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**When Seconds Count
SeraSeal is
The Savior**



WHAT IS SERASEAL?

SeraSeal is an innovative **primary haemostatic agent** that is designed to stop bleeding on contact and within seconds for arterial haemorrhages.

It is comprised of **Agar and Bovine Factor proteins II a, VII a, IX a and X a** and acts as a catalyst in the clot formation process.

This **single component system** can tackle any bleeding situation with the potential to save many lives.

When seconds count, SeraSeal can make the difference between life and death.

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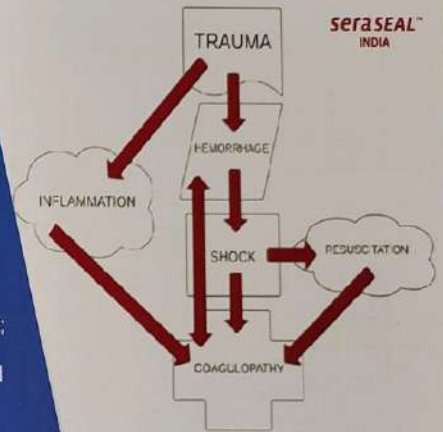
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STAGES OF TRAUMA

The first stage of trauma leads to **haemorrhage and inflammation**.

Haemorrhages lead to **shock and resuscitation**.

And finally all adverse events- Haemorrhage; Inflammation; Shock; and Resuscitation, on their own, all lead to **Coagulopathy**.



COAGULOPATHY

Coagulopathy has the potential to lead to haemorrhage, only to continue the cycle of haemorrhage.

Death is the result if haemorrhage is not arrested.

SeraSeal when used with other surgical modalities is able to effectively control bleeding in **Level III and Level IV** type haemorrhages in seconds and can be used in emergency and trauma cases.

Clinical studies and clinical use have demonstrated SeraSeal's **unique formulation** to be effective in a wide range of coagulopathies.



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WHEN SERASEAL IS APPLIED TO THE WOUND

...it does not create inflammation or damage to the tissues allowing the wound healing to occur sooner.

A one component haemostatic agent, SeraSeal requires no mixing or preparation.

It is available in multiple delivery systems to administer any wound, to any part of the body.



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Bleeding is controlled

Need for blood transfusion reduced

Risk and cost to patient is lowered

Reduced surgical time

Shorter hospital stays

HOW SERASEAL WORKS

Vit K factors in SeraSeal support both Intrinsic & Extrinsic Clotting Pathways to form a Fibrin clot in seconds instead of minutes

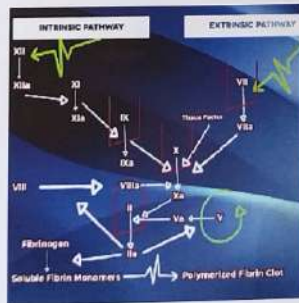
The fibrin clot adheres to the initial agar barrier reinforcing the physical sealant creating the "SeraSeal Clotting Cascade"

The effect of the coagulation cascade system is on blood outside the injured blood vessel and not on the intravascular system

SeraSeal catalyses factors VII, Factor IX, factor X and Factor II, where both the pathways share the common pathway to form a Fibrin Clot.

Factor VI is activated by the release of Thromboplastin before SeraSeal is administered.

SeraSeal is Heparin/ Warfarin Compatible.



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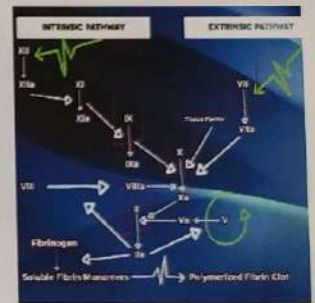
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ROLE OF AGAR IN SERASEAL

Agar in SeraSeal cross links with the ions of platelet phospholipids and cations from amine groups in fibrinogen, fibrin monomers and tissue proteins to form a platelet barrier over the wound

In addition, platelet inhibitors do not bind to the phospholipids on the platelet surface

Agar is effective in the presence of platelet inhibitors.



