# PM 1:1
## TWIST DRILL

**ENG** INSTRUCTIONS FOR USE


Rx Only

CE
0123

REF: 2100424-0000 / 2022.06

## Set supplied

**PM 1:1 TWIST DRILL**
REF 1601190-001

## Optional accessories

SLEEVE CONE PM 1:1 EXT SPRAY
REF 1500003-001

RING WITH SPRAY TUBE
REF 1500552-001


MAINT SPRAYNET (BOX 6 CANS)
REF 1600036-006


MAINT LUBRIFLUID (BOX 6 CANS)
REF 1600064-006


MAINT AQUA CARE BOX OF 6 CANS
REF 1600617-006

IRRIGATION LINES
REF 1500984-010

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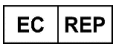
# ENG INSTRUCTIONS FOR USE

## 1 Symbols

### 1.1 Description of symbols used

| Symbol | Description | Symbol | Description |
|---|---|---|---|
|  | Manufacturer. |  | CE Marking with number of the notified body. |
|  | Medical device. |  | Serial number. |
|  | Catalogue number. |  | Authorized EC Representative in the European Community. |
| Rx Only | Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner. |  | Consult instructions for use or consult electronic instructions for use. |
|  | Use rubber gloves. |  | Thermo washer disinfectable. |
|  | CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed. |  | WARNING! hazard that could result in serious 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). |  | Sterilizable up to the specified temperature. |

### 1.2 Description of symbols used (accessory)

| Symbol | Description | Symbol | Description |
|---|---|---|---|
|  | Manufacturer. |  | CE Marking with number of the notified body. |
|  | Batch code. |  | Do not reuse. |
|  | Catalogue number. |  | Sterilized using ethylene oxide. |
|  | Refer to the accompanying documents. |  | Use by date. |
|  | Do not use if package is damaged. | | |

# 2 Identification & Intended Use

## 2.1 Identification

Medical device manufactured by Bien-Air Dental SA.

**Type**

Straight handpiece PM 1:1, external irrigation, without light, direct ratio, interchangeable nose with or without irrigation tube.

**Description**

Bien-Air Dental contra-angle and straight handpieces are designed to transmit and apply the mechanical energy produced by an electric or air micromotor.

## 2.2 Intended use

Product intended for use in oral and maxillofacial surgery.

## 2.3 Intended patient population

The intended patient population for the devices includes any person visiting a dental 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

The device is meant to be used only by surgeons in dental offices and hospitals.

## 2.5 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.

## 2.6 Patient contra-indications and side effects

No specific patient contra-indication, side effect nor warning exist for the device when it is used as intended.

## 2.7 In case of accident

If an accident occurs, the device must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.
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

This medical device must be used by professionals only 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.

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

⚠ WARNING

- Rest the device on a cleanable support to avoid risks of infection for yourself, the patient or third parties.
- 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.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6. Sterilization before first use is mandatory.
- 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.
- While performing surgical treatment, the handpiece must not receive pressurised cooling air from the unit, to prevent contamination of the area being treated.

**To prevent any risk of contra-angle/handpiece overheating, the cautions below must be observed:**

⚠ CAUTION

- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.

**To prevent any risk of injury and/or material damage the warnings below must be observed:**

⚠ WARNING

- The device is intended for professional use only.
- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.
- In the event of excessive vibrations, abnormal heating, unusual noise or other signs suggesting that the device is malfunctioning, work must be suspended immediately. In this case, contact a repair center approved by Bien-Air Dental SA.
- Never insert or remove a device while the micromotor is rotating.
- Do not touch the dental cutting tool while it is rotating.
- Never rotate the locking ring while the PM (straight handpiece) is in operation.
- Each time a cutting tool is inserted, check that the cutting tool is fully inserted to the stop and rotates freely. If it is blocked, contact your usual supplier or Bien-Air Dental SA for repair.

- Always check that the cutting tool is locked by gently pushing and pulling the cutting tool.
- Always check that the locking ring is fully tightened, passing the initial mechanical resistance to meet the abutment.
- Follow the guidelines for use, according to the cutting-tool manufacturer's instructions. Never use a cutting tool if the shaft is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or third parties.
- Comply with maximum lengths by always inserting the cutting tool as far as possible into the locking mechanism. If a cutting tool is operated at high speeds when incorrectly mounted (i.e. not fully inserted into the locking mechanism, or being longer than the values specified in section 4.2) a centrifugal force may be exerted which may bend or break the cutting tool.
- **Good practices of use** (e.g. for removing metal bridges, adjusting ceramic crowns or other milling operations on hard materials) **should always be followed**.
  They include but are not limited to: following the recommendation of the cutting-tool manufacturer, checking the integrity of the cutting tool and adapting the clinical protocol in order to avoid any risk of excessive vibration and damage to the device's integrity.
- Always ensure that the coolant supply is sufficient and adequate.

