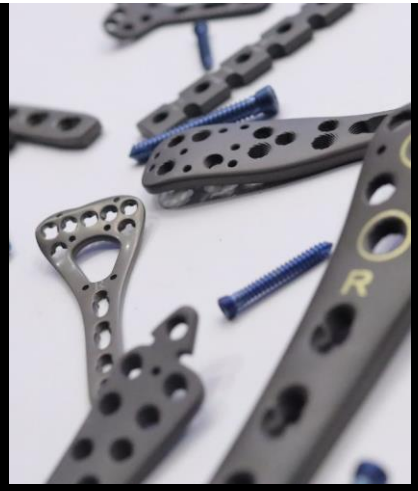

We help people do what they love by restoring mobility. We are committed to providing the best customer experience in orthopedics through our premium, clinically proven products, coupled with unparalleled service and value.

ORTHOMED E®

Manufacturing of Orthopedic Implants

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.

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Bone Plates

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Bone Plates

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Orthomed E
Orthopedic Implants Manufacture

The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.

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

➘ **Printed in: October 23, 2024**

Orthomed E® Bone Plates offer many clinical benefits for patients who undergo bone plate application including, stabilize a fractured orthopaedic bone (excluding spinal) to treat a traumatic/pathological fracture, to fuse a joint (arthrodesis) and/or as part of an osteotomy.

Various plate designs are available. These may be larger or smaller, thicker, or thinner as appropriate to various anatomic sites and the loads to which they will be subjected. The holes in the plate may be designed for locking screws, non-locking screws, or either and designed to facilitate dynamic compression.

Implementation of the device in rural, urban, secondary (general hospital), tertiary (specialists' hospital) requires operating room with sterile conditions, anesthesia personnel and machines, well trained nurses, and sterilizing personnel are all required.

Device Description and Materials

1. Straight Bone Plates

- Orthomed E-straight bone plates are provided in locking plates, and non-locking plates are intended to be used as defined in the indications. Locking plates are offered in either fixed angle/single direction (monoaxial), which features locking and combi holes, providing options for both compression and locking fixation, or dynamic compression plate (DCP), which is designed with non-locking features for traditional compression fixation.
- Orthomed E-straight bone plates feature non-bioabsorbable, non-customized, firm, implantable sheets manufactured by forging or machining with a geometrically defined cutter (as in milling) from stainless steel (SS) per ISO 5832-1, titanium unalloyed (TUA) per ISO 5832-2, and titanium alloy (TA) per ISO 5832-3 and has a glass-beaded surface finish (smooth-surfaced). Typically fit the shape of the bone. The midshaft of many long bones is straight, so plates applied to these regions may not need to be contoured. They are designed for metaphyseal fixation in both upper and lower limb fractures. These plates offer straightforward alignment and stability. Available in large and small fragment variations:
    - Large fragment plates accommodate 4.5mm screws with locking options of 5.0mm.
    - Small fragment plates utilize 3.5mm screws with locking options of 3.5mm.
    - Mini fragment plates utilize 1.5mm, 2.0mm, and 2.4mm screws with non-locking options of revision 2.0mm, 2.3mm, and 2.7mm respectively.
- Orthomed E-straight bone plates may incorporate a low-contact feature, minimizing contact between the plate and bone surface to reduce the risk of stress shielding and promote optimal bone healing. This feature enhances the biomechanical properties of the fixation construct, fostering a favorable environment for bone regeneration and remodeling.
- Orthomed E-straight bone plates are designed to be fixed in place with locking or non-locking selective metal-based screws; they do not incorporate a sleeve or blade.

2. Anatomical Bone Plates

- Orthomed E- anatomical bone plates are provided in locking plates, and non-locking plates intended to be used as defined in the indications. Locking plates are offered in either fixed angle/single direction (monoaxial), which featuring the screw with a threaded head can be locked and combi holes that function as Dynamic Compression Plates (DCP) and Locking Compression

Plates (LCP) to the plate only in a single designed direction, or variable angle (Polyaxial), which means the screw with a threaded head can be locked within 15° cone.

