

Date – 22-11-2022

**To whomsoever it may concern**

**Subject:** Statement referring to the Time to Hemostasis (TTH) of the product Surgi-ORC® (Oxidized Regenerated Cellulose Haemostat).

We, Aegis Lifesciences Pvt. Ltd., located at 215/216, Mahagujarat Industrial Estate-382213, Ahmedabad, Gujarat, India, hereby state that we have performed real world clinical studies for the evaluation of performance and safety for our product Oxidized Regenerated Cellulose Haemostat with brand name Surgi-ORC®, designed as a prospective, single arm, post-marketing, interventional study in 80 patients undergoing surgical procedure in various surgical categories involving mucosal membrane bleeding with 28 days' clinical follow up, with multiple primary and secondary end point. Results of the clinical study based on the criteria selected to meet primary and secondary end points of the performed study is summarized in below table-1.

**Table-1**

Description	
Product handling characteristics	All the surgeons have rated that handling characteristics of Surgi-ORC as easy and have not found any difficulty in application.
Bleeding Volumes	The average bleeding volume was 10 ml and in range of 5 to 15ml.
<b>Time To Hemostasis</b>	Within 3 minutes.
AE / SAEs Reported	0

**Conclusion for the Time to Hemostasis (TTH) of our product Oxidized Regenerated Cellulose Haemostat with brand name Surgi-ORC® is within 3 min.**

One of the primary end points of the study, haemostasis depends on the surgical site and the bleeding volumes etc. Though the product was used in different surgical sites, in 80% of the cases haemostasis was achieved within 3 minutes and in other within 10 minutes. At an average bleeding volume of 10 ml the haemostasis can be achieved within 3 minutes with Surgi-ORC®.

Surgi-ORC® has met its end points in effectiveness of TTH.

**Enclosed** –Real world clinical experience article published in BJBMR with title “Real World Clinical Experience of Oxidized Regenerated Cellulose in Various Surgical Procedure (RWCORC) Clinical Registry”.

Signature

  
Mr. Vivek Kumar Shahi

Regulatory Affairs Assistant

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Place: Ahmedabad, India





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## Research Article

## Real World Clinical Experience Of Oxidized Regenerated Cellulose In Various Surgical Procedures (RWCORC) Clinical Registry

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## ARTICLE INFO

## ABSTRACT

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## Keywords:

ORC, Safety, Efficacy,  
Clinical, Hemostasis

Oxidized Regenerated Cellulose (ORC) is a passive hemostat used in wide range of surgical procedures to stop bleeding. There is enough clinical data with studies conducted on selected surgeries as prospective or retrospective to prove the product safety and efficacy. As on now no real world experience studies were performed that includes most of the clinical indications of ORC and surgical procedures in randomized model. The current **Real World Clinical** experience with **Oxidized Regenerated Cellulose (RWCORC)** registry was done to substantiate the same. Surgi ORC an International brand of Oxidized Regenerated Cellulose was evaluated in RWCORC Clinical Registry. A prospective, single arm, randomized study was performed as real world experience with the product. The results evidently reveal that Surgi ORC met its primary and secondary clinical endpoints and was safe and effective in controlling bleeding at all surgical sites included in the study with no evidence of infection.

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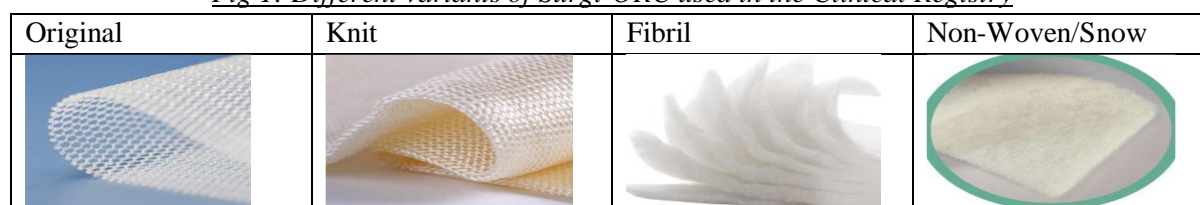
## INTRODUCTION

Oxidized Regenerated Cellulose (ORC), is a plant derived, passive hemostat that promotes hemostasis by providing a matrix for platelet adhesion and aggregation. It is available in various fabric formats allowing for multiple applications, can conform to irregular surfaces and hard-to-reach sites, adheres easily to bleeding surfaces and is suitable for many surgical procedures.<sup>[1]</sup> ORC is rapidly absorbed by hydrolysis within 7–20 days depending on the amount used.<sup>[2,3]</sup> Oxidized regenerated cellulose (ORC) is used broadly in surgical procedures as a hemostatic agent.

