CA 1:2.5 L MS

ENG INSTRUCTIONS FOR USE

Other languages available on www.bienair.com/ifu
Set supplied (REF) CA 1:2.5 L MS

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1601055-001</td>
<td>Set supplied (REF) CA 1:2.5 L MS</td>
</tr>
</tbody>
</table>

Optional accessories (REF)

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
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<tr>
<td>1600617-006</td>
<td>Optional accessories (REF)</td>
</tr>
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<td>1600036-006</td>
<td>Optional accessories (REF)</td>
</tr>
<tr>
<td>1600064-006</td>
<td>Optional accessories (REF)</td>
</tr>
<tr>
<td>1000001-010</td>
<td>Optional accessories (REF)</td>
</tr>
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# 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="CE Marking" /></td>
<td>CE Marking with number of the notified body.</td>
</tr>
<tr>
<td><img src="image" alt="Reference number" /></td>
<td>Reference number.</td>
<td><img src="image" alt="Serial number" /></td>
<td>Serial number.</td>
</tr>
<tr>
<td><img src="image" alt="WARNING" /></td>
<td>WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.</td>
<td><img src="image" alt="Medical Device" /></td>
<td>Medical Device.</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION" /></td>
<td>CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.</td>
<td><img src="image" alt="Recyclable materials" /></td>
<td>Recyclable materials.</td>
</tr>
<tr>
<td><img src="image" alt="Use rubber gloves" /></td>
<td>Use rubber gloves.</td>
<td><img src="image" alt="After initial mechanical resistance, tighten fully in the direction indicated" /></td>
<td>After initial mechanical resistance, tighten fully in the direction indicated.</td>
</tr>
<tr>
<td><img src="image" alt="Thermo washer disinfectable" /></td>
<td>Thermo washer disinfectable.</td>
<td><img src="image" alt="Sterilisation up to the specified temperature" /></td>
<td>Sterilisation up to the specified temperature.</td>
</tr>
<tr>
<td><img src="image" alt="Movement in the direction indicated" /></td>
<td>Movement in the direction indicated.</td>
<td><img src="image" alt="Movement to the stop in the direction indicated" /></td>
<td>Movement to the stop in the direction indicated.</td>
</tr>
<tr>
<td><img src="image" alt="Back and forth movement" /></td>
<td>Back and forth movement.</td>
<td><img src="image" alt="Light" /></td>
<td>Light.</td>
</tr>
<tr>
<td><img src="image" alt="Warning" /></td>
<td>Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.</td>
<td></td>
<td>Refer to the accompanying documents.</td>
</tr>
<tr>
<td><img src="image" alt="Rx Only" /></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Note: The symbols above are indicative of the types of warnings and information provided in the document.*
2 Identification & Intended Use

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

Type
Contra-angle handpiece (CA) speed multiplier ratio with light and external irrigation.

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

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

⚠️ WARNING
Any use other than that for which this device is intended is prohibited and may prove dangerous.

⚠️ WARNING
The contra-angle must not receive pressurized cooling air from the unit, in order to prevent contamination of the wound.
3 Precautions for use

Those medical devices 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, unusual noise 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.

⚠️ WARNING
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
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.

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) Bür (not supplied)
(4) Transmission ratio marking clip
(5) Push-button

4.2 Technical data

<table>
<thead>
<tr>
<th>Contra-angle</th>
<th>1:2.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard coupling</td>
<td>As per ISO standard 3964*</td>
</tr>
<tr>
<td>Drive speed</td>
<td>40 000 rpm max.</td>
</tr>
<tr>
<td>Speed of rotation</td>
<td>100 000 rpm max.</td>
</tr>
<tr>
<td>Typical operating torque</td>
<td>1.5 Ncm</td>
</tr>
<tr>
<td>Transmission ratio</td>
<td>Red instrument sleeve, 2.5x multiplier.</td>
</tr>
<tr>
<td>Length</td>
<td>88 mm</td>
</tr>
</tbody>
</table>

(*) The contra-angle can only be operated on dental motors with an ISO coupling measuring no longer than 23 mm.
Bur chuck

**FIG. 2**
Shaft diameter 1.60 mm, type 3 as per ISO 1797-1, recommended length 21 mm* code 4/5 as per ISO 6360-1 for the 1:2.5 range (Maximum working diameter 2 mm).

