Post Marketing Clinical Follow Up (PMCF) Study

A Retrospective Study for collecting data on
the Safety and Performance of the EndoFast Reliant SCP in
Vaginal Wall Reinforcement
Study Protocol

March 13, 2017

Study Synopsis

Study Design	A Single arm, single site, retrospective cohort Post Marketing Surveillance Study Evaluating the Safety and Performance of the *EndoFast Reliant SCP* for apical support
Study device:	*EndoFast Reliant SCP*
Intended use:	The *EndoFast Reliant SCP* is indicated for fixation of surgical mesh to tissue for tissue reinforcement during laparotomy or laparoscopic Sacrocolpopexy approach.
Device Regulatory status:	CE, AMAR and FDA Approval
Objective:	The objective of this study is to collect data on the anatomical cure and safety of the EndoFast Reliant SCP
Medical Centers	One site in Germany Catholic Hospital Hoxter, Germany Dr. Bettin
Population:	Female subjects >18 years old that underwent Pelvic Organ Prolapse repair utilizing the EndoFast Reliant SCP
Procedure:	Pelvic Organ Prolapse repair utilizing the EndoFast Reliant SCP
Follow-up:	Upon availability of the data (retrospective study)
Safety Endpoint:	The safety endpoint counts the rate of peri and post-operative device related Adverse Events.
Effectiveness Endpoints:	measures the relative improvement in Pelvic Organ Prolapse staging using the POPQ grading system
Inclusion criteria	All Female subjects >18 years old that underwent Pelvic Organ Prolapse repair utilizing the EndoFast Reliant SCP
Exclusion criteria	Patients without follow-up
Sponsor:	**IBI, Israel Biomedical Innovations Ltd.** 2 Ha-Eshel St., P.O.BOX 3081, Caesarea Industrial Park, 3088900 - Israel Tel: +972-4-6277166 Fax: +972-4-6277266