PARTICIPANT INFORMATION SHEET

PROSPECTIVE EVALUATION OF NANONEEDLE
(Nanoneedle Ankle Syndesmosis)

Thank you for your interest in participating in this study. This information sheet will refer to you as the *participant*, who is due to undergo surgery. It will also refer to the *study grou*p, which is the team of orthopaedic surgeons, research nurses and research investigators that carry out the study.

You have been offered arthroscopic (keyhole) ankle surgery because you have sustained an ankle joint injury which includes an injury to your ankle syndesmosis, that could make your ankle joint unstable. The syndesmosis is a complex joint that connects the two long bones (tibia and fibula) just above your ankle joint, which are held together by strong ligaments. The keyhole surgery is to assess your ankle ligament injury using Nanoscope technology. The Nanoneedle™ is a part of this technology and is a new single-use chip on tip camera system.

The procedure will be carried out under general or spinal anaesthetic, at the same time as the normal operation planned for your ankle injury. The Nanoneedle™ is placed inside the ankle joint through 1 or 2 tiny incisions to provide the surgeons with high quality images that can be a better alternative to scans like MRIs, this will allow the surgeons to look at the syndesmosis whilst moving your ankle joint. The images will help to assess your ankle for instability and plan your care.

The aim of the study is to determine how easy it is to use the Nanoneedle, the quality of the view and the diagnostic accuracy of the Nanoneedle in diagnosing the instability of the ankle injuries, compared with the normal arthroscopic techniques the surgeons use.

This Information Sheet will explain how and why the study is to be carried out. If you have any questions or there are parts that you do not understand, please ask a member of the study group. The contact details for the group are at the end of this document.

Please read the following information sheet before deciding whether or not you would like to participate.

As a participant, prior to any data collection or testing, you will be required to:

1. Read this ***Participant Information Sheet*** which will outline the procedures and the potential risks.
2. Complete and sign an ***Informed Consent Form***.

If you choose not to participate in the study, it will not affect your surgery or care in any way. You are also free to withdraw from the study at any point, again without it affecting your surgery or care. Whether or not you decide to participate, we appreciate your time and consideration.

1 - Participants for the study

The study requires 20 participants, aged over 18, who are listed for surgery with acute (not more than 6 weeks ago) unstable ankle syndesmosis injuries requiring an arthroscopic assessment. You will be consented for the study prior to any surgical procedure.

Participants will be identified and recruited by the team of orthopaedic surgeons involved in this study at the following sites:

- Hampshire Hospitals NHS Foundation Trust
    - Royal Hampshire County Hospital
    - Basingstoke & North Hampshire Hospital
- Fortius Clinic, London

2 - What are the aims of the study?

The aim of this study is to determine the ease of use, the quality of the view and the diagnostic accuracy of this technology in diagnosing the instability of ankle injuries.

4 - What information will be collected as part of the study?

We will need to collect personal information including your name, age, and gender for this study. We will also collect information including the date of your injury, the mechanism of your injury and the side you have injured.

Only appropriate personnel will have access to your record and all information will be treated with the strictest security and confidentiality.

No identifiable information will be shared between Trusts. To keep your information secure you will be allocated a unique Participant ID Number.

A copy of your Informed Consent Form and information we have collected about your health related to this study will be held by Hampshire Hospitals NHS Foundation Trust.

When the results of the study are reported and/or published, participants who have taken part will not be identified in any way. A summary of the study findings can be made available at the end of the study should you wish to receive a copy.

5 - How will the data be used?

Your pre-operative, operative and post-operative medical records will be used to provide an evaluation of the effectiveness of the Nanoneedle™ as a way of evaluating acute ankle joint syndesmosis injuries.

All data will be stored securely with only the research team having access to the data. All essential documents will be retained for a minimum period of 10 years after study completion.

The results of this study may be presented or published, but all information will be anonymised and will not be linked to any individual. Your anonymised data may also be used in future research related projects.

6 - What other information will be collected alongside the study?

When a patient undergoes surgery of their ankle, irrespective of whether they are involved in a study such as this one, the surgical team will collect the following information as part of their standard post-operative consultations. The information collected includes:

- X-rays of the affected ankle taken before the operation
- X-rays taken at 6 weeks or at later intervals if there is a clinical reason for them ie. ongoing symptoms
- Images of the inside of your ankle joint taken during the keyhole procedure
- Possible scans like MRI, CT, or US if there is a clinical reason for them before or after your surgery

By taking part in this study, you will have the same x-rays or CT scans that you would if you didn't take part. X-rays and CT scans use ionising radiation, but your exposure to ionising radiation will be the same whether you take part in the study or not.

Photographs may also be taken during your procedure; these will not contain any identifiable information and separate consent will be taken before your procedure.

7 - What are the potential risks and discomfort of the study?

As with all operations, there is a small risk of complications, and these will be determined and recorded by the surgical team, either in clinic or via telephone consultations. The risks of surgery will be discussed prior to the operation and you, the patient, will sign a standard consent form. Whether or not you agree to participate in the study it will not have any effect on the development of potential surgical complications.

Potential complications of this type of surgery include pain, swelling, stiffness, infection, blood clots, scar problems, nerve or vessel damage, bleeding and COVID-19.

Use of the Nanoneedle will add approximately 5 minutes to the surgical time compared with standard arthroscopy, and therefore does not add any significant risks to the standard surgery.

8 - Can you change your mind and withdraw from the study?

You are free to withdraw from the study at any time, even if you have already provided information towards the study. Should you withdraw, any data that has already been collected will still be used for the final study.

9 - What will you be asked to do if you agree to take part in the study?

Decision	Decision to treat an ankle syndesmotic injury
↓	
Before Surgery	• Read the Participant Information Sheet • Sign Informed Consent Form • Sign operation consent forms before surgery
↓	
Surgery	• Undergo surgery to evaluate your ankle ligaments using the Nanoscope technology
↓	
After Surgery	• Follow up at 2-weeks post-operatively with the surgical team • Follow up at 6-weeks post-operatively with the surgical team, with ○ An x-ray of the ankle

10 - What if you have any questions?

If, at any time, you would like further information about this study you can contact the Hampshire Hospitals Orthopaedic Research Team on:
01256 313204 or email orthopaedic.research@hhft.nhs.uk

If you are an NHS patient and concerned about your clinical care the Patient Advisory Liaison Services (PALS) is a confidential NHS service that can support you with any complaints and questions you might have about your care at your local NHS hospital. Please note that PALS is unable to provide specific information about this research study. The contact details of your local NHS hospital PALS services are:
Email: customercare@hhft.nhs.uk
Telephone: 01256 486766
If you are a Fortius patient and concerned about your clinical care you can contact Fortius directly and speak to the Quality Team. Their contact details are:
Email: feedback@fortiusclinic.com
Telephone: 020 3195 2442

11 - Who are the Evaluation Group?

Role	Name	Role and Institution
Chief Investigator(s)	Mr Robin Elliot	Consultant Trauma & Orthopaedic Surgeon Royal Hampshire County Hospital
Principle Investigator(s)	Mr Daniel Marsland	Consultant Trauma & Orthopaedic Surgeon Basingstoke and North Hampshire Hospital
Principle Investigator(s)	Prof James Calder	Fortius Clinic, London
Investigator	Mr Hossam Fraig	Speciality Trauma & Orthopaedic Registrar (ST8) University Hospital Southampton
Investigator(s)	Miss Angie Dempster	Orthopaedic Research, Evaluation & Audit Manager Hampshire Hospitals NHS Foundation Trust