Magdent

Electromagnetic Healing
Optimizing Implantology

Clinical Guidelines & Protocols for Optimal Use

www.magdentmed.com

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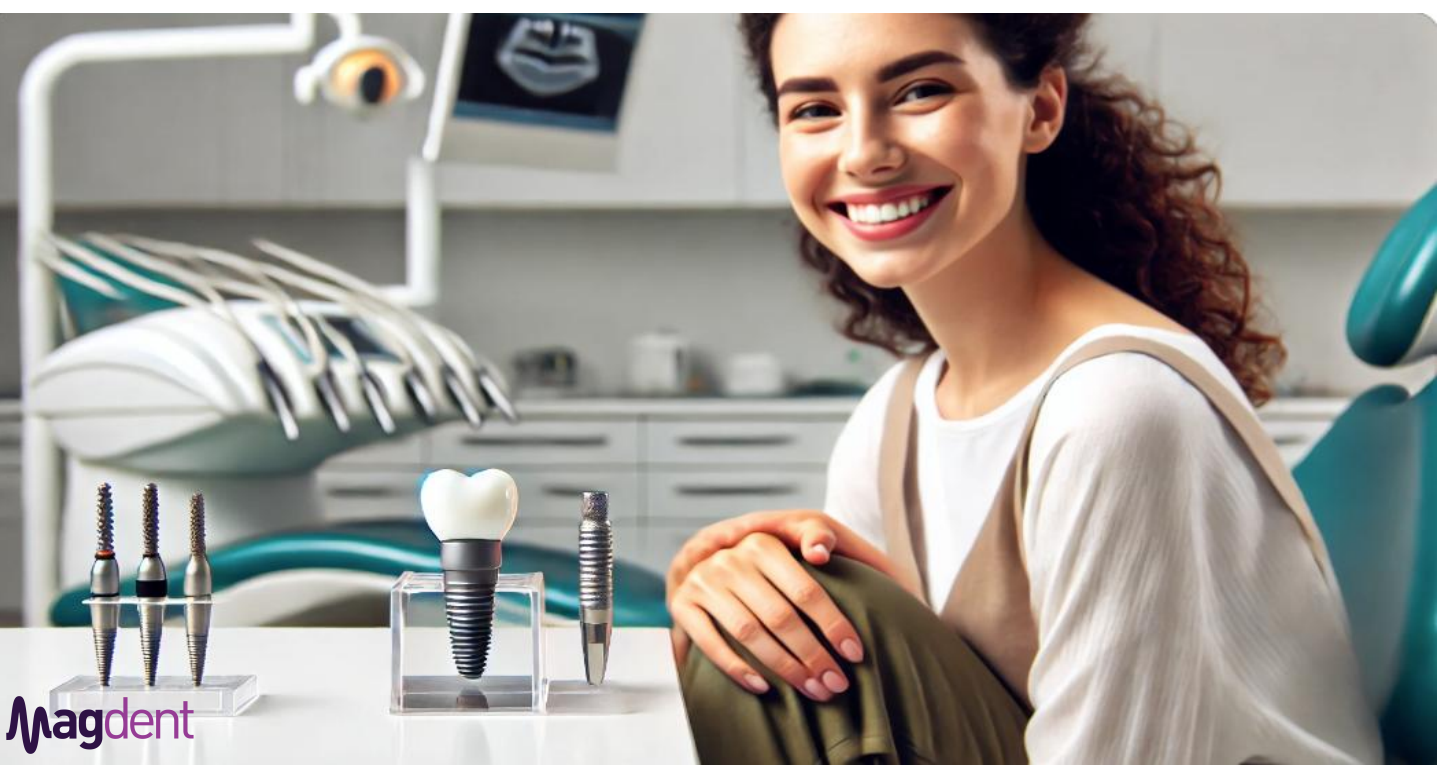


Introduction

Introduction

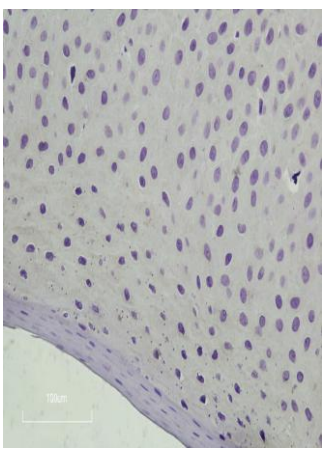
Magdent's Miniaturized Electromagnetic Device (MED) technology utilizes an electromagnetic field to stimulate, accelerate, and improve bone formation and quality for shorter and more successful dental implant procedures.[1,2,8]

The MED is threaded into the implant like a simple healing abutment. Each MED model is compatible with specific implant models.

