



Hip Implant Product Range

WARNING: The instruments described may only be used in combination with OrthoMedFlex products!

Instructions for Use OMF-IFU-001 RevB

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Caution:

Carefully read all the instruction and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

1 General Instructions

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. OrthoMedFlex instruments and implants should only be used with approved devices and accessories.

2 Device Descriptions

All devices described herein are supplied individually sterile packed and are intended for single patient use only. Additionally, all devices described herein are available in a range of sizes to allow correct selection to match the patient's anatomy.

Kratos™ Hip Stem

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with HA coating per ISO 13779-2

The Kratos Hip Stem is straight and tapered with a lateral chamfer to aid insertion intended for use without bone cement only. The stem has both vertical and horizontal grooves to resist axial and torsional loading. The stem is HA coated to promote biological fixation.

Orion™ Hip Stem

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with titanium bead and powder coating per ASTM F67

The Orion Hip Stem has a tapered wedge geometry and is intended for use without bone cement only. The stem is proximally coated with a titanium bead and powder coating to promote biological fixation.

TSI™ Hip Stem

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with titanium and HA plasma spray coating per ASTM F67 and ISO 13779-2 respectively.

The TSI Hip Stem is an anatomically curved tissue sparing implant. The patient's femoral neck is preserved during implant of the device. The stem is sequentially coated with titanium then HA to promote biological fixation.

Pelion™ Hip Stem

Material: High N₂ stainless steel per ISO 5832-9

The Pelion Hip Stem has a dual tapered geometry and is intended for use with bone cement. The stem has a polished surface finish.

Pelion™ Distal Centralizer

Material: Polymethyl methacrylate (PMMA)

The Pelion Hip Stems are to be used with the Pelion Distal Centralizer to ensure a uniform cement mantle is formed. The distal centralizer is placed on the end of the stem prior to definitive placement

Pelion™ Cement Plug

Material: Polyethylene (PE)

The Pelion Cement Plug is to be placed in the femoral canal prior to cementing the Pelion Hip Stem into place. The cement plug is to be placed distal to the stem location, and is used to prevent cement from filling the femoral canal

OrthoMedFlex CoCr Femoral Heads

Material: Cobalt-chromium-molybdenum alloy per ISO 5832-12

The OrthoMedFlex CoCr Femoral Head is spherical and highly polished. The OrthoMedFlex CoCr Femoral Head is intended to connect via 12/14 Morse taper to the Kratos, Orion, TSI, or Pelion hip

stem. The OrthoMedFlex CoCr Femoral Head is intended to articulate within the Tryon Acetabular Cup's UHMWPE liner.

OrthoMedFlex Ceramic Femoral Heads

Material: BioloX® Delta (Alumina and zirconia) or Forte® (Alumina) Ceramic

The OrthoMedFlex Ceramic Femoral Head is spherical and highly polished. The OrthoMedFlex Ceramic Femoral Head is intended to connect via 12/14 Morse taper to the Kratos, Orion, TSI, or Pelion hip stem. The OrthoMedFlex Ceramic Femoral Head is intended to articulate within the Tryon Acetabular Cup's UHMWPE liner.

Warning: The OrthoMedFlex BioloX® Delta Ceramic Femoral Head (containing Zirconia) is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that, when used with polyethylene acetabular cups, the partially stabilized Zirconium ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the long term biological effects of these particulates are unknown.

Tryon™ Acetabular Cup

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with titanium bead and powder coating per ASTM F67

The Tryon Acetabular Cup is hemispherical with an external titanium bead and powder coating and internal locking features for engaging the Tryon Acetabular Liner. The cup is available in no-hole and 3-hole variants to allow use of supplemental bone screws if required. Both variants include a threaded apical hole for insertion. The cup is intended for use without bone cement only.

Tryon™ Acetabular Liner

Material: Crosslinked UHMWPE per ASTM F648

The Tryon Acetabular Liner is hemispherical with external locking features to engage the Tryon Acetabular Cup. The liner's internal surface is intended to articulate against the Tryon CoCr Femoral Head. The liner is available in a neutral, 10° lipped, 20° lipped, lateralized, and constrained variants to allow the option to address potential joint stability concerns.

