# Hip Replacement Product Range

*Femoral Heads, Stems*
*Acetabular Cups*

Instructions for Use 111-142-004 Rev. A Issue Date: 21-Nov-12

***Caution:***

***Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. Additional warnings and precautions may be included in the surgical technique or on the label. This product must only be used by trained, qualified persons, aware of the directions for use.***

***Federal law restricts this device to sale, distribution and use by or on the order of a physcian.***

## 1 Device Descriptions

All devices described herein are supplied individually sterile packed and are intend for single patient use only without the use of bone cement (cementless use only). Additionally, all devices described herein are available in a range of sizes to allow correct selection to match the patient's anatomy.

**Origin™ Hip Stem**

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

The Origin™ Hip Stem is straight and tapered with a lateral chamfer to aid insertion. The stem has both vertical and horizontal grooves to resist axial and torsional loading. The stem is HA coated to promote biological fixation.

**NEO-T™ Hip Stem**

*Material:* Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with titanium 6-aluminium 4-vanadium powder coating per ASTM F1580

The NEO-T™ Hip Stem is straight and tapered with a rectangular cross-section. The stem has a distal slot and lateral chamfer to ease insertion. The stem is stem is titanium alloy powder coated to promote biological fixation.

**Signature CoCr Femoral Heads**

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

The Signature CoCr Femoral Head is spherical and highly polished. The Signature CoCr Femoral Head is intended to connect via 12/14 morse taper to the Origin™ or NEO-T™ hip stem. The Signature CoCr Femoral Head is intended to articulate within the Logical™ PX or G-series Acetabular Cup's UHMWPE liner.

**Signature Ceramic Femoral Heads**

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

The Signature Ceramic Femoral Head is spherical and highly polished. The Signature Ceramic Femoral Head is intended to connect via 12/14 morse taper to the Origin™ or NEO-T™ Hip Stem. The Signature Ceramic Femoral Head is intended to articulate within the Logical™ PX or G-series Acetabular Cup's UHMWPE liner.

***Warning: The Signature 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.***

**Logical™ PX-Series Acetabular Cup**

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

The Logical™ PX-Series Acetabular Cup is hemispherical with an external titanium bead coating and internal locking features for engaging the Logical 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 Logical™ PX-Series Acetabular Cup's threaded apical hole also includes a slot to allow rotational control while inserting.

**Logical™ G-Series Acetabular Cup**

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

The Logical™ G-Series Acetabular Cup is hemispherical with an external titanium bead and powder coating and internal locking features for engaging the Logical™ 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.

**Logical™ Acetabular Liner**

***Material:*** Crosslinked UHMWPE per ASTM F648

The Logical™ Acetabular Liner is hemispherical with external locking features to engage the Logical™ G or PX-Series Acetabular Cup. The liner's internal surface is intended to articulate against the Signature CoCr or Ceramic Femoral Head. The liner is available in a neutral and 10° hooded to allow the option to address potential joint stability concerns.

**Logical™ Bone Screw**

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

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

**Logical™ Hole Cover Screw**

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

The Logical™ Hole Cover Screw is intended to cover the apical insertion hole or unused supplementary bone screw holes in the Logical™ G or PX-Serives Acetabular Cup.

## 2 Indications

Components of the Signature Orthopaedics 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

## 3 Contraindications

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 Signature Biolox® Delta Ceramic Femoral Head (containing Zirconia) is contraindicated for use with any other than an UHMWPE cup or a metal backed UHMWPE cup. This head must only be used with the Logical™ Cup with a UHMWPE Logical™ Liner.

## 4 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 patients 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.

## 5 Possible Adverse Effects

***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.

***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.

***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.

***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.

***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.

***Infection***

Local or systemic, acute post-operative wound infection and late onset prosthetic infection.

***Hematoma***

Deep and superficial wound hematoma. Thromboembolic incidents including venous thrombosis, pulmonary embolus, cerebrovascular events or myocardial infarction.

***Material Sensitivity***

Metal sensitivity reactions and/or allergic reactions to foreign materials may occur.

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 medialisation, or lateralisation, causing gait change or pain in the joints of the affected or contralateral extremity.

## WARNINGS AND PRECAUTIONS

## 6 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.

## 7 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 fibre-releasing materials.

Surgical technique information is available for each device component. The surgeon should familiarise 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 Signature Orthopaedics 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 sterilised according to the manufacturer's protocols. Do not resterilise component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

The Signature Orthopaedics 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 Signature Orthopaedics Hip Replacement Product Range has not been tested for heating or migration in the MR environment.

## 8 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.

## 9 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.

## 10 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 minimise 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.

## 11 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 Signature Orthopaedics.

## 12 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilisation is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilisation of the implants is prohibited, as it may alter the mechanical integrity of the device.

Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilised prior to use. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following sterilisation method is recommended:

Method: Steam Autoclave
Cycle: Pre-vacuum
Temperature: 132°C (270° F)
Exposure time: 4 minutes
Drying time: 30 minutes

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

## 13 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 methodis 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 Sterilisation***

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.***

## 14 Storage and Handling

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

## 15 Limited Warranty / Liability

Signature Orthopaedics Europe. Ltd. 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.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

## 16 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 Signature Orthopaedics location for current information.For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:


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## 17 Label Symbol Legend

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|---|---|---|---|
| REF | Product code | STERILE EO | Sterilized by Ethylene Oxide |
| LOT | Batch number | STERILE R | Sterilized by radiation |
| | Consult instructions for use | | Manufacture date |
| | Do not resterilize | | Manufacturer |
| | Single Use | | Expiration date |
| | Do not use if package damaged | | Warning |