SURGISPON®

(ABSORBABLE HAEMOSTATIC GELATIN SPONGE)

STERILE HAEMOSTAT FOR SURGICAL USE

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 pharmaceutical grade gelatin granules and purified water for use in various surgical procedures.
When implanted in vivo and used in appropriate amounts, it is completely absorbed within <4 weeks.
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 porcine collagen (see WARNINGS).
- 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 When used with sterile saline, SURGISPON® should be first immersed in the solution and then withdrawn, squeezed between gloved fingers to expel air bubbles, and then replaced in saline until needed.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 liquifies.

WARNINGS:
- Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin sponge. Patients with history of allergies to porcine products may be at risk of serious acute hypersensitivity reactions, including anaphylaxis **[See Contraindications]**. If an anaphylactic reaction is observed, absorbable gelatin sponge administration should be immediately discontinued and removed any applied product.
- The over packing of absorbable gelatin sponge, 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.
- Absorbable haemostatic gelatin sponge 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 the presence of bone. This might lead to unintended pressure on neighbouring structures which may result in pain for the patient or might create the potential for nerve damage.
- Absorbable haemostatic gelatin sponge should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where absorbable gelatin sponge has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage.
- Do not resterilize! Do not use it if the package is opened or damaged. This device is designed, tested, and manufactured for single use only.
- Absorbable haemostatic gelatin sponge is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for haemostasis.
- Absorbable haemostatic gelatin sponge should not be used in instances of pumping arterial hemorrhage. It should not be used where blood or other fluids have pooled or in cases where the point of hemorrhage is submerged.

PRECAUTIONS:
- Absorbable haemostatic gelatin sponge should not be placed in the vicinity of the cerebral ventricular space or where there is a possibility of a cerebrospinal fluid fistula to the target bleeding site. Absorbable haemostatic gelatin sponge should also not be used as a tissue substitute to repair dural defects of the dura or the cranium. Absorbable haemostatic gelatin sponge may migrate from central nervous system (CNS) surgical sites into the cerebral ventricular space and compromise the cerebrospinal fluid circulation. Hydrocephalus and underlying fluid retention, requiring a re-intervention to remove Absorbable gelatin sponge residue, have been reported in adult and paediatric patients (see ADVERSE REACTIONS). In some cases, these complications occurred several months after use of Absorbable haemostatic gelatin sponge.
- Use only the minimum amount of absorbable haemostatic gelatin sponge needed for haemostasis, holding it at the site until bleeding stops and then removing the excess.
- Absorbable haemostatic gelatin sponge should not be used in conjunction with methylmethacrylate adhesives.
- Absorbable haemostatic gelatin sponge should not be used in conjunction with autologous blood salvage circuits.
- Absorbable haemostatic gelatin sponge is not recommended for the primary treatment of coagulation disorders.
- Absorbable haemostatic gelatin sponge should not be used in the presence of infection or should be used with antibiotics in infected wounds.
- Absorbable haemostatic gelatin sponge should not be used for controlling postpartum hemorrhage or menorrhagia.
- Users should be familiar with surgical procedures and techniques involving gelatin sponge before employing Absorbable haemostatic gelatin sponge.
- Absorbable haemostatic gelatin sponge sterile sponge is packed in qualified sterile barrier system which guarantee sterility.
- Once the package is opened, contents are subject to contamination. It is recommended that Absorbable haemostatic gelatin sponge should be used as soon as the package is opened and unused contents discarded. Open the Sterile barrier system by pulling its two loose ends/Peel mark away from each other –in such a way that the Absorbable haemostatic gelatin sponge falls out undamaged, on to a sterile surface.
- Discard any unused Absorbable haemostatic gelatin sponge remaining. Dispose of contaminated devices and packaging materials utilizing standard hospital procedures and universal precautions for bio hazardous waste.
- Positioning of the patient resulting in negative peripheral venous pressure during a procedure has been reported to be a contributing factor resulting in intravascular migration of gelatin and life-threatening thromboembolic events and should be avoided.

ADVERSE REACTIONS:
Followings are the potential adverse events that are generally associated with the use of gelatin haemostat SURGISPON®:
- Life-threatening anaphylactic reactions, including death, have been reported after exposure to absorbable gelatin (see WARNINGS).
- Product migration to the cerebral ventricular space followed by hydrocephalus or cerebrospinal fluid retention leading to secondary intervention, has been reported following neurosurgery in the vicinity of the ventricular space (see PRECAUTIONS).
- There have been reports of fever associated with the use of absorbable haemostatic gelatin sponge, without demonstrable infection. absorbable haemostatic gelatin sponge Sterile Sponge may serve as a nidus of infection and abscess formation, and has been reported to potentiate bacterial growth. Giant cell granuloma has been reported at the implantation site of absorbable haemostatic gelatin product in the brain, as has compression of the brain and spinal cord resulting from the accumulation of sterile fluid.
- Absorbable haemostatic gelatin sponge 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.
- It should not be left in the renal pelvis, renal calyces, bladder, urethra or ureters to eliminate the potential foci for calculus formation.
- After placement, absorbable hemostatic agents may be visible on imaging studies until they are fully absorbed, which could be interpreted as pseudo tumor / pseudo mass appearance.
- Pseudo infection / pseudo abscess has also been reported in the literature.
- Pseudotumor / pseudomass and pseudo infection / pseudo abscess may result in additional invasive procedures, reoperations, and prolonged hospital stays.
- When absorbable haemostatic gelatin sponge 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.
- Foreign body reaction, encapsulation of fluid, and hematoma have also been reported.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin products were used in severed tendon repair.
- Toxic shock syndrome has been reported in association with the use of absorbable gelatin sponge in nasal surgery.
- Fever, failure of absorption, and hearing loss have been reported in association with the use of absorbable gelatin sponge during Tympanoplasty.

