Knee Replacement Product Range

I-Knee Total Knee Replacement System

Instructions for Use 911-012-100 Rev. B Issue Date: 7-JUL-16

CE 0086

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 physcian.

1 Indications

Components of the Signature Orthopaedics knee replacement range are intended to replace a knee 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-nflammatory degenerative joint disease including osteoarthritis or osteonecrosis
- Inflammatory joint disease including rheumatoid arthritis, traumatic arthritis
- Correction of functional deformity including valgus, varus or post-traumatic deformity
- Failed previous knee reconstructions, osteotomy or arthrodesis.

Signature Orthopaedics knee 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.

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.
- Incomplete or deficient soft tissue surrounding the knee 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.

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.

It is recommended that the femoral and insert implants are not mismatched more than one size up or down, to optimise the intended implant constraint and contact stresses.

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.

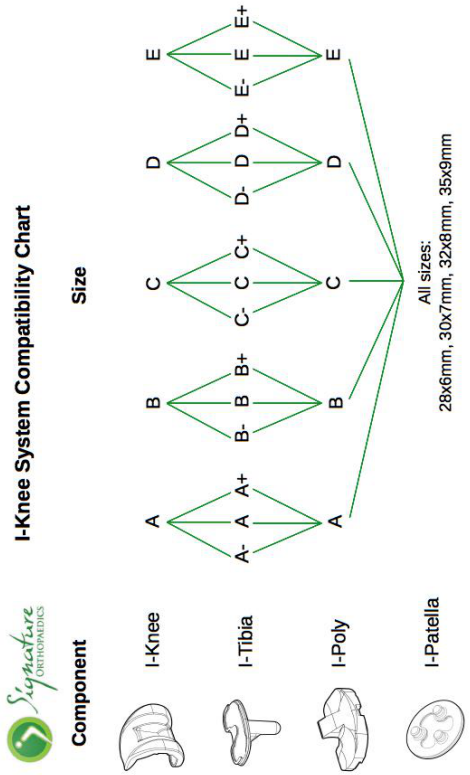
5 Material Composition and Compatibility

The material for each component is provided on the implant package label. I-Knee femoral components are manufactured from cast CoCrMo alloy. I-Tibia tibial trays are manufactured from Ti6Al4V alloy. I-Poly tibial inserts are manufactured from ultra-high molecular weight polyethylene (UHMWPE GUR1050). I-Patella patella components are manufactured from UHMWPE GUR1050.

6 Component Description

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

7 Component Compatibility



8 I-Knee System Components

The I-Knee system is a cemented, fixed-bearing, posterior-stabilised total knee replacement system. It consists of a femoral component, tibial tray, tibial insert and patella component. The I-Knee system is intended for cemented use only. Components must not be interchanged with those from another knee system.

Femoral components are available in 5 sizes. Articulating surfaces are mirror polished to minimise polyethylene wear. Components are asymmetric and designed in left and right configurations. Components have a femoral cam to assist in femoral rollback as per the posterior-stabilised design.

Tibial tray components are available in 15 sizes. For each femoral component, there are 3 corresponding tibial tray components, each with a varying inferior base area. Trays are symmetrical with a central rounded keel and mediolateral fins for rotational stability. A locking mechanism on the superior base surface is designed to secure the tibial insert. The tibial base is highly polished to minimise risk of backside wear.

Tibial inserts are available in 5 sizes, each with 4 thicknesses. The profile of the insert matches the condylar geometry of the femoral components. Inserts have a tibial post designed to articulate with the femoral cam during rollback. Inserts are secured within the tibial tray via a snap-fit locking mechanism.

Patella components are available in 4 sizes. All patella components have the same geometric radius, allowing them to articulate with the trochlear groove of all sizes of femoral component. The patella has 3 plugs on the anterior surface for fixation into the patella bone.

9 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 knee 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

Femoral or Tibial: 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.

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.

Other possible adverse events include; decreased range of motion, dislocation, subluxation, vascular injury and/or delayed wound healing, subsidence, and component disassociation.

WARNINGS AND PRECAUTIONS

10 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.

11 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.

12 Preoperative

Only qualified surgeons knowledgeable in anatomy, biomechanics and reconstructive surgery should utilise these devices. The surgeon must be fully knowledgeable of all aspects of the specific surgical technique and use the implants in accordance with the indications and contraindications specified for each component. Prior to performing the surgery, the surgeon must obtain training on the proper operative technique including the proper use of system instrumentation.

It is essential to implant the devices with the instrumentation specifically designed for this purpose. 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.

As part of the pre-operative assessment, the surgeon must ensure that there are no biological, biomechanical or other factors that might adversely affect the surgery and the postoperative period.

Selection of polyethylene components is a matter of physician discretion. There are many factors which may influence the performance of the polyethylene component. The physician may consider using thicker polyethylene components if the patient is young, overweight and/or physically active.

13 Intraoperative

Care should be utilized in the handling of the components to minimise damage or contamination of the component surfaces. The correct selection and positioning of the femoral component and the choice of the appropriate tibial insert/tray is important to prevent complications. Malposition of the components can result in loosening, dislocation, or subluxation, of the joint, as well as excessive wear of patella or tibial insert bearing surfaces.

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.

The surgeon or his designee should advise patients that the longevity of the implant may depend on their weight and level of activity. Patients should be instructed on the limitations of the prosthesis and be taught to govern their activities accordingly.

Implants must not be reused. The surgeon must not allow damage to polished bearing surfaces, because this can accelerate wear of the components. 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. Any prostheses so damaged should not be used. Any prostheses so damaged must not be used. Components of the I-Knee System should not be used with those of another manufacturer, as dimensional compatibility cannot be assured.

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 should be removed to reduce the possibility of reduced range of motion or dislocation.

14 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. 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 knee 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.

When manual patient handling is required, care should be taken to support the operative leg to minimise the risk of dislocation.

The use of post operative physiotherapy is recommended to rehabilitate the muscles affecting knee 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.

15 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.

16 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.

17 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 method is 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.

18 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.

19 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.

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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.

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