PatientInfo

Total and Partial Hip Replacements

Signature Orthopaedics

Total and Partial Hip Replacements

This brochure offers a brief overview of total and partial hip 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 hip 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 hip. Your surgeon will carefully make decision regarding which implant is most appropriate for you and may determine that either a total or partial hip replacement is the best method of treatment when other nonsurgical treatments are ineffective.

A diseased hip is when one or more parts of the hip 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 ball of your femur starts to grind in the socket of your pelvis, pain and stiffness occurs.

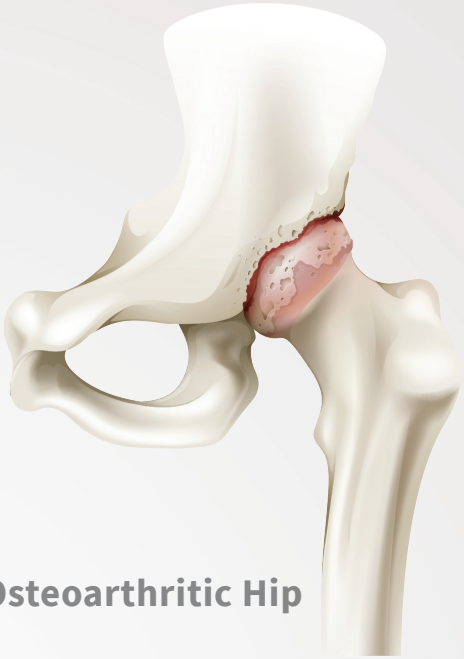
There are many reasons your hip may become damaged or diseased, including but not limited to:

- Non-inflammatory arthritis such as osteoarthritis or avascular necrosis
- Inflammatory arthritis such as rheumatoid arthritis or
- Traumatic injury

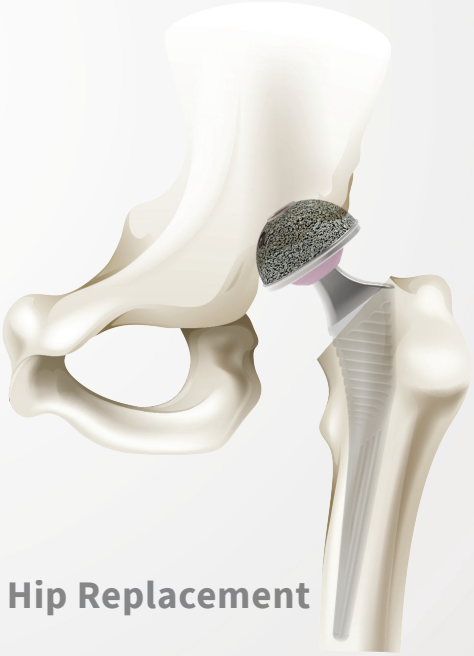
In these cases, Signature Orthopaedics hip replacement implants can be employed to replace the damaged bone and cartilage in a Total Hip Replacement (THR) or Partial Hip Replacement.

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 Hip



✓ Total Hip Replacement

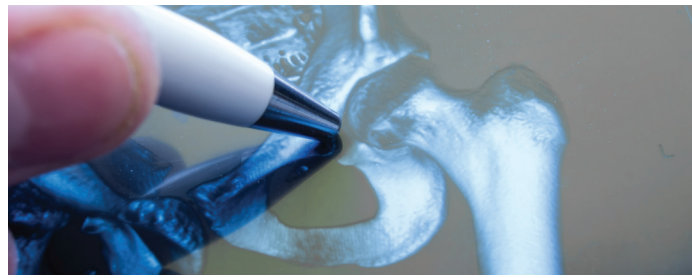
Total and Partial Hip Replacements

There are various surgical techniques your orthopaedic surgeon can use. To list a few, there is the Anterior Approach (from the front of the hip), Anterolateral Approach (from the side of the hip), or the Posterolateral Approach (from the back of the hip).

