

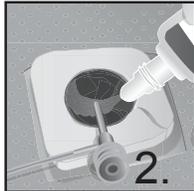


Instructions for Use - Femoral Sheath Removal

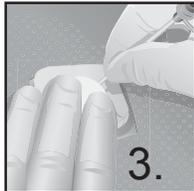
Application includes 1 bottle, 1 Powder Containment Device (PCD) and 1 product description label.



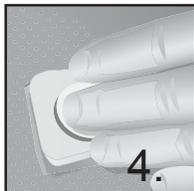
1. Clean and dry the area around the site.
Withdraw sheath leaving at least 3 to 4 centimeters under the skin. Remove PCD from package, peel paper backing and center (PCD) around sheath.



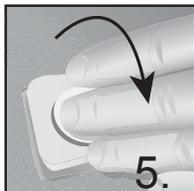
2. Pour powder into PCD* - lift sheath gently to ensure powder gets under sheath, then create a pile of powder around the sheath and completely fill the PCD.



3. Place PCD center (foam insert) over the powder.
Pull sheath slowly while applying pressure over the arteriotomy and the insertion site.



4. StatSeal Advanced is a manual pressure adjunct. For initial uses, start at current manual pressure hold times then gradually adjust down toward 5 to 10 minutes of **continuous** pressure. Extend hold times as necessary for hypertensive patients, anticoagulated patients, e.g. - low platelets, high ACT levels - or larger sheath sizes.



5. Release pressure slowly; Roll fingers off PCD**.



6. Place transparent dressing per protocol; Apply product description label on top of dressing to identify powder. Provide discharge instructions to patient or caregiver. Follow your normal ambulation protocol.

* Fill PCD completely; don't overfill; the bottle contains excess powder in case of a rebleed.

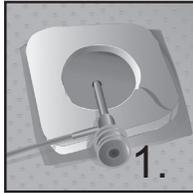
** If bleeding continues, reapply more powder (if necessary) with manual compression until bleeding has stopped. You may feel a slight warming from the powder as it forms the seal.

To remove Statseal Advanced: If Statseal Advanced Powder must be removed, as determined by a healthcare professional, brush away loose powder then wet the seal with sterile water/saline until seal starts loosening from the wound. Gently scrape off loosened seal with gloved finger, cotton swab or tongue depressor. Repeat as needed.

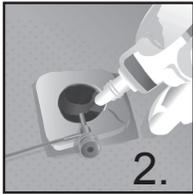


Instructions for Use - Sheath Removal Following Fistula/Graft Access

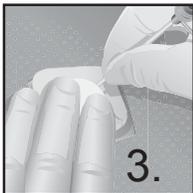
Application includes 1 bottle, 1 Powder Containment Device (PCD) and 1 product description label.



1. Clean and dry the area around the site.
Withdraw sheath as much as possible leaving at least 2-3 centimeters under the skin. Remove Powder Containment Device (PCD) from package, peel paper backing and center PCD around sheath.



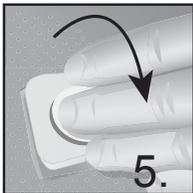
2. Pour powder into PCD - lift sheath gently to ensure powder gets under sheath, then create a pile of powder around the sheath and completely fill the PCD.



3. Place PCD center (foam insert) over the powder.
Pull sheath slowly while applying pressure directly over the puncture site.



4. StatSeal Advanced is a manual pressure adjunct. Hold **continuous** pressure for 5 minutes, focusing pressure over the access site. Extend hold times as necessary for larger sheaths, hypertensive patients or anticoagulated patients, e.g. - low platelets, high ACT levels.



5. After 5 minutes, relieve pressure slightly without removing the PCD center (foam insert); then roll fingers away to assess site.
 - If bleeding/oozing is visible through PCD, continue to apply additional pressure for 2 minutes and re-assess; if necessary, you can apply more StatSeal Advanced powder and resume holding.
 - If no bleeding/oozing is visible, carefully clean PCD with clean gauze if necessary.



6. Place transparent dressing per protocol; Apply product description label on top of dressing to identify powder.

7. Follow your normal ambulation protocol. Instruct patient to minimize arm flexion for at least 30 minutes and to leave seal in place once dressing is removed. Provide Patient Discharge Instructions to patient or caregiver. Avoid needle punctures through seal.