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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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Total Hip Prosthesis

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Total Hip Prosthesis

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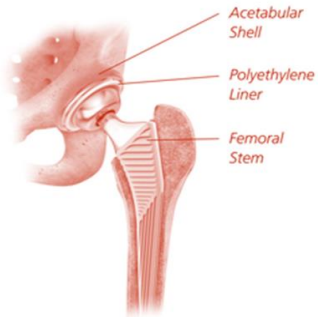
- Orthomed E has a variety of Total Hip Prosthesis. In this document the following items will cover:
  - AUTOFIT Femoral Stems;
  - AUTOFIT Femoral Heads;
  - AUTOFIT Bipolar Mobile Cup which is comprised of acetabular shells, acetabular liners and locking rings;
  - AUTOFIT Simple Mobility Cups
- Components are available in a variety of designs and size ranges intended for both primary and revision applications. All of materials we have machines are found acceptable for articulating surfaces of total hip prosthesis implants.



- 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.

Device Description and Materials

- AUTOFIT Standard Femoral Cemented Stem intended to be used for non-inflammatory degenerative joint disease such as osteoarthritis and femoral neck fracture for cemented arthroplasty and features a quadra-angular section distally and a rectangular section proximally. The stem is manufactured by forging or machining with geometrically defined cutter (as in turning, drilling, or milling) from stainless steel (SS) per ISO 5832-1, stainless steel (SS) per ISO 5832-9, or chromium cobalt as per ISO 5832-12 and has a glass-beaded surface finish (smooth-surfaced). The stem is available in standard with a CCD neck angle of 135°, tapered cone 12/14 for lengths 112mm–162mm, and cone length 12mm for sizes 8–16 (9 sizes).
- AUTOFIT Standard Femoral Cemented Long Stem intended to be used for revision procedures where other treatments or devices have failed for cemented arthroplasty and features a quadra-angular section distally and a rectangular section proximally. The stem is manufactured by forging or machining with geometrically defined cutter (as in turning, drilling, or milling) from stainless steel (SS) per ISO 5832-1, stainless steel (SS) per ISO 5832-9, medical-grade titanium alloy (TA) per ISO 5832-3/ASTM F136, or chromium cobalt as per ISO 5832-12 and has a glass-beaded surface finish. The stem is available in standard with a CCD neck angle of 135°, tapered cone 12/14 for length 250mm, and cone length 12mm for sizes 9–13 (5 sizes). The purpose of this structure is to ensure primary fixation of uncemented stems, transfer loads to calcar bone, and avoid prosthesis subsidence.
- AUTOFIT Standard Femoral Cementless Stem intended to be used for non-inflammatory degenerative joint diseases such as osteoarthritis and femoral neck fracture and features a quadra-angular section distally and a rectangular section proximally. The stem is manufactured by forging or machining with geometrically defined cutter (as in turning, drilling, or milling) from medical-grade titanium alloy (TA) per ISO 5832-3/ASTM F136. The stem possesses a 150-200 µm titanium plasma spray coating on a pre-prepared surface and 90-120 µm hydroxyapatite (HA), conforming to ASTM F1580, ISO 13779-2 and ASTM F1185. The stem is available in standard with a CCD neck angle of 135°, tapered cone 12/14 for lengths 115mm–170mm, and cone length 12mm for sizes 8–16 (9 sizes).
- AUTOFIT Femoral Heads are intended to be used for non-inflammatory degenerative joint disease such as osteoarthritis, femoral neck fracture, and revision procedures where other treatments or devices have failed. Femoral Heads are designed to connect to the femoral stem via the 12/14 taper. Femoral heads are provided in dimension 22.2 for neck offset -2.5, 0, +2.5, +5.0 and dimensions 28, 32, and 36 for neck offset -3.5, 0, +3.5, +7.0 for proper anatomic fit. Heads are highly polished for reduced friction and wear. 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.

