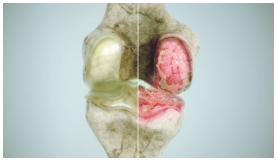
PatientInfo

Total Knee Replacements

Signature Orthopaedics



Total Knee Replacements

This brochure offers a brief overview of total knee replacement, and the devices offered by Signature Orthopaedics.
This information is for educational purposes only and is not intended to replace the expert guidance of your physician.

When do you need a knee implant ?

Your orthopaedic surgeon will evaluate your situation carefully if you are experiencing pain or poor range of motion as a result of a diseased, damaged or deformed knee. Your surgeon will carefully make decision regarding which implant is most appropriate for you and may determine that total knee replacement is the best method of treatment when other non-surgical treatments are ineffective.

A diseased knee is when one or more parts of the knee are damaged, and movement becomes stiff. Over time, the cartilage surrounding the bone will start to crack or wear away, causing the bones in the joint to rub together. When the cartilage continues to wear away, the joint becomes increasingly painful and difficult to move.

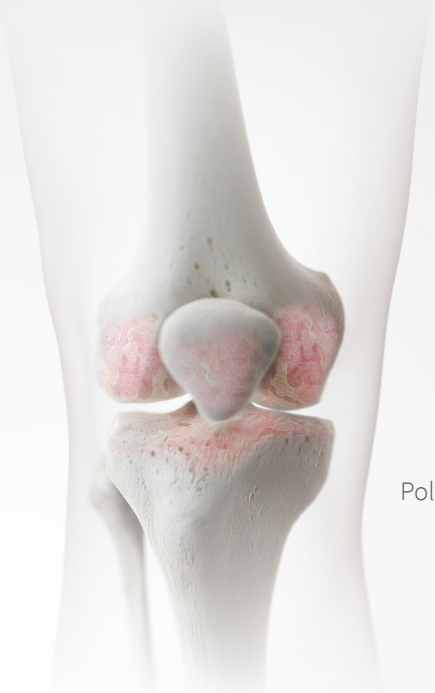
There are many reasons your knee may become damaged or diseased, including but not limited to:

- Non-inflammatory arthritis such as osteoarthritis or avascular necrosis
- Inflammatory arthritis such as rheumatoid arthritis
- Functional deformities

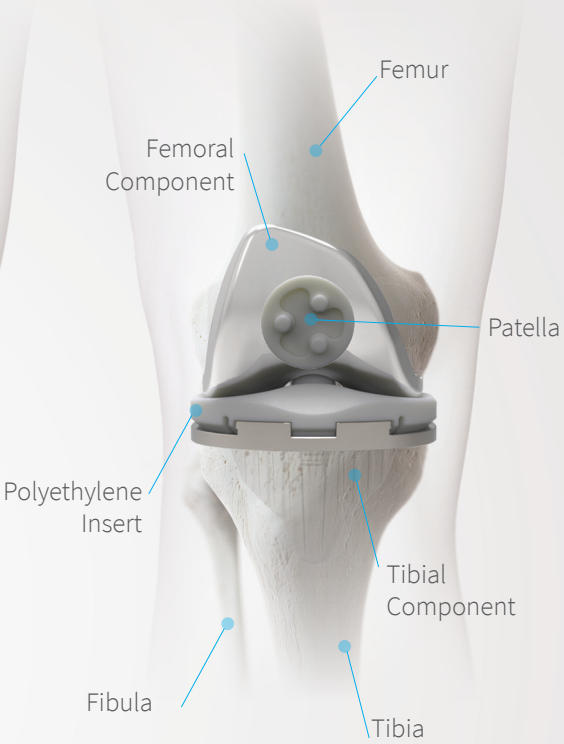
In these cases, Signature Orthopaedics knee replacement implants can be employed to replace the damaged bone and cartilage in a Total Knee Replacement (TKR).

For more details on possible adverse effects and risks, please refer to the eIFU.