Warning: Constrained liners restrict the range of motion (ROM) in order to capture the femoral head. Constrained liners will have a reduced ROM. ROM analysis has shown that the worst case liner has the following ROM values: Flexion/Extension - 120°, Abduction/Adduction - 71°, Internal/External rotation - 112°.

Tryon™ Bone Screw

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136

The Tryon Bone Screw is intended for use with the 3-hole variant of the Tryon™ Acetabular Cups. The screw's thread is designed for use in cancellous bone.

Tryon™ Hole Cover Screw

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136

The Tryon Hole Cover Screw is intended to cover the apical insertion hole or unused supplementary bone screw holes in the Tryon™ Acetabular Cup

BiPolar Head

Material: High Nitrogen Stainless Steel per ISO 5832-9 and UHMWPE per ASTM F648

The BiPolar Head mates with a 28mm CoCr femoral head and a femoral stem to complete a hip hemiarthroplasty. The CoCr femoral head articulates against a UHMWPE insert, and the highly polished outer shell articulates against the patient's natural acetabulum.

3 Indications

Components of the OrthoMedFlex hip replacement range are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

OrthoMedFlex's Kratos, Orion, and TSI femoral stems and Tryon acetabular cups are intended for cementless fixation only. OrthoMedFlex's Pelion femoral stems are intended for cemented fixation only.

OrthoMedFlex's constrained liner components are indicated particularly for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

OrthoMedFlex's BiPolar Head is intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The BiPolar Head is indicated for bone fractures or pathologies involving only the femoral head/neck and/or proximal femur, such as:

- Acute femoral head or neck fracture
- Fracture dislocation of the hip
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly

- Degenerative arthritis involving only the femoral head

4 Contraindications

a) In general, prosthetic components require adequate bone support for correct fit and function. The use of prosthetic components is therefore contraindicated where any pathological condition may reduce the quantity and or strength of the bone which is supporting the prosthesis. Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic arthroplasty should be considered based on the patient's overall evaluation and the possibility of alternative treatment. Examples of such conditions include; osteoporosis, osteomalacia, osteogenesis imperfecta, or hypophosphatemia. Other contraindications include:

- Conditions limiting blood supply to the bone or joint.
- Systemic or local infection.
- Previous high dose radiotherapy.
- Psychological or neurological conditions which would restrict the patient's ability or compliance in restricting physical activity.
- Skeletal immaturity
- Conditions or activity which may place excessive load on the components such as; obesity, muscle, tendon & ligament deficiencies, multiple joint disabilities, and Charcot joints

The OrthoMedFlex BioloX® Delta Ceramic Femoral Head (containing Zirconia) is contraindicated for use with any other than a UHMWPE cup or a metal backed UHMWPE cup. This head must only be used with the Tryon Cup with a UHMWPE Tryon Liner.

The OrthoMedFlex constrained liners are contraindicated particularly for active patients. OrthoMedFlex's constrained liners are also contraindicated for use with the OrthoMedFlex TSI stem due to decreased range of motion.

5 Patient Selection Precautions

The following factors may be relevant to the success of the procedure:

- The patient's body mass. An obese patient may place increased loads on the prosthesis which can lead to failure of the device or loosening in the bone. The risk increases with smaller size implants and increasing patient weight.
- The patient's regular type and level of activity or employment may affect the durability of the components. If the patient's occupation or activity includes significant impact loads, the increased forces can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with the bearing surface of prosthetic joints.
- Mental illness, or substance dependence which may tend to reduce the patient's compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, Preoperative tests should be conducted.

