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
- A total of 185 subjects will be enrolled

Reference No.	**CTRI/2017/01/007710**
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)**
Safety Endpoint	**Proportions of subjects achieving hemostasis at target bleeding sites (TBS). Hemostasis is defined as no detectable bleeding at the TBS.**
Efficacy Endpoints	**1. Absence of proven infection (No positive culture of blood results which indicate infection) [Time Frame: within 30 days of initial surgery].** **2. Absence of bleeding related adverse events (No adverse events which are specifically caused by bleeding) [Time Frame: up to 3 months of initial surgery].**
Clinical Sites	**10 sites across India**
Sample Size	**185 patients will be enrolled**
Follow-Up	**Clinical follow-up at 2 Weeks, 1-month, 3-month and 6-month**
Study Duration	**Study started on 17th January, 2017.** **Estimated study completion in August 2019.**

❖ Reference:

1. **Clinical Trial Registry- India (CTRI): CTRI/2017/01/007710**
   http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=17253&EncHid=&userName=CTRI/2017/01/007710