Rx Knee System Product Range

Femoral Implant
All-Polyethylene Tibial Implant
Universal Stem
Tibial Stems
Universal Tibial Stem Adapter and Locking Screws
Patella Component
Universal Femoral Augments
Tibial External Augments
Femoral and Tibial Cone Augments

Instructions for Use 121-250-020 Rev. A Issue Date: June-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. Additional warnings and precautions may be included in the surgical technique or on the label. This product must only be used by trained, qualified persons, aware of the directions for use. Surgical techniques are distributed to the surgical representatives or alternatively can be requested through info@signatureortho.com.au. Federal law restricts this device to sale by or on the order of a physician.

1 System Description

The Rx Knee System consists of femoral and all polyethylene tibial, stem extension and patellar components. If necessary, augment components can be used. It is designed as an adjunct to total knee replacement of the knee joint damaged due to a periprosthetic joint infection (PJI) with metal components and low-friction articulation with a polyethylene bearing cemented using gentamicin-loaded bone cement.

Femoral Implant – Cemented

The femoral component is a symmetrically designed prosthesis manufactured from cast cobalt-chromium-molybdenum (CoCrMo – ASTM F75) and consists of titanium nitride (TiN) coating. The design incorporates a symmetric 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.

The posterior stabilized and cruciate retaining femoral implants are to be used with their corresponding posterior stabilized or cruciate retaining all polyethylene tibia.

All-Polyethylene Tibia Implant – Cemented

The all-polyethylene tibial implant is symmetrical and has a webbed keel. It 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.

Femoral and Tibial Augments

The universal femoral augments are available in small, medium, and large sizes. These are intended to be fixed inbetween the distal and posterior surfaces of femur and femoral implant to accommodate for femoral bone loss. Femoral augments are available in titanium alloy (Ti6Al4V – ISO 5832-3) or polyethylene (UHMWPE).

The tibial external augments are intended for cemented fixation to the inferior surface of all poly tibia components. The augments are available in titanium alloy (Ti6Al4V – ISO 5832-3) or polyethylene (UHMWPE) material options. Full and partial geometries and are stackable to accommodate for proximal tibial bone loss.

Femoral and Tibial Cone Augments

The femoral and tibial cone augments are intended for cement fixation in the bone canal, and be fitted around the stem. Cone augments are available in small, medium, large sizes, where the large size has an additional stackable cone option. The cone augments are made of polyethylene (UHMWPE).

Universal Stem Assemblies, Tibial Stem and Stem Adapter

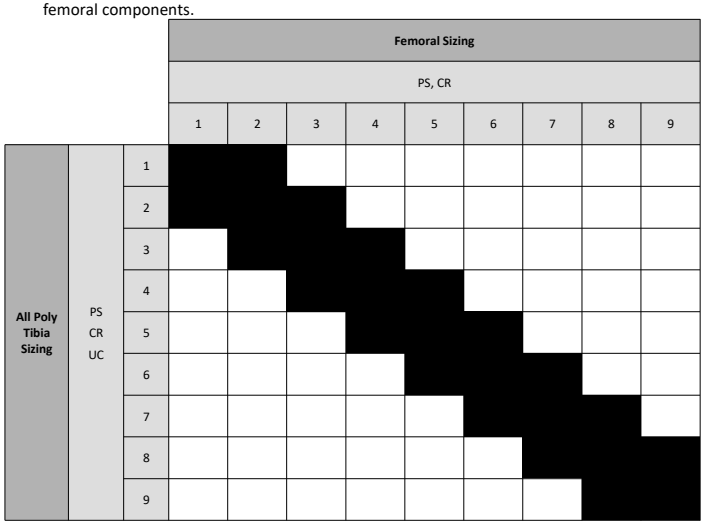
The universal stem is a titanium alloy structure that is over-molded with antibiotic loaded bone cement into the bone canal. Stems and end caps are available in various diameters to accommodate for varying diameters of bone cement. The stem is attached to the all poly tibia via the tibial stem adapter and secured with two locking screws. The universal stem assembly, tibial stem adapter and locking screw are manufactured from titanium alloy (Ti6Al4V – ISO 5832-3). Alternatively, a solid titanium tibial stem can be attached to the all poly tibia via a tibial stem and secured with two locking screws. These are available in various diameters and lengths. Tibial stems are manufactured from titanium alloy (Ti6Al4V – ISO 5832-3).

