CA 15:1 PROPHY
PM 10:1 PROPHY

ENG INSTRUCTIONS FOR USE

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

CE 0123 RX Only

REF 2100050-0002/2024-04

Devices

CA 15:1 PROPHY
REF 1600290-001

PM 10:1 PROPHY
REF 1600289-001

Optional accessories (REF)

SCREW-TYPE MANDRE
(10/pkg)
REF 033.41.11-010

HEAD PM PROPHY
DISPOSABLE (100/pkg)
REF 1100056-100

MAINT SPRAYNET
(BOX 6 CANS)
REF 1600036-006

MAINT LUBRIFLUID
(BOX 6 CANS)
REF REF 1600064-006

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.		

2 Identification & Intended Use

2.1 Identification

Medical devices manufactured by Bien-Air Dental SA.

Type

Dental contra-angled (CA) and straight handpiece (PM), sterilizable and thermos-desinfectable, with neither light nor spray.

Description

Bien-Air Dental contra-angles and straight handpieces 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 15:1 PROPHY		●	●	
● PM 10:1 PROPHY		●	●	

2.2 Intended Use

Devices intended for use in general dentistry for dental prophylaxis.

2.3 Intended patient population

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

Device 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 dental prophylaxis and address the maintenance or reestablishment of dental health.

2.7 Patient contra-indication and side effects

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

⚠ **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.
- The prophy tools are single use only. Do not re-use.

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

⚠ **WARNING**

- Do not touch the tool while the device is rotating.
- Each time a prophy tool is inserted, check that the tool is fully inserted or screwed to the stop. Always check that the tool is locked by gently pushing and pulling the tool.
- Never use a prophy tool if the tip is not compliant with specifications.

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

⚠ **CAUTION**

- The device must not be started without a prophy tool inserted.

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.

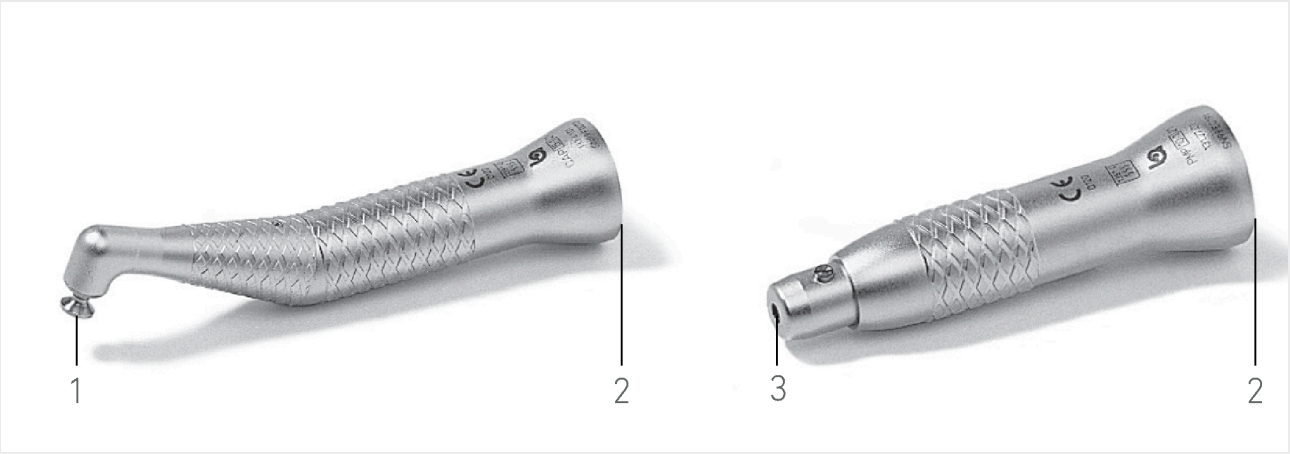

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) Screw-type mandrel for fixing Snap-On prophy tool

(2) Micromotor connection

(3) Handpiece head for prophy head insertion

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

Technical data	CA 15:1 PROPHY	PM 10:1 PROPHY
Motor coupling compatibility	Coupling according to ISO 3964	
Transmission ratio according to ISO 14457	Speed increasing ratio 15:1 (green color)	Speed increasing ratio 10:1 (green color)
Motor max speed	40'000 rpm	
Tool max speed	2'700 rpm	4'000 rpm
Tool compatibility	Screw type cup M 1.8 or "snap-on-cup" in combination with screw type mandrel	Prophylaxis heads with Doriot connector (shaft compliant with ISO 14457)

