

# RECIPROCATING MICROSAW



ENG INSTRUCTIONS FOR USE

## Set supplied (REF) RECIPROCATING MICROSAW



RECIPROCATING  
MICROSAW  
REF 1601098-001



Irrigation ring  
REF 1502918-001



O-rings  
REF 1308430-001

## Optional accessories (REF)



Spraynet®  
REF 1600036-006



Lubrifiuid®  
REF 1600064-006



Aquacare  
REF 1600617-006



Irrigation line  
REF 1500984-010
















Irrigation ring  
REF 1502918-001

# Table of contents

<b>1</b>	<b>Symbols</b>	<b>5</b>		
1.1	Description of symbols used	5		
<b>2</b>	<b>Identification &amp; Intended Use</b>	<b>6</b>		
2.1	Identification	6		
2.2	Intended use	6		
2.3	Intended patient population	6		
2.4	Intended User	6		
2.5	Intended medical condition	6		
2.6	Patient contra-indications	6		
2.7	In case of accidents	6		
<b>3</b>	<b>Warnings and Precautions of use</b>	<b>7</b>		
3.1	General information	7		
3.2	Warnings	7		
<b>4</b>	<b>Description</b>	<b>8</b>		
4.1	Overview	8		
4.2	Technical data	8		
4.3	Performances	9		
<b>5</b>	<b>Operation</b>	<b>10</b>		
5.1	Operating conditions and procedure	10		
5.2	Changing the cutting tool	11		
5.3	Changing the irrigation line	11		
5.3.1	Removing the irrigation line and (optionally) the irrigation ring.	12		
5.3.2	Connect a new irrigation line.	12		
5.4	Changing the O-rings	13		
5.4.1	Missing or damaged O-rings.	13		
			5.4.2 Replacing the O-rings.	13
<b>6</b>	<b>Cleaning and servicing</b>	<b>14</b>		
6.1	Maintenance - General information	14		
6.1.1	Precautions for maintenance.	14		
6.1.2	Suitable maintenance products.	14		
6.1.3	Microsaw and irrigation ring.	15		
6.2	Cleaning	15		
6.3	Disinfection	16		
6.3.1	Manual disinfection.	16		
6.3.2	Automatic disinfection (optional).	17		
6.4	Lubrication	18		
6.4.1	Verifying cleanliness.	18		
6.4.2	Lubrication with Lubrifluid®.	18		
6.5	Sterilization	18		
6.5.1	Procedure.	19		
6.6	Packing and storage	20		
6.7	Servicing	20		
<b>7</b>	<b>Transport &amp; disposal</b>	<b>20</b>		
7.1	Transport	20		
7.2	Disposal	20		
<b>8</b>	<b>General information</b>	<b>21</b>		
8.1	Terms of guarantee	21		
8.2	References	21		
8.2.1	Sets supplied (see cover).	21		
8.2.2	Optional accessories (see cover).	21		

## 1 Symbols

### 1.1 Description of symbols used

Sym	Description	Sym	Description
	Manufacturer.		Catalogue number.
	Sterilizable in a steam sterilizer (autoclave) up to the specified temperature.		Serial number.
Rx Only	Caution: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Data Matrix code for product information including UDI (Unique Device Identification).
	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		Washer-disinfector for thermal disinfection.
	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.		General symbol for recovery/recyclable.
	Water tap, open (to be cleaned under an open water tap)		Wear protective gloves.
	Refer to the accompanying documents.		Back and forth movement.

## 2 Identification & Intended Use

### 2.1 Identification

Medical device manufactured by Bien-Air Dental SA.

#### Type

Reciprocating microsaw\* handpiece, with internal irrigation, without light, to be connected to a E type short micro motor (ISO 3964).

\*Hereafter: Microsaw

#### Classification

Class I according to FDA Code of Federal Regulations 21 CFR 878.4820 relating to medical devices. This medical device complies with the legislation in force.

### 2.2 Intended use

The Microsaw is intended to be used in oral and maxillofacial surgery for cutting bone and hard tissues.