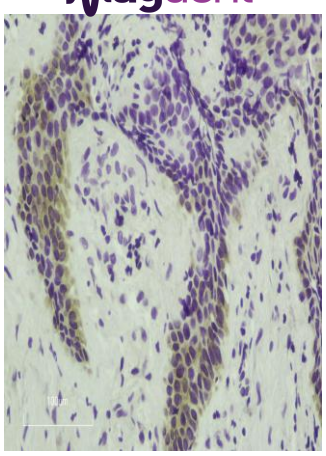
Did you Know? [4,7]

Magdent's PEMF forms new blood vessels and reduces pro-inflammatory cytokines, in addition to increasing the Mesenchymal Stem Cell differentiation to osteoblasts, also in inflammatory condition.

PEMFs increase anti-inflammatory cytokine, such as IL-10 expression, and reduce the expression of the pro-inflammatory cytokine IL-1 and TNF-α.

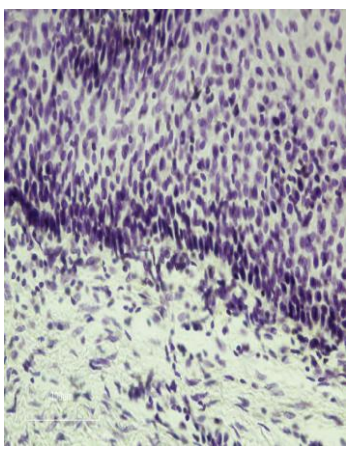


Control:
VEGF (-)

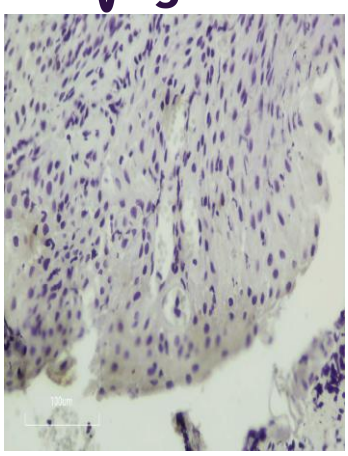


Magdent:
VEGF (+++)

PEMF amplifies the levels of Vascular Endothelial Growth Factor (VEGF), a crucial signal protein essential for **new blood vessel formation**, which plays pivotal roles in **inflammation and wound healing**.



Control:
TNF-α (+++)



Magdent:
TNF-α (+)

PEMF has demonstrated a remarkable **reduction** in the **pro-inflammatory activities** of tumor necrosis factor (TNF)-α.

PEMF Mechanism of Action

The MED enhances the healing process by accelerating osteogenesis **3 times faster** around the implant.[1, 2]

It achieves this through a pulsed electromagnetic field that remains active for up to 30 days following a single 3-second activation.

With Magdent's technology, patients can return for full restoration in 30 days for the mandible and 60 days for the maxilla.

