

MEDISPONGE®

Sterile Haemostatic Absorbable Gelatin Sponge (Porcine Origin)



INTRODUCTION:

Gelatin is a substantially pure protein food ingredient, obtained by the thermal denaturation of collagen, which are the structural mainstay and most common protein in the animal kingdom.

Gelatin sponges have been used in clinical practice as hemostats for more than 50 years and been proven to be effective and safe as other types of haemostats.

Due to the threat of BSE/TSE issues on Bovine origin materials, Porcine Gelatin Materials have been developed and now they are widely being used in Pharmaceutical Industry.

MEDISPONGE®

PRODUCT DESCRIPTION:

MEDISPONGE[®] is a surgical haemostatic sponge, manufactured from highly purified neutral gelatin material exclusively from porcine origin for use in various surgical procedures, where traditional hearnostasis is difficult or impractical and use of other non-absorbable materials are undesirable. Available in different convenient dimensions in Gamma sterilized form with suitable double sterile blister packaging or pouches for special sizes.

MEDISPONGE® absorbs approximately not less than 35 times, it's weight of water and adheres easily to the bleeding site. The uniform porosity.

MEDISPONGE® guarantees a favourable haemostasis. When implanted in vivo, it is completely absorbed within 3-4 weeks.

MEDISPONGE® is non-toxic, non-allergenic, non-immunogenic, non-pyrogenic and meets the Biocompatibility requirements as per EN ISO 10993 standards.

INDICATIONS:

- | Plastic Surgery
- | General Surgery
- I ENT and Dental Surgery
- Orthopedics and Trauma
- | Abdominal Surgery
- **I** Neurosurgery
- | Dermatology
- I Anorectal surgery
- | Gynaecology

APPLICATION & USER GUIDE:

MEDISPONGE® is white, pliable, light, and insoluble in water. It is removed from the package under strict aseptic conditions and can be cut to desired size, applied dry or saturated with physiological salt solution or thrombin or an antibiotic solution

of the desired concentration. Squeeze the material between two fingers to remove the air bubbles so that the sponge, while immersed in the solution will regain its original size and shape almost immediately. At the time of use, the superfluous solution may be allowed to drip upon a gauze compress. The saturated sponge is then applied to the haemorrhage area and is then held in place with moderate pressure for 10-15 seconds. Usually the first application of will control bleeding, but if not, additional applications should be made using fresh pieces of sponge. When bleeding is controlled, the pieces of **MEDISPONGE®** should be left in place, otherwise bleeding may start again. Since **MEDISPONGE®** causes little more cellular infiltration than the blood clot, the wound may be closed over it.

CONTRAINDICATIONS:

MEDISPONGE® should not be used in closure of skin incisions because it may interfere with the healing of skin edges.

PRECAUTIONS & WARNINGS:

- I **MEDISPONGE**[®] is a sterile product and should not be resterilised, as it would change the characteristics of the product.
- I Discard the unused portions of the sponge.
- I Use of **MEDISPONGE**® is not recommended for infected sites.
- I By absorbing the fluid, the sponge may expand and thus impinge on neighboring structures. Hence, minimal pre-compression is advised when packing into cavities.
- In neuro surgery, it should not be left in closed cavities, since it may cause compression of the nervous tissues when it expands.
- I While using **MEDISPONGE**® other normal haemostatic procedures including suture, pressure and ligature should be neglected.

STORAGE:

MEDISPONGE[®] stored in a dry Place between 15 degree Celsius to 30 degree Celsius.

ORDERING INFORMATION:

CODE	DESCRIPTION	UNITS
MSES 1001	MEDISPONGE® 80x50x10mm	Box of 10
MSES 1002	MEDISPONGE® 70x50x10mm	Box of 10
MSES 1003	MEDISPONGE® 80x50x1mm	Box of 10
MSES 1004	MEDISPONGE® 70x50x1mm	Box of 10
MSES 1005	MEDISPONGE® 80xdia30mm	Box of 5
MSES 1006	MEDISPONGE® 10x10x10mm	Box of 100
MSES 1009	MEDISPONGE® 200x70x0.5mm	Box of 10
MSES 1010	MEDISPONGE® 30x30x10mm	Box of 10
MSES 1012	MEDISPONGE® 14x14x7mm	Box of 10
MSES 1014	MEDISPONGE® 125x80x10mm	Box of 5

IMPORTER / DISTRIBUTOR:

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Promedica Toruń, Poland

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