PARTICIPANT INFORMATION SHEET

Study Title: Performance and Function of the Trident® II 3D printed Acetabular Component

Study Sponsor: South Tees Hospitals NHS Foundation Trust

Clinical Site: South Tees Hospitals NHS Foundation Trust

Chief Investigator: Simon Jameson, Consultant Trauma and Orthopaedic Surgeon, South Tees Hospitals NHS Foundation Trusts

Sub-Investigator: Paul Baker, Consultant Trauma and Orthopaedic Surgeon, South Tees Hospitals NHS Foundation Trusts

PLEASE READ THIS INFORMATION CAREFULLY AND MAKE SURE THAT YOU UNDERSTAND IT.

We would like to invite you to take part in a research study. Your decision to join the study is entirely voluntary. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read this sheet carefully. If at any time you have any questions, feel free to ask a member of our research team using the contact details provided at the end of this document or your treating consultant. Please feel free to talk to others about this study if you wish.

Why is the study being done?

The hip is a ball and socket joint. The ball is at the top of your thigh bone, and the socket is part of your pelvic bone. In a total hip replacement (arthroplasty), both the ball and the socket will be replaced. The Trident® II acetabular component is a new implant that will be used to replace the socket of the hip. Trident implants are routinely used in our hospital in patients who require a hip replacement. It is important to find out how the new Trident® II implant performs and how well you are doing after surgery. This is why we are conducting this study. Participants in this study will be amongst the first to receive the Trident® II acetabular component in our hospital.

Why have I been invited to take part in the study?

You have been invited to take part in this study because you are on the waiting list for a total hip replacement and your surgeon has made a separate clinical decision

confirming that you are suitable to receive the Trident® II acetabular component as part of your hip replacement surgery.

Do I have to take part in the study?

No, participation is entirely voluntary and it is your decision whether you would like to take part. If you do not want to take part, you do not have to give a reason and it will not affect the care you receive from the hospital.

You can take as much time as you like to decide. If after speaking to your surgeon you decide to take part, a member of the research team will ask you to sign and date a consent form for the study, this is separate to the consent form you will sign for your surgery. You are still free to withdraw from the study at any time, without giving a reason and without your care being affected.

What would taking part in the study involve?

This study will take place at South Tees Hospital NHS Foundation Trust, where your surgery and outpatient appointments will also take place. Your surgeon has reviewed your medical history to confirm you are eligible to join the study.

Before we collect any information for the study, you will be asked to read and understand **this Participant Information Sheet**. If you would like to take part in the study, a member of the research team will ask you to sign an Informed Consent Form for the study.

Before surgery: After you give consent for the study, the research team will collect information from your medical notes, including your x-rays. The team will also contact you via email or telephone to complete some questionnaires about your hip.

Your surgery and hospital stay: Your surgeon will perform the surgery using the Trident® II implant. The care you receive in hospital will be the same as standard care. The research team will collect information from your medical notes about the surgery and hospital stay. X-rays will be taken before you leave the hospital.

After surgery: After your surgery, you will be required to attend clinical appointments and receive additional x-rays as part of the enhanced follow-up process for up to 10 years. Please see below:

- **Outpatient appointments:** You will be required to attend outpatient appointments at 6-12 weeks, 1 year, 5 years and 10 years. We will collect information on any issues you might be having. X-rays will also be taken during the 1 year, 5 year and 10 year appointments.

- **Questionnaires:** You will be asked to complete questionnaires at 6-12 weeks, 1 years, 3 years, 5 years, 7 years and 10 years. You can complete these at your appointment, over the telephone or via email.

If there are any changes to your health while participating in our study, please let a member of the team know. You are still free to withdraw from the study at any time, without giving a reason and without your care being affected.

How many people will take part in this study?

100 participants

How long will I be in the study?

You will be followed-up for up to 10 years after your hip surgery.

What are the potential benefits of taking part?

We hope that the Trident® II will offer you:
- A better range of movement
- A lower risk of dislocation
- A more stable joint compared to the standard component.

The potential benefits relating to a total hip replacement in general include:
- Pain reduction
- Increased function
- Improved quality of life

What we learn from this study may help us to better treat future patients who need total hip replacement surgery as well as informing future research.

What are the potential disadvantages and risks of routine hip replacement surgery?

