HEMOSPONGE
Absorbable Gelatin Sponge USP

About product

HEMOSPONGE is sterile, off-white, non-elastic, porous and pliable foam prepared from highly purified gelatin (collagen derived protein). It absorbs many times of its weight blood and other fluids within its matrix.

Intended use

HEMOSPONGE is intended for application to bleeding surfaces as a haemostatic. It is particularly used when control of capillary, venous and arteriolar bleeding by pressure, ligature, and other conventional procedures is either ineffective or impractical.

Mechanism of haemostasis

HEMOSPONGE arrests the bleeding by the formation of an artificial clot. When applied to bleeding surfaces, porous structure of HEMOSPONGE facilitates the process of clotting. At the moment thrombocytes (platelets) come in contact with the matrix of the sponge, they change their surface characteristics to release a thromboplastin, activating the cascade of clotting.

Directions for use

- Always use aseptic technique to remove the sterile sponge from its packaging. Avoid contacting the product to the outer part of packaging and other non-sterile area. The product should either removed with the help of sterile forceps from its packaging or it need to drop freely on sterile place.
- For use at the site of application, either use the intact sponge or cut the sponge to the desired size. It can be applied dry or wet depending on conditions present at operation and preference of the surgeon.
    - **When applied dry**, a piece of HEMOSPONGE should be manually compressed before application to the bleeding site, and then held in bleeding site for few minutes with moderate pressure till haemostasis observed.
    - **When used wet,** (generally with sterile saline) HEMOSPONGE should be first immersed in the sterile saline and then withdrawn, squeezed between gloved fingers to remove all air bubbles, and then again placed in sterile saline till its use. The sponge should return to its original size and shape in the saline. If it does not, it should be removed again and kneaded between fingers vigorously until all air is expelled and should expand to its original size and shape when returned to the saline. At the time of use, HEMOSPONGE is blotted on sterile gauze to remove excess saline. The HEMOSPONGE should be held in the bleeding site with moderate pressure using a pledget of cotton or small gauze until haemostasis results. Removal of the pledget or gauze is made easier by wetting it with a few drops of saline, to prevent pulling up the HEMOSPONGE which by then should enclose a firm clot.
- The first application of HEMOSPONGE will usually control bleeding, but if not, additional applications may be made using fresh pieces, prepared as described above.

Contraindications

- HEMOSPONGE is not recommended for use other than as an adjunct for haemostasis.
- HEMOSPONGE is intended only as surface haemostatic during surgery and it should not be used for the primary treatment of coagulation disorders.

- HEMOSPONGE should not be used for controlling postpartum bleeding or menorrhagia.
- HEMOSPONGE should not be used in closure of skin incisions because it may interfere with healing of the skin edges.
- HEMOSPONGE should not be placed in intravascular compartments; it may travel to narrower vessel or heart and may cause serious cardio-vascular complications.
- HEMOSPONGE should not be used in patients with known allergies to animal collagen based haemostatic.
- The use of HEMOSPONGE is not recommended in the presence of infection. It has been observed that gelatin based sponge supports microbial growth at the site of application. Fever associated with the use of gelatin sponge has been reported without demonstrable infection.
- HEMOSPONGE should not be used in conjunction with autologous blood salvage circuits as gelatin particles may pass through the 40µ transfusion filters of blood scavenging systems.

Precautions

- Use only minimum amount of sponge and carefully remove any excess amount once the haemostasis is achieved. When placed into cavities or closed tissue spaces, minimal preliminary compression is advised. Avoid over packing - sponge may expand upon absorption of body fluids to its original size, resulting in the compression of neighbouring tissue. Particularly, avoid usage near to site where there is chance of nerve compression (which may result in reversible multiple organ paralysis).
- Whenever possible, HEMOSPONGE should be removed,
    - after use in laminectomy procedures - compressions of spinal cord, resulting in numbness in extremities and loss of bowl and bladder functions have been reported.
    - from foramina in bone - HEMOSPONGE may swell to its original size on absorbing fluids, and produce nerve damage by pressure within confined bony spaces.
- In urological procedures, sponge should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Compatibilities with drugs and biologics

- The product is neutral and has no physical-chemical interaction with drugs/biologics generally used in surgical environment. Though not necessary, HEMOSPONGE can be used with thrombin for quick haemostasis, with sterile solution of antibiotics and analgesics to reduce local post-operative infection and pain.
- HEMOSPONGE should not be used in conjunction with methyl methacrylate adhesives. Microfibrillar collagen has been reported to reduce the strength of methyl methacrylate adhesives.

Warning

- HEMOSPONGE is supplied in a sterile envelope (or blister pack) enclosed in an outer envelope. Sterility of the product is assured unless the outer envelope has been damaged or opened. If the envelope is torn or punctured, the contained HEMOSPONGE should not be used.
- Employ aseptic procedure in opening envelope and withdrawing HEMOSPONGE. Once the package is opened, contents are subject to contamination. The content must be used as soon as the package is opened. Any unused pieces should be discarded.
- This product is prepackaged sterile and should not be resterilized by heat, steam or ethylene oxide. Heating may alter physical characteristics of the sponge and may change absorption time, rate and capacity. Ethylene oxide is not recommended for resterilization because it may trap in the interstices of the foam.

- HEMOSPONGE is intended only for single use. Reuse can result in transmission of blood-borne pathogens (including HIV and hepatitis), potentially endangering patients and health care providers.

Storage

HEMOSPONGE should be stored between 15-30 °C, in dry place, away from direct sunlight.

Sizes

HEMOSPONGE is available in below sizes.

• STANDARD	80 × 50 × 10 mm
• UNIVERSAL	70 × 50 × 10mm
• ANAL/VAGINAL TAMPON	80 × 30 (Dia.)mm
• DENTAL SL	10 × 10 × 10mm
• DENTAL XL	20 × 20 × 07mm
• DIAL SIZE	30 × 30 × 10mm
• NASAL STRIP	80 × 15 × 07mm
• NASAL TAMPON	80 × 10 (Dia)mm
• GYNAEC STRIP	80 × 25 × 07mm
• SIZE 12-7	60 × 20 × 07mm
• FILM – 80	80 × 25 × 01mm
• FILM – 120	120×100×01mm
• FILM – 240	240×120×01mm

Hemosponge is also available in custom size on demand of physician for special application.

Symbols and meaning

	Consult instructions for use
	Temperature limit for product storage
	Keep dry
	Keep away from sunlight
	For single use only
	Do not re-sterilize
	Do not use if package is damaged
	Date of manufacture
	Use by date (Expiry Date): Month & Year
	Batch code
	Sterilised by irradiation

Manufactured by:

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Document reference: GL/AGS/IFU/GEN/01, Effective date: 01/04/2022