ENG INSTRUCTIONS FOR USE.

Other languages available on www.bienair.com/ifu
Set supplied (REF) CA 1:5

Set supplied (REF) CA 1:1

Set supplied (REF) CA 10:1

Set supplied (REF) HP 1:1

Optional accessories (REF)
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## 1 Symbols

### 1.1 Description of symbols used

<table>
<thead>
<tr>
<th>Sym</th>
<th>Description</th>
<th>Sym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer.</td>
<td><img src="image" alt="Reference" /></td>
<td>Reference number.</td>
</tr>
<tr>
<td><img src="image" alt="CE Marking" /></td>
<td>CE Marking with number of the notified body.</td>
<td><img src="image" alt="Serial Number" /></td>
<td>Serial number.</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION" /></td>
<td>Separate collection of electric and electronic equipment.</td>
<td><img src="image" alt="Recyclable Materials" /></td>
<td>Recyclable materials.</td>
</tr>
<tr>
<td><img src="image" alt="4-way Fitting" /></td>
<td>4-way fitting.</td>
<td><img src="image" alt="Use Rubber Gloves" /></td>
<td>Use rubber gloves.</td>
</tr>
<tr>
<td><img src="image" alt="Electric Power" /></td>
<td>Electric powered 4-way fitting (4VLM).</td>
<td><img src="image" alt="After Mechanical Resistance" /></td>
<td>After initial mechanical resistance, tighten fully in the direction indicated.</td>
</tr>
<tr>
<td><img src="image" alt="Thermo Washer" /></td>
<td>Thermo washer disinfectable.</td>
<td><img src="image" alt="Back and Forth Movement" /></td>
<td>Back and forth movement.</td>
</tr>
<tr>
<td><img src="image" alt="Movement Direction" /></td>
<td>Movement in the direction indicated.</td>
<td><img src="image" alt="Sterilisation Temperature" /></td>
<td>Sterilisation up to the specified temperature.</td>
</tr>
<tr>
<td><img src="image" alt="Movement to Stop" /></td>
<td>Movement to the stop in the direction indicated.</td>
<td><img src="image" alt="Light" /></td>
<td>Light.</td>
</tr>
</tbody>
</table>
2 Identification & Intended Use

2.1 Identification
Medical device manufactured in Switzerland by Bien-Air Dental SA.

Type
Dental contra-angles (CA), push-button bur locking, 3 sprays (4 mixed sprays on the EVO.15 range) with or without light.

2.2 Classification
Class IIa according to European Directive 93/42/EEC relating to medical devices. This medical device complies with the legislation in force.

2.3 Intended use
Product intended for professional use only. Used in general dentistry and oral surgery.

⚠️ CAUTION
The contra-angle must not receive pressurized cooling air from the unit, in order to prevent contamination of the wound.
Any use other than that for which this device is intended is prohibited and may prove dangerous.
- CA 1:1, CA 10:1 and EVO.15 1:1 for prophylaxis, restoration and endodontic procedures.
- CA 1:5, EVO.15 1:5 and HP 1:1 for general dentistry and restoration procedures.

⚠️ CAUTION
The device must not be used if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air current could propel infected material into the wounds, causing infection and a risk of embolism.
3 Precautions for use

This medical device accessory must be used by a competent person, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and these instructions for use.

In accordance with these provisions, the user is responsible for ensuring he or she only uses devices which are in perfect working order.

In the event of irregular operation, excessive vibrations, abnormal heating or other signs suggesting that the device is malfunctioning, work must be suspended immediately.

In this case, contact a repair centre approved by Bien-Air Dental SA.

⚠️ CAUTION
Install the device on an appropriate outlet to protect against the risk of injury or infection.

⚠️ CAUTION
Medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated must comply with universal precautions, in particular the wearing of personal protective equipment (gloves, goggles, etc.). Pointed and sharp instruments should be handled with great care.

