

# Magnetic Mallet



Medical device for surgery and dentistry

## Instructions for use

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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.

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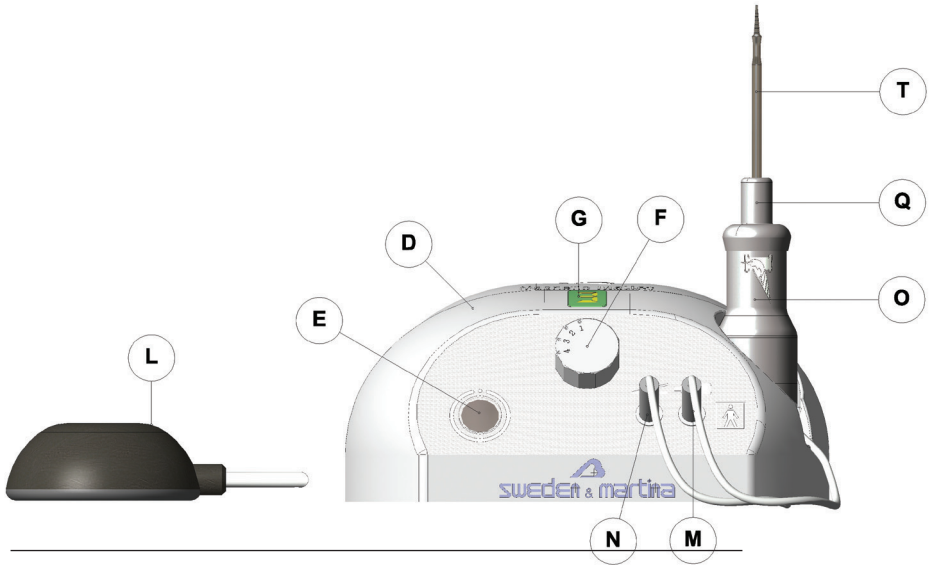
## 2.0. DEVICE ILLUSTRATIONS



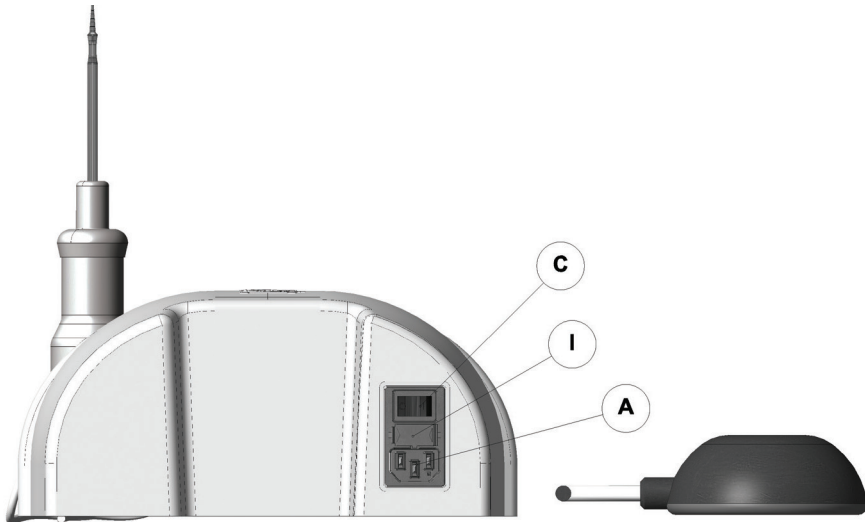
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### **MAGNETIC MALLET <sup>(1)</sup>**