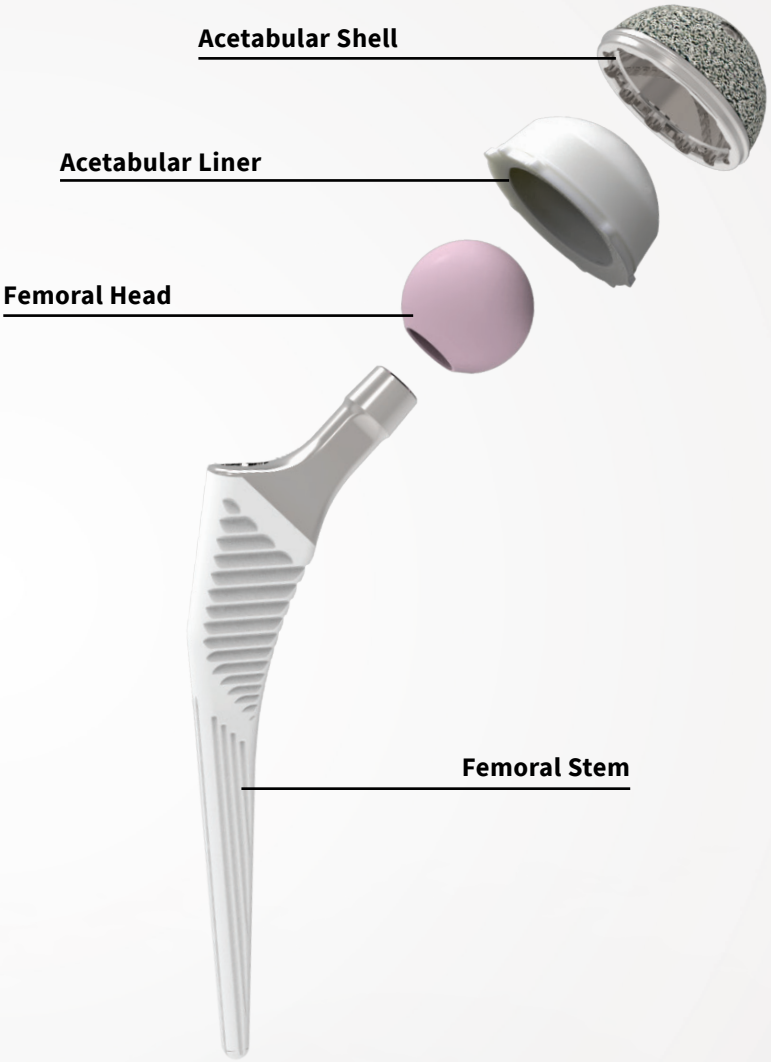
What is a total hip replacement ?

In a THR, the diseased hip ball (femoral head) will be removed and replaced with an artificial ball on a stem, which is inserted into the hollow part of the thigh bone. The hip socket (acetabulum) is prepared using special instruments and a metal shell (cup) is secured in place. A cup-shaped liner is then placed in this shell, together forming the socket portion of the joint.

If the acetabulum is relatively healthy with little arthritis, a hemiarthroplasty, or partial hip replacement may be an option. In this case, only the femoral head is replaced with an artificial head on a stem inserted into the thigh bone.



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


Acetabular Shell
Acetabular Liner
Femoral Head
Femoral Stem

Total and Partial Hip Replacements

As with any major operation, hip 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

It is important that patients know about the following possible risks and complications, which include but are not limited to;

- Wear
- Osteolysis
- Structural failure
- Fracture,
- Nerve injury
- Hematoma
- Materials sensitivity
- Infection,
- Blood clots
- Implant breakage
- Dislocation
- Malalignment
- Premature wear

Any of these can require additional surgery. Other possible adverse events include;

- Decreased range of motion
- Subluxation
- Leg length discrepancies
- Heterotopic bone formation
- Penetration of the femoral prosthesis through the femoral bone
- Squeaking/noise
- Intrapelvic protrusion of the acetabular component or prosthetic femoral head
- Femoral impingement
- Vascular injury and/or delayed wound healing
- Gait change or pain in the joints of the affected or contralateral extremity
- Aseptic loosening
- Pain
- Device corrosion
- Adverse reactions to metallic debris
- Sterilisation and contamination problems
- Device malfunction
- Packaging issue
- Pulmonary embolism
- Respiratory infection
- Trochanteric bursitis
- Subsidence
- Exostosis or metaphyseal debonding

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 Hip Replacement Implants

ARIASTEM

The Signature Aria™ stem is based on European philosophy of a flat tapered wedge. It is manufactured from Ti6Al4V alloy with 50% of the stem circumferentially Titanium plasma coated. The plasma coating is a macro-roughened surface for bone ongrowth. The distal stem is matte finished intended to reduce painful end loading. The flat rectangular geometry of the Signature Aria stem is intended for rotational stability. The stem is available with a neck angle of 132 degrees for 13 body sizes in both standard and lateral offsets.

