SIERRA Limb Rescue System

Proximal/Distal Femoral Components
Femoral/Tibial Augments
Tibial Components and Bearings
Connectors/Segments
Stems and Extramedullary Collars
Accessory Implants/Hinge Components

Instructions for Use 121-301-103 Rev A Issue Date: 12-FEB-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 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 SIERRA Limb Rescue System (LRS) is a modular knee and hip implant system designed to address the needs of patients undergoing severe total knee arthroplasty (TKA) and/or total hip arthroplasty (THA) procedures. It consists of a proximal femoral component, distal femoral components, femoral augments, auxiliary implants for a rotating hinge knee (RHK) construct, tibial components/bearings, tibial augments, stems, extramedullary (EM) collars, and connectors/segments to accommodate patient anatomy/needs. Limb salvage procedures are complex surgical interventions designed to preserve the functionality and structural integrity of a limb in extreme situations. The SIERRA LRS implants restore mobility and provide mechanical stability by replacing large sections of diseased or damaged bone with modular segments, re-establishing the anatomical alignment of the hip and/or knee.

Proximal/Distal Femoral Components

The femoral components are anatomically accurate prostheses manufactured from cobalt-chromium-molybdenum (CoCrMo – ASTM F75). The design incorporates a widened, angled patella track to reduce constraining forces in extension as well as patella shear stresses. The femoral component is available as in posterior stabilized (PS) and cruciate retaining (CR) designs and several sizes to suit different anatomies. Modular femoral pegs are provided with the CR femoral component, while available separately for use with the PS femoral components and are manufactured from titanium alloy (Ti6Al4V – ISO 5832-3).

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

Modular Tibial Assembly

The tibial assembly is modular and consists of the symmetrical tibial tray and a locking bolt that can incorporate either a finned or an I-Beam keel. The tibial implant is symmetrical and stemmed. The keel-stem joint is a taper connection. The stemmed implants are manufactured from titanium alloy (Ti6Al4V – ISO 5832-3). The tibial trays and keels are 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. infused meniscal (tibial) insert is symmetrical and available in posterior stabilised (PS), anterior stabilised (AS) and cruciate retaining (CR) designs to be used with the posterior stabilized or cruciate retaining femoral implants. Additionally, the PS variant is available in two types, standard PS and posterior stabilised plus (PS+)

Connectors/Segments

The infused meniscal (tibial) insert is symmetrical and available in posterior stabilised (PS), anterior stabilised (AS) and cruciate retaining (CR) designs to be used with the posterior stabilized or cruciate retaining femoral implants. Additionally, the PS variant is available in two types, standard PS and posterior stabilised plus (PS+) with a raised anterior lip and wider tibial post for increased constraint. All meniscal insert types are available in multiple sizes and thicknesses, with a minimum thickness of 6mm. The meniscal inserts are manufactured from Vitamin-E Stablised Ultra-High Molecular Weight Polyethylene (UHMWPE GUR1020E – ASTM F2695).

Stems and EM Collars

The patella component is manufactured from Vitamin-E Stabilised Ultra-High Molecular Weight Polyethylene (UHMWPE GUR 1020E – ASTM F2695) 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.

Accessory Implants/Hinge Components

The patella component is manufactured from Vitamin-E Stabilised Ultra-High Molecular Weight Polyethylene (UHMWPE GUR 1020E – ASTM F2695) 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

- The PS and CR
- Components of the Signature Orthopaedics SIERRA LRS 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 SIERRA LRS consist of manual orthopaedic surgical instruments. Refer to the surgical technique for the specific instructions for the appropriate use of SIERRA LRS instrument.

The SIERRA LRS instruments are manufactured from 630 stainless steel, aluminum, titanium alloys and polymers.

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

3 Indications for Use

The SIERRA Limb Rescue System is indicated for use in skeletally mature patients for disease treatment, pain relief, or improved function with the following clinical conditions:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus, or post-traumatic deformity.
3. Correction of revision of unsuccessful osteotomy, arthrodesis or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.
6. Treatment of non-unions, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques (proximal femoral components only).
7. Revision of previously failed total joint arthroplasty.
8. Trauma.

These devices are to be used with bone cement unless cementless use (i.e. splined stem or fully porous augment) is indicated.

4 Contraindications

Absolute contraindications include infection, sepsis, and osteomyelitis. Relative contraindications include:

- Uncooperative patient or patient with neurologic disorders who are incapable of following directions
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Distant foci of infections which may spread to the implant site
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- Vascular insufficiency, muscular atrophy, or neuromuscular disease

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 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 or hip 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.

The Sierra LRS 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 (e.g. steel, aluminum)
- 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.

MRI Safety Information

The Signature Orthopaedics SIERRA LRS product range has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the SIERRA LRS 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 patient implanted with a product from this implant range without prior consultation with an expert radiologist for assessment of potential adverse events.

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 the implant if the packaging is damaged as per the instructions provided under Section 9. Do not resterilize the implants, 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 sterilization 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. Do not attempt to reclean the implant. Dispose the implant if the packaging is damaged as instructed in Section 9.

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.

Disposal of used products should be according to appropriate institutional protocols for the handling of contaminated medical waste.

10 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. Signature Orthopaedics 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 Glossary of Symbols

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 #5-134
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 #5-134
	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 #5-134
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Ref # 5.2.6 FDA Recognition #5-134
	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 #5-134
	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 #5-134
Rx Only	**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
STERILE EO	**Sterilized by Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Ref # 5.2.3 FDA Recognition #5-134
STERILE	**Sterilized by steam or dry heat**	Indicates a medical device that has been sterilized using steam or dry heat.	ISO 15223-1 Ref # 5.2.5 FDA Recognition #5-134
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 Ref# 5.1.3 FDA Recognition #5-134
	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 #5-134
	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 #5-134
	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 #5-134