- AUTOFIT Bipolar Mobil Cup intended to be used for femoral neck fracture and aseptic necrosis of the femoral head and neck. Bipolar Mobil Cup which comprises the following:
    - Acetabular Shells are traditionally machined from Stainless Steel (SS) per ISO 5832-1, ISO 5832-9 or Chromium Cobalt as per ISO 5832-12; The solid shells are provided in multiple sizes, dimensions and ranges for proper anatomic fit. Acetabular Shells are provided in sizes 40-43 mm outer diameter with 1 mm increment between sizes, which are meant to articulate with femoral heads size 22.2 mm and sizes 44-60 mm outer diameter with 1 mm increment between sizes, which are meant to articulate with femoral heads size 28 mm. Acetabular Shells are highly polished and smooth-surfaced.
    - Acetabular liners and locking rings are machined from ultra-high-molecular-weight polyethylene (UHMWPE) per ISO 5834-1 and 2 and are available in one series standard together to form the locking mechanism with the acetabular shells.
- AUTOFIT Simple Mobility Cups intended to be used for non-inflammatory degenerative joint disease such as osteoarthritis, and a vascular necrosis, inflammatory degenerative joint disease such as rheumatoid arthritis, correction of functional deformity, revision procedures where other treatments or devices have failed, and treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement which are unmanageable by other techniques. AUTOFIT Simple Mobility Cups are offered in three series:
    - AUTOFIT Simple Mobility Cemented Cups are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2 and provided in a series of lipped shapes with an inner diameter of 28 for outer diameters 44 and 46mm and an inner diameter of 32 for outer diameters 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, and 64 mm, with a 10° lip angle for both for proper anatomic fit. It incorporates a metal orientation marker for radiographs, made of rough titanium 6-aluminium 4-vanadium alloy per ISO 5832-3 as the material of the X-ray indicator.
    - AUTOFIT Simple Mobility Cemented cup (BIMOTION) liners are designed for use with compatible shells to create a system with two articulating interfaces in the acetabular joint space of the hip. Liners are available in a series of lipped liners and are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2 and are available with inner diameters of 22.2 with outer diameters from 38-40 mm and inner diameters of 28 mm with outer diameter from 42-58 mm in 2 mm increments. Shells are manufactured by forging or machining with a geometrically defined cutter (as in turning, drilling, or milling) from stainless steel (SS) per ISO 5832-1, titanium alloy (TA) per ISO 5832-3, or chromium cobalt as per ISO 5832-12 and are available with an inner diameter of 22 for outer diameters 44, 46 and an inner diameter of 28 for outer diameters 48, 50, 52, 54, 56, 58, 60, 62, and 64 mm with vertical grooves on the outer blasted surface and a mirror polished inner surface finish.
    - AUTOFIT Simple Mobility Cementless Cup (BIMOTION) liners are designed for use with compatible shells to create a system with two articulating interfaces in the acetabular joint space of the hip. Liners are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE) per ISO 5834-1 and 2 and are available with inner diameters of 22.2 with outer diameters from 38-40 mm and inner diameters of 28 mm with outer diameter from 42-58 mm in 2 mm increments. Shells are available in a series of lipped angle 5° and are manufactured by forging or machining with a geometrically defined cutter (as in turning, drilling, or milling) from titanium alloy (TA) per ISO 5832-3 and are available with multiple inner diameters and outer diameters from 48 mm to 64 mm in 2 mm. The shells possess a 45 µm titanium plasma spray coating on a pre-prepared surface and 45 µm

hydroxyapatite (HA), conforming to ASTM F1580 and ISO 13779-2.

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.

INTENDED USE!

Orthomed E® AUTOFIT Total Hip Prostheses are intended for use in Total Hip Prostheses (THP) for reduction or relief of pain and/or improved hip function in skeletally mature patients (over 21 years of age).

INDICATIONS!

Destruction of hip joint caused by degenerative[1], posttraumatic[2], or inflammatory diseases.

Fracture or a vascular femoral head necrosis[3]

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

- Noninflammatory degenerative joint disease including osteoarthritis[4] and vascular necrosis;
- Rheumatoid arthritis[5].
- 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.; and
- Revision of previously failed total hip arthroplasty.

1This is a degenerative joint disease that affects mostly middle-aged and older adults. It may cause the breakdown of joint cartilage and adjacent bone in the hips

2 Posttraumatic arthritis: This can lead to a serious hip injury or fracture. The cartilage may become damaged and lead to hip pain and stiffness over time.

