# **HEMOSPONGE** Dental Cubes

Absorbable Gelatin Sponge USP

## **About product**

HEMOSPONGE cubes are small sized, gamma sterile, ready to use, haemostatic sponges prepared from purified Gelatin. The product is intended as haemostatic in surgical interventions and it is RESORBABLE. The cube size of sponge is specially developed to stop bleeding in routine as well as advanced dental surgeries. HEMOSPONGE cubes have 3D matrix structure which can absorb higher amount of blood and stabilizes the clot better than other cotton-based gauze. It absorbs the blood by capillary suction action.

# Features

HEMOSPONGE have following major advantages

- Fast and effective haemostatic stops oozing blood in 2-4 minutes
- **Haemostatic packing** fills bleeding sockets and absorbs continuously oozing tissue fluids/blood and provides physical supports for oozing blood to clot.
- Resorbable, non-toxic, non-allergic Complies ISO 10993 standard
- **Highly absorbent** 3D matrix structure of sponge absorbs and hold 40 to 45 times the weight of fluid or blood
- Pure, Safe and Biocompatible made up of pharma grade extra PURE GELATIN ONLY.
- Neutral pH Can be soaked with variety of medicine and biologics for enhanced effect
- Gamma sterile Ready to use, no need to sterilize the product before use
- No specific storage condition requires store at room temperature

## Sizes

HEMOSPONGE Cubes are available in two sizes.

- 1) HEMOSPONGE *Dental SL* (10 × 10 × 10 mm): 32 pieces per pack
- Socket size sponges, most suitable for use in dental surgeries
- 2) HEMOSPONGE *Dental XL* / ENT size (20 × 20 × 07 mm): 10 pieces per pack
- Slightly larger than socket size to suit advanced dental and ENT surgeries

## Intended use

HEMOSPONGE cube is intended as haemostatic for stopping the bleeding surfaces in dental surgery. It can also be used in minor surgical procedures like oral surgeries and tissue biopsies where only small sized haemostatic sponges are needed.

HEMOSPONGE cubes are also intended as most patient friendly packing material in ENT surgeries where product provides mechanical supports to healing tissues.

## Mechanism of haemostasis

Unlike other haemostatic products used in dental surgeries, HEMOSPONGE does not induce any chemical interaction with blood components to form clot. The product ACCELERATES THE NATURAL CLOTTING PROCESS ONLY. The matrix of HEMOSPONGE works as extrinsic factor in clotting process. The moment platelets of oozing blood come in contact with matrix, platelets get self-activated to release series of blood clotting factors, accelerating the natural clotting process.

#### **Directions for use**

HEMOSPONGE can be used dry or moistened, depending on preference of the physician.

Before insertion, HEMOSPONGE cube is rolled between the fingers and lightly compressed to the approximate diameter of the cavity or socket to be filled. Larger sizes of cubes are need to cut to desired size to fit into cavity or socket. Following insertion of the rolled pack, light finger pressure should be applied for one or two minutes to achieve quick haemostasis.

When used moistened, HEMOSPONGE cube is first immersed in solution of saline. The piece is then removed from the solution, squeezed thoroughly to remove air bubbles present in the meshes, and replaced in the solution where it will swell to its original size. It is then taken from the solution, blotted on sterile gauze to remove excess fluid, and placed in the cavity or wound.

Although not necessary, HEMOSPONGE can be used either with or without thrombin to obtain hemostasis.

#### **Biodegradation of product**

HEMOSPONGE cubes are made up of Gelatin (Protein) of highest purity. Once placed in tissue or socket, the product is slowly digested by proteolytic enzymes of tissues. The rate of digestion depends on the site of application and blood flow supply. When implanted in mucosal tissues and sockets, it gets liquified and completely removed from the site of application within 2-3 days. When implanted in deeper tissues, product get digested in 3-4 weeks. The metabolites are non-toxic and non-allergic.

#### Warning:

- Use only the minimum amount of HEMOSPONGE necessary to produce hemostasis, it should not be over packed in cavity.
- The product is pre-packaged gamma sterile DO NOT STERILIZE BEFORE USE by any means of heat (heating changes absorption time) or ethylene oxide (ethylene oxide may trap in the matrix of the sponge which may cause tissue irritation).
- To prevent contamination, EMPLOY ASEPTIC PROCEDURE in opening envelope and withdrawing HEMOSPONGE. Once the package is opened, contents are subject to contamination. It is recommended that HEMOSPONGE be used as soon as the package is opened and unused contents discarded.
- 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.
- Not recommended to use at the site of application showing sign of infection

## Storage

HEMOSPONGE should be stored between 15-40 °C away from direct sunlight, in dry place. Do not refrigerate.

## Symbols and meaning

15°  $\int 40^{\circ}$ C Temperature limit

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Ĵ	Keep dry
迷	Keep away from sunlight
$\otimes$	For single use only
$\odot$	Do not re-sterilize
\$	Do not use if package is damaged
$\sim$	Date of manufacture
Σ	Use by date - Expiry Date: Month & Year
LOT	Batch code
REF	Catalogue Number
STERILE R	Sterilised by irradiation

# Manufactured by:

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