Instructions for Use
Consult this Website
SignatureOrtho.com.au/eIFU



✕ **Osteoarthritic** Knee



✓ **Total Knee** Replacement

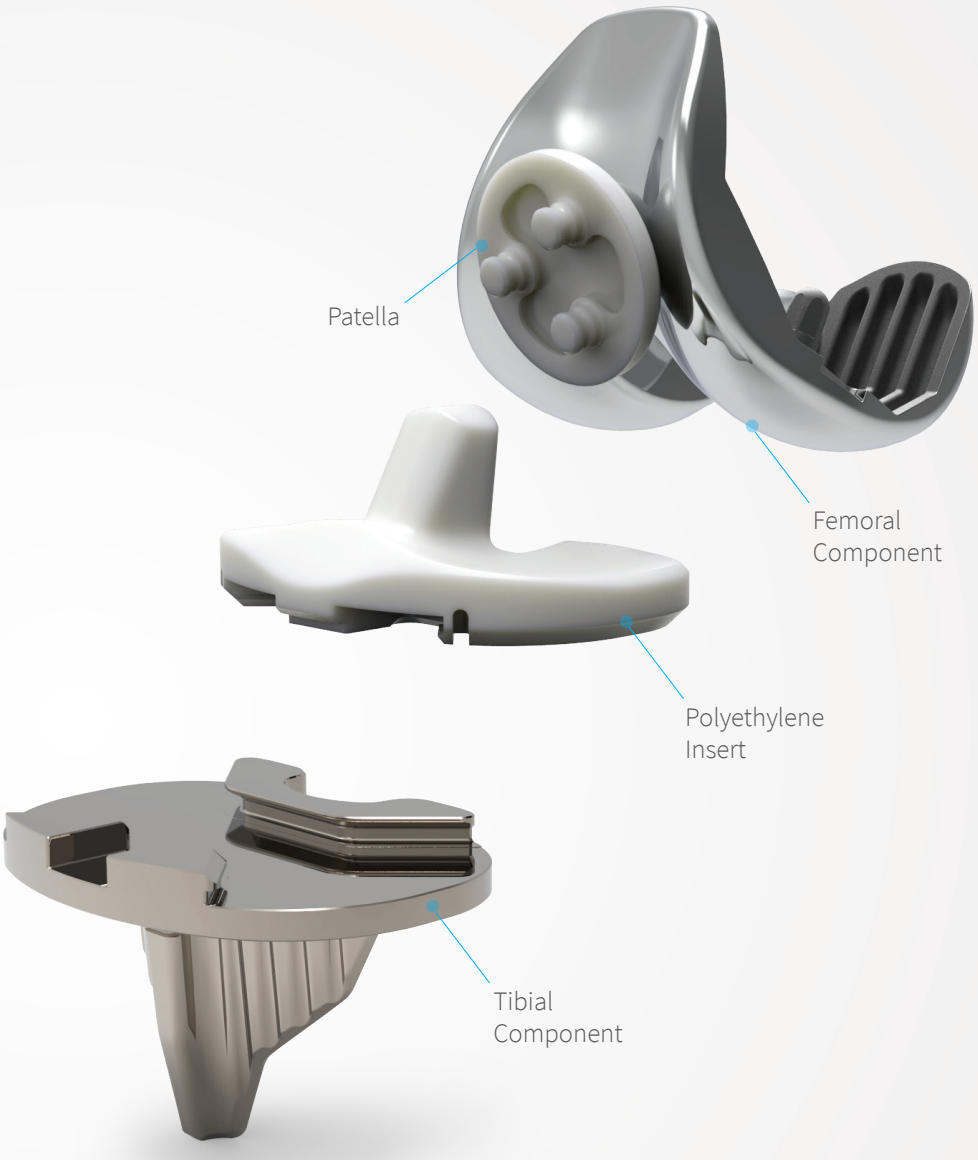
What is a total knee replacement ?

Total Knee Replacements

During the surgery, your surgeon will put you under anesthesia followed by a cut on the middle or side of your knee to access the knee joint. Your surgeon will only remove the damaged parts of your joint, not the entire knee.

In a TKR, the damaged or diseased bone ends are removed and replaced with components designed to recreate the anatomy of the bones in a healthy knee. The metal implants are implanted on the femur and the tibia. A polyethylene component is implanted in-between allowing the bones to smoothly glide against each other, just like your natural cartilage.

Your doctor will evaluate your condition and determine if or which surgery is right for you.


Patella
Femoral Component
Polyethylene Insert
Tibial Component

Total Knee Replacements

As with any major operation, knee replacement surgery has possible complications. Every possible effort is made by the medical team to prevent complications but this cannot be accomplished without your participation.

Adverse Events and Risks

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 motion
- Undesired shortening or lengthening of the leg as a result of poor positioning
- 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

Other possible adverse events include:

- Component disassociation
- Component migration
- Component subsidence

For more details on possible adverse effects and risks, please refer to the eIFU.

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When to visit the doctor?

You should phone your physician anytime you have questions regarding your condition, care and activity level.

Report any changes with your incisions, such as an increase in swelling, redness or drainage that worsens during your recovery. Call your physician if you experience persistent pain not relieved by pain medication, have side effects from medication or persistent swelling not relieved with ice or rest.

Signature Orthopaedics Knee Replacement Implants

Signature Orthopaedics' Knee Replacement Systems are 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.

