

## Freedom 400 Study

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 evaluate implant survivorship and performance of Freedom total knee system
- A total of 430 subjects at 20 sites across India

<b>Reference No.</b>	<b>CTRI/2016/11/007455</b>
<b>Study Objective</b>	<b>To obtain implant survivorship and clinical outcomes data for commercially available Freedom Total Knee System used in total knee arthroplasty</b>
<b>Primary Endpoints</b>	<ul style="list-style-type: none"><li>• <b>Implant Survivorship</b></li><li>• <b>Cumulative Revision Rate</b></li></ul>
<b>Secondary Endpoints</b>	<ul style="list-style-type: none"><li>• <b>Knee Society Score [Time Frame: Pre-Op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years]</b></li><li>• <b>WOMAC (Western Ontario and McMaster Universities Osteoarthritis) Pain [Time Frame: Pre-Op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years]</b></li><li>• <b>Range of Motion [Time Frame: Pre-Op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years]</b></li><li>• <b>SF-36 Questionnaire (Short Form Health Survey questionnaire) [Time Frame: Pre-Op, 6 weeks, 6 months, 1, 3, 5, 7 and 10 years]</b></li><li>• <b>Radiographic Analysis [Time Frame: Pre-Op, 6 weeks, 6 months, 1 year, (3, 5, 7 and 10 years- Optional)]</b></li></ul>
<b>Clinical Sites</b>	<b>20 sites across India</b>
<b>Sample Size</b>	<b>A total of 430 subjects</b>
<b>Follow-Up</b>	<b>Follow-up visits at 6 weeks, 6 months, 1 year, 3 years, 5 years , 7 years and 10 years</b>
<b>Study Duration</b>	<b>Study start date September 2016 Estimated study completion April 2029</b>

Reference:

**1. Clinical Trial Registry- India (CTRI)**

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