

PosiSep® C & C² NASAL DRESSINGS

Instructions For Use

Contraindications:

PosiSep® C & C² should not be used on patients who have known allergies to shellfish.

Intended Use:

PosiSep® C or C² 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® C or C² is indicated for use as a nasal hemostat to treat epistaxis.

PosiSep® C & C² are intended for use under the direction of a licensed healthcare provider.

Description:

PosiSep® C & C² are constructed of a patient-comfortable sponge which is manufactured from naturally occurring chitosan polymers. PosiSep® C & C² were specifically engineered for use as a nasal dressing to be used following clinic based procedures. PosiSep® C & C² are supplied as a compressed device which rapidly wicks fluid and immediately expands providing separation between the sinus tissues. PosiSep® C is available in 2 sizes; a 0.5" x 1.5" size and a 0.6" x 2.0" size. When fully hydrated in an unconfined space for typical space filling needs, PosiSep® C (0.5" x 1.5") expands to 0.25" while PosiSep® C (0.6" x 2.0") expands to 0.45". For situations where additional space filling is needed, PosiSep® C² expands to 0.75". PosiSep® C & C² will be naturally eliminated via mucociliary action, assisted by daily irrigation with fluid as prescribed by a licensed healthcare provider.

Warnings and Precautions:

- PosiSep® C & C² are not bacteriostatic toward pre-existing infections, nor do they prevent the occurrence of new infections. Appropriate treatment to be instituted in case of infection.
- Single Use Only.
- Sterility not guaranteed if package is damaged or opened. Discard damaged or opened packages.
- To prevent product contamination prior to application, always follow aseptic techniques.
- Clinician must inform the patient that the device contains materials 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.
- Do not use after the end of the year and month shown.
- PosiSep® C & C² should be kept dry prior to use.
- To avoid risk of aspiration, do not place in posterior nasal cavity.
- This product shall be disposed of in compliance with pertinent government regulations regarding medical devices.
- PosiSep® C & C² are intended for topical use only.
- PosiSep® C & C² have not been tested for use with other devices or medicines. Use only according to labeled instructions.

Instructions for Topical Dressing:

1. Peel open PosiSep® C or C² pouch and remove dressing using sterile technique to maintain product integrity.
2. Blot excess blood from the wound with gauze.
3. Apply PosiSep® C or C² dressing to cover wound.
4. As necessary, apply pressure and hold in place until hemostasis is achieved, which will generally take 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® C or C² from the wound site using gentle irrigation with saline or water and aspirate as needed. If decided to leave the PosiSep® C or C² in place, PosiSep® C or C² will be naturally eliminated between 4 to 5 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 Nasal Dressing:

1. Peel open PosiSep® C or C² pouch and remove dressing using sterile technique to maintain product integrity.
2. PosiSep® C & C² may be cut or bent to a size appropriate for the application.
3. Using forceps, insert PosiSep® C or C² longitudinally and apply to area of treatment.
4. If PosiSep® C or C² is broken during insertion, assess if size appropriate for application. If not, dispose and reapply PosiSep® C & C².
5. After placement, hydrate the PosiSep® C or C² with a sterile fluid.
6. Discard any unused product after opening.
7. PosiSep® C & C² will be naturally eliminated between 4 to 5 days after daily hydration.

How Supplied:

See pouch and carton labels for package quantity.

PosiSep® C & C² are terminally sterilized by gamma irradiation.

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
























STERILE R Store at room temperature.



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Symbol	Description
	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
	Sterilized by Irradiation
	Single Use Only. Do not reuse.
	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Keep Dry
	Manufacturer
	Catalog Number
	Lot Number
	Expiration Date (Use By). This device should not be used after the end of the year and month shown.