

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM  
Độc lập – Tự do – Hạnh phúc  
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# HƯỚNG DẪN SỬ DỤNG TIẾNG ANH MŨI MÀI XƯƠNG



CÔNG TY TNHH TBYT TRĂNG THI



GIAM ĐỐC  
*Nguyễn Diệu Linh*

Hà Nội – 2022



Instructions for use  
Please read carefully and retain for  
future reference.

Consiglia d'utilizzazione  
A respecter scrupuleusement et garder  
cette copie pour une utilisation ultérieure.

Gebrauchsanweisung  
Bitte unbedingt beachten und für späteren  
Gebrauch gut aufbewahren.

Instruções de emprego  
Ler atentamente e guardar esta cópia  
para uso futuro.

Istruzioni d'uso  
Si prega di leggere attentamente e conservare  
per un'eventuale consultazione.

Instruções de uso  
Favor ler atentamente e guardar  
para referência futura.

Supplier REF 1000270-02 Rev 3020-02  
0562001



Rx Only CE 1639

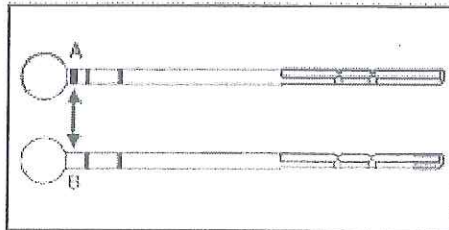


Fig. 1

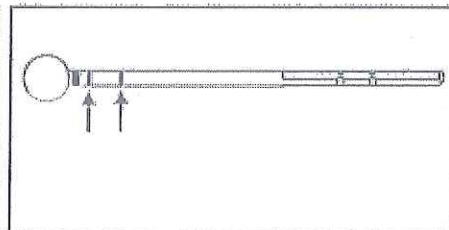


Fig. 2

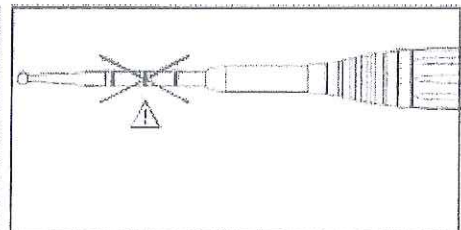


Fig. 3

Instructions for use and safety recommendations for this application of rotary instruments (sterile-packed) in the medical field.  
For single use only.  
Bien-Air Surgery SA instruments are manufactured from high-grade materials. They are designed, constructed and produced with the utmost care. These high quality instruments assure optimal functioning results along with a long life service provided they are used in the appropriate manner. Therefore, the following instructions of use and safety recommendations must be observed. Improper use can lead to damage to the tissue, premature wear, destruction of the instruments and injury to the operator, patient or other persons.

1. Proper use
  - Follow these directions as well as the instructions for use for Bien-Air Surgery SA motor systems when using rotary instruments.
  - Prior to use, make sure that the instruments are sterile and in perfect technical condition. Do not reuse damaged instruments.
  - Do not use the instruments for work on metal (e.g. implants) and do not allow them to come in contact with metal during use as this might cause nicks in the blades.
  - For safety reasons, the maximum permissible speed is to be observed at all times. Exceeding the maximum admissible speed tends to produce vibrations that can lead to the destruction of the instrument and a risk of severe injury for persons around.

2. Indication  
Bien-Air Surgery SA instruments have been designed for working on bone.  
Various instruments are available to suit the different materials to be treated:  
• Maxillo-facial/ENT/Neuro-surgery:  
Instruments made of stainless steel, tungsten carbide instruments and diamond instruments.  
The surgeon is responsible for the selection of the appropriate instrument.

3. Contraindications  
The instruments are not designed to be used on the CNS (brain and spinal cord).

4. Rotary instrument insertion and exposure  
Bien-Air Surgery rotary instruments from the PM2 range must only be used with Bien-Air Surgery handpieces from PM2 range.
  - Open the handpiece locking device.
  - Insert rotary instruments in the handpiece until the stop position is reached.
  - Close the handpiece locking device.
  - Prior to start-up, make sure that the instrument is firmly seated by pulling it. Prior to work on a patient, run the rotary instrument to check that there are no vibrations.
  - The PM2 rotary instrument shank has one to four engraved rings (except the 100% carbide bur range, which doesn't have any engraved rings. They can be used up to 80,000 rpm).
  - The ring close to the cutting area (Fig. 1.) indicates the maximum rotation speed with the minimum rotary instrument exposure.

