

# Post-market surveillance study of the ADAPTIS Total Ankle Replacement with EVERLAST polyethylene insert

<b>Submission date</b> 27/03/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/09/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

An ankle replacement procedure consists of replacing the worn-out joint surfaces of the ankle with metal and plastic components that are shaped to allow continued movement of the ankle. There are several different types of ankle replacement available. All current ankle replacements have limited durability, and developing systems with improved durability is important. INFINITY™ ankle implants are already routinely used in NHS hospitals. The INFINITY™ with ADAPTIS™ and EVERLAST™ ankle replacement system is a development of the INFINITY™ ankle implant. This new implant has been designed to attach to the bone better and to wear out more slowly, potentially providing a better outcome for patients. This study is being conducted to find out how the INFINITY™ with ADAPTIS™ implant performs and how well participants are doing after surgery. Participants in this study will be among the first to receive INFINITY™ with ADAPTIS™ and EVERLAST™ system in the hospital.

### Who can participate?

Patients aged over 21 years who are on the waiting list for a total ankle replacement and their surgeon has made a separate clinical decision confirming that they are suitable to receive the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System for the total ankle replacement surgery.

### What does the study involve?

**Before surgery:** After consenting for the study, the research team will collect information from the participant's medical notes, including x-rays. The team will also contact the participant at either their appointment, via email or telephone to complete some questionnaires.

**Surgery and hospital stay:** A surgeon will perform the surgery using the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System. The care received in the hospital will be the same as standard care. The research team will collect information from medical notes about the surgery.

After surgery: After surgery, participants will be required to attend clinical appointments and receive additional x-rays as part of the enhanced follow-up process for up to 5 years.

- Outpatient appointments: First follow-up visit will be at 6 weeks post-surgery. Participants will be required to attend outpatient appointments and undergo x-rays at 6 months, 1 year, 2 years and 5 years post-operatively. Teams will collect information on any issues.
- Questionnaires: Participants will be asked to complete questionnaires at 6 months, 1 year, 2 years and 5 years post-operatively. These can be completed at a face-to-face appointment, over the telephone or via email.

What are the possible benefits and risks of participating?

It is hoped that the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System will offer:

1. Bony integration of the metallic components
2. Reduced pain
3. Restored alignment
4. Replacement of flexion and extension movement in the ankle

The potential benefits relating to a total ankle replacement in general include:

1. Pain reduction
2. Increased function
3. Improved quality of life

This study may help us to better treat future patients who need total ankle replacement surgery and inform future research.

Any surgery carries potential risks, including the surgery as part of this study. The potential risks relating to a total ankle replacement in general include:

1. Aseptic loosening of the prosthesis
2. Infection
3. Deep venous thrombosis
4. Post-operative pain
5. Heterotopic ossification
6. Fracture of the prosthesis
7. Fracture of the bone
8. Loss of muscle force
9. Nerve and vessel injury
10. Wound healing problems
11. Implant failure
12. Medical complications
13. Death

The evidence from testing the INFINITY™ with ADAPTIS™ and EVERLAST™ Technology Total Ankle System tells us that the risks are unlikely to be higher than the alternative options.

For women, the surgeon must be aware if they become pregnant before/after their surgery, as there could be additional risks to them or their foetus. If they become pregnant after surgery, the study team will continue to keep them in the study and follow-up, however, they will not expose them to additional radiographs during maternity.

Participants will have an x-ray of the ankle taken before the surgery (within 12 months prior to surgery), and at 6 months, 1 year, 2 years and 5 years post-operatively. As a newer implant was chosen as part of a routine treatment, participants will be monitored more closely, and so it is possible they may get slightly more X-rays than if they didn't take part, however, any difference in the schedule will be small.

X-rays use ionising radiation. Ionising radiation may cause cancer many years or decades after exposure. Everyone is at risk of developing cancer during their lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during their lifetime. Taking part in this study will add only a very small chance of this happening.

Where is the study run from?  
North Tyneside General Hospital, UK

When is the study starting and how long is it expected to run for?  
December 2023 to April 2031. Participants will be followed up for up to 5 years after ankle surgery.

