

**CA 20:1 L, CA 20:1,
CA 20:1 L KM,
CA 20:1 L Micro-Series
CA 20:1 L KM Micro-Series**
External irrigation

Instruction

REF 2100209-0003/ENG



English

Medical devices entirely made in Switzerland by Bien-Air Dental SA.

Type
Contra-angle handpiece (CA) speed reducing ratio with or without light, push-button grip and external irrigation.

Intended use

Product intended for professional use only. Use in dentistry for implantology and dental surgery work. Any use other than that for which this device is intended is prohibited and may prove dangerous.

Important

The CA must not receive pressurized cooling air from the unit, in order to prevent contamination of the wound.

Technical data

Classification
Class IIa in accordance with European Directive 93/42/EEC concerning medical devices.

Coupling

The most commonly used coupling in the world as per ISO 3964 with light for the CA 20:1 L and CA 20:1 L KM and without light for the CA 20:1.

Transmission ratio

Green marker, reduced by ratio of 20.

Maximum torque

70 Ncm.

Motor speed

Maximum 40,000 rpm.

Rotation speed

Maximum 2,000 rpm.

Weight

CA 20:1 L, CA 20:1 L KM 87 g.

CA 20:1 86 g.

CA 20:1 L Micro-Series, CA 20:1 L KM Micro-Series

79 g.

Length

CA 20:1 L, CA 20:1 L KM, CA 20:1

94 mm.

CA 20:1 L Micro-Series, CA 20:1 L KM Micro-Series

85 mm.

Information

The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

Assembly

Bur

Diameter of shaft 2,35 mm (0.09 in), type 1 in accordance with ISO 1797, max. length 34 mm (0.87 in), code 4-6 in accordance with ISO 6360-1, fig. 1.

In implantology, longer burs can be used under the responsibility of the practitioner. For torques greater than 30 Ncm, the bur shanks must have a **hardness exceeding 50 HRC (520 HV)** to prevent their deformation and jamming in the chuck mechanism.

Changing the bur

Push-button grip:
Press the push-button and, at the same time, withdraw the bur fig. 2A. To fit a new bur, press the push-button and insert the bur firmly home fig. 2B.

If the Kirschner/Meyer irrigation system is used, it is recommended to leave the cooling tube in place to change the bur fig. 2C.

Whenever inserting a bur, check that the bur change system is working by lightly pushing/pulling on the bur, and check that it is correctly in position and can be turned around smoothly, fig. 2D.

Important

The device must not be started without a bur inserted into the chuck. To avoid overheating of the push-button, which could cause burns, it should not be pressed inadvertently while the instrument is rotating. Soft tissues (tongue, cheeks, lips etc.) must be protected by deflection with a retractor or a dental mirror.

