ETGAR MEDICAL'S DENTAL IMPLANTS AND PROSTHETIC / ABUTMENTS

- INSTRUCTIONS FOR USE -

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST.

INDICATIONS FOR USE:

Intended to replace one or more missing teeth in the upper or lower jaw in partially or fully edentulous patients (EH implant for partially edentulous patients only) in order to restore chewing function. Intended to support single or multiple tooth prostheses. The prostheses can be screwed or cement retained to the abutment. Intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

GENERAL INFORMATION:

ETGAR various dental Abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support single and multiple unit prostheses in the mandible or maxilla, the temporary ones for up to 180 days during endosseous and gingival healing. The prostheses can be screw and/or cement retained to the abutments.

The implantation procedure should be done by a licensed dentist with appropriate surgery skills and under aseptic conditions with specifically designed sterile surgical instruments.

An electrical surgical drilling system with internal and external irrigation is recommended for drilling the surgical site. Specific drilling sequences for placement should be followed.

For detailed information on the specific product system you are using, please consult the ETGAR catalogue.

INTENDED USE: ETGAR IMPLANTS [CONICAL, CYLINDRICAL AND HARMONY (MONO)] ARE INTENDED TO BE USED AT BONE LEVEL.

Etgar Implants products are intended for use only by certified dentists and authorized persons with specific implant training. Etgar implants are used for two-stage and one-piece implantation processes. The implants are made of titanium alloy and are delivered in sterile, sealed containers. They are supplied with the understanding that only Etgar Implants surgical instruments, which complement each implant, will be used during surgery. If these conditions are not met, the manufacturer will refuse to accept responsibility.

CONTRAINDICATIONS:

Placement of dental implants may be precluded by patient conditions that are contraindications for surgery. Customary observations should be made of the contraindications associated with implant materials used in oral surgery. First, the patient's general health and suitability for oral surgery must be assessed by the general practitioner. ETGAR Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate implant stability; Inadequate bone mass; Residual infections and inflammations occurring around the implant; Patients receiving chemotherapy or any other immunosuppressive treatment or who have been administered radiotherapy in the last 5 years. Patients with chronic or uncontrolled bleeding disorders such as: hemophilia, thrombocytopenia, etc. Patients who take steroid based anticonvulsant and anticoagulant drugs. Patients with Metabolic bone disorders, Degenerative diseases, osteoradionecrosis, renal failure, organ transplant recipients, malignant diseases, diseases that compromise the immune system such as: HIV positive patients. Patients with unbalanced diabetes mellitus, uncontrolled endocrine diseases. psychotic diseases, hypersensitivity to one of the components of the implant in general and titanium in particular, pregnant patients, inability of the patient to maintain reasonable oral hygiene, lack of patient cooperation, Children with undeveloped bones; alcoholic patients, drug abuse, and any systemic condition that is unbalanced and therefore precludes surgical procedures. Per dentist judgment, physiological medical and anatomic conditions that may negatively affect the implant performances, lack of adequate training of practitioner.

Relative contraindications: Patients who are treated with anticoagulant drugs or bisphosphonates, patients with previously irradiated bone, bruxism, patients with uncontrolled and/or untreated periodontal disease, parafunctional habits, Patients with temporomandibular joint disease and various pathologies of the oral mucosa.

Electrosurgery: Dental implants are made of a metallic alloy; therefore, they are characterized by high conductivity. Therefore, electro-surgery is strictly contraindicated near dental implants.

PRECAUTIONS:

Surgical techniques required to place endosseous dental implants are complex and require specialization and unique skills. For safe and effective use of ETGAR Dental Implants, abutments and other surgical and restorative dental accessories, they should only be used by trained professionals.

Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration or nerve injury.

CAUTION: This device is to be used by a licensed dentist only.

WARNINGS:

Warning: The abutments are not intended to be further modified.

Attention: The Etgar Dental Implant System has not been tested for heating, migration, or image artifact in the MR environment. Etgar implants are made of Titanium alloy which according to research is not magnetized and the MRI environment has no or minimal influence on it.

Single use Products - To avoid contamination or product malfunction, **DO NOT** reuse implants and abutments that are labeled for single use only by symbol.To avoid compromised sterility of sterile products, do not use sterile labeled products if the packaging has been damaged or opened.

