MERIZELLE ORC U.S.P Study

A study to evaluate safety and efficacy of MERIZELLE ORC U.S.P for the achievement of hemostasis across several surgical procedures

Study Design

- A prospective, multi-center, single-arm, observational, post-marketing surveillance study
- To evaluate the safety and efficacy of MERIZELLE ORC U.S.P for the achievement of hemostasis across several surgical procedures

Protocol No.	**MES/MERIZELLE™-1**
Study Objective	**To obtain clinical safety and efficacy data for achievement of hemostasis across several surgical procedures (e.g., general surgery, gastric resection, ENT, gynaecological operations, neurosurgery, implantation of vascular prostheses, biopsies, lung operations, face and jaw surgery, liver and gall bladder operations, thoracic and abdominal sympathectomies, thyroid operations, skin transplantations and treatment of superficial injuries)**
Device	**MERIZELLE ORC U.S.P**
Sample Size	**185 patients will be enrolled**
Clinical Sites	**Approximately 10 centers**
Primary Endpoint	**Proportions of subjects achieving hemostasis at target bleeding sites (TBS). [Time Frame: up to 10 minutes after application]** **Hemostasis is defined as no detectable bleeding at the TBS.**
Secondary Endpoints	**Absence of bleeding related adverse events (No adverse events which are specifically caused by bleeding) [Time Frame: up to 3 months of initial surgery].**
Follow-Up	**Clinical follow-up at 2 Weeks, 1-month, 3-month and 6-month**
Study status as in September 2020	**Patient recruitment is ongoing: Total 132 patients recruited from 07 sites** Patients completed 2 weeks follow-up visit: 130 Patients completed 1 months follow-up visit: 129 Patients completed 3 months follow-up visit: 128 Patients completed 6 months follow-up visit: 128

Reference:

Clinical Trial Registry- India (CTRI) number: CTRI/2017/01/007710
http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=17253&EncHid=&userName=CTRI/2017/01/007710