- One ring: maximum speed of 80,000 rpm (Fig. 1, A)
- No ring: maximum speed of 50,000 rpm. (Fig. 1, B)
- Seal rings show the different instrument exposures (Fig. 2.). These one are different according instrument size and function.
- PM2 80K burr can be used in every position up to 80,000 rpm, but for an optimum drill precision, we advise to fully insert the burr in the handpiece at the minimum exposure, when used at speeds above 50,000 rpm.
- Never expose the rotary instrument over the engraved ring (Fig. 3.).

5. Contact pressure  
Excessive contact pressure must be avoided.

- It can lead to damage of the instruments' working part (steel and tungsten carbide instruments) as well as nick in the blades. At the same time, extreme heats generated which increases the risk of thermal necrosis.
- Excessive contact pressure can cause stripping of the abrasive grit of diamond instruments leading to an increased generation of heat.
- At worst, the instrument might fracture if excessive contact pressure is applied. Jamming or leverage of the instrument must be avoided during operation.
- For best results, work with a contact pressure of approx 2N. This can be compared with the pressure which is applied with a fountain pen.

6. Cooling  
When using rotary instruments sufficient cooling with a physiological liquid supplied by a permanent external feeding device must be utilised to prevent the instrument blades from clogging up with chips. This might lead to increase heat generation and at worst to irreversible damage to the bone (thermal necrosis). Moreover, service life of the instruments will be reduced.

7. Elimination of blunt and damaged instruments  
Examine instruments for blunt or damaged blades under magnifying glasses. Look out for the following defects:

- Dull (fraying) blades and nicks.
  - Blank spots on diamond instruments.
  - Damage to the shank.
  - Bent or "out of true" instruments.
- Do not, under any circumstances, reuse blunt or damaged instruments. The reuse of imperfect instruments can lead to the fracture of the instrument and pose a risk of severe injury to the patient and operator. Moreover, use of blunt and damaged instruments, will lead to handpiece overheating and reduction of its lifetime.

8. Sterilization  
The instruments have been sterilized either by gamma (marked **STERILIZED** on the label) according ISO 11137, or by ethylene oxide (marked **STERILIZED** on the label) according ISO 11135.

9. Re-sterilization  
The manufacturer does not recommend re-sterilization after the expiry date and declines any liability for instruments re-sterilized by the customer. By re-sterilize the rotary instrument, a risk of infection is possible and the perfect functioning security can't be warranty.

10. Storage  
Storage should be at room temperature in a dry, light-protected environment. Do not use instrument after the expiry date.

11. Safety and liability  
The user is responsible to check the product prior to use whether it is suitable for the intended purpose.

- The user is responsible for the application of the instruments.
- In case of contributory negligence by the user, Bien-Air Surgery SA partially or totally declines liability for all resulting damages, particularly if these are due to non-observance of our recommendations for use or warnings as well as inadvertent misuse by the user.
- Avoid contact between rotary instrument shank and patient tissue to don't burn it, due to the friction at a high speed.
- These instruments has sharp blades, manipulation must be done with caution.
- Do not use an instrument if its packaging is open, damaged or after expiry date indicated on the packaging because there is no more protection against the risk of contamination.
- The instruments may only be returned in clean, disinfected and sterilized condition.

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

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# Bien-Air<sup>®</sup>

## Surgery

Bien-Air Surgery SA Tël. +41 (0)32 344 64 40  
Rue de l'Ouest 2b Fax +41 (0)32 344 64 45  
CH-2340 Le Noirmont surgery@bienair.com  
Switzerland www.bienair.com

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### Instructions for use and safety recommendations for the application of rotary instruments in the medical field

Bien-Air instruments are made of high-grade materials. They are designed, constructed and produced with utmost care. For optimum results and a long service life, make sure that the instruments are used correctly. To ensure this, the following instructions for use and safety recommendations have to be observed. Improper use can lead to damage to the tissue, premature wear, destruction of the instruments and injury to the operator, patient or other persons.

#### 1. Proper use

- Follow these directions as well as the instructions for use for Bien-Air motor systems when using rotary instruments.
- Prior to use, make sure that the instruments are sterile and in perfect technical condition. Do not reuse damaged instruments.
- Insert rotary instruments in the hand piece until the stop position is reached.
- Prior to start-up, make sure that the instrument is firmly in place.
- Do not use the instruments for work on metal (e.g. implants) and do not allow them to come in contact with metal during use as this might cause nicks in the blades.
- For safety reasons, the maximum permissible speed is to be observed at all times.