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TIME TO HAEMOSTASIS



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Levels 1 & 2: 1-3 seconds
Level 3: Less than 10 seconds
Level 4: Less than 30 seconds

FIBRIN GLUES

Level 1: 1-3 minutes
Level 2: 5-10 minutes
Level 3: > 10 minutes

COLLAGEN PATCH

Level 1: 1-5 minutes
Level 2: > 10 minutes

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HAEMOSTASIS IN HEPARIN AND COUMADIN PATIENTS

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- LEVEL 1 : Clotting time was 1-3 seconds
- LEVEL 2 : Clotting time was 1-5 seconds
- LEVEL 3 : Clotting time was 30 seconds
- LEVEL 4 : Clotting time was 60 seconds

FIBRIN GLUE

- LEVEL 1 : Clotting time was 5- 10 minutes
- LEVEL 2 : Failed to clot within 10 minutes

COLLAGEN PATCHES

Non Compatible with anticoagulant medications



CLINICAL COMPARISON

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SeraSeal was compared to Cauterization in Level 2 through Level 4 type haemorrhages in 6 surgical departments

- Cardiovascular
- Neurosurgery
- Head & Neck
- Orthopaedics
- General Surgery and
- Gynaecology

238 patients were enrolled

26 were on Heparin therapy and a mean dosage of 279 units per kilogram

The data obtained includes Procedures performed, Mean SeraSeal Dosage, Time to Haemostasis & Blood Loss Comparison



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CARDIOVASCULAR DEPARTMENT

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PROCEDURES PERFORMED

- Aortic valve replacement
- Mitral valve replacement
- Aortocoronary Bypass
- Heart transplant
- Carotid endarterectomy

CARDIOVASCULAR DEPARTMENT

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SERASEAL DOSAGE

5000 IU or 1.7 ML



Time to Haemostasis



Mean Blood Loss

| SERASEAL | CAUTERISATION |
|--------------|---------------|
| 1.05 Minutes | 9.31 Minutes |
| 351 ML | 747 ML |

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NEUROSURGICAL DEPARTMENT

PROCEDURES PERFORMED

- Laminectomy
- Craniotomy

NEUROSURGICAL DEPARTMENT

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SERASEAL DOSAGE

3818 IU or 1.3 ML

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HEAD & NECK SURGICAL DEPARTMENT

PROCEDURES PERFORMED

- Thyroidectomy
- Parotidectomy
- Parieto-occipital resection

HEAD & NECK DEPARTMENT

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SERASEAL DOSAGE

4456 IU or 1.5 ML

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Time to
Haemostasis



Mean Blood Loss

| SERASEAL | CAUTERISATION |
|-------------|---------------|
| 1 minute | 46 Minutes |
| 235 ML | 709 ML |



Time to
Haemostasis



Mean Blood Loss

| SERASEAL | CAUTERISATION |
|--------------|---------------|
| 2 Minutes | 48 Minutes |
| 10 ML | 183 ML |

ORTHOPAEDIC DEPARTMENT

PROCEDURES PERFORMED

- Amputation
- Femoral Osteomyelitis

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ORTHOPAEDIC DEPARTMENT

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SERASEAL DOSAGE

9643 IU or 3.2 ML

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GENERAL SURGERY DEPARTMENT

PROCEDURES PERFORMED

- Liver
- Spleen
- Pancreas
- Gastrectomy
- Cholecystectomy

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GENERAL SURGERY DEPARTMENT

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SERASEAL DOSAGE

3833 IU or 1.3 ML

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Time to
Haemostasis

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4.43
Minutes

CAUTERISATION

54
Minutes

80 ML

1180 ML

Mean Blood Loss



Time to
Haemostasis

SERASEAL

1.7
Minutes

CAUTERISATION

34.5
Minutes

190 ML

587 ML

Mean Blood Loss

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GYNAECOLOGY DEPARTMENT

PROCEDURES PERFORMED

- Mastectomy
- Ruptured Ovarian Cyst

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GYNAECOLOGY DEPARTMENT

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SERASEAL DOSAGE

3000 IU or 1 ML

| | SERASEAL | CAUTERISATION |
|---------------------|--------------------|-------------------|
| Time to Haemostasis | 0.7 Minutes | 32 Minutes |
| Mean Blood Loss | 85 ML | 275 ML |

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In this graph, the meantime to hemostasis and blood loss are summarized for each surgical department of SeraSeal versus cauterisation. The overall time to hemostasis of SeraSeal was **21 times faster** than cauterisation and SeraSeal **reduced blood loss by 69%**.

