



Fusion Taper System

Fusion Ceramic Heads

Fusion Taper Sleeve

Instructions for Use 111-37-9005 Rev. F

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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.

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

1 Device Description

All hip replacement components are individually sterile packed and designed 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.

Fusion Ceramic Heads

Material: Ceramic (Zirconia reinforced alumina)

The Fusion Ceramic Head is spherical and has a 16/18 inner taper which is designed to connect to the femoral stem via the Fusion Taper Sleeve.

Fusion Taper Sleeves

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

The Fusion Taper Sleeves are intended to connect the Fusion Heads via the 12/14 Morse taper to Signature Orthopaedics' range of femoral stems. The taper sleeves have an internal 12/14 taper and external 16/18 taper, and are available in a range of offsets. No more than one taper sleeve may be used per femoral component.

The Fusion Taper Sleeves and Fusion Ceramic Heads (Zirconia reinforced alumina) are only for use with Signature Orthopaedic Ti6Al4V femoral stems (TSI Stem, Origin Stem, Aria Stem, Remedy Stem, Spartan Stem and World Stem); and Signature Orthopaedic metal backed UHMWPE cups and liners (Logical™ Cup and UHMWPE Logical™ Liner, or, World™ Cup and World™ Liner).

2 Indications

Signature Orthopaedics' Fusion Taper System 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 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, hemi-arthroplasty, surface replacement, or total replacement

Signature Orthopaedics' Fusion Taper System is intended for cementless fixation only.

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 Fusion Ceramic Femoral Head (Zirconia reinforced alumina) 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, a UHMWPE Logical™ Liner, World™ Cup, a World™ Liner.
- Signature Orthopaedics' Fusion Taper System is contraindicated for use with Signature Orthopaedics' range of CoCr femoral stems, high nitrogen stainless steel femoral hip stems and constrained liners.

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 patient's 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.

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 patient's 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.

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 gently 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.

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

A complete guide for reprocessing reusable instruments is provided with non-sterile reusable instruments.

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:

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17 Label Symbol Legend



Product code



Sterilized by Ethylene Oxide



Batch number



Sterilized by radiation



Consult instructions for use



Manufacture date



Do not resterilize



Manufacturer



Single Use



Expiration date



Do not use if package damaged



Warning

