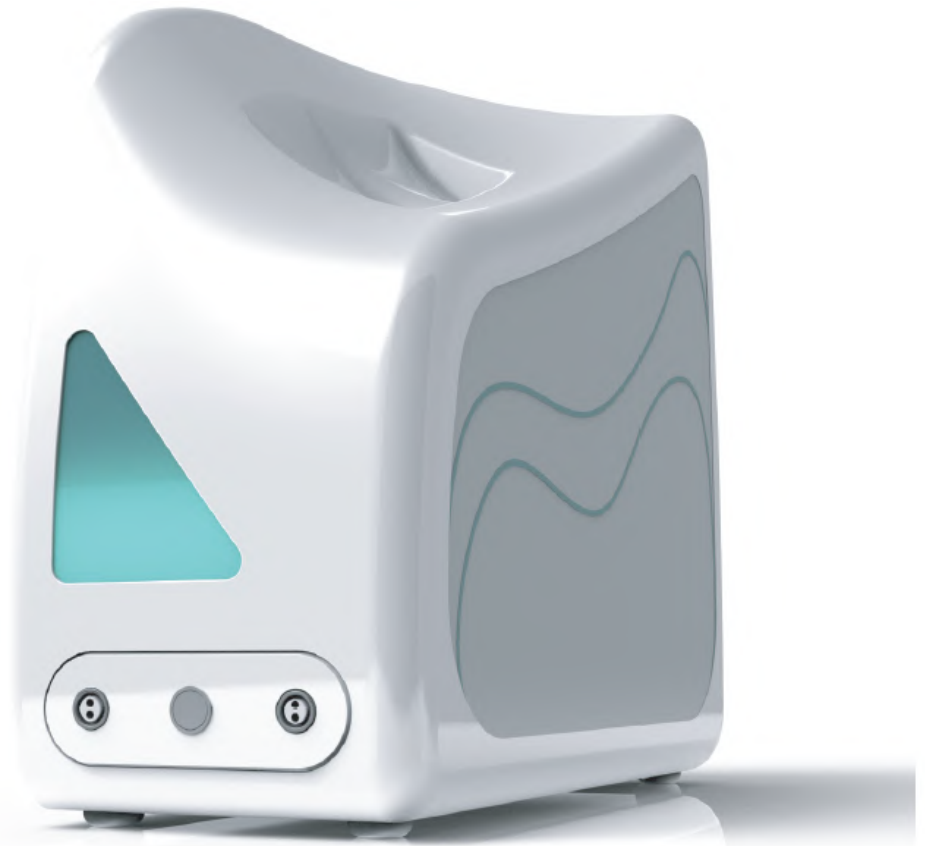


# easyroot



## MEDICAL DEVICE FOR SURGERY AND DENTISTRY

INSTRUCTIONS FOR USE

REV. 01 - FT 08 - 20.10.2021

**CE** 1936

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## 1.0. IMPORTANT INFORMATION FOR THE USER

This operating manual was made to help you to properly install and connect the Magnetic Mallet device. All the useful details for a proper use of this device are contained in this manual. You should read it very carefully and store it in its slipcase in a dry and clean place in order to gather any useful information in the future.