(*) When using longer rotary instruments (e.g. 25 mm surgical burs) the user must ensure, by selecting the correct operating conditions, that there is no danger to the user, patient or third parties.

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

5.1  Changing the bur

FIG. 3
Push-button bur locking.

1. Press the push-button and simultaneously pull out the bur.

2. Press the push-button, insert the new bur all the way to the stop and release the push-button.

3. Check that the bur rotates freely and that it is locked by gently pushing and pulling the bur.

⚠️ WARNING
The use of a coolant while the instrument is in operation is mandatory, failure to comply with this recommendation may result in overheating and burns or product failure. Set the water quantity for the cooling spray to at least 60 ml / min.

⚠️ CAUTION
The device must not be started without a bur inserted. 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.

⚠️ CAUTION
Never insert or remove a device while the micromotor is rotating.

⚠️ WARNING
Do not touch the dental bur while it is rotating.

⚠️ CAUTION
Never press the push-button while the instrument is in operation.

⚠️ CAUTION
Always check that the bur is in place and rotates freely. If it is blocked, contact your usual supplier or Bien-Air Dental SA for repair.

⚠️ CAUTION
Always ensure that the spray outlets are not obstructed.
6 Cleaning and servicing

6.1 Maintenance - General information
Clean, lubricate and sterilise the device between each patients.

⚠️ WARNING
The instrument is supplied "non sterile".

6.1.1 Precautions for maintenance
- 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.
- Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. For suitable maintenance products refer to section 6.1.2 Suitable maintenance products. Using other products or parts may cause faults during operation and/or void the warranty.

⚠️ CAUTION
- Carry out cleaning-disinfection-sterilisation without a bur in the chuck mechanism.
- Do not immerse in an ultrasonic cleaner.
- Do not submerge in physiological liquid (NaCl).
- Do not use detergents that are corrosive or contain chlorine, acetone aldehydes or bleach.
- Do not use a steam steriliser with a gravity displacement system.

6.1.2 Suitable maintenance products

Manual cleaning-disinfection:
- Spraynet.
- Aquacare.
- Alkaline detergent or detergent-disinfectant (pH 8-11) recommended for cleaning-disinfection of dental or surgical instruments. Disinfectant products composed either of di-decyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product. (e.g. Neodisher® mediclean) are also allowable.

Automatic cleaning-disinfection:
- Use an alkaline product recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).
6.2 Cleaning

Preparation
1. Disconnect the device from the electrical motor and remove the bur (FIG. 4 step 1).

Remove dirt / deposits
FIG. 4 step 1 and 2
1. Clean under tap water at 15°C-38°C.
2. Carefully remove all traces of dirt or deposits from the nozzles using the Bien-Air cleaning wire (optional).
3. After selecting the appropriate end-piece, perform preliminary cleaning of the device by using the product Aquacare. Spray the inside and the outside of the device and inside the irrigation tube (see FIG. 5).
Internal and external cleaning

1. After selecting the appropriate end-piece, spray the inside and the outside of the device with the product Spraynet (FIG. 6 and FIG. 7).

2. Dry with non-woven compresses.
6.3 Disinfection

6.3.1 Manual cleaning / disinfection

1. Dip the device in a bath containing a disinfectant product (e.g. di-decyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product which are allowable chemical agents). Follow the concentration and duration recommended by the fabricant of the disinfection product.

2. Rub the device with a flexible brush.

3. Optional:
   - Rinse the device with demineralized and sterilized water at 15°C-38°C (59°F-100°F).
   - Perform additional cleaning and disinfection of the external surfaces with non-woven wipes impregnated with a disinfection product (e.g. di-decyldimethylammonium chloride).
   - Rinse the external surfaces with sterile non-woven compresses impregnated with sterile, demineralized water.

4. Eliminate the excess of disinfectant (e.g. foam residue) over the external surfaces of the device by spraying it with Spraynet and drying it with sterile non-woven compresses.