⚠️ CAUTION
Any excess maintenance product (lubricant, cleaning and disinfection products) present on the contra-angle could find its way into the electric brush motor and adversely affect its operation. Always observe the maintenance instructions provided with each product. Never lubricate the electric brush motor.

Note: The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim.

For any further information, please contact Bien-Air Dental SA at the address given on the back cover.
4 Description

4.1 Overview

FIG. 1

(1) Centering for the micromotor
(2) Light output
(3) Bur (not supplied)
(4) Transmission ratio marking strip
(5) Push-button

Electric power supply
VDC or VAC: 3.4 ±0.3 V. The power supply systems must be in compliance with IEC 60601-1 and IEC 60601-1-2 standards.

4.2 Technical data

<table>
<thead>
<tr>
<th>Contra-angle</th>
<th>1:1</th>
<th>1:5</th>
<th>10:1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard coupling</td>
<td>As per ISO standard 3964 and Micro-Series version.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drive speed</td>
<td>40'000 rpm max.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speed of rotation</td>
<td>40'000 rpm max.</td>
<td>200'000 rpm max.</td>
<td>4'000 rpm max.</td>
</tr>
<tr>
<td>Typical operating torque</td>
<td>3 Ncm</td>
<td>1 Ncm</td>
<td>3 Ncm</td>
</tr>
<tr>
<td>Cooling Air consumption (imposed)</td>
<td>8 - 10 NL/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooling air pressure</td>
<td>250 - 490 kPa (depending on motor)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray water consumption</td>
<td>70 ml/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray air consumption</td>
<td>2 NL/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray water pressure</td>
<td>200 kPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spray air pressure</td>
<td>200 kPa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Bur chuck

**FIG. 2**
Tip diameter 2.35 mm, type 1 as per ISO 1797-1, max length 22 mm, code 4 as per ISO 6360-1 for the 1:1 and 10:1 ranges (max. working diameter 3 mm). Tip diameter 2.35 mm, type 3 as per ISO 1797-1, max length for short to long types 21 mm, code 4 as per ISO 6360-1 for the 1:5 range (max. working diameter 2 mm).

**FIG. 3**
Tip diameter 2.35 mm, type 2 as per ISO 1797-1, max length for short to long types 45 mm, code 4 as per ISO 6360-1 for the HP 1:1 (max. working diameter 3 mm).

⚠️ **CAUTION**
Follow the guidelines for use, according to the bur manufacturer’s instructions. Never use a bur if the tip is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, and the patient or third parties.
5 Operation

5.1 Changing the bur
CA 1:1, CA 1:5, CA 10:1, EVO.15 1:1 and EVO.15 1:5

FIG. 4
Push-button bur locking.
1. Press the push-button and simultaneously pull the bur.
2. Press the push-button, insert the new bur until locked in place and release the push-button.
3. Check that the bur rotates freely and check it is locked by gently pushing and pulling the bur.

HP 1:1

FIG. 5
1. Rotate the sleeve and remove the bur.
2. Fully insert the bur. Lock the bur changing mechanism by fully rotating the sleeve, it can be fully tightened after initial mechanical resistance.
3. Each time a bur is inserted, check that the clamping sleeve is fully tightened by moving the bur back and forth.

⚠️ CAUTION
Never insert a device on a rotating micromotor.

⚠️ CAUTION
Always ensure that the spray outlets are not obstructed.

⚠️ CAUTION
Always check that the bur is in place and rotates freely. If it does not, contact your usual supplier or Bien-Air Dental SA for repair.
6 Cleaning and servicing

6.1 Maintenance
Clean, lubricate and sterilise the device separately between patients.

⚠️ CAUTION
The instrument is supplied “non sterile”.

6.1.1 Precautions for maintenance
- Before first use and IMMEDIATELY after each procedure, clean, lubricate and sterilise the device.
- 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 marked with the logo can be cleaned in a washer-disinfector machine.
- Do not immerse in an ultrasonic cleaner.
- Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. Using other products or parts may cause faults during operation and/or void the warranty.

