

STATSEAL TOPICAL POWDER with 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; powder may be applied without the PCD.

Instructions for Use

1. Prepare skin around site per facility protocol.
2. Open sterile packaging and remove contents. Remove paper backing from PCD to expose adhesive.
3. 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. Fill PCD to brim with powder; **do not overfill**.^{*} Ensure powder completely covers and surrounds site. 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 PCD.
8. Place transparent dressing per facility protocol. Apply product description label over dressing.
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.



Consult Instructions for Use
for complete Warnings and Cautions.



Tips for Success

Placing the PCD

- Wick up excess blood with gauze.
- Approximate PCD edges, when possible.

Applying Powder

- To control powder flow, touch sterile tube tip to catheter exit site and slowly invert tube.
- For heavy bleeding, pour a small amount of powder **360° around catheter**, hold pressure, and then alternate between applying powder and pressure until hemostasis is achieved.
- 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 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 PCD in preparation for dressing application.

Dressing the Site

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

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Suggested Protocol for Dressing Change

1. Remove the transparent dressing and the PCD.
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 and the PCD.
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 and the PCD.
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

