GELITA-SPON® STANDARD

EN

Absorbable Gelatin Sponge Hemostat (USP)
Patient Information Leaflet

1. Product Description

The GELITA-SPON® STANDARD Absorbable Gelatin Sponge Hemostat (USP) is made of 100% purified gelatin. It is intended for use as topical hemostat. It is insoluble in water and fully bio-degradable. Its porous structure and interstices enables the product to absorb more than 40 times its own weight of blood and fluids. The absorptive capacity of GELITA-SPON® STANDARD is a function of its physical size, increasing as the amount of material increases. In addition, because of its neutral character and nature, it may be used as a carrier for any drug (the product literature for the applicable drug should be consulted for complete prescribing information). It is supplied in several sizes. It is packaged individually in (double) blister or container packaging, sterilized by means of Gamma Irradiation, and is for single use only.

2. Indications

Topical hemostat for use as an adjunct to hemostasis by tamponade effect, in particular where control of capillary, venous, and arteriolar bleeding, by pressure, ligature, and other conventional procedures, is either ineffective or impractical.

2.1 In Dental surgery, the GELITA-SPON® STANDARD Cube is an aid in providing hemostasis and fi lling dead space created by extraction of the teeth, root amputations and removal of cysts, tumours and impacted teeth.

2.2 For ENT surgery a “High Density” sponge is available. It has proven to be effective in supporting and keeping the fascia or perichondrium in the middle ear (dry application) in place or in the outer ear canal after tympanoplasty.

2.3 For rectal surgery, hemorrhoid operations and gynaecology the GELITA-SPON® STANDARD ”Tampon” form is available.

3. Contraindications

- Hypersensitivity to porcine products
- GELITA-SPON® STANDARD should not be used in closure of skin incisions as it may interfere with healing of the skin edges. This is due to mechanical interposition of gelatin and not to intrinsic interference with wound healing.
- The product should not be used without antibiotics in infected wounds.

4. Side effects

There have been no reported adverse reactions for product used correctly according to these Instructions for Use and when the product is not over-packed.

Formation of tissue granulation during middle ear procedures has been reported in at least one animal study.

5. Directions for use

Sterile technique should be applied when using GELITA-SPON® STANDARD. The gelatin sponge can be used dry or saturated with a sterile physiological saline solution.
If used dry, the sponge is cut into the desired size and is slightly compressed. The sponge must be applied to a bleeding area under light pressure for one or two minutes until the bleeding stops.
When used with saline, GELITA-SPON® STANDARD should be soaked in the solution, withdrawn, squeezed thoroughly to expel air bubbles present in the interstices, replaced in saline, and kept there until needed.
When bleeding is controlled, the material can be left in situ, however excess should be removed!
Depending on the method of use, amount of material left *in situ,* and the operation site, GELITA-SPON® STANDARD is totally bio-degraded in less than 4 weeks.

5.1 ENT sponge: The gelatin sponge is cut as needed, to fi t the otic, nasal or oral cavity or defect and inserted to support and separate tissues and to control bleeding by tamponade effect. The excess should be removed!

Residual risks

GELITA-SPON® STANDARD may expand with the absorption of fluid (e.g. sponges re-expands to its original shape). In radical cavities; laminectomy procedures; around or in proximity to foramina in bone; areas of bony confine; the spinal cord; the optic nerve and chiasm; or closed tissue spaces with presence of bone GELITA-SPON® STANDARD should be removed when bleeding has stopped, if possible. Failure to do so might result in unintended pressure on neighboring structures which may cause pain for the patient or could create the potential for nerve damage.

Possible harm to patient, allergic reaction to porcine

If used off-label, to block large arteries or when care is not taken while using near large arteries, blockage of the circuit/Embolism may occur by entry into circulation system.

