

Intended Use:

NexPak® X Intranasal Splint is a nasal dressing intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity, and act as an adjunct to aid in the natural healing process post-surgical intervention. NexPak® X is constructed of a patient-comfortable sponge which is manufactured from 100% plant-based polysaccharides. NexPak® X is intended for use under the direction of a licensed healthcare provider.

Contraindications:

NexPak® X should not be used on patients who have known allergies to potato starch.

Description:

NexPak® X was specifically engineered for use as a nasal dressing in the sinus cavity following surgical procedures. NexPak® X is supplied as a compressed device, providing good visualization during placement, which rapidly expands with hydration providing separation between the nasal tissues. NexPak® X will be naturally eliminated via mucociliary action, assisted by daily irrigation with fluid as prescribed by a licensed healthcare provider.

Warnings and Precautions:

- 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.
- Contains: Amylopectin and hydroxyethylcellulose.
- 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).
- NexPak® X exhibits no antimicrobial properties; it is not bacteriostatic toward preexisting infections, nor does it prevent the occurrence of new infections. Appropriate treatment to be instituted in case of infection.
- Do not ingest, do not inhale.
- Keep dry prior to use.
- To prevent risk of aspiration, do not place in posterior nasal cavity.
- Do not use after the end of the year and month shown.

Instructions:

- Peel open NexPak[®] X pouch and remove dressing using sterile technique to maintain product integrity.
- 2. NexPak® X may be cut or bent to a size appropriate for the application.
- 3. Insert NexPak® X longitudinally and apply to area of treatment.
- 4. If foam is broken during insertion, assess if size is appropriate for application. If not, dispose and re-apply NexPak®X.
- 5. After placement, hydrate the NexPak® X using a sterile fluid.
- 6. Discard any unused product after opening.
- 7. NexPak® X 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:

NexPak® X is packaged five (5) sterile units per carton. One (1) sterile unit contains one (1) device. NexPak® X is terminally sterilized by gamma irradiation. Store NexPak® X at room temperature.

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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Symbol	Description
\mathbf{R} 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.
\triangle	Caution: See Instructions for Use
STERILE R	Sterilized by Irradiation
2	Single Use Only. Do not reuse.
STEPLEE	Do Not Re-sterilize
	Do Not Use if Package is Damaged
Ť	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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