

STATSEAL®

WHAT IS STATSEAL®?

Standardize, simplify and minimize post procedure care and maintenance of vascular access sites and wounds with StatSeal®, a topical dressing that quickly forms a seal to stop the flow of blood and exudates.¹ Comprised of a hydrophilic polymer and potassium ferrate, StatSeal works independently of the clotting cascade to form a seal, which protects the site from contamination.

StatSeal is non-prescription, hypoallergenic, non-systemic and passed all FDA-required biocompatibility testing. It does not contain CHG and has no age contraindications.

THE STATSEAL SOLUTION

StatSeal is available in both powder and disc (compressed powder) form, to suit a wide variety of clinical applications.

Instantly creates a seal

- Prevents oozing and bleeding
- Creates a hostile barrier to microbial penetration²
- Works with any protein-rich body fluid

Minimizes dressing changes^{1,3}

- Reduces site exposure^{1,3}
- Eliminates need for 24 to 48 hour post-insertion dressing changes^{1,3}
- Keeps sites dry and intact^{1,3}

Improves outcomes

- Reduces nursing time, material cost and risk of infection^{1,3}
- Improves delivery of atraumatic care
- Improves patient comfort³



Above: Access site sealed with StatSeal Powder

CLABSI REDUCTION STRATEGY¹

The NICU unit at a large academic medical center in the southwestern United States initiated a quality improvement project to effectively reduce CLABSI rates. By utilizing a dedicated PICC maintenance team and standardizing CLABSI bundles, which included the prophylactic **use of StatSeal in the dressing change protocol**, the NICU unit was able to **decrease the CLABSI rate by 92%**, equaling a reduction of 7 CLABSI infections over 3 years.

★ StatSeal was integrated into the protocol in March, 2014.

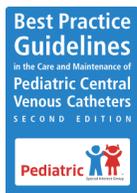
Year	CLABSI Rate Per 1000 Pts	Total CLABSI Infections
2011	3.9	8
2012	1.5	5
2013	1.4	5
2014	0.26	1

STATSEAL®

STATSEAL® APPLICATIONS

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

- PICC/CVC placement
- Peripheral artery lines
- Chest tubes
- Circumcisions
- Umbilical lines
- Skin tears
- Procedures resulting in external bleeding



AVA GUIDELINES: PEDIATRIC CENTRAL VENOUS CATHETERS

“Evolving practices include the use of a hemostatic agent at the CVC site . . . as a strategy to prevent bleeding.”⁴

HOW DOES STATSEAL WORK?

As an adjunct to manual pressure, 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.²⁻³

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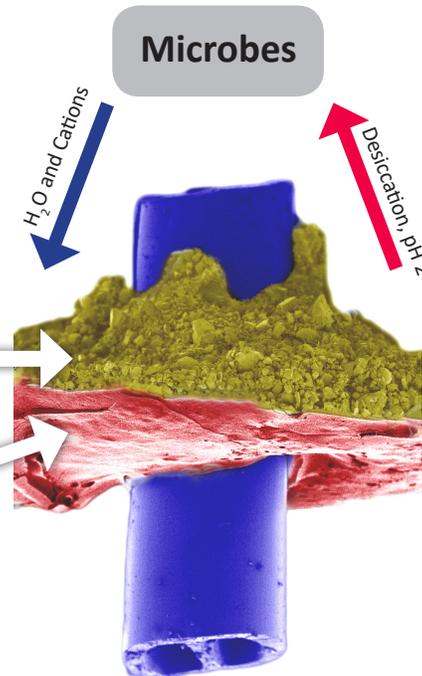
The Seal

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



Above: Access site sealed with StatSeal Powder

Below: Actual scanning electron microscopy image of StatSeal on an access site



References: [1] 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. [2] Biolife, LLC, 510(k) K080210, Section 18.3 [3] 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. [4] Doellman D, Buckner J, Garrett J, et al. *Best Practice Guidelines in the Care and Maintenance of Pediatric Central Venous Catheters.* 2nd ed. Association for Vascular Access; 2015:41.

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StatSeal® is Manufactured by Biolife, LLC