Any surgery carries potential risks, this includes the surgery as part of this study. The potential risks relating to a total hip replacement in general include:
- Failure of the implant due to a non-infection related cause (Aseptic loosening of the prosthesis)
- Infection
- Blood clot (Deep venous thrombosis)
- Postoperative pain
- New bone in the soft tissues (Heterotopic ossification)
- Fracture of the implant (prosthesis)

- Fracture of the bone
- Loss of muscle function (force)
- Dislocation
- Medical complications/death
- Leg length discrepancy
- Nerve and vessel injury

The evidence from testing the Trident® II acetabular component tells us that the risks are unlikely to be higher than the alternative options.

For women, it is important that you tell your surgeon if you become pregnant before/after your surgery as there could be additional risks to you or your foetus. If you become pregnant after surgery, we will continue to keep you in the study and follow-up, however we will not expose you to additional radiographs during maternity.

What are the risks of the radiation I will be exposed to?

You will have an x-ray taken before the surgery, prior to discharge from hospital, at 1 year, 5 years and 10 years. The x-rays taken before the surgery & prior to discharge from hospital are routine to any hip replacement. As a newer implant was chosen as part of your routine treatment, the series of x-rays will not exceed the national recommendations of the British Orthopaedic Association (BOA) when following-up a new implant.

Hip x-ray examinations are part of your routine care. If you take part in this study you will not undergo any additional imaging to what is nationally recommended. However, by enrolling in this study, you will be closely monitored by more x-rays and an enhanced follow-up to what you could expect with standard care at our hospital. These procedures use ionising radiation to form images of your body. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.

What alternatives are available to potential participants?

All participants consented into this study will receive the Trident® II acetabular component. There is a chance that even if you do not take part in the study that you may still receive the Trident® II acetabular component as standard of care if your surgeon decides this is needed. Being a part of this study allows us to monitor you and the implant long-term to assess how successful and effective this implant is compared to alternative options.

Please talk to your surgeon about other treatment options available to you as well as their potential benefits and risks before you enter this study.

What happens if I don't want to be in the study?

Your participation in this study is absolutely voluntary. If you do not want to participate within this study or if you decide to withdraw before the end of the study, your decision to do so will have no negative impact on your future or subsequent treatment.

A decision to stop the study will not affect the care you are otherwise entitled to. The study may also be stopped by a regulatory authority or South Tees Hospitals NHS Foundation Trust. Additionally, your surgeon may decide to stop your participation in the study, with or without your consent, for medical reasons or if you no longer meet the study criteria.

Your surgeon and the research team are available if you have any questions regarding your participation in this study (see also, **"What are your choices about how your information is used?"**.

Are there any costs and compensation?

You will not have to pay for the costs of any additional visits required for this study.

We will reimburse any travel costs for the 1, 5 and 10 year outpatient appointments up to a maximum of £30 per visit. In addition to this, we will be sending a thank you voucher worth £5 when you have returned completed questionnaires at 1, 3, 5, 7 and 10 years after your surgery.

The hospital or your surgeon will not be receiving any additional payments or benefits for conducting this study other than to cover the costs of undertaking the additional study procedures and follow up.

What if something goes wrong?

If you have a serious medical problem during the course of this study, please inform a member of our team as soon as possible. We will follow-up with you until the problem has resolved, or until it has stabilised.

For medical devices meeting regulatory requirements for marketing that are being used as part of standard care and in line with their produce specification, such as the one in this study, liability for all clinical care rests with the treating surgical team and the surgical team's NHS Trust.

For any additional study related activity that is unrelated to routine clinical care (for example study data collection or taking of x-rays) that is carried out in accordance with the clinical investigation plan for the study, liability rests with the research team and the research teams NHS Trust who is sponsoring the study.

As this is a single site study the surgical team's NHS Trust is also the research team's NHS Trust who have responsibility for leading and managing the research study as sponsor (both South Tees Hospitals NHS Foundation Trust).

If you have any concerns or questions about any aspect of this study or any complaint about the way you have been dealt with during this study, in the first instance you should speak to a member of the research team, or the principal investigator or study co-ordinator whose details can be found at the end of this participant information sheet.