- Orthomed E- anatomical bone plates feature non-bioabsorbable, non-customized, firm, implantable sheets manufactured by forging or machining with a geometrically defined cutter (as in milling) from stainless steel (SS) per ISO 5832-1, titanium unalloyed (TUA) per ISO 5832-2, and titanium alloy (TA) per ISO 5832-3 and has a glass-beaded surface finish (smooth-surfaced). Anatomic plates are intricately contoured to match the unique shapes of bones in the upper and lower limbs, enhancing stability and reducing the risk of soft tissue irritation. Available in various fragment sizes:
    - Large fragment plates accommodate 4.5mm screws with locking options of 5.0mm and 6.5mm.
    - Small fragment plates utilize 3.5mm screws with locking options of 3.5mm.
    - Mini fragment plates feature 2.7mm screws with 2.4mm locking screws.
- Orthomed E-anatomical bone plates may incorporate a low-contact feature, minimizing contact between the plate and bone surface to reduce the risk of stress shielding and promote optimal bone healing. This feature enhances the biomechanical properties of the fixation construct, fostering a favorable environment for bone regeneration and remodeling.
- They are designed to be fixed in place with locking or non-locking selective metal-based screws; they do not incorporate a sleeve or blade.

3. Angled Bone Plates

- Orthomed E- angled bone plates are provided in locking plates, and non-locking plates are intended to be used as defined in the indications. Locking plates are offered in either fixed angle/single direction (monoaxial), which features locking and combi holes, providing options for both compression and locking fixation, or dynamic compression plate (DCP), which is designed with non-locking features for compression fixation.
- Orthomed E- angled bone plates feature non-bioabsorbable, non-customized, firm, implantable sheets manufactured by forging or machining with a geometrically defined cutter (as in turning and milling) from stainless steel (SS) per ISO 5832-1, titanium unalloyed (TUA) per ISO 5832-2, and titanium alloy (TA) per ISO 5832-3 and has a glass-beaded surface finish (smooth-surfaced). Due to the angle of the bone, the contour of the concave plate aligns with the bone, providing an even compressive force along the fracture. They are designed for large fragment screws 4.5mm with locking options of 5.0mm and designed to be fixed in place with locking or non-locking selective metal-based screws; they do not incorporate a sleeve or blade.
- Orthomed E-angled bone plates may incorporate a low-contact feature, minimizing contact between the plate and bone surface to reduce the risk of stress shielding and promote optimal bone healing. This feature enhances the biomechanical properties of the fixation construct, fostering a favorable environment for bone regeneration and remodeling.

INTENDED USE!

Orthomed E® Bone Plates are intended for internal fixation, stabilization, and support of bone fractures, as well as bone fixation after osteotomies in skeletally mature patients (over 21 years of age). Normally used together with the bone screw system.

INDICATIONS!

Orthomed E® Bone Plates, including locking plates, non-locking plates, and mini plates in different morphologies—straight, anatomical, and angled shapes—are designed to provide fixation and stabilization of a fractured orthopaedic bone (excluding spinal) to treat a traumatic or pathological fracture, to fuse a joint (arthrodesis), and/or as part of an osteotomy. Typically attached to a bone of a limb, rib, sternum, or pelvis, it is designed to be fixed in place with screws; it does not incorporate a sleeve or blade. Instruments intended to facilitate implantation, or fixation implants (i.e., bone screws), may be included with the plate. In

general, these plates are indicated for fractures requiring additional stability.

