PEEK OPTIMA-India

A prospective, multicentre, first-in-human, pilot clinical investigation to evaluate the safety and performance of the Freedom® Total Knee System with the PEEK-OPTIMA™ Femoral Component

Study Design

- Prospective, multicentre, first-in-human, pilot clinical investigation
- To evaluate the safety and performance of Freedom® Total Knee System with the PEEK-OPTIMA™ Femoral Component

Protocol No.	**MLSIPL/PEEK OPTIMA™ FEMUR-01**
Study Objective	**To evaluate the safety and performance of Freedom® Total Knee System with the PEEK-OPTIMA™ femoral component**
Device	**Freedom® Total Knee System with the PEEK-OPTIMA™ femoral component**
Sample Size	**34 subjects**
Clinical Sites	**5 sites across India**
Primary Endpoint	**To evaluate the Knee Society Score (KSS) at 6 months post-treatment compared to pre-treatment**
Secondary Endpoints	• **Procedural success** • **KSS Knee scores at 6 weeks, 12 and 24 months post-treatment and KSS Function scores at 6 weeks, 6, 12 and 24 months post-treatment compared to pre-treatment** • **Subject reported outcomes (SF-36, Oxford Knee Score and WOMAC) at 6 weeks, 6, 12 and 24 months post-treatment compared to pre-treatment** • **Stability of the device through radiographic analysis to assess alignment and component position at prior to discharge, 6 weeks, 6, 12 and 24 months post-treatment** • **Stability of the device through MRI analysis to assess aseptic loosening, unexpected response to debris and fractures at 6 weeks, 6, 12 and 24 months post-treatment** • **Safety in terms of adverse events and device deficiencies throughout the clinical investigation including any additional knee treatments and/or surgery** • **Survivorship analysis of the device at 12 and 24 months and annually thereafter**
Follow-Up	**Follow-up visits at 6 weeks, 6 months, 12 months and 24 months post-treatment and annual telephonic follow up thereafter till the subject is willing.**
Study status as in September 2020	**Study in start-up phase: EC/IRB approval in progress**