(1) Magnetic Mallet can be also supplied with the Crown Remover Handpiece



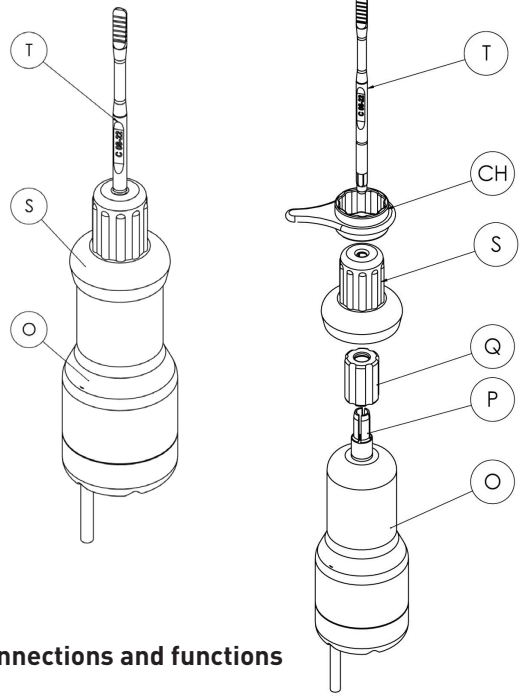
Front view



Rear view

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## Osteotome Handpiece



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

#### CONTROL UNIT





- A. Socket
- B. Mains plug
- C. ON/OFF switch
- D. Control unit
- E. Manual control push button
- F. Knob for the calibration of the force
- G. Display showing the force level
- H. Power cable
- I. Fuse holder
- L. Footswitch
- M. Handpiece connector
- N. Footswitch connector

#### OSTEOTOME HANDPIECE













- O. Osteotome function handpiece
- P. Chuck
- Q. Ring Nut
- S. Silicone cap for the Osteotome handpiece
- T. Bone expander/Osteotome
- CH. Wrench

### 3.0. EXPLANATION OF THE USED SYMBOLS

#### SYMBOLS PLACED ON THE MAGNETIC MALLET CHASSIS

-  Manual control push button  
.....
-  Handpiece connector  
.....
-  Footswitch connector  
.....
-  Gauge of the supplied force  
.....

## SYMBOLS LABELLING

-  Information on the manufacturer and date of manufacture  
.....
-  Device serial number  
.....
-  AC (Alternating current)  
.....
-  Coupled part "BF type" ( according to IEC 60601-1 rules )  
.....
-  Prior to setting the device going carefully read the instructions for use  
.....
-  Caution hazardous voltage  
.....
-  Store in a dry and clean place  
.....
-  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

**Magnetic Mallet** is an electro-medical device for surgery and dentistry practice with a double function according to the coupled part (handpiece 0) :

- **OSTEOTOME** version to obtain the bone plastic deformation thanks to the available forces and their application timing.
- **CROWN REMOVER** version to obtain the crown and bridge removal from the abutment or the implant.

This device is basically made up by a control unit, a footswitch and two interchangeable handpieces which can be used depending on the needed practice.

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

1. The ON/OFF switch (C)
2. 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 connector (M)
  - Footswitch connector (N)
3. Manual control push-button (E)
4. Plastic knob to calibrate the level of the force (F)
5. Display showing the selected force (G)

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 both footswitch (L) and manual control push-button (E).

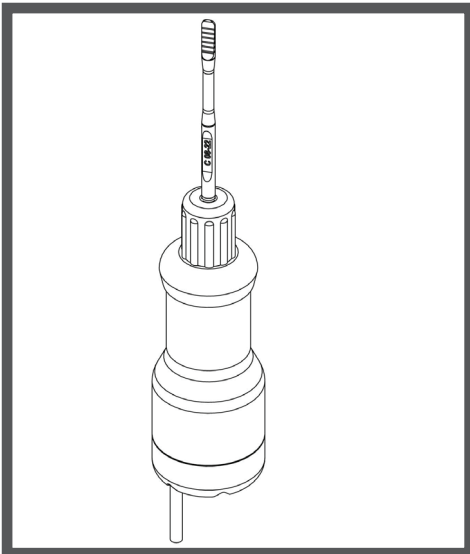
Both for the **OSTEOTOME** and for the **CROWN REMOVER** function the force applied to the handpiece through the pressure of the footswitch or of the push button is not continuous. Each pressure of the switch conveys a single force pulse

Turning the knob (F) you can select the desired level of the force among the four possible options (1-4); at the same time the selected force will be showed on the liquid crystal Display (G) and by the number selected on the knob .