Adverse Reactions Reported from Unapproved Uses
- Absorbable haemostatic gelatin sponge is not recommended for use other than for topical application to bleeding surfaces as a hemostatic agent.
- While some adverse medical events following the unapproved use of absorbable haemostatic gelatin sponge have been reported (see ADVERSE REACTIONS), other potential harms associated with such use may not have been reported.
- When absorbable haemostatic gelatin sponge has been used during intravascular catheterization for the purpose of producing vessel occlusion, the following adverse events have been reported; vessel recanalization, intravascular gelatin migration, fever, end-organ ischemia and infarction, pancreatitis, post-embolization syndrome, ischemia and infarction at unintended locations (such as duodenum and pancreas), duct stenosis (such as bile duct stenosis), gangrene, infection, necrosis, organ dysfunction, infertility, embolization of extremities, pulmonary embolization, splenic abscess, asterixis, and death.
- The following adverse medical events have been associated with the use of absorbable haemostatic gelatin sponge for repair of dural defects encountered during laminectomy and craniotomy operations: fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The following adverse medical events have been associated with the use of absorbable haemostatic gelatin sponge with or without bone dust for repair of dural and cranial defects encountered during burr-hole operations or craniotomies: cerebrospinal fluid retention and hydrocephalus leading to secondary intervention (see PRECAUTIONS).

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.

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.

DE – SURGISPON® (ABSORBIERBARER HÄMOSTATISCHER GELATINSCHWAMM) STERILER HÄMOSTAT FÜR CHIRURGISCHE ZWECKE

CS – SURGISPON® (VSTŘEBÁVAJÍCÍ SE HEMOSTATICKÁ ŽELATINOVÁ HOUBA) STERILNÍ HEMOSTAT PRO CHIRURGICKÉ POUŽITÍ

FR – SURGISPON® (ÉPONGE DE GÉLATINE HÉMOSTATIQUE RÉSORBABLE) HÉMOSTAT STÉRILE À USAGE CHIRURGICAL

IT – SURGISPON® (SPUGNA DI GELATINA HEMOSTATICA ASSORBIBILE) EMOSTATO STERILE PER USO CHIRURGICO

RO – SURGISPON® (BURETE DE GELATINĂ HEMOSTATICĂ ABSORBABILĂ) HEMOSTAT STERIL PENTRU UTILIZARE CHIRURGICALĂ

SK – SURGISPON® (VSTREBATEĽNÁ HEMOSTATICKÁ ŽELATÍNOVÁ ŠPONGIA) STERILNÝ HEMOSTAT PRE CHIRURGICKÉ POUŽITIE

ES – SURGISPON® (ESPONJA DE GELATINA HEMOSTÁTICA ABSORBIBLE) HEMOSTATO ESTÉRIL PARA USO QUIRÚRGICO

PL – SURGISPON® (WCHŁANIALNA ŻELATYNOWA GĄBKA HEMOSTATYCZNA) STERYLNY HEMOSTAT DO UŻYTKU CHIRURGICZNEGO

SV – SURGISPON® (ABSORBERBAR HAEMOSTATISK GELATINSVAMP) STERIL HAEMOSTAT FÖR KIRURGISK ANVÄNDNING

EL – SURGISPON® (ΑΠΟΡΡΟΦΗΣΙΜΟ ΑΙΜΟΣΤΑΤΙΚΟ ΣΦΟΥΓΓΑΡΙ ΖΕΛΑΤΙΝΗΣ) ΑΠΟΣΤΕΙΡΩΜΕΝΟΣ ΑΙΜΟΣΤΑΤΗΣ ΓΙΑ ΧΕΙΡΟΥΡΓΙΚΗ ΧΡΗΣΗ

PT – SURGISPON® (ESPONJA DE GELATINA HEMOSTÁTICA ABSORVÍVEL) HEMOSTATO ESTÉRIL PARA USO CIRÚRGICO

NO – SURGISPON® (ABSORBERBAR HAEMOSTATISK GELATINSVAMP) STERIL HEMOSTAT FOR KIRURGISK BRUK

TR – SURGISPON® (EMİLEBİLİR HEMOSTATİK JELATİN SÜNGER) CERRAHİ KULLANIM İÇİN STERİL HEMOSTAT

BG – SURGISPON® (АБСОРБИРАЩА се ХЕМОСТАТИЧНА ЖЕЛАТИНОВА ГЪБА) СТЕРИЛЕН ХЕМОСТАТ ЗА ХИРУРГИЧЕСКА УПОТРЕБА

LT – SURGISPON® (ABSORBUOJAMOJI HEMOSTATINĖ ŽELATINOS KEMPINĖ) STERILUS HEMOSTATAS, NAUDOJIMAS CHIRURGIJOJE

Caution, consult accompanying documents

Consult instructions for use

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

Batch code

Use by date - Expiry Date

Catalogue Number

Contains biological materials of animal origin

Phthalate free

Latex free

Non-pyrogenic

Single Sterile Barrier System & Sterilized using gamma irradiation

Double Sterile Barrier System & Sterilized using gamma irradiation

Double Sterile Barrier System with protective packagin outside & Sterilized using gamma irradiation

Medical Device

Manufacturer

CE-Mark and Identification number of notified body. Product conforms to the essential requirements of the medical device directive 93/42/EEC

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EC REP 93/42/EEC.
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