

TORNADO LED, LK
TORNADO^S LED, LK



ENG INSTRUCTIONS FOR USE.

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CE
0120

REF 2100277-0003/2018.02

Set supplied (REF) *see section 8.2 References, on page 13 for details



1600907-001



1600908-001



1600932-001



1600933-001

Optional accessories (REF) *see section "8.2 References" on page 13 for details



1600243-001



1600082-001



1600363-001



1600866-001



1600902-001



1000001-001



1600037-006



1000003-001



1600036-006



1600064-006



















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ENG INSTRUCTIONS FOR USE

1 Symbols

1.1 Description of symbols used

Sym	Description	Sym	Description
	Manufacturer.		Reference number.
	CE Marking with number of the notified body.		Serial number.
	CAUTION!		Separate collection of electric and electronic equipment.
	Refer to the accompanying documents.		Recyclable materials.
	4-way fitting.		Use rubber gloves.
	Electric powered 4-way fitting (4VLM).		After initial mechanical resistance, tighten fully in the direction indicated.
	Cleaning in machine authorised.		Back and forth movement.
	Movement in the direction indicated.		Sterilisation in an autoclave up to the specified temperature.
	Movement to the stop in the direction indicated.		Light.

2 Identification & Intended Use

2.1 Identification

Medical device manufactured in Switzerland by Bien-Air Dental SA.

Type

Turbine type high-speed handpiece. Unit supplied by a hose, via a special ISO 9168 coupling. Push-button bur locking with anti-heating system. Ceramic ball bearings, 4 mixed sprays.

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. It is intended for use in dentistry for restorative procedures.

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

CAUTION

The device must not be used if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air current could propel infected material into the wounds, causing infection and a risk of embolism.

3 Precautions for use

This medical device accessory 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

Install the device on an appropriate outlet to protect against the risk of injury or infection.

CAUTION

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.

CAUTION

To avoid adversely affecting the device's service life, ensure purified, dry compressed air is used. Ensure the quality of the air and water being supplied through regular

maintenance of the compressor and the filtration systems.

Note: *Using unfiltered hard water will speed up blockage of the hoses, couplings and spray diffusers.*

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.*

For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

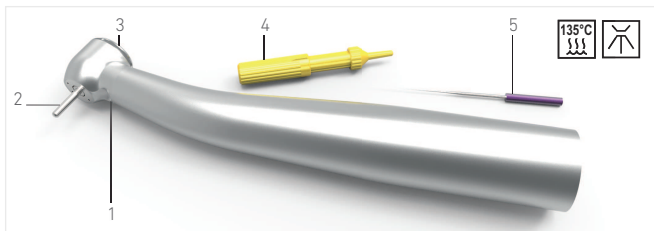


FIG. 1 (TORNADO LED)

4 Description

4.1 Overview

FIG. 1

- (1) Light output
- (2) Bur (not supplied)
- (3) Push-button
- (4) Lubrified greaser
- (5) Cleaning wire

Electric power supply

VDC or VAC: 3.4 ± 0.3 . The power supply systems must be in compliance with IEC 60601-1 and IEC 60601-1-2 standards. Declaration by the manufacturer regarding electromagnetic compatibility: refer to the tables 9 EMC, on page 14.

4.2 Technical data

Turbine	TORNADO LED / LK	TORNADO ^S LED, LK
Connection	Unifix 4-way coupling (LED, S LED) Multiflex® 4-way coupling (LK, S LK)	
Speed of rotation (no load)	Approx. 380'000 rpm	Approx. 420'000 rpm
Maximum torque	Approx. 0.25 Ncm	Approx. 0.25 Ncm
Weight	59 g (LED) / 58 g (LK)	59 g (S LED) / 58 g (S LK)
Dimensions of the head (Head height x diameter)	13.0x12.2 mm	12.1x10.8 mm
Length	112 mm	
Air consumption	50 NI/min	
Pressure	2.5-3.2 bar	
Spray water consumption	70 ml/min	
Spray air consumption	3 NI/min	
Spray water pressure	200 kPa	
Spray air pressure	200 kPa	

Type 3 / ISO 1797-1
Code 4-5 / ISO 6360-1

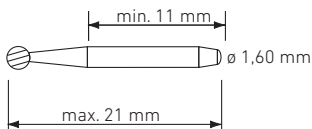


FIG. 2

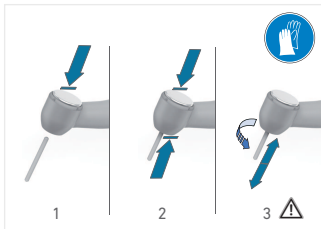


FIG. 3

Bur chuck

FIG. 2

Tip diameter 1.60 mm, type 3 as per ISO 1797-1; max length for short to long types 21 mm, code 4 to 5 as per ISO 6360-1 (max. working diameter 2 mm).

⚠ CAUTION

Follow the guidelines for use, according to the bur manufacturer's instructions. Never use a bur if the tip is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, and the patient or third parties.

5 Operation

5.1 Changing the bur

FIG. 3

Push-button bur locking.