Indications include:

1. **Locking plates are indicated for:**
    a. Osteopenia bone[1]
    b. Peri-articular comminuted fractures[2]
    c. Periprosthetic fractures[3]
    d. Extra articular fractures[4]
    e. Complete intra-articular[5] fractures including those with associated coronal fractures[6]
    f. Shaft fractures[7]
    g. Supracondylar fractures[8]
    h. Intra-articular fractures
    i. Nonunion[9] and malunions[10]
    j. Osteotomies[11]

2. **Non-locking plates are indicated for:**
    a. Fractures requiring additional stability (e.g. severely comminuted fractures, etc.)
    b. Extra articular fractures
    c. Complete intra-articular fractures including those with associated coronal fractures
    d. Metaphyseal fractures[12]
    e. Supracondylar fractures
    f. Periprosthetic fractures
    g. Intra-articular fractures
    h. Nonunion and malunions
    i. Osteotomies

3. **Mini plates are indicated for:**
    a. Fractures of metacarpal[13] and phalanx[14]

1 Osteopenia is a loss of bone mineral density (BMD) that weakens bones. It's more common in people older than 50, especially women. Osteopenia has no signs or symptoms, but a painless screening test can measure bone strength. Certain lifestyle changes can help patients preserve bone density and prevent osteoporosis.

2 A periarticular fracture occurs when a bone breaks inside or around a joint. In addition to the fracture, this type of break can also damage joint tissues and the cartilage on the ends of the affected bones.

3 Fractures around joint replacement prostheses are commonly called periprosthetic fractures, whereas fractures around plates, rods, or prostheses can be more generally termed peri-implant fractures

4 Fracture types can be described as “extra – articular” (which means the fracture line does not extend into the joint).

5 An intraarticular fracture is a fracture that crosses a joint surface. Such fractures also involve some cartilage damage.

6 Hoffa's fracture is a coronal-oriented fracture of the distal femur with the fracture line extending through the medial condyle, lateral condyle, or bicondylar region. This fracture is commonly present as an isolated fracture and, in rare instances, it is associated with other injuries around the knee joint.

7 The long, straight part of the bone region i.e. femur is called the femoral shaft. When there is a break anywhere along this length of bone, it is called a femoral shaft fracture

8 A supracondylar fracture occurs through the thin part of the distal humerus above the level of the growth plate

9 Nonunion describes the failure of a fractured bone to heal and mend after an extended period of time

10 malunion refers to a fracture that has healed in a deformed position, or with shortening or rotation of the limb

11 An osteotomy is a bone-cutting procedure to realign and reshape patients’ bones and joints

12 A metaphyseal fracture is a type of bone fracture that occurs in the metaphysis, the wider part of the bone near the growth plate

13 A metacarpal fracture is a type of bone fracture (broken bone). Patients’ metacarpals are the bones in your hand that connect patients’ thumb and finger bones (patients’ phalanges) to patients’ wrist. You can feel patients’ metacarpals by pressing them on the back of patients’ hand. Metacarpal fractures are common injuries

14 A phalanx is any bone of the fingers or toes. A phalanx fracture is a crack or complete break in one of these bones. A phalanx fracture can happen when a patient’s finger or toe is hit, pulled, jammed, crushed, or twisted. It is also possible for a tumor or cyst to weaken the bone, causing it to break easily when injured

TARGET POPULATIONS!

Bone plate application is a treatment for skeletal maturity patients (over 21 years of age) with

utilization at the appropriate anatomical structures as defined in the indications.

CONTRAINDICATION!

The choice of particular device must be carefully weighed against the patient's overall condition. Conditions listed below may preclude or reduce the chance of successful outcome:

a) Infection local to the operative site.

b) Signs of local inflammation.

c) Fever or leukocytosis.

d) Morbid obesity (defined according to WHO standards) an overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.

e) Pregnancy.

f) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.

g) Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g., the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells (WBC) count, or a marked left shift in the WBC differential count.

h) Suspected or documented allergy or intolerance to implant materials. The surgeon shall find out if the patient develops an allergic reaction to the material of the implant (content of the implant material is presented in Device Description).

i) Any case not needing a surgical intervention.

j) Any case not described in the indications.

k) Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.

l) Any case where the implant components selected for use would be too large or too small to achieve a successful result.

m) Any case that requires the simultaneous use of elements from different systems that are made of different metals.

n) Any case in which implant utilization would interfere with anatomical structures and disturb physiological processes.

o) Any case in which there is inadequate tissue coverage of the operative site.

p) Blood supply limitation in the operative site.

q) A comminuted fracture is difficult to fix and reset because of the small and many bone sheets.

r) Growth plates are not to be blocked with plates and screws

s) Skeletally immature patients (patient is less than 21 years of age at the time of surgery).

