BleedArrest® ER

TOPICAL HEMOSTAT SPONGE

Instructions for Use

Intended Use:
BleedArrest® ER Topical Hemostat Sponge is intended for use under the care of a health care professional as a topical dressing for the treatment of mild bleeding from nosebleeds.

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

Warnings:
- BleedArrest® ER Topical Hemostat Sponge is not intended as a substitute for appropriate standard of care procedures and meticulous surgical techniques.
- The safety and efficacy of BleedArrest® ER 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 or inhale. BleedArrest® ER is designed to treat anterior epistaxis only and should not be placed in the posterior nasal cavity.
- Clinician must inform the patient that the device contains potato starch.
- BleedArrest® ER 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.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.

Instructions:
1. Locate wound. Peel open BleedArrest® ER pouch and remove sponge.
2. Blot excess blood from the nostril with gauze. Place BleedArrest® ER sponge into nostril.
3. Apply pressure to the nostril until hemostasis is achieved. Repeat if bleeding hasn't stopped or use an alternate method. After hemostasis has been achieved, remove sponge with irrigation and/or aspiration.

How Supplied:
BleedArrest® ER is packaged as either five (5) single use, sterile units per carton or as one (1) single use, sterile unit per carton.
One (1) sterile unit contains one (1) hemostat sponge. Each sponge size is approximately 0.5" x 1.5" (1.3cm x 3.8cm)
BleedArrest® ER is terminally sterilized by gamma irradiation.

Storage and Handling:
BleedArrest® ER 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.

Hemostasis, LLC
5000 Township Parkway
St. Paul, MN 55110 USA
www.hemostasisllc.com
Manufactured with patented hemostatic polymer active ingredient, U.S. Patent 8,623,842.
Made in USA.

Symbol	Description
Rx 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
2	Single Use Only. Do not reuse.
2 STERILIZE	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Keep Dry
EC REP	Authorized Representative in the European Community
	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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