

(ABSORBABLE GELATIN SPONGE)

**DESCRIPTION**

**SURGISPON** that is non-toxic, non-allergenic, non-immunogenic, non-pyrogenic and overall biocompatible. **SURGISPON** is a surgical haemostatic sponge, manufactured from highly purified first extract grade gelatin material for use in various surgical procedures, where traditional haemostatic is difficult or impractical and use of other non-absorbable materials is undesirable. **SURGISPON** absorbs approximately 40-50 times, its weight of water/blood and adheres easily to the bleeding site. The uniform porosity of **SURGISPON** guarantees a favorable haemostatic. When implanted in vivo, it is completely absorbed within 3-4 weeks. **SURGISPON** gelatin sponges have 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 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 like:

**Dental Surgery:** **SURGISPON** may be used in oral surgery, dry or saturated with thrombin solution to control bleeding in extractions and apicentomies especially in patients with a tendency to bleed extensively.

**Malignancy:** **SURGISPON** moistened with physiological salt solution or thrombin solution stops bleeding from tumor beds after section or from tumor beds after enucleation.

**Abdominal Surgery:** **SURGISPON** may be used dry, saturated with physiological salt solution or with thrombin solution. It is highly effective in stopping bleeding of the denuded visceral surfaces especially of the gall bladder, liver and spleen.

**Orthopedic Surgery:** **SURGISPON** moistened with physiological salt solution or thrombin solution, can be used to control bleeding from bone tissue. It does not interfere with healing process and is readily absorbed.

**Neuro Surgery:** **SURGISPON** moistened with thrombin solution is effective in repairing torn Dural venous sinuses to which ligatures can not or should not be applied, in stopping oozing from the dura under edges of the bone flap, in controlling bleeding in herniated disc operations, in osseous bleeding and epidural bleeding in laminectomy.

**Genito- Urinary Surgery:** **SURGISPON** embedded nephrotomy incisions control the bleeding without interfering with the healing process. Urinary wetting will not prevent absorption of the gelatin sponge. It will control hemorrhage following suprapubic prostatectomy and retrobubic prostatectomy.

**Anorectal Surgery:** **SURGISPON** is effective and well tolerated as a haemostatic dressing for the control of anal bleeding during plastic repair of an imperforate anus, and following hemorrhoidectomy and fistula operations.

**Gynecological Surgery:** **SURGISPON** of inestimable value in controlling bleeding during vaginal plastic operations, extensive pelvic dissections, cervical amputation and biopsy and secondary bleeding after abdominal hysterectomy. It is not to be used menorrhagia or to control post-partum bleeding.

**Otolaryngological Surgery:** **SURGISPON** saturated with physiological salt solution eliminates post operative bleeding in sub mucous resections. Strip of **SURGISPON** placed in the nose and held for a few seconds will prevent bleeding following removal of nasal polyps. The same procedure can be utilized to control bleeding following sinus operations, adenoidectomy and tonsillectomy. The gel packing will disappear in approx. five days.

**DIRECTIONS OF USE:**

Sterile technique should always be used to remove **SURGISPON** Sterile Sponge from its packaging. 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 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 hemostasis 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 hemostasis 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**, cut to appropriate size, necessary to produce hemostasis. The **SURGISPON** may be left in place at the bleeding site, when necessary. 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.

**HANDLING AND STORAGE**

**SURGISPON** Sterile sponge is packed in double sterile envelopes and blisters with guaranteed absolute sterility. Once the package is opened, contents are subject to contamination. It is recommended that **SURGISPON** be used as soon as the package is opened and unused contents discarded. It should not be reused or resterilized as it may lose its physical characteristics as well as sterility.

**Storage: it can be kept under normal dry storage condition. No specific temperature condition is required for storage**

**PRECAUTION:** **SURGISPON** should not be used for controlling postpartum bleeding or menorrhagia.

Where possible **SURGISPON** should be removed after usages 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 neighbouring structures which may result in pain for the patient or might create the potential for nerve damage.

The over packing of **SURGISPON**, particularly within bony cavities, 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.

**PACKING:** Available in various shapes and sizes suitable for different kind of surgeries. Please refer the complete product list in brochure for your application.

**Manufactured in India and Marketed by:**

AEGIS LIFESCIENCES

AN ISO 13485 & GMP CERTIFIED

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