

All India Institute of Medical Sciences, Jodhpur

No. AIIMSJ-PROC0PROP/34/2024-PROC

Dated: 08th April, 2024

subject: **Proposal for purchase of Hemostatic Agent (Seraseal 3ml), Make: Wortham Laboratories for the Dept. of Pediatric Surgery on proprietary basis at AIIMS Jodhpur – inviting comments/objection thereon.**

The Institute is in the process of purchasing Hemostatic Agent (Seraseal 3ml), Make: Wortham Laboratories for the Dept. of Pediatric Surgery at AIIMS, Jodhpur from M/s Wortham Laboratories Inc. USA through its authorized dealer M/s Swasth Kare, Chandigarh. The proprietary certificate submitted are attached & uploaded on website.

The above documents are being uploaded for open information to submit objection, comments, if any, from any manufacturer regarding proprietary nature of the above said Hemostatic Agent (Seraseal 3ml), Make: Wortham Laboratories for the Dept. of Pediatric Surgery within 21 days from the date of issue/uploading of the notification. The comments should be sent to Deputy Director, AIIMS Jodhpur on or before 29th April, 2024 up to 03:00 PM, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Deputy Director (Admin.)

Enclosure: Related documents enclosed.

Receipt Receipt: Noro28587/2024/CS (Computer No. 28587) (PAEDIA_SURG) (Computer No. 19119)

Wortham Laboratories Inc. USA

6105 Preservation Drive (D) Chattanooga, Tennessee 37419 423.295.0090 www.worthamlabs.com

June 15, 2023

Swasth Kare Plot 152 Phase 2 Industrial Area Chandigarh, India Phone: +919815048888

10 WHOMSOEVER IT MAY CONCERN

PROPRIETARY ARTICLE CERTIFICATE (PAC)

Swasth Kare is the Exclusive Distributor of SeraSeal in India for Wortbarn Laboratories, Inc. Swasth Kare has exclusive rights to import and market Wortham Laboratories, Inc. products in

We hereby certify that SeraSeal, a topical primary hemostatic agent, is the proprietary product of

The active agents in SeraSeal are agar, bovine Factors IIa, VIIa, IXa, Xa, with an activity level of 3000 JU/ml in 3 ml and 5 ml viels

Features of SeraSeal:

- A one component, topical primary hemostatic agent
- 2. Activity level of 3000 IU/mi in 3 ml and 5 ml vials. 3. Catalysis the normal coagulation cascade system.
- . Time to hemostasis
- a. Venous blocd: 1-2 seconds
 - b. Small artery: 5-10 seconds
 - c. Medium artary: 20-30 seconds
 - d. Large artery 60 seconds

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Benefits of SeraSeal:

 Reduced surgical time - Surgical time is reduced by the amount of time it takes to arrest the bleed in each created wound. The use of cauterization requires each individual bleed within that wound to be treated one at a time, which may take 5-10 seconds or longer. While SeraSeal, as a liquid, will arrest all the individual bleeds in one motion in 1-3 seconds. When you total all the individual wound hemorrhages, the surgical time in some cases can be reduced as much as 50%.

 Access to hard-to-reach bleeds - SeraSeal can be applied to hemorrhages which may be difficult to reach or difficult to treat by standard surgical modalities

• Effective in all coagulopathies - Patients can be maintained on their anticoagulant

therapy during surgery, or the need of fresh frozen plasma (FFP) for a factor deficient patient

 Reduced blood transfusions - Clinical studies have shown that the need for blood transfusions is reduced by as much as 90%.

 Reduced anesthesia - By reducing the surgical time, the patient is subjected to less anesthetic medication and less risk.

 No loss of tissue - Cauterization creates a 3rd degree burn, while SeraSeal will arrest the bleed without destroying the tissue.

 No adhesions - Microscopic studies of tissues treated by cauterization or fibrin glues show signs of inflammation, which lead to adhesions. SeraSeal treated tissues show no signs of inflammation beyond the border of the initial incision.

 Faster healing - By reducing the amount of inflammation, the wounds heal faster. Investigational stucies have shown that in tissues harvested from a SeraSeal treated wound, the growth factors Interlukin-10 (IL-10) and Tissue Growth Factor Beta-1 (TGFB-1) were present within 24 hours after treatment, but these growth factors did not appear in the fibrin glue and cauterized tissues until 5 and 7 days later, respectively. (See the pediatric burn patient clinical

 Less pain medication - Reduced inflammation decreases the need for pain management.

 SICU - By reducing the amount of trauma during surgery, and the amount of blood transfusions, the required time in the surgical intensive care unit can be reduced or eliminated.

Shorter hospital stays - Faster wound healing results in shorter hospitalization.

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Receipt NoReceipt 2004,205 STH2 DZ PAES I (COURDER OVAN ASSET No. 19119) We certify that SeraSeal is the only topical primary hemostatic agent on the market and is exclusively marketed by Swasth Kare in the India Market. Leon Wortham President & CEO 11 GEREFATER HORM CONFICE BY PRADE RA ROLLING AND SKIPA PROCUREMENT HUNGE ADMINISTRATIVE OFFICER OF BOCHREMENT 2-7/09/2021 83/34/2024 10:30 AM