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®

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®

6th of October city, 3rd industrial area, 201/3.
Giza - Egypt
Tel. +202 38204966-77
Fax. +202 38204988
Email: info@orthomed-e.net
Website: www.orthomed-e.net

EC REP OBELIS S.A

Bd. General Wahis, 53
1030 Brussels – Belgium
Tel no: +32 2 732 59 54
Fax no: +32 2 732 60 03
Email: mail@obelis.net
Web: www.obelis.net

Total Hip Prosthesis

CE 0653

O-0517-PH-05-19

Orthomed E

www.orthomed-e.net
info@orthomed-e.net

002 02 3820 4977
002 02 3820 4988

Total Hip Prosthesis

IFU 001/05

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Orthomed E
Orthopedic Implants Manufacture

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

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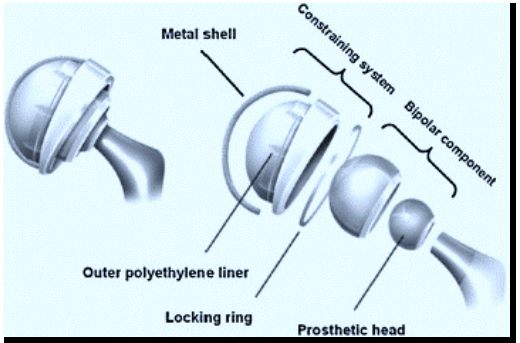
- Orthomed E has a variety of Total Hip Prosthesis. In this document the following items will cover:
  - AUTOFIT Femoral Stems;
  - AUTOFIT Femoral Heads;
  - AUTOFIT Bipolar Mobile Cup which is comprised of acetabular shells, acetabular liners and locking rings;
  - AUTOFIT Cups
- Components are available in a variety of designs and size ranges intended for both primary and revision applications.



Surgeons will select the design of the hip prosthesis and size of femoral ball to give the range of motion and stability that need to function. There are several different choices of hip implants to consider.

All of materials we have machined are found acceptable for articulating surfaces of total hip prosthesis implants.

MATERIALS?

- Femoral Stems are machined either from Stainless Steel (SS) per ISO 5832-1, Stainless Steel (SS) per ISO 5832-9 or medical grade titanium alloy (TA) per ISO 5832-3/ASTM F136 or Chromium Cobalt as per ISO 5832-12 with or without coating by two-layers of titanium and hydroxyapatite;
- Femoral Heads are machined from Stainless Steel (SS) per ISO 5832-1, Stainless Steel (SS) per ISO 5832-9 or Chromium Cobalt as per ISO 5832-12;
- Bipolar Mobil Cup, which comprise the following:
  - Acetabular Shells are machined from Stainless Steel (SS) per ISO 5832-1, ISO 5832-9 or Chromium Cobalt as per ISO 5832-12;
  - Acetabular Liners and locking rings are machined from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2.
- Cups are cemented or cementless with or without coating by two-layers of titanium and hydroxyapatite; and machined either from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2, or medical grade titanium alloy (TA) per ISO 5832-3/ASTM F136 and Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1, or medical grade Stainless Steel (SS) per ISO 5832-1 and Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1, or 2 or Chromium Cobalt as per ISO 5832-12 and Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2.

  The overall qualitative and quantitative information on those materials are 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!

Destruction of hip joint caused by degenerative, posttraumatic, or inflammatory diseases.

Fracture or a vascular femoral head necrosis

Consequences of previous intervention, total hip prostheses, osteotomy, etc.

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
- Revision of previously failed total hip arthroplasty.

CONTRAINDICATION!

- The choice of particular device must be carefully weighed against patient's overall condition.
- Conditions listed below may preclude or reduce the chance of successful outcome:
- Infection local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity (defined according to the WHO standards).
- Pregnancy.
- Infants and children.
- Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
- 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.
- Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant (content of the implant material is presented in Device Description).
- Any case not needing a surgical intervention.
- Any case not described in the indications.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- 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.
- Any case that requires the simultaneous use of elements from different systems that are made of different metals.
- Any case in which implant utilization would disturb physiological processes.
- Any case in which there is inadequate tissue coverage of the operative site.
- Blood supply limitation in the operative site.

WARNINGS!

- The important medical information given in this document should be conveyed to the patient.
- 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.
- Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
- No implant can withstand body loads without the biomechanical continuity of the bone.
- During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
- To avoid excessive wear or 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.
- 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.
- A successful result is not always achieved in every surgical case.

- This fact is especially true in the case where other patient's conditions may compromise the results.
- 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.
- Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
- 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.
- 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.
- The implant may break or become damaged as a result of strenuous activity or trauma and may need to be replaced in the future.
- The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.