3 An injury to the hip, such as a dislocation or fracture, may limit the blood supply to the femoral head. This is called osteonecrosis (also sometimes referred to as avascular necrosis). The lack of blood may cause the surface of the bone to collapse, arthritis will result. Some diseases can also cause osteonecrosis

4 Osteoarthritis: This is an age-related wear and tear type of arthritis. It usually occurs in people 50 years of age and older and often in individuals with a family history of arthritis. The cartilage cushioning the bones of the hip wears away. The bones then rub against each other, causing hip pain and stiffness. Osteoarthritis may also be caused or accelerated by subtle irregularities in how the hip developed in childhood.

5 Rheumatoid arthritis: This is an autoimmune disease in which the synovial membrane becomes inflamed and thickened. This chronic inflammation can damage the cartilage, leading to pain and stiffness. Rheumatoid arthritis is the most common type of a group of disorders termed inflammatory arthritis.

TARGET POPULATIONS!

Total Hip Prosthesis is a treatment for skeletal maturity patients (over 21 years of age) with noninflammatory degenerative joint disease, juvenile rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusio acetabuli, certain hip fractures, benign and malignant bone tumours, arthritis associated with Paget's disease, ankylosing spondylitis, and rheumatoid arthritis.

However, there are no absolute age or weight restrictions for total hip replacements, since this type of surgery is based on a patient's pain and disability, not age. Total hip replacements have been performed successfully at all ages, from the young teenager with juvenile arthritis to the elderly patient with degenerative arthritis. However, most patients who undergo total hip replacement are aged 50 to 80, but orthopaedic surgeons evaluate patients individually. Total hip replacements have been performed successfully at all ages, from the young teenager with juvenile arthritis to the elderly patient with noninflammatory degenerative joint disease, rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusio acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease, ankylosing spondylitis and juvenile rheumatoid arthritis treating with Total Hip Prosthesis.

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

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 should 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 patients' 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. Hip load is increasing linearly with body weight, and thus obesity is considered a risk factor that may compromise the long-term performance of THA. However, with increasing walking speed, hip load increases exponentially, which makes THA more demanding for younger patients. Especially frequent high peak loads as they occur, e.g., in contact sports, challenge the clinical outcome of THA. emphasize that patients must be aware that "operation of total hip arthroplasty marks the beginning and not the end of treatment," and this treatment should

last for up to 200 million gate cycles in a young patient.

- 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.
- Cobalt-chrome-based implants contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

  Cobalt; CAS No. 7440-48-4; EC No. 231-158-0
- The research does, however, support the finding that the cobalt released from cobalt chrome alloys in orthopaedic implants only amounts to a mere 1/25 of the exposure required to identify any systemic effects in patients.
- The accelerated aging process on UHMWPE-based implants and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces did not reveal any degradation.
- Questions regarding carcinogenicity have been raised in the literature; no test reports or studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.
- Unequal leg length can be caused by improper selection of the stem dimensions or problems occurring during surgery. Temporary pain may occur after THA since the muscles of the compromised hip before surgery have to readapt to the anatomical normal condition that shall be recovered. Chronic pain can be caused by nerve damage during surgery or by muscles rubbing against components of the prosthesis.
- The most frequent reason for revision surgery is the loosening of the stem and/or the acetabular cup, i.e., the loss of contact between bone and implant. The reasons are various, such as a misalignment of the cup that may increase hip loads and promote femoral loosening. Insufficient contact between bone and implant may locally cause stress shielding because the implantation of a femoral stem results in a load transmission, which differs from the natural physiological loading conditions in the femur. Where the bone-implant contact is weak, an adaptive remodeling occurs, and bone is locally resorbed where it no longer carries load.
- The use of antibiotics in THA patients may have eliminated Helicobacter pylori, which is thought to be a major risk factor for stomach cancer and may have contributed to the lower risk of stomach cancer. In addition, the patient shall disclose if they have undergone knee surgery before.
- In the event of an MRI examination request, patients should inform the requesting physician that they have an implant in order to assess whether an MRI is absolutely necessary or whether another type of scan could be envisaged to achieve the desired results. If the MRI examination is indispensable, the requesting physician should follow the MRI examination conditions provided by Orthomed E. This form should be systematically handed in by the patient through the implant card when the appointment for the MRI scan is made. A second verification of the examination conditions should be conducted by the radiographer or radiologist. The risks induced by the presence of a medical device in this magnetic resonance environment are set out below:
  - By inducing undesirable movements or the possible dislodging of the implant, these forces can damage surrounding tissues
  - Consequential heating of the implanted medical device and adjacent tissues is often localized and can be intense with a major risk of burns
  - Malfunction of the implant
  - The presence of metallic implants can generate artefacts on MR images. The artefacts generated can make it impossible to interpret the image or wrongfully lead to the interpretation of a

