

CA ENDO

ENG INSTRUCTIONS FOR USE.

Other languages available on www.bienair.com/ifu



CE
0123

REF 2100336-0002/2024.04

Set supplied (REF)



1600955-001

Accessories (REF)



1600617-006



1600036-006



1600064-006



1600677-001



1600678-001

















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ENG Instructions for use

1 Symbols

1.1 Description of symbols used

Symb	Description	Symb	Description
	Manufacturer.		Serial number.
	CE Marking with number of the notified body.		Separate collection of electric and electronic equipment.
	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.		Recyclable materials.
	Refer to the accompanying documents. (www.bienair.com/ifu .)		Use rubber gloves.
	Sterilisable up to the specified temperature.		Machine washable.
	Movement in the direction indicated.		After initial mechanical resistance, fully tighten in the direction indicated.
	Movement to the stop in the direction indicated.		Back and forth movement.
	Reference number.		Device supplied non-sterile.

2 Identification and intended use

2.1 Identification

Type

Dental contra-angle (CA) with push-button file locking.

Classification

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

2.2 Intended use

Product intended for professional use only.

The **CA ENDO** is intended for use in endodontics by dentists and dental professionals in a dental office.

CAUTION

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

CAUTION

The instructions contained in this manual must be followed, in particular the precautions for use.

3 Precautions for use

This medical device 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

Place the device on a suitable support to prevent injury and infection.

CAUTION

Universal precautions, in particular wearing of personal protective equipment (gloves, a mask and safety glasses), should be complied with by medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated. Pointed and sharp instruments should be handled with great care.

CAUTION

Device is supplied non-sterile and must be cleaned, disinfected, and sterilized prior to first use and before each subsequent use.

Clean, lubricate and sterilise the device separately IMMEDIATELY after each patient.

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.

CAUTION

The **CA ENDO** is not designed for use in an explosive atmosphere (anesthetic gas).

CAUTION

Only use with a dental unit that complies with the guidelines of the EN 60601 standard.



FIG. 1

4 Description

4.1 Overview

FIG. 1

- (1) Transmission ratio marking strip
- (2) Endodontic file (not provided)
- (3) Push-button

Note: (*) Indicative values. In the event of the use of a longer or wider file, the user is responsible for choosing the right operational conditions that avoids all risks to patients or third parties. Follow the instructions for use, in accordance with the files manufacturer's instructions.

4.2 Technical data

Description	Value
Standard coupling	ISO standard 3964
Maximum operating speed	9000 rpm
Maximal speed of motor	40000 rpm
Shanks for rotary and oscillating instruments	Type 1 according to ISO 1797
Root-canal instruments	According to ISO 3630-1
MAX motor speed when tool at 300 rpm	1200 rpm (*)
MAX motor speed when tool at 600 rpm	2400 rpm (*)

Type 1 / ISO 1797

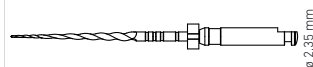


FIG. 2

CA ENDO file

FIG. 2

- Shank diameter 2.35 mm, type 1 according to ISO 1797.
- Tool dimensions complying with ISO 3630-1.

⚠ CAUTION

Follow the guidelines for use, according to the tool manufacturer's instructions. Never use a tool if the shank is not conform.

5 Assembly

5.1 Connection to the motor

⚠ CAUTION

Never insert a device on a rotating micromotor.

1. Check that the device is completely dry before connecting it to the motor.
2. Install the CA on the motor connection until ratcheting. For this, keep the motor and the CA in the same axle.
3. Apply light traction to the CA to check that it is properly attached to the motor connection.
4. Carry out an operational test: switch on the motor; start at low speed, then

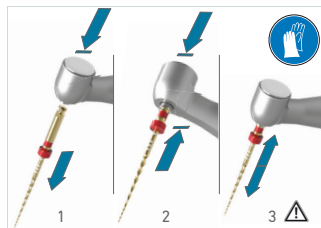


FIG. 3

gradually increase, outside of the patient's mouth.

5.2 Disconnection of motor

Remove the CA by pulling it away from the motor, along its axle.

⚠ CAUTION

In the event of prolonged non use of the device, do not leave it connected to the motor. Risk of damaging the motor.

5.3 Changing the file

FIG. 3

Push-button tool locking.

1. Press the push-button and simultaneously pull the file.
2. Press the push-button, insert the new file until locked in place and release the push-button.
3. Apply light traction to check that the file is correctly locked.

⚠ CAUTION

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

6 Operation


CAUTION

Insert a file before operating the device. To prevent the push-button from overheating, which could lead to burns, it must not be pressed accidentally when the device is rotating. Soft tissue (e.g. tongue, cheek and lips,) must be protected using a retractor or dental mirror.

7 Cleaning and servicing

7.1 Maintenance

7.1.1 Precautions for maintenance

- Before first use and IMMEDIATELY after each procedure, clean, disinfect and lubricate the device, then sterilise it. 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 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.

