Hip Replacement Product Range

Femoral Heads, Stems
Acetabular Cups

Instructions for Use 111-142-004 Rev. S Issue Date: JUL-19

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 physician.

1 Device Descriptions

All devices described herein are supplied individually sterile packed and are intend 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.

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 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.

Aria Hip Stem

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

The Aria Hip Stem is straight and tapered with a rectangular cross-section intended for use without bone cement only. 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.

Remedy™ Hip Stem

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

The Remedy™ 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.

Pegasus™ Hip Stem

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

The Pegasus™ Hip Stem is a double tapered, straight stem with rectangular cross-section intended for use without bone cement only. The stem has a lateral wing to engage the greater trochanter. The stem is grit blasted 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.

Evolve™ Masters Series Hip Stem

Material: High N_2 stainless steel per ISO 5832-9

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

Evolve™ Helios Series Hip Stem

Material: High N_2 stainless steel per ISO 5832-9

The Evolve™ Helios Series Hip Stem has a dual tapered geometry and is intended for use with bone cement. The stem has a polished surface finish. The Helios Series offers a different size range than the Masters Series.

Cobalt-Chrome Cemented TSI Hip Stem

Material: Forged Cobalt-28Chromium-6Molybdenum per ASTM-F799

The CoCr Cemented TSI™ Hip Stem is an anatomically curved tissue sparing implant. The patient's femoral neck is preserved during implant of the device. The stem has a polished surface finish.

High Nitrogen Stainless Steel Cemented TSI Hip Stem

Material: High N_2 stainless steel per ISO 5832-9

The HNSS Cemented TSI™ Hip Stem is an anatomically curved tissue sparing implant. The patient's femoral neck is preserved during implant of the device. The stem has a polished surface finish.

Cemented Origin Hip Stem

Material: High N_2 stainless steel per ISO 5832-9

The Cemented Origin Series Hip Stem is straight and tapered with lateral chamfer and is intended for use with bone cement. The stem has a polished surface finish.

Evolve™ Distal Centralizer

Material: Polymethyl methacrylate (PMMA)

The Cemented TSI (both CoCr and HNSS), Evolve™ Masters and Helios Series Hip Stems are to be used with the Evolve™ 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.

Evolve™ Cement Plug

Material: Polyethylene (PE)

The Evolve™ Cement Plug is to be placed in the femoral canal prior to cementing the Cemented TSI Hip Stem (both CoCr and HNSS), Cemented Origin Hip Stem, Evolve™ Masters or Helios Series 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.

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 a femoral stem from Signature Orthopaedics' range. The Signature CoCr Femoral Head is intended to articulate within the Logical XLPE Liner or BiPolar Head.

Signature Ceramic Femoral Heads

Material: Ceramic (Alumina and zirconia)

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 a femoral stem from Signature Orthopaedics' range. The Signature Ceramic Femoral Head is intended to articulate within the Logical XLPE Liner.

Warning: The Signature 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. The cup is intended for use without bone cement only.

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. The cup is intended for use without bone cement only.

Logical™ C-Series Acetabular Cup

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F136 with Titanium alloy per ASTM F1580 and HA per ISO 13779-2 coating

The Logical™ C-Series Acetabular Cup is hemispherical with an external dual layer titanium and HA powder coating and internal locking features for engaging the Logical™ Acetabular Liner. The cup is available in no-hole, 3-hole and multi-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.

Logical™ Acetabular Liner

Material: Crosslinked UHMWPE per ASTM F648 (and Titanium 6-aluminium 4-vanadium alloy per ASTM F136 for constrained liner)

The Logical™ Acetabular Liner is hemispherical with external locking features to engage the Logical ™ G, PX or C-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, 10° hooded, 20° hooded, lateralised and constrained variants to allow the option to address potential joint stability concerns.

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

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™ C, 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™ C, G or PX-Series Acetabular Cup.

BiPolar Head

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

The BiPolar Head mates with a 22mm or 28mm CoCr femoral head and a femoral stem to complete a hip hemi-arthroplasty. The CoCr femoral head articulates against a UHMWPE insert, and the highly polished outer shell articulates against the patient's natural acetabulum.

Evolve™ UniPolar Head

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

The Evolve™ UniPolar Head mates with a taper sleeve and femoral stem to complete a hip hemi-arthroplasty. The Evolve™ UniPolar Head is highly polished and articulates against the patient's natural acetabulum.

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

Signature Orthopaedics' Origin, Aria, Remedy, TSI and Pegasus femoral stems and Logical acetabular cups are intended for cementless fixation only. Signature Orthopaedics' Evolve, Cemented TSI (both CoCr and HNSS variants) and Cemented Origin femoral stems are intended for cemented fixation only.

Signature Orthopaedics' 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.

Signature Orthopaedics' Evolve UniPolar Head and BiPolar Head are intended for hemi-hip arthroplasty only, where the natural acetabulum does not require replacement. The Evolve UniPolar Head and BiPolar Head are 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
- Avascular necrosis of the femoral head
- Non-union of femoral neck fractures
- Certain high subcapital and femoral neck fractures in the elderly
- Degenerative arthritis involving only the femoral head

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 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.

The Signature Orthopaedics' constrained liners are contraindicated particularly for active patients.

Signature Orthopaedics' constrained liners are also contraindicated for use with the Signature Orthopaedics TSI stem (both cemented and cementless variants) due to decreased range of motion.

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.

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.

8 MRI Safety Information

The Signature Orthopaedics hip replacement product range has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Signature Orthopaedics hip replacement product range in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metal for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or extended liners).

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 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.

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 Signature Orthopaedics.

13 Cleaning and Sterilization

Unless otherwise explicitly labelled sterile, instrumentation is provided non-sterile and is intended for end-user cleaning and sterilisation. A complete guide for reprocessing reusable instruments may be provided upon request.

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 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:

Signature Orthopaedics Australia Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Sydney Australia
Tel +61 2 9428 5181
Fax +61 2 8456 6065

Signature Orthopaedics Europe Ltd
Unit A, IDA Business & Technology Park, Garrycastle
Athlone, N37 DY26, Co. Westmeath, Ireland
Tel: +353 (0) 906400539

Signature Orthopaedics USA LLC
46 Chagrin Plaza, #118
Chagrin Falls, Ohio 44022
USA
Tel: 661 349 8502
Fax: 440 543 2174

17 Label Symbol Legend

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

Signature ORTHOPAEDICS