### **Attention:**

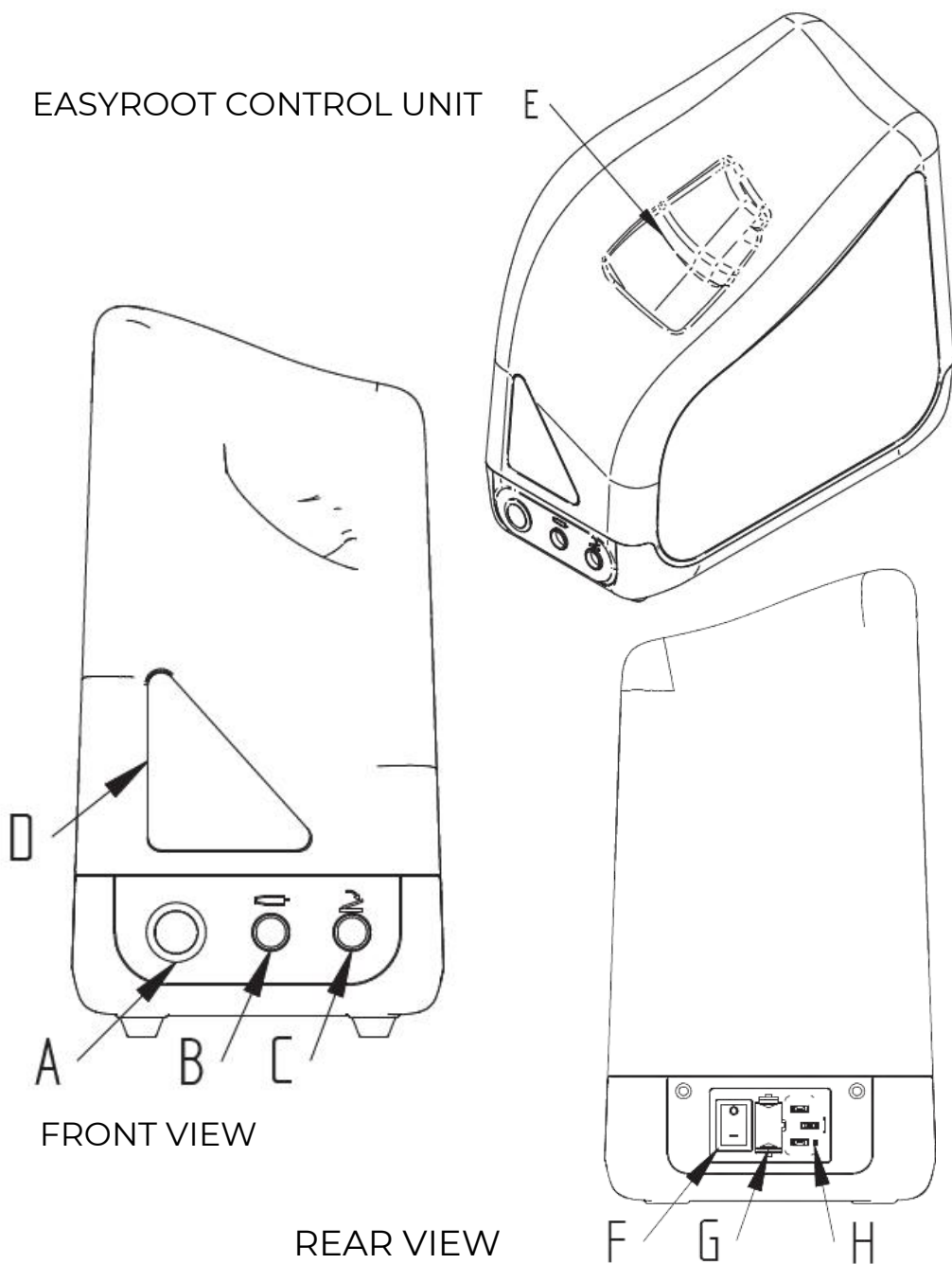
Please be aware you are referring to the last update of the instructions for use as the manufacturer reserves the right to make improvements at any time without prior warning. The images and drawings in this instructions for use are provided for illustrative purposes only.

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## 2.0. DEVICE ILLUSTRATIONS

