

### STOP POST PROCEDURE OOZING & BLEEDING

Standardize, simplify and minimize post procedure care and maintenance from interventional radiology procedures with StatSeal® topical hemostatic products. The products rapidly form an occlusive seal over procedural sites to stop the flow of blood and exudate, while protecting the site from contamination. StatSeal products work independently of the clotting cascade to seal the site, while accelerating hemostasis and reducing hold times, regardless of anticoagulation levels.<sup>1-5</sup>

### THE STATSEAL SOLUTION

Comprised of a hydrophilic polymer and potassium ferrate, StatSeal products are available in both powder and disc (compressed powder) form to suit a wide variety of clinical applications. For all interventional radiology procedures, StatSeal products are more than a hemostat; they work with any protein-rich body fluid to seal the site, while stopping oozing and bleeding. Integrating StatSeal products into IR lab protocols has been found to result in significant clinical, economical and operational efficiencies.<sup>1-5</sup>

#### Significantly accelerates hemostasis

- Reduces hold times<sup>1-5</sup>
- Works regardless of anticoagulation levels<sup>1-5</sup>

#### Minimizes post procedure care

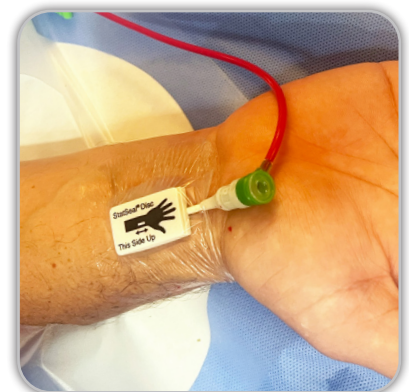
- Reduces complication rates<sup>1-5</sup>
- Facilitates same-day discharge<sup>1,2,4</sup>
- Reduces unplanned dressing changes<sup>6-8</sup>

#### Improves IR lab efficiency

- Reduces clinician burden, time and costs<sup>1-4</sup>
- Increases patient throughput<sup>1,2,4</sup>



Femoral procedure site with StatSeal Advanced Plus Disc



Radial procedure site with StatSeal Advanced RAD Disc



### Safety and efficacy of a rapid deflation algorithm for patent hemostasis following radial intervention (PROTEA)<sup>4</sup>

This study evaluated a rapid deflation protocol using StatSeal Advanced Disc in conjunction with a compression device in 323 patients undergoing transradial procedures, with a 7 Fr sheath size or less, and no more than 5000 IU of heparin.

#### Results:

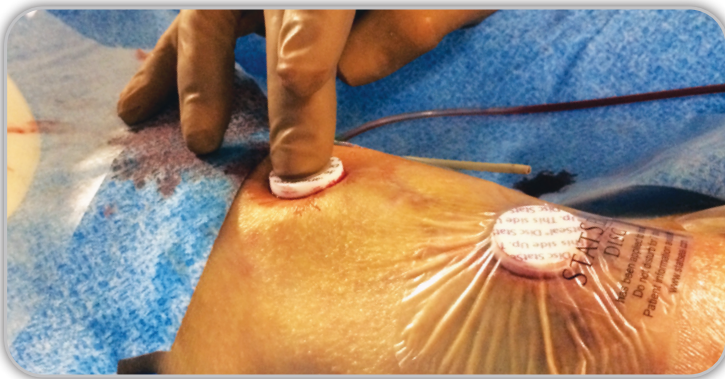
- 25-minute hemostasis time
- 2-hour, same-day discharge
- No increase in complications

The study concluded that **rapid hemostasis can be safely achieved within 25 minutes after transradial intervention using StatSeal Advanced Disc in conjunction with a compression device.**

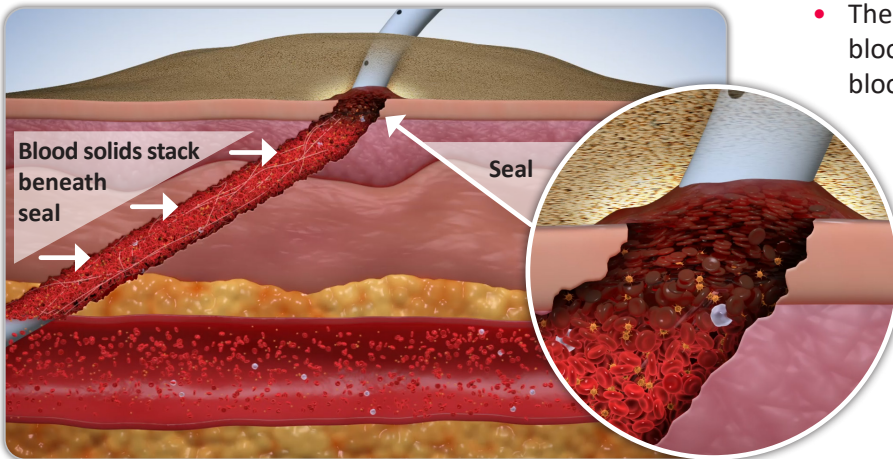
### STATSEAL® APPLICATIONS

StatSeal® seals the site while stopping oozing and bleeding from:

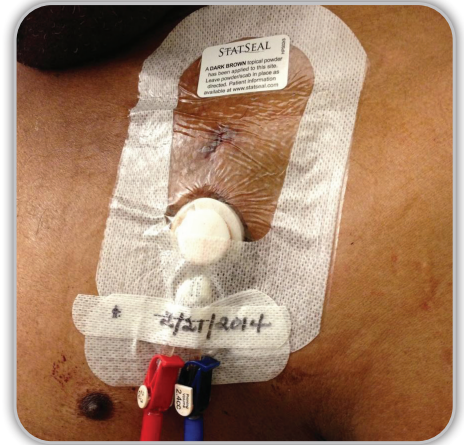
- Indwelling catheter placements and removals
- Arterial and venous sheath removals
- Biopsy and drainage procedures
- Pain management procedures and treatments
- Dialysis access and interventions
- Oncology procedures
- Any procedure resulting in external bleeding and oozing



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's mechanism of action is two-step and occurs simultaneously to instantly form a low pH occlusive seal that acts as a 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 the blood solids and proteins continue to stack naturally. Above the seal, the hydrophilic polymer exchanges protons for cations, resulting in desiccation and a pH of ~ 2, which creates a hostile barrier to microbial penetration.<sup>8,9</sup>

**References:** [1] 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. [2] Galusko V, Proty 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. [3] 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. [4] 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. [5] 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. [6] Ayala, M. PICC Insertion Dressing Protocol for the Hematological Oncology Patient: A Comparison of Biopatch and StatSeal. Poster presented at AVA Annual Meeting; October 4-7, 2019; Las Vegas, NV. [7] 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. [8] 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. [9] Biolife, LLC, 510(k) K080210, Section 18.3.