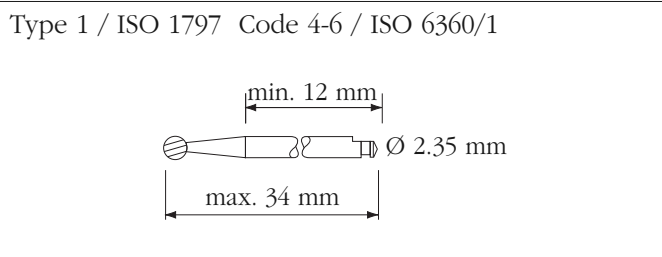


fig. 1

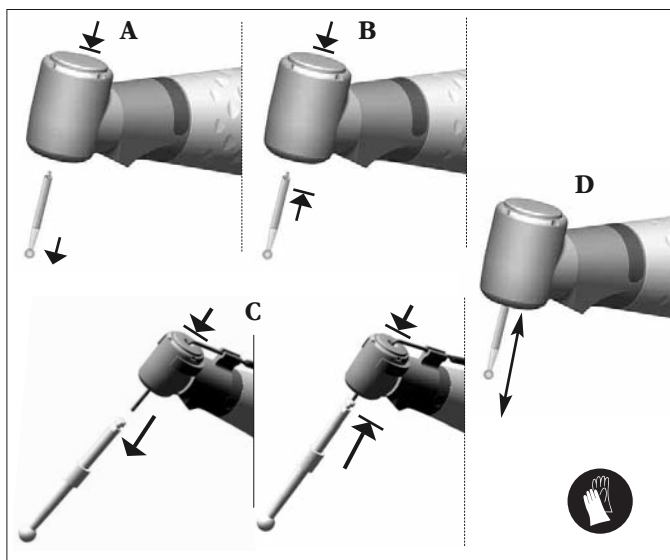


fig. 2

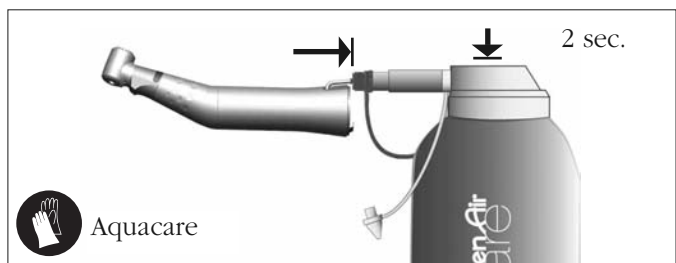


fig. 3

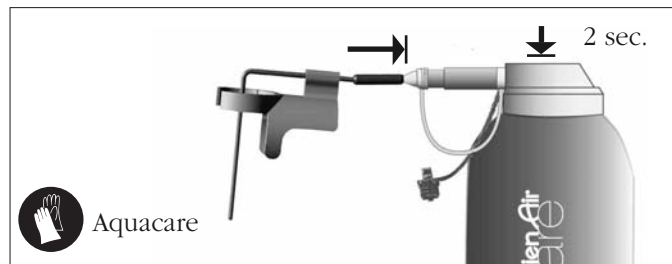


fig. 3A

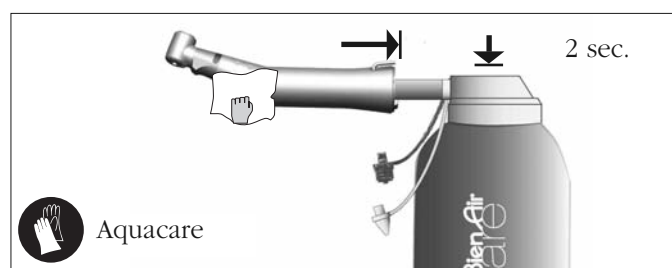


fig. 4

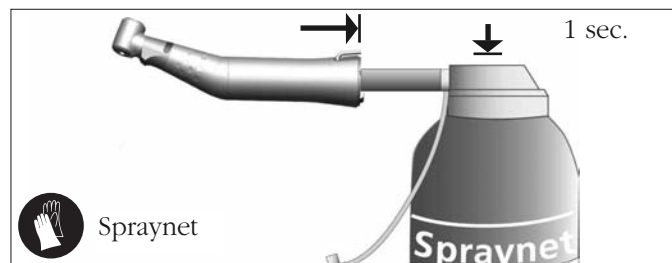


fig. 5

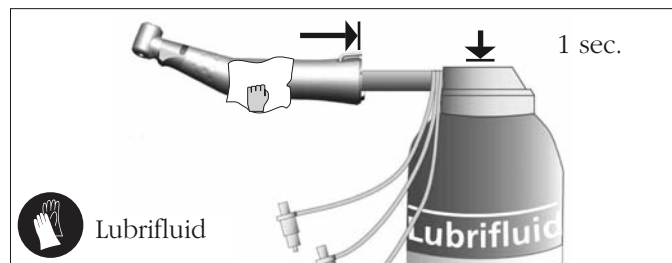


fig. 6

Never mount an instrument on a rotating motor.

Maintenance

Separately clean, lubricate and sterilise the device before the treatment of each patient.

⚠ Attention:

After a maximum of 10 sterilisations, the Kirschner/Meyer irrigation system must be disposed of.

For all maintenance stages, the Kirschner/Meyer irrigation system must be separated from the attachment, and the irrigation tube must be separated from the plastic holder.

⚠ Important

- **The instrument is delivered "non sterile".**
- 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 bearing a pictogram ☒ can be placed in the washer/disinfectant unit.
- **Do not immerse in an ultrasonic bath.**
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

Precautions for maintenance:

The universal precautions, in particular wearing of personal protective equipment (gloves, goggles, etc.), 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 caution.

Bur chuck mechanism (cutting tool)

- Carry out cleaning – disinfection – sterilisation without bur in the chuck mechanism.

Suitable detergent

For automatic cleaning-disinfection:

- Slightly alkaline enzymatic detergent recommended for cleaning in a washer-disinfectant for dental or surgical instruments.

For manual cleaning-disinfection:

- **Spraynet**
- Detergent or detergent-disinfectant (pH 6-9.5) recommended for cleaning-disinfection of dental or surgical instruments.
- Quaternary ammonium- and/or enzyme-based surfactants.
- **Do not use** detergents that are corrosive or contain chlorine, acetone aldehydes or bleaches.
- Do not soak in physiological liquid (NaCl).

⚠ Important

In the event of prolonged disuse, the instrument must be stored in a dry environment. Lubricate and sterilise the instrument before reuse.

After cleaning and disinfecting/sterilising the instrument and before using it, operate at moderate speed, with a bur in the chuck, for 10 to 15 seconds to circulate lubricant and remove excess.

