

STATSEAL®

Topical Powder

English

that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: Store in a clean, dry place. Use by expiration date listed. Discard if product is damaged or opened. Discard contents after use. After opening, contents are no longer sterile.

INSTRUCTIONS FOR USE

StatSeal® is intended for use under the care of a healthcare professional for the temporary external control of bleeding from wounds and procedures resulting in external bleeding. StatSeal can be used on all patient populations, regardless of age, gender, or ethnicity. Each application includes one (1) tube of **StatSeal Powder**, one (1) powder containment device (PCD), and one (1) PCD foam insert. Use of the PCD is optional.

INSTRUCTIONS FOR USE

1. Prepare skin around site per facility protocol.
2. Open sterile packaging and remove contents.
3. If using PCD, remove backing from PCD to expose adhesive and center PCD around site with adhesive side down.
4. Gently shake tube prior to opening. Invert tube to pour powder; **do not squeeze tube**.
5. Pour powder to completely cover and surround site. If using PCD, **do not overfill**, and place PCD foam insert over powder to cover.
6. Maintain **continuous, semi-occlusive** pressure over site for ≥ 2 minutes. Extend pressure times as clinically necessary.*
7. Slowly release pressure by rolling fingers off of site.
8. Place transparent dressing per facility protocol.
9. Leave powder in place until next scheduled dressing change.

*Tube contains extra powder in case of rebleed. If bleeding continues, apply more powder and semi-occlusive pressure as necessary until bleeding stops.

SAFE DISPOSAL

StatSeal Devices must be disposed of in accordance with clinical waste laws applicable in the location of use.

INGREDIENTS

Hydrophilic polymer and potassium ferrate

PERFORMANCE CHARACTERISTICS

StatSeal Devices have a simultaneous two-step mechanism of action whereby the hydrophilic polymer rapidly dehydrates the blood and absorbs exudate, while the potassium ferrate binds with blood proteins to create an occlusive seal to stop the flow of blood. The blood seal is left on the wound site until it is naturally sloughed off as the permanent seal is produced by the natural forces of the body's repair mechanism.

CLINICAL BENEFITS

StatSeal Devices work independently of the clotting cascade to seal wounds and procedural sites, to stop external bleeding, and to reduce time to hemostasis.

DURATION OF CONTACT

StatSeal Devices are intended to be in contact with patient body for 30 days or less.

WARNINGS: FOR EXTERNAL USE ONLY. For single use only. Do not reuse. Reuse may compromise the sterility, safety and performance of the device. Not intended to replace stitches. Do not apply to visibly infected wounds. May be harmful if inhaled or ingested. Avoid aspirating product into the nasal or oral cavity. Avoid contact with eyes; if contact should occur, thoroughly rinse eyes with water. Depending on patient condition and amount of pressure application, the following may occur: vascular occlusion, hypodermic hematoma, continued bleeding, skin breakdown, discomfort, or numbness. Check hemostasis progress and adjust pressure as clinically necessary. Discontinue use if inflammation, irritation, tissue damage, or granulomatous reaction occurs. Any serious incident

	Caution
	Do not use if package is damaged and consult Instructions for Use
	Medical Device
	Single use
	Do not resterilize
	Sterilized using irradiation
	Federal law (USA) restricts this device for use by, or under the supervision of a licensed healthcare practitioner.
	Manufacturer
	Authorized Representative in European Community
	Keep away from sunlight
	Keep dry
	Temperature limitation. 6°C - 32°C



Manufacturer:

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Authorized Representative:

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