The First FDA Approved and Novel Cyanoacrylate Product for Catheter Securement

Amanda Guido, Sheng Zhang and Marcia Wise
Adhezion Biomedical, LLC

Copyright © 2018
Contact Information:
Sheng Zhang and Amanda Guido
Email: szhang@adhezion.com
Phone: 828-728-6116 x 654

Introduction:

Each year over 1 billion intravascular catheters are used world wide. Complications such as Dislodgments, Phlebitis, and CRBSI occur in about 69% of all intravascular catheters when secured with the current standard of care. The current standard of care includes adhesive tapes, transparent dressings, or stabilization devices. In order to address the high rate of complications, SecurePortIV was developed. SecurePortIV is a medical grade cyanoacrylate adhesive that provides securement to the catheter hub and the insertion site and has the capabilities to prevent infection and provide hemostasis at the point of skin entry. SecurePortIV provides a 3 in 1 solution to intravascular catheter securement.

In Vivo Catheter Securement

SecurePortIV successfully secured PVCs, PowerPICCs, and CVCs subjected to stress tugs every hour for six hours. All catheters secured with SecurePortIV and secured in combination with Tegaderm 1683 successfully withstood all stress tugs. Figure 1 (To the right): Representative Image of In vivo Study Securement.

In Vitro Catheter Securement:

- SecurePortIV is significantly stronger than Tegaderm I.V. Advanced and Statlock
- Table 1: Adhesion Strength of SecurePortIV Compared to Competitor Products After 6 hours of Securement

Catheter Type	Securement Method	Adhesion Strength (lbf.) 6 hours After Initial Securement
BD Autoguard Catheters	SecurePortIV	3.300
	Statlock	0.544
	Tegaderm	1.883
	Dermabond	2.175
	Histoacryl	2.694

- SecurePortIV is up to 10x Stronger than Competitor Products such as Opsite, Hubguard, Durapore and Tegaderm
- Table 2: Adhesion Strength of SecurePortIV Over Time

Time After Initial Securement with SecurePortIV	Adhesion Strength (lbf.)	
	Catheter Type	
	BD Autoguard Catheters	BD Nexiva Catheters
3 mins.	1.017	1.709
30 mins.	2.804	3.008
6 hrs.	3.300	3.720
1 day	3.850	3.056
3 days	3.383	3.018
7 days	3.677	3.535

Sealant and Water Barrier:

- Figure 2 (to the right): SecurePortIV Sealant Layer Compared to Control Sample
- BD AutoGuard Catheter Secured with SecurePortIV.
- Aqueous Dye Applied On Secured Catheter and Left to Rest for 7 Days.
- After 7 Days the Dye was washed off and the insertion site was free from penetration

Results

In Vivo Hemostasis

- SecurePortIV preformed equivalently to known hemostats; Kaltostat and Gelfoam Powder.
- SecurePortIV provided Significant Hemostatic Effect Compared to Sham Control
- Figure 3 (To the right): Representative Image of In Vivo Hemostasis Study in Porcine

Clinical Hemostasis:

- Figure 4: (below) Before (a) and After (b) Images of hemostasis achieved in cancer patient with addition of SecurePortIV

In Vitro Hemostasis:

- SecurePortIV Reached Hemostasis 12 X Quicker Than Thromboplastin

Infection Prevention:

- Figure 5 (to the Left - top) Immobilization of SecurePortIV Formula
- Figure 6 (to the Left - bottom): Reference Publication on SecurePortIV & FloraSeal Formulation Immobilization Properties

Safety:

- SecurePortIV is FDA Approved for use to Secure Catheters and has passed all biocompatibility testing.
- Figure 7: (to the right) SecurePortIV Safely Used on the Sensitive Skin of an Infant

Conclusions:

- First Cyanoacrylate FDA Approved for use with Vascular Access Devices.
- Up to 10X Stronger than Conventional Securement Dressings Alone
- Reduces Catheter Movement, Migration, and Dislodgement
- Immediately Water-Resistant, Seals Insertion Site, Helps Prevent Early Dressing Changes
- Active against gram-negative and gram-positive bacteria, yeast, and fungi, Microbial Immobilization