lesion and thus prevent a precise diagnosis of the area targeted by the MRI examination.

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.
- 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 be re-sterilized under any circumstance even if they are not used.
- The application of uncemented THA is limited by factors that reduce bone growth capability, such as age or pathological conditions, because long-term stability depends on the patient's health status. Cement filling can compensate for bone defects and allows for a lower degree of accuracy in bone shaping in older patients with less vital bone tissue. Uncemented THA is preferred in younger patients because their bone tissue is biologically more active. Additionally, the likelihood of revision surgery for this group is higher, and the presence of cement and cement debris makes the procedure more difficult.
- 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.
- The taper components must be clean and dry before assembly. Prior to assembly, surgical debris and fluid must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, and female seat of the proximal body must be clean and dry before assembly. Impact according to the recommended surgical technique. Scratching of femoral heads and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint.
- 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.
- Correct selection of the prosthesis is extremely important. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.
- X-ray templates are used to estimate the size of the product to be used. The anatomy of the patient ultimately determines the size of the product for an individual patient. The extent of bone preparation is determined intraoperatively by reaming and/or broaching starting at the smallest size and continuing until bleeding cancellous bone is reached. Trial prostheses should be used to evaluate the position of the final implant and the joint range of motion. The final size of the implant selected during surgery may differ from the size originally planned during preoperative assessment or the combination chosen during preliminary trialing.
- Care is to be taken for Cemented Application to ensure complete support of all components of the prosthesis embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Complete cleaning including complete removal of bone chips, bone cement fragments, and metallic debris, prior to closure of the prosthetic site is critical to prevent accelerated wear of the articular surfaces of the prosthesis.
- Adequate fixation at the time of surgery is critical to the success of the procedure. Uncemented femoral stems and acetabular shells must press fit into the host bone, which necessitates precise operative technique and the use of specified instruments. Bone stock must be adequate to support the device.
- The smaller sized femoral implants are intended for patients with narrower intramedullary femoral canals. The geometry of these implants is reduced to accommodate the anatomy of the narrower intramedullary femoral canal, which also decreases the fatigue-strength and load-bearing characteristics of the implant
- Other Modular Components (Femoral Head and Stems). Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fatigue fracture or disassociation of the product. The taper components must be clean and dry before assembly. Prior to assembly, surgical debris and fluid must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body must be clean and dry before assembly. Impact according to the recommended surgical technique. Scratching of femoral heads and distal stem

tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint.