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

⚠ CAUTION

- Before performing any clinical application, always activate your device to ensure its proper operation.
- 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.

***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 those instructions for use is English.*
*For any further information, please contact Bien-Air Dental SA at the address given on the back cover.*

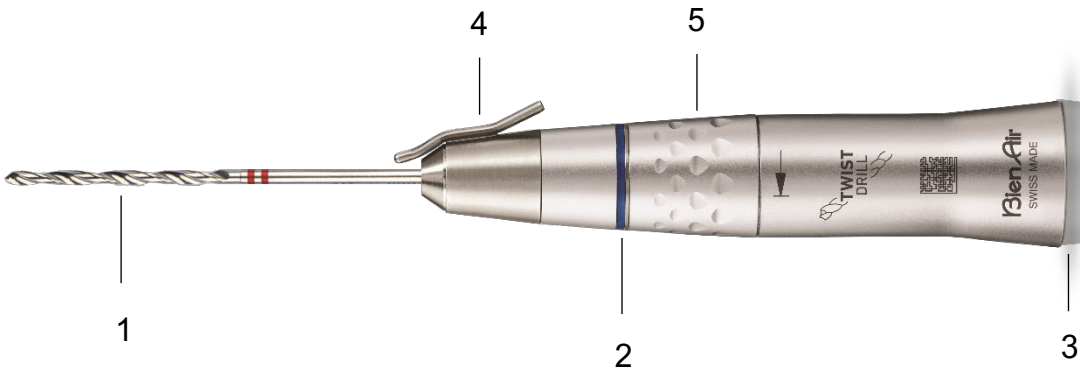



FIG. 1

# 4 Description

## 4.1 Overview

**FIG. 1**

(1) Cutting tool (not supplied)
(2) Transmission ratio
(3) Micromotor connection
(4) Irrigation tube
(5) Locking ring

## 4.2 Technical data

| PM 1:1 TWIST DRILL | |
|---|---|
| Standard coupling | ISO 3964 |
| Transmission ratio | Speed direct ratio |
| Motor drive speed | 40,000 rpm max |
| Cutting tool speed | 40,000 rpm max |

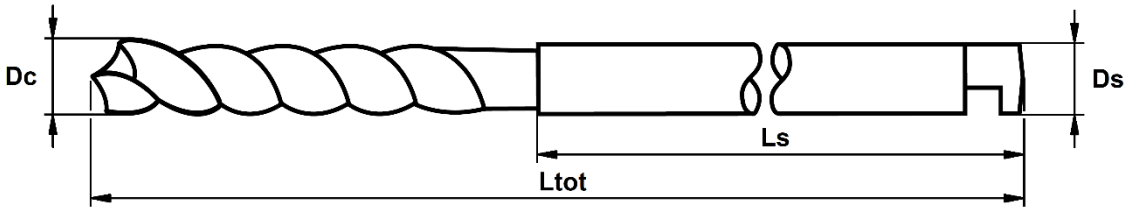



FIG. 2

| Designation | Shaft diameter Ds [mm] | Shaft length Ls [mm] | Cutting diameter Dc [mm] | Total length Ltot [mm] |
|---|---|---|---|---|
| TWIST DRILL | 2.35 (J-notch) | ≥ 26 | ≤ 2.2 | ≤ 115 |

⚠

For more information on the use of the cutting tools, please refer to the manufacturer IFU.

## 4.3 Classification

Class IIa in accordance with Regulation (EU) 2017/745 concerning medical devices.
Class I in accordance with Code of Federal Regulation (USA), title 21, 872.4200.

## 4.4 Performances

| Performances | |
|---|---|
| Irrigation flow 5 levels* | 25 - 110 ml/min |
| Torque transmission with multiplication ratio | 1:1±10% |

* In combination with Chiropro peristaltic pumps.

## 4.5 Operating Conditions

| Operating conditions | | |
|---|---|---|
| | Temperature range: | +10°C - +35°C (+50°F – +95°F) |
| | Relative humidity range: | 30% - 80% |
| | Air pressure range: | 700 hPa – 1060 hPa |