6 Possible Adverse Effects

- a) WEAR: The bearing surfaces of components may wear with use over time. The presence of third body particles of metal, bone or other materials which can develop as a result of the surgical procedure may cause abrasion of the articulating surfaces and lead to accelerated wear. Higher rates of wear may reduce the functional life of the hip replacement and result in the need for early revision surgery to replace the worn components.
- b) OSTEOLYSIS: Progressive bone resorption or osteolysis may occur around the prosthetic components as a consequence of the body's immune reaction to particulate wear debris. Particles are generated by interaction between the prosthetic components, as well as between the components and bone interface. Particles may also be generated by third-body debris between the articulating surfaces. Osteolysis can lead to failure of the fixation between the implant and bone requiring the removal or replacement of the prosthetic components.
- c) STRUCTURAL FAILURE: Deformation or fracture of implant components may result from failure to observe the Warnings and Precautions contained herein. Fracture of the implant can also occur as a result of traumatic injury, acute excessive loading, or improper anatomical alignment.
- d) FRACTURE: Pelvic or femoral: May occur intraoperatively, due to reaming, broaching or implant insertion. May occur postoperatively, due to prosthesis stress transfer caused by inappropriate early weight bearing or trauma.
- e) NERVE INJURY: Femoral, sciatic, peroneal nerve, and lateral femoral cutaneous nerve injury resulting in temporary or permanent nerve damage, with consequential pain or numbness of the affected limb.
- f) INFECTION: Local or systemic, acute post-operative wound infection and late onset prosthetic infection.
- g) HEMATOMA: Deep and superficial wound hematoma. Thromboembolic incidents including venous thrombosis, pulmonary embolus, cerebrovascular events or myocardial infarction.
- h) MATERIAL SENSITIVITY: Metal sensitivity reactions and/or allergic reactions to foreign materials may occur.
- i) Other possible adverse events include; decreased range of motion, dislocation, subluxation, leg length discrepancies, heterotopic bone formation, penetration of the femoral prosthesis through the femoral cortex, acetabular fracture, intrapelvic protrusion of the acetabular component or prosthetic femoral head, myositis ossificans or femoral impingement, vascular injury and/or

delayed wound healing, excess femoral medialization, or lateralization, causing gait change or pain in the joints of the affected or contralateral extremity.

7 Patient Consent

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular, the patient should be warned of limitations of the prosthetic device components being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged prostheses.

8 Preoperative

- Care should be taken when handling the prosthetic components to avoid damage to the surface of the device. Denting, notching or scratching can greatly reduce the tensile strength, fatigue resistance or wear properties of the component potentially leading to fracture or failure of the device.
- The porous or coated surfaces of the device should be protected from contact with gauze, cloth or other fiber-releasing materials.
- Surgical technique information is available for each device component. The surgeon should familiarize themselves thoroughly with the technique prior to consideration of the use of the device for any specific patient.
- Implants are only to be used with approved OrthoMedFlex instrumentation and/or devices. Implants have been designed and tested for use with one another, and use with third party devices is untested and strictly prohibited. The surgical instrumentation prescribed within the technique for the implantation of the prosthesis should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required.
- Instrumentation and implants should be sterilized according to the manufacturer's protocols. Do not resterilize component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.
- The OrthoMedFlex Hip Replacement Product Range, composed of devices described in section 1 of this document, has not been evaluated for safety and compatibility in the MR environment. The OrthoMedFlex Hip Replacement Product Range has not been tested for heating or migration in the MR environment.

9 Intraoperative

- Correct implant selection is extremely important. The use of preoperative imaging, templating and the intraoperative use of trial components is recommended to facilitate the choice of an optimum size and type of component for the specific patient. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant type or size may result in failure of the component and/or bone.
- The correct selection and positioning of the acetabular component and the choice of the appropriate neck length and/ or offset of the stem is important to prevent complications. Malposition of the components can result in loosening, or joint dislocation.
- Implants should be inspected before use. Do not use any implants that have visible damage such as scratching, chipping or bending. Do not use any implants that have been dropped on the floor.
- Penetration of the inner cortex of the pelvis should be avoided when drilling for or placing screws for fixation of the acetabular component as damage to neurovascular structures may occur from the drill or screws of excessive length. Similarly, drilling and/or placing screws in the acetabular prosthesis when oriented in an anterior or medial direction, is associated with a high risk of serious vascular injury. Screws must be completely seated in the shell to allow proper seating for the acetabular liner.
- The stem taper and femoral head bore must be clean and dry prior to assembly or postoperative separation of the head from the stem may occur. Assemble the stem and head by gentle placing the head on the stem while maintaining alignment, then sharply hitting the ball with the soft plastic hammer instrument to firmly connect the components.
- Before assembly of components, surgical debris must be cleaned from the surfaces. Debris may inhibit the component coupling mechanism. When inserting acetabular liners, ensure soft tissue does not impinge between the shell and liner. Modular components such as femoral heads must be assembled securely to prevent disassociation. Incorrectly seated acetabular liners may loosen and disassociate from the shell.
- If assembled modular components must be disassembled then those components must be disposed of and new components used. Disassembly can damage the components and cause a reduction in assembly strength. If a liner is disassembled from a cup, then the liner must be disposed of. If a femoral head is disassembled from a stem, both the stem and head must be disposed of.
- Where removal of the prosthetic femoral head is required in revision surgery, a ceramic head should not be placed on a previously used taper connection. Irregularities in the femoral taper may induce stress concentrations in the ceramic head, which could result in fracture of the ceramic head.
- Implants removed from the patient at revision surgery should never be reimplanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed.