### 2.3 Intended patient population

The intended patient population of the Microsaw includes any person visiting a dental or 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

The microsaw is intended to be used by oral and maxillofacial surgeons and plastic surgeons in an operating room.

### 2.5 Intended medical condition

Correction of craniofacial deformities, including but not limited to bone tumor, sleep apnea, cleft palate and bone grafting therapy.

**The main treatments may include:**

- Orthognathic surgery
- Genioplasty
- Rhinoplasty

### 2.6 Patient contra-indications

No specific patient contra-indication exist for the Microsaw device family when the device is used as intended.

### 2.7 In case of accidents

The Microsaw system (microsaw and cutting tools) must not be used until repairs of the microsaw have been completed by a qualified and trained technician authorized by the manufacturer. Damaged or deformed cutting tools must be disposed of.

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.

# 3 Warnings and Precautions of use

## 3.1 General information

The device must be used by qualified 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.

sharp instruments should be handled with great care.

### **WARNING**

Any modification of the medical device is strictly forbidden.

### **CAUTION**

Only operate the drive motor with a maximum speed as indicated in §4.2.

### **WARNING**

In order to prevent necrosis caused by the heat on the bone and blockage of the cutting tool with bone material, we recommend continuous irrigation during use.

### **WARNING**

Use physiological, sterile cooling fluid.

### **WARNING**

Always use sterile, single-use cutting tools and irrigation lines recommended by Bien-Air Dental SA. Replace blunt or bent cutting tools.

## 3.2 Warnings

### **WARNING**

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

### **WARNING**

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

**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.*

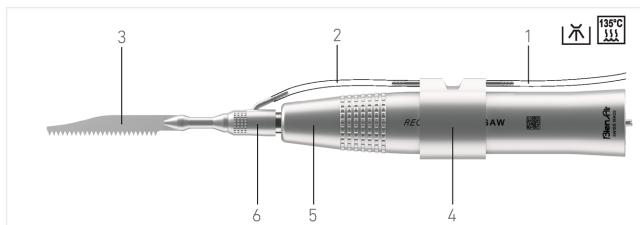


FIG. 1

## 4 Description

### 4.1 Overview

FIG. 1

- (1) Irrigation line (connected to the peristaltic pump)
- (2) Irrigation line cut portion
- (3) Cutting tool
- (4) Irrigation ring
- (5) Reciprocating micro-saw
- (6) Clamping ring

### 4.2 Technical data

The following technical data and performances apply to the reciprocating micro-saw device (the dispersion affecting these quantities is below or equal to 5%).

Technical data	Reciprocating micro-saw 1601098-001	Irrigation ring 1502918-001
Weight	118 g	12.3 g
Overall length	117 mm	34.9 mm (19 mm W/O tubes)
Maximum diameter	19.6 mm	23.5 mm (cylindrical: 21.2 mm)
Coupling type	ISO 3964	N/A
Multiplication ratio	2.6:1	N/A
Maximum reciprocating frequency (motor running at 40'000 rpm)	15200 cycle/min	N/A
Stroke length	2.7 mm	N/A
Maximum torque consumption in no-load	< 1.2 Ncm (*)	N/A

### 4.3 Performances

Performances	Reciprocating microsaw
Cutting speed	≥ 5.5 mm/s (**)
Maximum distribution of physiological liquid	≥ 100 ml/min (**)
Minimum distribution of physiological liquid	≥ 50 ml/min (**)
Noise in no-load (at 1 meter)	< 75 dBA (*)
Hand-transmitted vibrations in no-load	< 20 m/s <sup>2</sup> (*)

(\*) Measurement realized in combination with motor MX-i LED REF1600755, electronic console Chiropro L REF1600613 and cutting tool REF1502679, with motor speed 40000 rpm and without irrigation.

(\*\*) Measurement realized with the irrigation ring REF1502918 and the irrigation line REF1500984, in combination with motor MX-i LED REF1600755, electronic console Chiropro L REF1600613 and cutting tool REF1502679, with motor speed 40000 rpm. The Chiropro irrigation levels '2 drops' and '5 drops' correspond to the minimum and maximum distribution, respectively.