When taking out the implant from the inner tube, remove the dental implant in a straight-line movement to avoid friction between the implant's delivery and inner tube and formation of particles.

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 examples may adversely affect the implant endosseous and should be taken into consideration when placing dental implants: Poor bone quality, Poor oral hygiene Medical and 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 patient's 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.

Mild psychological disorders, aggression, smoking, use of chewing tobacco. Lack of adequate training of practitioner and lack of patient motivation.

Lactating or pregnant women and children with developed bones. LOCAL: Inadequate bone mass, residual infections and inflammations occurring around implant, hypersensitivity to components of the implant and unrealistic patient expectations, periodontal diseases.

Implant surgery is a highly complex procedure and practitioners are advised to take the necessary courses that teach implant surgery. Improper implant techniques may result in implant failure and loss of bone. Etgar Implants are intended to be used only per the protocol outlined above with Etgar Implants drill bits. Implants placed at sharp angles may lead to implant failure. Bone loss, infection and movement of the implant may indicate that the implant is failing. If any of these is observed, the problem should be treated or the implant removed, as soon as possible.

Risks include, immediate anesthetic and surgical risks, psychiatric risks, medical threats to long-term retention, long-term effects on health, and complications that may include: delayed healing, edema, hemorrhage, dehiscence, parenthesis, hematoma, allergic reaction, inflammation, perforation of the sinus, nerve damage, speech problems, and gingivitis. Long-term problems may include: nerve damage, bone loss, hyperplasia, local or systemic bacterial infection, endocarditic, long-term pain, and fractures of the bone, the implant of the teeth. The following organ systems may be affected: cardiovascular-coronary heart disease arrhythmias; Respiratory-chronic pulmonary disease; Renal - chronic renal failure; Endocrine- diabetes, thyroid disease, pituitary and adrenal disorders; Hematologic - anemia, leukemia, blood clotting disorders, Musculoskeletal - arthritis, osteoporosis; Neurologic - stroke, palsy, mental retardation.

Multi-Unit Adaptors and Abutments

The following components are ONLY intended for multi-unit loaded restorations:

Description	Diameter	Length	Abutment Shoulder Length	Abutment Angle	Etgar Cat no.
Straight Multi Unit Adaptor (H-1 mm)	5.00	9.00	1 mm	0	EI-4001
Straight Multi Unit Adaptor (H-2 mm)	5.00	10.00	2 mm	0	EI-4002
Straight Multi Unit Adaptor (H-3 mm)	5.00	11.00	3 mm	0	EI-4003
Angular Multi Unit Adaptor 18 (H-1 mm)	5.00	5.60	1 mm	18°	EI-4181
Angular Multi Unit Adaptor 18 (H-2 mm)	5.00	6.50	2 mm	18°	EI-4182
Angular Multi Unit Adaptor 18 (H-3 mm)	5.00	7.50	3 mm	18°	EI-4183
Angular Multi Unit Adaptor 30 (H-1 mm)	5.00	6.20	1 mm	30°	EI-4301
Angular Multi Unit Adaptor 30 (H-2 mm)	5.00	6.90	2 mm	30°	EI-4302
Angular Multi Unit Adaptor 30 (H-3 mm)	5.00	8.20	3 mm	30°	EI-4303
Titanium Sleeve Screw included	4.60	10.90	NA	NA	EI-4999
Titanium Short Sleeve Screw included	5.00	5.50	NA	NA	EI-4498

Straight Multi-Unit Adaptors, Angular Multi-Unit Adaptors, Connection Abutments, Esthetic Abutment Connections, and/or Screw Abutments which have an abutment post height less than 4mm and are to always be combined with coping or burn-out plastic sleeve for increasing the post height to be 4mm at minimum when used for single-unit loading.

Each of the Straight Multi-Unit Adaptors, Angular Multi- Unit Adaptors, Connection Abutments, Esthetic Abutment Connections, and/or Screw Abutments when combined with coping or burn-out plastic sleeve may be fabricated. Please be advised that a minimum post height of 4mm is clinically recommended for single-unit loading.