The above-mentioned list does not exhaust the topic of contraindications.

WARNINGS!

The important medical information given in this document should be conveyed to the patient.

a) The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking, or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands, and anatomy. Every implant must be used in

the correct anatomic location consistent with accepted standards of internal fixation. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document and who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for surgery using the Bone Plate System.

b) Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and should be considered by the surgeon in order to achieve success during operation. Preoperative instructions for the patient are essential. The patient should be made aware of the limitations of the implant and the potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken, or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions on activity are followed.

c) Bending of the bone plate system is not recommended. Bending will compromise the mechanical performance of the plate and may adversely affect the fit and function of the screw-retaining mechanisms.

d) No implant can withstand body loads without the biomechanical continuity of the bone.

e) During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.

f) To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.

g) If the patient is involved in an occupation or activity (e.g.: substantial walking, running, lifting weights, muscles strain) which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.

h) A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patients' conditions may compromise the results.

i) The proper patient selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among patients who smoke. These patients should be informed about this fact and warned of this consequence.

j) Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.

k) Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low-quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.

l) The implants are intended as an aid to the healing process and are NOT intended to replace body structures or bear the body weight when the treatment process has not yet finished.

m) The implant may break or become damaged as a result of strenuous activity or trauma and may need to be replaced in the future.

n) The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.

o) In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.

p) Do not use the Bone Plate System with components of other systems. Unless stated otherwise, Orthomed E devices

are not to be combined with the components of another system.

q) Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.

PRECAUTIONS!

a) Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with current hospital procedures.

b) Under no circumstances is it allowed to reuse, or re-implant a once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to early failure, fatigue wear, and as a result to e.g.: an implant breakage.

Note:

Not used refers to those single-use components that have not been in contact with blood, bone, tissue, or other body fluids. Any unused, single-use device that has been exposed to blood, bone, tissue, or body fluids must not be reprocessed and must be discarded.

c) Implant which had contact with tissues or body fluids of another patient cannot be re-implanted due to a potential risk of cross-infection caused by viruses, bacteria, and prions.

d) It is recommended that one should not combine different metals in orthopaedic devices. The least noble metal in such a galvanic coupling is more likely to corrode. However, some studies have failed to show increased corrosion when titanium and stainless steel are combined

e) Misuse of instruments or implants may cause injury to the patient or operative personnel.

f) Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.

g) Insertion, removal, and adjustment of implants must only be done with instruments specially designated for those implants.

h) Use of implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.

i) While rare, intraoperative fracture or breakage of the instrument can occur.

j) Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed, and attention paid. Instruments should be examined for wear or damage prior to surgery.

k) Polyaxial screw locking is achieved when the threads on the screw head deform to the threads in the hole of the plate. This allows a total of three attempts at polyaxially locking within each screw hole.

l) Orthopedic surgeons always investigate the possibility of osteoporosis in older patients with fracture due to minor trauma such as a fall from standing height to the floor. Patients with osteoporotic fractures are among the highest risk patients for further osteoporotic fractures, often within 1 year of the fracture. The surgeon's responsibilities include the following:

   I. Inform the patient about the need for an osteoporosis evaluation. The orthopedic surgeon should have a basic understanding about osteoporosis and its treatments.

   II. Investigate whether osteoporosis is an underlying cause of the fracture. The evaluation should include a clinical history of risk factors and bone mineral density (BMD) assessment, as appropriate.

