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	**188 patients were recruited**
Clinical Sites	**This study was planned to be conducted at minimum 10 sites within India. However, 4 sites actively enrolled the patients.**
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 proven infection (No positive culture of blood results which indicate infection) [Time Frame: within 30 days of initial surgery].** • **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-months and 6-months**
Study status as in July 2022	**All the 188 patients recruited from four sites have successfully completed all the clinical**

	follow-ups of 2 Weeks, 1-month, 3-months and 6-months from the date of index procedure and demonstrated favourable safety and efficacy of MERIZELLE™ ORC U.S.P haemostat across several surgical procedures.

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