CA eLINE 1:1 L
CA eLINE 1:5 L

ENG Instructions for use
Other languages available on https://dental.bienair.com/ifu

RX Only
2100050-0002/2024.06

CE 0123

Devices	
	
CA eLINE 1:1 L	CA eLINE 1:5 L
REF 1601143-001	REF 1601144-001

Optional accessories	
	
MAINT SPRAYNET (BOX 6 CANS)	MAINT LUBRIFLUID (BOX 6 CANS)
REF 1600036-006	REF 1600064-006

Table of contents

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
CE 0123	CE Marking with number of the notified body.		Manufacturer.
	WARNING! hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.		Consult instructions for use or consult electronic instructions for use.
	CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		Data Matrix code for product information including UDI (Unique Device Identification).
	Temperature limitation.		Humidity limitation.
	Atmospheric pressure limitation.	MD	Medical device.
	Keep away from rain.	SN	Serial number.
	Wear rubber gloves.	REF	Catalogue number.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.	EC REP	Authorized EC Representative in the European Community.
	General symbol for recovery/recyclable.		Sterilization up to the specified temperature.
	Can be processed in an automated washer/disinfector for thermal disinfection		

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type

Dental contra-angles handpiece (CA), push-button bur locking, with light, with 3 separated sprays.

Description

Bien-Air Dental contra-angle are designed to transmit the mechanical energy produced by an electric micromotor.

2.2 Intended Use

Device intended for use in general dentistry for restorative dentistry:

- CA eLINE 1:5 L

Devices intended for use in general dentistry for restorative dentistry, dental prophylaxis, orthodontics and endodontics:

- CA eLINE 1:1 L

2.3 Intended patient population

The intended patient population for the contra-angles and handpieces includes any person visiting a dental practitioner's office to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.4 Intended user

Product intended for professional use only. Used by dentists and dental professionals.

2.5 Use Environment

Professional healthcare facility environment.

2.6 Intended Medical Conditions

- General dentistry which includes restorative dentistry, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health.
- Endodontics procedure addresses root canal treatment.

2.7 Patient contra-indication and side effects

No specific patient contra-indication, side effects nor warnings exist for the contra-angle and handpiece devices when the devices are used as intended.

2.8 In case of accident

If an accident occurs, the device must not be used until repairs have been completed by a qualified, authorized and trained technician in a repair center.

If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

⚠ WARNING

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

3 User and Patient Safety: Warnings & Precautions for use

This medical device 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.

To prevent any risk of infection, the warnings below must be observed:

⚠ WARNING

- Rest the device on a cleanable support to avoid risks of infection for yourself, the patient or third parties.
- Personal protective equipment is mandatory when operating the devices.
- The device is supplied not sterile. Respect the maintenance and servicing procedures detailed in section 6. Sterilization before first use is mandatory.
- When disposing of the device, the user must return it sterilized to their dealer or contact an authorized body for the treatment and recovery of this type of equipment.
- 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.).
- The rotary burs are disposable and must be discarded after each treatment as detailed in section 5.

To prevent any risk of contra-angle/ handpiece overheating, the cautions below must be observed:

⚠ CAUTION

- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.

To prevent any risk of injury and/or material damage the warning below must be observed:

⚠ WARNING

- The device is intended for professional use only.
- Respect the maintenance and servicing procedures detailed in section 6
- In the event of 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 center approved by Bien-Air Dental SA.
- Never insert or remove a device while the micromotor is rotating.
- Do not touch the dental bur while it is rotating.
- Never rinse the devices to cool them.
- Each time a bur is inserted, check that the tool is fully inserted or screwed to the stop. If it is blocked, contact your usual supplier or Bien-Air Dental SA for repair.

- These medical devices are intended to be used at a maximum height of 1.5 m, to avoid damage in the event of a fall

To prevent any risk of device malfunction the caution below must be observed:

⚠ CAUTION

- Before performing any clinical application, always test your device to ensure its proper operation.
- Only use original Bien-Air Dental SA devices and accessories or those recommended by Bien-Air Dental SA.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.

