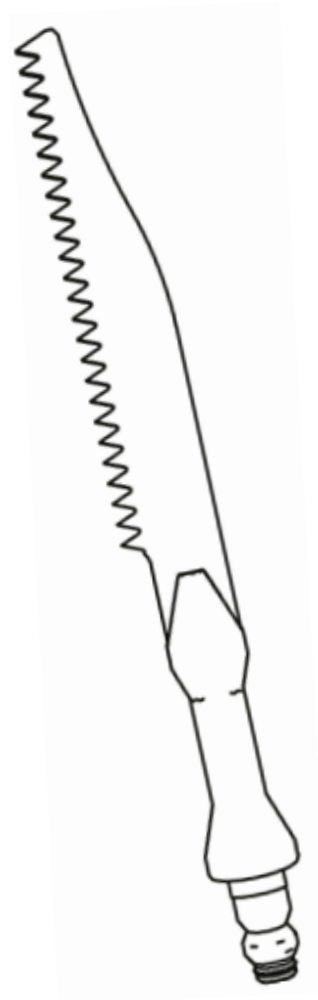

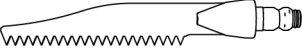
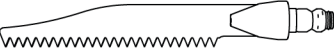



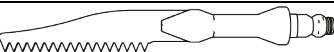
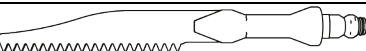
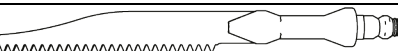
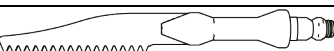
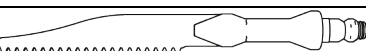
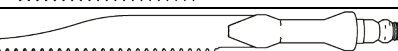


CUTTING TOOLS FOR RECIPROCATING MICROSAW

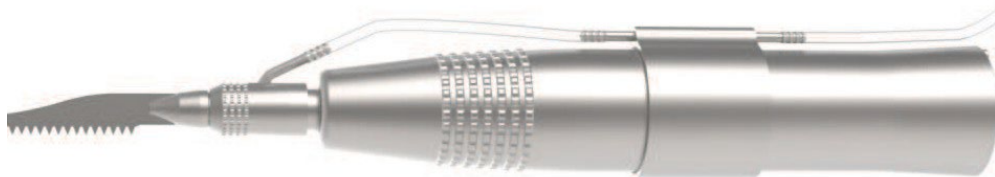
ENG INSTRUCTIONS FOR USE



Cutting tools range

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	

Related device






















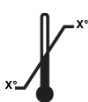
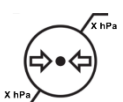

RECIPROCATING MICROSAW
REF 1601098-001

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1 Symbols

1.1 Description of Symbols used

Symbol	Description	Symbol	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 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

2.6 Patient contra-indications

No specific patient contra-indication exists for the cutting tools 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 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



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



The cutting tools are delivered in sterile condition.



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.



Use only Bien-Air approved components and accessories.



Never touch a cutting tool on a microsaw in motion.



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.



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

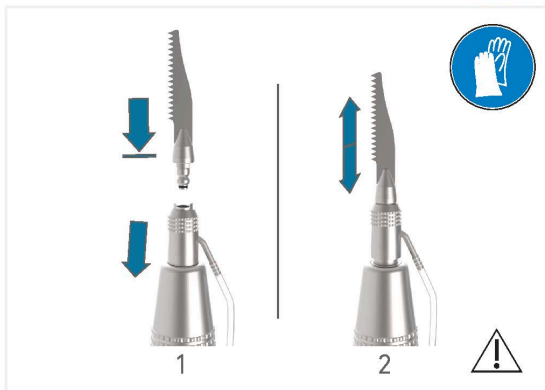


FIG. 1

4.1 Changing the cutting tool

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.



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



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.



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).



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



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.



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.



Do not use bent or twisted cutting tools!



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


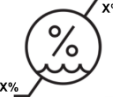
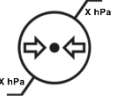




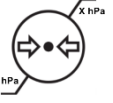


The cutting tools are delivered in a pouch containing one single sterile cutting tool.

6.2 Disposal



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

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.

8 Terms of guarantee

No warranty is granted for all cutting tools, since there 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



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