III. Ensure that appropriate intervention is initiated. The orthopedic surgeon should ensure that an osteoporosis evaluation is done, and appropriate intervention taken.

m) While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:

I. screwdriver should be set in the screw axis,

II. apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,

III. The final phase of tightening shall be performed carefully.

n) The sterilizing cases, instrument trays, and implant containers shall not be vigorously shaken or tipped over since the individual components may become damaged or fall out.

o) Twist drills and reamers: It is recommended not to exceed a maximum drilling speed of 1,000 revolutions per minute to avoid overheating the bone. With reamers, it is advisable to use a speed of less than 1’000 revolutions per minute or to use a handle for controlled, manual reaming.

p) Use the indicated screwdriver for the respective system size. Make sure that the screwdriver/screw head connection is precisely aligned in the axial direction. If not, there is a greater risk of damage to the implant and screwdriver blade. When inserting the screw, ensure that a sufficient axial force is used between the blade and screw. At the same time, the axial force should be within certain limits in order not to damage the bone structure.

DEVICE USERS AND SURGICAL TECHNIQUES!

- While there is no need to deviate from the ISO series of ISO 5836, ISO 5835, ISO 9269, ISO 6475, and ISO 9268, our bone plate has been designed despite the fact that numerous diverse designs of bone plates are in use around the world. As a result, our implants were created with the same precise specifications, and the surgical tools were then expertly created using the same strict guidelines.
- The sets can be modified to meet certain needs in order to produce the best set for bone plating surgical requirements. However, none of the bone plate implants in our lineup have any patents because they were created to be standard bone plate implants. Consequently, the implantation is performed by surgeons who are completely familiar with the implant system and surgical protocol, and complete preoperative planning should be carried out.
- The implantation is performed by surgeons who are completely familiar with the implant system and surgical protocol, and complete preoperative planning should be carried out. Additional user groups include nurses and reprocessing staff in handling, cleaning, and sterilization of the devices, where applicable. Orthomed E, as manufacturer, does not recommend a specific surgical procedure for a specific patient. The operating surgeon is solely responsible for choosing the appropriate implant for the specific case. The follow-up treatment as well as the decision of whether to retain or explain the implant is the responsibility of the user.
- The use of bone plates system ancillaries, such as bone screws and surgical instruments, in the case of surgical instrument application is explained in detail in the surgical technique protocol provided by Orthomed E for bone plating surgeries. Bone screws can be provided by Orthomed E where needed to guarantee the success of surgery since that implant is produced by Orthomed E under MDD and MDR regulation requirements. This product is now covered by an Orthomed E CE certificate based on EU MDD 93/42/EEC.
- Radiographic templates are available to assist in the preoperative prediction of component size and style
- Correct locking (±15°) of the locked screws in the plate: Visual inspection of the screw head projection provides an indicator of correct locking. Correct locking has occurred

only when the screw head has locked flush with the plate surface. However, if there is still a noticeable protrusion, the screw head has not completely entered the plate and reached the locking position. In this case the screw has to be retightened to obtain full penetration and proper locking. In case of poor bone quality, a slight axial pressure might be necessary to achieve proper locking. Due to the system characteristics, a screw head protrusion of around 0.2 mm exists when using plates with 1.0 mm thickness. Do not overtighten the screw, otherwise the locking function cannot be guaranteed any-more.

- Generally, implants are designed to remain in the body temporarily and be removed after sufficient (osseous) healing has taken place. They are not designed for long term bone replacement. Where they are mechanically supporting the osteosynthesis, the regular operating period of the implants is expected to be between 30 days and 6 months.
- Taking into account the individual fracture conditions and patient compliance, it is important for the surgeon to ensure adequate postoperative relief of the osteosynthesis in terms of adaptation or mobilization stability (e.g. splinting and/or immobilization). Postoperatively, the fixation achieved with the implants must be treated with care until the bone has fully healed. Patients must strictly observe follow-up instructions given by their physicians to avoid detrimental strain on the implants. Early load bearing can increase the risk of loosening, migration, or breakage of the implants.
- In the case of complications, it might be necessary to remove the implants. For removal use the indicated screwdriver. Make sure that the screwdriver/screw head connection is precisely aligned in axial direction.

WHAT HAPPENS BEFORE SURGERY?