**Magnetic Mallet** has been designed to give 2 pulses per second. You should not exceed the maximum threshold of 100 consecutive pulses per minute without having a break.

## 4.2. Description of the coupling parts

### Osteotome Function Handpiece with ring nut



**For the OSTEOTOME function you must use the Handpiece with the ring nut (O) and the Bone Expander/Osteotome (T).**

#### INTENDED USE

Medical device for dentistry surgery to perform the sinus lift. The pulse conveyed to the bone expander/osteotome allows you to achieve the plastic deformation of the bone in order to create the site for the implant.

The **Magnetic Mallet**, equipped with the handpiece and the bone expander/osteotome is a medical device fitted to plastically deform both maxilla and lower

In this way the surgeon can create the proper site for the implant.

Through the handpiece the bone-expander can be energized with 4 different forces so that the surgeon can replace the energy carried out by the human force in the manual practice (state of art).

You can select the desired level of the force among the 4 possible options (1-4) by turning the knob (F) placed on the control unit.

**In the pre-marketing tests we carried out the most used forces have been the 2nd and the 3rd one; nevertheless it's important to remember that the whole spectrum of the forces has a very close progressive range. That's why they can all be considered suitable for surgery. That's why it's entirely up to the surgeon to determine the more suitable one to achieve the desired result.**



**In order to familiarize yourself with the device, in the first stage you should always start from the lighter force (nr.1). It's also advisable to keep the bone expander/ osteotome between your fingers selecting the different levels of the forces. In this way you shall be able to assess the corresponding pulse.**

Bone expander/osteotome 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 bone expander/osteotome 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 Magnetic Mallet 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:** Prior to activating the device take sure you have connected the proper handpiece according to the intended practice/treatment.

**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 stalling in the device (for example. : power failure during the use).

**Caution:** You should unplug the device from the main power every time you goes 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 hand-piece connectors.

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

**Caution:** You should not exceed the maximum threshold of 100 consecutive pulses per minute.

**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 and kept it dry. Take care no liquid gets into the control unit since this can lead to malfunction.

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

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

**Warning:** Handle and use with care the power cable and the hand-piece/footswitch cordsets. In order to avoid cable stress use them in wide leeway situations.

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

**Attention:** According to an official test the Magnetic Mallet meets the requirements of Directive 89/336/EEC concerning electromagnetic compatibility and doesn't emit any interfering radiation.

**Attention:** In the first stage you should start by a low level force and increase it step by step as necessary.

**Attention:** It's up to the surgeon to determine the more suitable pressure to be applied on the bone in order to achieve the desired result.

**Attention:** It's up to the surgeon to determine the more suitable force to achieve 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 **Magnetic Mallet** is a medical device to be used in surgery and dentistry. According to the coupled handpiece it can have a different use:

- OSTEOTOME function                      HANDPIECE with ring nut
- CROWN REMOVER function\*              HANDPIECE with joint

### **Intended use : Osteotome function**

Medical device to be used in sinus lift practice. The pulse action plastically deforms the bone in order to implant partial denture.

The **Magnetic Mallet in OSTEOTOME function must be used with bone expander/osteotome supplied by Meta Ergonomica only.**

For your own safety you should not use the device in other areas of applicability.



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

\* N.B. For the crown-remover function you should refer to the dedicated Instruction for use you can download in our website

### 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 supplied 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**: You should not exceed the maximum threshold of 100 successive pulses per minute



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



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



**Warning** : Prior to activating the device make sure you have plugged into the device the proper 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 (Reference “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 – OSTETOME function
- 1 Footswitch
- 10 Bone expanders/osteotomes
- 1 Spare nut
- 2 Silicone protective caps
- 2 Wrenches
- 1 Instructions for use and maintenance

### **SUPPLY ONLY ON REQUEST**

For **OSTEOTOME** function:

- Axially double bended osteotomes
- Bone expander MM-PD-160

## 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.



**Attention:** To avoid electric shock risk this device should be powered by earthed power supply network.

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



**Caution:** Prior to the activation, take sure you've plugged in the proper handpiece according to the required use/treatment.

