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MEDICAL DEVICE SINGLE AUDIT PROGRAM



**AEGIS LIFESCIENCES**

PROTECTION THROUGH PERFECTION



**SURGISPON<sup>®</sup>**

Absorbable Haemostatic Gelatin Sponge

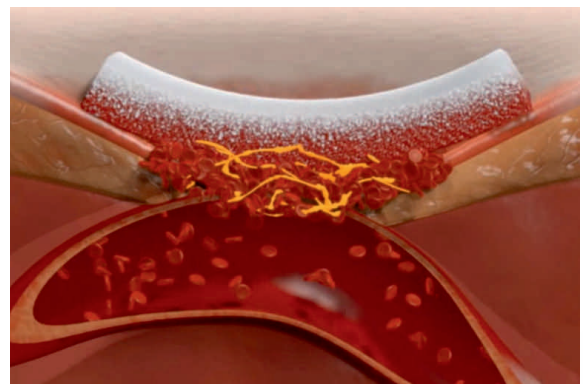


## SURGISPON®

SURGISPON® Absorbable Haemostatic Gelatin Sponge is a quick and effective haemostat which stops bleeding fast. It reduces intra operative bleeding and surgery time. SURGISPON® is non-toxic, non-allergenic, non-immunogenic, and non-pyrogenic. SURGISPON® is already gamma-sterilized, and thus does not need to be sterilized. It is available in a convenient, ready to tear sterile blister/envelope. SURGISPON® unlike many haemostatic agents, does not require special storage conditions. The uniform porosity of SURGISPON® guarantees a favourable haemostasis. When implanted in vivo, it is completely absorbed within <4 weeks, with no residue and encapsulation.

### How it work

SURGISPON® adheres to the bleeding site and absorbs approximately 45 times of its own weight of blood. It has a porous structure which activates the thrombocytes at the moment blood comes in contact with the matrix of the sponge. This causes the thrombocytes to release a series of substances which promote their aggregation. At the same time as their surface characteristic change, enabling them to act as a catalyst for the formation of the fibrin, which stops the bleeding. When implanted in the tissues, it is completely absorbed within <4 weeks.



### Key Benefits

SURGISPON® fulfils the surgical need for haemostasis with simple efficiency:

- Saves surgical time
- Reduces post operative time and fastens recovery time for the patient
- Gamma Sterilized and ready to use
- Easy to cut according to need
- Secure and speedy haemostasis
- Significantly reduces blood loss
- Absorbs approximately 45 times its own weight of oxalate blood
- No reported side effects
- Does not interfere with tissue healing
- Leaves no residue and encapsulation
- Extremely Cost effective.





## Application Areas

### As a Haemostat in Surgery

Abdominal Surgery | Anorectal Surgery | Dental Surgery | ENT Surgery | Genito Urinary Surgery | Gynaecological Surgery | Hysterectomy | Neuro Surgery | Orthopaedic Surgery | Otolaryngological Surgery | Partial Nephrectomy Plastic Surgery | Vascular Surgery | Cardiovascular Surgery | Spinal Surgery | Tumour Surgery | Hepatic Surgery

### As a Sealant with Thrombin

Gelatin-thrombin combinations are very helpful in achieving faster haemostasis. It is particularly useful in neurosurgical application near the spine, in liver surgery where there is raw liver surface bleeding, and in vascular surgery where needle holes in PTFE grafts continue to ooze.

### Vehicle for other Drugs

SURGISPON<sup>®</sup> is also used as a vehicle for drugs or antibiotics such as penicillin.

Product ID	Product Name	Dimensions (mm)	No. of Pieces Per Box
SSP-705010	REGULAR	70X50X10	10
SSP-303010	DIAL	30X30X10	10
SSP-804010	STRIFEN	80X40X10	10
SSP-802010	STRIP	80X20X10	10
SSP-802507	GYNAEC	80X25X07	10
SSP-602007	SIZE 12-7	60X20X07	10
SSP-100	SIZE 100	125X80X10	2
SSP-120	SIZE 120	120X100X10	2
SSP-200	SIZE 200	250X80X10	2
SSP-705001	SPECIAL	70X50X01	20
SSP-805001	SPECIAL	80X50X01	20
SSP-200705	FILM	200X70X0.5	10
SSP-100C	SIZE 100C	125X80X02	10
SSP-954805	SIZE 45	95X48X05	2
SSP-484805	SIZE 23	48X48X05	10
SSP-253005	SIZE 7	25X30X05	10