File chuck mechanism (cutting tool)

Carry out cleaning – disinfection – sterilisation without a file in the chuck mechanism.

7.1.2 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.
- Detergent or detergent-disinfectant (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.

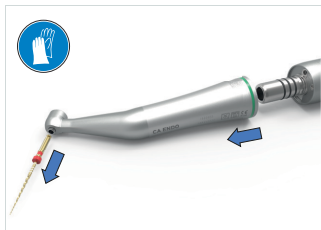


FIG. 4

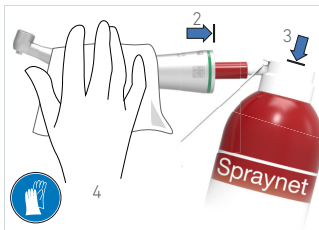


FIG. 5

7.2 Preliminary cleaning

Preparation

FIG. 4

1. Disconnect the motor and remove the file.

⚠ CAUTION

If there is a large amount of organic contaminants, clean the exterior of the device with disinfectant wipes.

FIG. 5

2. Insert the Spraynet end-piece in CA handle,
3. 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.
4. Leave any liquid residue to drip-dry, then wipe the exterior with a paper towel or move onto the cleaning-disinfection step immediately (see 7.3, on page 9).

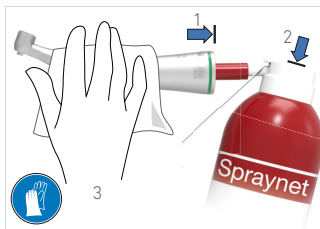


FIG. 6

7.3 Cleaning-disinfection

7.3.1 Manual cleaning/disinfection

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

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

FIG. 6

3. Spray the interior of the device with Spraynet 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.

7.3.2 Automatic cleaning-disinfection

⚠ CAUTION

Only for devices 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.

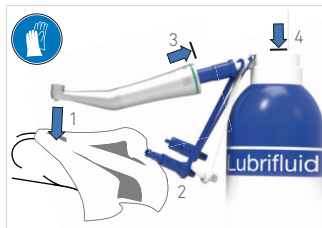


FIG. 7

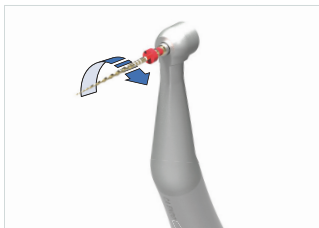


FIG. 8

7.4 Lubrication

7.4.1 Verifying cleanliness

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

7.4.2 Lubrication

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

FIG. 7

1. Remove the bur from the device and place the device in a cloth to remove surplus lubricant.
2. Select the correct end-piece and remove the protective cap.
3. Insert the end-piece of the can Lubrifiuid in the rear of the device's handle.
4. Actuate the spray for 1 second, and clean the excess oil on the exterior.

7.5 Sterilisation

⚠ CAUTION

The quality of the sterilisation is highly dependent on how clean the device 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 contra-angles are sterilisable in an autoclave up to 135°C. Duration: 3 or 18 minutes, depending on the national requirements in force.

FIG. 8

After cleaning, disinfecting and sterilising the device, and before using it, start it up at moderate speed with a file in the locking mechanism (FIG. 3, step 2.) for 10 to 15 seconds to distribute and remove the excess lubricant.

7.6 Servicing

Never dismantle the device. For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental SA directly.

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

8 Packing and disposal

8.1 Transport and storage conditions

Temperature between -40°C and 70°C inclusive, relative humidity between 10% and 100%, atmospheric pressure between 50 kPa and 106 kPa.

8.1.1 Packing

Pack the instrument 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.

8.2 Disposal



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



The CA and its accessories must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. Users should return devices to their distributors or directly contact an approved body responsible for processing and recovering this type of equipment (European directive 2002/96/EC).

9 General information

9.1 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 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 or interest, are excluded.

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

- Excessive wear
- Infrequent 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.

Claims under the terms of the warranty will be considered only on presentation, together with the product, of the invoice or the consignment note. The following information must be clearly indicated: The date of purchase, the product reference and the serial number.

9.2 References

9.2.1 Set supplied (see cover)

REF	Legend
1600955-001	CA ENDO

9.2.2 Accessories (see cover)

REF	Legend
1600036-006	Spraynet, 500 ml cleaning spray, box of 6
1600064-006	Lubrifiant, 500 ml spray lubricant oil, box of 6



Bien-Air Dental SA

Länggasse 60 Case postale 2500 Bienne 6 Switzerland

Tel. +41 (0)32 344 64 64 Fax +41 (0)32 344 64 91

dental@bienair.com

Other addresses available at

www.bienair.com

EC REP **Bien-Air Europe Sàrl**

19-21 rue du 8 mai 1945

94110 Arcueil

France