A PROSPECTIVE CASE SERIES EVALUATING SURGIMEND MP® IN PATIENTS UNDERGOING COMPLEX ABDOMINAL HERNIA REPAIR

February 20, 2020

Study Design

This study is a prospective, case series study evaluating the efficacy and performance of SurgiMend MP® during complex ventral hernia repairs. This case series involves a biologically derived hernia mesh under its cleared FDA indication for hernia repair. Efficacy will be determined by quantifying surgical complications, hernia recurrence, and cost effectiveness endpoints.

Study Objectives:

Primary Objective

The objective of this study is to evaluate the effectiveness and performance of SurgiMend MP® abdominal wall reinforcement in patients with complex ventral hernia repair as assessed by the frequency of hernia recurrence and/or bulging, defined as a contour deformity with or without a fascial defect based on physical examination or computed tomography.

Secondary Objectives

- To assess the frequency of intra-operative mesh-related complications
- To assess short term surgical complication rates in complex hernia repairs
- To assess the comparative cost effectiveness and quality of life (QOL) of interventions in complex hernia repairs

Treatments/Methods

The study will follow consenting adults with a large, complex abdominal wall hernia. The specific definition of this population is described in the Inclusion/Exclusion criteria. These consenting adults with complex abdominal wall hernias will undergo a hernia repair procedure. The treatment includes hernia repair reinforcement with SurgiMend MP® repair mesh.

Study Duration

A subject will participate in the study for approximately 3 years in total. Following enrollment into the study and the index operation, the patient will be followed until hospital discharge, with subsequent follow-up visits at approximately 3 months, 6 months, 1 year, 2 years, and 3 years.