



# The Science of a “Seal” for PICC Line Management: BioSeal CVC Powder

## An Alternative Hemostatic Agent That Keeps Sites Dry and Intact

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### Abstract

*The Science of a “Seal” for PICC Line Management: BIOSEAL CVC Powder As An Alternative Hemostatic Agent That Keeps Sites Dry And Intact*

### Purpose

*To assess the ability of BIOSEAL CVC™ Powder (Biolife, LLC, Sarasota, FL) to achieve hemostasis for Peripherally Inserted Central Catheter (PICC) line insertions; to eliminate the 48 hour dressing change prescribed by Centers for Disease Control.*

### Introduction

The Venous Access Services (VAS) team of Florida Hospital identified an alternative hemostatic agent for PICC line management in an effort to increase patient comfort and achieve time and financial savings.

### Review of Relevant Literature

The benefits of PICC lines as a safe and effective method of delivering infusion therapy has been clearly outlined by Paul (2007) and Burns (2005). Davis and Kokotis (2004) documented the financial improvements related to PICC lines, while Robinson et al (2005) demonstrated the efficiencies and safety related to a dedicated PICC line team. Patel (2007) documented the infection prevention benefits related to PICC line use in the intensive care patient.

### Methods

The researchers chose an observational retrospective study design and a convenience sample to perform this study. During a 39-day period, BIOSEAL CVC™ Powder was evaluated for all PICC line insertions (418) and for occasional bleeding at dressing changes or line discontinuations. A Case Reporting Form (CRF) was used to record the VAS nurses findings. Following product application, VAS staff rated the efficacy of the product as compared to controls: gauze and oxidized cellulose

gauze that was routinely used for problematic bleeds. Time to hemostasis was also recorded.

### Results

- **98%** of VAS nurses considered BIOSEAL CVC™ Powder to be effective for controlling PICC line access site bleeding
- In **94%** of applications BIOSEAL CVC™ Powder effectively stopped bleeding in  $\leq 2$  minutes
- Approximately **40%** reduction in Catheter-related Bloodstream Infections during and after trial according to a post-hoc review of catheter related infection trends
- No site infections or other complications associated with product use

### Conclusions

Results demonstrated an overwhelming majority of the VAS nurse team preferred BIOSEAL CVC™ Powder relative to the gauze control standard of care. BIOSEAL CVC™ Powder was considered to be effective in controlling PICC line access site bleeding. Extended post trial use of BIOSEAL CVC™ at Florida Hospital demonstrated a significant decrease in Catheter-related Bloodstream Infections with potential for substantial time and cost savings for PICC line management.

### Implications for Practice

Reduction in nursing time and cost with removal of the 48 hour dressing change. Perceived patient comfort with fewer manipulations to site.

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## Background

As a leading provider of patient healthcare, Florida Hospital Orlando (FHO), with 1,500 beds, uses an experienced team of registered nurses (RNs) who are in charge of Peripherally Inserted Central Catheter (PICC) line insertions, maintenance and discontinuation. This Venous Access Services (VAS) team included 23 certified PICC RNs and 8 RNs trained in maintenance and care of PICC lines, at the time of the study.

The challenge placed before all healthcare providers to attain a 'zero BSI' and maintain efficiencies within the workplace has set the stage for innovative ideas and products. The Venous Access Service team of Florida Hospital identified an alternative hemostatic agent for PICC line management to improve patient outcomes and achieve time and financial savings. BioSeal CVC™ is a topical powder that has allowed the VAS Team to attain the goal of time savings and cost savings while moving toward a 'zero BSI' (Picture 1).

Prior to this study, the VAS team was using a gauze wick on every PICC site to control bleeding and absorb exudate from the insertion process. Exudate is defined as the collective substances, plasma and blood cells, that respond to an area of injury as facilitators of the inflammatory response (McCance and Heuther, 1998). According to Infusion Nurses Society (INS) Standards of Practice (2006) and the Centers for Disease Control (CDC) guidelines for the prevention of Catheter Related-Blood Stream Infections (CRBSIs), gauze dressings must be changed within forty-eight (48) hours. This practice, although meant to decrease infection by removing the soiled gauze and give opportunity to assess the site, does provide opportunity for contamination of the site and dislodgement of the catheter. This practice adds to the cost of patient care. For many patients the removal of the dressing creates damage to the skin.

According to the equipment and supply charges logged on each PICC patient, approximately 20% of cases at FHO experienced problematic bleeding. For these cases it was necessary to use oxidized cellulose gauze. This is an expensive product used in many invasive procedures to control bleeding. The VAS team at FHO found the disadvantages of this product were not only the cost but the characteristic of the gauze after it is activated and then dries into a hard object at the site which stresses the skin integrity of many patients. Unlike BioSeal CVC™ powder, the hemostatic cellulose gauze is not a sealant or barrier.

