

ISO
13485

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM



AEGIS LIFESCIENCES

PROTECTION THROUGH PERFECTION



SURGISPON[®]

Absorbable Gelatin Sponge

Haemostatic Powder



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SURGISPON[®] Absorbable Gelatin Sponge Haemostatic Powder can be used to achieve rapid haemostasis for profuse and diffuse bleedings – even in difficult to reach surgical sites and regions. The modified Gelatine based, absorbable, natural polymer particulate powder accelerates the clotting process to achieve haemostasis quickly and effectively within 2 minutes.

KEY BENEFITS

- Natural, safe and biocompatible with inherent procoagulant activity
- Easy to apply to large areas and irregular surfaces
- Stops bleeding effectively with significantly faster time to haemostasis than other haemostatic powders
- Does not leave voids between clot material and tissue surfaces
- Better mechanical integrity to the clot providing more fibrin matrix within clots
- Better blood absorption capacity than other haemostatic powders with significantly lower chances of rebleeding
- Made from highly purified pharmaceutical grade gelatin
- pH-neutral can be combined with drugs as required
- Fast, complete resorption
- Indicated for use in capillary, venous and arteriolar bleeding
- No risk of encapsulation and overdose
- Can be used in patients on anticoagulant therapy.





Fig. 1

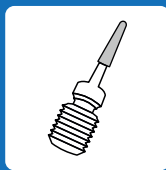


Fig. 2

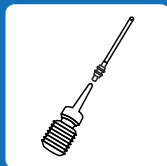


Fig. 3



Fig. 4

BELLOW PREPARATION

Fig. 1

Visually check both bellow powder and applicator packaging for any issue of previously opened or damage. If any issue noted, kindly replace with new packages.

Fig. 2

Open bellow powder packaging by removing its nozzle cap through twisting and breaking its seal.

Fig. 3

Connect bellow bottle to the applicator connector by firmly pushing and twisting applicator (2-3 times counterclockwise), to have a good grip between bellow nozzle and applicator connector.

Fig. 4

Pump the dispenser to deliver powder directly to the site of bleeding. It is advised to keep system as vertically inclined as possible for smooth and accurate release of powder at site. System is now ready for use.

APPLICATION TECHNIQUE



- Remove all excess blood from the intended site by blotting, wiping, or suctioning. Removing excess blood allows SURGISPON® powder to make direct contact with the site
- Immediately apply a generous amount of SURGISPON® powder
- For profuse bleeding, apply moderate compression to the source of bleeding using a dry compress. Irrigation with saline before carefully removing the gauze is recommended
- Moisten the compress with sterile saline solution before removal
- If bleeding continues, remove excess particles, and repeat the procedure.

SURGISPON[®]

ABSORBABLE HAEMOSTATIC GELATIN SPONGE POWDER PS (PREFILLED SYRINGE) KIT



SURGISPON[®] Haemostatic Powder prefilled syringe kit is a sterile, absorbable gelatin sponge powder provided in a prefilled syringe kit intended for haemostatic use by applying to a bleeding surface especially at a difficult to reach site.

KEY FEATURES

- Maintains uniform viscosity from beginning to end of the application after mixing with saline/thrombin
- Ready to use in 30 seconds once the sterile saline/thrombin is uniformly mixed
- Product after constitution (as directed below) envelops bleeding site to stop bleeding faster. It has a proven efficacy, safety, and efficiency, across blood transfusions, major and minor complications and surgical operating time
- Stays in place during active bleeding even after mixing with saline/thrombin, and it delivers faster haemostasis where it is intended
- It is easy to use and can be applied locally at the target site of bleeding.

