StatSeal®
POWERED BY MERIT MEDICAL

Interventional Radiology

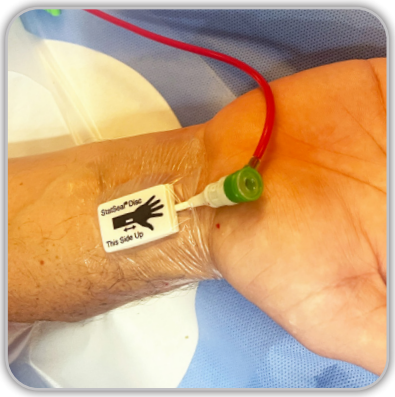
STOP POST-PROCEDURE OOZING & BLEEDING

Achieving hemostasis in interventional radiology patients can be challenging due to the prevalence of complex comorbidities and the routine use of anticoagulant therapies. StatSeal® topical hemostatic products help standardize, simplify and minimize post-procedure care by rapidly forming an occlusive seal over access sites. This seal stops oozing and bleeding, while helping to protect the access site from contamination. StatSeal products work independently from the clotting cascade to seal the site, helping to accelerate hemostasis and reduce hold times, even for patients prone to bleeding.[1-6]

Femoral procedure site with StatSeal Advanced Plus Disc

THE STATSEAL SOLUTION

For all interventional radiology procedures, StatSeal products work with any protein-rich body fluid to seal the site, while stopping oozing and bleeding. The products are available in both powder and disc form to suit a wide variety of clinical applications. All StatSeal products are non-systemic, hypoallergenic, have no age contraindications, and have passed all FDA-required biocompatibility testing. Whether it's a diagnostic or therapeutic procedure, StatSeal use results in standardized, simplified and shortened protocols, leading to significant clinical, operational and economical efficiencies. [1-8]



Radial procedure site with StatSeal Advanced RAD Disc

Significantly accelerates hemostasis

- Reduces hold times by 50% or more[1-6]
- Works regardless of anticoagulation levels[1-6]

Minimizes post-procedure care

- Facilitates same-day discharge[1-3, 5]
- Reduces exit site bleeding and dressing disruption[7,8]

Improves IR lab efficiency

- Reduces clinician burden, time and costs[1-3, 7, 8]
- Increases patient throughput[1-3, 5]

JVIR STUDY

Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis[6]

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

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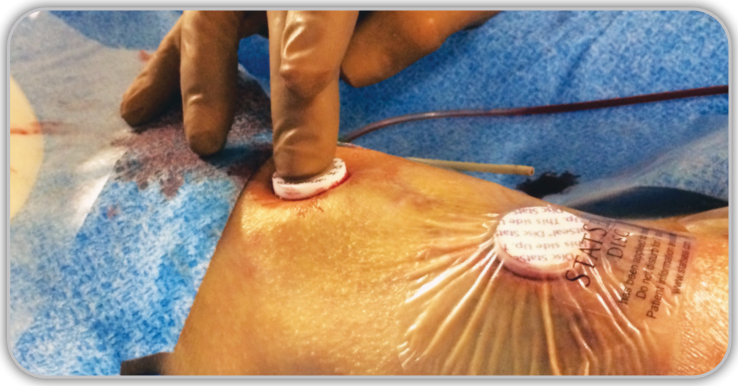
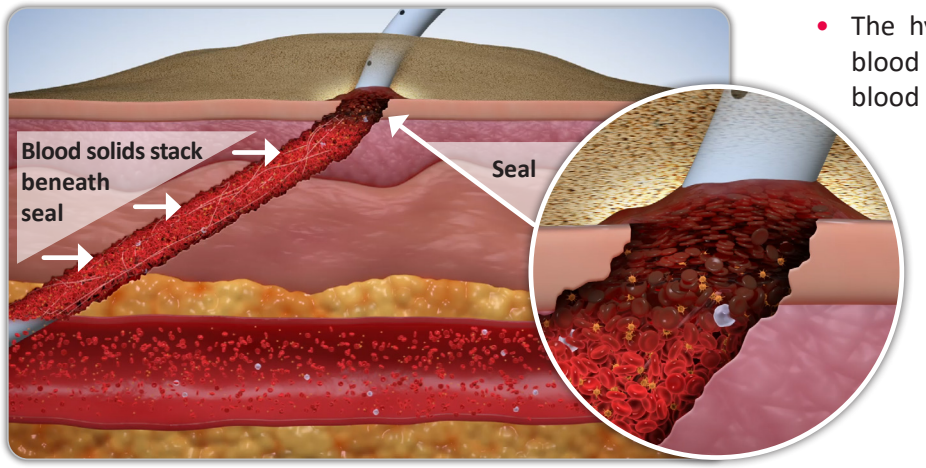
StatSeal® Applications

StatSeal seals the site while stopping oozing and bleeding from:

- Indwelling catheter placements and removals
- Arterial and venous sheath removals
- Biopsy and drainage procedures
- Pain managment procedures and treatments
- Dialysis access and interventions
- Oncology procedures
- Any procedure resulting in external bleeding and oozing



Fistuloplasty sheath removal with StatSeal Advanced Discs



StatSeal Powder seal formation around indwelling catheter

Dialysis catheter dressing with StatSeal Powder

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.[9]

References: [1] Proscia C, Kemp I, Barton J, et al. A randomised control trial to compare conventional and haemostatic dressings in radial arterial access: Assessment of Radial Artery Complications Whilst Achieving Rapid Haemostasis (ARCH Trial). Int J Cardiol. 2025 Feb 1;420:132740. [2] Safirstein JG, Tehrani DM, Schussler JM, et al. Radial Hemostasis Is Facilitated With a Potassium Ferrate Hemostatic Patch: The STAT2 Trial. JACC Cardiovasc Interv. 2022 Apr 25;15(8):810-819. [3] Galusko V, Protty M, Bharucha A, et al. The Quest for a Radial Lounge: StatSeal Reduces Transradial Coronary Angiography Turn-Around Time and Cost. Poster presented at: Thirty-First Annual Symposium Transcatheter Cardiovascular Therapeutics (TCT); September, 2019; San Diego, CA. [4] Khuddus M, Ayyaz Ul Haq M, Massaro J, et al. Meta-Analysis of Radial Hemostasis Trials Using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc. Poster presented at: Thirty-First Annual Symposium Transcatheter Cardiovascular Therapeutics (TCT); September, 2019; San Diego, CA. [5] De Korompay N, Klass D, Chung J, et al. Safety and efficacy of a rapid deflation algorithm for patent hemostasis following radial intervention (PROTEA). In: Proceedings from the Society of Interventional Radiology; March 4-9, 2017; Washington DC. Abstract 301. [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] 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. [8] Wilder KA, Wall B, Haggard D, et al. 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. [9] Biolife, LLC, 510(k) K080210, Section 18.3.

BIOLIFE®

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