



Instructions for use - Instruments  
**magnetic • easyroot**  
M A L L E T



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## 1.0. IMPORTANT INFORMATION FOR USERS

This instruction for use helps you to correctly connect and use the surgical instruments to the MAGNETIC MALLET and EASYROOT devices. All the details necessary for a proper use are explained below, therefore we suggest you to read the manual carefully and keep it in the protective case supplied with the device, for future reference.

Please always check the last update of the instruction for use as the manufacturer reserves the right to make any kind of modification in order to obtain functional technical improvements without any prior notice. The images and drawings contained in this manual are for illustrative purposes only.

### 1.1 Symbols and Labelling

	Attention read the Instructions for use
	Lot number
<b>Code</b>	Product code
	NON-STERILE product
	Certificate of Conformity CE

 Via Monte Nero, 19 - 20029 TURBIGO (MI) Tel. e Fax +39 0331 890280 info@metaergonomica.it	 Code FPCGENOA3
 DA STERILIZZARE A VAPORE PRIMA DELL'USO MUST BE STERILIZED BEFORE USE LEGGERE ATTENTAMENTE LE ISTRUZIONI PRIMA DELL'USO	 
 ET725	

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## 2.0. SAFETY RULES

The terms **Caution**, **Warning** and **Note** have a specific meaning. Please carefully read the related instructions, in order to ensure a safe and effective use of the equipment.

**Caution:** indicates a danger for the patient or the doctor. Failure of compliance with this indication can cause injury to the patient or to the doctor.

**Warning:** indicates maintenance or safety measures that should be taken in order to avoid damage to the equipment and its accessories.

**Note:** indicates particular information for the use of the devices with its accessories or other important information.

### ***Cautions***

**Caution:** Carefully read the instruction for use of Magnetic Mallet and Easyroot devices before using them with the dedicated instruments. In particular, carefully read the chapter on device functions and safety regulations in order to avoid endangering your patients, your staff and yourself.

**Caution:** For safety reasons, the use of the devices is not allowed in other fields of application, except their intended use.

**Caution:** Since the instruments are not supplied in a sterile package, proceed with their cleaning, disinfection, and sterilization before their first use. (See Section 4.0 - "Cleaning, disinfection and sterilization of instruments" for more information).

**Caution:** Handle with care the blades supplied with the blade holder. Blades by their nature are very sharp edged, and you should pay attention in inserting them into the blade holder. Do not insert into the handpiece the blade holder coupled to the blade, till the surgery begins. Do not leave the handpiece coupled to the blade holder and blade into the housing of the power supply.

## Warnings

**Warning:** For safety reasons, the use of the devices is not allowed in other fields of application, except their intended use.

**Warning: No alterations to the instruments are allowed.**

**Warning: The instruments supplied with the device have been specifically designed for it. The use of different instruments is strictly forbidden.**

## Notes

**Note:** Upon delivery, check the wholeness of the supply and verify the material is undamaged.

If the material grounds for complaint, immediately contact the manufacturer or distributor for the return, replacement, or integration of the material.

The instruments are supplied with specific labelling showing the code of the instrument. Always check the correspondence of the code shown on the label and the lasered one on the instrument. In case of discrepancy, immediately notify the distributor and / or the manufacturer.

**Note:** For measures relating to diameters, working depths and laser marking, refer to the specific brochure sent with the device.

 **STRUMENTI MAGNETIC MALLET**  
Tutti gli strumenti riportano i riferimenti della profondità di lavoro in accordo alle altezze dei principali sistemi implantologici.

 **MAGNETIC MALLET INSTRUMENTS**  
All the instruments have the depth measures laser marked on the tip. This depth is fitting the main implant systems.



magnetic  
MALLET



**STRUMENTI EASYROOT** (forniti con Easyroot)  
Tutti i disegni degli strumenti riportano i riferimenti relativi a diametro/larghezza e lunghezza della punta

**EASYROOT INSTRUMENTS** (supplied with Easyroot)  
All the drawings of the instruments show the diameter/large and the long of the tip (working part)