## SURGISPON® ENT

### SURGISPON® Absorbable Haemostatic Gelatin Sponge for ENT Surgeries - "Stop Bleeding effectively"

- Porous structure and intrices enables the high absorption of fluids
- SURGISPON® is effective in supporting the new graft in the outer ear canal after tympanoplasty and buttressing middle ear implants
- pH-neutral makes suitable for use with the antibiotics and other drugs.

#### Key Benefits: SURGISPON® ENT:

- Made from highly purified pharmaceutical grade gelatin
- Natural, safe and stops bleeding effectively
- Insoluble in water and fully absorbable
- High density sponge for prolonged support and scaffold function in graft and implant surgery
- Also used as a carrier for antibiotics or other medication
- pH neutral—ideal carrier for drugs
- Easy handling—does not stick to gloves or instruments
- High patient comfort— can remain in the body
- Total absorption time depending on application, it is completely absorbed within <4 weeks.



#### Why use SURGISPON® ENT:

##### Safe, no complications

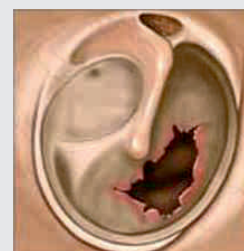
The postoperative period of 7 to 21 days can be passed without complications. There was no new bone formation either. The removal of ENT gelatin sponges cubes are easy without problems. A suction could be used occasionally with the use of a forceps. No remnants had to be removed in a second attempt.

##### User friendly application

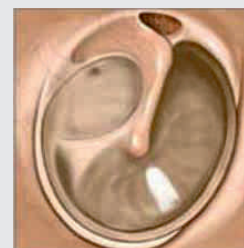
Excellent processing abilities and no fuzzing was observed, which is clinically of major importance. According to Priv. Doz Dr. "The pre operative preparations for the nurses are not time consuming and the application procedure was technically simple.

##### Unsurpassed anti-adhesive and haemostatic

Because of the firm higher density, the cubes stay longer in place, and are as such perfectly suited to be inserted to support and separate tissue to prevent adhesions and to control bleeding.



Before



After

Tympanoplasty & Myringoplasty

Product ID	Product Name	Dimensions (mm)	No. of Pieces Per Box
SSP-805010	STANDARD	80X50X10	10
SSP-101010	CUBES	10X10X10	32
SSP-202007	SHEET	20X20X07	20
SSP-801507	NASAL STRIP	80X15X07	10
SSP-8007	NASAL TAMPON	80X07Ø	20
SSP-01	POWDER	1 Gram	6
SSP-401010	STRIP	40X10x10	5



## SURGISPON® Anal Tampon

- Quick haemostasis in anorectal surgeries
- Best suitable for post operative haemostasis
- Painless and easy tampon discharge
- High blood absorption capacity
- SURGISPON® Tampon is provided with an opening into which a flatus drain can be introduced.



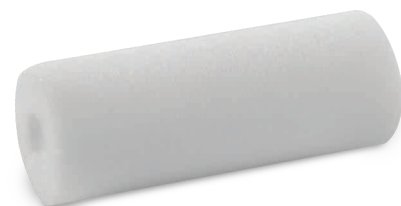
SURGISPON® is manufactured from highly purified and pH neutral pharmaceutical grade gelatin foam of uniform porosity. SURGISPON® is gamma sterilized and single use absorbable haemostatic gelatin sponge. SURGISPON® anal tampon is used in haemorrhoid operations and other surgical procedures in the anal, vaginal and rectal regions. Painless and easy tampon discharge. The SURGISPON® is easy expelled at first bowel movement, requiring no additional nursing intervention.

