DO NOT USE THE HANDPIECE PLUS BEFORE HAVING CAREFULLY READ THIS MANUAL FOR USE AND SCRUPULOUSLY ADHERE TO THE CAUTIONS CONTAINED IN THIS MANUAL
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ATTENTION:
Please be aware you are referring to the latest update of the instructions for use, as the manufacturer reserves the right to make improvements at any time without prior notice. The images and drawings in this instructions for use are provided for illustration purposes only.

ATTENTION:
This operating manual was made to help you to properly use the Magnetic Mallet PLUS handpiece.
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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The Plus handpiece is the ultimate evolution of the Magnetic mallet project.

The Plus handpiece specific design allows the delivering of calibrated pulses conveying a 30% higher force respectful to the ones obtained with the standard handpiece, supplied with the Magnetic Mallet.

These increased forces, applied in an optimal timing, allow the surgeon to achieve an easier penetration in the bone mass, even in the higher density part of the bone.

That way the plastic deformation of the bone mass is obtained in the best way and, consequently, the extraction of impacted teeth or roots is less invasive. Indeed, root or tooth extraction will take place more quickly reducing that way the risk to meet with a bone fracture. This safeguards the alveolus thanks to the possibility to keep the integrity of fresh socket walls and it leads to a faster full soft tissue secondary healing. The conclusion is to get an easy implant insertion and predictable results.

The surgeon determines the more suitable force to be applied in order to achieve the desired results according to the case and the patient will feel the surgery a less invasive way.

The Plus handpiece can be used with the standard instruments sold with Magnetic Mallet and with the extractors and expanders sold separately.
1.0. DEVICE ILLUSTRATIONS

Handpiece Version PLUS

1.1. HANDPIECE PARTS
O. Handpiece Osteotome function
P. Chuck
Q. Ring nut
R. Instrument

1.2. SYMBOLS LABELLING
- Information on the manufacturer and date of funding
- Device serial number
- Store in a dry and clean place
- You should not use the device if the packaging is damaged
- Storage temperature
- Disposal of special waste (electric and electronic devices)
- CE mark including the identification number of the Notified Body
- Caution! The improper use of this device can cause injury
2.0. INTENDED USE

Medical device for dentistry suitable to perform a wide range of surgeries thanks to the pulsing action of the handpiece allowing to get the plastic deformation of the spongy bone thus getting the easy insertion of dental implants.

The **Magnetic Mallet**, equipped with the handpiece with a ring nut, is an electro-medical device fitted to plastically deform the maxilla and lower jaw bone mass. Thanks to the specific instruments, designed to equip the device, the surgeon creates the implant site to position the implant at the best. The handpiece delivers 4 different forces which replace the manual force applied, in the hand technique, with a manual hammer. The desired force can be set by simply turning the knob placed on the front side of the control unit on the equivalent number (1-4)

⚠️ **Magnetic Mallet** can be used coupling Meta Ergonomica instruments only. No other instrument can be used with the device.

2.1. STANDARD SUPPLY

1 Handpiece with ring nut – PLUS version
1 Spare ring nut
2 Spare O-ring for the ring nut
1 Instruction for use manual

2.2. SAFETY GUIDELINES

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.

⚠️ **Attention:** The improper use of this device can cause injuries.

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 order to familiarize yourself with the device, in the first stage you should always start from the lighter force (No.1). It’s also advisable to keep the surgery instrument between your fingers selecting the different levels of the forces. In this way you shall be able to assess the corresponding pulse.

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

⚠️ **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:** Handle with care the blades supplied with the beaver. Blades by nature are very sharp-edged. You should pay attention in inserting them into the beaver. Do not insert beaver, with the blade coupled to it, into the handpiece, till the starting of the surgery. Do not leave the handpiece coupled with the beaver and the blade into the housing of the power supply.
3.0. INSTRUCTIONS FOR USE

3.1. INSTRUMENT INSERTION ON THE HANDPIECE OSTEOTOME FUNCTION

1. Insert the instrument (R) into 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.

3.2. RELEASE OF SURGERY INSTRUMENT

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

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 (No.1).

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

**Calibration of the forces**

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.
4.0. STERILIZATION INSTRUCTIONS

**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 cordset and connector (M), the ring nut (Q) 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 3.2) you should carry out the cleaning process. Brush parts off (instruments) 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:

121°C for 1 bar pressure // 135°C for 2 bar pressure

<table>
<thead>
<tr>
<th>ITEM</th>
<th>WASHING / DISINFECTION</th>
<th>STERILIZATION BY AUTOCLAVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece with cordset and connector</td>
<td></td>
<td>Items should be sterilized by autoclave before their first use as they’re non-sterilized supplied. Items should be sterilized by autoclave before all treatment.</td>
</tr>
<tr>
<td>Chuck, joint</td>
<td>Prior to sterilization by autoclave you should disinfect the chuck and the joint. Soak a cotton bud with an hospital grade disinfectant and wipe any visible debris from both inside and outside the piece. To get a proper disinfection of the parts you should use hospital grade disinfectants. You should carefully read the instructions for use on the disinfectant packaging in order to determine the suitability of the treatment.</td>
<td>Items should be sterilized by autoclave before their first use as they’re non-sterilized supplied. Items should be sterilized by autoclave before all treatment.</td>
</tr>
<tr>
<td>Osteotome/bone expanders, crown remover hook, inserter, cutter, beaver holder and beaver</td>
<td>Carry out the cleaning process. Brush off under flowing tap water then proceed with the sterilization by autoclave.</td>
<td>Items should be sterilized by autoclave before their first use as they’re non-sterilized supplied. Items should be sterilized by autoclave before all treatment.</td>
</tr>
</tbody>
</table>

**Caution:** Prior to disinfection and sterilization, carefully read the instructions contained in the instruments tray.
5.0. MAINTENANCE AND REPAIRS

⚠️ **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”).

⚠️ **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 ADVICE THE MANUFACTURER/DISTRIBUTOR SO THAT THE DEVICE WILL BE CALLED IN.**

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

6.0. 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.

6.1. RESPONSABILITY

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.
6.2. 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.

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.

6.3. 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.