Patella Component

The patella component is manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE – ASTM F-648) has a spherical dome shape with the reverse curvature of the femoral condyles. The patella is designed for fixation using antibiotic loaded bone cement.

System Compatibility

- Femoral components of the Rx Knee System are compatible with all-polyethylene tibia one size smaller or larger, as shown below. All patella components are compatible with all femoral components.



- The posterior stabilized and cruciate retaining femoral implants are to be used with their corresponding posterior stabilized or cruciate retaining all polyethylene tibias.
- Femoral augments of small size are for fixation to Size 1, 2 and 3 femurs, medium size are for fixation to Size 4, 5 and 6 femurs, and large size are for fixation to Size 7, 8 and 9 femurs.
- Components of the Signature Orthopaedics Rx Knee 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 Rx Knee System consist of manual orthopaedic surgical instruments. Refer to the surgical technique for the specific instructions for the appropriate use of each Rx Knee instrument.

The Rx Knee 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. The Rx Knee is indicated for temporary use (maximum 180 days) as an adjunct to a total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The device is intended for cemented use with any FDA cleared gentamicin-loaded cement.

The Rx Knee System is not intended for use for more than 180 days, at which time it should be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion etc.).

The device is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period, allowing basic joint mobility.

Signature Orthopaedics' Rx Knee replacement components are intended for cemented use. Please verify whether the particular component is intended for cemented 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:

- 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.
- Patient's two-stage arthroplasty procedure is contraindicated based on decreased immune response or systemic clinical conditions.
- Lack of adequate bone structure which precludes adequate support of the spacer.
- Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
- Infection of the TKR cannot be confirmed.
- Infecting bacterium/pathogens resistant to gentamicin.
- Infecting bacterium/pathogens are not susceptible to gentamicin.
- A remote infection (systemic/secondary) is suspected or verified.
- Myastenia gravis.
- The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient has neuromuscular disorders that do not allow control of the knee joint.
- Patient is unable or rejecting the use of protected weight bearing devices throughout the implantation period (canes, walkers, crutches, etc.).
- Age, weight or activity level, may cause the surgeon to expect possible, early failure of the knee spacer.
- Patient exhibits hypersensitivity (allergy) to PMMA bone cement, aminoglycosides or gentamicin.

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.

Surgical Risks (General): pulmonary embolism, myocardial infarction, arrhythmias, venous thrombosis, transitory hypotension.

Surgical Risks (TKR): difference in limb length, would healing issues, femur or tibia damage, blood vessel damage, nerve damage, bone bed damage, excessive blood loss, arthrofibrosis, phlebitis, thrombophlebitis, hematoma.

Notes: Surgeon should be aware of potential material related allergies in patients with metal hypersensitivity to implant materials.

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.

The Rx Knee System is not intended for use for more than 180 days, at which time it should be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

The device must be cemented with gentamicin-loaded cement. The use of bone cement is compulsory to achieve stability and to limit the risk of dislocation or spacer loosening.

Review of the Rx Knee System surgical technique for knee arthroplasty revision surgery and familiarity with the proper use of the Rx Knee is required for successful implantation of the device. Surgeons must refer to the surgical technique and be aware of the limitations of its application to perform the procedure for implantation of the Rx Knee System. The surgeon is not allowed to adjust or modify the device in any way.

