SURGISPON®

(ABSORBABLE GELATIN SPONGE) STERILE HAEMOSTAT FOR SURGICAL USE

Manufactured by:
Aegis Lifesciences Pvt. Ltd.
215/216, Mahagujarat Industrial Estate, Phase – III, Gam: Moraiya, PO: Changodar, Tal: Sanand, Dist.: Ahmedabad - 382 213, India.
Web: www.aegis-lifesciences.com
E-mail: info@aegis-lifesciences.com
Ph.: +91-9726903131, +91-9727103131
93/42/EEC.
EC REP
EC Representative
OBELIS S.A (www.obelis.net)
Bd. Général Wahis, 53 1030 Brussels, Belgium

This package insert is not a reference to surgical techniques. It is designed to assist in using this product.

DESCRIPTION:

SURGISPON® - Absorbable Haemostatic Gelatin Sponge is a sterile malleable, water insoluble, gelatin absorbable sponge intended for haemostatic use by applying to a bleeding surface. SURGISPON® is non-pyrogenic and biocompatible.

SURGISPON® is a surgical haemostatic sponge, manufactured from highly purified first grade gelatin material for use in various surgical procedures. When implanted in vivo and used in appropriate amounts, it is completely absorbed within 3-4 weeks. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days.

SURGISPON® Gelatin Sponges have 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 surfaces change character, thus enabling them to act as a catalyst for the formation of the fibrin.

INDICATIONS:

SURGISPON® can be effectively used in various surgeries for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical.

CONTRAINDICATIONS:

SURGISPON® should not be used:

- in closure of skin incisions because it may interfere with the healing of skin edges. This is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
- in patients with known allergies to collagen
- in intra vascular compartments because of the risk of embolization

HANDLING INSTRUCTIONS:

SURGISPON® may be used dry or saturated with physiological salt solution. Cut to the desired size, a piece of SURGISPON®, either dry or saturated with sterile, isotonic sodium chloride solution (sterile saline), can be applied with light pressure directly to the bleeding site. When applied dry, a single piece of SURGISPON® should be manually applied to the bleeding site, and held in place with moderate pressure until haemostasis results. When used with sterile saline, SURGISPON should be first immersed in the solution and then withdrawn, squeezed between gloved fingers to expel air bubbles, and then replaced in saline until needed. The SURGISPON® sponge should promptly return to its original size, with slight expansion in thickness and shape in the solution. If it does not, it should be removed again and kneaded vigorously until all air is expelled and it does expand to its original size, with slight increases in thickness and shape when returned to the sterile saline. SURGISPON® if used wet it may be blotted to dampness on gauze before application to the bleeding site. It should be held in place with moderate pressure, using a pledget of cotton or small gauze sponge until haemostasis results. Removal of the pledget or gauze is made easier by wetting it with a few drops of sterile saline, to prevent pulling up the SURGISPON® which by then should enclose a firm clot. Use of suction applied over the pledget of cotton or gauze to draw blood into the SURGISPON® is unnecessary, as SURGISPON® will draw up sufficient blood by capillary action.

The first application of SURGISPON® will usually control bleeding, but if not, additional applications may be made. For additional applications, fresh pieces should be used, prepared as described above. Use only the minimum amount of SURGISPON® necessary to produce haemostasis. Once haemostasis is achieved any excess Gelatin Sponge should be carefully removed because of the possibility of dislodgement of the device or compression of other nearby anatomic structures.

Since SURGISPON® causes little more cellular reaction than does the blood clot, the wound may be closed over it. SURGISPON® may be left in place when applied to mucosal surfaces until it liquefies.

WARNINGS:

The over packing of SURGISPON®, should be avoided, since recovering to its initial volume may interfere with normal function and/or could cause possible or eventual compression necrosis of surrounding tissue and nerve damage. While packing a cavity for Haemostasis is sometimes surgically indicated, Gelatin Sponge should not be used in this manner unless excess product not needed to maintain haemostasis is removed. SURGISPON® should be removed after usage and bleeding has stopped in radical cavities, laminectomy procedures, around or in proximity to foramina in bone, areas of bony confine, the spinal cord and /or the optic nerve and chiasma or closed tissue spaces with presence of bone. This might lead to unintended pressure on neighboring structures which may result in pain for the patient or might create the potential for nerve damage.