## Review of the Literature

The clinical value of peripherally inserted central catheters was first recognized for the infusion of antineoplastic agents, antibiotics and parenteral nutrition, all of which potentially benefit from rapid hemodilution or minimized endothelial contact time of irritant solutions and chemicals. Traditionally, PICC lines are inserted in the antecubital fossa of an arm by a specially trained nurse or radiologist (Paul, 2007; Burns, 2005). Procedurally, venipuncture may be accomplished with a standard peripheral catheter and, once venous access is gained, the central catheter is inserted through the peripheral catheter and threaded to a predetermined length based on pre-procedure measurements. The distal tip of the catheter usually lies in the superior vena cava, thus the rapid hemodilution. More recently technology has improved

Picture 1.



the PICC nurses ability to gain upper arm access therefore providing the patient with venous access that has less complications, is more comfortable and dwells longer (Simcock, 2008).

With respect to their clinical benefits, Burns (2005) reported on the results of a five-year retrospective study on PICCs with Pressure Activated Safety Valve (PASV) Technology, indicating a significant reduction in rates of both occlusion and infection.

In addition to their clinical benefits, the financial gains of PICCs are also becoming more apparent (Davis and Kokotis, 2004). For example, Robinson et al. (2005) reported a prospective study to determine if a team dedicated to placing PICCs would improve patient care and reduce costs. In their study, a dedicated team of physicians, physician assistants, nurses, and interventional radiologists was established to coordinate and approve all PICC placements. The authors concluded that a dedicated PICC team improves patient care by preventing inappropriate PICC placements and decreasing patient waiting times.

To determine whether using PICCs in intensive care decreases CRBSIs, Patel et al (2007) performed a retrospective review of a central-line database before and after the introduction of hemodynamic monitoring with PICCs in a closed, medical-surgical, 20-bed intensive care unit and a 10-bed intermediate care unit of a tertiary-care academic medical institution. CRBSI rates were compared for a 12-month control period and a 36-month intervention period with open-ended PICCs. Two thousand four hundred seventy-four central vascular catheters were inserted in 1788 critically ill patients (21,919 catheter-days). During the control period, centrally inserted central catheter (CICC) median dwell time was 6.4 days, with a CICC CRBSI rate of 2.3 per 1000 catheter-days and a total CRBSI rate of 1.6. During the third intervention year, CICC median dwell time was 3.2 days (50.0 % reduction;  $P < 0.001$ ), CICC-related CRBSIs were eliminated, and the total CRBSI rate was 0.3 per 1000 catheter-days (81.0 % reduction;  $P < 0.001$ ). These authors concluded that using open-ended PICCs in intensive care may be associated with shorter CICC dwell times, reduced CRBSIs, and reduced antibiotic usage; but, that further studies are necessary to evaluate early PICC utilization as part of future central-line infection prevention initiatives, especially considering their use may save more than 6000 lives and \$1.1 billion annually.

**Table 1. Procedural Cost Analysis**

| <b>Cost/Benefit Analysis</b>                 | <b>Surgicel</b>     | <b>BioSeal</b>      | <b>Savings</b>      |
|--|---------------------|---------------------|---------------------|
| Nursing Cost Per Hour                        | \$43.17             | \$43.17             |                     |
| Hours per work shift                         | 12                  |                     |                     |
| # dressing changes per Hour                  | 2                   |                     |                     |
| Average # dressing changes per work shift    | 24                  |                     |                     |
| Nursing cost for dressing change             | \$21.59             | \$21.59             |                     |
| Average cost of dressing change kit          | \$4.77              | \$4.77              |                     |
| Total Cost of Nursing time per Hour          | \$26.36             | \$26.36             | \$0.00              |
| <b>If Bleeding Complications:</b>            |                     |                     |                     |
| Cost of additional products:                 | \$58.00             | \$20.00             |                     |
| % of time additional products used:          | 20%                 | 100%                |                     |
| Total Cost if Bleeding Complications:        | \$11.60             | \$20.00             | -\$8.40             |
| <b>Cost of Dressing Change @ 24/48 Hours</b> |                     |                     |                     |
| Cost of Dressing Change @ 24/48 Hours        | \$26.36             | 0                   | \$26.36             |
| <b>Total Cost of Patient Care</b>            |                     |                     |                     |
| Total Cost of Patient Care                   | \$64.32             | \$46.36             | \$17.96             |
| <b># of PICCS/Month</b>                      |                     |                     |                     |
| # of PICCS/Month                             | 500                 | 500                 |                     |
| <b>Cost Per Month</b>                        | <b>\$32,160.00</b>  | <b>\$23,180.00</b>  | <b>\$8,980.00</b>   |
| <b>Cost Per Year</b>                         | <b>\$385,920.00</b> | <b>\$278,160.00</b> | <b>\$107,760.00</b> |

