CA 1:2.5 L
CA 1:2.5 L MS

ENG INSTRUCTIONS FOR USE

Other languages available on
https://dental.bienair.com/IFU

CE 0123 Rx Only
REF 2100439-0000/2023.06

Devices

CA 1:2.5 L

REF 1601163-001

CA 1:2.5 L MS

REF 1601164-001

Optional accessories (REF)

IRRIGATION LINE

(10/pkg)

REF 1500984-010

MAINT SPRAYNET®

(BOX 6 CANS)

REF 1600036-006

MAINT LUBRIFLUID®

(BOX 6 CANS)

REF 1600064-006

MAINT AQUACARE

(BOX 6 CANS)

REF 1600617-006

Table of content

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.	135°C	Sterilization up to the specified temperature.
	Can be processed in an automated washer/disinfector for thermal disinfection.		Lamp; lighting, illumination.

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type

Surgical contra-angles handpiece (CA), push-button bur locking, with light, speed increasing ratio and external irrigation.

Description

Bien-Air Dental contra-angles and straight handpieces (PM) are designed to transmit and apply the mechanical energy produced by an electric micromotor.

Contra-angle		Light		E-type connection (ISO 3964)	
Ratio		With light	Without light	Standard	Short
●	CA 1:2.5 L	●		●	
●	CA 1:2.5 L MS	●			●

2.2 Intended Use

Devices intended for use in oral surgery and maxillofacial surgery.

2.3 Intended patient population

The intended patient population for the contra-angles includes any person visiting a medical practitioners' 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

Device intended for professional use only. Used by oral and maxillofacial surgeons.

2.5 Use Environment

Professional healthcare facility environment.

2.6 Intended Medical Conditions

- Oral surgery treatments include impacted teeth extraction, wisdom teeth extraction, non salvageable decayed teeth extraction, guided and not-guided bone regeneration, apicoectomy, osteotomy, sequestrectomy and hemisection.
- Maxillofacial surgery includes procedures such as orthognathic surgery, genioplasty and rhinoplasty.

2.7 Patient contra-indications and side effects

No specific patient contra indication, side effects nor warnings exist for the contra-angle when it is 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

⚠ **WARNING**

The device must be used by qualified dental professionals in compliance with the current legal provisions concerning occupational safety, health and accident prevention measures, and these instructions for use. In accordance with such requirements, the operators:

- Must only use devices that are in perfect working order; in the event of irregular functioning, coolant failure, excessive vibration, abnormal heating, unusual noise or other signs that may indicate malfunction of the device, the work must be stopped immediately; in this case, contact a repair center that is approved by Bien-Air Dental SA and have the service personnel carry out repair work.
- Must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger.
- Any modification of the medical device is strictly forbidden.

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

⚠ **WARNING**

- The device is supplied not sterile. To avoid any infection, respect the cleaning, disinfection, sterilization and overall maintenance procedure detailed in section 6. Sterilization before first use is mandatory.
- 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.
- 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.

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

⚠ **WARNING**

- Never insert or remove a device while the micromotor is rotating.
- Never partially insert a bur to increase its active length.
- Do not touch the bur while the device is rotating.
- Each time a bur is inserted, check that the bur is fully inserted to the stop. Always check that the bur is locked by gently pushing and pulling the bur.
- Never use a bur if the tip is not compliant with specifications.
- Always ensure that the coolant supply is sufficient and adequate according to specifications.
- Soft tissues (tongue, cheeks, lips, etc.) must be protected by moving them

away using a retractor or dental mirror to avoid the risk of burns if the push-button is inadvertently pressed while the instrument is running.

To prevent any risk of device overheating, the cautions below must be observed:

⚠ **CAUTION**

- The device must not be started without a bur inserted into the chuck.
- To avoid overheating of the push-button, it should not be pressed inadvertently while the instrument is rotating.