Of the several ORC hemostats available in the market, Surgi-ORC is one brand of ORC product manufactured and marked by Aegis Lifesciences Pvt. Ltd, India. It is used to assist control of bleeding from capillary, venous and small arteriolar vessels. In emergency/trauma situation Surgi-ORC can assist well in haemostasis and serve as a haemostatic adjunct in the control of local hemorrhage. Surgi-ORC is available in different variants for different

clinical applications during surgeries. The Knitted variants of Surgi-ORC, ORIGINAL and KNIT are indicated for use in Cardiovascular and Thoracic Surgeries, General Surgeries including Cholecystectomy, Liver and Spleen Laceration, Port Site Bleeding, Tonsillectomy and Skin Grafting. The unknit variants of Surgi-ORC, FIBRIL and NON-WOVEN or SNOW models are mainly intended for use in different surgeries including Neurosurgery Laminectomy, Surgery on Tumor Bed, Head Trauma, Spine and Spinal Cord. It is so versatile because of its structure and design it can also be used in Cardiovascular and Thoracic Surgeries of Carotid Endarterectomy, Abdominal Aortic Aneurysm, Sternum Closure in CABG and Valve Repair/Replacement and Orthopedic, Gynecological Surgeries, Laparoscopic hysterectomy, and other General surgeries. However, the use of the variants is to discretion of the physician and not of patient's choice.<sup>[4]</sup>

*Fig 1: Different variants of Surgi-ORC used in the Clinical Registry*



## MATERIALS AND METHODS:

### Study Design and Conduct

#### Study Design:

Prospective, Single Arm, Post Marketing, Interventional study to evaluate safety and performance of the Oxidized Regenerated Cellulose – Surgi-ORC, absorbable haemostat in patients undergoing surgical procedure involving mucosal membrane bleeding. The product is advised to be used in patients undergoing an Abdominal Surgery, Anorectal Surgery, Dental Surgery, ENT surgery, Genito Urinary Surgery, Gynaecological Surgery, Hysterectomy, Neuro Surgery, Orthopaedic Surgery, Otolaryngological

Surgery, Partial Nephrectomy, Plastic Surgery and Vascular Surgery.

#### IEC/IRB:

Institutional Ethics Committee or Institution Review Board approval were obtained from the investigators of respective hospitals and institutes formally after submission of the consent letter and the CLINICAL REGISTRY Brochure (Product Information, Registry protocol, ICF, CRF etc.). The studies were conducted as per the regulatory guidelines of MDR 2017/745, Clinical Evaluation Requirements including clinical



investigation as defined on Chapter VI, Annex XIV and Annex XV respectively and MEDDEV 2.7.1/4 (June 2016) Guidance Clinical Evaluation: A Guide for Manufacturers and Notified Bodies. [5, 6]

#### **Enrolment, ICF, Inclusion Criteria:**

Of the total study initiated in 106 patients, Enrolment and ICF were taken from the 80 patients and the study was initiated in May 2021, clinician expert in the art has explained about the product, benefits and risks and follow up protocols during signing of ICF with the patient. However due to unprecedented Covid -19 situations, in 36 patients preoperative and in 30 patients' post-operative follow-up could not be done. In 50 patients, strictly following the Covid protocols as declared by GOI and IEC guidelines, complete follow-up, study could be conducted. All the patients enrolled met the inclusion criteria in the study which includes,

1. Subject is either male or female age 18 years or older at the time of study.
2. Subject with identified target bleeding site with moderate bleeding during surgery according to the Investigator's discretion can be enrolled.
3. The subject is willing and able to provide appropriate informed consent.
4. The subject is willing and able to comply with the requirements of the study protocol, including the predefined follow-up evaluations.

Inclusion criteria to be determined during the surgical procedure also enlists that if subject has an intraoperative bleeding site which the surgeon is unable to easily control with conventional methods (cautery, sutures).

## **Outcome Measures/ Endpoints**

### **Primary Endpoint**

- Proportion of wounds achieving haemostasis at target bleeding site [Time frame: measure up to 10 minutes of after application of Surgi-ORC]
- Haemostasis is defined as no detectable bleeding at the target bleeding sites (TBS).
- Time to haemostasis (TTH) - Evaluation for haemostasis to begin immediately following application of the Surgi-ORC. Haemostasis assessments are made every  $3\pm 1$  minutes for the first 10 minutes' post application. In case haemostasis is not observed within  $3\pm 1$  minutes, the treatment site is to be monitored and the research teams to record the specific number of minutes until haemostasis is observed

### **Secondary Endpoints**

- Absence of proven infection (No positive culture of blood results which indicate no infection) [Time Frame: Within 28 days of initial surgery/life time of the product].
- Effectiveness: Device Success (defined as the number of subjects with first bleeding site applications for which haemostasis was obtained within  $3\pm 1$  minutes of study device application without the need for adjunctive Treatment) [Time Frame: Procedure, up to  $3\pm 1$  minutes' post procedure].
- Effectiveness: Haemostatic Handling Characteristics (Surgeon's Questionnaire) [Time Frame: Procedure (application through end of procedure)].
- Safety: Incidence Rate of device-related Adverse Events [Time Frame: Procedure, up to 28 days' post procedure]

