StatSeal® ADVANCED

Not a pad…..a powder innovation.

Patented Technology to Seal Arterial Access Sites

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StatSeal ADVANCED Powder

- A topical hemostatic powder that controls external bleeding from arterial access procedures, hemodialysis maintenance and other diagnostic or interventional procedures.
- Powder ingredients are a hydrophilic polymer and potassium ferrate.
- The powder's mechanism of action is a simultaneous two-step action whereby the hydrophilic polymer rapidly dehydrates the blood while the potassium ferrate agglomerates the blood proteins to create a seal.

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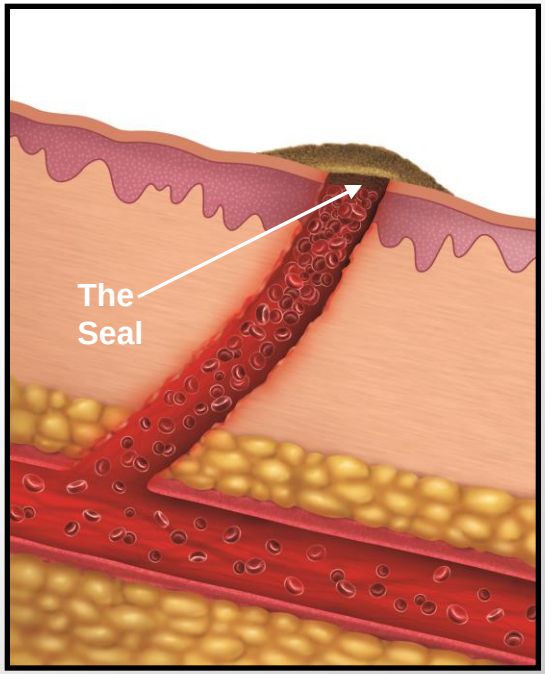
Benefits of StatSeal ADVANCED Powder

- Quickly creates a seal over a vascular access site
- Dramatically reduces hold times, thus increasing patient comfort
- Does not rely on the body's clotting cascade
- The seal stays with the patient
- Versatile – can be used for femoral access, radial access, fistulas
- More cost-effective than vascular closure devices or hemostatic pads



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Powder + Pressure = Seal

- When placed on an access site and combined with manual pressure to the site, StatSeal ADVANCED Powder quickly forms a seal that covers the access site and stops blood flow.
- StatSeal ADVANCED Powder forms a seal independently of the clotting cascade.
- Natural clotting occurs below the seal, along the tract and at the arteriotomy.
- The seal remains in place until wound healing is complete and it falls off naturally.

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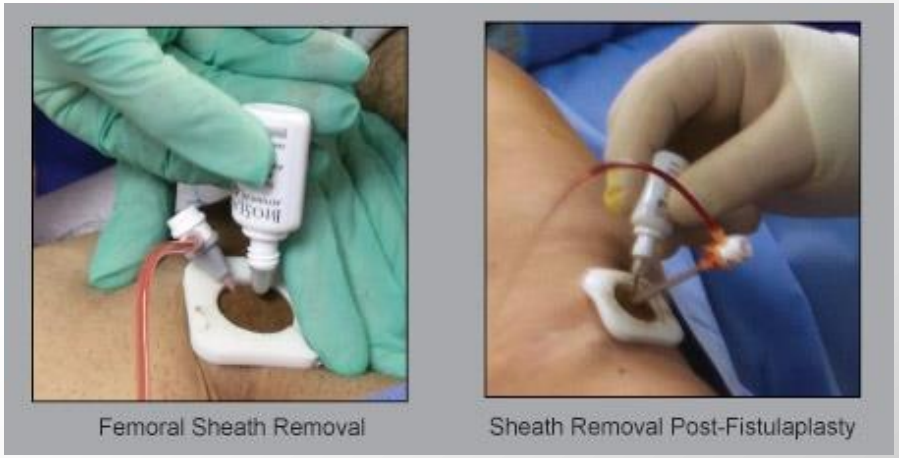
Target Applications

Cath labs:

- Sheath removal from diagnostic and interventional procedures
- Bleeding/oozing after closure device deployment

Interventional Radiology:

- Sheath removal from vascular access procedures
- Hemodialysis access maintenance (fistulas/grafts)
- Bleeding/oozing from temporary dialysis catheters
- Other diagnostic or interventional procedures resulting in external bleeding



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Proven Efficacy Through Clinical Studies

- **Fast hemostasis for diagnostic & interventional procedures**

In a trial* published in the ***Journal of Vascular and Interventional Radiology*** (January 2008) comparing the efficacy of two compression adjuncts in 176 percutaneous vascular access procedures, ***StatSeal ADVANCED reduced mean time hemostasis to under 4 minutes for arterial procedures.*****

Procedure Type	Time to Hemostasis (TTH) StatSeal	TTH D-Stat
Arterial - Therapeutic	**3.56**	9.99
Arteriovenous Dialysis Access	**3.41**	7.26

*Wang DS, Chu LF, Olson SE, Miller FJ, Valji K, Wong WH, Rose SC, Austin M, Kuo MD. Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis in Percutaneous Arterial, Venous, and Arteriovenous Dialysis Access Procedures. Journal of Vascular and Interventional Radiology January 2008; 19: 72-79.

** Hold times may vary due to anticoagulation levels, sheath sizes or clinical techniques.

- **Effective in Controlling Severe Bleeding**

  Results from a randomized 40-swine animal study of lethal arterial injury (6mm (18 Fr) femoral arterial punch biopsy performed under a Dept. of Defense grant at the University of Michigan):

  - StatSeal ADVANCED outperformed controls (other military products).**
    - Provided effective hemostasis in only 4 minutes
    - 100% survival rate
    - 77%+ decrease in hemorrhage volume
    - Reduced resuscitation fluid needs

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**Controls included hemostatic agents for traumatic wounds.