1. Press the push-button and simultaneously pull the bur.
2. Press the push-button, insert the new bur until locked in place and release the push-button.
3. Check that the bur rotates freely and check it is locked by gently pushing and pulling the bur.

5.2 Operation

⚠ CAUTION

Do not operate the device until a tool has been inserted in the chuck. To prevent the push-button from overheating, which could lead to burns, it must not be pressed accidentally when the instrument is rotating. Soft tissue (tongue, cheek, lips, etc.) must be protected by moving it away using a retractor or dental mirror.

⚠ CAUTION

Always ensure that the spray outlets are not obstructed.

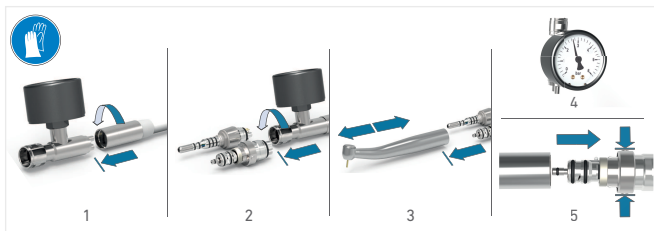


FIG. 4

5.3 Installing the turbine

The TORNADO LED and S LED are connected to a Unifix rotating quick-connect coupling (4-way) and the TORNADO LK and S LK to a MULTiflex® 4-way coupling.


FIG. 4

1. Connect the pressure gauge to the hose and screw it in fully.
2. Connect the coupling (Unifix or MULTiflex®) to the pressure gauge and screw it in fully.
3. Insert the turbine onto the coupling. Check that the turbine is correctly connected by moving it back and forth.
4. Adjust the required air pressure using the Bien-Air Dental SA pressure gauge (between 2.5 and 3.2 bar).
5. To remove the TORNADO LED turbine from the Unifix coupling, press the 2 push-buttons and simultaneously remove the turbine from the coupling.

⚠ CAUTION

The instrument is supplied "non sterile".

6.1.1 Precautions for maintenance

- Before first use and IMMEDIATELY after each procedure, clean, lubricate and sterilise the device.
- Only instruments marked with the  logo can be cleaned in a washer-disinfector machine.
- MULTiflex® and Unifix couplings cannot be sterilised.
- Do not immerse in an ultrasonic cleaner.
- Only use original Bien-Air Dental SA 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.

Bur chuck mechanism

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

6 Cleaning and servicing

6.1 Maintenance

Clean, lubricate and sterilise the device separately between patients.

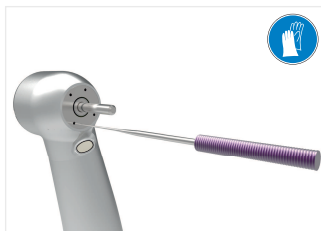


FIG. 5

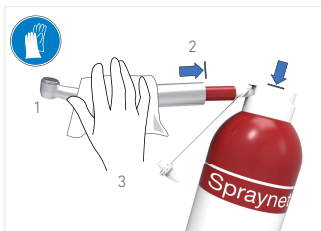


FIG. 6

6.1.2 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-disinfect (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.

6.2 Preliminary cleaning

Preparation

FIG. 5

1. Disconnect the device from the coupling and remove the bur (FIG. 3, step 1.).

6.2.1 Manual preliminary cleaning

FIG. 6

CAUTION

If there is a large amount of debris, clean the exterior of the device with disinfectant wipes. Observe the instructions given by the manufacturer.

CAUTION

Do not immerse in a disinfecting bath.

1. Unblock the spray tubes using the Bien-Air Dental SA cleaning wire.
2. Carry out manual pre-cleaning:
3. With the aid of a clean and disinfected soft bristled brush, clean the external surface of the motor under running water (< 38°C).
4. 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.

CAUTION

Do not immerse in an ultrasonic bath.

5. Leave any liquid residue to drip-dry, then wipe the exterior with a paper towel or move onto the cleaning-disinfection step immediately (see 6.3 Cleaning-disinfection, on page 9).

6.3 Cleaning-disinfection

6.3.1 Manual cleaning/disinfection

1. Disinfect instruments with disinfectant solution recommended for disinfection of dental instruments. Observe the instructions given by the manufacturer.

CAUTION

Do not immerse in a disinfectant bath.

6.3.2 Automatic cleaning-disinfection

CAUTION

Only for device 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.

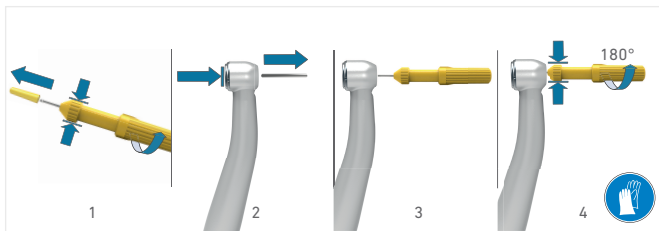


FIG. 7

6.4 Lubrication

Before each sterilisation, or at least twice a day, lubricate with Lubrimed medical grease, or with Lubrifluid lubricant.

