



Hip Replacement Product Range

Femoral Heads and Stems

Acetabular Cups

Instructions for Use 111-142-002 Rev. M

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Caution:

Carefully read all the instructions 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. 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 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 (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 including 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' ceramic option system is also indicated for the repositioning or replacement of a ceramic femoral head on a femoral stem left *in situ*.

The Signature Orthopaedics TSI Stem is subject to the following additional indications for use:

1. Young adult high demand patients who have
 - a) a long life expectancy
 - b) a high level of activity
 - c) a demanding work profile
2. Young adult male <65 years of age (or <70 years if good bone quality and high demand with long life expectancy)
3. Female <60 years of age
4. Good bone stock (Dorr a or b bone), T score of femoral neck >-2.0

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 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.
- 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 maximize 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.

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 chromium alloy. Femoral heads are manufactured from cobalt chromium alloy, high nitrogen stainless steel or BIOLOX® delta ceramic. Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE) or BIOLOX® delta ceramic. Cemented acetabular components are UHMWPE. Cementless acetabular shells are Ti-6Al-4V 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. HA coated components are coated to promote biological ongrowth. Uncoated 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 option head. Unipolar taper sleeves have a 12/14 Euro taper. Option 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 option heads connect to the option 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 shell and a UHMWPE or BIOLOX® delta ceramic liner (not available in USA).

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 may only be used with Signature Orthopaedics Ceramic femoral heads of matching size. Acetabular liners are designed for use only with acetabular shells from the same product line.

11 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 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

12 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.

13 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, 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. 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.

Signature Orthopaedics femoral components are not to be used with other manufacturer's products. This is important because the 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 BIOLOX®delta 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 exposure to pulsed radio frequency fields can generate heat within tissue and metal components significant enough to cause serious burns. Metallic implants may create imaging artefacts or distortions to varying degrees in MR images.

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 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 must be clean and dry prior to impacting the femoral head or taper sleeve or postoperative separation of the head from the stem may occur.

Use only system indicated titanium bone screws and hole covers with the same system acetabular components. Refer to product literature for proper adjunctive fixation and hole cover usage.

Before assembly of components, surgical debris must be cleaned from the surfaces. Debris, including bone cement, 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 and taper sleeves must be assembled securely to prevent disassociation. Incorrectly seated acetabular liners may loosen and disassociate from the shell.

Repeated assembly and disassembly of the modular components should be avoided as this could compromise the locking mechanism. Acetabular Cup Liners cannot be reused once removed from the Acetabular Cup, as removal permanently damages the locking mechanism on the liner.

For implants designed for bone cement fixation, care should be taken to assure that a complete cement mantle is achieved by the elimination of air inclusions, or areas where the

prosthesis is unsupported by bone cement. Insufficient support of the implant, by the bone cement, may lead to increased stress loads on the implant, on the cement, and/or cement-bone interface, resulting in failure of fixation, or fracture of the device.

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. In this case an option head should be used for revision. Extracting the femoral head that has remained in situ should be done using a suitable extraction instrument, to avoid unnecessary damage to the stem taper and/or to the polished neck of the stem.

After extraction, the remaining stem taper must be visually inspected and only in case the taper is undamaged can the Option head system be used with the taper. If the stem taper is damaged the Option head system cannot be used. Trial heads must be used to determine the neck length and to check the tissue balance and the range of motion.

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 waste regulations of the country where the implant is removed.

The wound site should be thoroughly cleaned of cement, 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.

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 pseudoacetabulum 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 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.

18 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.

19 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilisation is noted on the package label. All radiation sterilised components have been exposed to a minimum of 25kGy of gamma radiation. 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: 4 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.

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 methods are 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

Instruments 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/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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