Warning: “no additional angular correction” is intended for the Straight Multi-Unit Adaptors, Angular Multi-Unit Adaptors, Connection Abutments, Esthetic Abutment Connections, and/or Screw Abutments when combined with coping or burn-out plastic sleeve during the patient-specific customization.

Minimum post height above collar required

Description	*Drawing Description*	*Abutment Shoulder Length (mm)*	*Minimum post height above collar (mm)*	*Abutment Angle*	*Etgar Cat no.*
Esthetic Abutments Connection	*Connection Abutment*	*0.5*	*12.5*		*EIS-6701*
Esthetic Abutments Connection	*Connection Abutment*	*1.5*	*13.5*		*EIS-6702*
Esthetic Abutments Connection	*Connection Abutment*	*2.5*	*14.5*		*EIS-6703*
Multi Units (w. sleeve)	*Straight Multi Unit Adaptor (H-1 mm)*	*1*	*13 / 5.60**	*0*	*EI-4001*
Multi Units (w. sleeve)	*Straight Multi Unit Adaptor (H-2 mm)*	*2*	*14 / 6.60*	*0*	*EI-4002*
Multi Units (w. sleeve)	*Straight Multi Unit Adaptor (H-3 mm)*	*3*	*15 / 7.60*	*0*	*EI-4003*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 18 (H-1 mm)*	*1*	*13.49 / 6.09*	*18°*	*EI-4181*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 18 (H-2 mm)*	*2*	*14.44 / 7.04*	*18°*	*EI-4182*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 18 (H-3 mm)*	*3*	*15.39 / 7.99*	*18°*	*EI-4183*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 30 (H-1 mm)*	*1*	*13.54 / 6.14*	*30°*	*EI-4301*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 30 (H-2 mm)*	*2*	*14.43 / 7.03*	*30°*	*EI-4302*
Multi Units (w. sleeve)	*Angulated Multi Unit Adaptor 30 (H-3 mm)*	*3*	*15.31 / 7.91*	*30°*	*EI-4303*

** The length including the Sleeves that are attached to the Multi Unit adaptors: EI-4999 Titanium sleeve length: ~12.00mm / EI-4498 Titanium Short sleeve length: 4.60mm. For example: EI-4001 in the above table 1mm+12mm (long sleeve)=13mm / 1mm+4.6mm(short sleeve)=5.60*

GENERAL DISEASES AND MEDICATIONS:

Cardiovascular disorders associated with high endocarditic risk (SBE); Coronary insufficiency; Blood dyscrasias; Immuno- deficiency, AIDS; Cancers and radiation of the facial region in the past five years; respiratory disease; Thyroid or parathyroid disease: Patients with nodular enlargements, or inexplicable lumps on the head or neck region; Bone metabolism disorders; Diabetes; Hypertension above 170/110 mmHg; Drug abuse, alcoholism; Titanium hypersensitivity: Patients on corticosteroids, anticoagulants, anticonvulsive, an immune suppressant therapy; patients with abnormal values for creatine, BUN or serum calcium; Hemophilia; Granulocytopenia; Steroid use; Prophylactic antibiotics ; EhlerDanlos syndrome; Renal failure; Organ transplantation; Fibrous dysplasia.

SURGICAL RECORD - MANDATORY INITIAL INVESTIGATIONS:

Patient examination; Patients medical history; Clinical examination of patient's hygiene, teeth, occlusion, periodontium; Biological observations; Radiographic evaluation: CT scan. intra-oral, x-rays, pan-oral. etc. Lack of adequate practitioner training is one of the major factors influencing the success of implant surgery and subsequent long-term patient health.

SURGICAL AND RESTORATION PROCEDURES SURGERY:

The hard and soft tissues must be carefully managed, to ensure osseointegration. The site must be prepared with extreme precision. Any ancillary instruments employed must be properly sterilized. The surgical procedure requires drilling speeds from Max 1500 rpm for the first drill to min 200 rpm or the last one. Physiological saline must irrigate the area, while the culling sequence must be strictly adhered to. Thermal trauma will be reduced if these procedures are followed. The implant size (height and width) is chosen per preliminary X-rays. There must be a 2mm margin from anatomical obstacles and maximum bone height

STERILITY:

All dental implants supplied sterile and are sterilized by an appropriate validated method and are labeled accordingly. Abutments and accessories are supplied non-sterile.