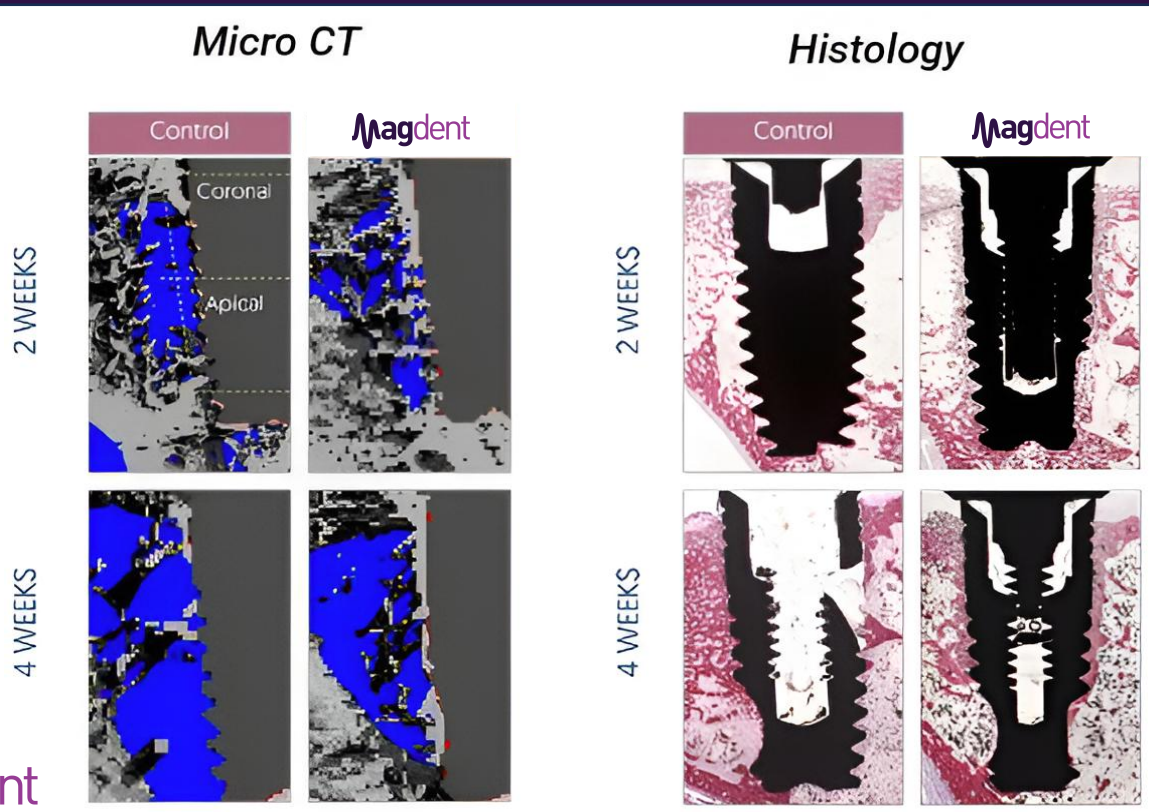
A new device for improving dental implant anchorage: a histological and micro-CT study in rabbits [3]

Clinical Oral Implants Research. 2016 Aug;27(8):935-42.

11 Test Vs 11 Control MEDs, PEMF used for 30 days.

Following morphometric parameters were calculated in the peri-implant trabecular bone (PIB) and compared between results using Magdent's MED and control group:

- 48% increase in Bone to Implant Contact (%OI) - quantifying the bone anchorage - ratio between bone and total voxels in contact with the implant.
- 62% increase in trabecular bone volume density (BV/TV)
- 44% increase in the number of trabeculae (Tb.N)
- 32% decrease in trabecular spacing (Tb.Sp)



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Foundations

Same Day Treatment:

Use the MED only in case that One Stage Surgery can be performed. Not suitable for immediate loading.

Enhanced Osteogenesis:

Producing Pulsed Electro Magnetic Field (PEMF), which has a major effect on osteoblasts, resulting in bone formation even in inflammatory conditions, enhancing the osteogenesis process. [2, 4]

High-risk Patients:

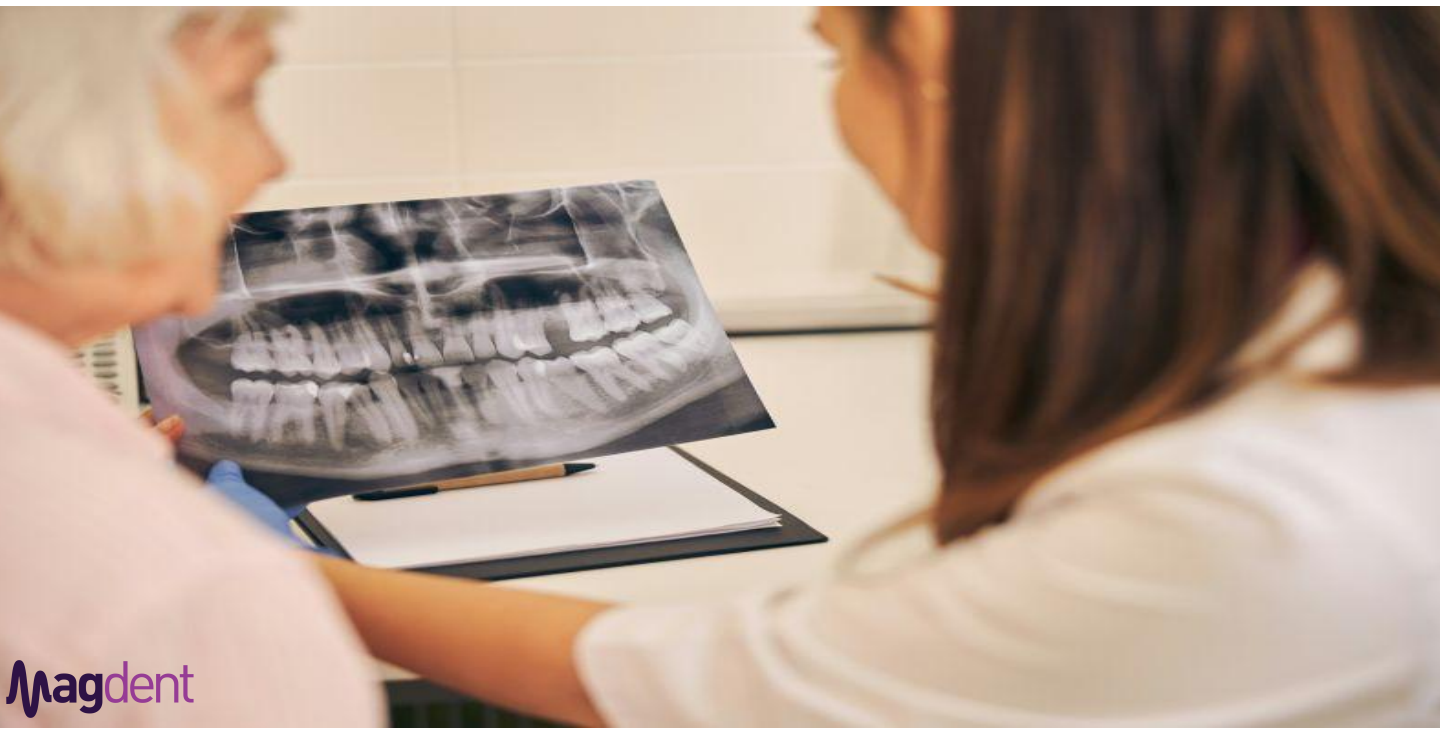
By increasing bone volume density, the MED may provide an effective solution for patients with osteoporosis, diabetes, smoking-related bone loss, and cancer-related conditions, ensuring better implant stability and healing. [3]

Temporary Partial Denture:

A partial acrylic denture can be used as a temporary solution by designing a recess in its inner surface to fit over the MED, ensuring aesthetic preservation during the healing phase.

Low Pulsed Electromagnetic Field:

A precisely controlled low-level current, measured in milli-tesla (mT), is generated within a 2mm radius around the implant, primarily affecting the upper 7mm of the implant and surrounding soft tissue. Patients do not experience any sensation while the MED is active in their oral cavity.



Indications & Contraindications

Indications

The MED is indicated for all patients undergoing dental implantation. Specially in high-risk patients with decreased bone density and poor bone quality such as patients with osteoporosis, cancer, diabetes, heavy smokers.

Peri-implantitis Treatment [6, 8]

The MED offers significant benefits in managing peri-implantitis and controlling biofilm colonization.

PEMF reduces inflammation, enhances soft tissue healing, and promotes bone regeneration, helping prevent and treat peri-implantitis.

It also reduces harmful biofilm colonization, supporting better implant stability and tissue health.

Clinical studies highlight the effectiveness of this approach in improving long-term implant outcomes and minimizing complications.

Refer to the full protocol for peri-implantitis on page 9.

The enhancement of soft tissue quality strengthens the soft tissue seal, leading to improved bone augmentation outcomes.