(\*\*\*) Measurement realized with the irrigation line REF1500984 (without the irrigation ring REF1502918), in combination with motor MX-i LED REF1600755, electronic console Chiropro L REF1600613 and cutting tool REF1502679, with motor speed 40000 rpm and the Chiropro irrigation level '2 drops'. A bloc of Sawbone PCF 30 (20x20mm) is cut by applying a constant force of 9.5 N.



## 5 Operation

### 5.1 Operating conditions and procedure

**Before operating the device, follow this procedure:**

1. Check that the ambient temperature ranges between +10°C to +35°C (+50°F to +95°F) and that it is under standard humidity conditions (relative humidity below 80%, without condensation).
2. Check that the settings parameters of the irrigation system are set so that the irrigation flow supplies the blade at least 60 ml/min. (**Note:** If the internal irrigation is used in combination with a Chiropro console, this corresponds to the irrigation level: « 2 drops »).
3. If required by the clinical operation, insert and push the irrigation ring on the micro-saw to set the irrigation ring on the cylindrical part of the micro-saw (as shown in the [FIG. 1](#), the irrigation ring must be pushed at least until the end of the front-side irrigation tube of the irrigation ring is aligned with the last knurled pattern).
4. Connect the irrigation line to the irrigation tube of the micro-saw device and, if the irrigation ring is mounted, to the 2 irrigation tubes of the irrigation ring.
5. Fix a suitable Bien-Air cutting tool to the micro-saw (which should already be equipped with the irrigation ring, if necessary) and orient the irrigation tube of the micro-saw and the irrigation ring so as to ensure a comfortable grip.
6. Connect the micro-saw system (after having mounted the irrigation ring and the cutting tool) to a micro-motor compatible with ISO 3964.

7. Operate without load the micro-saw system for at least 5 seconds and check that it performs properly.

#### CAUTION

Check the Microsaw handpiece for damage and loose parts before each use.

#### WARNING

**The use of a coolant while the instrument is in operation is mandatory,** failure to comply with this recommendation may result in overheating and burns or product failure. Set the coolant quantity for the cooling irrigation to at least 60 ml / min.

#### CAUTION

Depending on the angular position of the clamping ring, a difference of flow rate may be noticed for high flow rate.

#### CAUTION

Before each use, always check that the physiological solution flows freely and without leak out of the cutting tool.

#### CAUTION

Perform a test run during 5 seconds before each use. If the irrigation of the surgical site will be realized through the cutting tool, also activate the irrigation during the test run and check the irrigation flow.

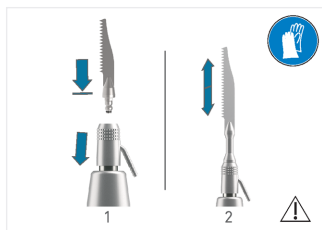



FIG. 2

 Movement to the stop in the direction indicated.

 Movement in the direction indicated.

### Description of pictograms used

## 5.2 Changing the cutting tool

1. Pull the clamping ring to the rear and gently insert the cutting accessory in the micro-saw handpiece up to the thrust stop. Then release the clamping ring, which should freely return to its initial position (FIG. 2 step 1).
2. Gently push and pull the cutting tool to check it is correctly attached (FIG. 2 step 2).
3. If the cutting tool is not correctly in place, pull the clamping ring to the rear, remove it and start operation again.

### WARNING

Follow the guidelines for use, according to the Bien-Air cutting tool's instructions. Never use a non-original Bien-Air cutting tool if the tip is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or any third parties.

### WARNING

The use of a non-original Bien-Air cutting tool will prevent proper irrigation of the surgical site through the orifice of the cutting tool.

### WARNING

Make sure that the cutting tool is correctly inserted by moving and rotating the latter back and forth. The cutting tool must remain in place.

### WARNING

Avoid applying too much force as the temperature may significantly increase. This entails a risk of thermal necrosis.

