

STATSEAL TOPICAL POWDER

Option for using **WITHOUT** Powder Containment Device (PCD)

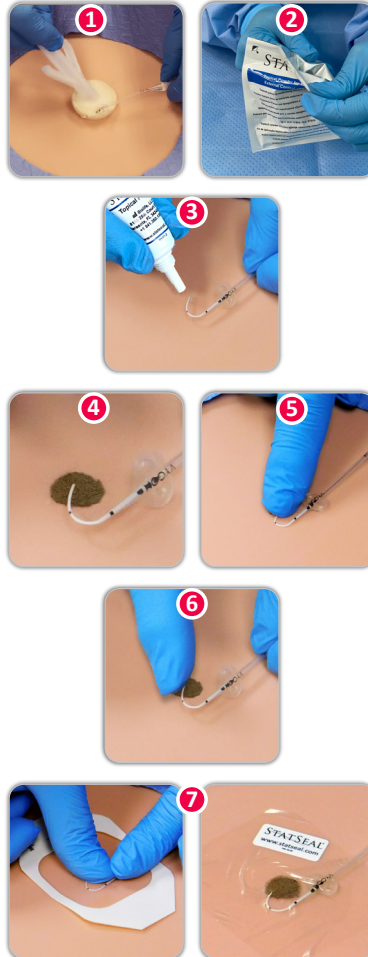
The following instructions for use pertain to StatSeal® Topical Powder. StatSeal is intended for use under the care of a healthcare professional for the temporary external control of bleeding wounds and procedures. Below are general guidelines that can be adapted to your specific application or protocol.

Each application includes one (1) bottle of StatSeal Topical Powder, one (1) powder containment device (PCD), one (1) PCD foam insert and one (1) product description label. Use of the PCD is optional. **These suggested instructions and protocols pertain to using StatSeal Topical Powder without the optional PCD.**

Instructions for Use

1. Prepare skin around site per facility protocol.
2. Open sterile packaging and remove contents.
3. Gently shake tube prior to opening. Invert tube to pour powder; **do not squeeze tube.**
4. Ensure powder completely covers and surrounds site.*
5. Maintain **continuous, semi-occlusive** pressure over site for 2 minutes. Extend pressure times as clinically necessary.
6. Slowly release pressure by rolling fingers off of site.
7. Place transparent dressing per facility protocol. Apply product description label over dressing.
8. 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.



Tips for Success

Applying Powder

- Wick up excess blood with gauze.
- To control powder flow, touch sterile tube tip to catheter exit site and slowly invert tube.
- Apply a small amount of powder **360° around catheter** exit site.
- Determine powder amount by current or expected bleeding; entire tube is not necessary.

Holding Pressure

- Do not use gauze to hold pressure as it may disrupt the seal when removed.
- Hold pressure over powder with sterile gloved finger.
- Hold pressure for a **minimum of 2 full minutes and NO PEEKING** during this time.
- While holding pressure, use other hand to brush away excess powder around site in preparation for dressing application.

Dressing the Site

- Place transparent dressing over powder, then slowly mold dressing around catheter exit site, working toward outer edges to secure.
- Do not stretch dressing during application.



Consult Instructions for Use
for complete Warnings and Cautions.

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Suggested Protocol for Dressing Change

1. Remove the transparent dressing.
2. Use dry, sterile gauze to brush away any loose particles.
3. Clean around the access site per facility protocol; do not remove the seal when cleansing. Allow site to dry fully.
4. Additional StatSeal Powder may be applied for bleeding as necessary.
5. Apply new transparent dressing, per facility protocol.

NOTE: The seal falls off naturally over time with subsequent dressing changes. StatSeal has no interaction with CHG.

Suggested Protocol for Catheter Adjustment

1. Remove the transparent dressing.
2. Use dry, sterile gauze to brush away any loose particles.
3. Wet the dried seal with sterile water/saline as needed.
4. Adjust the catheter per facility protocol; you may physically feel the seal release as you adjust the catheter. Use sterile water/saline to remove any powder that may have adhered to the catheter.
5. Additional StatSeal Powder may be applied for bleeding as necessary.
6. Apply new transparent dressing, per facility protocol.

Suggested Protocol for Catheter Discontinuation

1. Remove the transparent dressing.
2. Use dry, sterile gauze to brush away any loose particles.
3. Wet the dried seal with sterile water/saline as needed.
4. Remove catheter per facility protocol; you may physically feel the seal release as you remove the catheter.
5. Additional StatSeal Powder may be applied for bleeding as necessary.
6. Apply new transparent dressing, per facility protocol.



Above: StatSeal Powder remaining after dressing removal

Below: Seal remains at access site after cleaning