Check that the steriliser and the water used are clean. After each sterilisation cycle, remove the device from the sterilising apparatus immediately, in order to reduce the risk of corrosion.

1 Pre-disinfection

Preparation

- Disconnect the attachment from the drive motor and remove the bur **fig. 2**.
- Wash out the physiological liquid from the duct by spraying (2 secs.) in the tube at the rear with **Aquacare fig. 3**.
- Wash out the physiological liquid by spraying (2 secs) into the irrigation system tube with **Aquacare fig. 3A**.
- Carry out a manual pre-clean or a bath pre-clean.

Manual pre-cleaning

Use **Aquacare** cleaning product.

- Spray for 2 seconds on the inside and outside of the attachment remove of residues and any remaining physiological liquid **fig. 4**.
- Carefully clean the surfaces.
- Leave to drip-dry and wipe the outside surfaces with absorbent paper or immediately proceed with step no 2.

or

Pre-cleaning by bath

⚠ Warning: the preliminary bath cleaning **should be followed** by automatic cleaning-disinfection.

- Totally submerge the instrument in a new cleaning bath containing the suitable detergent following the manufacturer's instructions (duration, concentration, temperature, renewal...).
- After the bath, wash out the liquid of the bath in the irrigation system tube by spraying (2 secs.) in the tube at the rear with **Aquacare, fig. 3**.
- Rinse the inside and outside of the device in cold running water (<35°C/ <95°F) for about 30 seconds.
- Leave to drip-dry and wipe the outside surfaces with absorbent paper or immediately proceed with automatic cleaning-disinfection.

2 Cleaning-disinfection

Manual cleaning-disinfection

Dip the instrument in a tank containing appropriate detergent and, using a soft-haired brush, clean and disinfected, clean the outside of the instrument in accordance with the detergent manufacturer's instructions (time, concentration, temperature, renewal, etc.).

Rinsing:

Rinse the inside and outside of the device with running water (<38°C/ <100°F) for about 30 sec.

Drying:

Spray the interior of the instrument with **Spraynet** product **fig. 5** immediately to remove all traces of detergent and rinsing water to prevent any adverse impact on the internal components, e.g. which might cause them to seize. If necessary, clean with a dry paper towel.

or

Automatic cleaning-disinfection

⚠ Attention: only for devices engraved with ☒

Cleaner - disinfectant unit:

Use an approved cleaner-disinfectant unit with a suitable amount and type of detergent.

Washing cycle:

Select the specified washing cycle for these instruments which should be compatible with the detergent manufacturer's instructions.

Recommended temperatures for the devices:

Pre-wash

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

Wash

Water: 50 to 65°C (122 to 149°F) – Duration 5 mins.

Rinsing

Water: cold to maximum 35°C (95°F) – Duration 2 mins.

Thermal disinfection

Water: 80 to 97°C (176 to 206.6°F) – Duration 5 mins.

Drying

Air: 65 to 75°C (149 to 167°F) – Duration 25 mins.

⚠ Important:

Never rinse the devices to cool them.

3 Lubrication, checks and conditioning process

Verifying cleanliness

Visually check the cleanliness of the instrument. If required, re-clean with a soft brush.

Lubrication before each sterilisation, and at least twice a day.

Only use the spray **Lubrifiuid**.

- Remove the bur before lubricating
- Place the instrument in a cloth so as to catch the debris and foreign matter expelled by the atomizer jet.
- Remove the protective cap and insert the nozzle into the back of the instrument sleeve.
- Spray for about 1 second **fig. 6**.

Clamp operation inspection

- Insert a bur in the chuck mechanism of the instrument **fig. 2B**.
- Verify that the bur can be turned around smoothly.
- Check that the bur remains in position when traction is applied **fig. 2D**.
- Remove the bur to sterilise.

Packaging process

Wrap the instrument in approved packaging for steam sterilisation.

4 Sterilisation

⚠ Important

The quality of the sterilisation depends very much on the cleanliness of the device.

Only perfectly clean devices may be sterilised.

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

Procedure:

With steam after fractioned initial vacuum phase, Class B cycle acc. to EN13060. The procedure has been validated according to ISO 17664. Nominal temperature: 134°C (273°F). Duration: 3 or 18 min., according to the national guidelines in force.

Servicing

Never disassemble the device. For any modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental directly. Bien-Air Dental asks the user to have its dynamic instruments checked or inspected at least once a year.

Transport and storage conditions

Temperature between -40°C (-40°F) and 70°C (158°F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 106 kPa (7.3 to 15.3 psi).

Other precautions for use

The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- 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, and must avoid contamination through the use of the product.

Rest the device on a suitable support to avoid risks of infection for yourself, the patient or third parties.