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

6.1.2 Suitable maintenance products

Automatic cleaning-disinfection:
Low alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 6 - 9.5).

Manual cleaning-disinfection:
- Spraynet.
- Aquacare.
- Detergent or detergent-disinfect (pH 6 - 9.5) recommended for cleaning-disinfection of dental or surgical instruments. Surface-active quaternary enzymatic/ammonium detergent.

⚠️ CAUTION
- Do not use detergents that are corrosive or contain chlorine, acetone aldehydes or bleach.
- Do not submerge in physiological liquid (NaCl).
- Check that both the steriliser and water used are clean. After each sterilisation cycle, remove the device from the sterilisation unit immediately to reduce the risk of corrosion.
6.2 Preliminary cleaning

Preparation
1. Disconnect the device from the coupling and remove the bur (FIG. 3 step 1).

⚠️ CAUTION
If there is a large amount of debris, clean the exterior of the device with disinfectant wipes. Observe the instructions given by the manufacturer.

FIG. 6, FIG. 7
1. Unblock the spray tubes using the Bien-Air Dental SA cleaning wire.
2. Carry out manual preliminary cleaning (see 6.2.1, on page 11).

6.2.1 Manual preliminary cleaning
1. Spray the exterior and interior of the device for 1 second with Spraynet. Carefully clean the surfaces using a soft cloth. Disinfectant wipes may also be used.
2. Leave any liquid residue to drip-dry, then wipe the exterior with a paper towel or move onto the cleaning-disinfection step immediately (see , on page 1).
6.3 Cleaning-disinfection

6.3.1 Manual cleaning/disinfection

**FIG. 8**

1. Dip the device in a tank containing appropriate detergent and, using a soft brush, clean and disinfect the device, clean the exterior of the device in accordance with the instructions of the detergent manufacturer (time, concentration, temperature, renewal, etc.)

2. Rinse the interior and exterior of the device with demineralised water (<38°C) for 30 seconds.

3. Spray the interior of the device with Spravnet to remove the rinsing water immediately, which will prevent damage to or blockage of the internal components, then dry the exterior surfaces with paper towels.

6.3.2 Automatic cleaning-disinfection

⚠️ **CAUTION**

Only for device engraved with 🏬

**Washer-disinfector**

Carry out automatic cleaning-disinfection using an approved washer-disinfector which complies with ISO standard 15883-1 (e.g. Miele G 7781/G 7881 or Steris Hamo LM-25).

**Detergent and washing cycle**

Use a low alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 6 - 9.5) (e.g.: neodisher® mediclean).

Select the washing cycle recommended for the device and compatible with the detergent manufacturer’s indications (e.g.: VARIO-TD).

⚠️ **CAUTION**

Never cool devices by rinsing them.
6.4 Lubrication

6.4.1 Verifying cleanliness
Visually inspect the device to ensure it is clean. If necessary, clean again using a soft brush.

6.4.2 Lubrication
Lubricate before each sterilisation or at least twice a day. Only the Lubrifluid spray must be used.

**FIG. 9**
1. Remove the bur from the device, and place the device in a cloth to collect the excess.
2. Select the appropriate end-piece.
3. Insert the end-piece of the can Lubrifluid in the rear of the device’s handle.
4. Actuate the spray for 1 second, and clean the excess oil on the exterior.

6.5 Sterilisation

⚠️ CAUTION
The quality of the sterilisation is highly dependent on how clean the instrument is. Only perfectly clean instruments may be sterilised.

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

Procedure
Enclose the device and its accessories in sterilisation bags which are large enough to ensure the items can move around, and which comply with the standards in force (e.g.: EN 868-5). Sterilise using steam on a class B cycle as per EN 13060 / ISO 17665-1.

