

roeko Gelatamp white

Instructions for use

EN

PRODUCT DESCRIPTION

Gelatamp white is a sterile gelatine sponge from animal origin, insoluble in water, easy to handle and re-absorbable. Its purpose is to facilitate the stopping of bleeding. The sponge is whitish with uniform porosity.

ACTION MECHANISM

Once saturated with blood, the product promotes coagulation by serving as a coadjutant for controlling local haemorrhage. If utilised correctly and in suitable amounts, Gelatamp white is reabsorbed within 3-4 weeks. The amount of product to be used and its re-absorption depend on the extension of the bleeding surface and the type of tissue on which it is applied.

INDICATIONS

Gelatamp white can be used dry or soaked with sterile saline solution, for surgical interventions, except for ophthalmic ones, through simple application or by exerting slight pressure like a haemostatic device for controlling the bleeding of venous or arteriolar capillaries, and in cases where other conventional haemostatic procedures (sutures, compression, ligatures etc.) cannot be carried out. Gelatamp white can be cut to the desired size without crumbling, using sterile scissors, and it has low adhesiveness with respect to forceps and surgery instruments.

CONTRA-INDICATIONS

- Do not use Gelatamp white for closing skin cuts as it could interfere with healing and cicatrization.
- Do not use Gelatamp white in intravascular cavities due to the risk of embolization.
- Do not use Gelatamp white for embolization procedures.
- Do not use Gelatamp white in patients with ascertained allergy towards the product.
- Do not use Gelatamp white on infected wounds.

BEWARE

- The use of Gelatamp white does not authorise abandonment of normal haemostatic intervention.
- After achieving haemostasis, if possible remove the product from the site of application to avoid the risk of displacing the product and possible compression of the adjacent structures.
- Remove Gelatamp white from the site of application when used on bone holes, in the spinal cord and/or in the nerve or optical chiasm or in the areas surrounding or adjacent thereto.
- Remove Gelatamp white from the site of application if used in neurosurgery or in the areas surrounding or adjacent to the nerves given that by increasing the volume the product may cause compression leading to damage of nervous tissue.
- Do not use Gelatamp white in cases of strong arterial haemorrhage, in cases of blood stagnation or stagnation of other organic liquids where the source of haemorrhage is entirely occluded.
- Do not use Gelatamp white in post-partum interventions and for controlling menorrhagia.
- The safety and efficiency of Gelatamp white in ophthalmic interventions is not verified.
- The safety and efficiency of Gelatamp white on children and expectant women is not verified.

PRECAUTION MEASURES

- Beware: Gelatamp white is supplied sterile and disposable. Unutilised fractions of the product should be discarded. Any opened and unutilised packaging should be discarded.
- Warning: When in use on closed or narrow tissue spaces preliminary compression of the product is not advisable to prevent its increase volume-wise, due to contact with organic fluids, causing damage.
- Warning: When indicated to fill a cavity to obtain haemostasis, Gelatamp white shall not be used this way unless all surplus product is removed after achieving haemostasis.
- Warning: Use Gelatamp white in minimal amounts to reach haemostasis and always remove any surplus product from the site of application.
- Warning: Do not use Gelatamp white together with autologous blood recovery systems, given that it has been proven that particles of haemostatic agents could pass through the transfusion filters of the purification systems.
- Warning: Do not use Gelatamp white together with methyl methacrylate cement. It has been proven that the porous structure weakens the cement used for fixing the prosthesis to the bone surface.
- Warning: There have been cases of incomplete re-absorption and loss of hearing due to the use of haemostatic sponges in ear-drum-plastic operations.
- Warning: Do not use Gelatamp white in cases of coagulation disorders.
- Warning: The association of Gelatamp white with pharmacologically active substances or other substances shall be evaluated by the surgeon and the responsibility thereof.
- Warning: The safety and efficiency of Gelatamp white in urology surgical procedures is not verified. Gelatamp white should not be left in renal pelvis, in renal calyces, in the urethra or in the ureter so as to avoid the possible formation of calculi.
- Warning: Gelatamp white is not recommended for treating cases of epistaxis given that the product could be inhaled thus causing respiratory problems.
- Warning: Gelatamp white can cause fever.

- Warning: literature reveals cases of similar products hence, after carrying out radiography tests, product residues, not fully absorbed, have been confused to tumour diseases.

HOW TO USE

- Carefully read the present use instructions for use before using the product.
- Ensure that the packaging is whole before using. Sterility is guaranteed only if the packaging is not damaged or wet.
- Always be cautious when it comes to asepsis whenever handling the product.
- Always use the minimal amount of product to achieve haemostasis.
- Gelatamp white can be used dry as it is or soaked with saline solution.
- Apply the product on the area subject to haemorrhage by applying slight pressure until haemostasis is achieved.
- If the product cannot be removed upon achieving haemostasis, carefully eliminate the surplus used product.
- Use the product by the expiry date indicated on the primary packaging, secondary packaging and on the box.
- The product is supplied as per the formats indicated in the present instructions leaflet.

PRESERVATION

Gelatamp white shall be stored at room temperature and in a dry place. Gelatamp white shall be stored away from direct sunlight.

Should you observe effects not described in the present illustration leaflet, please report promptly by writing to the following email address: complaint@masciabrunelli.it

	Read the instructions leaflet
	Preserve away from direct sunlight
	Single use only
	CE Marking and the identification number of the notifying body
	Manufacturer data
	Batch Code
	Medical Device
	Date of manufacture
	Use by year/month
	Maximum storage temperature
	Sterile. Sterilised with ionising radiation
	Reference Number
	Preserve in a dry place
	Do not re-sterilise
	Do not use if packaging is damaged
	Contains biological material of animal origin
	Warning read the use instructions

Gelatamp white, 10x10x10 mm, 60052842

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