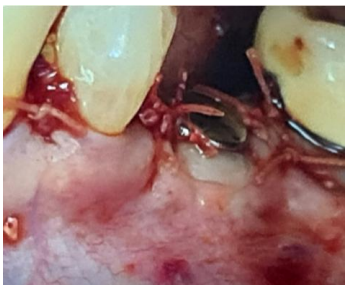
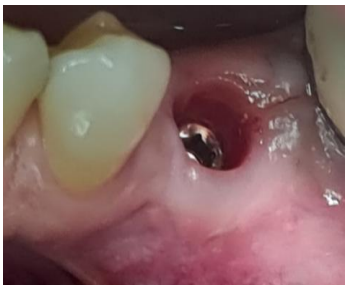
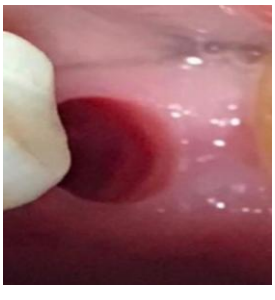
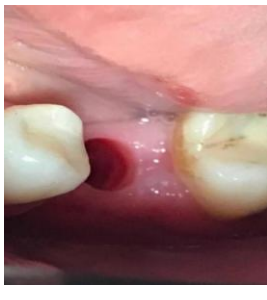
Soft Tissue [5]

The MED has demonstrated a beneficial effect on soft tissue, particularly in the formation of keratinized gingiva. In the early healing stages, the soft tissue exhibits weak attachment and continues to reorganize even beyond 60 days.

However, with continuous MED use, the soft tissue becomes well-structured and maintains close contact with the device, creating a more stable and healthier peri-implant environment.

By improving soft tissue integration around implants, the MED supports long-term oral health and enhances implant success.

The attached gingiva at the surgery day and 30 days following the MED use

Indications & Contraindications

Contraindications

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

Safety considerations

- The MED is intended for single use only.
- Don’t sterilized the MED in an autoclave. It will destroy the electric components and will defect the MED. Each MED is delivered ready for use, according to the highest standards of ISO 13845 regulation.
- The safety of the MED in a Magnetic Resonance (MR) environment has not been evaluated. If a patient requires an MRI scan, it is recommended to remove the MED prior to the procedure.

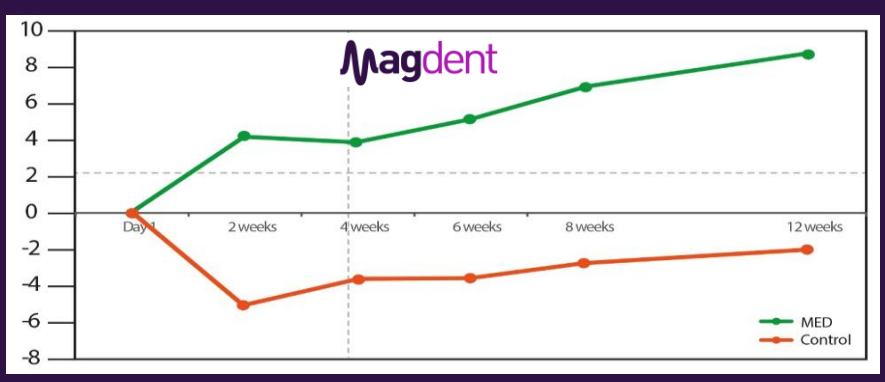
Standard Protocol

Standard, Seamless Protocol

- MED should only be tightened gently BY HAND until it can no longer be screwed on.
- For MEDs with a diameter of 1.6mm, tighten the MED at a setting of up to 4 Ncm.
- For MEDs with a diameter of 1.8mm or thicker, tighten at a setting of up to 10 Ncm. Don't damage the MED.
- Use the MED during the rehabilitation process to maintain the gums' health, and increase attached gingiva width.
- The implant must be positioned at or above the bone level (crestal) prior of placing the MED.
- Don't cover the MED under the gingiva.
- Make sure there's no occlusal interference with opposing teeth.
- For further instructions, please refer to the Instructions for Use (IFU) provided with the MED.

