PosiSep® HEMOSTAT DRESSING/
INTRANASAL SPLINT

Instructions For Use

Contraindications:

PosiSep® should not be used on patients who have known allergies to shellfish.

Intended Use:

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

Description:

Hemostasis, LLC offers two different platforms of hemostat dressings/intranasal splints. Both PosiSep and PosiSep X are patient-comfortable sponges manufactured from naturally occurring Chitosan polymers. Both PosiSep and PosiSep X expand when hydrated providing separation between the sinus tissues. However, if extra gelling properties are desired, PosiSep will form a smooth gel surface when exposed to liquids. If extra expansion properties are desired, PosiSep X will expand more than PosiSep to fill in spaces.

Warnings and Precautions:

- PosiSep 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.
- When utilized as an intranasal splint, if the PosiSep 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.
- Clinician must inform the patient that the device contains material derived from shellfish.
- 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 should be kept dry prior to use.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.
- PosiSep is intended for topical use only.
- PosiSep has not been tested for use with other devices or medicines. Use only according to the labeled instructions.

Instructions for Topical Dressing:

1. Peel open PosiSep pouch and remove dressing using sterile technique to maintain product integrity.
2. Blot excess blood from the wound with gauze.
3. Apply PosiSep dressing to cover wound.
4. As necessary, apply pressure and hold in place until hemostasis is achieved, which generally takes minutes depending upon the nature of the bleeding site and specifics of the patient.
5. If hemostasis has not been achieved, repeat steps 2-4 or use an alternate method of hemostasis treatment.
6. Once hemostasis is achieved, remove PosiSep from the wound site using gentle irrigation with saline or water and aspirate as needed. If decided to leave the PosiSep in place, PosiSep will be naturally eliminated between 3 to 4 days via mucociliary action, assisted by daily irrigation with fluid which helps with fragmentation of the device.
7. Discard any unused product after opening.

Instructions for Intranasal Splint:

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

How Supplied:

PosiSep is packaged five (5) sterile, single use units per carton.
One (1) sterile unit contains one (1) device.
PosiSep is terminally sterilized by gamma irradiation.

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
866-612-2568

www.hemostasisllc.com
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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