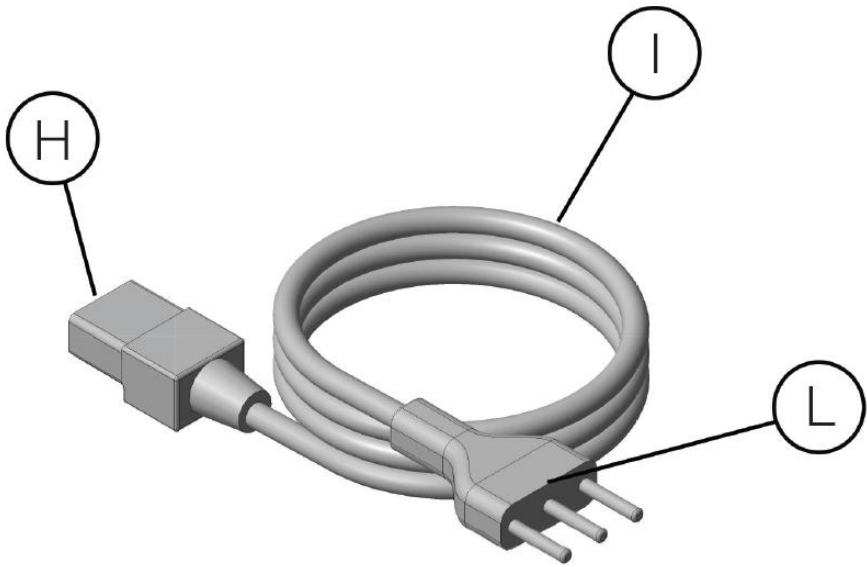
EASYROOT CONTROL UNIT



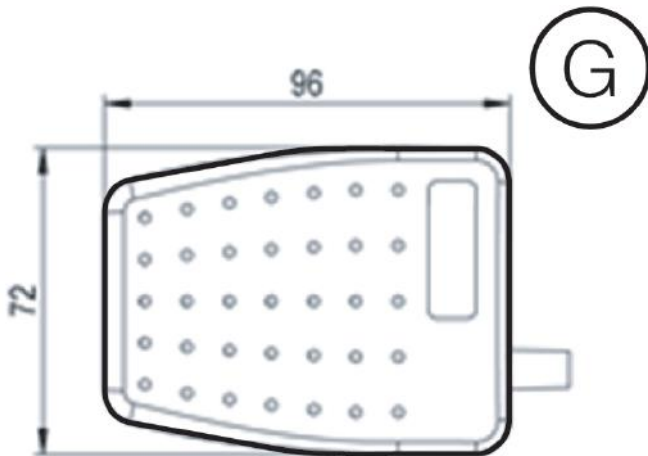
FRONT VIEW

REAR VIEW

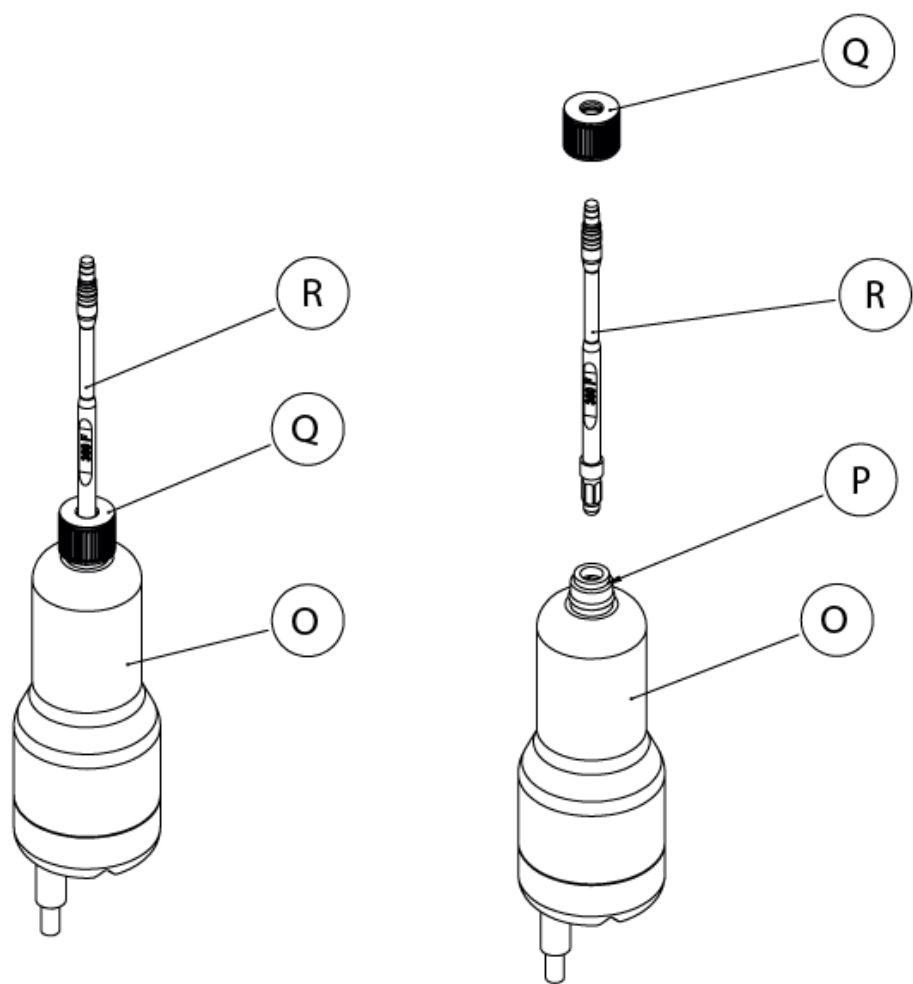
# CABLE



# FOOTSWITCH



## EXTRACTION HANDPIECE



## **2.1. Control elements, indicators, connections and functions**

### **CONTROL UNIT**




- A. Switch to select force level
- B. Handpiece connector
- C. Footswitch connector
- D. Led showing the force level
- E. Handpiece housing
- F. ON/OFF switch
- G. Fuse case
- H. Power cable plug
- I. Power cable
- L. Power cable socket
- M. Footswitch

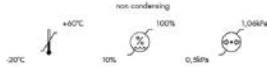
### **EXTRACTOR HANDPIECE**



- O. Extraction handpiece
- P. Chuck
- Q. Ring nut
- R. Surgica instrument






### 3.0. EXPLANATION OF THE USED SYMBOLS - LABELLING

#### SYMBOLS PLACED ON THE EASYROOT CHASSIS

	Handpiece metal connector
	Footswitch plastic connector
	Latching button













<b>MOD: 99.0300.0000</b>	<b>META ERGONOMICA S.r.l.</b>
EASYROOT	Via Monte Nero, 19 20029 Turbigo (MI) ITALY mail: info@metaergonomica.it Tel/Fax: +39.331.890280
Apparecchio base: 99.0300.0002	MADE IN ITALY
SN XXXX-XXX-00001	CE 1936
Manipolo: 99.0300.0001	
SN XXXX-XXX-00001	
	

	<b>META ERGONOMICA S.r.l.</b>
	Via Monte Nero, 19 20029 Turbigo (MI) ITALY mail: info@metaergonomica.it Tel/Fax: +39.331.890280
<b>IN THE EVENT OF FAILURES CONTACT THE MANUFACTURER</b>	
	<b>EASYROOT</b>
<b>PATENT EP2696793</b>	<b>SN: xxxx.xxx.xxxxx</b>