#### 2. Indication

Bien-Air instruments have been designed for work on bone, skin and soft tissue. Various instruments are available to suit the different materials to be treated:

- Dermabrasion:  
Instruments with diamond-coated working part
- Maxillo-facial surgery:  
Instruments made of stainless steel, tungsten carbide and diamond instruments
- ENT surgery:  
Instruments made of stainless steel, tungsten carbide and diamond instruments
- Neurosurgery:  
Stainless steel, carbide and diamond instruments  
The surgeon is responsible for choosing the appropriate instrument.

#### 3. Contact pressure

- Excessive contact pressure has to be avoided.
- This can lead to damage to the instrumental working part (steel and tungsten carbide instruments) as well as nick in the blades. At the same time, extreme heat is generated which increases the risk of thermal necrosis.
- Excessive contact pressure can cause stripping of the abrasive grit of diamond instruments, leading to an increased generation of heat.
- At worst, the instrument might fracture if excessive contact pressure is applied. Jamming or leverage of the instrument must be avoided during the operation.
- For best results, work with a contact pressure of approx. 2N. This can be compared with the pressure which is applied when writing with a fountain pen.

#### 4. Cooling

- When using rotary instruments, sufficient cooling has to be supplied to prevent the instrument blades from clogging up with chips. This might lead to increased heat generation and at worst to irreversible damage to the bone (thermal necrosis). Moreover, the service life of the instruments will be reduced.

#### 5. Elimination of blunt and damaged instruments

Examine instruments for blunt or damaged blades under magnifying glasses. Look out for the following defects:

- blunt (rounded) blades and nicks
- blank spots on diamond instruments
- damage to the shank
- bent or lost of true instruments

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Bitte unbedingt beachten und für späteren  
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Conseils d'utilisation  
A respecter scrupuleusement et garder  
cette copie pour une utilisation ultérieure !

Instrucciones de empleo  
Leer detenidamente y guardar este ejemplar  
para uso más tarde

Istruzioni d'uso  
Si prega di leggere attentamente e conservare  
per un'eventuale consultazione!

Do not, under any circumstances, reuse blunt or damaged instruments. The reuse of imperfect instruments can lead to the fracture of the instrument and poses a risk of injury to the patient and operator.

#### 6. Cleaning, disinfection, sterilization and storage

- The instruments are delivered in "non-sterile" condition.
- Prior to first use and immediately after each use, rotary instruments have to be cleaned, disinfected and sterilized. The instruments should be stored in their original packages at room temperature, protected against dust and humidity.
- After surgical operation, immediately remove blood, secretion, tissue and bone residues. Dried residues can cause corrosion.
- Make sure that all residues are removed; this applies especially to hollow burs.
- It is recommended to use anticorrosive disinfection and cleaning agents.
- Disinfection of rotary instruments can be carried out in the gentle cycle (e.g. Vario TD) of the thermo-disinfector. Use cleaning and disinfection agents with approved material compatibility. We recommend deaconex 28 AlkaOne (co. Borer Chemie).
- Bien-Air instruments can be cleaned in the ultrasonic bath. However, care should be taken that the instruments do not come in contact with each other; otherwise the blades can be damaged.
- For immersion time and suitability of disinfection and cleaning substances for specific instrument types see instructions for use of the manufacturer of these agents.
- Contact with H<sub>2</sub>O<sub>2</sub> (hydrogen peroxide), chlorous disinfection and cleaning agents as well as oxalic acids are to be avoided because these agents may lead to pitting and corrosion.
- Disinfection and cleaning agents must be rinsed off thoroughly under running water immediately after use; otherwise corrosion can occur due to chemical reactions.
- The instruments should be placed in hygienic bur blocks, dishes or other suitable containers. The same applies to sterilized instruments and instruments in sterile packages. The instruments are to be stored in an environment free of dust and humidity, to exclude recontamination.
- Sterilization should take place in the steam sterilizer. Bien-Air recommends the following parameters, in order to guarantee a SAL of 10<sup>-4</sup>: B Type cycle, 134°C, 2.2 bar, exposure time 5 minutes.
- A temperature above 180°C has to be avoided. Exceeding this temperature would result in loss of hardness of the working part and thus reduction of service life.
- Make sure that the chosen disinfection and sterilization method is suitable for the specific instrument. The instruments may only be returned in clean, disinfected and sterilized condition.

#### 7. Safety and liability

- The user is responsible for checking the product prior to use to ensure that it is suitable for the intended purpose.
- The user is responsible for the application of the instruments.
- In case of contributory negligence by the user, Bien-Air partially or totally declines liability for all resulting damages, particularly if these are due to non-observance of our recommendations for use or warnings as well as inadvertent misuse by the user.

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