We help people do what they love by restoring mobility. We are committed to providing the best customer experience through our premium, clinically proven products, coupled with unparalleled service and value.

ORTHOMED E®

Orthopedic Implant Manufacture

Orthomed E implants are manufactured with pride using the most advanced materials, latest technologies, and a steadfast commitment to quality.

Patient safety is our top priority, and all product is inspected, cleaned, packaged, and shipped from the company's headquarters in Egypt.

ORTHOMED E®

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Dental Implant System

CE 0653

PROUDLY MADE IN EGYPT O-0517-PH-05-19

Orthomed E

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Dental Implant System

IFU 001/06

PROFESSIONAL USE ONLY

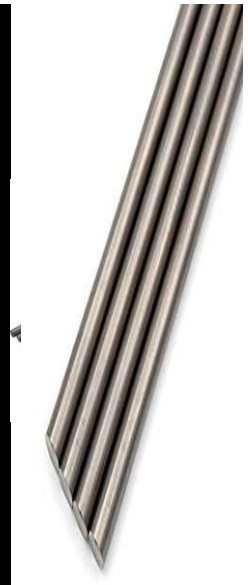
Orthomed E
Orthopedic Implants Manufacture

Manuals are subject to change; the most current version of each manual is always available online.

➘ **Printed in: July 6, 2022**

- In this document the following items will cover:
  - Dental Implant;
  - Implant Abutment;
  - Healing Cap;
  - Connection Screw;
  - Cover Screw.
- Components are available in a variety of designs and size ranges intended for both primary and revision applications.

All of materials we have machined are found acceptable for dental implants.



MATERIALS?

- The Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, healing cap, connection screws and cover screws. All components of the Dental Implant System are made of titanium unalloyed for dental body per ISO 5832-2 & titanium alloyed per ISO 5832-3 for retention component and the implants feature (sandblasted acid-etched) bone anchoring surface. The overall qualitative and quantitative information on those materials is available in the European database on medical devices (**Eudamed**), where it is linked to the Basic UDI-DI, since our latest summary of safety and clinical performance (SSCP) can be stated provided.

INDICATION!

- A sterile device that is intended to be surgically implanted into alveolar and/or basal bone of the mandible or maxilla to provide support and a means of retention for a dental prosthesis. These Dental Implants are intended for use only by certified dentists and authorized persons with specific implant training. The implants are used for two-stage and one-piece implantation processes. The dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. The dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. The prosthetic restorations used are single crowns, bars, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

CONTRAINDICATION!

- 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. Mild psychological disorders, aggression, smoking, use of chewing tobacco; Lack of adequate training of practitioner: Lack of patient motivation.

Lactating or pregnant women; Children with undeveloped bones. LOCAL: Inadequate bone mass; Residual infections and inflammations occurring around the implant; Poor oral hygiene; Hypersensitivity to components of the implant; Unrealistic patient expectations; Periodontal diseases

- Non-completed jawbone growth, drug or alcohol abuse, allergies or hypersensitivity to chemical ingredients of materials used (titanium grade), all conditions which would normally be contraindicated for oral surgery, patient situations in which adequate sizes, numbers or desirable positions of implants necessary to provide safe support of safe functional load are not achieved. The 6 mm implants are contraindicated for immediate loading.

WARNINGS!

- improper implant techniques may result in implant failure and loss of bone.
- Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment for patients on any such medication.
- 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.
- Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure. Orthomed E implants and Recovery accessories have not been evaluated for safety and compatibility in the MR environment and not been tested or heating or migration in the MR environment.
- The Straight and Angled Abutment have not been evaluated for safety and compatibility in the MR environment. The Straight Angled Abutment has not been tested for heating or migration in the MR environment.
- 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 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 or 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.
- Placement of an implant adjacent to an infected tooth or a failing root canal treated tooth may cause the implant to fail. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site. One may either allow site to heal as though it were a traumatic extraction or perform guided tissue regenerative procedures as indicated. Due to the metal conductivity, electro surgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure.
- Implant and abutment fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 25 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing clenching), improper casting procedures, inadequate prosthesis fit, and physical trauma

PRECAUTIONS!

- It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudates around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).
- Adequate palpation and visual inspection of the future implant site must be carried out in order 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 a metallic device and may affect the performance of MRI apparatus.
- The hard and soft tissues must be carefully managed, to ensure osseo-integration. The site must be prepared with extreme precision. Any ancillary instruments employed must be properly sterilized. The surgical procedure requires drilling speeds from 1000 rpm for the first drill to 500 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.
- Proper case planning is essential to the long-term success of both the prosthesis and the implant. Overload is one of the key contributors to implant failure. One should ensure the implant size and abutment angulations are appropriate for the occlusal load. Highly angulated abutments (>25°) should be avoided and are not recommended. Splinting of off-axis loaded implants may be required to give better support.
- The implant size (height and width) is choosen according to preliminary X-rays. There must be a 2-mm margin from anatomical obstacles and maximum bone height.