Refer to individual product labels for sterilization information. All **sterile** products are labeled as: "**Sterile-R**" and all **Non-sterile** products are labeled as **"Non-Sterile"**. See guiding symbols on page 10.

Do not use sterile products if the packaging has been opened or damaged.

Do not re-sterilize or autoclave products that are labeled "for single use only".

Single use products - All **Implants** are provided **'sterile'**. Implants are intended for **single use only** and are to be used **only once** before the expiration date printed on the product label.

Sterility of reusable products – Reusable **products** provided and labeled as **non-sterile** are to be sterilized **before first use** and be cleaned and sterilized **before every reuse**.

Cleaning of the abutments is not necessary due to the abutments are end user sterilized!!

STEAM STERILIZATION INSTRUCTIONS FOR REUSABLE PRODUCTS AND NON-STERILE SINGLE USE PRODUCTS:

GENERAL INSTRUCTIONS: These sterilization instructions are applicable to ETGAR reusable products only. No sterilization before use is required for products that are labeled as **'STERILE'**.

PACKAGING BEFORE STEAM STERILIZATION: Place the product before sterilization in a standard Polyethylene/Tyvek (or equivalent) sterilization pouch, compatible with steam sterilization process. Sets of instruments may be loaded into dedicated instrument trays or general-purpose trays for seam sterilization.

THE FOLLOWING STEAM STERILIZATION PROCESS IS RECOMMENDED:

a) Follow the autoclave manufacturer's instructions to sterilize the products. Care must be taken **not to exceed** the autoclave maximum recommended load.

b) Sterilize in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of **15 minutes** at a temperature of **132ºC (270ºF)** (with 15 minutes Drying Time) or for a holding time of **six (6) minutes** at a temperature of **minimum 134ºC (273 ºF)**.

c) The holding time is the **minimum time** for which the minimum temperature **(132ºC/270ºF** or **134ºC/273ºF)** is sustained.

d) Please use sterilization pouch K803293, BI for sterility verification K082756, and Tuttnauer autoclave K993856.

NOTE: *Local infection control practice may recommend a different combination of holding time and temperature.*

INSTRUCTIONS FOR USE - IMPLANTS

PRECAUTIONS:

Adequate palpation and visual inspection of the future implant site must be carried out to determine if there is sufficient quality and volume of bone for an implant. After implant failure, the quality and volume of residual bone must be evaluated. The implant is supplied in sterile packaging. Do not re-sterilize. An opened, damaged, or defective package should be returned to the supplier for free replacement. The use of an implant does not require the use of any unusual preoperative antibiotic prophylaxis. In the case of unexpected pain, the surgeon must be contacted immediately. Physical exertion should be avoided following surgery. Patients must be informed that the implant is metallic device and may affect the performance of MRI apparatus.

GUIDE TO CHOOSING THE PROPER IMPLANT:

The implant size (height and width) is chosen per preliminary X-rays. There must be a 2mm margin from anatomical obstacles and maximum bone height.

During the planning phase, it is important to determine if there is sufficient quality and volume of bone for an implant and to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information may vary with each patient and abutment used; therefore, it should be carefully evaluated before placing any dental implant.

After making a preliminary diagnosis, an X-ray and/ or CT, in conjunction with a transparency that displays the necessary measurements, the dimensions of the implant suitable for the site in question should be determined. As a rule, the widest and longest implant suitable for a site (density and dimensions of bone, dimensions of gums) should be used, for rehabilitation to be most effective. Another general rule is that implant and abutment combinations offer the greatest range of rehabilitation options. The choice of an integrated implant/abutment (one-piece) requires immediate loading and rehabilitation, and cementing of the restoration device. There is no affixing of the abutment by screw, and no choice as to the structure of the abutment. That choice is made beforehand.

The **final prosthesis** should be designed prior to the placement of the dental implant.

During procedure, utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising osseous integration. This is mandatory during all procedures.

