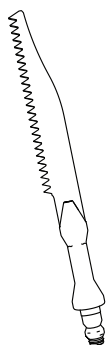



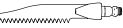

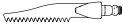


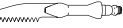
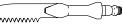



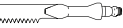
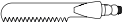
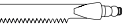

CUTTING TOOLS FOR RECIPROCATING MICROSAW





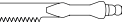


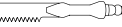

ENG INSTRUCTIONS FOR USE



REF 2100390-0003/2024.07

Rx Only

Cutting tools range		
1502671-001	Short Microsaw Blade 22x0.4 mm	
1502672-001	Short Microsaw Blade 27x0.4mm	
1502673-001	Short Microsaw Blade 32x0.4mm	
1502674-001	Short Microsaw Blade 22x0.6mm	
1502675-001	Short Microsaw Blade 27x0.6mm	
1502676-001	Short Microsaw Blade 32x0.6mm	
1502677-001	Long Microsaw Blade 22x0.4mm	
1502678-001	Long Microsaw Blade 27x0.4mm	
1502679-001	Long Microsaw Blade 32x0.4mm	
1502680-001	Long Microsaw Blade 22x0.6mm	
1502681-001	Long Microsaw Blade 27x0.6mm	
1502682-001	Long Microsaw Blade 32x0.6mm	
1502731-001	Short Bullnose Blade 22x0.4mm	
1502732-001	Short Bullnose Blade 27x0.4mm	
1502733-001	Short Bullnose Blade 32x0.4mm	

Cutting tools range		
1502734-001	Short Bullnose Blade 22x0.6mm	
1502735-001	Short Bullnose Blade 27x0.6mm	
1502736-001	Short Bullnose Blade 27x0.6mm	
1502737-001	Long Bullnose Blade 22x0.4mm	
1502738-001	Long Bullnose Blade 27x0.4mm	
1502739-001	Long Bullnose Blade 32x0.4mm	
1502740-001	Long Bullnose Blade 22x0.6mm	
1502741-001	Long Bullnose Blade 27x0.6mm	
1502742-001	Long Bullnose Blade 32x0.6mm	





Related device



RECIPROCATING MICROSAW REF 1601098-001

1. Symbols

1.1 Description of Symbol used

Sym	Description	Sym	Description
	Manufacturer.		Distributor.
	Catalogue number.		Batch code.
	Medical Device.		Sterilized using ethylene oxide.
	Quantity.		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.		Use by date.
	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.
	Operator's manual; operating instructions.		Refer to instruction manual/booklet.
	Do not re-use.		Do not use if package is damaged.
	Keep away from rain.		Keep away from sunlight.
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Humidity limitation.
	Temperature limitation.		Atmospheric pressure limitation.
	Single Sterile barrier system with protective packaging inside.		

2. Identification & Intended Use

2.1 Identification

Medical device manufactured by Bien-Air Surgery SA and distributed by Bien-Air Dental SA.

Type

Cutting tools made of stainless steel, available in different sizes and shapes (standard or bullnose type) for different clinical applications. The cutting tools are single use devices which are supplied sterile. They can only be used with Bien-Air Dental's Reciprocating 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 cutting tools are 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 cutting tools 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 cutting tools are 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

 **Bien-Air Surgery SA**
Rue de l'Ouest 2B CH-2340 Le Noirmont Switzerland
Tel. +41 (0)32 344 64 64 Fax +41 (0)32 344 64 91
surgery@bienair.com

 **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 adresses available at
www.bienair.com

 **Bien-Air Europe Sàrl**
19-21 rue du 8 mai 1945
94110 Arcueil
France

2.6 Patient contra-indications

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

2.6.1 Complications / Side effects

- Nickel allergy or other immunological defense reactions; fever
- Bone healing disorders
- Extension of the operation / narcosis
- Nerve lesions which can entails short-term numbness or paralysis
- Bleeding; hematomas
- Breaking of the cutting tools
- As in any moving device, in case of improper use or in case of accidental movement in the active state, the following may occur:
 - Injuries to surrounding tissue
 - Injury to nearby blood vessels
 - Necrosis of surrounding tissue when exposed to excessive temperature

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. No repair possible on the cutting tool as it is single use.

