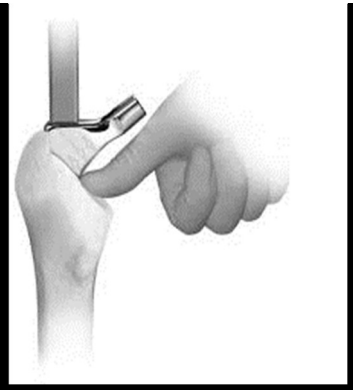

We help people do what they love by restoring mobility. We are committed to providing the best customer experience in orthopedics through our premium, clinically proven products, coupled with unparalleled service and value.

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.

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Cement Restrictor

CE 0653

EGYPT

O-0517-PH-05-19

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Cement Restrictor

IFU 001/07

PROFESSIONAL USE ONLY

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 adopt with the modern cementing techniques that rely on occluding and sealing of the intramedullary canal in order to generate sufficient pressure to enhance cement penetration. Each plug design we provide, be able to withstand intramedullary pressure levels which can be expected with contemporary cementing procedures and should occlude the canal sufficiently to prevent leakage.
- Cement Restrictor sizes are available in three sizes 'Small' Φ 16, which fit for femoral stems sizes 08-10; 'Medium' Φ 18, which fit for femoral stems sizes 11-13 and 'Large' Φ 20, which fit for femoral stems sizes 14-16.

Our artificial cement restrictors have different abilities to meet these recommendations and the surgeon should carefully choose the right product.

MATERIALS?

All of materials we have machined are found acceptable.

Ultra-high-molecular-weight polyethylene (UHMWPE) per ISO 5834-1 and 2 as material of cement restrictor and Wrought stainless steel per ISO 5832-1, Wrought high nitrogen stainless steel per ISO 5832-9 or Wrought titanium 6-aluminium 4-vanadium alloy per ISO 5832-3 as materials of X-ray indicator.

INDICATIONS!

The product line of the medical device is an implantable device designed to be inserted into the medullary canal of a bone during orthopaedic surgery to prevent cement progression in the diaphysis and therefore facilitate cement pressurization during the introduction of an implant. It may incorporate a metal orientation marker for radiographs and is not intended for spinal indication.

CONTRAINDICATION!

The choice of particular device must be carefully weighed against patient's overall condition, beside taking into account the information referred to in IFU 001/05 'Total Hip Prosthesis'

Conditions listed below may preclude or reduce the chance of successful outcome:

- Infection (or a history of infection), acute or chronic, local or systematic.
- Severe musculature, neurological or vascular deficiencies, which compromise the affected extremity
- Destruction of bone or poor bone quality which may affect stability of prosthesis
- Any concomitant disease which may compromise the function for the prosthesis.
- Severe osteoporosis
- Severe deformities, dislocation congenital
- Local tumor of the bone
- Systematic and metabolic disorders
- History of infectious disease or falls
- Drug addiction and/or abuse
- Obesity. An overweight or obsess patient can produce loads on the prothesis which can lead to failure of the fixation of the device or the failure of the device itself

- High levels of physical activity also involving severe jarring in which prothesis is subject to a pounding and/or excessive strains (e.g. heavy physical labor, competitive sports, marathon runs etc.)

Important[1]: If the use of total hip system has been determined to be the best for the patient and the patient has one or more of the conditions outlined above, it is important to instruct the patient on the effects of these conditions regarding the success of his surgery. It is recommended to advise the patient to any activities which are suitable to reduce the effects of these conditions.

These implants should be used by orthopaedists with appropriate training and experience in hip arthroplasty only.

WARNINGS!

The important medical information given in this document should be conveyed to the patient, beside the information referred to in IFU 001/05 'Total Hip Prosthesis'.

- The selection of proper 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.
- 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 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.

Important[2]: This device should not be used with implant components from another manufacturer since the matching of parts from different manufacturers cannot be assured.

This device has not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

PRECAUTIONS!

- Implant is intended for single use only. After in case 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 shall not re-sterilized under any circumstance even they are not used.
- Misuse of instruments or implants may cause injury to the patient or operative personnel.
- Certain femoral prostheses rely on subsidence (average of 1.2mm) for maintenance of fixation. The surgeon should be well aware of this subsidence factor when utilizing the Cement Restrictor
- 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.

- 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 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.
- 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 procedure begins, all implants should be carefully checked to ensure that there is no damage (surface scratching, dents and shape deformations). Damaged implant cannot be inserted into the body.

Utilization and Implantation

- It is recommended that all sizes of cement restrictors and trails be available at surgery.
- The femoral canal is reamed in a manner consistent with the type or style of femoral prosthesis to be utilized.
- The size of hip prosthesis to be implanted is determined in the normal manner.
- The correct size trial hip prosthesis is placed next to the calibrated restrictor inserter. The depth to which the restrictor is to be implanted is then noted.

NOTE: A distance of 2cm between the distal tip of the prosthesis and the proximal surface of the cement restrictor should be maintained.

- The inserter with trial attached, is placed within the medullary canal to the predetermined depth.
- If a snug fit is obtained, the trial number is noted and cement restrictor with the identical number is presented into the sterile field.

  NOTE: If a snug fit is not present, sizing should continue until the proper fit is found.
- The cement restrictor is threaded onto the inserter.

  NOTE: The end with an etched sizing number is the proximal surface when implanted.
- The cement restrictor is then placed within the medullary canal to the predetermined depth.

  NOTE: The outside diameter of the cement restrictor is larger than the corresponding trial because the implant uses flexible fins that assist in obtaining a tight fit when implanted.
- The inserter is then disengaged from the cement restrictor by unscrewing in a counterclockwise direction.

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, since our implant is supported with x-ray indicator is fabricated from Stainless Steel or Titanium Alloyed.
- 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 important medical information given in IFU 001/05 'Total Hip Prosthesis' should be as well conveyed to the patient.

MAGNETIC RESONANCE COMPATIBILITY!

- Orthomed E Cement Restrictor has not been tested for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. Scanning a patient who has this device may result in patient injury.
- Risks associated with other passive implants in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.
- Nevertheless, Orthomed E Cement Restrictor is supported with X-ray indicator made completely from either
  - Implantable stainless steel was not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these accessories (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.
  - Or, implantable titanium is 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. Sterile version - one piece of the product. Polyamide/Vacuumed Polyethylene clear pouches are a typical primary packaging material + PET plastic pouch as a secondary packaging, then packed into solid boxboard as a tertiary 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.

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. 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.

SYMBOLS ON THE LABELS!