DRILLING PROCEDURE-

Avoid excessive pressure **during preparation** of the bone site. Since the drilling speed varies (The surgical procedure requires drilling speeds from Max 1500 rpm for the first drill to min 200 rpm or the last one) based on the instrument and the surgical procedure, recommendations for speed can be normally found in the instructions provided by the dental drills manufacturers.

ALL IMPLANTS: After good surgical exposure of the bony surface, the position for the implant should be determined and a guide hole should be made using our Marking drill, taken down into the cortical bone to the level of the neck beneath the bur head. Do not attempt to drill deeper with the Marking drill use the guide hole for position; the color-coded drill bits will be utilized to drill the hole to the desired depth. The color coding on the bits indicates the diameter of the bit. Almost all drilling should commence using the 2.0-millimeter bit or lance drill. The bits are used in graduated order to slowly increase the diameter of the implant hole until the desired diameter is reached. This will allow safe progression and decrease trauma to the surrounding bone structures. The accurate depth of the hole is determined by the length of each implant and is indicated by the depth lines around each bit, to allow good position of the implant in the bone so that its end is flush with the alveolar ridge.

Only sharp instruments of the highest quality should be used for any surgical procedure involving bone to minimize trauma to the bone and surrounding tissue and thus enhancing the potential for successful osseointegration. Any ancillary instruments employed must be properly sterilized.

Use only surgical tools provided by ETGAR to avoid wear-out of the implant's hexagonal connection.

To eliminate contaminants and other sources of infection, all reusable and non-sterile devices should be handled according to the "STERILITY “section on page 4 of this IFU.

Proper occlusion should be evaluated on the implant restoration to avoid excessive force.

EH (Mono/Harmony) Implants – using the transfer remove the implant from the tube (package) and insert it in the previously drilled hole. **Detach the transfer** from the implant and attach the key then attach the ratchet to the

key and fasten the implant into the hole, remove the ratchet and key. Now it is possible to measure using the transfer.

PROCEDURAL, RESTORATION:

The healing period varies from patient to patient and depends on the quality of the bone at the implantation site, the tissue response to the implanted device, the surgeon's skills and evaluation of the patient's bone density at the time of the surgical procedure.

During the healing period, excessive force applied to the dental implant should be avoided.

INSTRUCTIONS FOR USE - ABUTMENTS

Abutments Location in the mouth:

- Straight - Located in all the sectors (areas) of the mouth.
- Angled - Located in all the sectors (areas) of the mouth. Sectors where the defects existing made impossible implant perpendicular to occlusal plane.
- Ball Attachment/Locator systems- Located in all the areas of the mouth but usually used in the anterior area for overdentures.
- Healing Abutments / Caps - Located in all the areas of the mouth.

DESCRIPTION: The restorative abutments have a hex which engages the internal hex of the implants. The abutments are available in multiple cuff heights in straight and offsets in both 15° and 25° angulated configurations to provide correction for off-angle implant placement. The abutment is secured to the implant with an abutment retaining screw which is preassembled in the abutment. The abutment screw is not removable from the abutment. The abutment has an internal screw access for the attachment of various restorative components using a separate coping screw. Abutments are packed with a screw in a blister or bag. The abutment and abutment retaining screw are fabricated from titanium alloy.

TECHNICAL INFORMATION: Procedure for Etgar Implants angled abutments.

NOTE: During implant placement, it is recommended to orient the flat of the internal hex of the implant to be opposite the angle correction. The pre-attached multi-purpose fixture mount can be used to index the internal hex of the implant. The flat side on the wall of the fixture mount will fine up with the flat side of the internal hex.

NOTE: To put the abutment in the mouth use the abutment driver. The driver should be hand tightened (max. 30 Ncm) to the abutment to confirm adequate attachment of the tool to the abutment.