5. After selecting the appropriate nozzle, spray inside the device with Spraynet (FIG. 8).

6. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

6.3.2 Automatic disinfection

⚠️ CAUTION

Only for device engraved with ✖

Note: the automatic cleaning-disinfection can replace the previous steps 4 to 6.

Washer-disinfector

Carry out automatic cleaning-disinfection using an approved washer-disinfector which complies with ISO standard 15883-1.

Detergent and washing cycle

Use an alkaline or detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).
Recommended specifications for the thermo-disinfection cycle.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cleaning</td>
<td>&lt;45°C (113°F); ≥ 2 minutes</td>
</tr>
<tr>
<td>Cleaning</td>
<td>55°C-65°C (131°F-149°F); ≥ 5 minutes</td>
</tr>
<tr>
<td>Neutralization</td>
<td>≥ 2 minutes</td>
</tr>
<tr>
<td>Rinsing</td>
<td>Tap water, ≤30°C (86°F), ≥ 2 minutes cold water</td>
</tr>
<tr>
<td>Thermal Disinfection</td>
<td>Demineralized water, 90°C-95°C (194°F-203°F), 5-10 minutes</td>
</tr>
<tr>
<td>Drying</td>
<td>18-22 minutes</td>
</tr>
</tbody>
</table>

⚠️ **CAUTION**

Never cool devices by rinsing them.

⚠️ **CAUTION**

If an automatic washer is used at the place of the washer/thermo-disinfector, respect the previous program for the Pre-cleaning, Cleaning, Neutralization and Rinsing phases. If local tap water has pH outside the range 6.5-8.5 or contains more than 100 mg/l chloride (Cl-ion), do not dry the device inside the automatic washer but dry it manually with low linting textiles.
6.4 Lubrication

6.4.1 Verifying cleanliness
Visually inspect the device to ensure it is clean. Repeat the cleaning and disinfection procedure if necessary.

6.4.2 Lubrication with Lubrifluid

**FIG. 9**

1. Place the device in a non-woven, sterile compress to collect the excess of lubricant.
2. Select the appropriate nozzle.
3. Insert the nozzle of the Lubrifluid can in the rear of the device’s handle.
4. Activate the spray for 1 second, and clean the excess oil on the exterior with a sterile, non-woven compress.

6.5 Sterilisation

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

⚠️ CAUTION
Do not expose the device at the maximum temperature of 135°C (275°F) for more than 18 minutes.

Procedure

⚠️ CAUTION
Pack the device in a packaging approved for steam sterilisation.

⚠️ CAUTION
Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.

Sterilise using steam, following dynamic air removal cycle (ANSI/AAMI ST79, Section 2.19), i.e. air removal via forced evacuation (ISO 17665-1, ISO/TS 17665-2) at 135°C (275°F), during 3 minutes. In jurisdictions where sterilization for prions is required, sterilise at 135°C for 18 minutes.
6.6 Packing
The device must be stored inside the sterilisation pouch in a dry and dust-free environment. The temperature must not exceed 55°C (131°F). If the device will not be used for 7 days or more after the sterilisation, extract the device from the sterilisation pouch and store it in the original package. If the device is not stored in a sterilisation pouch or if the pouch is no longer sterile, clean, lubricate and sterilise the device before using it.

⚠️ CAUTION
If the medical device has been stored refrigerated, allow it to warm up to room temperature prior to its use.

⚠️ CAUTION
Comply with the expiration date of the sterilised items which depends on the storage conditions and type of packaging.

6.7 Servicing

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

7 Transport & disposal

7.1 Transport and storage conditions
Follow the general requirements applicable for micromechanical devices.

7.2 Disposal

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

All contra-angles and handpieces must be recycled. In order to avoid any risk of contamination, the user must return the device sterilised 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 for this medical device is 12 months 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
8.2.1 Set supplied (see cover)

<table>
<thead>
<tr>
<th>REF</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1601055-001</td>
<td>CA 1:2.5 L MS contra-angle</td>
</tr>
</tbody>
</table>

8.2.2 Optional accessories (see cover)

<table>
<thead>
<tr>
<th>REF</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1600617-006</td>
<td>Aquacare, cleaning spray for physiological liquid 500ml, box of 6 cans</td>
</tr>
<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>