<b>Tensione di alimentazione:</b>	<b>230V</b>	
<b>Power Voltage:</b>		
<b>Frequenza nominale:</b>	<b>50 Hz</b>	
<b>Nominal Frequency:</b>		
<b>Corrente nominale in stand-by:</b>	<b>0.070 A</b>	
<b>Nominal stand-by current:</b>		
<b>Corrente nominale durante l'impulso:</b>	<b>0.38 A</b>	
<b>Nominal current during the pulse:</b>		
<b>Fusibili:</b>	<b>F - 5x20 - 250V - 1,6A</b>	
<b>Fuses:</b>		
	<p>Seguire le istruzioni per l'uso. Prima di mettere in funzione l'apparecchiatura leggere attentamente le istruzioni d'uso. <i>Scrupulously adhere to the instructions for use Before activating the device you should carefully read the instructions.</i></p>	
	<p><b>ATTENZIONE!</b> Un uso scorretto del dispositivo può provocare seri danni. <i>An improper use of this device can cause injuries.</i></p>	
	<p><b>ATTENZIONE!</b> ON: 1 colpo/sec (max 200 colpi) OFF: 40 minuti ON: 1 pulse/sec (max 200 pulses) OFF: 40 minutes</p>	
	<b>CE 1936</b>	



## **LABELLING SYMBOLS**

	Information on the manufacturer
	device serial number
	AC (Alternating current)
	Coupled part "BF type" (according to IEC 60601-1 rules)
	Before activating the device carefully read the instructions for use
	Caution hazardous voltage
	Store in a dry and clean place. Avoid water spray
	Caution! The improper use of this device can cause injury
	You should not use the device if the packaging is damaged
	Storage temperature
	CE mark including the identification number of the Notified Body
	Disposal of special waste (electric and electronic devices)

## 4.0. DEVICE DESCRIPTION

### 4.1. Device general description

The EASYROOT device is an electromedical device for surgery and dentistry practice to be used to perform extraction of teeth, roots and implants.


This device is basically made up by a control unit, a footswitch and a handpiece which is the applied part to be coupled with the extraction instruments.

The control unit case is made by self-extinguishing plastic. On the control unit you can find:

- The ON/OFF switch (F)
- Two different connectors. One for the footswitch and the other one for the handpiece. The two connectors are identifiable by the following graphic symbols:
  - ▶ Handpiece metal connector (B)
  - ▶ Footswitch plastic connector (C)

The control unit, the control/operational electronics together with the electronic/electric safeties are housed into the control unit case.

The handpiece is powered by the control unit with a 58V c.c. maximum voltage. The handpiece is connected to the control unit by a cordset which can be manually unplugged. The handpiece can be activated by the pressure of the footswitch (H).



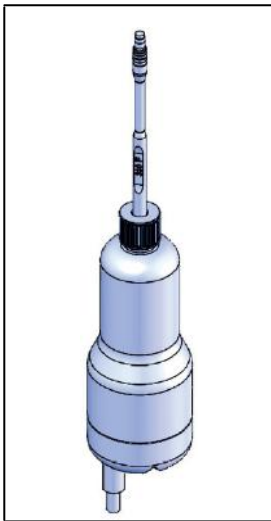
The force applied to the handpiece through the pressure of the footswitch is not continuous.

Each pressure of the switch conveys a single force pulse.

Pressing the latching button (A) on the control unit you can select the desired force (1 or 2); the level of the chosen force is displayed by the led bar lightening on the control unit (Force nr. 1 bar half lit - Force nr. 2 complete lit).

The **EASYROOT** has been designed to give 1 pulses per second. **You should not exceed the maximum threshold of 200 consecutive pulses without having a 40 minutes break.**

## 4.2. Description of the coupling parts



### INTENDED USE

Medical device to be used to perform dentistry surgery to extract teeth, roots or implants by means of a handpiece delivering pulses.

The Easyroot device allows the atraumatic extraction of teeth, roots or implants allowing the safeguard of alveolus and ligaments.

The pressure or the release of the latching button on the control unit, selects the level of the desired force (nr. 1 or nr. 2)

**It's important to remember that the whole spectrum of the forces has a very close progressive range and both of them are suitable for the surgery techniques.**

**It's entirely up to the surgeon to determine the more suitable one to achieve the desired result.**

Surgery instrument action is led both by the pressure exerted by the surgeon on the handpiece and by the axial forwards of the energy. In any case the maximum forwards of the surgery instrument is of about 1 mm.



**Attention:** The surgeon must always determine the pressure to be exerted on the bone in order to achieve the desired result.

## 5.0. SAFETY GUIDELINES



### 5.1. Warning and Caution

Please carefully read this Manual for use and rigorously adhere to the instructions. The captions “Caution”, “Warning” and “Attention” have a precise meaning. You should carefully read the related instructions in order to grant a safe and effective working of this device.

- **Caution:** indicates a danger/risk for the patient or the surgeon. The failure in comply with the indication can carry injuries to the patient or to the surgeon.
- **Warning:** indicates the maintenance to comply with in order to avoid any possible damaging in the appliance.
- **Attention:** indicates special information related to the use of the Easyroot device or other important information.

