World Knee System Product Range

Femoral Implant
Meniscal Insert
Tibial Implant
Patella Component

Instructions for Use 121-200-039 Rev. E Issue Date: Dec-2021

Caution:

The latest version of this Instructions for Use document are provided on Signature Orthopaedics' eIFU website. It is highly recommended that the latest version is consulted to ensure the most current information is referenced. The latest version can be retrieved by following the directions on the eIFU website, signatureortho.com.au/eIFU.

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 by or on the order of a physician.

1 System Description

The World Knee Total Knee Replacement (TKR) System 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 and 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 component is available as in posterior stabilized and cruciate retaining designs and several sizes to suit different anatomies. Modular femoral pegs are available for use with CR and PS femoral components and are manufactured from wrought cobalt chromium-molybdenum (CoCrMo – ASTM F1537).

The femoral component is also available as variant symmetrical prosthesis, suitable for replacement of right or left knees. This variant incorporate a symmetric trochlear groove for patellar tracking in either of the patient's knees.

The posterior stabilized and cruciate retaining femoral implants are to be used with their corresponding posterior stabilized or cruciate retaining meniscal inserts.

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

The cementless femoral implant is interiorly coated with cobalt-chromium-molybdenum beads (CoCrMo – ASTM 1377) and hydroxyapatite (HA – ISO 13779).

Tibial Implant – Cemented

The tibial implant is symmetrical and stemmed. The, stemmed implants are manufactured from titanium alloy (Ti6Al4V – ISO 5832-3). The tibial implant is available in several sizes to suit different patient anatomies.

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

Meniscal (Tibial) Insert

The meniscal (tibial) insert is symmetrical and available in posterior stabilized and cruciate retaining designs to be used with their corresponding posterior stabilized or cruciate retaining femoral implants. The cruciate retaining meniscal insert is available in two different styles; Standard and Ultracongruent. Both types are also available in multiple sizes and thicknesses, with a minimum thickness of 10mm. The meniscal insert is available in two material variants, The first is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE – ASTM F648) and the second is manufactured from Vit-E HXLPE for increased wear resistance.

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

All-Polyethylene Tibia Implant – Cemented

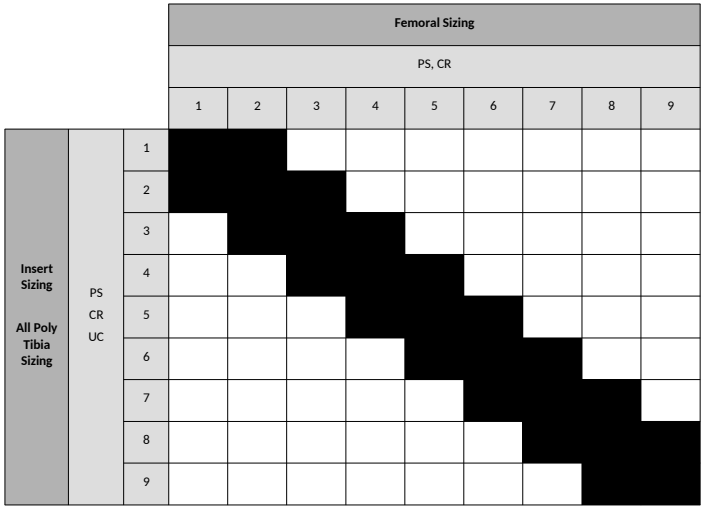
The all-polyethylene tibial implant is symmetrical and has a webbed keel. It is available in two material variants. The first is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE – ASTM F648) and the second is manufactured from Vit-E HXLPE for increased wear resistance. The all-polyethylene tibial implant is available in multiple sizes and thicknesses with a minimum thickness of 10mm. The all-polyethylene tibial component is available in Standard Cruciate Retaining, Ultracongruent Cruciate retaining and Posterior Stabilized variants.

Patella Component

The patella component is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE – ASTM F-648) 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 shapes and sizes to suit different anatomies.

System Compatibility

- Femoral components of the World Knee System are compatible with tibial inserts or the all-polyethylene tibia one size smaller or larger, as shown below. Modular tibial inserts match tibial trays size to size. All patella components are compatible with all femoral components. World Knee femoral pegs are able to be screwed into the World Knee modular peg femoral components only.



- The posterior stabilized and cruciate retaining femoral implants are to be used with their corresponding posterior stabilized or cruciate retaining meniscal inserts and all polyethylene tibias.
- Components of the Signature Orthopaedics World 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.

2 System Instrumentation

The associated instruments for the World Knee TKR System consist of manual orthopaedic surgical instruments. Refer to the surgical technique for the specific instructions for the appropriate use of each World Knee instrument.

The World instruments are manufactured from 630 stainless steel, 420 stainless steel, aluminum, acetal polymer, silicone, polypropylene and titanium nitride.

Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request.

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.
- Revision procedures where other treatments or devices have failed.
- Fractures that are unmanageable using other techniques.

Signature Orthopaedics' World 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.

4 Contraindications

Contraindications may be qualified or total, and 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

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 he 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 hematoma.
- Wound hematoma 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.

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.

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.

- Allergies to surgical instrument materials, metals steel, aluminum as well as acetal polymer, silicone, polypropylene and titanium nitride
- Overweight patients.
- Localized bone tumors 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.

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.

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

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 surgical technique is recommended to be followed.

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.
- **Caution:** 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.

7 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is EO (ethylene oxide) as noted on the package label. Dispose of the implant if the packaging is damaged. Resterilization 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 sterilized 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. 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.

9 Storage and Handling

Always handle implants with sterile powder-free gloves. Prior to use, implants should be stored in clean, dry conditions and should not be exposed to direct sunlight, ionizing radiation, and extremes of temperature or contamination.

Instruments are to be stored in dry, clean surroundings at room temperature, in their sterilization tray.

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 orthopaedic surgical techniques.

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

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD REFERENCE
REF	**Catalogue Number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 Ref # 5.1.6 FDA Recognition #5-117
LOT	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Ref # 5.1.5 FDA Recognition #5-117
	**Consult instructions for use**	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Ref # 5.4.3 FDA Recognition #5-117
	**Do not resterilize**	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-117
	**Do not re-use**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Ref # 5.4.2 FDA Recognition

			#5-117
	**Do not use if package damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Ref # 5.2.8 FDA Recognition #5-117
	**Symbol for Prescription Device**	Caution: Federal law restricts this device to sale by or on the order of a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labelling Requirements
	**Sterilized by Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Ref # 5.2.3 FDA Recognition #5-117
	**Sterilized by irradiation**	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1 Ref # 5.2.4 FDA Recognition #5-117
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-117
	**Manufacturer**	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 89/79/EC	ISO 15223-1 Ref # 5.1.1 FDA Recognition #5-117
	**Use-by-date**	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Ref # 5.1.4 FDA Recognition #5-117
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Ref # 5.4.4 FDA Recognition #5-117