

HEMOSTASIS CHALLENGES IN RENAL CARE PATIENTS

Hemostasis and site integrity are critical in renal therapy settings, where repeated access and fragile vasculature demand efficient, atraumatic care. Prolonged hold times, rebleeds, and dressing disruption not only delay recovery and extend chair time, but also compromise catheter performance and increase infection risk.^{1,2} Patients with end-stage renal disease (ESRD) often have impaired clotting, making hemostasis harder to achieve and maintain, especially at needle puncture sites or catheter exit sites prone to bleeding and oozing.

THE STATSEAL SOLUTION

StatSeal topical dressing products offer a novel solution that helps standardize, simplify and minimize post-procedure care and maintenance of renal therapy access sites. StatSeal products work independently from the clotting cascade to rapidly create an occlusive seal over access sites to stop oozing and bleeding, making them an ideal pressure adjunct for achieving fast, consistent hemostasis following renal therapy access. StatSeal use improves post-procedure site care for renal patients by streamlining protocols, protecting access sites, and reducing rebleeds, resulting in improved patient recovery times and outcomes. Integrating StatSeal into renal therapy recovery protocols has been found to result in significant clinical, economical and operational efficiencies.³⁻⁶

Creates an instant seal³⁻⁶

- Does not rely on clotting cascade – works for patients prone to bleeding
- Accelerates hemostasis – reduces prolonged manual pressure and chair time

Minimizes post-procedure care³⁻⁶

- Reduces rebleeds and unplanned dressing changes
- Keeps sites dry and intact, until the scheduled dressing change

Improves Outcomes³⁻⁶

- Reduces clinician burden, time and costs
- Improves patient comfort and delivery of atraumatic care



Above: Dialysis catheter without StatSeal Powder
Below: Dialysis catheter with StatSeal Powder



JVIR STUDY

Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis⁶

This study assessed the relative efficacy of manual pressure adjuncts for reducing time to hemostasis and found that StatSeal Powder outperformed D-Stat in all four procedure types. StatSeal use significantly shortened time to hemostasis, by ~ 50%, without increasing complication rates. StatSeal effectiveness was not impacted by anticoagulants, antiplatelets, or thrombolytics.

Mean Time to Hemostasis According to Procedure Type				
Procedure Type	D-Stat		StatSeal	
	Number of Procedures	Time to Hemostasis (min)*	Number of Procedures	Time to Hemostasis (min)*
Arterial - Diagnostic	10	7.91 ± 1.08	15	3.36 ± 1.07
Arterial - Therapeutic	9	9.99 ± 1.18	14	3.56 ± 1.14
Arteriovenous Dialysis Access	12	7.26 ± 1.13	16	3.41 ± 1.11
Venous	10	3.96 ± 1.16	14	1.93 ± 1.16

*Data are given as means ± standard errors

STATSEAL® PRODUCTS FOR RENAL THERAPIES

StatSeal topical dressing products are available in both powder and disc form to suit a wide variety of clinical applications. The discs are made from compressed powder encased in foam. All StatSeal products are non-systemic, hypoallergenic, have no age contraindications, and have passed all FDA-required biocompatibility testing, further enhancing their safety profile for repeated use in renal patients. StatSeal applications for renal therapies include:

- **Temporary & Long Term Indwelling Dialysis Catheters**
 - Maintain a dry and intact insertion site
- **Fistuloplasty**
 - Closure after sheath removal
- **Hemodialysis:**
 - Hemostasis after needle removal



Fistuloplasty sheath removal with StatSeal Advanced Discs



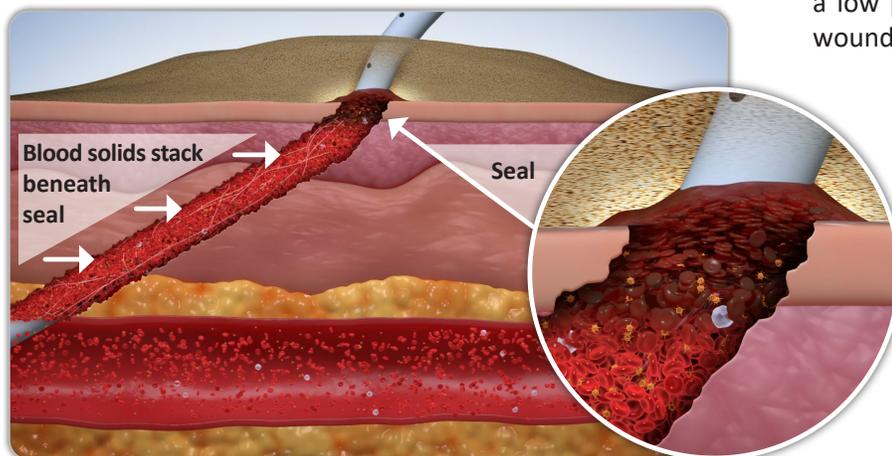
Hemodialysis needle pull with StatSeal Advanced Plus Disc

HOW DOES IT WORK?

StatSeal products are comprised of a hydrophilic polymer and potassium ferrate. As a manual pressure adjunct, StatSeal products have a two-step mechanism of action that occurs simultaneously to instantly form a low pH occlusive seal or physical barrier over the wound site, letting nothing in or out.

- The hydrophilic polymer rapidly dehydrates the blood and absorbs exudate, stacking up desiccated blood solids beneath to form a seal.
- The potassium ferrate binds the blood solids and proteins together, adhering the seal to the wound to stop bleeding and oozing.

Beneath the seal, the pH is neutral and blood solids and proteins continue to stack naturally. Above the seal the hydrophilic polymer acts as a desiccant and creates an acidic environment with a pH of ~ 2.⁷



StatSeal Powder seal formation around indwelling catheter

References: [1] Timsit JF, Bouadma L, Ruckly S, et al. Dressing disruption is a major risk factor for catheter-related infections. *Crit Care Med.* 2012 Jun;40(6):1707-14. [2] Olaechea PM, Palomar M, Álvarez-Lerma F, et al. Morbidity and mortality associated with primary and catheter-related bloodstream infections in critically ill patients. *Rev Esp Quimioter.* 2013 Mar;26(1):21-9. [3] Hastings A, Barton A. Rapid haemostasis to achieve dressing longevity: evaluation trial results using StatSeal catheter exit site protection. *Br J Nurs.* 2024 Jul 18;33(14):S8-S14. [4] Wilder KA, Wall B, Haggard D, Epperson T. CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative Integrating Line-Rounding Principles and a Team Approach. *Adv Neonatal Care.* 2016 Jun;16(3):170-7. [5] Blough L, Hinson K, Hen J. The science of a seal for PICC line management: bio seal CVC powder. *J VAS Access.* 2010;15(2):66-73. [6] Wang DS, Chu LF, Olson SE, et al. Comparative evaluation of noninvasive compression adjuncts for hemostasis in percutaneous arterial, venous, and arteriovenous dialysis access procedures. *J Vasc Interv Radiol.* 2008 Jan;19(1):72-9.

[7] Biolife, LLC, 510(k) K080210, Section 18.3.