

WHAT IS STATSEAL®?

Standardize, simplify and minimize post procedure care and maintenance from cath lab procedures with StatSeal, a topical hemostat that quickly forms an occlusive seal to stop the flow of blood and exudates. Comprised of a hydrophilic polymer and potassium ferrate, StatSeal works independently of the clotting cascade to seal the site, while **accelerating hemostasis and reducing hold times by 50% or more**, regardless of anticoagulation levels.¹⁻³

THE STATSEAL SOLUTION

StatSeal is available in both powder and disc (compressed powder) form to suit a wide variety of clinical applications, from bleeding control after closure device deployment, to sheath removals from diagnostics and interventional procedures. Integrating StatSeal into cath lab protocols has been found to result in significant clinical, economical and operational efficiencies.¹⁻³

Instantly creates an occlusive seal

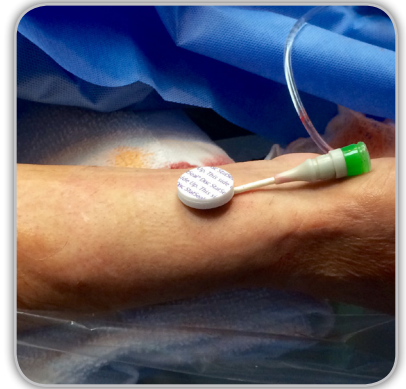
- Significantly accelerates hemostasis; seal strengthens with pressure and over time¹⁻³
- Reduces hold times by 50% or more¹⁻³
- Creates a hostile barrier to microbial penetration⁴

Minimizes post procedure care

- Facilitates same-day discharge; seal goes home with patient
- Improves hemostasis time, without increasing hematoma rates¹⁻³
- Allows for timely re-access of site

Improves outcomes

- Minimizes site complications; improves patient comfort and satisfaction¹⁻³
- Reduces nursing hours and increases patient throughput¹⁻³
- Reduces material cost; less expensive than pads, patches or closure devices³



Above: Radial procedure site with StatSeal Advanced Disc



Above: Electrophysiology procedure site with StatSeal Advanced Powder

ACCELERATE RADIAL HEMOSTASIS

Utilization of StatSeal Advanced Disc in Transradial Cardiac Procedures²

The cath lab in a well recognized heart hospital in Arkansas initiated a study in which the StatSeal Advanced Disc was utilized on all patients having diagnostic and PCI procedures. The results were advantageous and found **StatSeal Advanced Disc simple to use, safe, and effective in achieving rapid hemostatic band deflation, despite anticoagulation**. No increase of complications or evidence of acute radial arterial occlusion were observed.

StatSeal Advanced Disc Procedure Data Summary			
		PCI	Dx
N		15	36
Minutes to full deflation	mean range	44.3 40 - 50	44.72 40 - 50
Hematoma (Class I)		0	1 (1.9%)
Hematoma (Major)		0	0
RAO		0	0

STATSEAL IN CATH LAB PROCEDURES

Radial

StatSeal, in conjunction with any radial hemostasis band or manual pressure, can help standardize, simplify and shorten the recovery process to under an hour.

For radial procedures:

- StatSeal Advanced Disc
- StatSeal Advanced RAD Disc

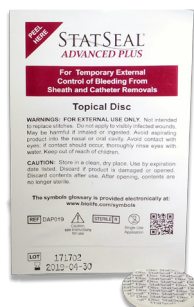


Femoral

As a manual pressure adjunct, StatSeal controls external bleeding from sheath removal and oozing after closure device deployment, while minimizing hematoma risk.

For femoral procedures:

- StatSeal Advanced Plus Disc



Electrophysiology

StatSeal helps achieve fast, consistent hemostasis on sheath removals, drastically shortening recovery time, even on patients who are prone to bleeding.

For electrophysiology procedures:

- StatSeal Advanced Powder

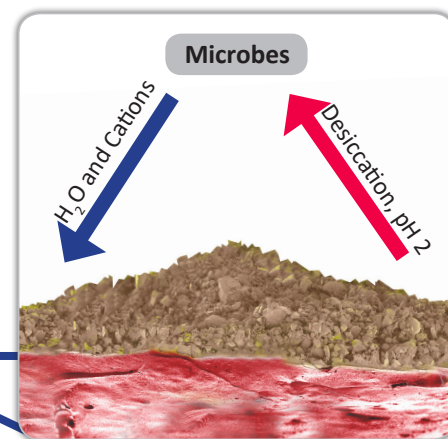
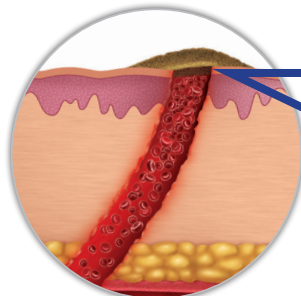


HOW DOES STATSEAL WORK?

As a manual pressure adjunct, StatSeal's mechanism of action is two-step and occurs simultaneously to instantly form a low pH, "nothing in/nothing out" seal or physical barrier:

- The hydrophilic polymer rapidly dehydrates the blood and absorbs exudate, stacking up blood solids beneath to form a seal.
- The potassium ferrate agglomerates the 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.⁴



Above seal: pH=2
Below seal: pH=neutral

References: [1] Condry H, Jara C. Use of StatSeal Advanced Disc to Decrease Time to Hemostasis in Transradial Cardiac Procedures/ A Quality Improvement Project. International Journal of Nursing Science. 2016; 6(4):103-107. [2] Rollefson W, Nash G, Cilingiroglu M, et al. Utilization of Potassium Ferrate Hemostatic Disc to Accelerate Time to Hemostasis in Transradial Cardiac Procedures. Poster presented at SCAI, Orlando, FL. 2016; May. [3] 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. [4] Biolife, LLC, 510(k) K080210, Section 18.3