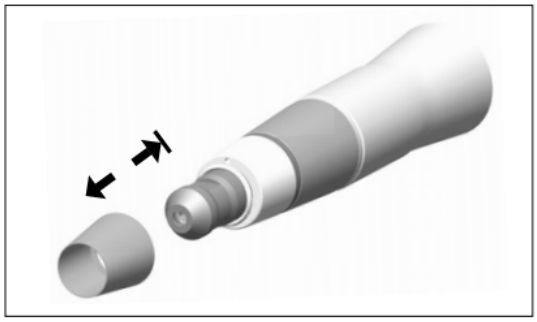


FIG. 3

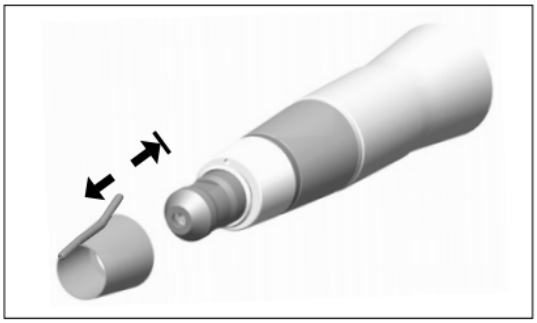


FIG. 4

**Irrigation / detachable noses**

Both detachable noses with and without irrigation tube (**see the section "optional accessories" or** FIG. 3 & FIG. 4) can be connected to the handpiece. The irrigation tube cannot be detached from its nose and is not meant to be bent by the user. An external irrigation line can be connected to the irrigation tube.

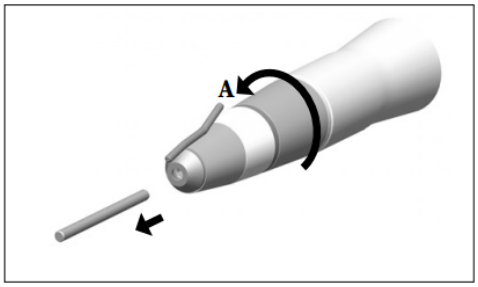



FIG. 5

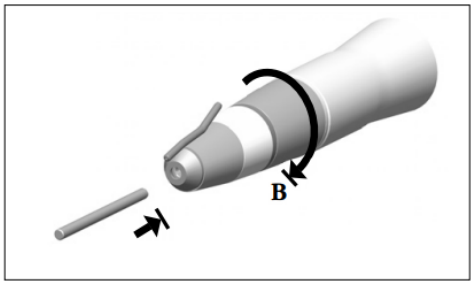



FIG. 6

**Changing the cutting tool**

Turn the locking ring completely in the direction of the arrow, insert the new cutting tool until the stop:
**A**: unlocking FIG. 5
**B**: locking FIG. 6
Once locked in, exert traction on the tool to check that it is correctly in place.


FIG. 7

**Cutting tool locking operation check** FIG. 7
Hold the handpiece upright by the cutting tool between your thumb and index finger and rotate the handpiece; the handpiece should rotate freely (more than 3 rotations).

# 6 Cleaning and servicing

## 6.1 Maintenance – General information

Clean, dry, lubricate and sterilize the device prior to first use.
Within a maximum of 30 minutes after each treatment, clean, disinfect and lubricate the instrument. Observing this procedure eliminates any blood or saliva residues and prevents the transmission system from being blocked.
Before surgical treatment, the handpiece must be sterilized.
**The following procedure applies to both the handpiece and attachment.**

⚠ WARNING

- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.
- The irrigation tube must be cleaned, disinfected and, if required by country-specific directives or by a surgical procedure, sterilized.

**Suitable maintenance products**
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.

- Spraynet®
- Aquacare
- 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.

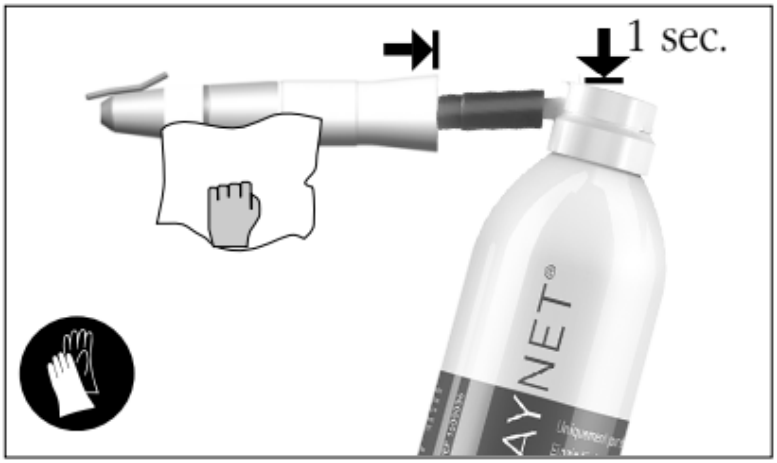



FIG. 8

## 6.2 Cleaning

- Do not submerge in physiological liquid (NaCl) nor 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 the cleaning, disinfection and sterilization processes without a cutting tool in the chuck mechanism.

**Preparation**

- Disconnect the drive motor attachment, rotate the locking ring, remove the cutting tool and leave the locking ring loosened FIG. 5.
- Disconnect the irrigation line, remove the detachable nose.

