

A Prospective, Pre-market, Multi-center Study of Insignia Hip Stem in THA to Determine Implant Survivorship and PROMS.

NCT06108934

Status	RECRUITING
Phase	Not Applicable
Sponsor	Stryker Australia Pty Ltd.
Enrollment	313 participants

Plain Language Summary

This study follows patients who receive the Insignia Hip Stem, a new cementless hip implant, during total hip replacement surgery. The goal is to track how well the implant lasts over time and measure patient-reported outcomes like pain and mobility.

****You may be eligible if...****

- You have joint disease that requires a primary (first-time) total hip replacement, such as osteoarthritis, avascular necrosis, or rheumatoid arthritis
- You are a candidate for a cementless hip replacement
- You have signed informed consent and are willing to attend follow-up visits

****You may NOT be eligible if...****

- You have an active or suspected infection in or near the hip
- You have a mental or neuromuscular disorder that would make the hip implant unstable
- You have poor bone quality that cannot support the implant
- You are on long-term high-dose steroids that suppress your immune system
- You are involved in an active Workers' Compensation case
- You are known to be sensitive to the implant materials

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (4)

- The patient has signed the study specific, Human Research Ethics Committee (HREC) approved, Patient Information Consent Form for the use of the study device
- Primary non-inflammatory degenerative joint disease (including osteoarthritis or avascular necrosis) and/or rheumatoid arthritis
- The patient is a candidate for a primary cementless THA.
- Patients who are informed of the conditions of the study and are willing to participate for the length of the prescribed follow-up period.

Exclusion (7)

- Active or suspected latent infection in or about the affected hip joint and the time of study device implantation.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in post-operative care.
- Has bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Is immunologically suppressed or receiving steroids in excess of normal physiological requirements (e.g. >30 days.)
- Requires revision THA or hip fusion to the affected joint.

<https://clinicaltrials.gov/study/NCT06108934>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.

Locations (1 total)

St John of God Subiaco Hospital, Subiaco, Western Australia, Australia