- Tapered cone 12/14 Stems should only be used in combination with tapered cone femoral heads 12/14. Cobalt chrome femoral heads with 12/14 Taper are designed for use with cobalt-chromium-molybdenum, titanium alloy and ISO 5832-9 stainless steel femoral components with 12/14 Taper.
- NEVER combine components made by different manufacturers.
- Always follow the recommended surgical technique. Failure to adhere to the advised assembly instructions may have potential to increase risk of fretting corrosion, fretting fracture or disassociation of the product. Prior to assembly, surgical debris must be cleaned from the interior of the female seat to ensure proper locking. Ensure components are firmly seated to prevent disassociation.
- Care should be taken to restore the proper joint alignment and to balance ligamentous tension.
- Malalignment of the joint can cause excessive wear, loosening of the prosthesis, and pain leading to premature revision of one or more of the prosthetic components.
- The hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty
- NEVER combine these metals in non-articulating contact surfaces:
  - Stainless steel (excluding the stainless steel described in ISO 5832-9)/cobalt chrome alloy
  - Stainless steel (excluding the stainless steel described ISO 5832-9)/unalloyed titanium.
- Do not attempt to seat the implant beyond the envelope of femoral bone preparation. Forcing to seat the implant beyond the prepared femoral bone may increase the chance of bone fracture. In some cases, a portion of the proximal body with or without coating may be visible above the proximal resection level.
- Bipolar cups should not be used in combination with skirted (collared) femoral heads. Once a removal key has been used to disassociate a head from a bipolar cup, the head must be replaced with a new implant to avoid potential scratch damage.
- Stem length critically influences device stability. A longer stem would improve stability; however, more reaming of medullar canal would be required, cement would have to be injected more distally and less bone would be available for revision surgery. In primary THA a stem in the range of 130 to 140 mm presents a reasonable compromise.
- 32 mm and 36 mm are the most commonly used femoral head sizes, as reported by several arthroplasty registries. One postulated disadvantage of larger heads might be corrosion at the taper-trunnion junction potentially resulting in groin pain and influencing the longevity of THA. Depending on the articulating materials, 32 mm and 36 mm heads seem to be superior regarding dislocation rate and implant survival. Until recently, no long-term reports have been published confirming the safety of a femoral head larger than 36 mm.

DEVICE USERS AND SURGICAL TECHNIQUES!

- While there is no need to deviate from the ISO series of ISO 7206, our hip joint has been designed despite the fact that numerous diverse designs of hip joint prosthesis are in use around the world. As a result, our hip 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 hip replacement surgical requirements. However, none of the hip replacement implants in our lineup have any patents because they were created to be standard hip 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.
- The surgeon must have experience in the preparation of the bone cement from the solid (a powder of pre-polymerized MMA) and liquid (the MMA monomer) components,

which is done in a short time window just before the cement is needed to fix the implant

- The use of hip ancillaries, such as cement restrictors and PMMA, in the case of hip cement application is explained in detail in the surgical technique protocol provided by Orthomed E for hip replacement surgeries. Cement restrictors 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.
- The surgical protocols for total hip replacement provide additional procedural information. The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style
- All AUTOFIT Femoral Heads are compatible with AUTOFIT Standard Femoral Stems
- AUTOFIT Femoral Heads size 22.2 are compatible with AUTOFIT Bipolar Mobil Cup sizes 40-43mm with 1mm increment and AUTOFIT Femoral Heads size 28 are compatible with AUTOFIT Bipolar Mobil Cup sizes 44-60mm with 1mm increment.
- AUTOFIT Femoral Heads size 28 are compatible with AUTOFIT Simple Mobility Cemented Cups sizes 44 and 46mm and AUTOFIT Femoral Heads size 32 are compatible with AUTOFIT Simple Mobility Cemented Cups sizes 48-64mm with 2mm increments.
- AUTOFIT Femoral Heads size 22.2 are compatible with AUTOFIT Simple Mobility Cemented Cups (BIMOTION) size 44 and AUTOFIT Femoral Heads size 28 are compatible with AUTOFIT Simple Mobility Cemented Cups (BIMOTION) sizes 46-64mm with 2mm increments.

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.
- 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® AUTOFIT Total Hip Prostheses 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 below. Once an unevaluated component is added to the device 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® AUTOFIT Total Hip Prostheses 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 0.115 N with a mean offset angle of 2°, and the maximum magnetically induced torque is 0.028 N with a maximum deflection angle of 4°.
    - 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 1.9°C at 1.5- tesla after 15 minutes of continuous scanning.
- Maximum artefact length in the three directions of length, width, and thickness is 49.89 mm, 43.54 mm, and 32.82 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 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 establish.

