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(EN) Product Description

SPONGOSTAN™ Absorbable Haemostatic Gelatin Sponge is a sterile, water-insoluble, malleable, porcine gelatin absorbable sponge intended for haemostatic use by applying to a bleeding surface. The sponge is off-white and porous in appearance.

Actions

When used in appropriate amounts SPONGOSTAN™ Sponge is absorbed completely within 4 to 6 weeks. In an animal implantation study, tissue reactions were classified as negligible when observed macroscopically, and moderate when observed microscopically with SPONGOSTAN™ Sponge. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days.

Intended Use/Indications

SPONGOSTAN™ Sponge, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. Although not necessary, SPONGOSTAN™ Sponge can be used with thrombin to achieve haemostasis.[1]

Contraindications

Do not use SPONGOSTAN™ Sponge in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
Do not use SPONGOSTAN™ Sponge in intravascular compartments because of the risk of embolization.
Do not use SPONGOSTAN™ Sponge in patients with known allergies to porcine collagen.

Warnings

- SPONGOSTAN™ Sponge is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for haemostasis.
- SPONGOSTAN™ Sponge should not be used in the presence of infection. SPONGOSTAN™ Sponge should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where SPONGOSTAN™ Sponge has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage.
- SPONGOSTAN™ Sponge should not be used in instances of pumping arterial haemorrhage. It should not be used where blood or other fluids have pooled or in cases where the point of haemorrhage is submerged. SPONGOSTAN™ Sponge will not act as a tampon or plug in a bleeding site, nor will it close off an area of blood collecting behind a tampon.
- SPONGOSTAN™ Sponge should be removed if possible once haemostasis has been achieved because of the possibility of dislodgement of the device or compression of other nearby anatomic structures.

- SPONGOSTAN™ Sponge should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.
- The safety and effectiveness of SPONGOSTAN™ Sponge for use in ophthalmic procedures have not been established.
- SPONGOSTAN™ Sponge should not be used for controlling post-partum bleeding or menorrhagia.
- The safety and effectiveness of SPONGOSTAN™ Sponge have not been established in children and pregnant women.

PRECAUTIONS

Caution: SPONGOSTAN™ Sponge is supplied as a sterile product and cannot be resterilized. Unused open envelopes of SPONGOSTAN™ Sponge should be discarded.

Caution: When placed into cavities or closed tissue spaces, minimal preliminary compression is advised and care should be exercised to avoid overpacking (the sponge expands upon absorption of liquid). SPONGOSTAN™ Sponge may swell to its original size on absorbing fluids creating the potential for nerve damage.

Caution: While packing a cavity for haemostasis is sometimes surgically indicated, SPONGOSTAN™ Sponge should not be used in this manner unless excess product not needed to maintain haemostasis is removed.

Caution: Only the minimum amount of SPONGOSTAN™ Sponge needed to achieve haemostasis should be used. Once haemostasis is achieved any excess SPONGOSTAN™ Sponge should be carefully removed.

Caution: SPONGOSTAN™ Sponge should not be used in conjunction with autologous blood salvage circuits. It has been demonstrated that fragments of collagen-based haemostatic agents may pass through 40µ transfusion filters of blood scavenging systems.

Caution: Incomplete absorption and hearing loss have been reported in association with the use of SPONGOSTAN™ during tympanoplasty.

Caution: SPONGOSTAN™ Sponge should not be used in conjunction with methyl methacrylate adhesives. Microfibrillar collagen has been reported to reduce the strength of methyl methacrylate adhesives used to attach prosthetic devices to bone surfaces.

Caution: SPONGOSTAN™ Sponge should not be used for the primary treatment of coagulation disorders.

Caution: Although the safety and effectiveness of the combined use of SPONGOSTAN™ Sponge with other agents such as topical thrombin, antibiotic solution or antibiotic powder have not been evaluated in controlled clinical trials, if in the physician's judgement, concurrent use of topical thrombin or other agents is medically advisable, the product literature for that agent should be consulted for complete prescribing information.[1]

Caution: The safety and effectiveness for use in urological procedures have not been established through a randomized clinical study.

