Freedom® 450 Study

A prospective, multi-centre, non-comparative, post-market clinical follow-up study to evaluate the survivorship, safety and performance of the Freedom® Total Knee System in United Kingdom

Study Design

- Prospective, multi-centre, non-comparative, post-market clinical follow-up study
- To obtain implant survivorship and clinical outcomes data of Freedom® Total Knee System

Protocol No.	**MLSIPL/Freedom® 450**
Study Objective	**To obtain implant survivorship and clinical outcomes data for commercially available Freedom® Total Knee System used in total knee replacement.**
Device	**Freedom® Total Knee System**
Sample Size	**450 subjects**
Clinical Sites	**Approximately 15 centres in the United Kingdom (UK)**
Primary Endpoint	**Implant Survivorship at 3 years**
Secondary Endpoints	• **Oxford Knee Score at 1 and 3 years** • **Knee Society Score at 1 and 3 years** • **Range of Motion at 1 and 3 years**
Follow-Up	**Clinical follow-up visits at 8 weeks, 1 year, 3 years, 5 years (Clinical follow-up/ Telephonic follow-up) and 10 years (Clinical follow-up/ Telephonic follow-up)**
Study status as in September 2020	**Study in start-up phase: EC approval received**

References:

1. NCT04033588
https://clinicaltrials.gov/ct2/show/NCT04033588

2. IRAS Project ID: 257462