PosiSep® X BAM
BIONOCC Antimicrobial
Non-Shellfish Chitosan

HEMOSTAT DRESSING/ INTRANASAL SPLINT

Instructions For Use

Intended Use:

PosiSep® X BAM Hemostat Dressing/Intranasal Splint is indicated for use in patients undergoing nasal/sinus surgery as a space occupying splint and hemostat to:

- Separate tissue or structures compromised by surgical trauma;
- Separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity;
- Help control minimal bleeding following surgery or trauma;
- Help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and
- Act as an adjunct to aid in the natural healing process.

PosiSep® X BAM is indicated for use as a nasal hemostat to treat epistaxis.
PosiSep® X BAM is intended for use under the direction of a licensed healthcare provider.

Description:

Hemostasis, LLC offers multiple different platforms of hemostat dressings/intranasal splints. PosiSep® X BAM is a patient-comfortable sponge manufactured from BIONOCC, a modified non-shellfish chitosan. PosiSep® X BAM does not contain any animal tissue. PosiSep® X BAM contains methylene blue and gentian violet as antifungal and dual acting antimicrobial agents. PosiSep® X BAM expands when hydrated providing separation between the sinus tissues.

Antimicrobial Efficacy:

Microbial efficacy testing has shown a complete absence of viable cells after the sponge was inoculated with various gram positive bacteria, gram negative bacteria, and fungi (greater than 4-log or 99.99% reduction of all organisms tested) for up to 7 days. Therefore, the PosiSep® X BAM offers protection against a broad spectrum of microorganisms that are commonly associated with morbidities of the nose. Microorganisms tested include: *Staphylococcus aureus; MRSA, Streptococcus pneumoniae, Pseudomonas aeruginosa, Klebsiella pneumoniae, Moraxella catarrhalis, Candida albicans, and Aspergillus brasiliensis*. Note: A correlation between in-vitro testing and clinical effectiveness has not been established.

Warnings and Precautions:

- PosiSep® X BAM is not designed to treat pre-existing infections. Appropriate treatment to be instituted in case of infection.
- When utilized as an intranasal splint, if the PosiSep® X BAM becomes completely coated with blood prior to hydration then the function of the device as a hemostat may subsequently diminish the expansion of the device via hydration.
- Sterility not guaranteed if package is damaged or opened. Discard damaged or open packages.
- Single Use Only.
- To prevent product contamination prior to application, always follow aseptic techniques.
- In rare instances, the physiochemical condition associated with nasal surgery, both with and without nasal packing, may present a risk of toxic shock syndrome (TSS).
- Appropriate treatment to be instituted in case of infection.
- In the case of prolonged bleeding seek medical attention.
- Do not ingest, do not inhale.
- To avoid risk of aspiration, do not place in the posterior nasal cavity.
- Do not use after the end of the year and month shown.
- When used as a topical dressing, PosiSep® X BAM should be kept dry prior to use.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.
- PosiSep® X BAM is intended for topical use only.
- PosiSep® X BAM has not been tested for use with other devices or medicines. Use only according to labeled instructions.

Instructions for Use as Hemostat Dressing/Intranasal Splint:

1. Peel open PosiSep® X BAM pouch and remove dressing using sterile technique to maintain product integrity.
2. PosiSep® X BAM may be cut or bent to a size appropriate for the application.
3. Using forceps, insert PosiSep® X BAM longitudinally and apply to area of treatment.
4. If PosiSep® X BAM is broken during insertion, assess if size is appropriate for application. If not, dispose and reapply PosiSep® X BAM.
5. After placement, hydrate the PosiSep® X BAM using a sterile fluid.
6. Discard any unused product after opening.
7. PosiSep® X BAM will be naturally eliminated between 5 to 10 days via mucociliary action, assisted by daily irrigation with fluid which helps with fragmentation of the device.

How Supplied:

See pouch and carton labels for package quantity.

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Made in USA.

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℞ ONLY	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
#	Quantity Symbol: numeral (in place of #) indicates the quantity of units in package.
MD	Medical Device
	Single sterile barrier system with protective packaging outside
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 expiration date.
UDI	Unique Device Identifier
	Consult Instructions for Use
Store at room temperature	