**Note:** All Bien-Air Dental SA instruments are sterilisable in an autoclave up to 135°C. *Duration: 3 or 18 minutes, depending on the national requirements in force.*

**FIG. 10**
After cleaning, disinfecting and sterilising the device, and before using it, start it up at moderate speed with a bur in the locking mechanism for 10 to 15 seconds to distribute and remove the excess lubricant.

6.6 Servicing

**Note:** Bien-Air Dental SA recommends that the user has his or her dynamic devices checked or serviced every three years.
7 Packing & disposal

7.1 Transport and storage conditions
There are no particular transport and storage conditions required.

Packing
Pack the device in packaging approved for steam sterilisation.

⚠️ CAUTION
If not to be used for a prolonged period, the device must be stored in a dry environment. Clean, lubricate and sterilise the instrument before reuse.

7.2 Disposal

The disposal and/or recycling of materials must be performed in accordance with the legislation in force.

The CA and EVO contra-angles must be recycled. In order to avoid any risk of environmental contamination, the user must return the device to his dealer or contact an authorized body for the treatment and recovery of this type of equipment.

8 General information

8.1 Terms of guarantee
Bien-Air Dental SA grants the user a warranty covering any operating fault, or material or manufacturing defect.

The warranty period is:
- 12 months for the CA 10:1 range
- 24 months for the CA 1:1, CA 1:5, HP 1:1 and EVO.15 ranges from the date of invoicing.

In the event of a justified claim, Bien-Air Dental SA or its authorised representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, are excluded.

Bien-Air Dental SA cannot be held liable for damage or injury and the consequences thereof, resulting from:

- Excessive wear and tear
- Infrequent or improper use
- Failure to observe the servicing, assembly or maintenance instructions
- Damage caused by unusual chemical, electrical or electrolytic influences
- Faulty air, water or electrical connections.
⚠️ **CAUTION**

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorised by Bien-Air Dental SA. Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

### 8.2 References

Translated from original French Instructions for use.

#### 8.2.1 Set supplied (see cover)

<table>
<thead>
<tr>
<th>REF</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600939-001</td>
<td>EVO.15 1:1L (light)</td>
</tr>
<tr>
<td>1600938-001</td>
<td>EVO.15 1:1L Micro-Series</td>
</tr>
<tr>
<td>1600941-001</td>
<td>EVO.15 1:5L (light)</td>
</tr>
<tr>
<td>1600940-001</td>
<td>EVO.15 1:5L Micro-Series</td>
</tr>
<tr>
<td>1600384-001</td>
<td>CA 10:1 (light)</td>
</tr>
<tr>
<td>1600424-001</td>
<td>CA 10:1 (without light)</td>
</tr>
<tr>
<td>1600385-001</td>
<td>CA 10:1 (light)</td>
</tr>
<tr>
<td>1600425-001</td>
<td>CA 10:1 (without light)</td>
</tr>
<tr>
<td>1600691-001</td>
<td>CA 10:1 Micro-Series (light)</td>
</tr>
<tr>
<td>1600386-001</td>
<td>CA 10:1 (light)</td>
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<td>1600325-001</td>
<td>CA 10:1 (without light)</td>
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<tr>
<td>1600690-001</td>
<td>CA 10:1L Micro-Series (light)</td>
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<tr>
<td>1600383-001</td>
<td>HP 1:1 Standard</td>
</tr>
<tr>
<td>1600693-001</td>
<td>HP 1:1 Micro-Series</td>
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#### 8.2.2 Optional accessories (see cover)

<table>
<thead>
<tr>
<th>REF</th>
<th>Legend</th>
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<tbody>
<tr>
<td>1600036-006</td>
<td>Spraynet, 500ml cleaning spray, box of 6</td>
</tr>
<tr>
<td>1600064-006</td>
<td>Lubrifluid, 500ml spray lubricant oil, box of 6</td>
</tr>
<tr>
<td>1600001-010</td>
<td>Cleaning wire, box of 10</td>
</tr>
</tbody>
</table>