Active Knee System Product Range

Femoral Implant

Tibial Implant

Meniscal Insert

Patella Component

Instructions for Use 121-132-016Rev. I Issue Date:MAY-21

Caution: Carefully read all the instructions and be familiar with the Active Knee surgical technique(s) (121-132-040) 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 System Description

The Active Knee Total Knee Replacement (TKR) System available in both cemented and hybrid (cemented tibial implant and cementless femoral implant) versions, consists of a femoral implant, a meniscal (tibial) insert, a patella component, and a tibial implant. It is designed to achieve total reconstructive replacement of the deficient and damaged tibiofemoral joint surfaces with metal components and provide a low-friction articulation with a polyethylene bearing. This is to restore optimum function and have longevity of the knee replacement.

Femoral Implant – Cemented & Cementless

The femoral component is an anatomic, asymmetrically designed prosthesis manufactured from cast cobalt-chromium-molybdenum (CoCrMo - ASTM F75). The design incorporates a trochlear groove, which conforms to the geometry of the patellar prosthesis and allows for sliding articulation. From the medial/lateral view, the condylar geometry has a radial inward and upward sweep in the coronal plane, which assists in maximizing the contact area. The femoral implant is available in several sizes to suit different anatomies.

The cemented femoral implant has a grit blast finish on the interior surfaces for enhanced polymethylmethacrylate (PMMA – ISO 5833) fixation.

The interior of the cementless femoral implant has a hydroxyapatite coating including a beaded distal surface to encourage bony ingrowth on the prosthesis.

Tibial Implant - Cemented

The tibial implant is symmetrical and stemmed. The stemmed implants are manufactured from cast cobalt-chrome-molybdenum (CoCrMo - ASTM F75). The tibial implant is available in several sizes in both a narrow and a wide version of each size.

The cemented tibial implant has a grit blast finish on the interior surfaces. The stemmed tibial implant is available for enhanced polymethylmethacrylate (PMMA – ISO 5833) fixation.

Meniscal (Tibial) Insert

The meniscal (tibial) insert is symmetrical and available in three different styles, including Standard, Ultracongruent, and Ultra Plus. All types are also available in multiple sizes and thicknesses, with a minimum thickness of 6mm. The meniscal insert is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE - ASTM F-468).

The Standard insert is a semi-constrained condylar design. Additional posterior stability can be provided by utilizing the Ultracongruent insert, which is designed with an anterior lip.

Patella Component

The patella component manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE ASTM F-468) has a dome shape with the reverse curvature of the femoral condyles. The patella is designed for fixation with polymethylmethacrylate (PMMA - ISO 5833) cement. The patella component is available in several sizes to suit different anatomies.

System Compatibility

- Components of the Signature Orthopaedics Active Knee replacement system are only to be used with Signature Orthopaedics approved components. Any misuse will negate the responsibility of Signature Orthopaedics for performance of the resulting mixed component implant.
- Signature Orthopaedics instruments are to be used for the insertion of Signature Orthopaedics knee replacement systems. Any misuse may result in damage to either the instrument or the implant.

FEMUR	BASE PLATE	INSERT	Ultracongruent & Ultracongruent Plus	PATELLA
F1	1 A/B	1		1
	2 A/B	2N		1
F2N	1 A/B	1		1
	2 A/B	2N		1
F2	1 A/B	1		2
	2 A/B	2		2
	3 A/B	3N		2
F3N	1 A/B	1		2
	2 A/B	2		2
	3 A/B	3N		2
F3	2 A/B	2		3
	3 A/B	3		3
	4 A/B	4N		3
F4N	2 A/B	2		3
	3 A/B	3		3
	4 A/B	4N		3
F4	3 A/B	3		4
	4 A/B	4		4
	5 A/B	5N		4
F5N	3 A/B	3		4
	4 A/B	4		4
	5 A/B	5N		4
F5	4 A/B	4		5
	5 A/B	5		5

2 Intended Use

The Active Knee is intended to replace the articulating surface of the knee joint as part of a knee replacement procedure to provide pain relief and improved range of motion. The subject device is used in accordance with the conditions set in sections 3 and 4.

3 Indications for Use

The patient should be skeletally mature to receive a knee replacement. Patients should have adequate bone stock and size to support and accept the prosthesis.

The patient's need for knee replacement should be due to one or more of the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Functional deformity such as varus, valgus or flexion deformities.

4 Contraindications

Contraindications need to be taken into consideration when evaluating the prognosis in each case. Alternative management techniques to knee replacement may need to be taken into consideration under the following conditions:

- Acute or chronic infections, either local or systemic.
- Severe muscular, nervous or vascular disease endangering the leg.
- Defective bone structures, which would impede adequate anchoring of the implant
- Patients who are younger than 60 years whose joint disease is such that good results may be achieved by using other reconstructive procedures such as osteotomy.
- Any associated diseases which could endanger the function and success of the implant
- Allergies to implanted materials, particularly metals (e.g. cobalt, chromium) as well as polyethylene and bone cement
- Signature Orthopaedics' Active Knee meniscal inserts are contraindicated for insufficient ligaments or joint instability.

5 Potential Adverse Effects

The following adverse effects are the most common resulting from an implantation:

Loosening of the implant may result from changed alignment or wearing and fracture of the cement bed and/or tissue reaction to the implant and the associated abrasion products.

- Early and late infection.
- Dislocation, sub-dislocation, insufficient range of movement, undesired shortening or lengthening of the leg as a result of poor positioning of the implant.
- Bone fracture resulting from unusual stress or weakened bone substance.
- Temporary or chronic neural damage resulting from pressure or haematoma.
- Wound haematoma and delayed wound healing.
- Vascular disease including venous thrombosis, pulmonary embolism and cardiac arrest. Heterotopic ossification
- 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.