TREATMENT PLANNING

- Appropriate imaging techniques should be used to determine if adequate bone is available, and to determine the location of important anatomical landmarks, such as the mandibular canal, maxillary sinuses and adjacent teeth. Thorough clinical evaluation is imperative prior to all implant surgeries
- Only patients that meet the criteria described in the Intended use/purpose should be selected.
- Patients' conditions and/or predispositions such as those addressed in the above-mentioned CONTRAINDICATIONS should be avoided.
- Before deciding about implantation, the surgeon shall inform the patient about indications and contraindications of such procedure and possibility of complications occurrence after the operation. Patient shall be introduced to the purpose and manner of the procedure, and to functional and aesthetic effects of such treatment.
- Proper clinical diagnosis and accurate operation planning and performance are needed to achieve good final result of treatment.
- Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation (alloying elements of implant material are presented in IMPLANT MATERIAL).
- The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
- The operation procedure shall be carefully planned. The size of implant should be determined prior to the beginning of the

surgery. An adequate inventory of implants with required sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

- The implantation shall be carried out by surgeons have received training and tools are given by surgeons familiar with the technique (over +10 surgeries), and who have acquired practical skills of using instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
- Do not use the implant if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the packaging is not intact. The packaging shall be carefully checked prior to use.
- Implants are delivered in protective packages. The package should be intact at the time of receipt.
- Before procedure begins, all implants should be carefully checked to ensure that there is no damage (surface scratching, dents, signs of corrosion and shape deformations). Damaged implant cannot be inserted into the body.

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.

HYGIENE AND MAINTENANCE

- Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

MAGNETIC RESONANCE COMPATIBILITY!

- Implants made of titanium are conditionally compatible with magnetic resonance imaging.
- The patient can be scanned under the following conditions:
  - static magnetic field of ≤ 3 Tesla,
  - maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
  - maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

CAUTION:

The user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.

- MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
- Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

PACKAGING AND STORAGE!

- Implants are single-use devices, provided sterilized by exposure to a minimum dose of 25 kGy of gamma radiation.
- The unit package contains: Sterile version - one piece of the product. Clear plastic tubes are a typical packaging material
- The packaging is equipped with the product label. The label contains e.g.: for sterile product
  - Logo Orthomed-E and the address of the manufacturer.
  - Name and size of the device.

- Manufacturing and expiration date in format of YYYY-MM-DD
- Production batch number (LOT), e.g. OExxxxxxx.
- Material of the implant (see IMPLANT MATERIAL).
- Sterile sign - indicates sterile product.
- Informative symbols and QR Code for Instruction for Use.

- In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package (e.g. legal requirements of the country in which the device will be distributed).
- The package may contain: Instructions for Use and labels to be placed in a patient's medical record.
- Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

ADVERSE EFFECTS!

- The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, damage to adjacent teeth, loss of bone or teeth, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

SAFE DISPOSAL!

Because Orthopaedic implants are strictly regulated and must achieve rigid accuracy and precision standards due to the nature of their use, implants are susceptible to producing unused implant waste from implants that do not qualify for use or reuse based on predefined standards. Typically, unused implant waste is totally secured against infection, microbial and physical hazards then, incinerated or sent to landfills. Additionally, waste implants that are high metal content are typically sent to landfills.

In contrast, incineration, which is the destruction of waste materials via burning, is often used to dispose of unused implant waste when the implant waste does not have a high metal content. Incineration can be subcategorized into RCRA and non-RCRA incineration, depending on the material incinerated. RCRA waste materials, also called solid wastes.

At any rate, after removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with the local regulations and current hospital procedures.

Make Attention Here!↘

1. Implant can last for upwards of 20 years for implantable Titanium implants.
2. Clinical surveys are indeed meaningful for our device improvement so kindly request to be filled for each device via this **LINK** and keep you updated with our latest summary of safety and clinical performance (SSCP) through the European database on medical devices (**Eudamed**), where it is linked to the Basic UDI-DI.
3. Reporting a suspected medical device-related issues i.e. serious adverse events, serious incidents, etc. shall be submitted immediately by the end user and/or patient to Orthomed E and the competent authorities via this **LINK** or by using this **FORM**.
4. Orthomed E provides a Comprehensive Information Platform (**OECIP**) to their product distributers, end users and even for patients, which its present best resources on MDR law, always up to date. Simply select and view the resource to be displayed.
5. We are cognitive that there is a fair chance of detection of orthopaedic implant by airport security, a major disruption to the patient's journey is unlikely. However, for those who are concerned about the potential for inconvenience we advise them to complete this form via this **LINK** before two days at least from their travel., whereby this form we could offer an official

letter beside the case report you'll have received from healthcare provider when asked to prove the presence of an orthopaedic implant.

SYMBOLS ON THE LABELS!

Device name

Manufacturer

Authorized representative

Date of manufacture

Use-by date

Catalogue number

Batch code

Sterilized using irradiation

Do not re-sterilize

Do not re-use

Do not use if package is damaged

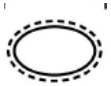
Keep away from sunlight

Temperature Limit ≤30℃

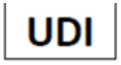
Keep dry

Consult instructions for use

Caution



Single sterile barrier system with protective packaging outside



Unique Device Identification