Latitud™ 180

A prospective, multi-center, observational, post-marketing surveillance study to evaluate the survivorship and performance of the Latitud™ Hip Replacement System in subjects requiring a hip replacement

Study Design

- Prospective, multi-center, observational, post-marketing surveillance
- To obtain components survivorship and performance of Latitud™ Hip Replacement System used in total hip replacement

Protocol No.	**MHCPL/Latitud™180**
Study Objective	**The primary objective of this study is to obtain components survivorship and performance of commercially available Latitud™ Hip Replacement System used in total hip replacement**
Device	**Latitud™ Hip Replacement System**
Sample Size	**180 subjects**
Clinical Sites	**Minimum 10-15 centres across India**
Primary Endpoint	• **Implant Survivorship at 6 weeks, 6 months, 1 year, 2 years, 5 years, 7 years and 10 years** • **Performance of implant at 6 weeks, 6 months, 1 year, 2 years, 5 years, 7 years and 10 years** • **Cumulative Revision Rate at 6 weeks, 6 months, 1 year, 2 years, 5 years, 7 years and 10 years**
Secondary Endpoints	• **Harris Hip score at Pre-op, 6 weeks, 6 months, 1, 2, 5, 7 and 10 years** • **Radiographic analysis at Pre-op, 6 weeks, 6 months, 1, 2, 5, 7 and 10 years** • **Oxford Hip score at Pre-op, 6 weeks, 6 months, 1, 2, 5, 7 and 10 years** • **Adverse events at 6 weeks, 6 months, 1, 2, 5, 7 and 10 years**
Follow-Up	**Clinical Follow-up visits at 6 weeks, 6 months, 1, 2, 5, 7 and 10 years**
Study status as in September 2020	**Patient recruitment is ongoing: Total 162 patients recruited from 10 sites** • **Patients completed 6 weeks follow-up visit: 154** • **Patients completed 6 months follow-up visit: 120** • **Patients completed 12 months follow-up visit: 81** • **Patients completed 24 months follow-up visit: 16**

Reference:

1. CTRI Number: CTRI/2017/06/008774
http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=16218&EncHid=&userName=CTRI/2017/06/008774