

HP 1:2

Instruction

REF 2100103-0003/2019.02



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.

Typical operating torque

1.5 Ncm.

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, fig. 1.

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. 2.

Bur max. diameter

2 mm.

⚠ Important

The handpiece must not receive pressurised cooling air from the unit, to prevent contamination of the rea being treated.

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 indi-

cated on the back cover.

Using the handpiece

Changing the bur

Rotate the sleeve fig. 3 step A and remove the bur fig. 3 step B. Disconnect the flexible hose, remove the spray nose fig. 4 step A and remove the single use Bur Guard fig. 4 step B.

Discard the Bur Guard; it cannot be reused, fig. 4 step C.

⚠ Warning: Before inserting a bur in the attachment, the Bur Guard must be fitted fig. 5.

⚠ 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. 5 step A, and secured with the spray nose firmly attached fig. 5 step B. Connect the flexible hose for the irrigation line.

Fully insert the bur fig. 6 step A.

Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance fig. 6 step B.

Clamp operation inspection

⚠ Each time a bur is inserted, check that the clamping sleeve is fully tightened by moving the bur back and forth fig. 6 step C.

• Hold the handpiece upright by the bur between your thumb and index finger fig. 4 and rotate the handpiece; the handpiece should rotate freely (more than 3 rotations).

⚠ 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.

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 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.

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 nose must be cleaned, disinfected and sterilised in the same way as the attachment.
- Only attachments marked with the logo 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 ...), must be complied with by healthcare personnel working with contaminated or potentially contaminated 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.

For manual cleaning-disinfection:

- Aquacare and 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.

Ⓞ Pre-disinfection (at place of operation)

Preparation

- Disconnect the drive motor attachment, rotate the sleeve, remove the bur and leave the sleeve loosened fig. 3.
- Disconnect the flexible hose, remove the spray nose and remove the single use Bur Guard. Discard the Bur Guard; it cannot be reused, fig. 4.
- Carry out manual pre-cleaning or pre-clean in a cleaner.
- Verify that the chuck mechanism is open and that the bur is removed.

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. 8.
- Spray for 1 sec. on the inside and outside of the attachment remove of residues and any remaining physiological liquid fig. 8.
- Carefully clean the surfaces.
- Leave to drip-dry and wipe the outside surfaces with absorbent paper or immediately proceed with step no 2.

or

Pre-cleaning by bath

⚠ Warning: the preliminary bath cleaning should be followed by automatic cleaning-disinfection.

- Totally submerge the instrument in a cleaning bath containing the suitable detergent following the manufacturer's instructions (duration, concentration, temperature, renewal...).
- After the bath, rinse the inside and outside of the device in cold running water (<35°C/ <95°F) for about 30 seconds.
- Leave to drip-dry and wipe the outside surfaces with absorbent paper or immediately proceed with automatic cleaning-disinfection.

Ⓞ 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 instructions of the detergent manufacturer (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 seconds.

Drying:

Spray the interior of the instrument with Spraynet product fig. 9 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

⚠ Caution: only for devices engraved with

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 206.6°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.

Ⓞ Lubrication, checks and conditioning process

Verifying cleanliness

Visually inspect the cleanliness of the attachment and the spray nose. 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. 10**.
- Operate the spray for 1 sec.

Conditioning process

Wrap the instrument and the spray nose 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 (275°F). 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 center 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 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. Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

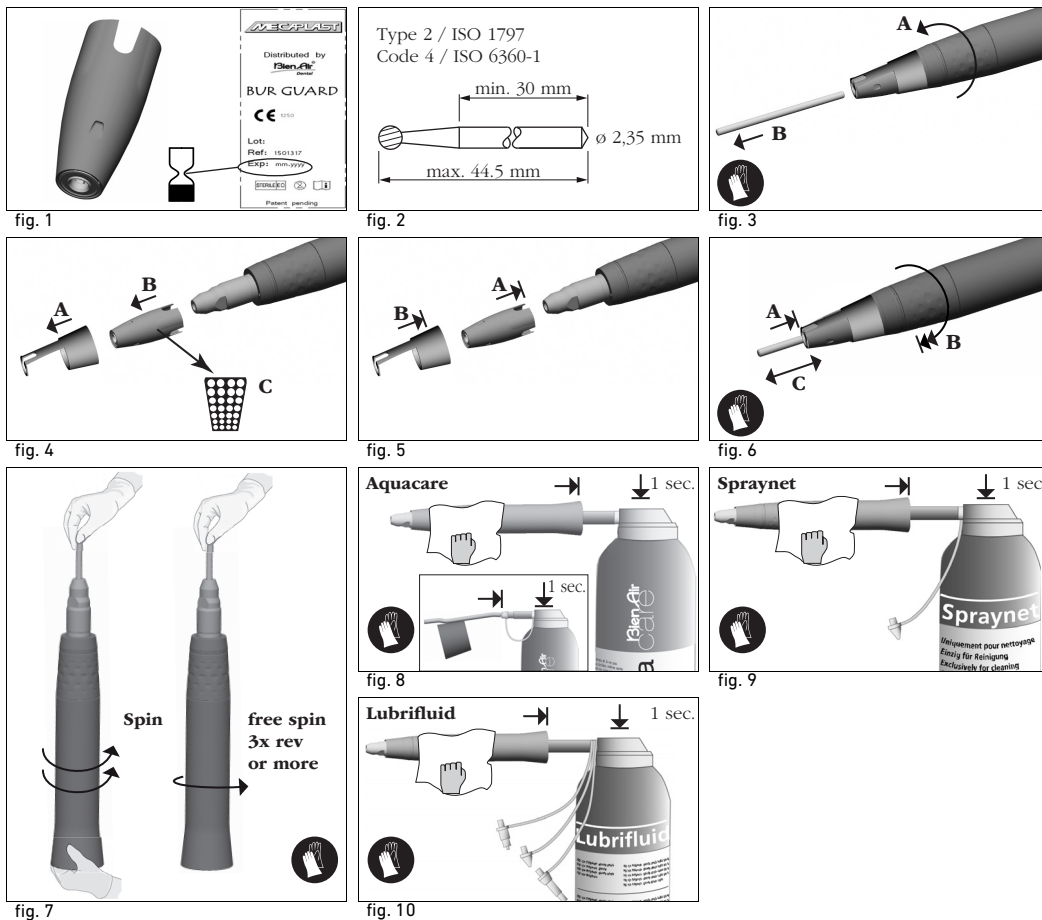
Bien-Air Dental shall not be held responsible for damage or injury and the consequences thereof, resulting from:

- 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.



Set supplied



HP 1:2
REF 1600436-001



1x
REF 1501318-001



10x Bur Guard



1x
REF 1502158-001

Optional accessories



100x

REF 1501317-100



6x

REF 1600617-006



6x

REF 1600036-006



6x

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 1600436-001 HP 1:2 SPRAY EXT

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, micro-motor, tube, electronics, connectors, station etc.

REF	Legend
1600436-001	HP 1:2 straight handpiece (x2 multiplier), 2 detachable external spray nose, 10 sterile single use Bur Guards, 102 mm spray hose
1501317-100	Box of 100 sterile Bur Guards
1501318-001	Detachable spray nose with irrigation for HP 1:2
1502158-001	Detachable spray nose for HP 1:2
1600617-006	Aquacare, cleaning spray for physiological liquid 500 ml, box of 6
1600036-006	Spraynet, cleaning spray 500 ml, box of 6 cans
1600064-006	Lubrifiuid, lubricant 500 ml, box of 6 cans
2100103-0001	Instruction

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 up to the specified temperature.		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.		

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