### CAUTION

The micro-saw must be activated before it is put on the bone. Perform cutting operations with a slight pressure exerted in the direction of the bone or hard tissues.

### WARNING

Never touch a cutting tool on a micro-saw in motion.

## 5.3 Changing the irrigation line

### WARNING

Irrigation lines are single use. The irrigation ring is reusable.

### CAUTION

Prior to changing the irrigation line and ring, always remove the cutting tool, as it may damage the irrigation ring O-rings.

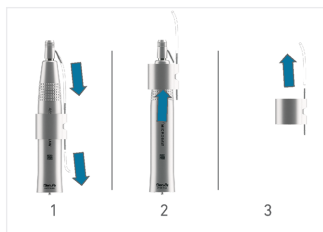


FIG. 3

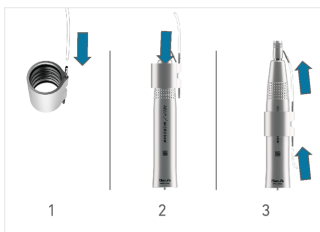


FIG. 4

### 5.3.1 Removing the irrigation line and (optionally) the irrigation ring

1. Gently pull out the irrigation line from the rear side of the irrigation ring (FIG. 3 step 1).
2. Gently pull out the irrigation line cut portion from the front tube of the micro-saw (FIG. 3 step 2).
3. a) If the irrigation ring stays on the micro-saw, gently pull out the remaining irrigation line from the irrigation ring).  
b) If the irrigation ring does not stay on the micro-saw, carefully slide the irrigation ring toward the front side of the micro-saw (FIG. 3 step 2), then gently pull out the remaining irrigation line cut portion from the other tube of the removed irrigation ring (FIG. 3 step 3).

### 5.3.2 Connect a new irrigation line

1. a) If the irrigation ring has been removed before reprocessing the device, inspect the irrigation ring. Make sure the two O-rings are in the grooves. Cut off an irrigation line portion of 50-60mm (about 2 inches) with sterile scissors, insert on the front side tube of the irrigation ring (FIG. 4 step 1) and insert the irrigation ring on the micro-saw by sliding it from the front side to the rear side (FIG. 4 step 2).  
b) If the irrigation ring has not been removed before reprocessing the device, cut off an irrigation line portion of 50-60mm (about 2 inches) with sterile scissors. Insert on the tube in the front side of the irrigation ring.
2. Connect the irrigation line portion of the irrigation ring to the front tube of the micro-saw. Make sure the irrigation line is loose enough to allow the reciprocating motion of the micro-saw nose (FIG. 4 step 3).
3. Connect the remaining irrigation line to the rear side of the irrigation ring (FIG. 4 step 3).

## 5.4 Changing the O-rings

### 5.4.1 Missing or damaged O-rings

#### In case of insufficient irrigation and leakage:

- Make sure that all O-rings are on the irrigation ring and are undamaged.
- If at least one O-ring is missing on the irrigation ring or damaged: replace the O-rings.

### 5.4.2 Replacing the O-rings

1. Use a removal tool such as a dental hook or tweezers to extract the O-ring from its groove.
2. Carefully pull the O-ring out. Avoid scratching the metal.
3. Insert the new O-ring by gently pressing it between your fingers to form a loop.  
Do not use a tool to prevent O-ring damage.

#### **CAUTION**

Improper care of the O-rings may lead to insufficient irrigation and leakage.

1. Do not use Vaseline or other grease oil.
2. The O-rings on the irrigation ring may only be lubricated with a cotton ball wetted with Bien-Air Dental Lubrifluid® or Lubrimed®.

## 6 Cleaning and servicing

### 6.1 Maintenance - General information

#### **WARNING**

The microsaw and the ring are supplied "non sterile". Clean, dry and sterilize the device prior to first use.

#### 6.1.1 Precautions for maintenance

- Within a maximum of 30 minutes after each treatment, clean and disinfect the instrument (lubrication and sterilization can be done later). Observing this procedure eliminates any blood, saliva or physiological solution 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 warranty.