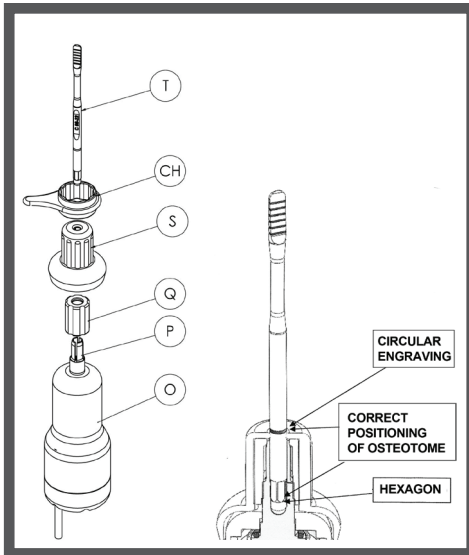
### 7.3. Activation

1. Switch on the device pushing the ON/OFF push button (C) placed on the rear panel of the control unit (D)
2. The display (G), placed on the front panel of the control unit, lights up.



**Attention:** When the display (G) lights up it will show a number (from 1 to 4) according to the positioning of the knob (F)

### 7.4. Bone expander/osteotome insertion on the handpiece OSTEOTOME function



1. Insert the ring nut (Q) and slightly screw it on the chuck (P).
2. Push the silicone protective cap (S) all the way to the bottom of the ring nut (Q) such that it adheres.
3. Choose the proper bone expander/osteotome (T) and couple it to the handpiece (O) inserting it into the chuck (P) through the ring nut (Q).
4. Screw back on the nut (Q) operating the protective silicone cap (S).
5. The bone expander/osteotome has an hexagonal base which must be inserted into the chuck (O). Please pay attention to insert the base in order to fit it together the hexagon placed inside

On the osteotome there is a special circular engraving allowing you to verify the correct insertion of the osteotome into the chuck.

6. The wrench supplied with the handpiece can be used to loosen the ring nut, if needed.
7. Ensure the bone expander/osteotome is tightly fastened then press the footswitch (L) or the manual control (E).

## **7.5. Release of bone expander/osteotome**

1. Loosen the ring nut (Q) turning the protective silicone cap (S).
2. Pull out the bone expander/osteotome (T).

For sterilization by autoclave (see : “Disinfection and sterilization of the parts”) :

3. Pull out the silicone protective cap (S).
4. Thoroughly unscrew the ring nut (Q).

## 7.6. How to activate the handpiece

1. To activate the handpiece, press the footswitch (L) or the manual control (E) which is placed on the front panel of the control unit (D).

**Each pressure of the footswitch (L) or of the manual control (E) conveys a single pulse.**



**Attention:** In the first stage you should always start by the lighter force (nr.1).



**Caution:** You should not exceed the maximum threshold of 100 consecutive pulse/minute.

## 7.7. Calibration of the force

1. Turn the knob (F) on the control unit front panel in order to calibrate the force level (from 1 to 4).

2. The display (G) shows the calibrated force level according the knob (F) positioning.



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

**The bone expander/osteotome action is mainly due to the pression exerted by the surgeon on the handpiece and by the axial forwards movement of the energy.**



**Attention:** It's up to the surgeon to determine the pressure to be exerted on the bone in order to achieve the desired result.

## 8.0. MAINTENANCE

### 8.1. Cleaning and maintenance



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



**Caution:** You should never put your fingers or any tool inside the connector of the handpiece or into the footswitch one.



