Cautions:
Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product may only be used by trained, qualified persons, aware of the directions for use. TSI stem specific training must be completed prior to the stem’s use.

To arrange training, please contact the TSI Study Group at: www.jisrf.org/tissue-sparing-implant/jisrf.html

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

1 Indications
Signature Orthopaedics’ hip replacement range is 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 involving osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis (excluding TSI stem)
- 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 involving internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement

Signature Orthopaedics hip replacement components may be intended for cemented or cementless use. Please verify whether the particular component is intended for cemented or cementless use by checking the package label. 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’ Fusion Ceramic Head is also indicated for the repositioning or replacement of a ceramic femoral head on a femoral stem left in situ.

2 Contraindications
In general, prosthetic components require adequate bone support for correct fit and function. The use of prosthetic components is therefore contraindicated where any pathologic condition may reduce the quantity and or strength of the bone which is supporting the prostheses. Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic orthopaedics 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
- 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.
- Signature Orthopaedics’ constrained liners are contraindicated particularly for active patients.
- Signature Orthopaedics’ TSI stem is contraindicated for patients with rheumatoid arthritis, where bone stock may not be sufficient to support the device.

3 Implant Selection Precautions
Selection of an implant of the correct size, shape and type of bone fixation is extremely important to maximise the potential for a successful, long term, outcome for the patient.

When selecting a cemented acetabular cup, it is recommended that the largest diameter that fits the patient’s acetabulum is used to maximise the surface for cement fixation.

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. Constrained liners are strongly recommended against use in active patients.
- 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.

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

- Dilution: The femoral component may dilute from the spherical cavity. Component selection, positioning and patient activity may impact the likelihood of dilution. Intraarticular dilution may also occur, where the femoral head mobile polycrystalline assembly in a dual mobility prostheses disassembles. This may result following closed reduction of a dislocated dual mobility component. In case of dislocation, the clinician should first identify that their patient has a dual mobility cup by identifying a ‘halo’ in the radiograph around the prosthetic femoral head, which is caused by the retained poly liner. Then, once the prosthesis is identified as a dual mobility, the clinician should perform a closed reduction, and confirm that it was successful noting concentric femoral head and acetabular shell in radiographs following reduction. If the femoral head is eccentric to the acetabular shell then intraarticular dilatation is likely high and surgical intervention to revise the poly liner is required to prevent further complications.

Other possible adverse events include: decreased range of motion, subluxation, leg length discrepancies, heterotropic 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

12 Possible Adverse Effects

Wear: The bearing surfaces of components may wear with use over time. The presence of third body particles of bone cement, 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 the 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. Failure 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 stress prosthesis transfer caused by inadequate 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.

5 Material Composition and Compatibility

The material for each component is provided on the implant package label. Femoral stem components are manufactured from Ti-6Al-4V or Ti-6Al-7Nb alloy. High nitrogen stainless steel or cobalt chrome are also available. Femoral heads are manufactured from cobalt chromium alloy, high nitrogen stainless steel or ceramic. Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE), cobalt chromium alloy or ceramic. Cemented acetabular components are UHMWPE. Cementless acetabular shells are Ti-6Al-4V or cobalt chromium alloy.

6 Component Description

All hip replacement components are individually sterile packed and designed for single patient use only.

7 Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. Non-coated components are coated to promote biological ongrowth. Uncoted femoral components intended for cemented fixation may be used with PMMA centralisers that help produce a uniform cement thickness.

Femoral components are available with a 12/14 Euro taper for connecting modular femoral heads.

8 Taper Sleeves

A taper sleeve is required to attach a unipolar head or Fusion head. Unipolar taper sleeves have a 12/14 Euro taper. Fusion taper sleeves have an internal 12/14 Euro taper and external 16/18 Euro taper, and are available in a range of offsets. No more than one taper sleeve may be used per femoral component.