- Patients' conditions and/or predispositions such as those addressed in the above-mentioned CONTRAINDICATION 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.
- The implantation shall be carried out by surgeons who 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 the 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 surgeon should be familiar with all components of the implant system before use and should personally verify if all components and instruments are present before the surgery begins.
- 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 the 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.

WHAT HAPPENS AFTER SURGERY?

- It is essential to follow all of physician's postoperative directions and warnings.
- It is essential to confirm the proper position of the implant by roentgenographic examination.
- In postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
- The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up clinical examination.
- The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
- The patient should be informed about the type of implant material.
- The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.
- The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.
- If the patient is involved in an occupation or activity which may apply excessive stress on the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause implant failure.
- The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma and may need to be replaced in the future.
- Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened, or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.

IMPLANT REMOVAL AFTER TREATMENT

- When bone union is achieved, the implants serve no functional purpose, and their removal is recommended. The possibility of another surgical procedure and associated risks must be analyzed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.
- If the device is not removed following completion of its intended use, one or more complications may occur, in particular:
- Corrosion, with localized tissue reaction or pain.
- Migration of the implant, possibly resulting in injury.
- Risk of additional injury from postoperative trauma.
- Bending, loosening, or breakage, which could make implant removal difficult or impossible.
- Pain, discomfort, or abnormal sensation due to the presence of the implant.
- Increased risk of infection.
- Bone loss due to stress shielding.
- Potentially unknown and/or unexpected long-term effects.
- Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

MAGNETIC RESONANCE COMPATIBILITY!

- Orthomed E® Bone Plates do possess an MR conditional symbol on the package labels.
- MR Conditional, if applicable, is determined by experimental testing and is denoted on a product's immediate package labeling by the MR Conditional symbol defined in the Table 1 legend below. Once an unevaluated component is added to the devcie assembly, the entire system becomes unevaluated. There are inherent risks associated with the use of metallic implants in the MR environment, including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants. Orthomed E® Bone Plates that possess the MR Conditional symbol on the package label have been experimentally tested in the following conditions. Non-clinical testing has demonstrated that items bearing the MR Conditional symbol on the package label are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
    - Static magnetic field of 1.5 Tesla only
    - Maximum spatial gradient magnetic field of 2.400 T/m
    - The maximum magnetically induced displacement force is 0.028 N with a mean offset angle of 3°. Maximum magnetically induced torque is 1.05×10-4 N·m with a maximum deflection angle of 21°
    - The maximum MR system reported a whole-body averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.
    - Normal operating mode of operation for the MR System
    - Under the scan conditions defined above, devices bearing the symbol for MR conditionality are expected to produce a maximum temperature rise of 2.3°C at 1.5- tesla after 15 minutes of continuous scanning.

    Maximum artefact length in the three directions of length, width, and thickness is 21.12 mm, 16.57 mm, and 11.62 mm, respectively.

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 procedures.

- 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 establish.

PACKAGING AND STORAGE!

- Implants are single-use devices, provided non-sterile.
- The unit package contains: Non-sterile version - one piece of the product. Clear plastic bags or medical pouches are typical packaging material.
- The packaging is equipped with the product label. The label (as a primary label) contains e.g.: for non-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).
    - Non-Sterile sign - indicates non-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.

IMPLANTS PROVIDED NON-STERILE!