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

4.3 Classification

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

4.4 Performances

Performances	CA 15:1 PROPHY	PM 10:1 PROPHY
Speed transmission ratio	15:1	10:1

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]
	Keep away from rain	

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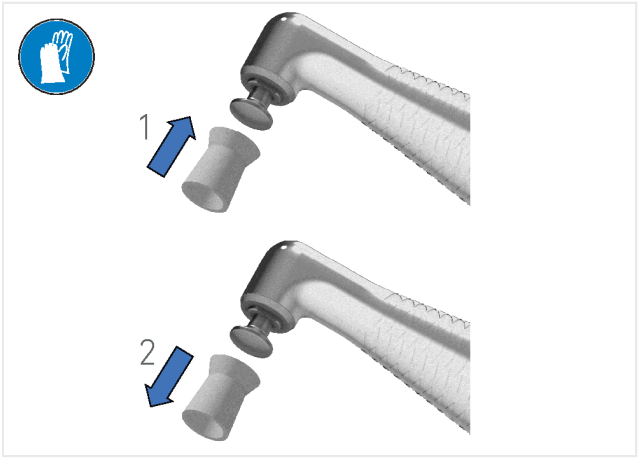


FIG. 2

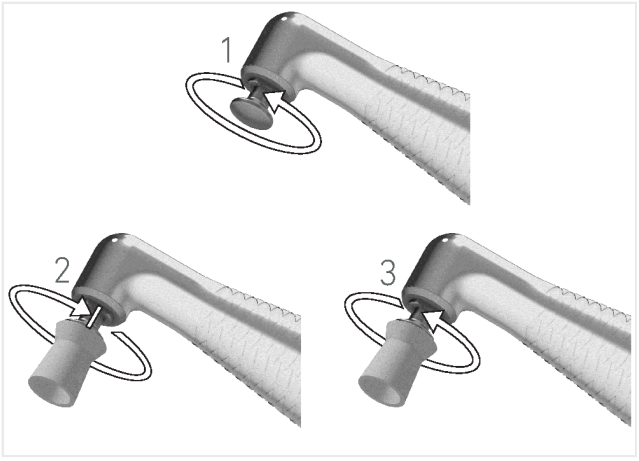


FIG. 3

5 Operation

5.1 Pictograms used

Sym	Description	Sym	Description
	Movement in the direction indicated.		Movement to the stop in the direction indicated.

5.2 Changing the prophy tool

For CA 15:1

For the snap-on cup, clip the tool on the screw-type mandrel (FIG. 2, step 1). After clinical treatment unclip the snap-on cup (FIG. 2, step 2) and dispose it then unscrew the screw-type mandrel (FIG. 3, step 1) before proceeding with the reprocessing cycle.
For screw-type cup, screw the tool to the head of the contra-angle (FIG. 3, step 2). After clinical treatment unscrew the screw-type cup (FIG. 3, step 3) and dispose it before proceeding with the reprocessing cycle.
For replacing and/or reprocessing the screw-type mandrel, unscrew it from the contra-angle (FIG. 3, step 1).
For disposal, follow the indication in Disposal.

Note : If unscrewing the screw-type mandrel or cup is hard, connect the CA to the motor turned off.

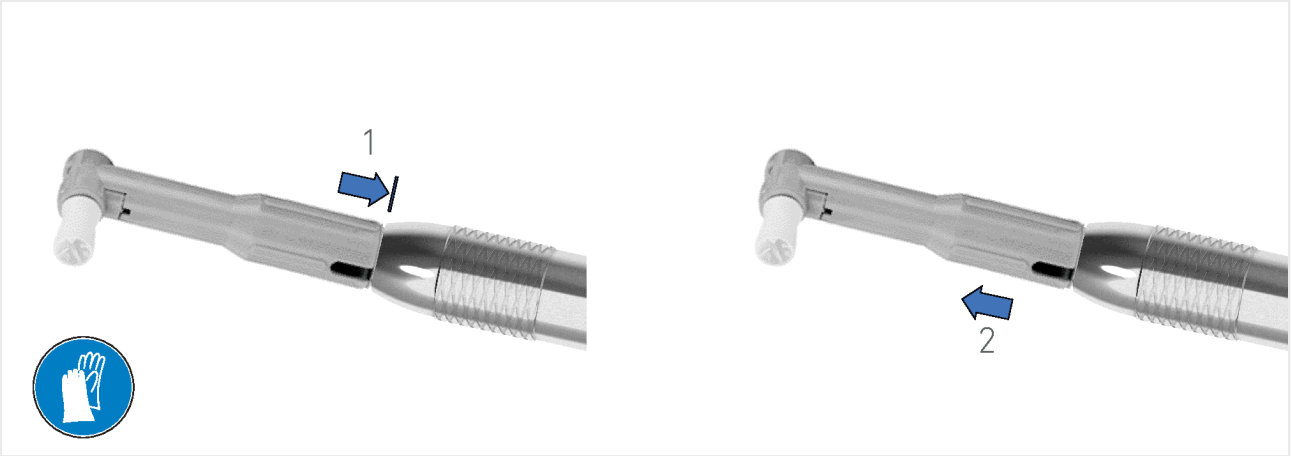


FIG. 4

For PM 10:1

Before connecting the handpiece to the motor, fit the disposable head in the handpiece chuck, by simply pushing it to the stop (FIG. 4, step 1).
Disassembling the head Disconnect the handpiece from the motor. Then, disassemble the disposable head, by simply pulling it (FIG. 4, step 2).
Dispose it before proceeding with the reprocessing cycle.

