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

**Type**
Dental straight handpiece, with external spray, without light, 2x multiplier.

**Intended use**
Product intended for professional use only. Used in dentistry, for restoration and extraction work on wisdom teeth as well as for apex resection. 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. This medical device is in compliance with the legislation in force. USA: RX only. Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

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

**Drive**
The HP 1.2 can be coupled to a micromotor of the ISO Standard 3964 type.

**Motor speed**
max. 40,000 rpm.

**Transmission ratio**
Red instrument sleeve, 2x multiplier.

**Rotation speed**
max. 80,000 rpm.

**Dimensions**
Overall length: 110 mm (4.33 in).
Max. diameter: 19.8 mm (0.78 in).
Weight: 95 g.

**Bur Guard (single use nose tip)**
Dynamic and sterile blister-packed nose tip which prevents liquid or particles from entering the HP 1.2.

**Bur**
Diameter of shaft 2.35 mm type 2, in accordance with ISO 1797, max. length 45.5 mm code 4, in accordance with ISO 6866/1.

**Using the handpiece**

**Changing the bur**
Rotate the sleeve and remove the bur fig. 4 (A loose fig. 4 B tighten fig. 5). Disconnect the flexible hose, remove the spray nozzle and remove the single use Bur Guard.

**Discard the Bur Guard; it cannot be re-used, fig. 6**

**Warning:** Before inserting a bur in the attachment, the Bur Guard must be fitted.

**Caution:** check that Bur Guard packaging is intact and also check the expiry date, fig. 1.

The Bur Guard must be fully inserted in the nose of the handpiece, fig. 3 step 1 and second with the spray nose firmly attached, fig. 3 step 2. Connect the flexible hose for the irrigation line.

Fully insert the bur fig. 5 step 1.

Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance fig. 5 step 2.

**Each time a bur is inserted,** check that the clamping sleeve is fully tightened by moving the bur back and forth fig. 5 step 3.

**Recommendations**
Follow the recommendations provided by the bur manufacturer.

**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/un-clamping 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 length 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.

**Spray HP 1:2**
The spray tube, connects the hand-piece to the motor. The socket, which holds the spray tube, is detachable.

The single use Bur Guard is supplied sterile, in individual blister packs.

**Important**
Undue reuse of the single use Bur Guard may lead to contamination of the patient.

**Maintenance**

**Important**
- The instrument is supplied “non sterile”. Bur Guards are supplied sterile and individually blister-packed.
- Before first use and within 30 minutes of each treatment, the attachment must be cleaned and disinfected without the Bur Guard fitted, and then sterilised. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked due to the use of physiological liquid.
- Clean, disinfect and sterilise without the Bur Guard fitted. The Bur Guard cannot be reused; it must be replaced with each new patient treatment.
- The spray nozzle must be cleaned, disinfected and sterilised in the same way as the attachment.
- Only attachments marked with the logo [X] can be cleaned in a washer-disinfector.
- Do not immerse in an ultrasonic cleaner.
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. The use of other products and parts could result in operating faults and/or invalidation of the warranty.

**Precautions of use:**
The standard precautions in particular wearing individual protection equipment (gloves, glasses, shoes, mask, . . .) must be complied with by healthcare personnel working with contaminated or potentially contaminated and medical instruments. Pointed and sharp instruments should be handled with great caution.

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.

**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, without a bur and without a Bur Guard installed.

**Suitable detergent**
For automatic cleaning-disinfection:
- Slightly alkaline enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments.

**Manual cleaning-disinfection:**
- Aquacare and Spraynet
- Detergent or detergent-disinfectant (pH 6-9.5) recommended for cleaning-disinfection of dental and 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.

**Pre-disinfection (at place of operation)**

**Preparation**
- Disconnect the drive motor attachment, rotate the sleeve, remove the bur and leave the sleeve loosened fig. 4.
- Disconnect the flexible hose, remove the spray nozzle and remove the single use Bur Guard. Disconnect the Bur Guard; it cannot be reused, fig. 6.
- Carry out manual pre-cleaning or pre-clean in a cleaner.

**Manual pre-cleaning**
Use Aquacare cleaning product.
- Spray the Aquacare for 1 second in the spray nose tube to expel residue and remove residual physiological liquid fig. 7.

- Spray for 1 sec on the inside and outside of the attachment, remove of residues and any remaining physiological liquid fig. 7.
- Carefully clean the surfaces.
- Leave to drip-dry and wipe the outside surfaces with absorbent paper or immediately proceed with step no 2.

**Cleaning and disinfection**

**Manual cleaning-disinfection**
Dip the instrument in a tank containing appropriate detergent and, using a soft-bristled brush, clean and disinfected, clean the outside of the instrument in accordance with the instructions of the detergent manufacturer (time, concentration, temperature, renewal, etc.).

**Spraying:**
Spray the interior and outside of the device with cold running water (< 35°C/< 95°F) for about 30 seconds.

**Cleaning:**
Spray the interior of the instrument with Spraynet product fig. 8 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.

**Automatic cleaning-disinfection**

**Caution:** only for devices engraved with [X]

**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.

**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°F) – Duration 5 mins.

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

**Important:**
Never rinse the devices to cool them.

**Lubrication, checks and conditioning process**

**Verifying cleanliness:**
Visually inspect the cleanliness of the attachment and the spray nozzle. If required, re-clean with a soft brush.

**Lubrication:**
Use Lubrifluid lubricant spray from Bien-Air Dental.
- Place the instrument in a cloth to collect all surplus lubricant.
- Insert the spray tip in the back of the instrument handle fig. 9.
- Operate the spray for 1 sec.

**Bur locking operation check**
- Fully insert the bur fig. 10A step 1.
- Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance fig. 10A step 2.
- Each time a bur is inserted, check that the clamping sleeve is fully tightened by moving the bur back and forth fig. 10B.
- Hold the handpiece upright by the bur between your thumb and index finger fig. 10C and rotate the handpiece; the handpiece should rotate freely (more than 3 rotations).
- Rotate the sleeve and remove the bur to sterilise and leave unlocked in the open position fig. 10D.

**Warning**
- If the handpiece does not rotate freely, there is a risk of burns to the patient.
- Never disassemble the device. For any modification or 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.

**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 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.

**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. Duration: 3 or 18 minutes, depending on the national requirements 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 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.

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.

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

**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.
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.

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List of Bien-Air Dental SA registered trade mark products ®:
Aquilon® Eolia® Lubrifluid® Prestilina®
Bora® Gyro® Lubrimed® Spraynet®
Boralina® Gyrolina® MX®
ChiroPro® Isolute® PowerCare®

Symbols

Manufacturer. To-and-fro movement.
Wear rubber gloves. Move in the direction indicated.
Machine washable. Move fully to the stop, in the direction indicated.
Caution! After initial mechanical resistance, fully tighten in the direction indicated.

Sterilisable in an autoclave.

Rx Only
Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

Sterilised using ethylene oxide.

CE Marking with number of the notified body.

Do not reuse.