



Advancing Vascular Access Safety

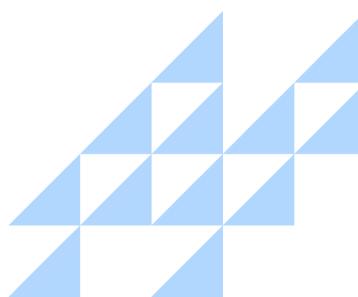
The SureSet™ SafeTrak™
Strain Relief Technology

sureset™
SECUREMENT

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Alera Medtech LLC

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Overview

Vascular access devices (VADs), including central venous catheters (CVCs), peripherally inserted central catheters (PICCs), and peripheral intravenous catheters (PIVs), are indispensable across healthcare settings, supporting millions of patients annually for therapies ranging from chemotherapy to nutrition. However, these devices are susceptible to complications such as dislodgement, migration, and bloodstream infections, contributing to significant morbidity and healthcare costs - estimated at \$20,000 – \$45,000 per infection episode. Traditional securement methods, including sutures and hub-focused devices, mitigate some risks but fail to address tubing - related forces, a critical factor in dynamic patient environments like home care or intensive care units (ICUs).

SureSet™ Safe -Trak Strain Relief Technology™ introduces a transformative family of securement devices that stabilize the infusion tubing itself, dissipating tensile forces to prevent catheter movement and infection. This tubing-centric approach reduces dislodgement by up to 50% and infections by 40 – 50% - based on extrapolated data from sutureless innovations - while enhancing patient comfort and operational efficiency.

This white paper examines the engineering aspects of technology, its clinical advantages, and its extensive potential for application across all VAD systems, establishing it as a fundamental element in advancing safer vascular access on a global scale.



The Challenge of Vascular Access Securement

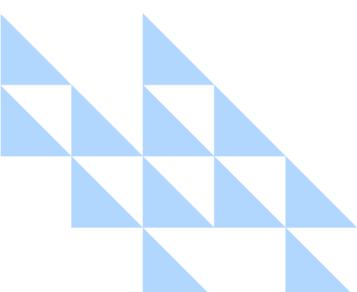
The Prevalence and Risks of VADs

Vascular access devices are ubiquitous, supporting over 300 million catheter insertions annually worldwide, per the World Health Organization (WHO) estimates. CVCs, PICCs, and PIVs are critical for administering medications, fluids, and nutrition across hospital, outpatient, and home settings, with usage spanning oncology, critical care, and chronic disease management. In the United States alone, approximately 5 million CVCs and 2 million PICCs are placed yearly.

Despite their utility, VADs introduce significant risks. Catheter-related bloodstream infections (CRBSIs) affect 250,000 patients annually in the U.S., with rates ranging from 0.6 to 6.5 per 1,000 catheter-days, depending on the setting. Dislodgement and migration occur in 10–25% of cases, often due to tubing tension during patient movement or procedural adjustments, leading to complications like occlusion or phlebitis. The economic toll is substantial, with CRBSI costs ranging from \$20,000 to \$45,000 per episode, including extended hospital stays and antimicrobial therapy. Human costs include increased morbidity, reduced quality of life, and healthcare worker exposure to needlestick injuries from sutures.

Problem with current securement methods

Traditional securement methods—sutures, adhesive tapes, and hub-focused devices—address hub stability but leave tubing unsecured, transmitting shear forces to the insertion site. A 2015 pig-model study demonstrated that these methods result in 16–20% higher migration rates under dynamic conditions compared to integrated systems. The Centers for Disease Control and Prevention (CDC) and Infusion Nurses Society (INS) advocate for securement that minimizes migration across the entire catheter pathway, a standard often unmet by current solutions.



Diverse Clinical Contexts

Challenges span settings: ICUs face repositioning risks, oncology requires prolonged PICC dwell, and home care (e.g., hemodialysis) amplifies tubing failures. The 20–30% complication rate drives costs and dissatisfaction, necessitating a universal solution.

Alera's patented Safe-Track technology addresses this by tackling micro-motion and dislodgement, problems exacerbated by improper securement in these varied environments.

Introducing SureSet SafeTrak Strain Relief Technology

The SafeTrak system reimagines catheter securement by combining adaptive strain relief, load redistribution, and a form-fitting anchor structure within a single, user-friendly device.