Effect of the Pulsed Electromagnetic Field (PEMF) on Dental Implants Stability: A Randomized Controlled Clinical Trial, 20 patients, 40 implants and MEDs. [1]

Optimizing implant stability within 4 weeks

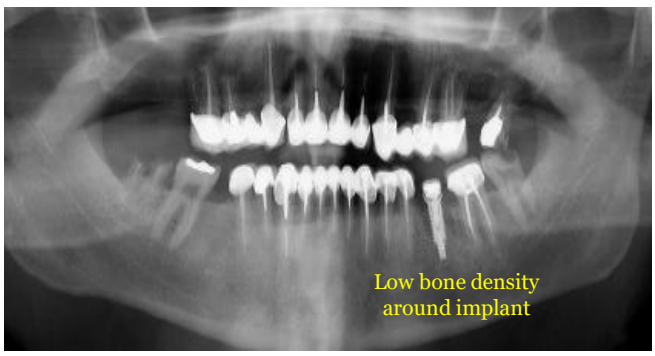


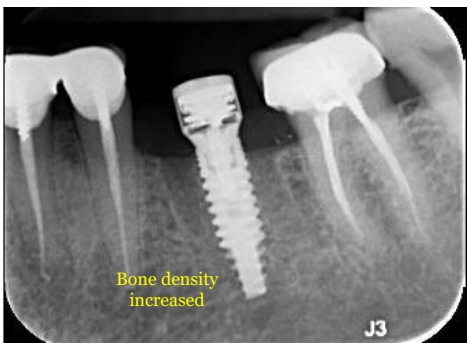
Age: 71 Years old; **Patient Condition**: Healthy; **Procedure**: Implants & Stable Bridge

Extraction & Insertion Day

60 days

Impression Day





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Peri-implantitis Protocol

1. Following the delivery of local anesthesia and removal of the supra-structure (crown), carefully unscrew the abutments.

2. Perform thorough implant surface debridement using a combination of manual and rotary instruments. In case of infection concerns, consider local delivery of antibiotics or antiseptics as needed.

3. Activate the Magdent Active MED abutments and screw them into the implant fixtures. The MED will remain active for 30 days.

4. Instruct the patient to incorporate brushing of the MED abutment into their daily oral hygiene routine. This should be done gently, using a soft-bristle toothbrush, not electric toothbrushes during this healing phase.

5. Recommend the use of mouthwash twice a day as part of their oral hygiene regimen.

6. Take a radiograph on the day of MED insertion to ensure proper placement.

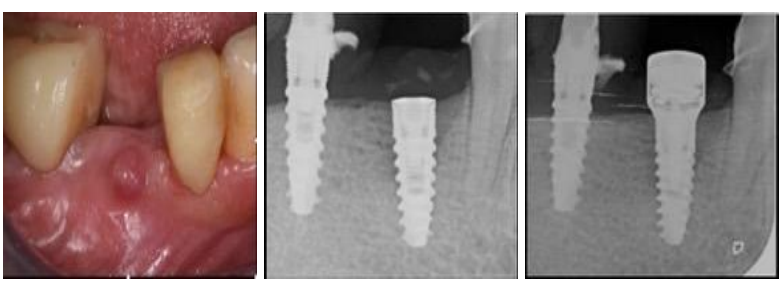
7. After 30 days, the first MED should be replaced with a new, activated MED for an additional 30 days.

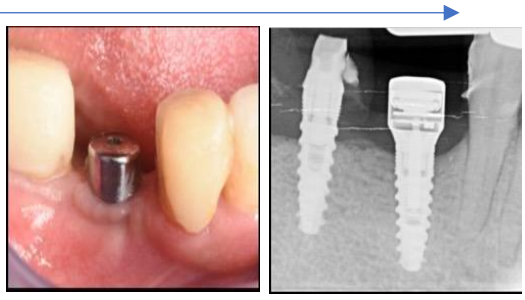
8. Schedule follow-up radiographs at 2 months and 6 months post-insertion to assess the healing progress.

Age: 35 Years old; **Patient Condition**: Peri-Implantitis **Procedure:** Treatment of Peri implantitis

A 35 years old woman was referred to the extraction of tooth #45 due to vertical root fracture.