#### **CAUTION**

- Carry out the cleaning-disinfection-sterilization processes without a cutting tool or an irrigation line in the chuck mechanism.
- Use detergents that are pH 8-11, are neither corrosive nor contain chlorine, acetone and/or aldehydes.
- 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).

- As with all instruments, following each sterilization cycle, including drying, remove the device to avoid excess exposure to heat which can result in corrosion.
- Use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system.

#### 6.1.2 Suitable maintenance products

##### Manual cleaning:

- Spraynet®.
- Aquacare.

##### 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 or alkaline enzymatic product. (e.g. neodisher® MediClean) are also allowable.

##### Automatic cleaning-disinfection:

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

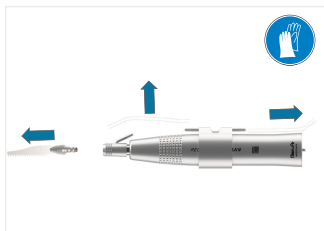


FIG. 5

### 6.1.3 Microsaw and irrigation ring

- For cleaning, disinfection, and sterilization, if present, the irrigation ring may be either cleaned separately or left on the microsaw. For the last case, after a maximal amount of 25 uses, the irrigation ring must be disconnected, checked, and the microsaw with the irrigation ring must be cleaned, disinfected, and sterilized separately.

#### **WARNING**

At any time, if the irrigation ring is in a clogged state or damaged, proceed to change with a new one.

## 6.2 Cleaning

### Preparation

#### FIG. 5

1. Disconnect the microsaw from the motor.
2. Remove the cutting tool (see FIG. 5).
3. Disconnect the irrigation line from the microsaw (see FIG. 5).
4. If present, the irrigation ring may be either cleaned separately or left on the microsaw.
5. After selecting the appropriate nozzle, perform preliminary cleaning of the microsaw by using the product Aquacare. Spray the inside and the outside of the device and inside the irrigation tube.
6. Check that the coolant outlets are rinsed out.
7. Dry the microsaw with non-woven compress.

### Internal and external cleaning

1. After selecting the appropriate nozzle, spray the inside and the outside of the device as well as the inside of the clamping ring with the product Spraynet®.
2. Dry with non-woven compresses.



FIG. 6

## 6.3 Disinfection

### 6.3.1 Manual disinfection

1. Dip the devices (both the micro-saw and the irrigation ring), separately or assembled in a bath containing a 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 outside of the micro-saw and, if separated, the interior of the irrigation ring with a smooth, flexible brush (e.g. soft-bristled toothbrush) especially the grip surfaces, recesses and corners and clean the interior of the micro-saw on the drive side with an appropriate swab (FIG. 6 step 1). The use of an alkaline product at low concentration and at room temperature for a duration of 5-10 minutes is recommended (for example, Neodisher® Mediclean Forte at 0.5% for 5-6 minutes).
3. Check the freedom of movement of the clamping ring. To do this, pull it several times to full stop and release it. It must always return to the starting position (FIG. 6 step 2).
4. **Optional:**
  - a) Rinse the device 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 sterilized water instead (FIG. 6 step 3).
  - b) Perform additional cleaning and disinfection of the external surfaces with non-woven wipes impregnated with a disinfection product (e.g. didecyldimethylammonium chloride).
  - c) Rinse the external surfaces with sterile non-woven compresses impregnated with sterile, demineralized water.

5. Eliminate the excess of disinfectant (e.g. foam residue) over the external surfaces of the device by spraying it with Spraynet® and drying it with sterile non-woven compresses.
6. Spray inside the irrigation tube of the microsaw (and inside the tubes of the irrigation ring, if this latter has been left on the microsaw during reprocessing) with Spraynet®, using the appropriate nozzle.
7. Dry the external surfaces with sterile non-woven compresses.