**Caution:** Prior to activating the device carefully read the manual for use. Pay close attention to the sections related to the device working and to safety guidelines in order to avoid any risk for the patient, your staff and yourself.

**Caution:** Install the Magnetic Mallet device keeping it out of the reach of the patient.

**Caution:** Always check the cables. If the cable is somehow damaged you should immediately replace it calling the authorized service provider.

**Caution:** Prior to activating the device you should always have a functional operational test (FOT) pressing the footswitch or the manual control push-button.

**Caution:** Before activating the device make sure you have properly connected the handpiece.

**Caution:** It's strictly forbidden to open the control unit – Electric shock risk! Any opening of the control unit by non authorized persons nullifies the warranty.

**Caution:** You should move away the device from the patient every time there is a stalling in the device (for example: power failure during the use).

**Caution:** You should unplug the device from the main power every time you go on working on the control unit (for example : disinfection/cleaning, unplugging of the connector).

**Caution:** It's forbidden to put fingers or any tool inside the footswitch or the handpiece connectors.

**Caution: 1 pulse / second for a maximum of 200 pulse then a 40 minute work break.**

**Caution:** Handle with care the packaging and avoid all sort of strikes or damages.

**Warning:** Keep dry! Make sure no liquid gets into the control unit. Do not lean liquid holders on it.

**Warning:** You should install the device in dry environments only . Take care no liquid gets into the control unit since and into the handpiece. This can lead to malfunction.

**Warning:** The device must be only powered with the voltage which is stated on the rating plate placed on the rear panel of the control unit.

**Warning:** Handle and use with care the cables of the main power and of the handpiece/footswitch in order to avoid any cable stress. Use them in wide leeway situations.

**Warning:** Use fuses having a value corresponding to the one stated on the line filter rating plate.

**Attention:** The warranty coverage is nullified by improper usage of the device.

**Attention:** According to an official test the Easyroot meets the requirements of Directive 2014/30/UE concerning electromagnetic compatibility and doesn't emit any interfering radiation.

**Attention:** Do not use on patients:

- Less than 14 years old
- With health problems
- With systemic chronic dependency
- With problems in maxillary sinus
- With handicaps
- With coagulation disorders
- With periodontal infection in alveolar bone
- Smokers
- Drugs or alcohol addicted



**Contraindicated in all patients with implantable cardiac devices without medical advice.**

**Note:** Easyroot meets the requirements of Directive Rohs, Reach, ISO4074, EN 455-3 and does not contain:

- Other dangerous substances referring to Reach
- Latex
- Human blood derivatives
- Animal substances

**Attention:** In the first stage always start with the lower force in order to familiarize with the device working.

**Attention:** It's up to the surgeon to determine the more suitable force to achieve the desired result.

**Attention:** It's up to the surgeon to determine the pressure to be exerted on the bone with the handpiece to get the desired result.

**ATTENTION: You should be knowledgeable about the device and its working before using it on a patient.**

## 5.2. Intended use

The EASYROOT is a medical device for dentistry surgery to perform extraction of teeth, roots and implants.

The pulse action plastically deforms the spongy bone allowing to get an atraumatic extraction preserving both alveolar and periodontal ligaments.

**The Easyroot must be used with surgery instruments supplied by Meta Ergonomica only.**

For safety reasons Easyroot must be used as per its intended use only.



**Attention:** For your own safety you should not carry out alterations on the device.

### 5.3. User's qualifications

The Magnetic Mallet should be used in medical environments only and performed by a dentistry surgeon cognizant on the device use.

### 5.4. Use conditions:

Temperature  $-5^{\circ}/+45^{\circ}$

### 5.5. Safety guidelines for the installation environment

The device should be used in dentist's surgery or medical environments only.



**Warning:** The device should be installed in dry environments only and kept dry.



**Warning:** The device must be only powered with the voltage which is stated on the rating plate placed on the rear panel of the control unit.

### 5.6. Operating safety guidelines

Prior to your first treatment on a patient you should be cognizant on the working of this medical device.



**Warning:** 1 pulse/sec for a maximum of 200 consecutive pulses then a 40' break



**Warning:** Prior to activating the device you should always carry a functional operational test (F.O.T.)



**Warning:** Instruments are not provided in a sterile package and must, therefore, be sterilised before their first use (see "Disinfection and sterilization of the parts" section)



**Warning:** Move away the device from the patient every time there is a stalling in the device working (for example: power failure)



**Warning:** Before activating the device make sure you corectly plugged the handpiece into the corresponding plug (B) and the footswitch in the corresponding plug (C).



**Warning:** Handle with care the blades supplied with the device. Blades by nature are very sharp-edged. . Do not leave the handpiece coupled with the beaver and the blade into the housing of the power supply.



