

CA 1:2.5 L MS



ENG INSTRUCTIONS FOR USE

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CE
0123

Rx Only REF 2100337-0003/2020.09

Set supplied (REF) CA 1:2.5 L MS



1601055-001

Optional accessories (REF)



1600617-006



1600036-006



1600064-006



1000001-010

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ENG INSTRUCTIONS FOR USE

1 Symbols

1.1 Description of symbols used

Sym	Description	Sym	Description
	Manufacturer.		Catalogue number.
	CE Marking with number of the notified body.		Serial number.
	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.		Medical Device.
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		General symbol for recovery/recyclable.
	Use rubber gloves.		After initial mechanical resistance, tighten fully in the direction indicated.
	Thermo washer disinfectable.		Sterilization up to the specified temperature.
	Movement in the direction indicated.		Movement to the stop in the direction indicated.
	Back and forth movement.		Lamp; lighting, illumination.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Refer to the accompanying documents.

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured 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 professionals 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.



FIG. 1 (CA 1:2.5 L MS)

4 Description

4.1 Overview

FIG. 1

- (1) Micromotor connection
- (2) Light output
- (3) Bur (not supplied)
- (4) Transmission ratio
- (5) Push-button with a bur-locking system

4.2 Technical data

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

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

Type 3 / ISO 1797-1
Code 4-5 / ISO 6360-1

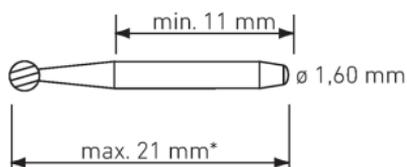


FIG. 2

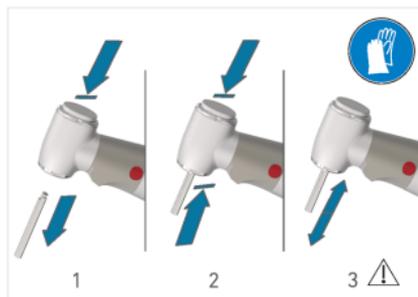


FIG. 3

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

WARNING

The instrument is supplied "non sterile". Clean, lubricate and sterilize the device prior to first use and between each patients.

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 sterilize. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
- 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-sterilization without a bur in the chuck mechanism.
- Use detergents that are pH 8-11, are neither corrosive nor contain chlorine, acetone and/or aldehydes.
- Do not immerse in an ultrasonic cleaner.
- Do not submerge in physiological liquid (NaCl) nor use saline to keep the device moist until it can be cleaned.

- Only instruments marked with the  logo can be cleaned in a washer-disinfector machine.
- As with all instruments, following each sterilization cycle, including drying, remove the device to avoid excess exposure to heat which can result in corrosion.
- Use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system.

6.1.2 Suitable maintenance products

Manual cleaning:

- Spraynet.
- Aquacare.

Manual disinfection:

- Alkaline detergent or detergent-disinfectant (pH 8-11) recommended for cleaning-disinfection of dental or surgical instruments. Disinfectant products composed either of didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product. (e.g. Neodisher® medicine) 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).



FIG. 4

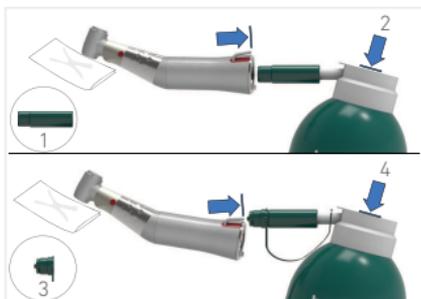


FIG. 5

6.2 Cleaning

Preparation

1. Disconnect the device from the electrical motor 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.

Remove dirt / deposits

FIG. 4 step 1 and 2

1. Clean the exterior and interior of the device under tap water at 15°C-38°C (59°F-100°F) provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/L. If the local tap water does not meet these requirements, use demineralized (deionized) water instead. Carefully remove all traces of dirt or deposits from the nozzles using the Bien-Air cleaning wire (optional).
2. After selecting the appropriate nozzle, 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).



FIG. 6

6.3 Disinfection

6.3.1 Manual 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. Brush the device with a smooth, flexible brush (e.g. soft-bristled toothbrush). DO NOT USE a wire brush.
3. **Optional:** perform additional cleaning and disinfection of the external surfaces with non-woven wipes impregnated with a disinfection product (e.g. di-decyldimethylammonium chloride).
4. Rinse the device twice with running tap water (15°C-38°C) (59°F-100°F) provided that the local tap water has a pH within the range of 6.5 - 8.5 and a chloride content below 100 mg/l. If the local tap water does not meet these requirements, use de-mineralized (deionized) water instead.

5. After selecting the appropriate nozzle, spray inside the device with Spraynet (FIG. 6).

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.

Phase	Parameters
Pre-cleaning	<45°C (113°F); ≥ 2 minutes
Cleaning	55°C-65°C (131°F-149°F); ≥ 5 minutes
Neutralization	≥ 2 minutes
Rinsing	Tap water, ≤30°C (86°F), ≥ 2 minutes cold water
Thermal Disinfection	90°C-95°C (194°F-203°F), 5-10 minutes
Drying	18-22 minutes

 **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 the local tap water has a pH outside the range of 6.5-8.5 or if it 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.



FIG. 7

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. 7

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

1. Place the device in a sterile, non-woven cloth 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 Sterilization

⚠ CAUTION

The quality of the sterilization is highly dependent on how clean the instrument is. Only perfectly clean instruments may be sterilized.

⚠ CAUTION

Do not use a sterilization procedure other than the one described below.

6.5.1 Procedure

1. Pack the device in a packaging approved for steam sterilization.
2. Sterilize 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), for 3 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C for 18 minutes.

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C, i.e. the nominal temperature of the autoclave is set at 134°C, 135°C or 135.5°C taking into account the uncertainty of the sterilizer as regards temperature.
- The maximum duration of the interval at the maximum temperature of 137°C is in accordance with national requirements for moist heat sterilization and does not exceed 30 minutes.
- The absolute pressure in the chamber of the sterilizer is comprised in the interval 0.07 bar to 3.17 bar (1 psia to 46 psia).
- The rate of change of temperature does not exceed 15°C/min for increasing temperature and -35°C/min for decreasing temperature.
- The rate of change of pressure does not exceed 0.45 bar/min (6.6 psia/min) for increasing pressure and -1.7 bar/min (-25 psia/min) for decreasing pressure.
- No chemical or physical reagents are added to the water steam.

CAUTION

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

6.6 Packing and storage

The device must be stored inside the sterilization 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 sterilization, extract the device from the sterilization pouch and store it in the original package. If the device is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, lubricate and sterilize 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 sterilization pouch 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

There are no particular transport and storage conditions required.

7.2 Disposal



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

All contra-angles must be recycled. In order to avoid any risk of contamination, the user must return the device sterilized 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)

REF	Legend
1601055-001	CA 1:2.5 L MS contra-angle

8.2.2 Optional accessories (see cover)

REF	Legend
1600617-006	Aquacare, cleaning spray for physiological liquid 500m, box of 6 cans
1600036-006	Spraynet, 500ml cleaning spray, box of 6
1600064-006	Lubrifiuid, 500ml spray lubricant oil, box of 6
1600001-010	Cleaning wire, box of 10

NOTES

A series of horizontal dotted lines for writing notes.

NOTES



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