MITSU™ Polyglactin 910 Suture Study

A study to evaluate safety and efficacy of MITSU™ Polyglactin 910 Suture with coated VICRYL® Polyglactin 910 Suture in closure of surgical incision

Study Design

- Prospective, multi-center, post-marketing, randomized-controlled, single-blind, comparative study
- To evaluate the safety and efficacy of MITSU™ Polyglactin 910 Suture with coated VICRYL® Polyglactin 910 Suture in closure of surgical incision

Protocol No.	**MES/MITSU™ - 1**
Study Objective	**To evaluate the safety and efficacy of MITSU™ Polyglactin 910 Suture with coated VICRYL® Polyglactin 910 Suture in closure of surgical incision**
Device	**MITSU™ Polyglactin 910 Suture**
Sample Size	**122 subjects [MITSU: 61 subjects; Coated VICRYL: 61 subjects]**
Clinical Sites	**3 sites across India**
Safety Endpoint	**Overall wound dehiscence [Time frame: at post-procedure, 14 days, 30 days and 6 months]** **Wound dehiscence is defined as a complete wound disruption that needed emergent reoperation**
Efficacy Endpoints	• **Rate of Surgical Site Infection (SSI) resulted from suturing material as per judgment of study investigator [Time frame: at baseline, post procedure/discharge, 14 days, 30 days and 6 months.** • **Hospital length of stay** **Length of stay is calculated by subtracting day of admission from day of discharge.**
Follow-Up	**Clinical follow-up was scheduled at 14 days, 30 days and 6 months**
Study status as in September 2020	**Study has been completed.**

Reference:

1. Clinical Trial Registry- India (CTRI): CTRI/2017/01/007717 http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=16381&EncHid=&userName=CTRI/2017/01/007717
2. Dixit A, Nadkarni P, Shah V, Patel B, Turiya PK, Thakkar A. Evaluation of safety and efficacy of polyglactin 910 suture in surgical incision closure: clinical study protocol for a randomized controlled trial. International Journal of Clinical Trials. 2018. 2018; 5(1):6.