**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, SILICONE CAP, OSTEOTOME/ BONE EXPANDER, WRENCH.**

**The handpiece (O) with its cordset and connector (M), the bone-expander/osteotome (T), and the wrench (CH) should be sterilized by autoclave before its first use as they're non-sterilized supplied.**

**The handpiece (O) with its cordset and connector (M), the nut (Q), the silicone cap (S), the bone-expander/osteotome (T) and the wrench (CH) should be sterilized by autoclave before all treatment.**

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

#### **AUTOCLAVE DIRECTIONS FOR USE:**

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

- 121 °C per 1 Bar
- 135 °C per 2 Bars

#### **N.B.**

**THE HANDPIECE MUST BE SUBMITTED TO AN INSPECTION AFTER 3 YEARS FROM ITS FIRST USE. THE USER, AFTER THAT PERIOD, MUST SEND THE HANDPIECE TO THE DISTRIBUTOR/MANUFACTURER FOR THE NECESSARY CHECK WHICH WILL BE HANDLED BY THE MANUFACTURER SERVICE REPAIR.**

### 8.3. Maintenance



**Caution:** Do not open the device! Electric shock danger! Any intervention on the device by un-authorized 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 - Malfunctions). The only maintenance you can carry out is the fuses replacement.

### 8.4. Repairs



**Caution:** Do not open the device! Electric shock risk! Any opening of this device by un-qualified 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 IN.

The distributor/manufacturer will carry out the failures test and the repair works.

### 8.5. Fuses replacement

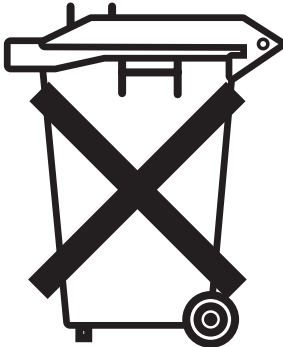


**Warning:** You should replace fuses with some new one having the amperage value indicated in the rating plate on the fuse holder.

1. Take off the fuse holder (I) 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. Take 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 OF WASTE



This device meets the requirements of **Directive 2002/96/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 refers to the warranty indicated in the trade general conditions.

**Any opening, repair or alteration carried out by un-authorized 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 component list, all descriptions and information usefull to the technical assistance in order to carry the authorized repairs.

## 10.0. TECHNICAL DESCRIPTION

### **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.
- Power cable damaged.
- Internal circuit failure.

Possible solution

- Verify the electrical supply presence .
- Fuse/fuses replacement (see section “Maintenance”) or power cable replacement with a PVC cable 3x0,75. If the malfunction is still present after the fuse/fuses and power cable replacement contact the authorized service provider.
- Contact the authorized service provider.

#### **Failure / Malfunction**

The display shows the capital letter “E”, 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 or to the hook.

Possible cause

- The footswitch is damaged.
- Internal circuit failure

Possible solution

- Verify if the pulse is conveyed to the bone expander/osteotome or to the hook by pressing the manual control push-button. If so contact the authorized service provider and ask for a new footswitch.
- Even if the footswitch doesn't work you can follow through the treatment using the manual control push-button.

### **Failure / Malfunction**

If you press the manual control push-button no pulse is conveyed to the bone-expander/osteotome or to the hook.

Possible cause

- The manual control push-button is damaged.
- Internal circuit failure

Possible solution

- Verify if the pulse is conveyed by pressing the footswitch. If so contact the authorized service asking for the manual control switch repair/replacement.
- Contact the authorized service.

### **Failure / Malfunction**

The display is switched off or it shows some nondescript number.

Possible cause

- The display is damaged.
- Internal circuit failure.

Possible solution

- Take note that the level of the force is all the same indicated by the knob positioning (1-2-3-4). In that event you can follow through the treatment before calling 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 100 consecutive pulses per minute without having had the necessary break.

Possible solution

- Switch off the device. Wait some minute before switching on the device again.

## 11.0. TECHNICAL DESCRIPTION

Power supply voltage	230 V
Nominal frequency	50 Hz
Nominal stand-by current	0,070 A
Nominal current during the pulse	0,38 A
Fuses	F – 5 x 20 – 250V – 1,6A

**Medical device class IIa in accordance with MDD 93/42/CEE**  
**Medical device class I – BF type in accordance with IEC 60601-1**

Dimensions (l x h x d)	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°
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 COMPLIANCE DECLARATION

Guidance and manufacturer's declaration– Electromagnetic emissions		
The ME equipment is intended for use in the electromagnetic environments specified below. The customer or the user of the ME equipment should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emission CISPR 11	Group 1	The ME equipment uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipments.
RF emission CISPR 11	Class B	The ME equipment is suitable for use in all establishments including domestic establishments and those connected to the public low-voltage power supply networks that supplies buildings used for domestic purpose.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