60 days





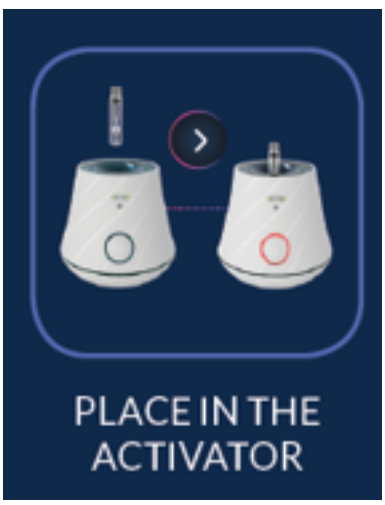
1. After 2 months of healing the edema was reduced and concentrated to a round red elevated bulge of 2.5mm diameter.
2. At this stage a periapical x-ray reveled a radiolucency/ remineralization at the coronal part of the implant.
3. a healing cap containing PEMF-emitting (“active”) healing cap was connected.

1. Two months after the induction of PEMF, the implant was clinically stable, with no clinical signs of edema or inflammation.
2. In a periapical x-ray the bone level was increased and denser compared to the period before using the MED.

6 Step-by-Step Instructions for Use

STEP 1

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



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.

STEP 3

Press the activation button – the activation button will blink in blue for 3 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 10 seconds to indicate that the MED is generating an electromagnetic field and that it is ready for use.

6 Step-by-Step Instructions for Use

STEP 4

Irrigate the surgical site with sterile water and then suction, ensuring 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.

STEP 6

1. Use the 1.25mm supplied hex driver to seat the MED into the implant, ensuring 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.
3. 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.
4. 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.

Recommendations Post MED Use

Care and Maintenance

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

End of Use

The operation time of the device is up to 30 days from the activation and 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 tool in a counter-clockwise direction to retract the MED and remove it from the implant.

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Troubleshooting & Maintenance

Warning

Never install a device whose expiration date has elapsed.

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.

Do not use excessive force while tightening the device.

Caution

The device is supplied in a non-sterile condition, based on CE and ISO 13845 requirements.
Do not sterilize Magdent's MED by autoclave or any other method.

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.

Storage

Storage the device at room temperature.

FAQ's

1. Can it be used with all implant systems?
The MED is designed to be compatible with most implant systems, ensuring versatility and ease of use across different brands. Please contact your local representative to find the compatible MED.

2. How long does the MED last?
The maximal shelf life of the Med is up to 18 months, please see the expiry date on the label. Once is activated the MED will release PEMF during 30 consecutive days.

3. What are the storage requirements?
Store the MED in a dry, cool environment, away from direct sunlight. Avoid exposing it to extreme temperatures or moisture to ensure optimal performance.

4. What happens if the MED doesn't turn on the blue light?
If the blue light does not turn on, it may indicate an issue with the battery or connection. Check the battery charge and ensure the device is properly connected. If the problem persists, contact support for troubleshooting.

5. Do patients feel anything while having an operational MED after placed in their mouth?
Patients typically do not feel any discomfort when the MED is operational. The device is designed to work gently and effectively without causing pain or irritation.

6. Is the MED safe for all patients?
Yes, the MED is safe for most patients, including those with metal implants. However, always consult with a healthcare professional before using it with patients who have specific health concerns or conditions.

7. Can the MED be used during all stages of the implant process?
The MED can be used in various stages, from initial placement to the final restoration. It helps improve the integration process by supporting healing and the treatment of peri-implantitis.

8. Is the MED easy to use for dental professionals?
Yes, the MED is designed with ease of use in mind. It requires minimal training, and its ergonomic design ensures a comfortable experience for the dental professional.

9. What is the optimal torque setting for using the MED?
The optimal torque setting varies depending on the implant system and thickness of the MED's thread, but typically a setting of 10 Ncm is recommended for most cases.

10. How does the MED enhance the success of implant procedures?
The MED supports proper integration by providing controlled mechanical stimulation, promoting bone growth and stability around the implant, which increases the likelihood of long-term success.

11. Can the MED be used for both single and multiple implant placements?
Yes, the MED is versatile and can be used for both single and multiple implant placements, ensuring effective and efficient treatment.

12. Is the MED reusable?
No, the MED is designed for single use only. Once activated, it will release a low frequency of Pulsed Electromagnetic Field for 30 days, after which the battery will be discharged.

If you have any other questions, please email us at info@magdentmed.com. Our scientific department will get in touch with you to provide answers as soon as possible.

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