MERIFEIM - IFU

Date : 02.11.2021

MERIFEIM™
Absorbable Gelatin Sponge USP

Meril Endo-Surgery

INSTRUCTIONS FOR USE:
This package insert is not a reference to surgical techniques. It is designed to assist in using this product.

PRODUCT DESCRIPTION: MERIFEIM™ (Absorbable Gelatin Sponge USP)
MERIFEIM™ - Absorbable Gelatin Sponge USP is a sterile malleable, water-insoluble, gelatin absorbable sponge intended for Hemostatic use by applying to a bleeding surface. MERIFEIM™ is non-pyrogenic and biocompatible.
MERIFEIM™ is a surgical Hemostatic sponge, manufactured from highly purified first grade gelatin material for use in various surgical procedures. When implanted in vivo and used in appropriate amounts, it is completely absorbed within 3-4 weeks. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days. MERIFEIM™ 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:
MERIFEIM™ can be effectively used in various surgeries for hemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical.

CONTRAINDICATIONS:
MERIFEIM™ should not be used:
- In closure of skin incisions because it may interfere with the healing of skin edges
- In patients with known allergies to collagen
- In intravascular compartments because of the risk of embolization
- In conjunction with methyl methacrylate adhesives
- In conjunction with autologous blood salvage circuits
- For the primary treatment of coagulation disorders
- In the presence of infection
- For controlling post-partum bleeding or menorrhagia
- In instances of pumping arterial haemorrhage
- Were blood or other fluids have pooled or in cases where the point of hemorrhage is submerged. MERIFEIM™ 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. The safety and effectiveness of MERIFEIM™ have not been established:
- For use in ophthalmic procedures
- In children and pregnant women

The safety and effectiveness for use in urological procedures have not been established through a randomized clinical study. In urological procedures, gelatin sponge should not be left in the renal pelvis, renal calyces, bladder, urethra or ureters to eliminate the potential foci for calculus formation.
MERIFEIM™ as a hemostatic agent should not be used in neurosurgery close to viable cerebral tissue, as it can induce a marked giant cell granulomatous reaction. Although the safety and effectiveness of the combined use of gelatin 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.

HANDLING INSTRUCTIONS / WARNINGS / PRECAUTIONS:
MERIFEIM™ may be used dry or saturated with physiological salt solution. Cut to the desired size, a piece of MERIFEIM™ either dry or saturated with sterile, isotonic sodium chloride solution (sterile saline), can be applied with light pressure directly to the bleeding site. When applied dry, a single piece of MERIFEIM™ should be manually applied to the bleeding site, and held in place with moderate pressure until hemostasis results.
When used with sterile saline, MERIFEIM™ 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 MERIFEIM™ 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.
MERIFEIM™ 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 MERIFEIM™ which by then should enclose a firm clot.
Use of suction applied over the pledget of cotton or gauze to draw blood into the MERIFEIM™ is unnecessary, as MERIFEIM™ will draw up sufficient blood by capillary action. The first application of MERIFEIM™ 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 MERIFEIM™ necessary to produce hemostasis.
Once hemostasis is achieved any excess Gelatin Sponge should be carefully removed because of the possibility of dislodgement of the device or compression of other nearby anatomic structures.
When placed into cavities or closed tissue spaces, minimal preliminary compression is advised. The over packing of MERIFEIM™ 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 and nerve damage. While packing a cavity for hemostasis is sometimes surgically indicated, Gelatin Sponge should not be used in this manner unless excess product not needed to maintain hemostasis is removed.

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PANTONE SHADE
BLACK

MERIFEIM™ should be removed after usage 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 neighboring structures which may result in pain for the patient or might create the potential for nerve damage.
Since MERIFEIM™ causes little more cellular reaction than does the blood clot, the wound may be closed over it. MERIFEIM™ may be left in place when applied to mucosal surfaces until it liquefies.

MERIFEIM™ is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.
MERIFEIM™ should not be used for the primary treatment of coagulation disorders.
MERIFEIM™ should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where MERIFEIM™ Sponge has been positioned, reoperation may be necessary in order to remove the infected material and allow drainage. Users should be familiar with surgical procedures and techniques involving gelatin sponge before employing MERIFEIM™
Particular factors of each patient should be considered regarding healing process in vivo.
Contaminated or infected wounds should be managed with acceptable surgical practice.

MERIFEIM™ sterile sponge is packed in sterile blisters which guarantee sterility. Once the package is opened, contents are subject to contamination. It is recommended that MERIFEIM™ should be used as soon as the package is opened and unused contents discarded. It should not be reused or resterilised as it may lose its physical characteristics as well as sterility. Open the blister pack by pulling its two loose ends away from each other – in such a way that the MERIFEIM™ falls out undamaged, onto a sterile surface.
The product is intended for single use!
Discard any unused MERIFEIM™ remaining. Dispose of contaminated devices and packaging materials utilizing standard hospital procedures and universal precautions for bio hazardous waste.

STERILISATION:
MERIFEIM™ is sterilised by gamma radiation. Do not resterilise! Do not use if the package is opened or damaged. This device was designed, tested and manufactured for single patient use only. Reuse, or use of the device with opened or damaged packaging, reprocessing and/or resterilisation of this device may lead to its failure and subsequent injury, illness or death of the patient and/or create the risk of contamination and patient infection, illness or death of the patient.

STORAGE:
The product should be protected from direct sunlight and heat, and stored in its original packaging in a clean, dry room at a temperature from 5°C to 30°C.
Do not use after the expiry date!

PACKING:
Available in various shapes and sizes suitable for different kinds of surgeries.

SYMBOLS USED ON THE LABEL:

	Consult use instructions
	Temperature limit
	Keep dry
	Keep away from sunlight
	Do not re-use/ for single use only
	Do not resterilize
	Do not use if package is damaged
	Date of manufacture
	Use by date - Expiry Date: Month & Year
LOT	Batch code
REF	Catalogue Number
STERILE R	Sterilised using irradiation

Manufactured by:
Meril Endo Surgery Pvt. Ltd.
At - 215 - 216, Mahagujarat Industrial Estate, Sarkhej - Bavla Road, Po: Changodar, Gam: Moraiya, Tal: Sanand, Dist: Ahmedabad - 382213, Gujarat, India.
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