## Guidance and manufacturer's declaration– Electromagnetic immunity

The ME equipment is intended for use in the electromagnetic environments specified below. The customer or the user of the ME equipment should assure that it is used in such an environment

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	6kV contact ±8kV air	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	± 2kV power supply line	Mains power quality should be that of a typical commercial or hospital environment
IEC 61000-4-4 Surge IEC 61000-4-5	± 1kV line to line	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11	<5 % UT per 0.5 cycle 40% UT per 0.5 cycle 70% UT per 25 cycle <5 % UT per 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME equipment requires continued operation during power mains interruptions is recommended that the medical equipments be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location or typical commercial or hospital environment



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## Dichiarazione di Conformità CE CE Declaration of Conformity

Il Dispositivo Medico/ *The medical device:*

**Nome del Prodotto/ Product name: MAGNETIC MALLET**  
**Codice del Prodotto/ Product code: MM-STD-OST**  
**Numero di Registrazione/ Registration number: HD60076022 0001**

Progettato e fabbricato da/ *Designed and manufactured by:*

**Meta Ergonomica di Merlo Mario**

E' conforme alle prescrizioni della Direttiva 93/42/CE successivamente emendate dalla 2007/47/CE, attuata con DLgs. n° 46 del 24/02/1997, Allegato II art 5./ *Complies the Essential Health and Safety requirement following the provision of the Directive 93/42/CE later amended by 2007/47/CE, enforced by DLgs. Nr. 46 of 24/02/1997, Annex II - Article 5.*

L'Azienda **Meta Ergonomica di Merlo Mario** con sede in Via Monte Nero 19 – 20029 Turbigo (MI), Fabbricante del dispositivo sopracitato, dichiara sotto sua completa responsabilità che la progettazione, la costruzione e i controlli finali sono stati eseguiti in accordo con il Sistema di Qualità approvato il **26.03.2012** dall'Ente Notificatore **Tuv Rheinland Italia Srl– Codice 1936** sotto le prescrizioni della Direttiva 93/42/CEE allegato II, articolo 5/ *The company Meta Ergonomica di Merlo Mario - Via Monte Nero 19 – 20029 Turbigo (MI), Manufacturer of the above mentioned device , declare under its sole responsibility that designing and manufacturing processes together with final test processing comply with the procedure of evaluation of Quality System examined and approved on March, 26 2012 by the notified body Tuv Rheinland Italia Srl– Code 1936 according to the Directive 93/42/CEE Annex II, Article 5.*

Il Fabbricante dichiara inoltre sotto sua completa responsabilità che il Dispositivo appartiene alla **Classe I tipo BF/ The manufacture declares too, under its sole responsibility, that the Device is part of Class I - type BF devices.**

Firma/Signature: \_\_\_\_\_

Nome/Name: Mario Merlo

Qualifica/Status: Responsabile di progetto/Project manager

Data/Date : 30.09.2011

**Meta Ergonomica di Merlo Mario** – Via Monte Nero 19 – 20029 Turbigo (MI) – Italia – 0331-890280  
Email : [info@metaergonomica.it](mailto:info@metaergonomica.it) - P.IVA 07024880960 - C.F. MRL MRA 44 R 02 L 471 I



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**META ERGONOMICA di Merlo Mario**

Via Monte Nero, 19 - 20029 TURBIGO (MI) - ITALY

Tel/Fax +39 331.890280

Email: [info@metaergonomica.it](mailto:info@metaergonomica.it)

**Sole Distributor for  
(Italy, Japan, Portugal and Spain):**



SWEDEN & MARTINA SPA

Via Veneto 10

35020 Due Carrare (PD)

Italy

Tel : +39 49.9124300

[www.sweden-martina.com](http://www.sweden-martina.com)

[info@sweden-martina.com](mailto:info@sweden-martina.com)

**Technical Assistance:**

[Support@sweden-martina.com](mailto:Support@sweden-martina.com)