PRECAUTIONS!

- 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. hospital procedures.
- 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.
- Implants containing UHMWPE and sterilized by ionizing radiation, shall not re-sterilized under any circumstance even they are not used.
- Avoid notching, scratching, or striking the prosthesis. Do not use any component if damage is found or caused during setup or insertion
- Misuse of instruments or implants may cause injury to the patient or operative personnel.
- Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
- Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants.
- 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.
- Improper component selection, placement, positioning, or fixation may result in unusual stress conditions, reducing the service life of the prosthetic implants.
- Do not impact stem into the femoral canal after the components are assembled. Further impaction could damage the head component or taper attachment
- Protect the Hip System porous-coated surfaces from mechanical damage, and do not allow contact between the surface and any metallic or other hard surface. Do not allow the porous coating to interface with cloth or other lint-shedding or dirty materials prior to implantation. Do not rely on conventional cleaning techniques to remove lint, dirt, or body tissue from porous coating.
- Repeated assembly/disassembly of modular components could compromise the critical locking action of the Morse-style tapers. Use the trial components during trial reductions. Change the components only when clinically necessary.
- Do not assemble a Femoral Head, 12/14 Taper, onto a Femoral Stem taper that has had a femoral head previously removed. Use the Femoral Head only if taper exhibits minor scratches from previous femoral head assembly and removal. Do not use Head on excessively damaged stem tapers.
- Exercise care with the heads of femoral hip prostheses. Remove protective coverings only prior to implantation.

- Femoral Head, 12/14 Taper, Femoral Head must not be re-used if previously impacted and removed.
- While rare, intraoperative fracture or breakage of the instrument can occur.
- 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.
- 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:
- Inform the patient about the need for an osteoporosis evaluation. The orthopedic surgeon should have a basic understanding about osteoporosis and its treatments.
- 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.
- Ensure that appropriate intervention is initiated. The orthopedic surgeon should ensure that an osteoporosis evaluation is done, and appropriate intervention taken.

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 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.

WHAT HAPPENS AFTER SURGERY?

- It is essential to follow all of physician's postoperative directions and warnings.
- It is essential to confirm 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.

MAGNETIC RESONANCE COMPATIBILITY!

- Orthomed E implants made completely from or containing elements made of implantable steel were not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these implants (especially in the magnetic field with a significant induction) may pose a potential risk of, i.e.:
  - implant displacement or heating up,
  - artifacts on MR images.
- 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. Polypropylene clam pack are a typical primary packaging material, then packed into High Density Polyethylene rigid boxboard as a secondary packaging material.

- The packaging is equipped with the product label. The label (as a primary 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 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:
  - Implant damage (fracture, deformation or detachment).
  - Early or late loosening, or displacement of the implant from the initial place of insertion.
  - Possibility of corrosion as a result of contact with other materials.
  - Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
  - Compression on the surrounding tissue or organs.
  - Infection and/or Death.
  - Disassembly of modular components
  - Dislocation and subluxation
  - Early or late loosening of components
  - Ectopic ossification
  - Fatigue fracture
  - Heterotopic bone formation
  - Inflammatory reactions or osteolysis
  - Metal sensitivity
  - Perforation of the acetabulum or femur
  - Peripheral neuropathies
  - Possible detachment of coatings
  - Subclinical nerve damage
  - Trochanteric problems
  - Vascular complications
  - Wear
  - Bone fractures or "stress shielding" phenomenon causing loss of bone above, below or at the operative site.
  - Hemorrhage of blood vessels and /or hematomas.
  - Pain and/or Inability to perform everyday activities.
  - Mental condition changes.
  - Deep vein thrombosis, thrombophlebitis.
  - Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
  - Scar formation that could cause neurological impairment, or nerves compression and /or pain.

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. Patient receiving total hip prosthesis should be advised that the longevity of the implant may depend on their weight and level of activity.
2. Implant card should be provided together with each device i.e., femoral stem. Moreover, 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 will have received from healthcare provider when asked to prove the presence of an orthopaedic implant.
3. 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.
4. 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**.
5. 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.

SYMBOLS ON THE IMPLANT CARD!

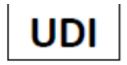
Patient name/ID

Date of implantation

Name and Address of the implanting healthcare institution/provider

Information website for patients

Device name



UDI as AIDC format

SYMBOLS ON THE LABELS!

Device name

Manufacturer

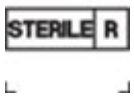
Authorized representative

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

L/R

Left/Right side Implant

ANT/ POST

Ant/Posterior orientation of implant

SYMBOLS ON THE LABELS!

Single sterile barrier system with protective packaging outside

UDI

Unique Device Identification