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 & Precaution for 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

⚠ WARNING

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

⚠ WARNING

We recommend continuous irrigation during use in order to prevent necrosis caused by the heat on the bone and blockage of the handpiece with bone material.

In case irrigation lines are used, always check that the physiological solution flows freely out of the cutting tool. Never use a handpiece with a damaged component.

⚠ WARNING

Do not tilt or lever the cutting tools as they might bend or even break in some extreme cases. This significantly increases the risk of accident.

⚠ CAUTION

Do not use bent or twisted cutting tools!

⚠ WARNING

Change the cutting tool after every treatment.

5. Cleaning and servicing


As the cutting tools are single use only, neither cleaning nor servicing are required. Dispose of the cutting tool at the end of every operation.

6. Packing and disposal

6.1 Packing

The cutting tools are delivered in a pouch containing one single sterile cutting tool.

6.2 Disposal

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

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. No repair possible on the cutting tool as it is single use.

- 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.

3.2 Warnings

⚠ WARNING

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

⚠ CAUTION

The cutting tools are delivered in sterile condition.

⚠ WARNING

All cutting tools are intended for single use only and intended to be used with Bien-Air Dental's reciprocating microsaw. Reuse may cause cross-contamination and significantly increase wear on the cutting tool and handpiece. Failure to comply may result in patient and/or room staff injury.

⚠ CAUTION

Use only Bien-Air approved components and accessories.

⚠ WARNING

Never touch a cutting tool on a microsaw in motion.

⚠ 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.






4. Operation






Check the product, the expiration date on the label as well as the packaging for any damage. If there is damage to the sterile packaging, retain the package and the contents and notify the manufacturer.

⚠ WARNING

Do not use if the package is damaged or if the expiration date has passed.

7. Transport and storage conditions

Transport		
	Temperature range:	-20°C / +50°C
	Relative humidity range:	5% - 80%
	Air pressure range:	650 hPa - 1060 hPa
	Keep away from rain	
	Keep away from sunlight.	

Storage		
	Temperature range:	0°C / +40°C
	Relative humidity range:	10% - 80%
	Air pressure range:	650 hPa - 1060 hPa
	Keep away from rain	
	Keep away from sunlight.	

Environmental conditions for use

- Temperature from 10°C to 35°C (50°F to 95°F)
- Relative humidity less than 80%, without condensation.

4.1 Changing the cutting tool

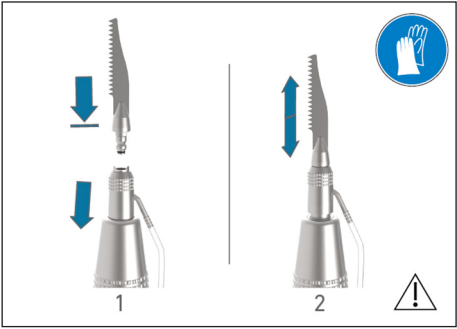


FIG. 1

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

⚠ WARNING

A poorly fitted cutting tool may result in patient and/or room staff injury.

⚠ WARNING

The cutting tools are exclusively designed for bones and hard tissues. Avoid all contact of the cutting tool with any other surface or material especially harder than bone. Failure to comply with this instruction may result in damaging the cutting tool and/or the microsaw.

⚠ WARNING

The handpiece has to be activated before it is put in contact with the bone. Failure to comply with this instruction may result in the cutting tool not functioning properly (e.g. it may slip or break when excessive force (contact force) is applied).

8. Terms of guarantee

No warranty is granted for all cutting tools, since they are single use devices.

9. Troubleshooting

Problems	Cause	Solution
Cutting tool vibrates at use	Cutting tool not correctly inserted	Insert cutting tool correctly and check again
Poor sawing result	Cutting tool isn't sharp anymore	Replace cutting tool