, but not the Unifix connections.

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

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.

#### 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.

### Cleaning

Use **Spraynet** cleaner fig. 6-7. Spray the inside and outside of the equipment to remove the residues and carefully clean the surfaces.

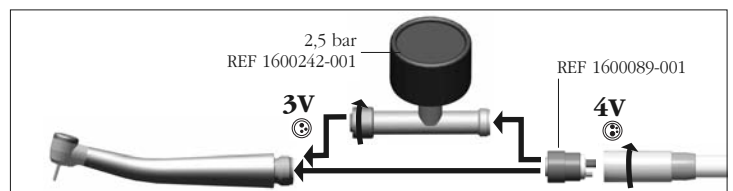


fig. 1

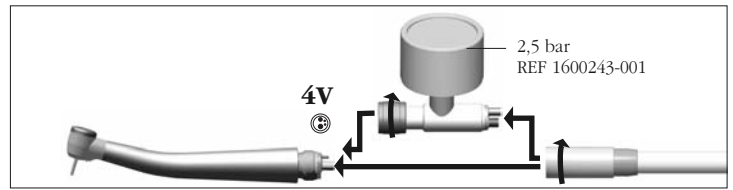


fig. 2

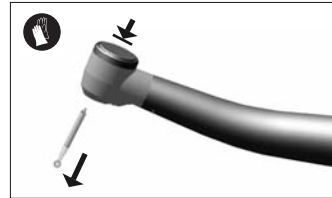


fig. 3

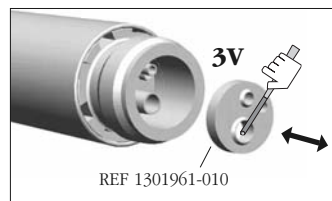


fig. 4

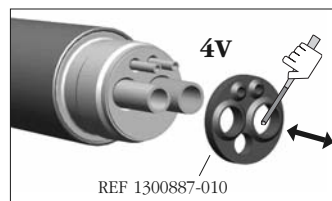


fig. 5

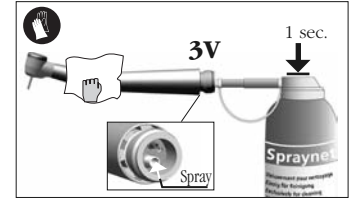


fig. 6

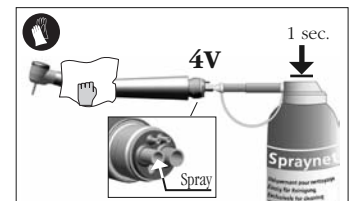


fig. 7



fig. 9

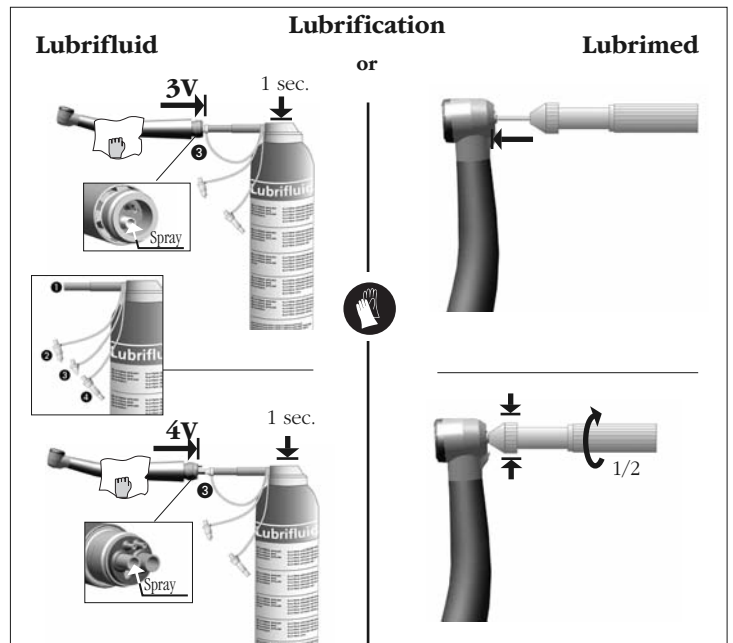


fig. 8

#### Disinfection

Disinfect using a clean cloth soaked in a suitable product. Products containing acetone, chlorine and bleaches are not recommended as disinfectants. Never immerse in disinfectant solutions. Not suitable for ultrasonic bath.

#### Before sterilisation

Remove residue, carefully clean the device. Lubricate instrument.

#### Lubrication

**Lubrication with Bien Air Dental products** shows **Lubrifluid** or **Lubrimead** medical grease.

Use either the one or the other for lubrication purposes (i.e. never mix them up) prior to every sterilisation procedure or a minimum of twice a day fig. 8.

#### With Lubrifluid spray.

- Remove tool from instrument gripper before lubrication
- Place the instrument in a cloth so as to catch the debris and foreign matter expelled by the atomizer jet.
- Insert the plastic nozzle ③ of the Lubrifluid fully into the back of the instrument sleeve.
- Spray for about 1 second

- or with **Lubrimed** medical grease and greaser.
- First-time use: Remove the cap, screw the knurled back-housing until the grease appears at the end of the rod. Wipe off surplus grease and replace cap after use.
  - Remove the bur and introduce the rod of the greaser to the bottom. The dose corresponds to one half-turn of the knurled backhousing. Use the guidemarks.

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

#### Cleaning of spray tubes fig. 9

Wire cleaner

#### 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.

#### 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.

After a period of prolonged use, the device must be cleaned and serviced according to these instructions.

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.

The device is not authorised for use in an explosive atmosphere (anaesthetic gas).

The device must not be used in the presence of open lesions, injury to the soft tissues or recent extrac-

tions. The exhaust air could propel infected material into the wounds and cause infections and risk of embolism.

#### 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
1600039-001	Black Pearl turbine Eco, push button and 3-hole fitting
1600040-001	Black Pearl turbine Eco, push button and 4-hole fitting
1301961-010	Seal 3V
1300887-010	Seal 4V
1600242-001	Gauge for 3-hole attachment
1600243-001	Gauge for 4-hole attachment
1000001-010	Wire probe, box of 10 wires
1600037-006	Lubrimed medical grease cartridges, box of 6 cartridges
1000003-001	Lubrimed greaser
1600036-006	Spraynet, cleaning spray 500 ml, box of 6 cans
1600064-006	Lubrifluid, lubricant 500 ml, box of 6 cans

#### Symbols

- Manufacturer.
- CE Marking with number of the notified body.
- Wear rubber gloves.
- 3-hole connection.
- 4-hole connection.
- Attention.
- Machine washable.
- Sterilisable in autoclave up to the specified temperature.
- Move in the direction indicated.
- Move fully to the stop, in the direction indicated.

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 1600039-001 TUR BLACK PEARL ECO 3H /  
REF 1600040-001 TUR BLACK PEARL ECO 4H

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

Aquilon®	Gyro®	MX®
Bora®	Gyrolina®	PowerCar®
Boralina®	Isolite®	Prestilina®
ChiroPro®	Lubrifluid®	Spraynet®
Eolia®	Lubrimed®	

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

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#### Set supplied



**Black Pearl Eco 3V**

REF 1600039-001



**Black Pearl Eco 4V**

REF 1600040-001

#### Optional accessories



10x

REF 1301961-010



10x

REF 1300887-010



3-hole

REF 1300243-010



4-hole

REF 1300242-010



10x

REF 100000-010



REF 1600037-006



REF 1000003-001



6x

REF 1600036-006



6x

REF 1600064-006