6.4.1 Verifying cleanliness

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

6.4.2 Lubrication with Lubrimed

FIG. 7

1. Remove the cap from the yellow greaser and screw the knurled rear section whilst holding the front of the greaser until grease appears in the middle of the lubrication tip.
2. Remove the bur from the device.
3. Insert the tip of the greaser as far as it will go.
4. Screw the knurled rear section whilst holding the front of the greaser to inject the grease (the required amount corresponds to a $\frac{1}{2}$ turn of the knurled rear section; use the markers).
5. Put the cap back on after use.

6.4.3 Lubrication with Lubrifluid

FIG. 8

1. Remove the bur from the device, and place the device in a cloth to collect the excess.
2. Select the appropriate end-piece.
3. Insert the end-piece of the can Lubrifluid in the rear of the device's handle.
4. Actuate the spray for 1 second, and clean the excess oil on the exterior.

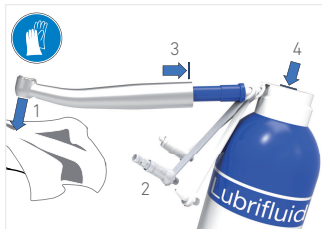


FIG. 8

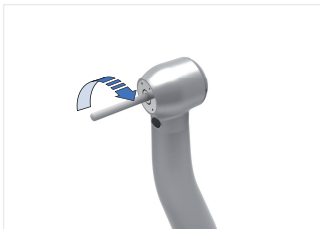


FIG. 9

6.5 Sterilisation

⚠ CAUTION

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

FIG. 9

After cleaning, disinfecting and sterilising the device, and before using it, start it up at moderate speed with a bur in the locking mechanism for 10 to 15 seconds to distribute and remove the excess lubricant.

6.6 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.

7 Packing and disposal

7.1 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.

Packing

Pack the device 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.

7.2 Disposal



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



The TORNADO turbine 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).

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 for this medical device is 24 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, 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 use
- failure to observe the servicing, assembly or maintenance instructions
- 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.

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

Translated from original French Instructions for use.

8.2.1 Set supplied (see cover)

REF	Legend
1600908-001	Turbine TORNADO LED
1600907-001	Turbine TORNADO LK
1600932-001	Turbine TORNADO ^S LED
1600933-001	Turbine TORNADO ^S LK

8.2.2 Optional accessories (see cover)

REF	Legend
1600243-001	Gauge for 4-way coupling
1600082-001	4-way Unifix coupling, for instruments without light
1600363-001	4-way Unifix coupling, for instruments with light
1600866-001	LED ADJ MULTiflex® 4-way coupling, with valve
1600902-001	LED 4-way MULTiflex® coupling
1000001-001	Cleaning wire, box of 10

REF	Legend
1600037-006	Lubrimed medical grease, box of 6 cartridges
1000003-001	Lubrimed greasers
1600036-006	Spraynet 500 ml cleaning spray, box of 6
1600064-006	Lubrifiuid 500 ml spray lubricant oil, box of 6

9 EMC

Electromagnetic Compatibility (technical description)

The intended EM environment (per IEC 60601-1-2 ed. 4.0) is *Professional healthcare facility environment*.

CAUTION

The TORNADO turbine complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. The device is not suitable for being used close to high-frequency surgical equipment, magnetic resonance imaging (MRI) and other similar devices where the intensity of electromagnetic disturbances is high. In any case, ensure that no high frequency cables are routed above or near the device. If in doubt, contact a qualified technician or Bien-Air Dental SA.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TORNADO turbine, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

CAUTION

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air Dental SA as spare parts for internal components, may result in increased emissions or decreased immunity.

CAUTION

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.


The TORNADO turbine is intended for use in the electromagnetic environment specified below. The customer or the user of the TORNADO turbine must ensure that it is actually used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The TORNADO turbine uses RF energy for its internal operation only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The TORNADO turbine is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

The TORNADO turbine is intended for use in the electromagnetic environment specified below. The customer or the user of the TORNADO turbine must ensure that it is actually used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for other lines	N/A N/A	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	N/A N/A N/A N/A N/A	Mains power quality should be that of a commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<p>0 % U_T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles at 0°</p>	<p>N/A</p> <p>N/A</p>	Mains power quality should be that of a commercial or hospital environment. If the user of the TORNADO turbine requires continued operation during mains power interruptions, it is recommended that the TORNADO turbine be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands 0,15 MHz – 80 MHz 80 % AM at 1 kHz	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM and amateur bands 0,15 MHz – 80 MHz 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹ should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	

1. *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TORNADO Turbine is used exceeds the RF compliance level mentioned above, the TORNADO turbine should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the TORNADO turbine.*

Immunity test	Test freq. [MHz]	Max power [W]	Immunity test level [V/m]	Electromagnetic environment - guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	385	1.8	27	Distance: 0.3 m
	450	2	28	
	710, 745, 780	0.2	9	
	810, 870, 930	2	28	
	1720, 1845, 1970	2	28	
	2450	2	28	
	5240, 5500, 5785	0.2	9	

Note: U_T is the AC mains voltage prior to application of the test level.

Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES

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