9 Femoral Heads

Femoral heads are designed to connect to the femoral stem via the 12/14 euro taper. The Fusion heads connect to the Fusion taper sleeve via the 16/18 Euro taper. Femoral heads are available in multiple neck lengths and diameters for proper anatomic fit. Heads are highly polished for reduced friction and wear.

10 Acetabular Components

Acetabular components can be one-piece UHMWPE, or two-piece, consisting of a titanium or cobalt chromium alloy shell and a UHMWPE, cobalt chromium alloy or ceramic liner (not available in USA). Acetabular components can be single articulation, or dual mobility with a mobile polycrystalline component. Signature Orthopaedics’ UHMWPE (or UHMWPE lined) acetabular components may be used with metallic or ceramic femoral heads of matching size. Signature Orthopaedics’ Ceramic lined acetabular components are intended for use only with Signature Orthopaedics Ceramic femoral heads of matching size. Acetabular liners are designed for use only with acetabular shells from the same product line.

Femoral Heads and Stems

Acetabular Cups

Instructisons for Use 111-142-002 Rev. Q Issue Date: Sep 18

Operative Information

Prosthetic components from different manufacturers must not be combined. All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature.

14 Preoperative

Care should be taken when handling the prosthetic components to avoid damage to the surface of the device. Denting, notchting 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 gaze, 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. 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 fractures prior to use if required.

Instrumentation and implants should be sterilised according to the manufacturer’s protocols. Do not resterilise component parts which have been assembled, or implanted connected to surgical instruments. Do not cool hot components in cold water.

Signature Orthopaedics femoral components are not to be used with other manufacturer’s products. This is to minimise the risk of a taper on the stem is machined to tightly mate and lock with the ceramic head, preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head. The patient should be warned about the potential adverse events associated with exposure to strong magnetic fields after implantation of device components made of stainless steel, cobalt chrome or titanium alloys. During MR imaging expose to pulsing radio frequency fields can generate heat within tissue and metal components significant enough to cause serious burns. Metallic implants may be used for the patient or for surgery if required.

Signature Orthopaedics does not recommend MR imaging for any patients implanted with metallic hip component(s) without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device. The safety of the devices in the MR environment is unknown, and scanning of patients who have the device may result in patients’ injuries (i.e. the device is MR unsafe).

15 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, dislocation or subluxation, of the joint.

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. The use of screws is not recommended for the fixation of acetabular component. Also, an improperly seated acetabular liners may loosen and disassociate from the shell. Incorrectly seated acetabular liners may loosen and disassociate from the shell.

16 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 pseudocapsulitis should not be utilized as a placement site for the acetabular cup.

17 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 unsanitised activity, particularly the use of bathing and toilet facilities and other activities requiring significant groin 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 follow up with x-ray comparison to the immediate postoperative image is recommended to detect evidence 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 therapy may be required for subsequent treatments, procedures, or situations which may result in bacteremia.

18 Packing and Labeling
Components should only be used if the factory packaging and labelling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

19 Sterilization and Reстерilization
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 not recommended, 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: 12 minutes
  - Drying time: 30 minutes

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

20 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.

Reusable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request. As a guideline, the following cleaning methods recommended:

- Manual Cleaning
  - Instruments are to be cleaned immediately after use with warm water and a mild detergent. Instruments consisting of multiple components must be disassembled prior to cleaning. After cleaning, the parts should be rinsed thoroughly with de-ionized water and dried.
  - Cleaning before Sterilisation

Inputs may be cleaned using a broad spectrum bactericide and fungicide agent in accordance with the instructions of the manufacturer of the agent.

Caution:
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. Instruments should be returned to Signature Orthopaedics at the address provided below at least once every 2 years for review / repair / replacement. Instruments may be returned to Signature Orthopaedics for review / repair / replacement earlier if the user deems necessary.

21 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.

22 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 having received appropriate training in orthopaedic surgical techniques.

23 Contact Information
If more than 2 years have elapsed between the date of issue/review 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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Fax: 440 543 2174

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