**Remove dirt / deposits**

FIG. 8

1. Clean the exterior and interior of the device under tap water between 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.
2. After selecting the appropriate nozzle, perform preliminary cleaning of the device by using the product Aquacare. Spray the inside and the outside of the device and inside the irrigation tube.

## 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. didecyldimethylammonium chloride, quaternary ammonium carbonate or neutral enzymatic product which are allowable chemical agents). 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 device twice with running tap water (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. 8**).
6. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

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

**Recommended specifications of the thermo-disinfection cycle:**

| Phase | Parameters |
|---|---|
| Pre-cleaning | <45°C (113°F); ≥ 2 minutes |
| Cleaning | 55°C-65°C (131°F-149°F); ≥ 5 minutes |
| Neutralization | ≥2 minutes |
| Rinsing | Tap water<br>≤30°C(86°F), ≥ 2 minutes cold water |
| Thermal Disinfection | 90°C-95°C(194°F-203°F), 5-10 minutes |
| Drying | 18-22 minutes |

⚠ CAUTION
Never cool devices by rinsing them.

⚠ CAUTION
If an automatic washer is used at the place 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.

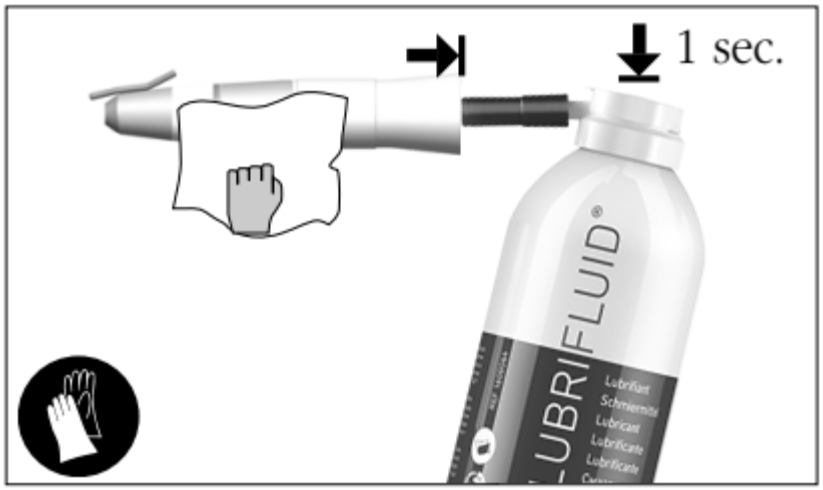



FIG. 9

## 6.4 Lubrication

### 6.4.1. Verifying cleanliness

Visually inspect the cleanliness of the attachment and the irrigation tube. Repeat the cleaning and disinfection procedure if necessary.

### 6.4.2 Lubrication

**FIG.9**

Lubricate before each sterilization or at least twice a day. Only the Lubrifluid® spray must be used.

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.

**Note:** If, during the test run of the handpiece before the clinical treatment, an excess of lubricant is ejected from the handpiece, prolongate the test run until the ejection stops.

## 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 handpiece and the attachment are 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 excess exposure to heat which can result in corrosion.

### 6.5.1 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 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).
- The rate of change of temperature does not exceed 15°C/min for increasing temperature and -35°C/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 water steam.

## 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: | 650 hPa - 1060 hPa |
|  | Keep away from rain. | |

The device must be stored inside the sterilization pouch in a dry and dust free environment. 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 its use.

⚠ CAUTION

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

## 6.7 Servicing

Bien-Air Dental SA recommends a regular service for the handpiece after 4,000 processing cycles or five 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 & disposal

## 7.1 Transport

| Transport conditions | | |
|---|---|---|
|  | Temperature range: | -20°C - +50°C (-4°F – 122°F) |
|  | Relative humidity range: | 5% - 80% |
|  | Air pressure range: | 650 hPa -1060 hPa |
|  | Keep away from rain. | |

## 7.2 Disposal

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

The handpiece 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 warranty covering any operating fault, or material or manufacturing defect.

The warranty period is:

- 12 months

from the date of invoicing.

In the event of a justified claim, Bien-Air Dental SA or its authorised representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, 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
- Faulty air or water 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.

| REF | Legend |
|---|---|
| 1601190-001 | PM 1:1 TWIST DRILL |
| 031.16.42-010 | Hose |
| 1500552-001 | Detachable nose with irrigation tube for PM 1:1 |
| 1500003-001 | Detachable nose without irrigation tube for PM 1:1 |
| 1600064-006 | Lubrifluid®, lubricant 500 ml, box of 6 cans |
| 1600036-006 | Spraynet®, cleaning spray 500 ml, box of 6 cans |
| 1600617-006 | Aquacare, rinsing spray 500ml, box of 6 cans |

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