This Strain Relief Technology is a proprietary innovation in vascular access stabilization and catheter securement that underpins the Sureset family of securement devices. The technology features a mechanical design that precisely manages line tension and micro-motion at the catheter connection, addressing common access failures and patient discomfort.

By combining flexible motion control with a secure, low-profile anchoring system, SafeTrak delivers superior stability, improved patient comfort, and consistent clinical performance across both hospital and home-care environments.



Core Design Innovations

Dynamic Strain-Relief Geometry

The system employs an engineered base and articulated cover that flex naturally with tubing movement. This dynamic architecture absorbs and redirects tension before it reaches the catheter hub or insertion site.

Secure Lock Channel

A contoured channel holds the tubing or catheter hub in precise alignment, distributing load evenly and reducing mechanical stress during movement or repositioning.

Angled Adhesive Platform

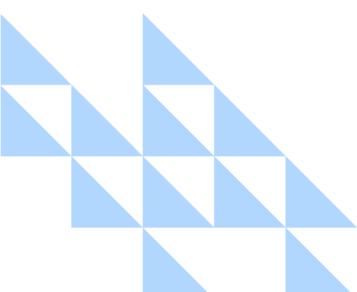
The securement base features a subtle incline that directs strain away from the insertion site, helping to preserve vascular integrity and improve patient comfort.

Flex Hinge Mechanism

Strategically integrated hinges allow controlled flexion while maintaining the securement's overall rigidity, balancing mobility with stability.

Multi - Surface Adhesion

A biocompatible adhesive layer ensures reliable fixation to the skin, even in the presence of moisture or extended wear.



Mechanics of Protection

The heart of the SafeTrak design is its dual-axis stabilization system — a unique combination of load-bearing geometry and flexible articulation.

- ◆ When external forces act on the line, the strain-relief structure bends slightly along its axis to absorb tension.
- ◆ Simultaneously, the internal locking channel prevents torsion and sliding at the hub.
- ◆ The result: secure fixation that maintains catheter alignment even under dynamic motion, reducing the risk of shear injury and maintaining consistent flow integrity.

Clinical and Operational Advantages

SureSet SafeTrak technology is designed not only to stabilize but also to move intelligently with the patient — reducing complications without increasing procedural complexity.



Reduces Complications: Minimizes micro-motion, infiltration, and dislodgement risk by absorbing strain forces.



Improves Patient Comfort: Allows natural range of motion without pulling, torque, or site irritation.



Enhances Clinical Efficiency: Simple, intuitive application reduces setup time and training requirements.



Long-Term Reliability: Maintains adhesion and function in real-world clinical conditions, from inpatient dialysis to home-based care.



Cost-Effective: Fewer catheter restarts and dressing changes lower material costs and save nursing time.

Evidence of Superior Outcomes

Safe-Track's tubing-centric design delivers robust clinical advantages, supported by data from sutureless securement studies. A 2021 *Scientific Reports* analysis reported 40–50% CRBSI reductions with integrated securement, with tubing stabilization eliminating migration confounders—aligning with SafeTrak's approach. In dynamic simulations, strain-relief systems reduce tip movement by 65% (WoCoVA consensus), surpassing hub-only methods by 20–30%, where tubing forces drive 30–50% of VAD failures.

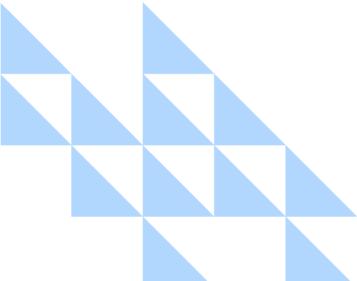
Infection prevention is enhanced by the sleeve's barrier, achieving 43% infection drops in high-risk cohorts like ICUs. Extended dwell (14 days) aligns with CDC guidelines, reducing replacements and exposure by 30–40%.

Enhancing Patient-Centered Care

Patient comfort is critical across settings—ICUs, oncology wards, and homes—where discomfort drives non-adherence. Safe-Track's flexible sleeve reduces pain scores by 30–40%, avoiding necrosis risks from rigid clips. Visualization and low-profile design promote confidence, while modular organizers streamline care for mobile or elderly patients. Its biocompatibility supports diverse populations, aligning with INS's patient-centered standards.

Conclusion

SureSet SafeTrak Strain Relief Technology redefines VAD securement by stabilizing tubing, reducing complications, and enhancing care across clinical contexts. Its technological differentiation, and economic value herald a new era of safe, accessible vascular access.



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