If you are unhappy with any aspects of the study you can also contact the Research & Development department as below:
Address: South Tees Institute of Learning Research & Innovation, The James Cook University Hospital, Marton Road, Middlesbrough, TS4 3BW
Email: stees.researchdevelopment@nhs.net
Telephone: 01642 854089

If you remain unhappy, and wish to proceed with a complaint, you can contact the National Health Service's complaints mechanism by contacting the Participant Advice and Liaison Services (PALS).

Contact details:

Participant Advice and Liaison Service (PALS)
The James Cook University Hospital
Marton Road
Middlesbrough
TS4 3BW
Email: stees.pals@nhs.net
Freephone: 0800 0282451
Phone: 01642 854807/01642 282657

How will we use information about you?

We will need to use information from you and your medical records for this research study. This information will include:

- Your name and initials
- NHS/hospital number
- Contact details
- Date of birth

South Tees Hospitals NHS Foundation Trust, as sponsor, is the data controller and is responsible for looking after your information and using it properly. We will keep all information about you safe and secure. We will remove any details that would identify you personally. The results of the study will be written in a way that no-one could identify you

personally from the reports and publications. Any data collected will be anonymised and may be used to inform future research. See, "**How will my information be kept confidential?**".

If you wish to know the results of the study, you can contact a member of the research team. The study findings will also be available to view via the sponsor's website *https://www.southtees.nhs.uk/about/research/research-innovation/* and social media.

What are your choices about how your information is used?

- You can stop being a part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients/
- By asking a member of the research team
- By contacting a member of the research team via email or telephone

How will my information be kept confidential?

Your privacy is important. All information collected during this study will be kept private and personal data will be handled in accordance with the GDPR and Data Protection Act (2018). Your medical records may also be inspected by regulatory authorities and the sponsor (South Tees Hospitals NHS Foundation Trust) Research & Development department staff to check that the study is being carried out correctly.

Information collected for the study will be accessed for the purposes of analysing the results. However, your identity as a participant in this study will remain strictly confidential. Details such as your name, date of birth and address will not be shared outside the hospital.

By consenting to take part, you accept that the information from this study, including anonymised data and results of examinations and tests, will be collected and processed for the purposes of the study and for any additional scientific research under the supervision of Stryker in compliance with the Data Protection Act (2018). This information may be used for product registration, product performance monitoring and scientific research investigating new treatments, interventions and

management procedures so that participant care outcomes are continually improved. The study results may be used for regulatory, scientific or commercial purposes and may be published but it will not be possible to identify you.

All electronic participant identifiable information (including contact information) will stored securely in REDCap data capture system hosted by the South Tees Hospitals NHS Foundation Trust within its password protected servers. Access will only be granted to essential study personnel within the central study team and local research team and the contact details will be deleted once the information is no longer required to contact you. Participants will be identified by a code number only for any analysis and cannot be identified from study reports or any other outputs.

What if relevant new information becomes available?

You will be notified in a timely manner of any new information that develops over the course of this study that may affect your willingness to participate in this study.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests.
This study has been reviewed and was given a favourable opinion by the South West - Central Bristol Research Ethics Committee (Ref: 22/SW/0024) and Health Research Authority approval (IRAS ID: 276445).

Further information and contact details

If you want more information about this study, please contact any of the research team members. You should inform your surgeon or a member of research team if you have any complications or been hospitalised for any reason during the study.

Contact Information

Chief Investigator:
Mr Simon Jameson,
Orthopaedics Department,
The James Cook University Hospital,
South Tees Hospitals NHS Foundation Trust,
Marton Road,
Middlesbrough,
TS4 3BW
Email: simonjameson@nhs.net
Phone: 01642864521

Sub-Investigator:
Professor Paul Baker,
Orthopaedics Department,
The James Cook University Hospital,
South Tees Hospitals NHS Foundation Trust,
Marton Road,
Middlesbrough,
TS4 3BW
Email: paul.baker1@nhs.net
Phone: 01642854479

Project Manager:
Dr Lucksy Kottam
Research & Development Department,
STRIVE,
Marton Road,
Middlesbrough,
TS4 3BW
Email: lucksy.kottam@nhs.net
Phone: 01642854814

Research Nurse:
Juliet James,
12B19, STRIVE
Marton Road,
Middlesbrough,
TS4 3BW
Email: Juliet.nazareth@nhs.net
Phone:01642854954

Thank you for reading this information sheet and considering your participation.