### 6.3.2 Automatic disinfection (optional)

**Note:** *The automatic cleaning-disinfection can replace the previous steps 4 to 6 but is not necessary for obtaining a proper cleaning and disinfection of the device,*

*if steps 1-3 are properly and timely realized.*

#### 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 for 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, ≤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. 7

## 6.4 Lubrication

### 6.4.1 Verifying cleanliness

Before lubrication, visually inspect the device to ensure it is clean. Repeat the cleaning and disinfection procedure if necessary.

### 6.4.2 Lubrication with Lubrifiuid®

Before each sterilization lubricate with Lubrifiuid®. Never lubricate after sterilization. If the irrigation ring is left on the microsaw during cleaning-disinfection, it should be left on the microsaw during lubrication as well.

#### 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 can Lubrifiuid® in the rear of the microsaw and activate the spray for about 1 second.
4. Clean the excess oil on the exterior with a sterile, non-woven compress.

**Note :** If, during the test run of the microsaw before the clinical treatment, an excess of lubricant is ejected from the microsaw, prolongate the test run until the ejection stops. Then, modify the lubrication procedure, by reducing

*the quantity of lubricant inserted before sterilization or operate the microsaw for 2 seconds after lubrication and before sterilization.*

## 6.5 Sterilization

### ⚠ WARNING

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 device is completely dry before and after the sterilization.

### ⚠ CAUTION

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

### 6.5.1 Procedure

1. Pack the device in a packaging approved for steam sterilization. If the irrigation ring has been removed before reprocessing, the microsaw and the irrigation ring should be packed in two different sterilization pouches. If the irrigation ring is left on the microsaw during cleaning/decontamination and lubrication, it should be left on the microsaw during steam sterilization as well.
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 at 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 (278.6°F), i.e. the nominal temperature of the autoclave is set at 134°C (273.2°F), 135°C (275°F) or 135.5°C (275.9°F) taking into account the uncertainty of the sterilizer with regard to temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278.6°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 0.07 bar to 3.17 bar (1 psia to 46 psia).
- The rate of change of temperature does not exceed 15°C/min (59°F/min) for increasing temperature and -35°C/min (-31°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 water steam.

#### CAUTION

Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.

## 6.6 Packing and storage

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

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 :***The microsaw should be returned for servicing at least one time per two years due to possible wear. This operation is strongly recommended for maintaining the device in optimal working condition.*

**Note :***It is recommended that the irrigation ring be replaced regularly, at least after every 50 patients treated.*

# 7 Transport & disposal

## 7.1 Transport

There are no particular transport and storage conditions required.

## 7.2 Disposal



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

The device must be recycled. In order to avoid any risk of contamination, the user must return it sterilized to his 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 for this medical device 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

#### 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

### 8.2.1 Sets supplied (see cover)

REF	Legend
1601098-001	RECIPROCATING MICROSAW
1502918-001	Irrigation ring
1308430-001	O-rings

### 8.2.2 Optional accessories (see cover)

REF	Legend
1502671-001	Short Microsaw Blade 17x0.4mm
1502672-001	Short Microsaw Blade 21x0.4mm
1502673-001	Short Microsaw Blade 25x0.4mm
1502674-001	Short Microsaw Blade 17x0.6mm
1502675-001	Short Microsaw Blade 21x0.6mm
1502676-001	Short Microsaw Blade 25x0.6mm
1502677-001	Long Microsaw Blade 17x0.4mm
1502678-001	Long Microsaw Blade 21x0.4mm
1502679-001	Long Microsaw Blade 25x0.4mm
1502680-001	Long Microsaw Blade 17x0.6mm
1502681-001	Long Microsaw Blade 21x0.6mm
1502682-001	Long Microsaw Blade 25x0.6mm
1500984-010	Pack of 10 disposable sterile irrigation lines (1x)
1600036-006	Spraynet®, 500ml cleaning spray, box of 6
1600064-006	Lubrifluid®, 500ml spray lubricant oil, box of 6
1600617-006	Aquacare, cleaning spray for physiological liquid 500ml, box of 6 cans



**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](mailto:dental@bienair.com)

Other addresses available at

**[www.bienair.com](http://www.bienair.com)**