

NEXSTAT® TOPICAL HEMOSTAT POWDER WITH APPLICATOR

Instructions for Use

Intended Use:

NexStat® Topical Hemostat Powder is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

Contraindications:

NexStat® Topical Hemostat Powder should not be used on patients who have known allergies to potato starch.

Warnings:

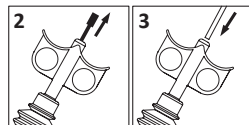
- NexStat® Topical Hemostat Powder is not intended as a substitute for appropriate standard of care procedures and meticulous surgical techniques.
- Care should be taken to avoid introduction of NexStat® Topical Hemostat Powder into the airway during application.
- Do not inject powder into blood vessels as vessel occlusion could occur.
- The safety and efficacy of NexStat® Topical Hemostat Powder in combination with other hemostatic devices has not been clinically evaluated and is therefore not recommended.
- Contains potato starch

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 expiration date shown.
- The flexible applicator tips are supplied along with the NexStat® Topical Hemostat bellows dispenser as a sterile (single use only) product and cannot be re-sterilized.
- To prevent product contamination prior to application, always follow aseptic techniques.
- If the flexible tip becomes clogged with blood, remove tip, discard and replace with new tip. NexStat® Hemostat Powder is supplied with 3 sterile tips.

Instructions:

1. Peel open pouch to remove contents.
2. Remove cap from bellow tip. Discard cap. (see below)
3. Insert one flex tip into applicator handle. (see below)
4. Remove excess blood from the wound site.
5. Apply NexStat® Topical Hemostat Powder in a sufficient amount to cover wound. Note: If the flexible tip becomes clogged with blood, remove tip, discard and replace with new tip.
6. Use a gauze pad to cover the powder once it has been applied to the wound site and hold in place. Periodically check the site to ensure that hemostatic control has been achieved.
7. To remove the gauze pad, soak the gauze pad using sterile water and gently remove from the wound site and verify hemostasis.
8. If hemostasis has not been achieved, repeat the above steps until hemostasis has been achieved or use an alternate method of hemostasis treatment.
9. NexStat® Topical Hemostat Powder leaves the site of placement by natural elimination, or it may be aspirated from the application site at the direction of the physician.
10. Discard any unused product after opening.



How Supplied:

NexStat® Topical Hemostat Powder is terminally sterilized by gamma irradiation. See pouch and carton labels for package quantity.

Storage and Handling:

NexStat® Topical Hemostat Powder 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 law restricts this device to sale by or on the order of a physician.

Store at room temperature.



Manufactured by:


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 St. Paul, MN 55110 USA
 www.hemostasisllc.com

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.