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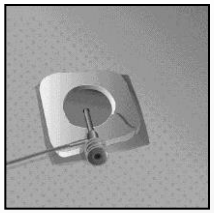
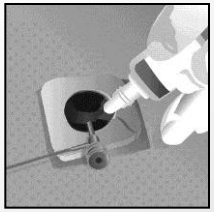
Protocol for Femoral Sheath Removal

- Clean and dry the area around the site.
- Withdraw sheath leaving at least 3 to 4 centimeters under the skin.
- Open package and remove PCD; remove paper backing and center PCD around sheath with slit towards the patient's head.
- Pour powder into PCD to create a pile of powder around the sheath and completely fill the PCD. Lift sheath gently to ensure powder gets under sheath.
- Place foam insert over the powder.
- Pull sheath slowly while applying pressure over the arteriotomy and the insertion site.
- StatSeal ADVANCED is an adjunct to manual pressure. For initial uses, start at current manual pressure times, then gradually adjust down towards 5 to 10 minutes of **continuous** pressure. Extend hold times as necessary based on anticoagulation levels (low platelets, high ACT levels), hypertensive patients or larger sheath sizes.





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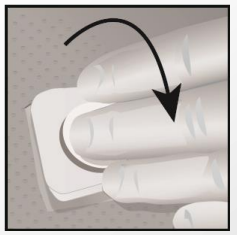
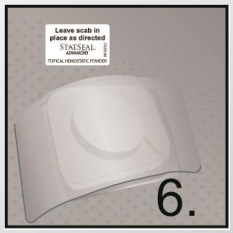
Protocol for Femoral Sheath Removal (cont'd)

- Release pressure slowly, rolling fingers off PCD.
- Dress securely with transparent dressing or tape.
- Place StatSeal ADVANCED product label on top of dressing to identify powder.
- Follow your normal ambulation protocol.
- Provide discharge instructions to patient or caregiver.





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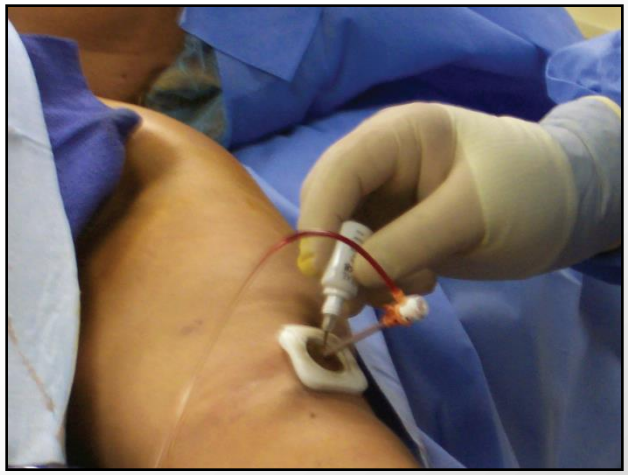
StatSeal ADVANCED for Fistula Declots and other AVDA Procedures

Use StatSeal ADVANCED for:

- Challenging declots
- Fistulagrams
- Fistulaplasties
- Other access procedures



"I routinely use StatSeal in access procedures. I tell people I call it "magic dust" ... and to try it, they will love it."

Scott O. Trerotola, MD
Professor of Radiology and Surgery
Associate Chair and Chief, Interventional Radiology
University of Pennsylvania School of Medicine

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Protocol for Graft/Fistula Access Procedures

- Clean and dry area around site thoroughly.
- Withdraw sheath as much as possible leaving at least 2-3 cm under the skin.
- Open package and remove Powder Containment Device (PCD); remove paper backing and center PCD around sheath with slit towards head.
- 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.
- Place foam insert over the powder.
- Pull sheath **slowly** while holding pressure **directly** over the puncture site. (*Ideally use one finger to ensure pressure is focused on puncture site).*

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Protocol for Graft/Fistula Access Procedures

- Hold **continuous** pressure for 5 minutes, focusing pressure over the access site to ensure initial seal forms. Increased hold times may be needed for:
  a) large sheaths (one minute of pressure per French size is a general guide.)
  b) Hypertensive or anticoagulated patients.

- After 5 minutes, relieve pressure slightly without removing the foam center; then ➔ 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.

- Dress securely with transparent dressing or tape.

- Place StatSeal ADVANCED sticker on top of dressing to identify powder.

- Remind patient to **minimize arm flexion for at least 30 minutes** and to remove dressing as directed, leaving seal in place. Provide Patient Discharge Instructions to patient or caregiver. Avoid needle punctures through seal.

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Tips for Success

Remember **“PAPC”**

- **Prep** – patient assessment, including sheath size, blood pressure and level of anticoagulants (i.e., Heparin, Integrillin, Angiomax)
- **Apply** – completely apply powder under and around the sheath, creating a pile inside the PCD
- **Pressure** – hold consistent, normal pressure in the initial 5 minutes over the access site to allow seal formation.
- **Cover** – apply foam insert to assist with powder compression; secure with tape or transparent dressing.

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StatSEAL ADVANCED Ordering Information

Order Number	Product Description
LP607	6 Applications per Box*
LP637	24 Applications per Case*

* Each application includes bottle, Powder Containment Device (PCD), PCD foam insert and product description label.

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In-Service/Support Tools Available

- Brochures for Patients and Medical Staff
- Protocol Sheets
- Posters

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For More Information

- Contact CardioMed Supplies Inc
- www.cardiomed.com

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