

## PROJECT DESCRIPTION

<b>Description:</b>	Placement of the SUI Sling (a bio-compatible mesh) under the urethra to provide support to the pubourethral ligaments and hence help in urethral closure and treatment of Stress Urinary Incontinence
<b>Therapeutic Focus:</b>	Urology
<b>Study Phase:</b>	Pilot Study with 10 patients, 5 male and female patients
<b>Trial Sites:</b>	1
<b>No. of Patients:</b>	10 patients
<b>Committed TAT Timelines:</b>	<ul style="list-style-type: none"> <li>- Patient Recruitment and Screening of 10 Patients completed in 2 Weeks</li> <li>- Regulatory and EC approvals closed within 12 weeks</li> <li>- End-to-end Study Completion within 16 Weeks from date of Site Initiation Visit</li> <li>- 1 Week for closure of DCFs at Site from LPLV</li> <li>- 2 Weeks for Final CSR Closure (ICH E3 Format)</li> </ul>

## KEY CHALLENGES

- Lack of clear regulatory guidelines for Medical Devices created hurdles to identify the device in non-drug category
- Convincing leading PIs for participating in the study and the benefits of the device took robust persuasive skills
- Patient availability of male patients with SUI was extremely difficult
- Extremely crunched timelines due to schedule of US surgeons as Co-Investigators for the study

## KARMIC'S APPROACH

- Karmic involved a team of renowned Urologists in India with a consolidated experience of conducting over 5 Urology related medical devices trials for the study design of the trial
- Comprehensive due diligence across leading journals and [clinicaltrials.gov](http://clinicaltrials.gov) website for similar clinical trials designs
- Campaigns at identified sites to quicken patient recruitment
- Hired a team of renowned American surgeons to conduct the surgery

## ACTIVITIES SUPPORTED

- Concept Generation
- Design & Development
- Clinical Trial Conduct
- Study Protocol & CRF Design
- Regulatory/MCI Approvals
- Ethics Committee Approvals
- Site Selection & Feasibility
- Study Initiation
- SUI Patient Screening & Recruitment
- Trial Monitoring
- Data Management
- Final Analysis and Report Closure

## KEY ACHIEVEMENTS

- Karmic was able to identify leading Urology sites and complete the patient enrolment and trial completion procedures before the estimated trial time
- Trial conducted at 35% cost saving as compared to trial procedures in US
- Protocol was prepared in record TAT time of 4 business days
- Patients were screened, enrolled, study procedures and follow-up was closed within 20 weeks
- Database lock was done within 1 week of LPLV, CSR completed within 2 weeks of database lock