**Warning:** Make sure no liquids penetrate into the handpiece



## 6.0. TRANSPORT AND STORAGE

### 6.1. Transport and storage conditions



**Caution:** Handle with care. Take care the package is not damaged.

Take care the external labelling is undamaged.

On the delivery please inspect the device into the packaging. Verify the device is undamaged and the wholeness of the supply (see “Unpacking” section).

## **7.0. INSTALLATION AND INSTRUCTIONS FOR USE**

### **7.1. Unpacking**

Take care in pulling the device and the accessories out from the package. Verify no article is missing or damaged. Should any article be missing or be damaged, please immediately contact the manufacturer or the supplier.

#### **STANDARD SUPPLY**

- 1 Control unit
- 1 Handpiece with ring nut - EXTRACTION function
- 1 Footswitch
- 3 Surgery instruments for extraction
- 1 Spare nut
- 2 Spare O-rings for the ring nut 1 Instructions for use and maintenance

#### **SUPPLY ONLY ON REQUEST**

Extension Kit Easyroot

## 7.2. Installation and connection



**Warning:** Install the device in dry environments only. Take care no liquid gets into the control unit.



**Caution:** The device should be installed and kept away from the patient.

1. The power source should have the same nominal voltage of Easyroot. The nominal voltage is indicated on the rating panel placed on the rear panel of the control unit.
2. Connect the power cable (i) to the device through the socket (H)
3. Plug in the power cable (L) of the device
4. Jack in the handpiece (O) into the connector panel mount (B)
5. Jack in the footswitch (M), into the connector panel mount (B)

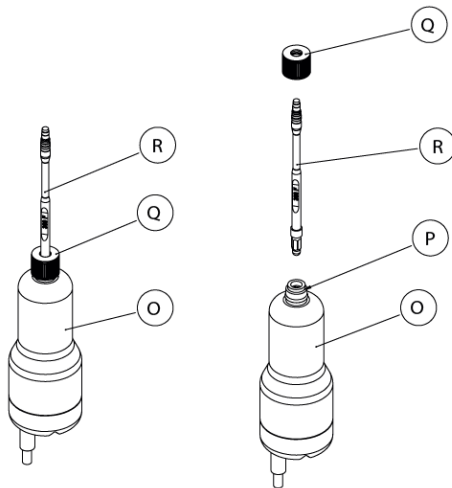


**Caution:** Prior to the activation, take sure you've plugged properly the handpiece.

## 7.3. Activation

1. Turn on the device using the switch (F) located on the back of the power supply.
2. The led bar lights on according to the desired force level (nr. 1 or nr. 2)

## 7.4 Surgery instrument insertion into the handpiece



1. Insert instrument (R) on the handpiece
2. Insert the ring nut (Q) on the instrument
3. Screw the ring nut (Q)
4. Ensure the surgery instruments is tightly fastened in order to avoid any possible ejection of the instrument during surgery. This could cause severe risk for the operator, the assistant and the patient.

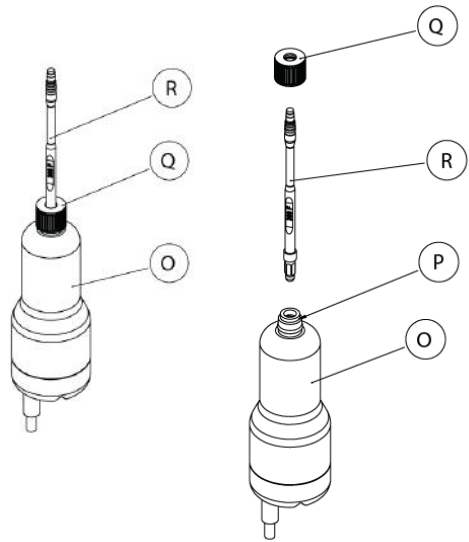


### Warning:

Handle with care the blades. Pay attention in inserting them into the handpiece and do not leave the handpiece coupled with the beaver instrument into the housing of the handpiece

## 7.5. Release of surgery instrument

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



## 7.6. How to activate the handpiece

1. To activate the handpiece, press the footswitch (M)



**Attention:** In the initial phase of use, to familiarize yourself with the device, it is advisable to always start with the lowest strength (value 1).



**Caution:** 1 pulse/sec for a maximum of 200 consecutive pulses then a 40' break

## 7.7. Calibration of the forces

1. Press or release the latching button (A) on the control unit front panel in order to calibrate the force level (from 1 or 2).
2. The led bar (D) shows the selected force level (half lit force nr. 1 - complete lit force nr. 2)



**Attention:** The most suitable level of the force is determined by the surgeon according to the practice/treatment.

**The Surgery instrument action is mainly due to the pressure exerted by the surgeon the handpiece and by the axial forwards movement of the energy.**

## 8.0. MAINTENANCE

### 8.1. Cleaning and maintenance



**Caution:** It is necessary to disconnect the plug from the power supply socket every time the operator goes to act on the power supply (eg cleaning, disconnection of the connectors).