Excess material from products used for maintenance (lubricants, cleaning products and disinfectants) originating from CA or PM may penetrate into the electric brush motor and interfere with its functioning. It is essential to follow the maintenance instructions accompanying each product. Never lubricate the electric brush motor.

Recommendations

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.

The device must not be used in the presence of open lesions, injury to the soft tissues or recent extractions. The exhaust air could propel infected material into the wounds and cause infections and risk of embolism.

Adhere to the Instructions for Use, in accordance with the instructions of the bur manufacturer. Never use a bur with an incorrect diameter, as there is a risk of this becoming detached during the treatment and causing injury to yourself, to your patient and to third parties.

The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorised and may be dangerous.

The medical device meets all the current legal requirements.

Guarantee

Terms of guarantee

Bien-Air Dental grants the user a guarantee covering all functional defects, material or production faults. The device is covered by this guarantee for 12 months from the date of invoicing.

Bien-Air Dental offers a 24-month guarantee for the glass-bar light conductors.

In the event of justified claim, Bien-Air Dental or its authorised representative will fulfil the company's obligations under this guarantee by repairing or replacing the product free of charge.

Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

Bien-Air Dental shall not be held responsible for damage or injury and the consequences thereof, resulting from:

- excessive wear and tear
- improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible "fibre optic" type conductors, or any parts made of synthetic materials.

The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorised by Bien-Air Dental.

Claims under the terms of the guarantee will be considered only on presentation, together with the product, of the invoice or the consignment note, on which the date of purchase, the product reference and the Serial No. should be clearly indicated.

Set supplied



CA 20:1 L
REF 1600598-001



CA 20:1
REF 1600632-001



CA 20:1 L KM
REF 1600785-001



CA 20:1 L Micro-Series
REF 1600692-001



CA 20:1 L KM Micro-Series
REF 1600786-001

Optional accessories



REF 1501621-010



REF 1501635-010



REF 1500984-010



REF 1600617-006



REF 1600036-006



REF 1600064-006

Symbols

Manufacturer.

Wear rubber gloves.

Light.

Machine washable.

Sterilisable at the specified temperature.



CE Marking with number of the notified body.



Attention.



Move in the direction indicated.



Move fully to the stop, in the direction indicated.



To-and-fro movement.

This product may be covered by one or more of the following patents:

EP Europe: 745358 / 688539 / 948294 / 1145688 / 1563800 / 1563801 / 1675523 / 1753360 **DE Germany:** 29616023.7
DK Denmark: 9600315 **FR France:** 2722972 **CH Switzerland:** 693922 **CN China:** 100528099 / 100522100 / 100522099 / 100553584 **JP Japan:** 3892485 / 4298933 / 7000419 **US United-States:** 5453008 / 6033220 / 6319003 / 7214060 / 7448870
RU Russia: 2361540 / 2361541 / 2372046

REF 1600598-001 CA 20:1L / REF 1600632-001 CA 20:1 / REF 1600785-001 CA 20:1L KM /
REF 1600692-001 CA 20:1L Micro-Series / REF 1600786-001 CA 20:1L KM Micro-Series

REF Legend

1600598-001	Contra-angle handpiece speed reducing ratio CA 20:1 L with light, push-button grip, external irrigation
1600632-001	Contra-angle handpiece speed reducing ratio CA 20:1 L without light, push-button grip, external irrigation
1600692-001	Contra-angle handpiece speed reducing ratio CA 20:1 L Micro-Series with light, push-button grip, external irrigation
1600785-001	Contra-angle handpiece speed reducing ratio CA 20:1 L KM with light, push-button grip, external irrigation + Kirschner/Meyer type detachable irrigation system. Including irrigation set REF 1501621-010
1600786-001	Contra-angle handpiece speed reducing ratio CA 20:1 L KM Micro-Series with light, push-button grip, external irrigation + Kirschner/Meyer type detachable irrigation system. Including irrigation set REF 1501621-010
1501621-010	Kirschner/Meyer type detachable irrigation set for CA 20:1 L KM and CA 20:1 L KM Micro-Series, comprising 10 rings and 10 tubes
1501635-010	Kirschner/Meyer pack of 10 disposable sterile lines
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	Lubrifiuid, lubricant 500 ml, box of 6 cans

List of Bien-Air Dental SA registered trade mark products ®:

Aquilon®	Eolia®	Lubrifiuid®	Prestilina®
Bora®	Gyro®	Lubrimed®	Spraynet®
Boralina®	Gyrolina®	MX®	
ChiroPro®	Isolite®	PowerCare®	

In these instructions, "Device" corresponds to the product described in the heading "Type". For example, turbine, contra-angle, handpiece, micromotor, tube, electronics, connectors, station etc.

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