- The wound site should be thoroughly cleaned of bone and other debris before closure. Range of motion should also be assessed before closure. Osteophytes, ectopic bone or old scar tissue causing impingement should be removed to reduce the possibility of reduced range of motion or dislocation.

10 Precautions for Specific Conditions

A higher incidence of sciatic nerve palsy is associated with arthroplasty in the treatment of congenitally dislocated hips. Also, in such patients, a pseudoacetabulum should not be utilized as a placement site for the acetabular cup.

11 Postoperative Care

- It is extremely important that patients are provided with clear directions regarding the extent, type and progression of post-operative physical activity. The level of weight bearing should be determined for the individual patient depending on the type of procedure and components used. In the event of bone grafting or extensive revision surgery a non-weight bearing period should be considered.
- Patients should be warned against unassisted activity, particularly the use of bathing and toilet facilities and other activities requiring significant non-gait motion of the hip.
- When manual patient handling is required, care should be taken to support the operative leg and pelvis to minimize the risk of dislocation.
- The use of post-operative physiotherapy is recommended to rehabilitate the muscles affecting hip function as physical activity is increased.
- Staged follow up with x-ray comparison to the immediate postoperative imaging is recommended to detect evidence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucencies, or osteolysis should be monitored carefully for the potential need of early revision surgery.
- The patient should be advised that prophylactic antibiotics therapy may be required for subsequent treatments, procedures, or situations which may result in bacteremia

12 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to OrthoMedFlex.

13 Sterilization and Resterilization

- Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilization of the implants is prohibited, as it may alter the mechanical integrity of the device.
- Unless specifically labeled sterile, instruments are supplied non-sterile and must be sterilized prior to use. During sterilization, the recommended wrap is 2 layers of 1-ply polypropylene (Kinguard KC600). A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following sterilization method is recommended:

STEAM AUTOCLAVE PRE-VACUUM
Condition: Double-Pouched
Temperature: 270° F (132° C)
Time: 4 minutes
Drying Time: 20 minutes

Note: Drying time is subject to variation depending on machine load.

14 Cleaning

- Implants are supplied sterile and intended for single use only. Dispose of the implant if the packaging is damaged. Cleaning of the implants is not recommended.
- Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning method is recommended.
- MANUAL CLEANING:
 - Instruments are to be cleaned immediately after use with warm water and a mild detergent. Instruments must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.
- CLEANING BEFORE STERILIZATION:
 - Instruments may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.
- Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH).
- Corrosive products or abrasive instruments should not be used.
- Instruments should be thoroughly inspected to ensure that they are in good condition and operating order.

15 Storage and Handling

- Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray respectively.

16 Limited Warranty / Liability

- OrthoMedFlex products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.
- OrthoMedFlex LLC shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. OrthoMedFlex LLC neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. OrthoMedFlex LLC intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

17 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate OrthoMedFlex location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate OrthoMedFlex location as listed below:

OrthoMedFlex LLC
1104 Spruce Street
Belmont, NC 28012
USA
Tel 1-844-663-3539
Fax 704-215-5833



18 Label Symbol Legend



Product code



Sterilized by Ethylene Oxide



Batch number



Sterilized by radiation



Consult instructions for use



Manufacture date



Do not resterilize



Manufacturer



Single Use



Expiration date



Do not use if package damaged



Warning