## 2.1 User qualification

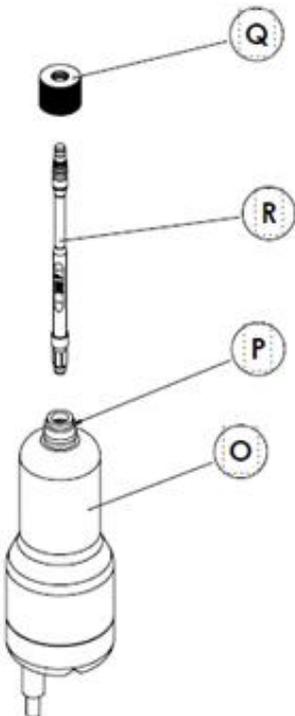
The surgical instruments coupled to the Magnetic Mallet or Easyroot should be used in medical environments only and performed by a dentist cognizant on the device use.

**ATTENTION: Make sure you are fully aware of the operating mode of the device and its accessories before using the Magnetic Mallet and / or Easyroot devices for the first time on a patient.**

The instruments should be used according to the intended use and cannot be used in fields of application other than that established ones.

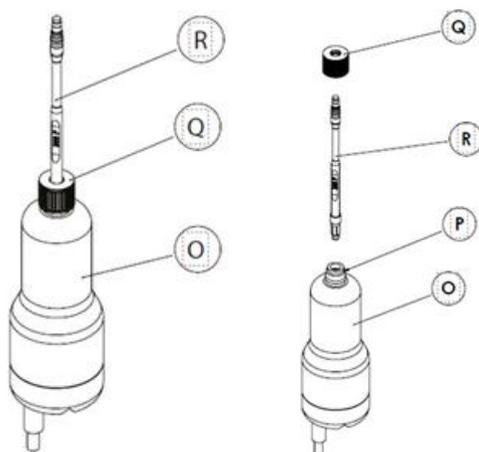
## 3.0 INSERTION AND REMOVAL OF INSTRUMENTS FROM THE HANDPIECE

### 3.1. Insertion into the handpiece



1. Insert the instrument (R) into the handpiece (O)
2. Insert the ring nut (Q) on the instrument
3. Tighten the ring nut (Q)
4. Always check that the instrument is firmly fixed in order to avoid any leakage of the instrument from the handpiece during the operation. Any leakage cause serious risk to the operator, assistants and patient.
5. Any challenge in correct coupling of the instrument to the handpiece involves the non-use of the device and the need to contact the distributor and / or the manufacturer.

### 3.2 Removal from the handpiece



1. Unscrew the ring nut (Q)
2. Remove the instrument (R)



**Handle with care the blades supplied with the blade holder**

**Note:** It is the surgeon's responsibility to determine the type of pressure to be exerted with the handpiece on the instrument to obtain the desired result.

The action of the instrument is determined both by the pressure exerted on the handpiece by the surgeon and by the axial forward. In any case, the progression of the tip cannot exceed approximately 1 mm, each footswitch pressure.

**Warning:** The instruments must always be thoroughly cleaned, disinfected, and sterilized before each use on the patient.

**Warning:** Always check the instruments before using them to verify their integrity. Any deformity found in the instrument results in non-use and disposal. In the presence of wear, the instrument should be immediately replaced.

**Warning:** Always verify the proper retention of the ring nut when coupling the instrument to the handpiece. Any deformity calls for a replacement of the ring nut with a new one.

## 4.0 CLEANING, DISINFECTION AND STERILIZATION OF INSTRUMENTS

After the removal of the instruments (following the instructions given in **Section 3.2**), the parts are cleaned, washed and disinfected and then sterilized in an autoclave.

PARTICULAR	CLEANING-DISINFECTION	STERILIZATION
Instruments MAGNETIC MALLET and/or EASYROOT	Proceed with the washing of the parts. Wash under running water and brush carefully	Proceed with the sterilization of the parts in an autoclave before their first use as the products are non-sterile supplied.
	Disinfect the instruments avoiding the use of products containing Benzalkonium Chloride (for example Golmar G-Decos, Lysol or similar).	Proceed with the sterilization of the parts after each use. The parts must be sterile before being used.

### **PREMISE:**

Surgical stainless steel is an alloy made up of iron, carbon and chromium. Each of these elements produces a specific advantage and is combined according to its function. Both hardness and potential to keep the tip sharpness in time depend on the percentage of carbon, while chromium increases corrosion resistance.

