

HEMOSTASIS CHALLENGES & COSTS

In electrophysiology (EP) labs, interventional procedures often involve multiple femoral puncture sites and large-bore sheaths (≥ 10 Fr). Achieving hemostasis in these patients can be challenging due to the prevalence of complex comorbidities and the routine use of anticoagulant therapies. After sheath removal, the standard approach to hemostasis is manual pressure for ≥ 20 minutes or sutures. However, the manual pressure method can be inconsistent, and it requires significant time and effort from clinicians, as does the suture method. Alternatively, high-cost closure devices specifically designed for large-bore venous closure are increasingly used, with prices ranging from \$250 to \$1,000 per patient, depending on the number of sheaths.



THE STATSEAL® SOLUTION

StatSeal Advanced Plus Disc has the unique ability to create an instant, occlusive seal over access sites to stop bleeding, making it an ideal pressure adjunct for large-bore venous procedures. By reducing time to hemostasis, integrating StatSeal into EP lab recovery protocols has been found to result in significant clinical, economical and operational efficiencies.^{1,2} Unlike traditional hemostatic products that rely on the clotting cascade, StatSeal products require only protein and moisture to create a rapid seal over access sites, making them especially useful for patients on anticoagulant therapies. This unique mechanism helps standardize, simplify and minimize the recovery process, offering a more effective solution for EP venous sheath removal and enabling same-day discharge.



Significantly accelerates hemostasis^{1,2}

- Reduces hold times
- Works regardless of anticoagulation levels

Minimizes post procedure care^{1,2}

- Reduces complication rates
- Facilitates same-day discharge

Improves lab efficiency^{1,2}

- Reduces clinician burden, time and costs
- Increases patient throughput



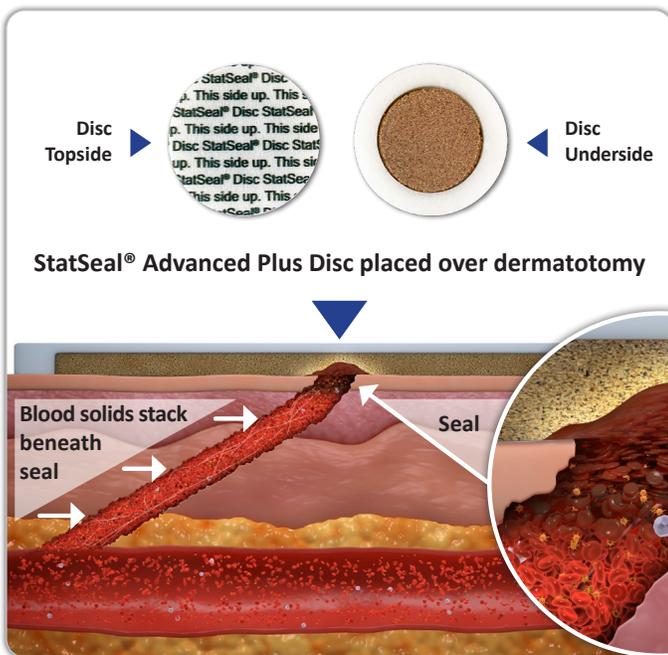
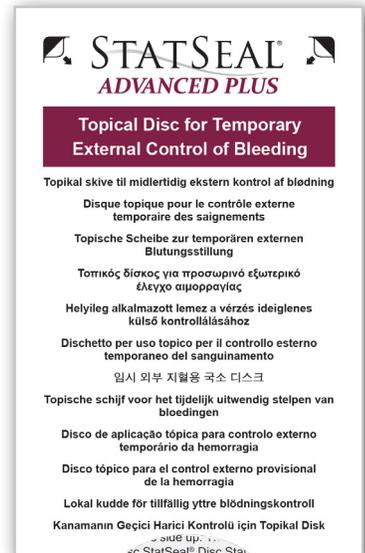
ATRIAL FIBRILLATION STUDY¹

This investigator-initiated study performed at the Essex Cardiothoracic Centre in the UK, evaluated using StatSeal Advanced Plus Disc for femoral vein groin closure of atrial fibrillation (AF) ablation patients who remained on their anticoagulation medications. The previous closure method used was physician-placed sutures. StatSeal use resulted in a more than 50% decrease in recovery time, with no rise in complications, allowing patients to safely mobilize and get home up to 1 hour earlier compared to the suture closure method. The study concluded that StatSeal use will likely lead to increased same-day discharge and less overnight stays following AF ablations.

Essex AF Ablation Study Results	Suture Closure Method	StatSeal Advanced Plus Disc
Median Recovery Time	4 hours	2 hours
Median Discharge Time	5 hours	2.5 hours

STATSEAL® ADVANCED PLUS DISC

StatSeal Advanced Plus Disc helps achieve fast, consistent hemostasis on multiple puncture sites, drastically shortening recovery time without increasing complications, even on patients prone to bleeding. StatSeal Advanced Plus Disc presents a cost-effective alternative to manual pressure, sutures, or closure devices. A single StatSeal Advanced Plus Disc can cover 2-3 puncture sites for a fraction of the cost of a closure device. Typically, just 10 minutes of consistent femoral compression with StatSeal is sufficient to achieve hemostasis. However, additional hold time may be needed depending on clinical judgment, patient condition, or product experience.



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. The distal tract seal helps promote stasis at the arteriotomy.³

References: [1] Peralta R, Sharma A, Srinivasan N, et al. Stat Seal Groin Closure After AF Ablation to Allow Rapid Same Day Discharge. AF Healthcare Pioneer Report. Jun 2023; 19-20. [2] Hartman M, VanElls S, Neuswanger A, et al. Utilizing a hemostatic agent to decrease post-ablation bedrest time: A pilot project. Poster presented at: Heart Rhythm Society; April 26, 2025; San Diego, CA. [https://www.heartrhythmjournal.com/article/S1547-5271\(25\)01593-0/fulltext](https://www.heartrhythmjournal.com/article/S1547-5271(25)01593-0/fulltext). Accessed June 16, 2025. [3] Biolife, LLC, 510(k) K080210, Section 18.3.