PEEK India Study

A Multi-Centre Clinical Investigation to Evaluate The Safety And Performance of The Freedom Total Knee System With The PEEK-OPTIMA Femoral Component

Study Design

- Prospective, multi-centre, non-comparative, clinical investigation
- To evaluate long-term safety and performance of Freedom Total Knee System With The PEEK-OPTIMA Femoral Component
- 34 subjects at
- 5 sites across India

Protocol No.	**MLSIPL/PEEK OPTIMA FEMUR-01**
Study Objective	**To evaluate the safety and performance of the Freedom Total Knee System with the PEEK- OPTIMA femoral component**
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**
Clinical Sites	**5 sites across India**
Sample Size	**34 subjects**
Device	**Freedom Total Knee System with the PEEK-OPTIMA femoral component**
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 Duration	**Estimated study start date March 2019** **Estimated study completion December 2021**