To prevent any risk of device failure or malfunction the cautions below must be observed:

⚠ **CAUTION**

- Before performing any clinical application, always test your device without any load to ensure it is in perfect order.
- 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.
- 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.
- Never insert or remove a device while the micromotor is rotating.

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Push-button with a bur-locking system

(2) Transmission ratio

(3) Bur (not supplied)

(4) Light output

(5) Micromotor connection

(6) External irrigation connection

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 these 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

Contra-angle	Information
Motor coupling compatibility	Coupling according to ISO 3964 - Microseries (MS) CA & PM can be coupled to short and extra short Motor couplings - Standard CA & PM can be coupled to all coupling types
Lighting	"L" letter means light CA & PM without L letter means no lighting
Transmission ratio according to ISO 14457	Speed increasing ratio 1:2.5 (red color)
Motor max speed	40'000 rpm
Bur max speed	100'000 rpm
Irrigation type	External irrigation
Maximum Irrigation flow*	110 ml/min

**Using Bien-Air Chiropro device at maximum irrigation level (5 drops).*

⚠ **WARNING**

- Always ensure that the coolant supply is sufficient and adequate according to specifications.
- The minimum irrigation quantity at the entrance of the CA must be set to at least 60mL/min (corresponding to 2 drops level if used in association with Chiropro devices).

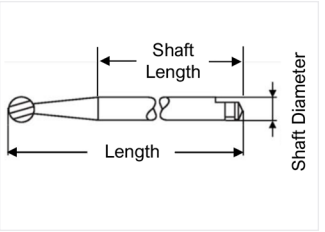

FIG. 2

Compatibility of the chuck mechanism

Shaft diameter 2.35 mm, type 1 as per ISO 1797, recommended length 26mm* code 4/5 as per ISO 6360-1 (Maximum working diameter 2.3 mm) **FIG. 2**.
(*) When using longer rotary instruments (e.g. 34 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. Intensive use of burs with code 6 can accelerate the wear of the device.

Bur compatibility	
Shaft diameter ISO 1797	2.35 mm (Type 1)
Shaft length ISO 1797	≥ 12 mm
Bur max. working diameter	≤ 2.3 mm
Bur recommended length ISO 6360-1	≤ 26 mm (code 4-5)
Bur max. length ISO 6360-1	≤ 34 mm (code 4-5-6)

⚠ **WARNING**

- Never use a tool if the tip is not compliant with specifications.
- Follow the guidelines for use, according to bur manufacturer's instructions.

4.3 Classification

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

4.4 Performances

Performances	CA 1:2.5 L & CA 1:2.5 L MS
Speed transmission ratio	1:2.5

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]

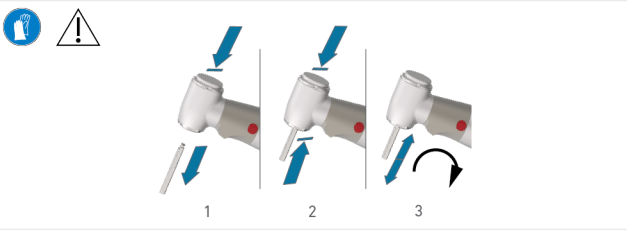

FIG. 3

5 Operation

5.1 Pictograms used

Sym	Description	Sym	Description
	Movement in the direction indicated.		Movement to the stop in the direction indicated.
	Back and forth movement.		

5.2 Changing the bur

Clamping system operation

1. Press the push-button to disengage the clamping system. While keeping the push-button pressed, pull out the bur (FIG. 3 step 1). Release the push-button to engage the clamping system.
2. Press the push-button to disengage the clamping system. While keeping the push-button pressed, insert the new bur all the way to the stop (FIG. 3 step 2). Release the push-button to engage the clamping system.

Clamping system inspection

Verify that the bur can be turned around smoothly and check that the bur remains in position when traction is applied (FIG. 3 step 3).