**Caution:** The silicone cable with the connector and the handpiece should be sterilized by autoclave before any usage.



**Caution:** You should never put your fingers or any tool inside the connectors of the handpiece and of the footswitch.



**Warning:** Take sure no liquids enter into the control unit. You should not hold liquids on it.

The control unit case should be routinely disinfected with cleaning products which aren't harmful for plastics.

### 8.2. Disinfection and sterilization of the parts



**Caution:** You should unplug the device from the main power every time you go working on the control unit (for example: cleaning, connectors unplugging).

**DISINFECTION AND STERILIZATION BY AUTOCLAVE OF THE HANDPIECE WITH ITS CORDSET AND CONNECTOR, THE RING NUT AND THE SURGERY INSTRUMENT.**

The handpiece (O) with its cable and metal connector and the surgery instrument (R) must be submitted to autoclave sterilization before their first use and before all treatment.

After having uncoupled the parts (see the section 7.5) you should carry out the cleaning process. Brush instruments off under flowing tap water, then proceed with the sterilization by autoclave.

**AUTOCLAVE DIRECTIONS FOR USE:**

Achievement of the dew point through the proper combination of temperature and pressure values which should be the following ones:

- 135°C for 2 bar pressure - Sterilize for 8 minutes minimum

PART	CLEANING/ DISINFECTION	STERILIZATION BY AUTOCLAVE
Handpiece with cable and connector	Avoid any liquid penetration into the handpiece. Do not use liquids for disinfection	handpiece and Instruments should be sterilized by autoclave before the first use as they're non-sterile delivered. Handpiece and instruments must be sterilized by autoclave after every use and before any treatment
Ring nut	Before sterilization you should carry a cleaning and disinfection process. Soack a cotton bar with high grade disinfectant and carefully clean the parts inside and outside. Pay attention o the instructions on the disinfectant bottle in order to evaluate the suitability of the disinfectant components	Carry on the sterilization by autoclave before their first use and after each treatment
Extraction instruments	Avoid any use of IUPAC (benzalkonium chloride) to clean instruments	Carry on the sterilization by autoclave before their first use and after each treatment



**Caution:** Prior to disinfection and sterilization, carefully read the instructions contained in the instruments IFU

### 8.3. Maintenance



**Caution:** Do not open the device! Electric shock danger! Any intervention on the device by unauthorized people nullifies the warranty.

**NO LUBRICATION AND/OR MAINTENANCE IS NEEDED ON THIS DEVICE**  
**NO INTERVENTION ON THIS DEVICE IS ALLOWED.**

In the event of any failure you should immediately contact the manufacturer/distributor (see section “Failures and malfunctions”). The only maintenance you can carry out is the fuses replacement (see section “Fuses replacement”).

### 8.4. Repairs

**Caution:** Do not open the device! Electric shock risk! Any opening of this device by unqualified people nullifies the warranty.

**Warning:** FOR YOUR OWN SAFETY YOU SHOULD NOT MAKE ALTERATIONS TO THIS DEVICE.

IN THE EVENT OF FAILURES OR MALFUNCTIONS CALLING FOR REPAIRS YOU SHOULD PROMPTLY ADVISE THE MANUFACTURER/DISTRIBUTOR SO THAT THE DEVICE WILL BE CALLED BACK.

**Only the distributor/manufacturer is authorized to carry out the failures test and the repair works.**

### 8.5. Fuses replacement



**Warning:** You should replace fuses with some new one having the amperage value indicated in the rating plate on the fuse holder.

1. Take off the fuse holder (C) from the line filter using a little screwdriver.
2. In the fuse holder you will find two 1,6 A fuses.
3. Verify if one or both fuses are burnt out.
4. Pull out the burnt out fuse/fuses.
5. Pull into the holder the new fuse/fuses. Make sure they have the same amperage value indicated in the rating plate placed on the fuse holder.
6. Verify the correct working of the device.



## 9.0. DISPOSAL

This device meets the requirements of Directive 2012/19/UE2002/96/CE for electric and electronic devices disposal - RAEE. At the end of the period of use the device and the accessories, must be sent for recycling of the materials or for disposal in a manner which poses no threat to humans or the environment. The manufacturer is responsible for the compliance with National requirements.

## 9.1. Responsibility

The manufacturer is liable for safety, reliability and performances of this device only if:

- The installing has been performed in order to adhere rigorously to the instructions.
- All necessary alterations or repairs have been carried out by authorized repair service only.
- The device has been used in accordance with the instructions for use and its intended use.

## 9.2. Warranty

The manufacturer undertakes to provide the final customer of this device with a warranty of satisfactory functions freedom from faults in both and manufacturing process for the duration of 24 months from the delivery date. In case of justifiable complaints the manufacturer will provide repairs and/or spare parts free of charge. Nevertheless, the manufacturer will charge the final customer with shipment costs and it is not accountable for risks arising from the shipment itself. For other instances the manufacturer will refer to the warranty indicated in the trade general conditions.

**The use of instruments different from the ones supplied by the manufacturer is not allowed**

Any opening, repair or alteration carried out by unauthorized persons relieves the manufacturer of all responsibility concerning the safe working of the device and nullifies the warranty.