FINDINGS

In the SeraSeal group of normal patients the time to hemostasis was **1.56 minutes for adults** and **1.74 minutes for paediatric patients** versus **29 minutes for adults** and **51.45 minutes for children** in the cauterisation group.

The blood loss mean was **200 ML for adults** and **73 ML for paediatrics** versus **600 ML and 329 ML** for the adult and paediatric patients respectively.

In the **heparin patients** SeraSeal achieved hemostasis in 45 seconds versus 10.42 minutes in the cauterisation group, nearly **14 times faster**. Blood loss was **370 ML** versus **766 ML** for SeraSeal and cauterisation respectively.

| SeraSeal™ 2200 Patient Study Summary: Hemostatic Time (min), Blood Loss (ml) with Hemostatic Product | | | | | |
|--|------|----------|---------------|---------|--------------|
| Parameter | Unit | SeraSeal | Cauterisation | p-value | Significance |
| Normal Patients (n=100) | min | 1.56 | 29 | <0.001 | Significant |
| Paediatric Patients (n=100) | min | 1.74 | 51.45 | <0.001 | Significant |
| Mean Blood Loss (ml) | ml | 200 | 600 | <0.001 | Significant |
| Paediatric Mean Blood Loss (ml) | ml | 73 | 329 | <0.001 | Significant |

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SUMMARY

238 patients in a clinical study of SeraSeal versus cauterisation in 6 surgical departments and 32 surgical procedures as a primary haemostatic agent.

The adult meantime to hemostasis was **1.56 minutes** for SeraSeal versus **28.74 minutes** for cauterisation.

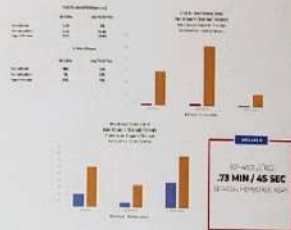
The adult mean blood loss for the SeraSeal was **200.6 ML** versus **600.08 ML** for cauterisation, nearly three times the blood loss of the former.

The median blood loss for the SeraSeal paediatric patients was **72.92 ML** compared to **329.16 ML** in the cauterisation group, **4.5** times the amount of blood loss.

SeraSeal versus cauterisation with heparinised patients the mean time to hemostasis was **0.73 minutes** versus **10.42 minutes** respectively.

And the mean blood loss was **370 ML** for SeraSeal and **766.67 ML** in the cauterisation group.

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MULTI-FACETED COST SAVINGS

Faster time to haemostasis reduces the cost of the surgical theatre and the amount of anaesthetic medication administered during surgery.

A 69% reduction in blood transfusions SeraSeal is noninflammatory and does not destroy tissue thereby pain medication is reduced.

A significant reduction of blood loss during surgery would shorten or eliminate the need of an ICU stay.

Wounds heal faster with SeraSeal since there is no tissue loss, shortening hospital stays.

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ADVANTAGES OF SERASEAL

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- SeraSeal is a **primary haemostatic agent**
- Haemostasis occurs in seconds
- SeraSeal is **effective** in all forms of coagulopathy
- SeraSeal has **multiple delivery systems**
- There is **no preparation** of SeraSeal
- SeraSeal can be **used immediately** and in **emergency** and **trauma** cases
- SeraSeal **reduces** surgical time and results in **less blood loss**
- With SeraSeal there is **no loss of tissue** or adhesions and promotes healing
- SeraSeal can be used **outside** of the clinical setting
- SeraSeal can undergo **freeze - thaw cycles** without loss of activity
- And SeraSeal results in **substantial cost savings**



Save Blood
Save Life

#SwasthKare

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