## **RESULTS AND DISCUSSION:**

### **Study Report:**

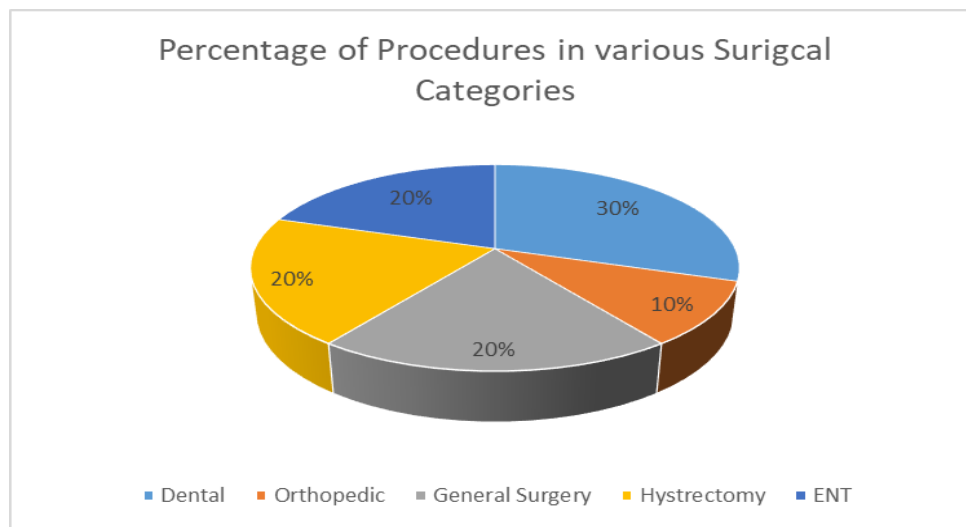
#### **Study population: Age, Sex, Medical and Treatment history:**

Study population age was  $35.5 \pm 7.5$  years, with 60 % of males. Four patients had medical history of diabetes mellitus, adenomycosis of

uterus, sinusitis and tonsillitis and are on treatment with Glycomet (500mg), Intimacy (2mg), Atrovin, gentamycin nasal drops and erythromycin (500 mg), respectively. All have met the inclusion criteria on preoperative diagnosis.

In total, 30 % of the patients were in Dental, 20% in ENT, 20% in Hysterectomy, 20% patients in general surgery (appendicitis, Tonsillitis) and 10% in orthopaedic surgery categories.

*Fig 2: Percentage of procedures performed in various Surgical Categories in the Clinical Registry*



#### **Operative Data:**

The wound dimensions and bleeding volumes differed based on the surgical site. There were more bleeding volumes in nasal and hysterectomy surgeries than the others. The dimensions of the wound are more in hysterectomy and orthopaedic and general surgeries. The wound length, width and depth ranged from 6mm to 4 cm, 4mm to 2cm and 4 mm to 8 mm, respectively. The average bleeding volume was 10 ml and in range of 5 to 15ml.

#### **Surgi-ORC Handling Characteristics:**

Effectiveness of handling characteristic was assessed by ease of application to bleeding site, conformance to tissue, ease of preparation for use, ease of delivery to hard-to-reach surfaces. All the surgeons have rated that handling characteristics of Surgi-ORC as easy and have not found any difficulty in application. Ease of delivery to hard-to-reach surfaces was well appreciated.

#### **Haemostasis:**

One of the primary end points of the study, haemostasis depends on the surgical site and the bleeding volumes etc. Though the product was used in different surgical sites, in 80% of the cases haemostasis was achieved within 3 minutes and in other within 10 minutes. At an average bleeding volume of 10 ml the haemostasis can be achieved within 3 minutes with Surgi-ORC. Time To Haemostasis (TTH) without use of adjuvant treatment was achieved within 10 minutes. The study met the primary and secondary end points in its effectiveness in Haemostasis. No Infections was observed in all cases of use.

#### **Adverse Events (AE) or Severe Adverse Events (SAE):**

In all the cases of clinical application in different surgical sites, there were no adverse events or severe adverse events reported during the day of operation or surgery and 28 days follow up. Surgi-ORC was well tolerated,

compatible to all the surgical sites in the body and biodegraded without any complications.

### CONCLUSION:

- a. The RWCORC Clinical Registry of Surgi-ORC was conducted in strict adherence to the Study protocol without any study deviations.
- b. Due to unprecedented situations of Covid-19, total study population could not be enrolled. However, with adherence to Covid protocols and IEC guidelines, 50% of the patients enrolled could be followed up to complete the study to meet the primary and secondary end points.
- c. The study conducted included 4 Hospitals/Institutes and more than 5 different surgical sites of implantation.
- d. Surgi-ORC handling characteristics during surgery and implantation were well accepted and appreciated by all surgeons.
- e. Due to unavoidable circumstances, with 50 % patient study, Surgi-ORC has met its primary and secondary clinical end points, in effectiveness of haemostasis, Time to Haemostasis (TTH) and no evidence of Infection.
- f. No adverse events AE/SAEs were reported in the study with full mandated clinical follow-up of 28 days.
- g. No new risks or new Indications of use were identified in the present - RWCORC Clinical Registry.

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### Financial Disclosure statement:

No Financial disclosures with any party/Will be submitted as separate document

### Conflict of Interest:

There is no conflict of interest with any party/Will be submitted as separate document

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