⚠ WARNING

- Never insert or remove a bur while the device is rotating.
- Never partially insert a bur to increase its active length.
- Do not touch the bur while the device is rotating.
- Each time a bur is inserted, check that the bur is fully inserted to the stop. Always check that the bur is locked by gently pushing and pulling the bur.

⚠ CAUTION

- If the bur cannot be easily and fully inserted into the chuck, contact your usual supplier or Bien-Air Dental SA for repair.
- Test your device without any load to ensure the bur rotates stably and its dynamic eccentricity is acceptable for the planned clinical procedure.

6 Maintenance and Servicing

6.1 Maintenance - General information

⚠ **WARNING**

- The device is supplied "nonsterile". Clean, dry, lubricate and sterilize the device prior to first use.
- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.
- Rest the device on a cleanable support to avoid risks of infection for yourself, the patient or third parties.

6.1.1 Precautions for maintenance

- Within a maximum of 30 minutes after each treatment, clean and disinfect the instrument. Observing this procedure eliminates any blood, saliva or 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 guarantee.

6.1.2 Suitable maintenance products

Preliminary cleaning:

- Use tap water if the local tap water has pH within the range 6.5 - 8.5 and chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.
- Aquacare.

Manual cleaning:

- Spraynet®.

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® mediclean) are also allowable.

Automatic cleaning-disinfection:

- Use an alkaline or enzymatic product recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

Lubrification:

- Lubrifluid®.

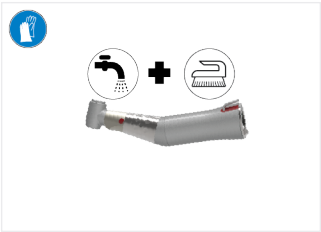

FIG. 4

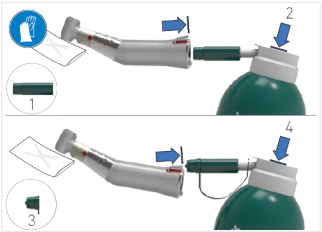

FIG. 5

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 in the chuck mechanism.

Preparation

1. Remove the irrigation line then disconnect the device from the electrical motor.
2. Remove the bur (FIG. 3 step 1).
3. If there is a large amount of debris, clean the exterior of the device with disinfectant wipes.

⚠ **CAUTION**

- Use the Aquacare maintenance pro duct as soon as possible, to remove NaCl deposits.
- 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

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. 4)
2. After selecting the appropriate nozzle, perform preliminary cleaning of the device by using the product Aquacare. Spray the inside (FIG. 5), the outside of the device and inside the irrigation tube (FIG. 5).

FIG. 6

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. an alkaline product like neodisher Mediclean). 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 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.
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), preferably impregnated with Spraynet® or other blends of drying alcohols, like ethanol or isopropyl alcohol suitable for metals and polymers.

6.3.2 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 de tergent 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 instead 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.

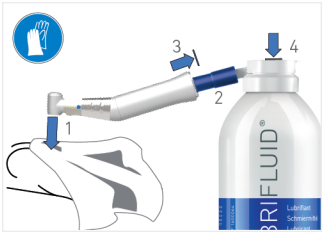

FIG. 7

6.4 Lubrification

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. 7

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 contra-angle is 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 must be disassembled from the device prior to sterilization.

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 1000 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 Hg 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 2,000 processing cycles or 2 years. Never dismantle the device. 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 guarantee covering all functional defect, or material or manufacturing faults.

The guarantee period is 12 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 guarantee 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. Guarantee 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
1601163-001	Contra-angle handpiece speed increasing ratio CA 1:2.5 L with light, push-button grip, external irrigation
1601164-001	Micro-series contra-angle handpiece speed increasing ratio CA 1:2.5 L MS with light, push-button grip, external irrigation
1500984-010	Pack of 10 disposable sterile lines
1600617-006	Aquacare, cleaning spray for physiological liquid 500 ml, box of 6 cans
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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