EVOLVESTEM

The Signature Evolve™ stem is manufactured from high nitrogen stainless steel. The system has 4 different offsets (35mm, 37.5mm, 44mm, 50mm) with 2 to 4 stem sizes per offset. This combination of offset/sizes and collarless design, allows the surgeon to adjust hip offset and leg length independent of each other. It has a 12/14 taper connection for adaption to multiple head and taper sleeve options. The PMMA distal centraliser is intended to reduce point loading of the stem onto the cement, while allowing distal migration of the stem within the cement mantle.

ORIGINSTEM

The Signature Origin™ cementless hip stem manufactured from Ti6Al4V, is coated on its full length with hydroxyapatite and has a 12/14 taper which is compatible with the range of Signature femoral heads as well as Ceramtec BIOLOX® delta ceramic heads. The low profile lateral shoulder is intended to ease insertion to assist in reduced insertion techniques, including anterior approach. The stepped stem geometry is intended to convert hoop stresses into compressive loads. Vertical and horizontal grooves are intended for rotational and axial stability. The Origin stem is available in a variety of offsets and neck angles to provide options to match patient anatomy. Collared stems are also available, which are intended to resist subsidence and add rotational stability.

LOGICALCUP

The Signature Orthopaedics Logical™ system is a modular cup system which offers a wide range of cup, fixation and bearing options for intraoperative flexibility. The cup is manufactured from titanium alloy and coated with a range of coating technologies intended to promote biological cementless fixation. The cups (I.e. sintered Ti bead coating, plasma sprayed HA coating, and sintered TI and plasma sprayed HA coating) are available in no hole, 3 hole and multi-hole options. Cups may be used with the range of crosslinked polyethylene liners, including hooded, lateralised and constrained variants. Ceramic liner options made of BIOLOX delta material are also available.

FEMORALHEADS

The Signature Femoral Heads are intended to mate with a femoral stem from Signature Orthopaedics' range as part of a hip replacement prosthesis. The femoral heads are highly polished with high spherical conformity to reduce articular surface wear. The femoral head includes a 12/14 style morse taper connection to connect with Signature Orthopaedics' range of femoral stems. The Signature Femoral Heads are available in sizes from 28-44mm diameter, with S to XL lateral offset, in Ceramic, Stainless Steel (SS) or Cobalt Chromium (CoCr) versions.

UNIPOLARHEADS

The Evolve™ UniPolar Head is a CoCr ball with a tapered bore. The head connects to a femoral stem from Signature Orthopaedics' range via the taper sleeve. The taper sleeve is also manufactured from cobalt-chromium alloy per ISO 5832-12, and includes a 12/14 taper. The head's outer surface is highly polished to articulate against the patient's natural acetabulum as part of a hip hemi-arthroplasty.

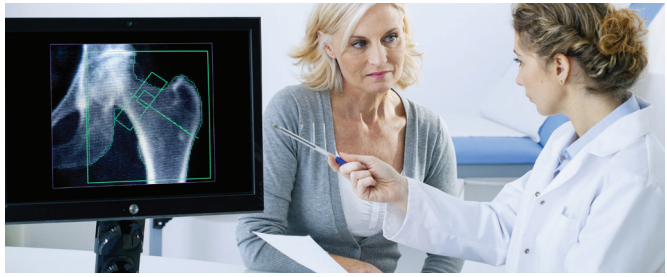
Total and Partial Hip Replacements

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 body 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 and discuss all complication and risks with you prior to surgery.

Signature Orthopaedics' hip replacement 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.

Total and Partial Hip 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.

How long will my implants last ?

The warnings and precautions detailed in the “Complications and Risks” section list factors that may lead to a shorter lifetime of the implant. In the absence of any possible adverse events or side effects, the implants are expected to function indefinitely for your lifetime.

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 hip 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.

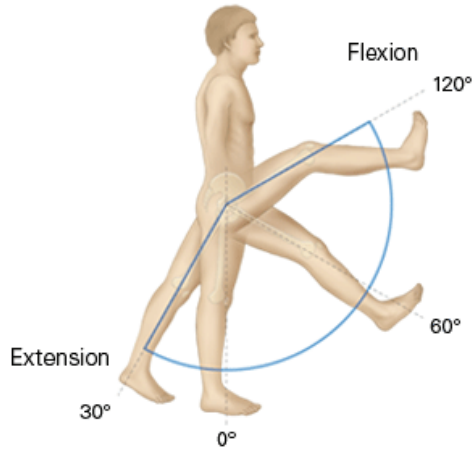
Total and Partial Hip Replacements

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

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 hip would have a range of motion up to 120-130 degrees of flexion (bending) and 20-30 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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