SURGISPON® should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where SURGISPON® Sponge has been positioned,

reoperation may be necessary in order to remove the infected material and allow drainage.
Do not re-sterilize! Do not use if the package is opened or damaged. This device is designed, tested and manufactured for single use only.
SURGISPON® is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for haemostasis.

PRECAUTIONS:
Use only the minimum amount of SURGISPON® needed for haemostasis, holding it at the site until bleeding stops and then removing the excess.
SURGISPON® should not be used conjunction with methyl methacrylate adhesives.
SURGISPON® should not be used in conjunction with autologous blood salvage circuits.
SURGISPON® is not recommended for the primary treatment of coagulation disorders.
SURGISPON® should not be used in the presence of infection.
SURGISPON® should not be used for controlling postpartum hemorrhage or menorrhagia.
It is not recommended that SURGISPON® be saturated with an antibiotic solution or dusted with antibiotic powder.
Users should be familiar with surgical procedures and techniques involving gelatin sponge before employing SURGISPON®.
SURGISPON® sterile sponge is packed in sterile blisters/envelopes which guarantee sterility.
Once the package is opened, contents are subject to contamination. It is recommended that SURGISPON® should be used as soon as the package is opened and unused contents discarded. It should not be reused or re-sterilized as it may lose its physical characteristics as well as sterility.
Open the blister/envelope pack by pulling its two loose ends away from each other –in such a way that the SURGISPON® falls out undamaged, on to a sterile surface.
Discard any unused SURGISPON® remaining. Dispose of contaminated devices and packaging materials utilizing standard hospital procedures and universal precautions for bio hazardous waste.

ADVERSE REACTIONS:

There have been reports of fever associated with the use of SURGISPON®, without demonstrable infection. SURGISPON® Sterile Sponge may serve as a nidus of infection and abscess formation, and has been reported to potentiate bacterial growth. Giantcell granuloma has been reported at the implantation site of absorbable gelatin product in the brain, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.
In very rare cases, there have been reports on the formation of granuloma after use of haemostatic gelatin-based products.
SURGISPON® should not be used if there is recurrent massive upper gastrointestinal haemorrhage It may result in extensive gastric necrosis/massive gastric gangrene and therapeutic transcatheter embolization of the left gastric artery.
Gelatin sponge should not be left in the renal pelvis, renal calyces, bladder, urethra or ureters to eliminate the potential foci for calculus formation.
Foreign body reactions, encapsulation of fluid and hematoma have also been reported.
When SURGISPON® was used in laminectomy operations, multiple neurologic events were reported, including but not limited to spinal stenosis.
When SURGISPON® was used in laminectomy operations, multiple neurologic events were reported, including but not limited to cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.

STERILIZATION:
SURGISPON® is sterilized by gamma radiation. Reuse, use of the device with opened or damaged packaging, reprocessing and/or re-sterilization of this device may lead to its failure and subsequent injury, and/or create the risk of contamination and patient infection, illness or death of the patient.

STORAGE:
The product should be stored in its original packaging and the outer package must therefore be closed immediately after use. The box should be stored in a clean, dry room at a temperature not more than 30°C.
Do not refrigerate or freeze.
Do not use after the expiry date!

PACKING:
Available in various shapes and sizes suitable for different kinds of surgeries

SYMBOLS USED:

	Caution, consult accompanying documents
	Consult instructions for use
30°C	Upper Limit of Temperature
	Keep dry
	Do not re-use/ 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
LOT	Batch code
REF	Catalogue Number
STERILE R	Sterilized using irradiation
MD	Medical Device
CE 2460	CE-Mark and Identification number of notified body. Product conforms to the essential requirements of the medical device directive 93/42/EEC.
	Manufacturer