Use appropriate abutments and angulated components that correspond to the implant system being restored.

a. Remove the angled abutment from the abutment packaging in a sterile field. Hand tighten the abutment with the Abutment Hand Driver to confirm the attachment to the cone of the abutment.

b. Thread dental floss through nose hole in the top. Utilizing the abutment Driver, deliver the abutment to the mouth. Aligning the angled abutment in the appropriate orientation for desired angulation correction.

c. Use 1.27mm [0.50”] Hex Driver to hand tighten (max. 30 Ncm) the abutment retaining screw. The long driver must be used if the abutment delivery tool is attached to the abutment. The standard driver can be used if the abutment delivery tool is removed from the abutment.

d. Verify with periapical radiograph that the abutment is seated completely into the implant and has engaged the internal hexagon.

e. Tighten the abutment retaining screw to 30 Ncm with a calibrated torque wrench. The Torque Wrench can be used with the abutment driver for ratchet, removed from the abutment can be used.

f. If the abutments will not be immediately restored with a provisional or final restoration, it is recommended to place the abutment titanium Healing Cap to prevent irritation of the soft tissue and to prevent the ingress of material the screw access of the abutment cone.

NOTE: The usage of ratchet is recommended up to 35 Ncm maximum. More force will cause a break or malfunction of the ratchet head.

Cleaning of the abutments is not necessary due to the abutments are end user sterilized!!

INSTRUCTIONS FOR USE - BALL ATTACHMENT

DEVICE'S DESCRIPTION AND EXPECTED PERFORMANCES: Retentive elastic attachments for the construction of dental prosthesis.

PRECAUTIONS: Choosing the right attachment is a dentist or dental technician responsibility according to the prosthetic project. Safety, Responsibility and Warranty: Etgar attachments and components are manufactured in accordance to the Europeans and USA norms on medical devices.

TECHNICAL SPECIFICATIONS: Ball Attachment on implants: Titanium single over- denture attachment to be screwed on endosseous implants, the retention is provided by the elastic cap which goes over the sphere's equator. Sphere's vertical dimension has been reduced to obtain a smaller attachment.

INSTRUCTIONS FOR USE: Ball Attachment Titanium: Screw the attachment to the implant with the proper square screw driver, make sure the insertion of the metal tip is corrected. Screw tightly by hand until the process is completed, then unscrew the attachment and screw it another time. Repeat this process a couple of times until the thread get the proper micro modeling shape of the female part. In alternative screw the attachment by using the proper dynamo-metrical drill extension tool tightening up to 25 N/cm2.

APPLICATION OF THE PROSTHESIS IN THE PATIENT'S MOUTH: Once the Ball Attachment is screwed into the implants, proceed with the insertion of the protective disk over the equator of the attachment. Insert the retentive female cap inside the metal house by using the proper insertion tool, choose the female cap with the proper retention per the case, then insert the metal house over the attachment with accurate pressure to have it snap over the equator. Test the prosthesis in the patient's mouth which will have the proper spaces corresponding to the attachments. Make sure the space is enough, if any interference should occur enlarge the space by using a bur until the interferences with the metal house are removed. Fill up the spaces, insert the prosthesis inside the patient's mouth, verify the correct position, have the patient close his mouth. Remove the prosthesis, refine and polish every exceeding material than deliver the prosthesis to the patient. To maintain the high-quality standard offered by the Ball Attachment and Locate-It lines we recommend the substitution of the retentive elastic components yearly. Any use of the Ball Attachment and components which does not follow the present instructions or the others Etgar literature is considered improper.

MR SAFETY:

THE ETGAR DENTAL IMPLANT SYSTEM HAS NOT BEEN EVALUATED FOR SAFETY AND COMPATIBILITY IN THE MR ENVIRONMENT. IT HAS NOT BEEN TESTED FOR HEATING, MIGRATION, OR IMAGE ARTIFACT IN THE MR ENVIRONMENT. THE SAFETY OF ETGAR DENTAL IMPLANT SYSTEM IN THE MR ENVIRONMENT IS UNKNOWN. SCANNING A PATIENT WHO HAS THIS DEVICE MAY RESULT IN PATIENT INJURY.

SEATING TORQUE:

Spiral	*Cylindrical*	*Harmony*
Final Placement Torque	*Final Placement Torque*	*Final Placement Torque*
Minimum 25 NCM Min. 35 NCM for immediate loading Maximum 65 NCM-70NCM	*Minimum 25 NCM* Min. 35 NCM for immediate loading Maximum 65 NCM-70NCM	*Minimum 25 NCM* Min. 35 NCM for immediate loading Maximum 65 NCM-70NCM

SURGICAL PROCEDURES:

Prior to implant placement refer to Instructions for Use.
Table 1: The uses of various types of abutments.