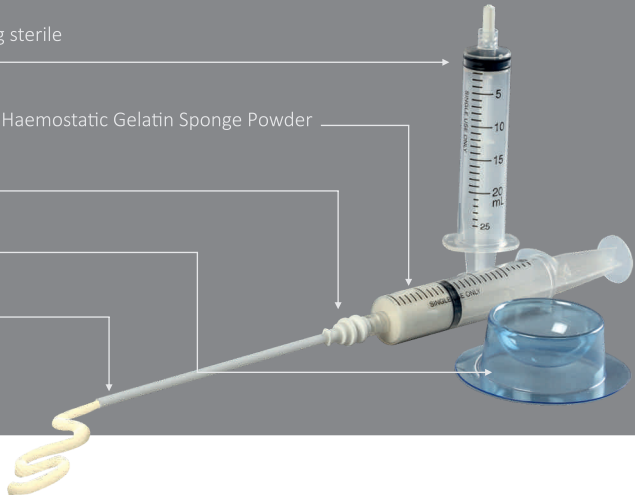
An empty syringe for mixing sterile solution with powder

SURGISPON® Absorbable Haemostatic Gelatin Sponge Powder

A connector luer

A liquid transfer cup

An applicator tip



HAEMOSTATIC MATRIX PREPARATION



Step 1: Take sterile saline/thrombin-Tranfer sterile solution into the sterile liquid transfer cup. Draw up all the sterile solution from the sterile liquid transfer cup into empty syringe.



Step 2: Connect the syringes – Remove cap from SURGISPON® powder prefilled syringe and attach this syringe to the sterile syringe carrying sterile solution, through luer connector.



Step 3: Mix the contents of syringes – Begin mixing both by pushing the sterile solution into the SURGISPON® powder prefilled syringe. Continue exchanging the solution between syringes until all components are thoroughly mixed and the consistency is even.



Step 4: Attach the applicator tip for product to be ready for clinical use.



SURGISPON[®] PUTTY

SURGISPON[®] ABSORBABLE GELATIN SPONGE POWDER can be applied in a dry form, or as a paste mixed with saline solution. Different consistencies and grades of viscosity can be achieved by varying the powder-to- fluid ratio for optimum use on irregular structures such as bone, and for filling any cavity or fissure as required.

KEY FEATURES

- High flexibility, adaptability, and easy handling
- Can be easily formed into any shape, according to surgical site
- Stops bleeding fast, within 2 minutes
- Made from highly purified pharmaceutical grade gelatin
- Does not cause bone dehiscence like conventional bone waxes
- Can be applied by hand or with a standard syringe to areas that are hard to reach
- Reduces the time the Surgeon needs to revisit cut bone surfaces, to clean up bleeding
- Fast & proven haemostasis for those hard to reach areas and from oozing spongy bone
- pH neutral character – can be combined with drugs
- No risk of encapsulation
- Totally biodegraded in within < 4 weeks
- High patient comfort – can be left in situ.

Ordering information available on last page

WHERE TO USE

In sternotomy and craniotomy procedures – irregular structures such as bone and for filling any hard to reach areas like cavities or fissures to control venous and arteriolar bleeding.



COMMON SURGICAL APPLICATIONS

- General Surgery
- Cardiac Surgery
- Orthopaedic and Trauma Surgery
- Spinal Surgery
- Plastic Surgery
- Gynaecology and Caesarean Section
- ENT Surgery
- Visceral and Transplantation Surgery
- Vascular and Cardiothoracic Surgery
- Neurosurgery
- Tumour Surgery
- Breast Surgery
- Oral and Maxillofacial Surgery
- Minimal and Robot Assisted Surgery

ORDERING INFORMATION

Product ID	Product Name	Weight/volume	No. of Pieces Per Box
SSP-01B	BELLOW POWDER	1 gm	6
SSP-02B	BELLOW POWDER	2 gm	6
SSP-03B	BELLOW POWDER	3 gm	6
SSP-05B	BELLOW POWDER	5 gm	6
SSP-PS06KIT	POWDER KIT	550 mg/6ml*	1
SSP-PS10KIT	POWDER KIT	1 gm/10ml*	1
* Deliverable volume after preparation			
SSP-01	POWDER	1 gm	6
SSP-03	POWDER	3 gm	1
SSP-05	POWDER	5 gm	1

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