General warnings

- GELITA-SPON® STANDARD is not intended as a substitute for careful surgery and the proper use of sutures and ligatures or other conventional procedures for hemostasis
- Avoid using GELITA-SPON® STANDARD in infected areas. Embedding the product in a contaminated wound without drainage may lead to complications and should be avoided.
- GELITA-SPON® STANDARD is not recommended for the primary treatment of coagulation disorders. For application in patients with coagulation disorders no scientific data is available.

- The use of the product in patients on anticoagulant therapy may cause an extended time to hemostasis.
- Care should be taken to avoid the introduction of fragments of the material directly into the circulatory system.
- GELITA-SPON® STANDARD should not be used for embolization and care should be taken not to treat bleeding from large arteries, as hemostatic devices used near moderate to large blood vessels may result in embolization of the blood vessel. Such embolization has been associated with severe adverse effects, including fever, duodenal and pancreatic infarct, and embolization of lower extremity vessels, pulmonary embolization, splenic abscess, necrosis, asterixis and even death.
- Precautions should be taken in otorhinolaryngology surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis)
- Due to the neutral properties of the product, it may be combined with drugs (please pay attention to the information of the package insert of the respective medication). The safety and efficacy of GELITA-SPON® STANDARD in combination with those agents such as topical thrombin has not been evaluated in clinical trials. If in the physician's judgement concurrent use of topical thrombin or other agents are medically advisable, the respective instructions for use should be consulted.

Serious incidents should be reported to the manufacturer and competent authority (Therapeutic Goods Administration; https://www.tga.gov.au/reporting-problems).

Manufacturer
GELITA MEDICAL GmbH
Uferstrasse 7
69412 Eberbach,
Germany
Email: quality@gelitamedical.com
Phone: +49 (0) 6271 84-01
Fax: +49 (0) 6271 84-2700
www.gelitamedical.com

GELITA® MEDICAL
Complete Care! Completely Safe!
CE 0344

Store at room temperature

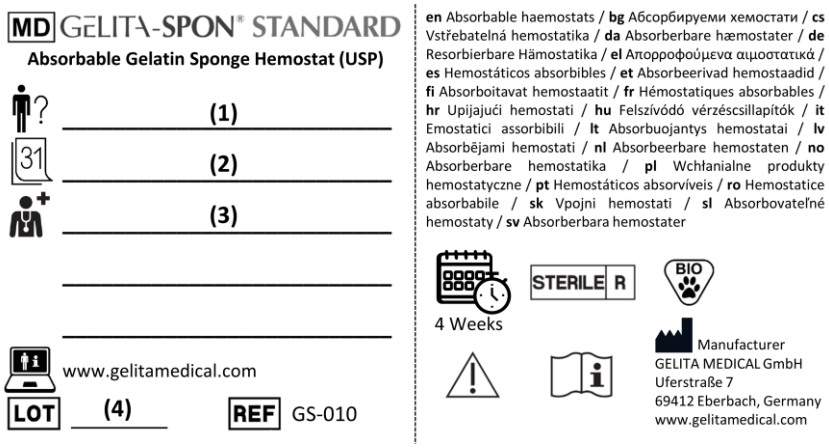
Explanation of symbols:

- Manufacturer
- Date of manufacture
- Expiry Date
- LOT Batch code
- REF Order number
- Do not use if the packaging is damaged
- Warning
- BIO Animal Origin
- Store dry
- Single use
- Consult instructions for use
- STERILE R Radiation sterilization
- Do not re-sterilize
- Keep away from sunlight
- MD Medical Device

Revision Date: November 2021

Patient Information Leaflet – Implant Card

Name of the Patient or Patient ID (1), date of implantation (2), name of the healthcare institution / provider (3), and the LOT number of the product (4) must be filled by the healthcare institution / provider. The implant card must then be clipped to the patient record.



Explanation of Symbols

Patient identification

Health care center or doctor

Expected reabsorption time

Date of Implantation

Information website for website

Device Name

Revision Date: November 2021