Freedom® 400-PMS

A prospective, single-arm, multi-centre, observational, real-world, post marketing surveillance to evaluate implant survivorship and performance of the Freedom® Total Knee System in total knee arthroplasty.

Study Design

- Prospective, single-arm, multi-centre, observational, real-world, post marketing surveillance
- To obtain implant survivorship and clinical outcomes of Freedom® Total Knee System in total knee arthroplasty

Protocol No.	**MLSIPL/Freedom® 400**
Study Objective	**The primary objective of this study is to obtain implant survivorship and clinical outcomes data for commercially available Freedom® Total Knee System used in total knee arthroplasty**
Device	**Freedom® Total Knee System**
Sample Size	**449 subjects**
Clinical Sites	**10 sites in India**
Primary Endpoint	• **Implant Survivorship at 6 weeks, 6 months, 1 year, 3 years, 5 years, 7 years and 10 years** • **Cumulative Revision Rate at 6 weeks, 6 months, 1 year, 3 years, 5 years, 7 years and 10 years**
Secondary Endpoints	• **Knee Society score at Pre-op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years** • **WOMAC at Pre-op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years** • **Range of motion at Pre-op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years** • **SF-36 Questionnaire at Pre-op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years** • **Radiographic analysis at Pre-op, 6 weeks, 6 months, 1 year, Optional: 3, 5, 7 and 10 years** • **Adverse events at 6 weeks, 6 months, 1, 3, 5, 7 and 10 years**
Follow-Up	**Clinical Follow-up visits at 6 weeks, 6 months, 1, 3, 5, 7 and 10 years**
Study status as in September 2020	**Patient recruitment is completed and study is in follow-up phase.** • **Patients completed 6 weeks follow-up visit: 447** • **Patients completed 6 months follow-up visit: 444** • **Patients completed 12 months follow-up visit: 424** • **Patients completed 36 months follow-up visit: 46**

Reference:

1. CTRI Number: CTRI/2016/11/007455
http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=15630&EncHid=&userName=CTRI/2016/11/007455