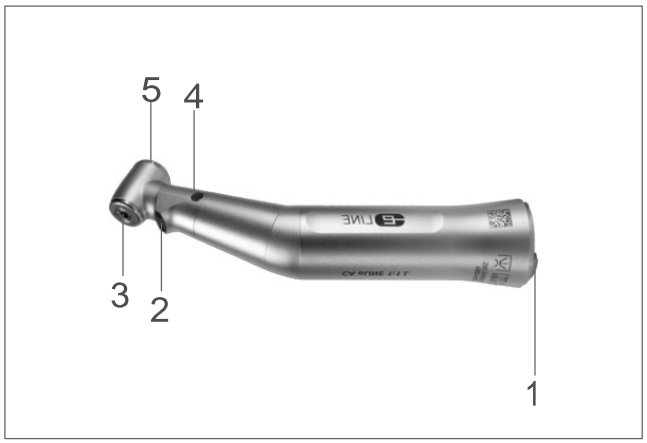

FIG 1

4 Description

4.1 Overview

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

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.
The original language of those instructions for use is English.
For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

4.2 Technical Data

Technical Data	CA eLINE 1:1 L	CA eLINE 1:5 L
Motor coupling compatibility	Coupling according to ISO 3964	
Transmission ratio according to ISO 14457	Speed direct ratio 1:1 (blue color)	Speed increasing ratio 1:5 (red color)
Motor max speed	40’000 rpm	
Irrigation type	Internal Intramatic® irrigation	
Maximum tool speed	40’000 rpm	200’000 rpm
Recommended spray water pressure (for an optimal cooling mist)	100-200 kPa	
Recommended spray air pressure (for an optimal cooling mist)	200-400 kPa	

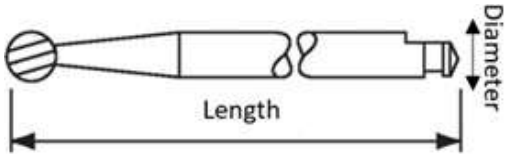

FIG 2

Cutting tool compatibility	
Shaft diameter ISO 1797-1	2.35 mm (Type 1)
Shaft length ISO 1797-1	≥ 11 mm
Cutting tool diameter ISO 6360-1	≤ 3 mm
Total length ISO 6360-1	≤ 22 mm (code 4)

4.3 Classification

Class IIa in accordance with European Medical Regulation (EU) 2017/745.

4.4 Performances

Performances	CA eLINE 1:1 L	CA eLINE 1:5 L
Spray water flow at 200 kPa	Min. 60ml/min	
Spray air flow at 200 kPa	Min. 2Nl/min	
Speed & torque transmission ratio	1:1 ±10%	1:5 ±10%

4.5 Operating conditions

Operating conditions		
	Temperature range:	+10°C — +35°C (+50°F — +95°F)
	Relative humidity range:	30%— 80%
	Air pressure range: Barometric pressure range:	700 hPa — 1060 hPa 490 mmHg— 795 mmHg

5 Operation

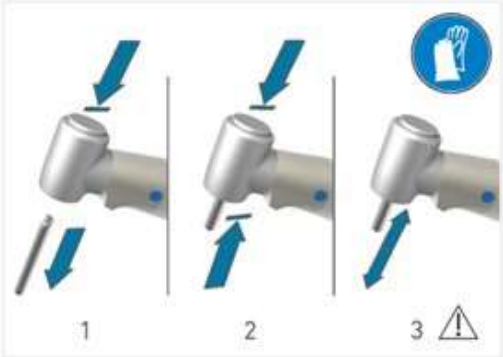

FIG 3

	Movement in the direction indicated.		Movement to the stop in the direction indicated.
	Back and forth movement.		After initial mechanical resistance, tighten fully in the direction indicated.

5.1 Changing the bur

⚠ WARNING

- The device must not be use if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air flow could propel infected material into the wounds, causing infection and a risk of embolism.
- Never touch soft tissue with the handpiece head. The improper use of the device could lead to burns or injuries.

⚠ 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.

FIG 3

Push-button bur locking system.

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. For the CA1 :1 range, while pressing the push-button insert and rotate the bur inside the chuck system until it fully engages.
3. Check that the bur rotates freely and that it is locked by gently pushing and pulling the bur

6 Maintenance and Servicing

6.1 Maintenance - General information

Clean, lubricate and sterilize the device prior to first use. Within a maximum of 30 minutes after each treatment, clean, disinfect and lubricate the instrument. Observing this procedure eliminates any blood or saliva residues and prevents the transmission system from being blocked.

⚠ WARNING

- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.

