Signature ORTHOPAEDICS

Cambridge Partial Knee System

Femoral Implant
Tibial Implant

Instructions for Use 121-261-101 Rev. A Issue Date: 17-DEC-2025

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 version 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 of use.

Federal Law restricts this device to sale by or on the order of a physician.

Signature Orthopaedics' Cambridge Partial Knee is intended to be used with Signature Orthopaedics designed instruments and prosthetics only. The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical technique are available on request.

1 System Description

The Cambridge Partial Knee System consists of a femoral implant and a tibial bearing implant. It is designed to achieve a reconstructive replacement in a single compartment 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

The femoral component is an anatomic, asymmetrically designed prosthesis manufactured from cast cobalt chromium/molybdenum (ASTM F75 and ISO 5832). The femoral component is intended for use with bone cement. The femoral component range consists of 5 sizes, XS, S, M, L and XL. The unicondylar prosthesis is designed for optimal weight transmission and flexion as well as giving maximum contact area to reduce material stress on the meniscal insert.

The symmetric implant mirrors the anatomic shape of the condyles through angled anterior-posterior curvature. Hence the femoral implant for the right medial component is equivalent for the left lateral condyle, and similarly the right lateral component can be used on the left medial condyle. The femoral component articulation surfaces are polished to Ra 0.05µm while the fixation surfaces are textured through dry abrasive blasting to Ra 4-8µm, the latter to enhance cement fixation. The design incorporates two parallel pegs, which significantly protrude from planar resection, to further aid fixation during implantation.

Tibial Component

The tibial base plate is manufactured from wrought Ti6Al4V alloy (ISO5832-3 and ASTM F136) and further overmolded with an Ultra-High-Molecular-Weight Polyethylene (UHMWPE) blended with Alpha-Tocopherol (Vitamin E) (ASTM F2695). The inferior fixation surfaces of the tibial base plate is abrasive blasted to Ra 4-6µm to enhance cement fixation. The keel on the inferior surface further assist the fixation of the tibial component. The articulating surface was designed for unconstrained femoral motion. The articular surface of the tibial component have a finish with maximum surface roughness Ra 1.0µm or better. The minimum overall thickness of the baseplate and overmolded bearing is 8.6mm. The tibial components are asymmetric and available in 7 different sizes: AA, A, B, C, D, E and F. The tibial component thicknesses are available in sizes 5, 6, 7, 8 and 9, for a total of 35 unique products, per side.

2 System Instrumentation

The associated instruments for the Cambridge Partial Knee System consist of manual orthopedic surgical instruments. Refer to the surgical technique for the specific instructions for the appropriate use of each Cambridge Partial Knee instrument. The Cambridge Partial Knee instruments are manufactured from 630 stainless steel, aluminum, Propylux polymer, silicone, and polypropylene. Unless specifically marked, Cambridge Partial Knee instruments are re-usable. Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request.v

3 Indications for Use

The Signature Orthopaedics' Cambridge Partial Knee is designed for a single compartment replacement of the natural knee joint. The Cambridge Partial Knee is indicated for cemented use in partial knee arthroplasty procedures. Partial replacement of the articulating surfaces of the knee is indicated only when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

4 Contraindications

The Signature Orthopaedics Cambridge Partial Knee system is contraindicated for use under the following conditions:

- Progressive local or systemic infection
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Rapid joint destruction, marked bone loss or bone resorption apparent on the roentgenogram.
- Incomplete or deficient soft tissue surrounding the knee.
- Severe instability secondary to advanced destruction of condylar structures.
- Permanent valgus or varus deformity that requires correction post-op
- Mental or Neuromuscular disorders
- Allergy to materials used in the components

5 Material Composition

The material for each component is provided on the part package label. The femoral component is made of CoCr and the tibial component is made of Ti6Al4V and overmolded with ultra-high-molecular-weight polyethylene (UHMWPE) blended with alpha-tocopherol (Vitamin E).

6 Potential Adverse Effects

Following are specific adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that may occur in surgery, but are important considerations particular to the devices included in this document.

- Prosthesis dislocation
- Early or late loosening, tibial subsidence, bending, fissure fracture, fracture, deformation or wear of one or more of the prosthetic components.
- Early or late infection which may require removal of the implant followed by arthrodesis or 2-stage re-implantation.
- Pain, dislocation, subluxation, flexion contracture, mobility reduction, leg shortening or lengthening, resulting from improper positioning, loosening or wear of components.
- Excessive wear of the polyethylene component due to damage to the femoral component, loose cement or bone fragments and/or high levels of activity and weight.
- Fracture of the tibia or femur.
- Cardiovascular disorders and thromboembolic diseases including thrombosis, embolism, and myocardial infarction.
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.
- Myositis ossificans

7 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.

8 Intended User

Signature Orthopaedics intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

9 Preoperative

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical

status of the patients. Care should be taken when handling the components of the Cambridge Partial knee to avoid damaging the devices. Denting, notching or scratching can greatly reduce the compression strength, fatigue resistance or wear properties of the components potentially leading to fracture or failure of the devices. Surgical technique information is available for the subject devices. The surgeon should familiarize themselves thoroughly with the technique prior to consideration of the use of the devices for any specific patient. Implants are only to be used with approved Signature Orthopaedics instrumentation. The surgical instrumentation prescribed within the technique for the implantation of these devices 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 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.

10 MRI Safety Information

The Signature Orthopaedics Cambridge Partial knee components have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Cambridge Partial Knee in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Signature Orthopaedics does not recommend MR imaging for any patients implanted with product from their knee implant range without prior consultation with an expert radiologist for assessment of potential adverse events.

11 Intraoperative

Correct implant selection is extremely important. The use of preoperative imaging and templating is recommended to facilitate the choice of an optimum size. 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 size may result in failure of the device and/or bone. Implants should be inspected before use. Do not use any implants that have visible damage such as chipping or bending. Do not use any implants that have been dropped on the floor.

Implants removed from the patient at revision surgery should never be re-implanted 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 debris before closure.

12 Postoperative Care

To secure the long term treatment outcomes, it is advised to provide comprehensive regular patient follow up after implant treatment and provide information and precautions about their activities post-op. For adverse events, contact your local sales representative or the appropriate Signature Orthopaedics location as listed in the document.

13 Packaging and Labelling

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.

14 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label. Dispose of the implant if the packaging is damaged. **Do not re-sterilise an implant provided sterile. Do not reuse any implant under any condition.** 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.

15 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.

16 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 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 neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product.

17 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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18 Glossary of Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD REFERENCE
	**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
	**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
	**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

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