Caution: In urological procedures, SPONGOSTAN™ Sponge should not be left in the renal pelvis, renal calyces, bladder, urethra or ureters to eliminate the potential foci for calculus formation.

How Supplied

SPONGOSTAN™ Standard, Film and Special are individually packed and sterilised by dry heat for direct use in the operating theatre.
SPONGOSTAN™ Anal and SPONGOSTAN™ Dental are individually packed and sterilised by E-beam irradiation for direct use in the operating theatre.
SPONGOSTAN™ is a single-use product which should not be resterilised.

Storage and Handling

SPONGOSTAN™ Sponge should be stored dry at controlled room temperature 15°-30° C.
It is recommended that SPONGOSTAN™ Sponge be used as soon as the package is opened.

Directions for Use

Before using, inspect the package for signs of damage. If the package is damaged or wet, sterility cannot be assured and the contents should not be used.
Sterile technique should always be used to remove the SPONGOSTAN™ Sponge from its packaging.

Cut the sponge to the desired size. Use only the minimum amount necessary to achieve haemostasis. This piece of SPONGOSTAN™ Sponge can be applied to the bleeding site either dry or saturated with sterile isotonic sodium chloride solution (sterile saline) or sterile topical thrombin solution.[1]

Open packages of SPONGOSTAN™ Sponge should be discarded, since they are not intended for reuse and/or resterilization.

<u>Dry use of SPONGOSTAN™:</u>
Cut the SPONGOSTAN™ Sponge to desired size and shape.

Manually compress the SPONGOSTAN™ Sponge prior to applying to the bleeding site but avoid tightly packing into site.
Hold the SPONGOSTAN™ Sponge in place with moderate pressure until haemostasis is achieved.
Removal of excess SPONGOSTAN™ Sponge upon achieving haemostasis can be accomplished by gentle irrigation of the site with sterile saline solution to completely wet the sponge.
Use only the amount required to achieve haemostasis and remove any excess.

<u>Use of SPONGOSTAN™ with Sterile Saline or Thrombin Preparation:</u>[1]
Cut the SPONGOSTAN™ Sponge to desired size and shape.

Immerse the SPONGOSTAN™ Sponge cut to size in the solution.
Withdraw sponge and squeeze between gloved fingers to expel air bubbles.
Return sponge to the solution until needed.
The SPONGOSTAN™ Sponge should promptly return to its original size and shape in solution. If it does not, remove the sponge from the solution and vigorously knead it between gloved fingers until all air is expelled and it can return to its original size and shape when placed in the solution.
Blot sponge to desired dampness on gauze before applying to the bleeding site.
Hold the SPONGOSTAN™ Sponge in place with gauze using moderate pressure until haemostasis is achieved.
Removal of gauze is aided by wetting with a few drops of saline, which helps to prevent removal of the SPONGOSTAN™ Sponge and clot.
Removal of excess SPONGOSTAN™ upon achieving haemostasis can be accomplished by gentle irrigation to the site with sterile saline solution to completely wet the sponge.
Use only the amount required to achieve haemostasis and remove any excess.

<u>SPONGOSTAN™ Anal</u>
Following completion of the hemorrhoidectomy, insert directly or use an anal retractor or anoscope to visualize the surgical site and aid in the placement of a dry SPONGOSTAN™ Anal tampon. Rapid decomposition and spontaneous discharge of the sponge can be expected.

<u>SPONGOSTAN™ Dental</u>
To be used in oral surgery either dry or saturated in physiological sodium chloride solution and slightly compressed to secure haemostatic effect in cavities after tooth extractions, etc. May also be used in areas where the small size of the sponge is an advantage, e.g., Epistaxis.

[1]Note: The use of thrombin is not covered by the EC certification and the H.S.A. approval of SPONGOSTAN™ Absorbable Haemostatic Gelatin Sponge.

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