The Rx Knee System must not remain implanted for more than 180 days. The operative area should be rigorously irrigated and rinsed after device extraction to remove all cement debris prior to implantation of the permanent prosthesis or other surgical procedures (fusion, resection arthroplasty, etc.). Survival of the revision implant may be jeopardized if cement and/or bone debris are not thoroughly removed. The device has specific indications for use. Thus its use under conditions other than the intended ones are unlikely to provide any benefit to the patient.

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 Rx 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 Rx 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 must be followed.
- The operative site must be irrigated with Ringer or physiological solution while thorough debridement must be executed after removal of the prosthesis and before inserting the Rx Knee components. Excess cement or debris from the previous device must be removed to ensure a clear operative area.
- In cases at risk consider the user of a brace (possibly articulated) to assist in flexion to lower the risk of dislocation.

Size selection: The size is selected in relation to the dimensions of the removed implant, the type of bone defect, the condition of the ligamentous apparatus and the flexion-extension spaces. Other consideration shall be given in relation to the stability of the implant and the range of movement: the achievement of full extension and 90^{o} flexion is important, in particular with a flexion area sufficiently dose to avoid antero-posterior movement of the flexed knee. Correct measurement can be determined by measuring the removed tibial and femoral components along with the use of trial components.

Trial Use: Using the trial prosthesis components, select the appropriate size femoral and tibial components. If augments are necessary, select between the available sizes. Select between available sizes of the tibial stem to ensure the stem is fully seated. It is important that the joint is neither loose nor tight, therefore the surgeon will have to consider the additional room occupied by the cement needed for the fixation.

Notes: Care should be taken in placing the spacer to preserve the bony tissue during the implantation procedure.

Antibiotic susceptibility testing should be performed prior to implantation of the Rx Knee System following a fine needle aspiration from the joint site.

Cement Use: Apply **Palacos® G** bone cement (FDA cleared gentamicin-loaded cement) over component surfaces in contact with the bone and for cementing augments.

Ensure proper cement fixation of the components with gentamicin-loaded bone cement.

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.
- 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.
- Loosening or failure of implants and other complications may result from failure to follow and observe the listed warnings and precautions.
- 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.

Notes: Patients should be informed of the limitations of the implant and the requirement for additional surgery to implant a permanent knee prosthesis.

Patients should be instructed to adjust their activities and be informed that postoperative care is essential.

Postoperative treatment is comparable with a primary knee implant, however, weight-bearing can be only partial (use of canes, crutches, etc.). It is recommended that partial weight-bearing be assessed on an individual basis in relation to the anatomic conditions of the femur and tibia, bone trophism and the clinical conditions of the patient during rehabilitation stages. Avoid weight bearing or forced mobilization which could cause the implant to damage the biological structure. If needed, a brace (possibly articulated) to assist flexion may be suggested in cases at risk of dislocation (in relation to the stability and/or the condition of the extensor apparatus).

Explantation

The Rx Knee System must be removed within 180 days of implantation and is not intended for use as a permanent prosthesis. Revision instruments (mallets, osteotomes, etc.) can be used in the surgical procedure. The would site should thoroughly be cleaned of all bone cement debris prior to implantation of a definitive implant or performing an alternative surgical procedure (e.g., resection arthroplasty, fusion, etc.). Cement or bone debris may shorten survival of the revision implant if not removed.

Patient precautions

Surgeon-to-patient instructions

- Pain, discomfort or trauma with the affected limb must be communicated to the surgeon.
- Canes, crutches, walkers, etc., (protected weight-bearing mobility devices) must be used at all times while the device is implanted.
- The Rx Knee must be removed after temporary implantation (not to exceed 180 days).
- Excessive loading/weight on the Rx Knee must be averted (sports activity, obseity, falling, unprotected weight bearing, etc.).

The patient's anatomic conditions of the knee district, bone trophism and other relevant clinical conditions during the rehabilitation phase should be periodically reviewed as the Rx Knee was designed for temporary implantation under protected load bearing conditions.

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 Pty 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 Pty 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 Pty 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 Pty 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
	**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 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
	**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