Implant	*Interfacing Abutments*
Spiral and Cylindrical	*Healing Cap Standard, Healing Cap Standard, Healing Cap Wide, Standard Straight, Narrow Straight, Straight, Anatomic Straight, Standard Angulated, Angulated, Anatomic Angulated, Ball Attachment, Esthetic*
Harmony	*One-piece implant (usually for immediate loading)*

LOCATION IN THE MOUTH:

- Straight – Located in all the sectors (areas) of the mouth.
- Angled – Located in all the sectors (areas) of the mouth. Sectors where the defects existing made impossible implant placement perpendicular to occlusal plane (angulated 25°).
- Ball Attachment Located in all the areas of the mouth but usually used in the anterior area.
- Healing Caps – Located in all the areas of the mouth.

MAINTENANCE AND PERIODIC CARE: Dentists have the responsibility to keep the proper functionality and retention of the devices and assuring the safety of the patient by constant care. Guidelines for the patients: Patients are recommended to follow the indications provided by the dentist, to attend periodical controls and perform daily accurate hygiene.

DISCLAIMER:

Operating surgeons/ practitioners should be fully familiar with all indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) of our system. They should be able to fully comply with these processes. Detailed instructions beyond those contained in these instructions for use concerning the possible combinations, product specific risks, preparatory steps, indications, contraindications, etc. can be found in the product descriptions. These include of the surgical technique and descriptions of the product(s) as found in the appropriate catalogue sheet. Etgar also recommends attending appropriate education, continuing education and user-training courses. Negative effects or damages that might occur for reasons such as incorrect indications or surgical technique, unsuitable choice of material or handling there of unsuitable use or handling of the instruments, asepsis and so on. The operating surgeon is responsible for any such complications or other consequences. It is also the operating surgeon's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks

POTENTIAL ADVERSE EVENTS:

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

- Failure to integrate,
- Loss of integration;
- 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.

PACKAGE, STORAGE AND HANDLING:

All Implants packaging process is taking place in a clean room using bacterial barrier materials in order to maintain product's sterility.

All implants are provided with labels identifying the implant's catalogue number, lot number, expiration date and additional information that is important to the dentist. This information should be kept in patients' record for future reference.

Sterile Package includes: one dental implant and one cover screw.

Implants Shelf Life: 5 Years. The year and month of expiration is indicated by the hourglass symbol on the product label. **Do not** use the product if the shelf life date has expired or if the bacterial barrier package is opened or damaged!

Abutments/Prosthetics: are provided non sterile, it is recommended to use within 5 years of the manufacture date stated on the package.

Storage and transportation process: The implants should be stored in a dry and clean place, at room temperature, kept in their original packaging when possible. Light packages should be stacked on top of heavier ones. Do not store implants near dangerous or toxic materials.

SYMBOLS INTERPRETATION:

Symbols on the product package should be interpreted as follows:

	Expiration date (use by)		Single use – Do not re-use
	Consult operating instructions;		Date of manufacture
	Do not use if sterile package is compromised		Manufacturer
STERILE R	Sterilized using Irradiation	NON STERILE	Non-Sterile
CE 0425	CE-Mark Symbol	CE	CE-Mark Symbol
LOT	Batch code/number	REF	Catalogue number
CAUTION	Caution		Do not use if package is damaged
	Do not resterilize	Rx only	Symbol for "Use by Prescription only"
EC REP	Authorized Representative in the European Community		

NOTE: For additional information please refer to ETGAR MEDICAL IMPLANT SYSTEM website at: www.etgar-implants.com or at the details below.

Etgar Medical Implant Systems
P.O.B 499 Northern Industrial Area
Nahariya 2210401, Israel
Phone: +972-4-622 1000
Fax: +972-4-622 1200

EC REP
MedNet EC-REP GmbH
Borkstrasse 10, 48163
Münster, Germany

Reviewed & Approved by:

Full Name	Position	Date	Signature
Dr. Boaz Hetsroni	Medical Advisor	19/06/19	
Ronen Atias	CEO	19/06/19	
Yehudit Friedlander	QA/RA Manager	19/06/19