The Evolve™ Cement Plug is to be placed in the femoral canal prior to cementing the Cemented TSI Hip Stem. The Evolve™ Masters and Helios Series Hip Stem is to be placed into the canal. The cement plug is to be placed distal to the stem location, and is used to prevent cement from filling the femoral canal.

**Signature CoC Femoral Heads**

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

The Signature CoC Femoral Head is spherical and highly polished. The Signature CoC Femoral Head is intended to be fixed by a cementless taper into the femoral stem from Signature Orthopaedics’ range. The Signature CoC Femoral Head is intended to articulate within the Logical® XPE 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 a 12/14 morse taper to a femoral stem from Signature Orthopaedics’ range.

**Cemented TSI Hip Stem**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163 with titanium bead coating per ASTM F67

The LogiCal® S/P-Series Acetabular Cup is hemispherical with an external titanium bead coating and internal locking feature to engage the LogiCal® A-Series 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 threedimensional hole for insertion. The cup is intended for use without bone cement only.

**Logical® G-Series Acetabular Cup**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163 with titanium bead coating per ASTM F67

The LogiCal® G-Series Acetabular Cup is hemispherical with an external titanium bead and powder coating and internal locking feature to engage the LogiCal® A-Series 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 threedimensional 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 F163 with titanium bead and powder coating per ASTM F67

The LogiCal® C-Series Acetabular Cup is hemispherical with an external titanium bead and powder coating and internal locking feature to engage the LogiCal® A-Series 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 threedimensional hole for insertion. The cup is intended for use without bone cement only.

**Logical® B-Series Acetabular Cup**

Material: Crosslinked UHMWPE per ASTM F648 (and Titanium 6-aluminium 4-vanadium alloy per ASTM F163 for constrained liner)

The Logical® B-Series Acetabular Cup is hemispherical with external locking features to engage the LogiCal® G, P, Q or C-Series Acetabular Cup. The liner’s internal surface is intended to articulate against the Signature CoC or Ceramic Femoral Head. The Signature Liner is available in a 10°, 20°, 20°d, 20°d, lateralised and constrained variants to allow the option to address potential joint stability concerns.

Warming: Constrained liners restrict range of motion in order to capture the femoral head. Constrained liners 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 = 30°, Internal/External rotation = 122°.

**Logical® Bone Screw**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163

The LogiCal® Bone Screw is intended for use with the 3-hole variant of the Logical® G, P, Q or C-Series Acetabular Cups. The screws through the ilium for use with the bone.

**Logical® Hole Cover Screw**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163

The LogiCal® Hole Cover Screw is intended to cover the apical insertion hole or unused supplementary bone screw holes in the LogiCal® G, P or C-Series Acetabular Cup.

**Cemented C-Series Femoral Head**

Material: Cobalt-chromium-molybdenum alloy per ISO 5832-12 with titanium and HA plasma spray coating per ASTM F67 and ISO 13779-2 respectively

The Cemented C-Series Femoral Head is hemispherical with an external dual titanium layer and HA powder coating and internal locking features for engaging the Cemented TSI stem. The signature CoC Femoral Head is intended to use without bone cement only.

**Cemented C-Series Acetabular Cup**

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

The Cemented C-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature CoC or Ceramic Femoral Head. The cup is intended for use without bone cement only.

**Cemented G-Series Acetabular Cup**

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

The Cemented G-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Gory. The cup is intended for use without bone cement only.

**Cemented B-Series Acetabular Cup**

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

The Cemented B-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Bory. The cup is intended for use without bone cement only.

**Cementless C-Series Acetabular Cup**

Material: Crosslinked UHMWPE per ASTM F648

The Cementless G-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Gory. The cup is intended for use without bone cement only.

**Cementless B-Series Acetabular Cup**

Material: Crosslinked UHMWPE per ASTM F648

The Cementless B-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Bory. The cup is intended for use without bone cement only.

**Cementless C-Series Femoral Head**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163

The Cementless C-Series Femoral Head is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature CoC or Ceramic Femoral Head. The cup is intended for use without bone cement only.

**Cementless G-Series Acetabular Cup**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163

The Cementless G-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Gory. The cup is intended for use without bone cement only.

**Cementless B-Series Acetabular Cup**

Material: Titanium 6-aluminium 4-vanadium alloy per ASTM F163

The Cementless B-Series Acetabular Cup is hemispherical with an external dual titanium layer and HA powder coating and internal highly polished surface for articulating against the Signature Bory. The cup is intended for use without bone cement only.
5 Possible Adverse Effects

Wear: The bearing surface component 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 implant and result in the need for early revision surgery to replace 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 the 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 may lead to failure of the fixation between the implant and bone requiring the removal or replacement of the prosthetic component.

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 or excessive loading or biomechanical examination. Removal of the implant is required to treat or prevent adverse effects caused by bone degradation for bone loss and/ or bone cement failure through the use of the orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

Fracture: Pelvic or femoral: May occur intraoperatively, due to reaming, broaching or implant insertion. May postoperatively, due to prosthetic stress transfer caused by inappropriate early weight bearing or trauma.

Infection: Femoral, sciatic, perianal nerve, and lateral femoral cutaneous nerve injury resulting in temporary or permanent nerve damage, with consequential pain or numbness of the affected limb.

Iatrogenic or iatrogenic adverse events include: decreased range of motion, dislocation, sulcation, leg length discrepancies, heterotopic bone formation, penetration of the femoral prosthesis through the femoral cortex, acetabular fracture, intrapelvic projection of the acetabular component or prosthetic femoral head, myositis ossificans or femoral impingement, vascular injury and/or delayed wound healing, extravasation mediolateralisation, causing gas or pain in the juxta-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 the limits of the prosthetic component 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

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 with third party devices is untested and strictly prohibited. The surgical instrumentation prescribed in the technique manual, 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 reutilise 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 in their body 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 patient overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future progression of post operative physical activity. The level of weight bearing should be assessed for the individual patient depending on the type of procedure and components used. In the event of bone graft, extensive revision surgery a non-weight bearing period should be considered.

Patients should be advised against unassisted activity, particularly the use of bathing and toilet facilities and other activities requiring significant non-gentle 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.

Stage followed up with x-ray comparison to the immediate postoperative imaging is recommended to determine presence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucent lines, or osteolysis should be monitored carefully for the potential need of early revision surgery. The patient should be advised that prophylactic antibiotics for treatment may be required for subsequent treatments, procedures, or situations which may result in bacteraemia.

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 pseudocapsule should not be utilised 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 particulars of post operative physical activity. The level of weight bearing should be assessed for the individual patient depending on the type of procedure and components used. In the event of bone graft, 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-gentle 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 determine presence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucent lines, or osteolysis should be monitored carefully for the potential need of early revision surgery. The patient should be advised that prophylactic antibiotics for treatment may be required for subsequent treatments, procedures, or situations which may result in bacteraemia.

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 warranty, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd is not liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. reserves the right to authorise a 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 services, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

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17 Label Symbol Legend

Sterilized by Ethylene Oxide
Sterilized by Radiation
Batch number
Manufacturer
Manufacturer date
Expiry date
Do not resterilize
Single Use
Do not use if package damaged
Warming
Consult instructions for use
REF LOT
Sterile L
Sterile R
Product code
Sterilized by Radiation
Sterilized by Ethylene Oxide