Suitable maintenance products

This procedure has been validated using Bien-Air Dental SA maintenance products or those recommended by Bien-Air Dental SA. The use of other products or parts is possible only after having obtained Bien-Air Dental SA's approval.

- Spraynet®
- 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® MediClean) are also allowable.

6.2 Cleaning

- Do not use saline solution to keep the device moist until it can be cleaned.
- Clean using manual cleaning or automated washer/disinfector only (do not use ultrasonic cleaner).
- Carry out cleaning and sterilization without a bur fastened.
- 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.

Preparation

1. Submit the disassembled screw type mandrel to the following reprocessing steps (except for the lubrication) together with the contra-angle.
2. If there is a large amount of debris, clean the exterior of the device with disinfectant wipes.

Remove dirt / deposits

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.

FIG 2

6.3 Disinfection

6.3.1 Manual cleaning and disinfection

1. Dip the device in a bath containing a cleaning and disinfectant product (e.g. didecyldimethylammonium 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. didecyldimethylammonium 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 demineralized (deionized) water instead.
5. After selecting the appropriate nozzle, spray inside the device with Spraynet® (FIG 2).
6. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

Automatic disinfection

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 cleaning products (e.g. alkaline detergent or detergent-disinfectant pH 8-11 or neutral enzyme detergent pH 7-8) recommended for washer-disinfector.

Recommended specifications for the thermo-disinfection cycle.

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

⚠ CAUTION

Never rinse the devices to cool 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 3

6.4 Lubrication

Verifying cleanliness

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

Lubrication

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

FIG 3

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.
- To improve the effectiveness of the sterilization, make sure the handpiece and the attachment are completely dry before and after the sterilization.
- Do not use a sterilization procedure other than the one described below
- Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.
- If the sterilization is required by national directives, use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system.
- As with all instruments, following each sterilization cycle, including drying, remove the device to avoid an excessive exposure to heat which can result in corrosion.
- The bur and the metallic screw must be disassembled from the device prior to starting the cleaning, disinfection and sterilization procedure.

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 or 132°C (269.6°F) for 4 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C (275°F) for 18 minutes.

The device can be used for more than 1,000 sterilization cycles

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C (278°F), i.e. the nominal temperature of the autoclave is set between 132°C - 135.5°C (269.6°F – 275.9°F) taking into account the uncertainty of the sterilizer as regards temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278°F) 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 between 0.07 bar to 3.17 bar (1 PSIA to 46 PSIA/28 HgV to 31 PSIG).
- The rate of change of temperature does not exceed 15°C/min (27°F/min) for increasing temperature and -35°C/min (-63°F/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 boiler feedwater.

6.6 Packing and storage

Storage conditions		
	Temperature range:	0°C — +40°C (+32°F — +104°F)
	Relative humidity range:	10% — 80%
	Air pressure range: Barometric pressure range:	650 hPa — 1060 hPa 490 mmHg — 795 mmHg
	Keep away from rain	

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 removal from its packaging and use.

⚠ CAUTION

Comply with the expiration date of the sterilization pouch which depends on the storage conditions and type of packaging.

6.7 Servicing

Bien-Air Dental SA recommends a regular service for the handpiece after 4000 processing cycles or five years. Never dismantle the device.

It is recommended to replace the screw-type mandrel every 100 sterilization cycles.

For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental SA directly.

7 Transport and Disposal

7.1 Transport

Transport Conditions		
	Temperature range:	-20°C — +50°C (-4°F — -122°F)
	Relative humidity range:	5% — 80%
	Air pressure range: Barometric pressure range:	650 hPa — 1060 hPa 490 mmHg — 795 mmHg
	Keep away from rain	

7.2 Disposal

The disposal and/or recycling of materials must be performed in accordance with the local, national or international regulations. All contra-angles and handpieces must be recycled. In order to avoid any risk of contamination, the user must return the device sterilized to their 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:

- 24 months from the date of invoicing.

In the event of a justified claim, Bien-Air Dental SA or its authorized 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

⚠ CAUTION

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized 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

REF	LEGEND
1601143-001	CA eLINE 1:1 L
1601144-001	CA eLINE 1:5 L
1600036-006	Spraynet, cleaning spray 500 ml, box of 6 cans
1600064-006	Lubrifluid, lubricant 500 ml, box of 6 cans

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