

Magdent MED

Instructions for Use

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Intended use

This device is designed to treat patients undergoing dental implantation by accelerating the osseogenesis process surrounding the dental implant via generation of a pulsed electromagnetic field throughout a period of up to 30 days.

Introduction

Magdent's Miniaturized Electromagnetic Device (MED) technology utilizes an electromagnetic field to stimulate, accelerate, and improve bone formation and quality for shorter and more successful dental implant procedures. The MED is threaded into the implant like a simple healing abutment. Each MED model is compatible with specific implant models.

! Make sure you have the correct MED model for your implant of choice.

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 (e.g., 2-stage surgical procedure).

Note

⊗ The MED is intended for single use only.

Caution

⚠ NON STERILE
The device is supplied in a non-sterile condition. Do not sterilize Magdent's MED by autoclave or any other method.

Packaging

The package contains one MED and ONE 1.25 mm hex driver.

Expiration date



The product's expiration date is indicated by the hourglass symbol on the MED label. The month and year of expiration is the latest date the MED can be installed into an implant.

Warning

! Never install a device whose expiration date has elapsed.

Point of Use

The health care institution is the point of use.

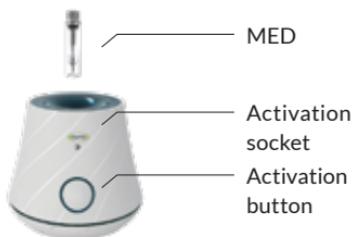
Installation

To install the MED:

STEP 1 -

1. Remove the device from its package
2. Open the outer tube and extract the inner vial containing the MED.

! Do not use if the outer tube seal is broken.



The Activator is not included.

STEP 2 -

Place the inner vial containing the MED in the activation socket.

The activation button will light up in red

NOTE: The MED can be taken out of the inner vial only **after** the activation step and just before threading it into the implant.



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STEP 3 -

Press the activation button – *the activation button will blink in blue* for 2 seconds during the activation process and the Activator will emit a **beeping** sound.

After the activation process is over, *the activation button will light up in blue* for 15 seconds to indicate that the MED is generating an electromagnetic field and that it is ready for use.

STEP 4 -

Irrigate the surgical site with sterile water and then apply suction to ensure that the implant's internal chamber is clear of bone and tissue debris and/or blood.

STEP 5 -

Remove the inner vial and carry the MED to the surgical site using the supplied 1.25mm hex driver.

Warning

! To prevent choking/swallowing of the MED, ensure that the MED is held firmly by the supplied 1.25mm hex driver before placement into the patient's mouth.

STEP 6 -

1. Use the supplied 1.25mm hex driver to seat the MED into the implant. Make sure the MED and the hex driver are in alignment with the implant axis for proper thread engagement
2. Use finger pressure to tighten in a clockwise direction. Do not use a surgical motor. Once the MED is fully seated into the implant, a restorative torque wrench may be used to tighten the MED at a setting of 10Ncm.

NOTE: if resistance is felt or the MED seems difficult to seat, the MED may be misaligned with the axis of the implant. Retract the MED and rethread it into the implant in proper alignment.

3. Carefully replace the soft tissue around the MED. Use the suture material of choice and suture with one or more of the available suture methodologies.

Warning

! Do not use excessive force while tightening the device.

Care and Maintenance

Check the MED to make sure that it is properly seated during each maintenance visit.

End of Use

The device operates for up to 30 days from the installation date. The device can remain longer in the implant until the placement of the prosthetic abutment and crown.

Removal instructions

Use a 1.25mm hex driver in a counter-clockwise direction to retract the MED and remove it from the implant.

Storage

Store the device at room temperature.

Manufacturer's Information:

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0482
CE Marking

Rx Only

Prescription
only



Follow instructions for
use on the website



Do not throw away -
Electrical equipment



Type BF
applied part

For electromagnetic safety and compliance information, please visit our website

www.magdentmed.com