

STATSEAL TOPICAL POWDER with Powder Containment Device (PCD)

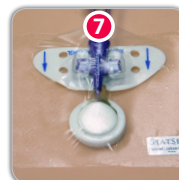
The following instructions for use pertain to StatSeal[®] Topical Powder. StatSeal is intended for use under the care of a healthcare professional for the temporary external control of bleeding wounds and procedures. Below are general guidelines that can be adapted to your specific application or protocol.

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.

Instructions for Use

1. Open sterile packaging and remove contents. Remove paper backing from PCD to expose adhesive.
2. Center PCD around site with adhesive side down.
3. Fill PCD to brim with powder; do not overfill.* Ensure powder completely covers and surrounds site. Place PCD foam insert over powder to cover.
4. Hold continuous pressure over site for 2 minutes. Extend hold times as necessary for anticoagulated patients.
5. Release pressure slowly by rolling fingers off of PCD.
6. Place transparent dressing per protocol. Apply product description label over dressing.
7. Leave powder in place until next scheduled dressing.

* The bottle contains extra powder. If bleeding continues, reapply more powder as necessary with manual compression until bleeding stops.



Tips for Success

Placing the PCD

- Use of the PCD is optional; powder may be applied without the PCD
- Place PCD around catheter with slit facing up
- Best practice is to approximate PCD edges, whenever possible

Applying Powder

- Try to make application area as flat as possible (more horizontal, less vertical)
- The tip of the bottle may be popped off if a speedy pour is necessary

Holding Pressure

- Do not use gauze to hold pressure as it may disrupt the seal when removed
- Hold time by the clock and **NO PEAKING** during hold time
- Extend hold times as necessary for anticoagulated patients and patients with large bore catheters
- While holding pressure, use other hand to clean area around PCD in preparation for dressing application

Dressing the Site

- Start by placing dressing directly over PCD, then slowly mold dressing around the PCD, working toward outer edges to secure