### Key Benefits: SURGISPON® Anal Tampon

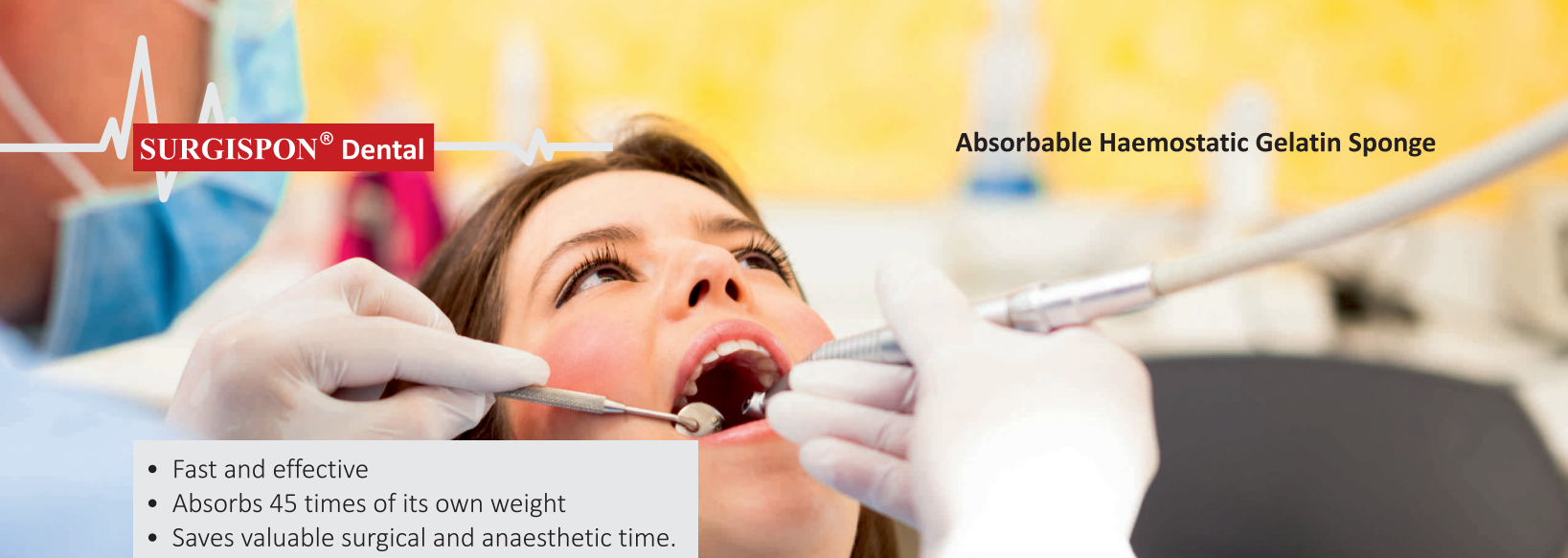
- SURGISPON® Anal Tampon reduces post-operative pains more effectively than other known forms of Anal Tampons
- High absorption capacity - approximately 45 times of its own weight
- SURGISPON® Anal Tampon liquefies rapidly and is spontaneously expelled within 1 to 2 days
- Used as a carrier for drugs like antibiotics, thrombin and haemostats glue
- The gelatin sponge application can reduce 4 days of hospital stay for each rectal patient
- Significantly increases haemostasis without pain and discomfort
- It has a water in soluble property
- Implantable and completely resorbable
- Does not stick to instruments
- Attaches to the bleeding tissue
- Used dry or soaked with physiological solution
- Non-toxic, Non allergenic, Non-immunogenic, Non-pyrogenic and Biocompatible
- The immediate insertion of an absorbable haemostatic gelatin sponge can reduce the frequency of rectal bleeding.

### Where to Use

- Anorectal surgery — suitable to facilitate better post operative haemostasis
- To achieve fast hemostasis in :
  - Haemorrhoidectomies
  - Anal fistula and fissures
  - Curettage and Hysterectomies
  - Surgery for rectal cancer
  - Rectal prolapse
  - Colorectal surgery
  - Transrectal prostate needle biopsy
- Vaginal application.



Product ID	Product Name	Dimensions (mm)	No. of Pieces Per Box
SSP-8030	Anal Tampon	80x30 Ø	06



- Fast and effective
- Absorbs 45 times of its own weight
- Saves valuable surgical and anaesthetic time.

