

# ETGAR MEDICAL INSTRUMENTS LTD.

## USER INSTRUCTIONS

**Description:** ETGAR MD Dental Implants are manufactured from bio compatible titanium and titanium alloy and abutments from titanium or titanium alloy. ETGAR MD Dental Implants and Abutments include various surface treatments and coatings. Other restorative components are manufactured with titanium or titanium alloy, stainless steel and a variety of polymers.

For specific product description refer to individual product labels.

**Indications for Use:** ETGAR MD Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain over dentures.

ETGAR MD Dental Implants are intended for immediate function on single tooth and/or *multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.*

**Additional Indications:** ETGAR MD Dental Abutments and Over denture Bars are intended for use as an accessory to end osseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

PEEK Abutment Posts and Temporary Cylinders are intended for use as an accessory to end osseous dental implants to support a prosthetic device in a partially or fully edentulous patient. These are intended for use to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during end osseous and gingival healing, and are for non occlusal loading of single and multiple unit provisional restorations. The prostheses can be screw and/or cement retained to the abutment. These Temporary Posts and Cylinders require a minimum inter arch space of 6mm and a maximum angulation of 15°. These also allow for occlusal loading of single and multiple unit restorations of integrated implants for guided soft tissue healing. The Quick Bridge Provisional Components are intended to be mated with ETGAR MD Conical Abutments for use as an accessory to end osseous dental implants to support a prosthetic device in a partially or fully edentulous patient.

**Contraindications:** Placement of dental implants may be precluded by patient conditions that are contraindications for surgery. ETGAR MD Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate implant stability. Cardiac conditions involving the risk of endocarditis, coronary insufficiency blood dyscrasias, cardiovascular disorders, patients on anticoagulant Rx A.I.D.S., cancers and chemotherapeutic treatments, corticosteroids treatment radiotherapy of the cervico-facial region osteoporosis, uncontrolled or insulin-dependant diabetes pregnancy, endocrine disorders.

### **Possible contraindications**

Poor oral hygiene, bruxism alcoholism, smoking, drug abuse psychological problems aggressive behavior.

### **Temporary contraindications**

Systemic infection, local oral or respiratory infection.

### **Local contraindications**

Insufficient alveolar bone width and height to ensure the encompassing of the implant with at least one millimeter of bone Infections, cysts, tumors, periodontal disease, prostodontic problems

**Storage and Handling:** Devices should be stored at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

**Warnings:** Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants. The following should be taken into consideration when placing dental implants:

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- Poor bone quality
- Poor oral hygiene
- Medical conditions such as blood disorders or uncontrolled hormonal conditions

It is recommended that small diameter implants not be restored with angled abutments in the molar region.

Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing.

Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver hex interface inside the implant, stripping the driver, cold welding of the mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.

Clinical data have demonstrated enhanced performance of OSSEOTITE Implants as compared to other ETGAR MD Dental Implants in patients with poor quality bone.

**Precautions:** For safe and effective use of ETGAR MD Dental Implants, abutments and other surgical and restorative dental accessories, these products or devices should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.

**Sterility:** All dental implants and some abutments are supplied sterile and are sterilized by an appropriate validated method. Refer to individual product labels for sterilization information; all sterile products are labeled "**STERILE**". All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave except where instructions to do so are provided on the product label, in the Surgical Manual, in the Restorative Manual or in any additional marketing literature for that product. Products provided non-sterile must be cleaned and sterilized according to the directions found in Surgical Manuals prior to use.

## **Procedural Precautions, Surgery:**

*For a detailed explanation of the procedural precautions refer to the Surgical Manual.* During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore it should be carefully evaluated before placing any dental implant. The final prosthesis should be designed prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising osseointegration. This is mandatory during gall procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual. Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue enhances the potential for successful osseointegration. In order to eliminate contaminants and other sources of infection, all non-sterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

**Procedural Precautions, Restoration:** The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Excessive force applied to the dental implant should be avoided during the healing period. Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

**Potential Adverse Events:** Potential adverse events associated with the use of dental implants may include:

- Failure to integrate
- Loss of integration

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- Dehiscence requiring bone grafting
- Perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, gingiva
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency
- Persistent pain, numbness, paresthesia
- Hyperplasia
- Excessive bone loss requiring intervention
- Implant breakage or fracture
- Systemic infection
- Nerve injury

## TECHNIQUES

- Determine local anatomy with the use of local X-rays and CT...etc.
- Planning the site, the technique and the dimensions of the implant to be used.
- Careful management and high precision is recommended.

**Caution:** U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

## USED MEDICAL SYMBOLS



For single use only



Use by YYYY-MM



Date of manufacture



Catalog number



Reference to the hazards in the operating instructions



Lot number



Sterilized using irradiation  
Sterility guaranteed if pack unopened or undamaged



0120

European  
Authorized  
Representative

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