- Prior to use of a non-sterile device the following rules apply:
    - The device must undergo washing, disinfection, and sterilization procedures. It is recommended to use automated procedures for washing and disinfecting in the washer-disinfector.
    - Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning (manual, ultrasonic, with the use of washing/disinfecting machine), the proper rinsing and drying, the proper preparation of the device, the time, the temperature, and carefulness of the person conducting this process.
    - Labels to be placed in patient's medical records (delivered together with the implant) must be protected against loss or damage during the implant washing and sterilization.
    - The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging, and sterilization processes with the use of existing equipment, materials, and properly trained personnel.
- **Preparation for washing**
    - After taking the device out from the original package, remove possible surface contamination (resulting from e.g.: damage to unit package) using a disposable cloth, paper towel or plastic brushes (nylon brushes are recommended). Do not use brushes made of metal, bristles or materials which could damage the implant.
- **Cleaning and disinfection process**
    - The chosen washing and disinfecting detergents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.
- **Manual cleaning**
    - Apply washing detergent to implant surface and brush carefully. Suitable brushes must be used for holes cleaning.
    - If applicable, ultrasonic cleaning may be performed. The ultrasonic bath must be prepared according to the manufacturer's instructions.
    - Rinse thoroughly under running water. It is recommended to rinse with demineralized water.
    - Visually inspect the entire surface of the device for damage and contaminants. Damaged implants must be removed.
    - For contaminated implants, the cleaning process should be repeated.
- **Cleaning in the washer-disinfector**
    - The device should undergo a process of machine washing in the washer-disinfector (use washing-disinfecting agents recommended for medical devices). CAUTION: The equipment used for washing/disinfection should meet the requirements of EN ISO 15883.
    - The procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and

instructions for use prepared by the washing disinfecting agent manufacturer. Disinfection should be carried out at a temperature of 90°C (soak in demineralized water) for at least 10 minutes without the use of detergents.

- **Drying**
  - Drying of the device must be performed as a part of the washing/disinfection process.

- **Packaging**
  - The device supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of EN ISO 11607-1. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during removal from the package, when used, there is no risk for its contamination. Sterilization packages are designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.
- **Sterilization**
  - Washed, disinfected, and dried devices shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization (with water vapor under overpressure):
    - temperature: 134°C,
    - minimum exposure time: 7 min,
    - minimum drying time: 20 min.

CAUTION:

Sterilization must be effective and in accordance with requirements of the EN 556 standard to ensure the required level of guaranteed sterility SAL 10-6 (where SAL stands for Sterility Assurance Level).

Implant must not be sterilized in the package in which it was delivered.

Validated sterilization methods used by sterilization facilities are allowed.

The above-mentioned rules of cleaning and sterilization must be followed when dealing with any device intended for implantation.

RE-STERILIZATION!

The adverse effects may necessitate It is permitted to re-sterilize devices by end-user.

ATTENTION: The user of the product bears all responsibility for re-sterilization. In such case the device shall be washed and sterilized in a way described in Instruction for Reprocessed Orthopedic Implants.

ADVERSE EFFECTS!

- The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence. The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown etiology which may be caused by many unpredictable factors. Potential adverse events include but are not limited to:

a) Implant damage (fracture, deformation, or detachment). These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load-sharing devices that are intended to hold fractured bone surfaces in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.

b) Early or late loosening, or displacement of the implant from the initial place of insertion. Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization, and poor bone formation can cause loosening, bending, cracking, fracture of the device, or premature loss of rigid fixation with the bone.

c) Possibility of corrosion as a result of contact with other materials.

d) Body reaction to implants as foreign bodies e.g., possibility of tumor metaplasia, autoimmune disease and/or scarring.

e) Compression on the surrounding tissue or organs.

f) Improper alignment can cause a malunion of the bone and/or bending, cracking, or even breakage of the device.

g) Increased fibrous tissue response around the fracture site due to unstable comminuted fractures

h) Infection and/or Death.

i) Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.

j) Hemorrhage of blood vessels and /or hematomas.

k) Pain and/or Inability to perform everyday activities.

l) Mental condition changes. Deep vein thrombosis, thrombophlebitis.

m) Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.

n) Scar formation that could cause neurological impairment, or nerves compression and /or pain.

o) Late bone fusion or no visible fusion mass and pseudarthrosis. Loss of proper curvature & length of bone.

p) Bone graft donor site complication.

q) Leg length discrepancy

r) Fever after the surgery

s) Redness, swelling, bleeding, or other drainage from the incision site that doesn’t stop after a few days after the surgery.

t) Increased pain around the incision site after the surgery

u) Pain in the lower leg that is unrelated to the incision after the surgery.

v) New or increased swelling of the lower leg after the surgery

w) Chest pain after the surgery

x) Shortness of breath after the surgery.

y) Material sensitivity reactions in patients following surgical implantation have rarely been reported; however, their significance awaits further clinical evaluation.