Clamping system inspection

Verify that the prophy tool can be turned around smoothly and check that the tool is fully inserted or screwed to the stop. Always check that the tool is locked by gently pushing and pulling the tool.

⚠ **WARNING**

- Never insert or remove a prophy tool while the device is rotating.
- The prophy tools are single use only, do not re-use.
- Do not touch the prophy tool while the device is rotating.
- Each time a prophy tool is inserted, check that the prophy tool is fully inserted to the stop. Always check that the tool is locked by gently pushing and pulling the tool.

⚠ **CAUTION**

- If the prophy tool 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

Immediately after the treatment, disconnect and eliminate the prophy disposable tool.

⚠ **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®.

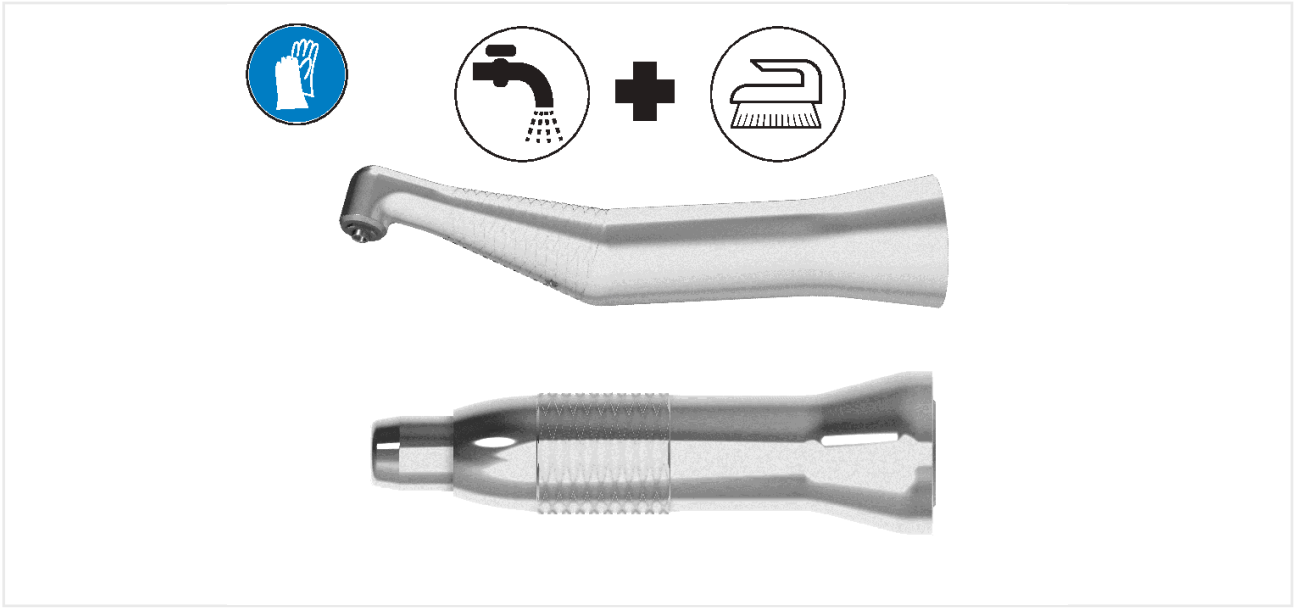


FIG. 5

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 prophy tool fastened.
- If there is a large amount of debris, clean the exterior of the device with disinfectant wipes.

Preparation

1. Remove the irrigation line then disconnect the device from the electrical motor.
2. For CA 15:1, remove the screw-type mandrel (FIG. 3 step 1).
3. Submit devices to the following cleaning process.

Remove dirt / deposits

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. 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 concen- tration 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

Never rinse the devices to cool them.
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 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. 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 or the straight handpiece 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 prophy tool and the metallic screw-type mandrel of the CA15:1 PROPHY must be disassembled from the device prior to sterilization.

6.5.3 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 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.

ENG

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.

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

6.7 Servicing

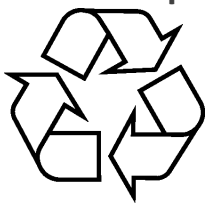
Bien-Air Dental SA recommends a regular service for the handpiece after 4,000 processing cycles or 5 years. Never dismantle the device.
It is recommended to replace the screwtype mandrel every 100 sterilization cycles.
For all servicing or repair operations, you are advised to contact your usual supplier 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 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
1600290-001	Contra-angle handpiece decreasing ratio 15:1 without light nor spray
1600289-001	Straight handpiece decreasing ratio 10:1 without light nor spray
033.41.11-010	Metallic screw type mandrel to allow “Snap-on” prophy tool fixation
1100056-100	Head PM Prophy disposable
1600036-006	Spraynet®, cleaning spray 500 ml, box of 6 cans
1600064-006	Lubrifluid®, lubricant 500 ml, box of 6 cans

ENG

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