



MED

Instructions for Use

Intended use

The device intends to treat patients undergoing dental implantation, by accelerating the osseogenesis process surrounding the dental implant, via generation of pulsed Electromagnetic field, over a period of up to 50 days.

Introduction

MagDent's MED (Miniaturized Electromagnetic Device) technology utilizes an electromagnetic field to stimulate, accelerate, and improve bone formation and quality for shorter, more successful dental implant procedures.

The MED is screwed into the implant, just like an ordinary healing abutment, and it fits most standard implant systems/models.


Indications

The MED is indicated for all patients undergoing dental implantation.

Contraindications

The MED should not be used if the implants need to be maintained submerged.

Note

 The MED is intended for single use only.

Caution



The device is supplied non sterile.

Do not sterilize MagDent's MED by autoclave or any other method.

Expiration date



The product sticker (enclosed inside the product package) indicates the expiry date, which is the final date for installing the device.

Warning



Never install a device whose expiration date has elapsed.

Point of Use

The Health Care institution is the Point of Use.

Installation

To install the MED:

1. Remove the device from its package, open the outer plastic package, and extract the inner tube.



Do not use if plastic seal of outer plastic package is broken

2. Insert the inner tube with the MED into the activation socket.



3. Place the MED, while still in the inner tube, in the Activation socket – The activation button will light in red.



The MED is to be taken out of the inner tube **after** the activation, and just before screwing it to the implant.



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4. Press the Activation button – The activation button will blink in blue for 2 seconds during the activation process, and you will hear a beeping sound.
5. After the activation process is over the activation button will light in blue to indicate the MED is generating an electromagnetic field and is ready for use in patients.
6. Irrigate the implant to remove any blood and debris.
7. Remove the inner tube cap and put the MED on a sterile tray.
8. Using a 2.4mm Hex Driver, hand-tighten the MED, applying no more than 10 N/cm torque force.

Contact Information

Please contact MagDent Ltd or its Authorized Representative if you wish to submit a complaint regarding the safety or performance of the device.



Company Headquarter

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Warning



Do not use excessive force while tightening the device.

Care and Maintenance

During each maintenance visit, check the device and make sure that it is hand-tightened.

End of Use

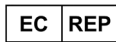
The operation time of the device is up to 50 days from the expiration date. The device can remain on the implant after the 50 operating days, until the placement of the prosthetic abutment and crown.

Removal instructions

Using a 2.4 mm Hex Driver, loosen the MED device and remove it from the dental implant.

Storage

Store the device at room temperature.



European Authorized Representative Office

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Safe decommissioning according to local regulations.



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