Stainless steel is not completely discoloration proof. In fact, while it has excellent corrosion resistance, it can nevertheless discolour or rust during sterilization procedures or when exposed to some chemical factors including iodine, stannous fluoride, sodium hypochlorite and benzalkonium chloride.

### **PRE-STERILIZATION CLEANING PROCESS**

- Clean instruments using warm water and neutral pH detergent at the dilution recommended by the detergent manufacturer.
- Soak the instruments, then rinse them with running water while brushing the outside to remove any residue. Use a soft brush.
- For the inserter, use a soft pipe cleaner to clean the inside of the concave part in order to eliminate any debris.
- Then insert the instruments in a surgical layer with ethyl alcohol (Ethanol) and mineral water in order to eliminate any residual detergent. This prevents corrosion and oxidation problems.
- Remove the instruments from the container and make them dry off, one by one, with a soft cloth. Each instrument must be completely dry before being placed in the autoclave in order to prevent oxidation or discoloration problems.
- Always separate stainless steel instruments from aluminum ones.

After having cleaned and disinfected the instruments, proceed with the steam sterilization process in the autoclave according to the following parameters:

### **VALIDATED STANDARD STERILIZATION CYCLES:**

The autoclaves must comply with the Medical Device Directive 93/42 / EEC and subsequent amendments, or the Medical Devices Regulation (EU) 2017/745.

### **STERILIZATION PROCESS**

- After making sure that the instruments are perfectly dry, place them in the surgical layer.
- Insert the layer into the autoclave and follow the sterilization instructions of the autoclave manufacturer. Use only approved and certified equipment.
- The achievement of the saturated vapor state at a combination of temperature and pressure values will be equal to:

135 ° C for 2 Bar (2 Atmospheres) - sterilization time at least 8 minutes

- Never exceed 140 ° C
- Store the instruments in order to avoid subsequent contamination.
- The instruments are non-sterile supplied so the sterilization process must be carried out both before the first use and before any surgery.



**Caution:** Incorrect compliance with the sterilization instructions, contained in the "Section 4.0", can cause damage to the instruments and their subsequent disuse. **The manufacturer is not liable for any corrosion processes caused by failure to comply with the procedures for cleaning, disinfection and sterilization.**



**Warning:** The manufacturer is not liable for any corrosion and / or discoloration problems due to the use of unsuitable chemical agents.



**Caution:** Failure to comply with the instructions related to cleaning, disinfection and sterilization can lead to cross infections and intraoperative complications



**Warning:** After sterilization, the product must remain in the bags used for sterilization. Sterilizing bags should only be opened immediately before reuse. The sterilizing bags are conceived to keep products sterile unless the bag is damaged. In this case the instrument should be newly sterilized and stored in the new bag.

## 5.0. WARRANTY

### 5.1. Liability

The manufacturer of these instruments is responsible for their safety, reliability and performance only if:

- The insertion of the instruments into the handpiece was carried out by carefully following the instructions for use.
- No alterations have been carried out on the instruments.
- The instruments are used in accordance with the instructions for use and the intended use
- The cleaning, disinfection and sterilization operations were carried out as per instructions.

### 5.2 Warranty

The manufacturer guarantees free replacement in the event of defective material or workmanship, provided this is proven, for a period of two years from delivery to the end customer. However, it does not assume the shipping costs and responsibility for the risks arising from transport. For all other instances, the guarantee stated in the General Terms and Conditions remains valid.

**Any alteration carried out by unauthorized persons relieves the manufacturer of all responsibility concerning the safety of the instruments and of the devices they are coupled to. Such operations invalidate the warranty.**

**Any improper use of the instruments that does not take into account the field of application (intended use) exempts the manufacturer from any liability towards the operator and the patient.**

**Any failure to comply with the instructions for use contained in this manual may cause injury to the operator and patient and invalidates the warranty.**

## 6.0 DISPOSAL PROCEDURES

Surgical instruments, if used, must be treated as biological waste for their disposal, according to local regulations. Before disposing of the instruments, proceed with their cleaning, disinfection and sterilization.



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System  
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