Magnetic Mallet™

Handpiece crown remover version

Instructions for use

DON'T GO ON WORKING WITH THE CROWN REMOVER HANDPIECE BEFORE HAVING CAREFULLY RED THIS MANUAL FOR USE AND SCRUPOLOUSLY 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 crown remover 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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0.0. RELEVANT INFORMATION FOR THE USER

The removal of definitive cast crowns is always challenging. In fact breaking the retention cement used to fix crowns and bridges to the abutment always implies a very careful assessment of the patient and of the status of the teeth by the clinician.

With the permanent cements the crown retention, having to last for a long time, is always very effective. That's why a mechanical action to get the loosening of the crown is always traumatic, even if it's carried out by means of effective and targeted mechanicals. In fact none of the available systems are universally applicable.

This entails that it's always mandatory for the clinician to previously assess the alveolar root firmness which could vary from one abutment to the other one in relation with a variation going from about 10 Newton to hundreds of Newton. Furthermore the intrinsic difficulty in decementation must take into consideration the shaping of the abutment and the tilt angle degrees. Inadequate tooth preparation could bring to a failure in treatment.

In fact if the tilt angle degree goes from 3° to 6° the operation will be easier, while if the abutment shaping didn't take care about the tilt angle degree the operation will be harder.

This is the reason why the clinician assessment is always though, subtle and mandatory to determine if the crown should be removed by a mechanical pulse or if it's better to consider to section the crown. Anyhow in this kind of operation some complication always arise and the pratictioner should always consider that this kind of operation can easily cause the abutment fracture or removal.

If the need is to remove a crown from a metal implant the surgeon should always remember that this one is normally small-sized in comparison with an abutment and that it has a mechanically predetermined tilt angle. This means that removing a crown from a metal implant is easier and more convenient.
Provided that the screw in the meantime didn't cause perimplantisis.

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It follows that the **Magnetic Mallet** in the crown remover version, properly used and with a prior careful clinic assessment by the clinician , according to the laboratory tests is a great and effective help in the crown removal technique.

Therefore, in the event that the clinician determines the feasibility of the surgery, the **Magnetic Mallet** in crown remover version will allow the surgeon to use a more effective device in comparison with the manual technique and the automatic devices of the state of the art.

Furthermore it's nice to consider that the manual technique based on sliding hammers can be always considered traumatic irrespective of the ability of the practitioner.

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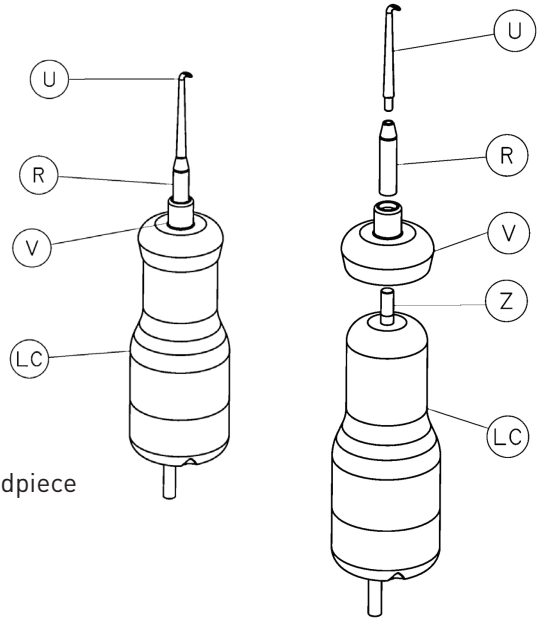
1.0. HANDPIECE ILLUSTRATIONS

Crown Remover Handpiece (only on request)



1.1. CROWN REMOVER HANDPIECE PIECES

R. Nipple
U. Crown Remover hook
V. Silicone cap for the Crown Remover handpiece
Z. Rod thread
LC. Crown Remover function handpiece

1.2. SYMBOLS LABELLING

	Information on the manufacturer and date of manufacture
	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

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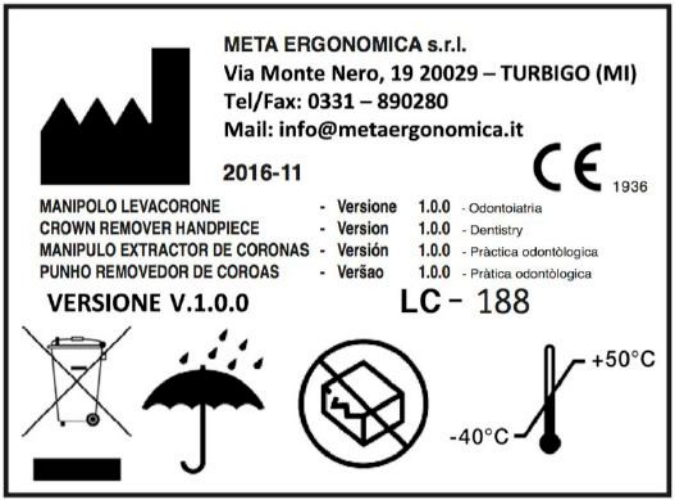

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2.0. INTENDED USE – CROWN REMOVER HANDPIECE

Medical device for dentistry to be used in crown or bridge removal from abutments or implants.

The action of the adjustable force allows to break the retentions cement used to fix the crown or the bridge getting its consequent loosening and removal.