Other possible adverse events include; component disassociation, component migration and component subsidence, vascular injury and/or delayed wound healing.

Use of bone cement may lead to hypotensive reaction, hypersensitivity reaction, tissue damage due to exothermic polymerisation, or other adverse events related to the use of bone cement. Please consult the instructions for use provided with the bone cement for a complete listing of possible adverse events.

Lifetime: The lifetime of the subject device is indefinite when used in accordance with the IFU as the device is intended to remain implanted for the lifetime of the patient. The devices have undergone pre-clinical testing to show that it they are capable of withstanding the long-term use in-vivo. The warnings and precautions detailed herein list factors that may lead to a shorter lifetime of the implant. In the absence of possible adverse events / side effects, the devices are expected to function as intended at followup time points over 10 years.

6 Warnings and Precautionary Information

It is vital for the operating surgeon to take an active role in the medical management of their patients. The surgeon should thoroughly understand all aspects of the surgical procedure, instruments and limitations of the devices. Care in patient/implant selection, and the use of proper surgical procedures and techniques are the responsibility of the surgeon and surgical team. Adequate surgical training should be completed before implanting any knee prosthesis. The patient's attention should be drawn to the contents of the IFU as well as to factors that may impair the results of the operation and to possible complications that may arise. The patient should also be informed about the measures, which the surgeon will use to minimize the possible effects of these factors.

Knee implants are manufactured from metal and polymer materials and are not expected to withstand activity levels and loads, associated with a normal healthy knee joint, in the long term.

The Active Knee system is designed to provide a flexion-extension range of motion of 0-120°. At flexion angles beyond this range, the contact between the femoral and tibial articulating surfaces may cause increased wear and may reduce the longevity of the implant. Therefore, the Active Knee system should not be used where a flexion-extension range of motion beyond 0-120° is required.

Malfunction of the implant and other complications may result from a failure to take into account the following, but should not be limited to the advice given below.

- Allergies to implanted materials, particularly metals (e.g. cobalt, chromium) as well as polyethylene and bone cement.
- Overweight patients.
- Localised bone tumours or bone defects.
- Osteoporosis or osteomalacia.
- Deformations, excessive axial deformity of the knee.
- Systemic disease and metabolic disturbances.
- Alcohol and drug abuse.
- Physical activities involving excessive shocks, whereby the implant is exposed to excessive forces and/or excessive loading (e.g. heavy physical activity, competitive sports, marathons etc.).
- Conditions of senility, and mental illness where patient compliance to doctor's instructions are not likely.

Use of the cementless femoral component without patella resurfacing is not recommended due to an increased risk of revision resulting from patellofemoral pain or patella erosion.

Patients receiving knee joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.

Preoperative Planning

The operation planning is carried out following a thorough clinical evaluation of the patient. Also X-rays must be taken to allow preoperative templating as well as a clear indication of the bony anatomy and associated deformities. At the time of the operation, the corresponding Signature Orthopaedics implantation instruments in addition to a complete set of implants must be available. It is important to determine preoperatively whether the patient is allergic to any of the implant materials.

Intraoperative Care

- The correct selection of the prosthesis size and satisfactory placement is critical.
- All instruments and prosthesis sizes need to be present and checked in the operating environment before commencing surgery. All packaging should be checked for external damage, and the availability of additional components is recommended in case of errors.
- Implants should be handled with care. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.
- Trials should be used to confirm preoperative templating.
- Trial prosthesis components should be used for trial purposes only.
- Do not modify the implants in any way.
- The Active Knee surgical technique (121-132-040) is recommended to be followed.
- Only operate the instrumentation as intended. Subjecting the instruments to excessive force, or force that it is not intended to withstand, may result in instrument failure.

Postoperative Care

- The willingness and ability of the patient to cooperate with the recommended postoperative regime is vital. This regime should exclude heavy labour, active sports or any activity that places heavy, abrupt or percussive forces on the knee replacement.
- Loosening or failure of implants and other complications may result from failure to follow and observe the listed warnings and precautions.
- Patient monitoring, including periodic x-rays are recommended for comparative evaluation with immediate postoperative conditions to assess evidence of long term complications, such as implant loosening, cracking, etc. with due consideration being given for the revision of the implant.
- All existing medical conditions should be taken into consideration for the postoperative management of the patient. Mental attitude or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant fixation failure.

MRI Safety Information

The Signature Orthopaedics knee 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 knee replacement product range in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions for Specific Cautions

- Following the implantation of prosthesis, the patient may feel little or no pain in the early postoperative period and must be cautioned to comply with the postoperative regimen.
- 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. 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).
- 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.

7 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The entirety of the implants listed hereby, included in the Signature Orthopaedics Knee Replacement Product Range IFU, are either EO (ethylene oxide) sterilised or gamma sterilised. The method of sterilisation is noted on the package label. Return the implant to Signature Orthopaedics if the packaging is damaged. Resterilisation of the implants is not recommended, as it may alter the mechanical integrity of the device. Do not sterilise implants using moist heat.

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.

8 Cleaning

Implants are supplied sterile and intended for single use only. The implant should be returned to Signature Orthopaedics 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. 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.

9 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature (22±3°C), in their original packaging or sterilisation tray respectively.

10 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 Active Knee surgical techniques (121-132-040).

11 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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12 Label Symbol Legend and Abbreviations

REF	Product code	STERILE EO	Sterilized by Ethylene Oxide
LOT	Batch number	STERILE R	Sterilized by radiation
	Consult instructions for use		Manufacture date
	Do not resterilize		Manufacturer
	Single Use		Expiration date
	Do not use if package damaged		Warning
Rx Only	Federal law restricts this device to sale, distribution and use by or on the order of a physician.		