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 have 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.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS!

- When used according to the manufacturer’s instructions for use and labelling, Orthomed E® Bone Plates are intended to support bone consolidation by providing stabilization of bones and bone fragments, to be used with Orthomed E® Bone Screws together.

- Orthomed E® Bone Plates offer many clinical benefits for patients who undergo orthopedic surgery including, improved stability of fixation/resistance to failure of fixation, improved quality of life, and facilitate reduction (length, alignment, rotation) especially in Peri-articular fractures and bridging constructs (comminuted fractures, segmental fractures, bone defects). These accusations are supported

by a study of clinical data derived from one or more of the following sources: national oorthopedics and traumatology registries, clinical studies, and/or a review of the clinical literature. These results, along with supporting bench-top test data and technical analysis, demonstrate that the device works as intended and remains SOTA for use in bone fracture repair to keep the bone securely held in the correct position while it heals and reduce the chances of nonunion (the bone cut not healing) and malunion (the bone cut healing crooked).

- Locking plates were designed to provide a solution for indications including comminuted fractures and osteopenic bone. Locking plates can provide a construct that resists angular varus deformity, as well as prevents primary and secondary loss of reduction.
- The shape, design and the material properties of the Non-locking plates take into account the demands from surgeons for high fatigue strength, optimized load transfer and ease-of-use instruments.
- Mini plates were low profile to reduce soft tissue irritation and pre-contoured for anatomic fit. The broad range of Mini plates were available to address various fracture patterns.
- The surgeon should be cautious of the following while employing implants:
    - It is critical that the implant be chosen correctly. The selection of the right size, shape, and form of the implant improves the chances of success the surgery. Bone plaste necessitate precise positioning and appropriate bone support. As with all implants, the durability of these components is influenced by a variety of biologic, biomechanic, and other external factors, limiting their service life. As a result, thorough attention to the **product's indications, contraindications, precautions, and warnings** is required to potentially optimum the service level.
    - The following variables can be extremely important in selecting patients for bone fracture repair:
        - A state of senility, mental sickness, chemical dependency, or drunkenness. These situations, among others, may cause the patient to disregard some important constraints and safeguards in the use of the implant, resulting in failure or other consequences.
        - Sensitivity to foreing objects. If material sensitivity is suspected, suitable studies should be performed prior to material selection or implantation.
- Although there is not enough information yet available to calculate exactly how long metal implants last in the body using available orthopaedic and trauma registry data, once fracture union is confirmed both clinically and radiologically, the patients should be advised during the follow-up after surgery that the implants could be left indefinitely if they so desired or removed after twelve and eighteen months for upper and lower limb fractures, respectively, on confirmation of fracture union. In general, patients harboring implants that have symptoms that could be traceable to the implants in situ should always have them removed. Plates are stress-shielding devices and are generally advised to be removed in the lower extremities

Make Attention Here!↘

1. 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.
2. 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**.
3. 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.

4. 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.
5. The above information is intended for users/healthcare professionals and patients. Therefore, the healthcare professionals should communicate with Orthomed E's sales team in case they have a question or received any formal/informal question/inquiry from any patient regarding misunderstanding/unobvious data enclosed in this document. Understanding of lay persons are indeed meaningful for readability improvement so kindly request to be filled this short survey via this LINK.

SYMBOLS ON THE LABELS!

Device name

Manufacturer

Authorized representative

Date of manufacture

Use-by date

Catalogue number

Batch code

Non-sterile

Do not re-use

Do not use if package is. damaged

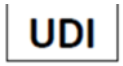
Keep away from sunlight

Temperature Limit ≤30:

Keep dry

Consult instructions for use

Caution



Unique Device Identification

MR Conditional

Importer

Distributer