NEXFOAM®

TOPICAL HEMOSTAT SPONGE

Instructions for Use

Intended Use:
NexFoam® Topical Hemostat Sponge is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Contraindications:
NexFoam® Topical Hemostat Sponge should not be used on patients who have known allergies to potato starch. Contains Amylopectin (potato starch) and hydroxyethylcellulose.

Warnings:
- NexFoam® Topical Hemostat Sponge is not intended as a substitute for appropriate standard of care procedures and meticulous surgical techniques.
- The safety and efficacy of NexFoam® Topical Hemostat Sponge in combination with other hemostatic devices has not been clinically evaluated and is therefore not recommended.

Precautions:
- Carefully read the Instructions for use prior to application.
- Single Use Only.
- Sterility not guaranteed if package is damaged or opened. Discard damaged or open packages.
- Expiration Date: This device should not be used after the end of the year and month shown.
- To prevent product contamination prior to application, always follow aseptic techniques.
- Keep dry prior to use.
- Do not ingest, do not inhale. To avoid risk of aspiration, do not place in the posterior nasal cavity.
- Clinician must inform patient that the device contains potato starch.
- NexFoam® is not bacteriostatic toward pre-existing infections, nor does it prevent the occurrence of new infections. Appropriate treatment to be instituted in case of infection.
- The product shall be disposed of in compliance with pertinent government regulations regarding medical devices.

Instructions:
1. Peel open NexFoam® pouch and remove sponge.
2. Blot excess blood from the wound with gauze.
3. Apply NexFoam® sponge to cover wound.
4. Apply gauze over sponge and hold in place until hemostasis is achieved.
5. If hemostasis has not been achieved, repeat steps 2-4 or use an alternate method of hemostasis treatment.
6. NexFoam® leaves the site of placement by natural elimination or it may be aspirated from the application site at the direction of the physician.
7. Discard any unused product after opening.

How Supplied:
NexFoam® is packaged five (5) single use, sterile units per carton.
One (1) sterile unit contains one (1) hemostat sponge. Each sponge size is approximately 1.5 cm x 4.83cm (0.6” x 1.9”).
NexFoam® is terminally sterilized by gamma irradiation.

Storage and Handling:
NexFoam® Topical Hemostat Sponge should be stored at room temperature. Once product package is opened, contents may be subject to contamination. Discard any unused product after opening.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Store at room temperature.

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Made in USA. Patent Pending.

Symbol	Description
℞ ONLY	CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician
#	Quantity Symbol: numeral in symbol (in place of #) indicates the quantity of units in package.
	Caution: See Instructions for Use
STERILE R	Sterilized by Irradiation
	Single Use Only. Do not reuse.
	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Keep Dry
	Manufacturer
REF	Catalog Number
LOT	Lot Number
	Expiration Date (Use By). This device should not be used after the end of the year and month shown.

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