The **Magnetic Mallet** in the **CROWN REMOVER** function should be equipped with hooks produced by **ASA DENTAL only**.

MODELLO/PART NUMBER

ASA DENTAL PART NUMBER 2306 – 2307 – 2308

2.1 STANDARD SUPPLY:

1 handpiece with junction - Crown remover function
3 Crown remover hooks
2 Silicone caps
1 Replacement junction

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.

Take not that the hook action is mainly determined by its impact on the prosthesis and incidentally by the extraction strength exerted by the surgeon.

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 crown remover hook between your fingers selectingthe different levels of the forces.
In this way you shall be able to assess the corresponding pulse.

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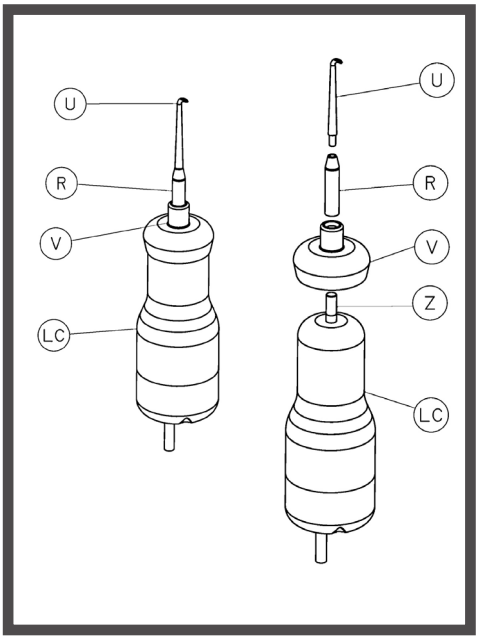
3.0. INSTRUCTIONS FOR USE



3. 1 CROWN REMOVER HOOK INSERTION ON THE HANDPIECE CROWN REMOVER FUNCTION

1. Screw the nipple (R) on the rod thread (Z) of the handpiece (LC)
2. Push the silicone protective cap (V) on the nipple (R) all the way to the bottom such it adheres
3. Choose the proper hook (U) and couple it to the handpiece inserting it in the nipple (R) you've assembled to the handpiece (LC)
4. Screw the crown remover hook (U) tightening it.
5. Ensure the crown remover hook is tightly fastened then press the footswitch (L) or the manual control (E).

3.2 RELEASE OF THE CROWN REMOVER HOOK

1. Unscrew the crown remover hook (U).
2. Pull out the crown remover hook (U).
3. Pull out the silicone protective cap (V).
4. Unscrew the nipple (R).

Take not that the hook action is mainly determined by its impact on the prosthesis and incidentally by the extraction strength exerted by the surgeon.

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Nota: It's up to the surgeon to determine the more suitable force to be applied by the hook to the prosthesis in order to achieve the desired result. The surgeon should always provide an axial pull (the axial pull is related to the abutment position) in order to avoid breaking.

PRECAUTIONS: The removal of prosthesis always presents a risk of damage to the prosthesis itself as well as the patients' hard, soft and anchorage tissues.

Take appropriate measures to prevent swalling and/or aspiration of loosen parts and substances during treatment.

Crown and bridges that are cemented into place with a special genre of cements cannot be possible or at increase risk.

The practice performed with the Magnetic Mallet and its CROWN-REMOVER handpiece is very gentle. Nevertheless the stability of the root should be carefully verified in case of advanced periodontiis in order to prevent extraction of the root.

Pay close attention in determining whenever the Magnetic Mallet is suitable for the treatment you have to perform.

IT'S UP TO THE SURGEON TO OPERATE WITH GREAT CARE. SPECIAL ATTENTION SHOULD BE GIVEN IN VERIFYING THE FITNESS OF THE MAGNETIC MALLET IN THE SURGERY.

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4.0. INSTRUCTIONS FOR THE STERILIZATION

STERILIZATION BY AUTOCLAVE OF THE HANDPIECE (LC) WITH ITS CORDSET AND CONNECTOR (M), NIPPLE (R), SILICONE CAP (V) AND CROWN REMOVER HOOK (U).

The handpiece (LC) with its cordet and connector (M), nipple (R), silicone cap (V), and the crown remover hook (U) should be sterilized by autoclave before its first use as they're non-sterilized supplied.

The handpiece (LC) with its cordset and connector (M), nipple (R), silicone cap (V), and the crown remover hook (U) should be always sterilized by autoclave before any practice/treatment

After having uncoupled the parts, (see the section 3.1) 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

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ITEM	WASHING / DISINFECTION	STERILIZATION BY AUTOCLAVE
Handpiece with cordset and connector		**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.**
Chuck, joint	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.	**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.**
Osteotome/bone expanders, crown remover hook, inserter, cutter, beaver holder and beaver	Carry out the cleaning process. Brush off under flowing tap water then proceed with the sterilization by autoclave.	**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.**

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5.0. MAINTENANCE AND REPAIRS

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 only will carry out the failures test and the repair works

The handpiece doesn't require lubrication and/or maintenance. No technical intervention or alteration should be carried out

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 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.

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 just

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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.

6.3 TECHNICAL LITERATURE

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

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META ERGONOMICA S.r.l.
Via Monte Nero, 19 - 20029 TURBIGO (MI) - ITALY
Tel/Fax +39 331.890280 // + 39 331.899540
Email: info@metaergonomica.it

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