Who is funding the study?  
Stryker European Operations Limited

Who is the main contact?  
stees.ukadaptisstudy@nhs.net

## Contact information

**Type(s)**  
Public, Scientific

**Contact name**  
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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT06941558

## **Integrated Research Application System (IRAS)**

338603

## **Central Portfolio Management System (CPMS)**

61149

# **Study information**

### **Scientific Title**

INFINITY™ with ADAPTIS™ and EVERLAST™ technology total ankle replacement follow-up

### **Acronym**

UK ADAPTIS™ Study

### **Study objectives**

There are several different types of ankle replacement available. Infinity ankle implants are already routinely used in NHS hospitals. The INFINITY™ with ADAPTIS™ and EVERLAST™ ankle replacement system is a development of the Infinity ankle implant, designed to attach to the bone better and to wear out more slowly.

The hypothesis of the UK ADAPTIS™ Study is to evaluate the performance and function of the newly introduced INFINITY™ with ADAPTIS™ and EVERLAST™ technology Total Ankle System for total ankle replacement (TAR) or arthroplasty (TAA) and EVERLAST™ Poly Insert that modernises and streamlines Stryker's TAA/TAR portfolio.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 28/03/2024, Yorkshire & The Humber – South Yorkshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8021, (0) 2071048075; southyorks.rec@hra.nhs.uk), ref: 24/YH/0053

### **Study design**

Observational interventional case series

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

INFINITY™ with ADAPTIS™ and EVERLAST™ Technology with Poly Insert for patients requiring primary total ankle replacement/arthroplasty (TAR/TAA) across up to 10 UK NHS Hospital Trusts regularly performing TAA/TAR.

### **Interventions**

Study design

A prospective multi-centre observational cohort series of INFINITY™ with ADAPTIS™ and

EVERLAST™ Technology with Poly Insert for patients requiring primary total ankle replacement /arthroplasty (TAR/TAA) across up to 10 UK NHS Hospital Trusts regularly performing TAA/TAR.

The study will have a minimum 12-month recruitment period and up to 5 years post-operative follow-up (6 weeks, 6 months, 1 year, 2 years, and 5 years).

#### Intervention and indication

INFINITY™ with ADAPTIS™ and EVERLAST™ technology with Poly Insert for patients requiring primary TAA/TAR.

It is intended to give a patient limited mobility by reducing pain, restoring alignment, and replacing flexion and extension movement in the ankle joint with benefit for patients with ankle joints damaged by severe rheumatoid, posttraumatic, or degenerative arthritis or a failed previous ankle surgery.

#### Screening and recruitment

Patients will primarily be screened from theatre lists of patients waiting for a TAA/TAR and are eligible to receive the INFINITY™ with ADAPTIS™ and EVERLAST™ technology Total Ankle System for TAA/TAR as part of their routine care. Patients may also be screened from orthopaedic outpatient clinics where patients have been referred through standard practice.

Members of the healthcare team or a delegated member of the research delivery team will screen for eligible patients and have their eligibility confirmed by their treating clinician.

All patients who have been screened will need an eligibility form completed on REDCap. For those who are eligible, a contact details form will also need to be completed, and they will be contacted by a delegated member of the research delivery team. They will be provided a patient information sheet (PIS) in person, via their email or post, depending on patient preference.

If a patient is interested, consent will be collected (a) electronically via REDCap (in person or via a link sent); (b) written consent (in person or via post) and uploaded to REDCap; (c) verbal consent, which will be documented on REDCap – this will need to be followed up by either electronic or written consent.

Each site will keep an electronic screening log, documenting the date of screening, results of screening and the primary reason for excluding a patient or the reason a patient has decided not to participate, as available. The screening log will be held on the secure database REDCap as hosted by the study management team at South Tees Hospitals NHS Foundation Trust.

#### Data collection

The study data will be collected and managed using REDCap electronic data capture tools, hosted at South Tees Hospital NHS Foundation Trust. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; and (3) automated export procedures for seamless data downloads to common statistical packages; (4) procedures for data integration and interoperability with external sources.