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 (Stem, Head or Cup) is provided either in
- PETG clam pack are a typical primary packaging material, then packed into High Density Polyethylene rigid boxboard as a secondary packaging material.
- Polyamide/Vacuumed Polyethylene Pouch as a primary pack, then (PET trans/Alu/PE Trans Vacuum) Pouch as a secondary pack, then packed into Plain Carton boxboard as a tertiary Packaging material
- The packaging is equipped with the product label. Labels are affixed to the primary package and on three sides of the boxboard; on the fourth side, a chemical indicator is positioned to indicate the device sterilization status. 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:
  1. Implant damage (fracture, deformation or detachment).
  2. Early or late loosening, or displacement of the implant from the initial place of insertion.
  3. Possibility of corrosion as a result of contact with other materials.
  4. Body reaction to implants as foreign bodies e.g. possibility of tumor metaplasia, autoimmune disease and/or scarring.
  5. Compression on the surrounding tissue or organs.
  6. Infection and/or Death.

7. Disassembly of modular components
8. Dislocation and subluxation
9. Early or late loosening of components
10. Ectopic ossification
11. Fatigue fracture
12. Heterotopic bone formation
13. Inflammatory reactions or osteolysis
14. Metal sensitivity
15. Perforation of the acetabulum or femur
16. Peripheral neuropathies
17. Possible detachment of coatings
18. Subclinical nerve damage
19. Trochanteric problems
20. Vascular complications
21. Wear
22. Bone fractures or “stress shielding” phenomenon causing loss of bone above, below or at the operative site.
23. Hemorrhage of blood vessels and /or hematomas.
24. Pain and/or Inability to perform everyday activities.
25. Mental condition changes.
26. Deep vein thrombosis, thrombophlebitis.
27. Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
28. Scar formation that could cause neurological impairment, or nerves compression and /or pain
29. Leg length discrepancy
30. Fever after the surgery
31. Redness, swelling, or bleeding or other drainage from the incision site that doesn’t stop after a few days after the surgery
32. Increased pain around the incision site after the surgery
33. Pain in the lower leg that is unrelated to the incision after the surgery
34. New or increased swelling of the lower leg after the surgery
35. Chest pain after the surgery
36. Shortness of breath after the surgery.
37. Trunnionosis due to the use of different materials at modular junctions
38. Releasing of metal ions contribute to the increased incidence of melanoma
39. Increasing stomach cancer risk is due to the probability of the presence of helicobacter pylori

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.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS!

- To be able to achieve the intended benefits, the Orthomed E® AUTOFIT Total Hip Prostheses must be able to be implanted in the proximal femur.
- Orthomed E® AUTOFIT Total Hip Prostheses offer many clinical benefits for patients who undergo total hip arthroplasty including, the reduction or relief of pain, improved quality of life, and improved hip function. These accusations are supported by a study of clinical data derived from one or more of the following sources: national joint replacement 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 state of- the-art for use in primary and/or revision Total Hip Arthroplasty (THA) to relieve pain and restore hip joint function.
- The progress of complete hip replacement has presented the surgeon with a method of regaining mobility and lowering discomfort using implanted prosthetic devices. While

these devices have proven to be successful in achieving these goals, they are made of metal, plastic, or other biomaterials. As a result, any total hip replacement system cannot be anticipated to sustain the same activity and loads as typical healthy bone. The system will not be as strong, dependable, or durable as a normal human hip joint, and it will not have an indefinite lifespan. The surgeon must inform patients about the device limitations.

- The surgeon should be cautious of the following while employing complete joint 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 in total joint replacement. Total joint prostheses necessitate precise positioning and appropriate bone support. As with all prosthetic 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 total joint replacements:
        - 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 a hip replacement will last, using available arthroplasty registry data, it estimate that about three-quarters of hip replacements last 15–20 years and just over half of hip replacements last 25 years in patients with osteoarthritis. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

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.

6. 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 regard 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 IMPLANT CARD!

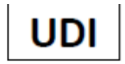
Patient name/ID

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

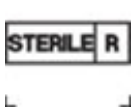
Authorized representative

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:

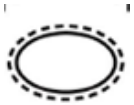
Keep dry

Consult instructions for use

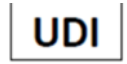
Caution

Left/Right side Implant

Ant/Posterior orientation of implant



Single sterile barrier system with protective packaging outside



Unique Device Identification

MR Conditional

Importer

Distributer