ETERNAL-1 Study

A Prospective, multi-centre, non-comparative, clinical investigation to evaluate the safety and performance of the ETERNAL Total Knee Replacement System in patient with end-stage symptomatic primary knee osteoarthritis

Study Design

- Prospective, multi-centre, non-comparative, clinical investigation
- To evaluate the safety and performance of the ETERNAL Total Knee Replacement System
- 60 subjects at to enrolled at10 sites across India

CIP No.	**MHCPL/ETERNAL-1**
Study Objective	**Primary Objective: To evaluate the Survivorship and safety of the ETERNALTotal Knee Replacement System** **Secondary Objective: To further evaluate clinical performance of the ETERNAL Total Knee Replacement System and quality of life (QOL) of the patients**
Primary Endpoints	• **Survivorship analysis of the device** • **Safety in terms of adverse events and device deficiencies throughout the clinical investigation including any additional knee treatments and/or surgery**
Secondary Endpoints	• **Procedural success** • **KSS at 6 weeks, 6 months, 12 months, 24 months, 36 months, 48 months and 60 months compared to pre- treatment.** • **Subject reported outcomes (SF-12 and KOOS) at 6 weeks, 6 months, 12 months, 24 months, 36 months and 60 months post-treatment compared to pre-treatment.** • **Stability of the device through radiographic analysis to assess alignment and component position at immediate post-treatment, 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 months and 24 months post-treatment.** • **Bone quality through DEXA analysis at 6 months post- treatment to assess bone density and risk of fracture.**
Clinical Sites	**10 sites across India**
Sample Size	**60 subjects**
Follow-Up	**Follow-up visits at 6 weeks, 6 months, 12 months, 24 months, 36 months, 48 months, 60 months and annual telephonic follow up thereafter up to 10 years**

Study Duration	**Estimated study start date March 2019** **Estimated study completion December 2030**