## 9.3. Technical Literature

The manufacturer will furnish on request circuit diagram, the components list, all descriptions and information useful to the technical assistance in order to carry the authorized repairs.

## 10.0. TECHNICAL DESCRIPTION

### 10.1. Failures and malfunctions

**Caution:** Every time you go on working on the control unit you should unplug the device from the main power.

#### **Failure / Malfunction**

Break down without sonic alarm.

#### **Possible cause**

- Failure of electrical supply.
- Line filter fuse burnt out.
- Internal circuit failure.

#### **Possible solution**

- Verify the electrical supply presence.
- Fuse/fuses replacement (see section "Maintenance"). If the malfunction is still present after the fuse/fuses and/or the power cable replacement, contact the authorized service provider.
- Contact the authorized service provider.

#### **Failure / Malfunction**

The led bar lights on in red color, The sonic alarm is ringing and you notice a mild heating of the handpiece.

#### **Possible cause**

- Internal circuit failure.

#### **Possible solution**

- Switch off the device.
- Contact the authorized service provider.

#### **Failure / Malfunction**

When you press the footswitch no pulse is conveyed to the bone expander/osteotome.

#### **Possible cause**

- Possible wrong connection of the footswitch in the corresponding plug.
- The footswitch is damaged.
- Internal circuit failure.

#### **Possible solution**

- Verify you correctly connected the footswitch in the plug.
- Contact the authorized service provider and ask for a new footswitch.

**Failure / Malfunction**The led bar doesn't lit**Possible cause**

- The led circuit is damaged.
- Internal circuit failure.

**Possible solution**

Call the authorized service for display replacement or repairs.

**Failure / Malfunction**Mild heating of the handpiece**Possible cause**

- Improper use.

You have exceeded the maximum threshold of 200 consecutive pulses without having had the necessary break.

**Possible solution**

- Switch off the device. Wait 40 minutes before switching on the device again.

**Failure / Malfunction**The o-ring type 108 of the handpiece is no more working as anti-unscrewing for the ring nut**Possible cause**

- O-ring consumption or breaking

**Possible solution**

- Replace the O-ring with the spare one supplied with the handpiece (see blades container).
- If the problem endures, contact the authorized service provider.

## 11.0 TECHNICAL DATA

Supply voltage:	230 V
Frequency:	50/60 Hz
Current input (stand by):	0.070 A
Current input (operative condition):	0.38 A
Fuse:	F – 5x20 – 250V- 1,6 A

### **Medical device class IIa in accordance with MDD 93/42/CE Medical device Class II BF type in accordance with IEC 60601-1**

Dimensions (l x h x w)	226.5 mm x 223 mm x 109 mm
Control unit weight	Kg. 2,600
Handpiece weight	Kg. 0,390

#### Transport/storage conditions


Storage temperature range	- 40 °C / + 50 °C
Humidity (relative humidity, without condensation)	10% . 90%
Air pressure	+700hPa / +1060 hPa

#### Conditions for use

Temperature range for use	-5 °C / + 45 °C
Humidity (relative humidity, without condensation)	15% . 85%
Air pressure:	+700hPa / +1060 hPa

## 12.0. ELECTROMAGNETIC DECLARATION OF CONFORMITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, 4, 8, 15kV air	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/Burst IEC 61000-4-4	±2kV for input power ports ±1kV for I/O ports	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Input power ports: 0.5 and 1.0kV (line to line) 0.5, 1.0 and 2.0kV (line to earth) Signal I/O: 2kV (line to earth)	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Dips: >95% UT for 0.5 and 1 cycle 30% UT for 25 cycles (50Hz) 30% UT for 30 cycles (60 Hz) Interruption: >95% UT for 250 cycles (50Hz) >95% UT for 300 cycles (60Hz)	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Compliant	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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<p>Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150KHz to 80MHz 3V/m 80 MHz to 2,5 GHz</p>	<p>3 Vrms 3 V/m</p>	<p>Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance.</p> <p><math>d=1,167 \cdot \sqrt{P}</math></p> <p><math>d=1,167 \cdot \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d=2,2333 \cdot \sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>3</sup>, should be less than the compliance level in each frequency range. b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Note 1: at 80 MHz and 800 MHz, the higher frequency range applies

Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum power of communications equipment.

SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	150 KHz to 80 MHz $d=1,17*\sqrt{P}$ m	80 MHz to 800 MHz $d=1,17*\sqrt{P}$ m	800 MHz to 2,5 GHz $d=2,33*\sqrt{P}$ m
0,01	0,117	0,117	0,233
0,01	0,370	0,370	0,740
1	1,17	1,7	2,33
10	3,70	3,70	7,40
100	11,7	11,7	23,3

For transmitters rated at maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



**MANUFACTURER: Meta Ergonomica S.R.L.**  
Via Monte Nero, 19 - 20029 Turbigo (MI) - Italy  
Tel: + 39 0331 890280