- a. Screening and eligibility
- b. Consent (valid for 12 months)
- c. Pre-operative clinical history (including radiographs) and PROMs
- d. Intra-operative evaluation

- e. Post-operative clinical history (including radiographs) and PROMs (6 months +/- 5 weeks, 1 year +/- 6 weeks, 2 years +/- 3 months, and 5 years +/- 6 months). Clinical history only at 6 weeks post-op +/- 2 weeks.
- f. Withdrawal or discontinuation
- g. Adverse events

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

INFINITY™ with ADAPTIS™ and EVERLAST™ technology with Poly Insert

### **Primary outcome(s)**

1. Functional status measured using the Manchester-Oxford Foot Questionnaire (MOXFQ) at 2 years post-operative
2. Device survivorship, defined as the removal or exchange of one or more of the components (excluding incidental polyethylene exchange for infection) at 2 years

### **Key secondary outcome(s)**

The following secondary outcome measures will be measured using data collected in study records:

1. Survivorship, defined as the removal or exchange of one or more of the components (excluding incidental polyethylene exchange for infection), at 2 years, 5 years and post-operative.
2. Revision of any components (excluding incidental polyethelene exchange for infection) by the end of the study
3. Re-operation without revision by the end of the study
4. Type and frequency of adverse events (AEs), specifically operative and device-related AEs and Serious AEs (SAEs) by the end of the study
5. Functional status, pain and disability (MOXFQ & AOS) and health-related quality of life (EQ5D-5L) at 6 months, 1 year, 2 years, and 5 years post-operative.

### **Completion date**

01/04/2031

## **Eligibility**

### **Key inclusion criteria**

1. Male or non-pregnant female over the age of 21 years with a diagnosis of end-stage ankle arthritis and requiring primary TAA/TAR and is suitable for the use of the ADAPTIS TAA/TAR.
2. Patients who are physically and mentally willing and able to comply with the post-operative follow-ups and an appropriate rehabilitation schedule.
3. The patient can understand and provide written consent.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

21 years

**Sex**

All

**Total final enrolment**

206

**Key exclusion criteria**

1. Patients with previous ankle arthrodesis or Patients who require revision of previously implanted TAA/TAR.
2. Any patients presenting with clinically relevant conditions prior to implantation that would contraindicate the implantation of a TAA/TAR.

**Date of first enrolment**

18/04/2024

**Date of final enrolment**

27/08/2025

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

**Royal National Orthopaedic Hospital**

Brockley Hill

Stanmore

United Kingdom

HA7 4LP

**Study participating centre**

**The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust**

Gobowen

Oswestry  
United Kingdom  
SY10 7AG

**Study participating centre**  
**NIHR Nottingham Biomedical Research Centre**  
Queens Medical Centre  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**NHS Lothian**  
Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
United Kingdom  
EH1 3EG

**Study participating centre**  
**Poole Hospital**  
Longfleet Road  
Poole  
United Kingdom  
BH15 2JB

**Study participating centre**  
**Royal Devon University Healthcare NHS Foundation Trust**  
Royal Devon University NHS Ft  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Royal Albert Edward Infirmary**  
Wigan Lane  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**  
**North Tyneside General Hospital**  
Rake Lane  
North Shields  
United Kingdom  
NE29 8NH

**Study participating centre**  
**Northern General Hospital**  
Northern General Hospital NHS Trust  
C Floor, Huntsman Building  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**  
**Southmead Hospital**  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**  
**Torbay Hospital**  
Newton Road  
Torquay  
United Kingdom  
TQ2 7AA

## **Sponsor information**

**Organisation**  
Northumbria Healthcare NHS Foundation Trust

**ROR**  
<https://ror.org/01gfeyd95>

# Funder(s)

## Funder type

Industry

## Funder Name

Stryker

## Alternative Name(s)

Stryker Corporation, Orthopedic Frame Company

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

Information collected for the study will be accessed to analyse the results. The identities of the participants in this study will remain strictly confidential. Details such as name, date of birth and address will not be shared.

Analysis of results will be organised by the CI and the study management team. A detailed Statistical Analysis Plan will be agreed with an expert statistician before conducting any analyses. The analyses will be mainly descriptive. Continuous data will be summarised using means and standard deviations (or median, interquartile range, minimum and maximum as appropriate). Categorical data will be summarised using counts and percentages. Graphs will be produced to display trajectories in outcomes over time. Linear or logistic regression models (as appropriate depending on the outcome) will be used to evaluate the influence of patient, clinical and surgical factors on outcomes.

AEs and SAEs will be summarised descriptively and using graphs by whether they are operative or device-related.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol file</a>	version 1.1	11/03/2024	09/09/2025	No	No