WORLDKNEE

The **World Knee** Total Knee Replacement (TKR) System consists of a femoral implant, a meniscal (tibial) insert, a patella component, and a tibial implant. The system offers femoral and tibial combinations in cruciate retaining and posterior stabilising, and is offered in nine sizes of femur and nine sizes of tibia. The innovative femur/bearing/tibia interface allows for interchangeability between components to allow flexibility across the size range. Femoral options are then further enhanced with symmetrical PS versions along with the asymmetrical femurs which are cross-compatible with all metal-backed and all-poly PS and CR bearing options. Femoral components are offered in cobalt-chrome, and bearing options in highly crosslinked polyethylene. Tibial components are offered in all-polyethylene and titanium. Polyethylene bearings are available in insert thicknesses from 10mm to 18mm in 1mm increments, and for all nine sizes.

ACTIVEKNEE

The Signature Orthopaedics **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. 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. 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 meniscal (tibial) insert is symmetrical and available in three different styles, including Standard, Ultracongruent, and Ultra Plus. The patella component manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE ASTM F-468) and is available in several sizes to suit different anatomies.

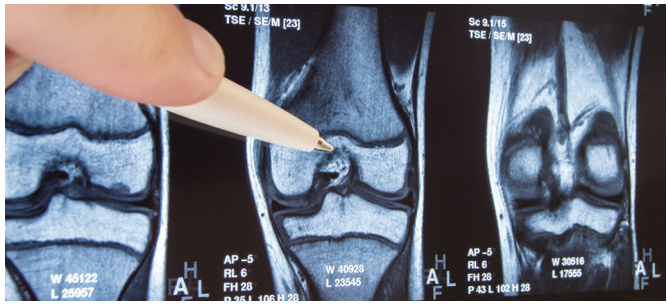
Total Knee Replacements

Signature Orthopaedics offers a range of products applicable for various situations and anatomies, as determined by your physician. These are all available in a variety of sizes to accommodate different bone sizes and shapes.

Which implant is right for me ?

Although implant surgery is extremely successful in most cases, some patients will still experience pain and stiffness. Your physician will evaluate your particular situation carefully before making any decision regarding which implant is most appropriate for you and discuss all complication and risks with you prior to surgery.

Signature Orthopaedics' knee implant range is intended for use with Signature Orthopaedics' range of joint replacement components only. The selection of an implant of the correct size, shape, and type of bone fixation is extremely important to maximise the potential for a successful, long-term outcome for you.



Your physician will evaluate your particular situation carefully before making any decision regarding which implant is most appropriate for you.

How long will my implants last ?

Total Knee Replacements

The lifetime of the Signature Orthopaedics devices are indefinite, when used in accordance with the Instructions For Use, as the prosthesis is intended to remain implanted for your lifetime.

The warnings and precautions detailed in the “Complications and Risks” section list factors that may lead to a shorter lifespan of the implant. In the absence of any possible adverse events or side effects, the implants are expected to function as intended at a follow up of 10 years.

There are numerous factors that will affect the longevity of a hip replacement, including patient factors (such as age, weight and activity level), implant design and materials used during surgery. Your knee implants will also be subject to wear from friction caused by motions such as bending, straightening and supporting your body weight. In particular, the bearing surfaces of the implant will slide against each other.
As such, great care should be taken to ensure the least amount of friction possible.

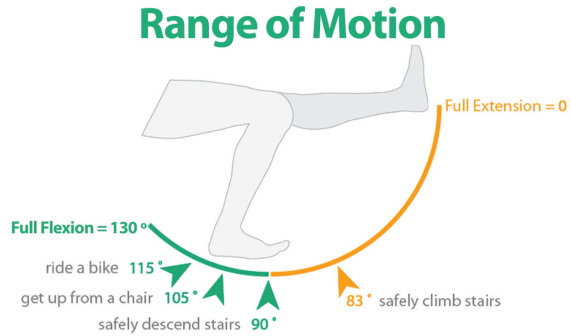
Total Knee Replacements

After successful surgery, your surgeon will evaluate your range of motion and your ability to use the muscles around your knee.

Will I return to everyday activites ?

The degree to which you can perform day to day movements is based on your range of motion as shown below. A normal knee would have a range of motion up to 0 to 135 degrees of flexion (bending) and 120 to 0 degrees of extension (straightening).

The decision on your post-operative activity level is dependent on your surgeon's recommendations and guidelines as well as your compliance with recommended post-operative therapy.



CONTACT US

How To Report Adverse Events

Any serious incident that occurs in relation to the device should be reported to your physician and the manufacturer, **Signature Orthopaedics**, by contacting the healthcare provider or emailing ***info@signatureortho.com.au*** ***info@signatureortho.eu***

If within Australia, you may also report an adverse event to the Therapeutic Goods Administration (TGA). More information regarding adverse events and how to report can be found at *https://www.tga.gov.au/reporting-adverse-events*

Signature ORTHOPAEDICS

This leaflet is intended for use in Europe and Australia.
For the latest version of this leaflet,
please refer to ***www.signatureortho.com.au/patientinfo***

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