**SURGISPON®**

SURGISPON® is a sterile haemostatic absorbable gelatin sponge made from highly purified pharmaceutical grade gelatin (lyophilized hydrolyzed collagen) foam, which gives it a uniform porosity and reacts neutrally. The dried foam is cut, packaged and sterilised using gamma radiation. SURGISPON® is immediately available for use in the operating theatre and does not require any sterilisation by dry heat or autoclaving.

SURGISPON® may be used in combination with antibiotics, thrombin, chemotherapeutics without reduction of the sponges haemostatic effect. Carefully read applicable instructions for use (IFU) before application.



**WHERE to use SURGISPON® Dental**

To achieve immediate hemostasis in:- Extractions, Oral bone and soft tissue surgery



**TOOTH EXTRACTIONS**  
Oozing bleeding from alveolus is stopped by application of SURGISPON® Dental cube



**ENUCLEATION OF CYSTS**  
Bleeding from the cavity is controlled with the Dental cube



**DETAIL**  
Dental cube place in cavity



**CONTROL OF PROFUSE BLEEDING**  
In tooth extraction by means of several dental cubes

Product ID	Product Name	Dimensions (mm)	No. of Pieces Per Box
SSP-101010.12	CUBES	10X10X10	12
SSP-101010.32	CUBES	10X10X10	32
SSP-101010.50	CUBES	10X10X10	50 Per Jar
SSP-1208	DENTAL TAMPON	12X08Ø	32
SSP-202007	SHEET	20X20X07	20



## SURGISPON® Powder

- The flexible surgery assistant
- For fast and proven hemostasis for hard to reach areas and from oozing spongy bone
- SURGISPON® Powder can be easily formed into any shape, according to surgical site
- SURGISPON® Powder stops bleeding fast, within 2 minutes.



SURGISPON® powder can be applied dry in powder 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.

Surgeons and operating room staff benefit from the product's high flexibility, adaptability and easy handling. SURGISPON® powder can be applied by hand or with a standard syringe to areas that are hard to reach. It is adhesive, especially when applied in sternotomy and craniotomy procedures, it is not known to cause bone dehiscence unlike conventional bone waxes.

### Key Benefits: SURGISPON® Powder

- Natural and safe
- Use dry or mix into paste
- Easy to apply at irregular structures
- Made from highly purified pharmaceutical grade gelatin
- pH neutral character—can be combined with drugs
- Stops bleeding effectively
- Easy handling, Fast and complete resorption
- High patient comfort—can be left in situ
- Indicated for use in capillary, venous and arteriolar bleeding
- No risk of encapsulation
- Totally bio-degraded within < 4 weeks
- SURGISPON®, a worldwide proven hemostatic material, offered by Aegis Lifesciences, being exported into more than 70 countries
- SURGISPON® absorbable hemostatic sponge powder also used as effective drug carrier.



### 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



Product ID	Weight/Volume	No. of Pieces Per Box	Packing Description
SSP-01	1gm	6	1 gm of SURGISPON® Powder in a container packed within a foil pouch.
SSP-03	3gm	1	3 gm of SURGISPON® Powder in a container packed within a foil pouch.
SSP-05	5gm	1	5 gm of SURGISPON® Powder in a container packed within a foil pouch.
SSP-PS06KIT/ SSP-PS10KIT	550mg/6ml* 1gm/10ml*	1	Following contents are packed within kit. A. 550mg/1gm of SURGISPON® Powder pre-filled in a 25 mL syringe B. A connector luer C. An applicator tip D. A 25 mL empty syringe E. One liquid transfer cup
SSP-01B	1gm	6	1 gm of SURGISPON® Powder in a bellow bottle packed within a foil pouch.
SSP-02B	2gm	6	2 gm of SURGISPON® Powder in a bellow bottle packed within a foil pouch.
SSP-03B	3gm	6	3 gm of SURGISPON® Powder in a bellow bottle packed within a foil pouch.
SSP-05B	5gm	6	5 gm of SURGISPON® Powder in a bellow bottle packed within a foil pouch.

\*Deliverable volume after preparation

# GLOBAL PRESENCE



**30+**

Customised size products to take care of almost all types of Surgeries and convenience to surgeons.



Only facility in the world for exclusive manufacturing of absorbable haemostatic products, with largest production.

**30%+**

Annual growth and growing.



Most cost effective solutions to the ailing Humanities.

**70+**

Countries presence across the globe.

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BROCHURE



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