**Purpose of Study**

To assess the ability of BIOSEAL CVC™ Powder to achieve hemostasis/seal for PICC line insertions, to eliminate the need for oxidized cellulose gauze and to eliminate the 48 hour dressing change and any other compromised dressing changes through 7 days; assessment of the product ease-of-use at the time of application and the vascular access site tissue integrity upon removal. A post-hoc assessment of potential complications such as infection, bleed-through, skin impressions and rash due to the use of BIOSEAL CVC® Powder was also conducted. The advantages of PICC lines include the relative ease of insertion, long dwell time, and optimal hemodilution as may be required for some medications, increased patient comfort due to decreased need for peripheral venipuncture, and a low complication rate (Burns, 2005). The management of PICC lines is generally considered a minor aseptic procedure. Typically, dressing changes are prescribed 24-48 hours post insertion, and then weekly unless 1) the dressing is compromised 2) there is exudate under the dressing, or 3) the dressing is wet or soiled. Clearly, elimination of the 48 hour PICC line dressing change would save valuable staff time and contribute to increased patient comfort. The purpose of the study, therefore, was to assess the ability of an alternative dressing to reduce the frequency of PICC line dressing changes.

**Objectives**

The primary objectives were to evaluate the efficacy of Bio-life's BioSeal CVC Powder for achieving rapid hemostasis and the effect on nursing time for PICC site wound management resulting from the elimination of the standard 48 hour dressing change protocol.

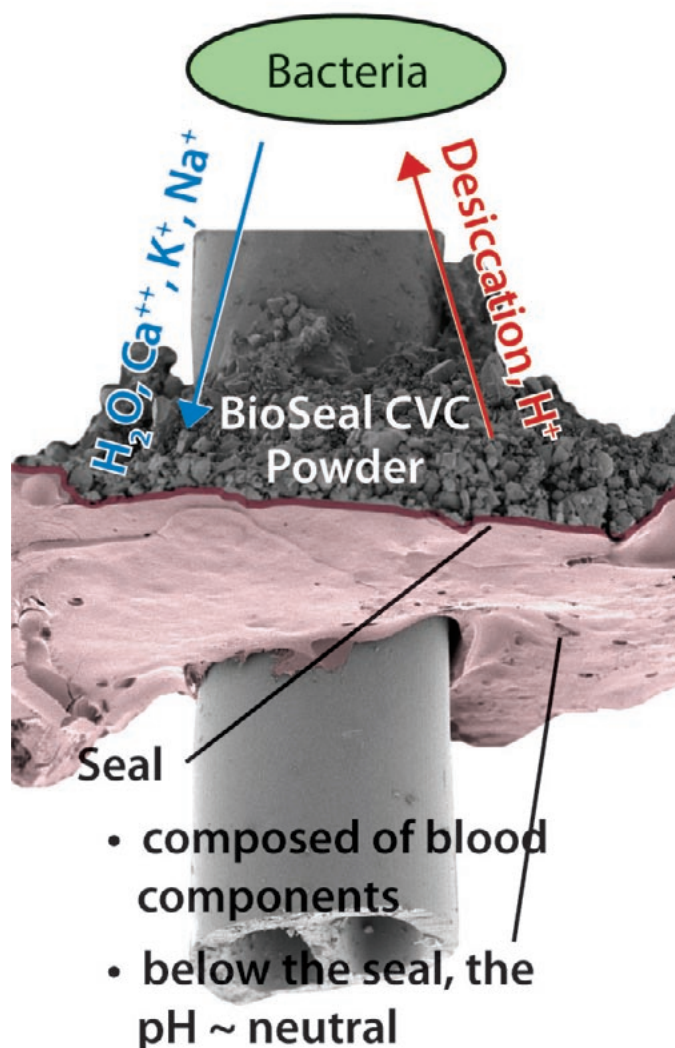
Secondary objectives were to report the incidence of complications such as re-bleeds, hematomas, skin integrity issues, frequency of catheter-related bloodstream infections, and other observations that occurred during the evaluation. A cost analysis of using the BioSeal CVC powder was conducted post evaluation (Table 1).

**Definition of Terms**

BioSeal CVC Powder is an FDA Cleared not approved topical powder made of a hydrophilic polymer and potassium ferate. The powder's mechanism of action coagulates interfacial blood proteins to form an occlusive seal, independent of the clotting cascade, to protect an access site and keep it dry and intact. The seal keeps blood and exudates from coming out of the site and microbes and air from going in. The "BioSeal" allows nothing in, nothing out of the site.

The area above the 'seal' has a unique function towards the building of a microbial barrier. The bacteria which are full of wa-

Picture 2.



ter and salts come in contact with the powder on the top side of the seal which contains water, calcium, sodium, and potassium. As a result, the bacteria desiccate. The moisture that is pulled from the bacteria contains salts. The cations of these salts are then exchanged for hydrogen, creating an acidic or low pH environment of approximately 2 at the seal and powder interface.

Below the ‘seal’ the BioSeal powder floats on the blood – it doesn’t penetrate the seal. This results in a neutral pH below the seal (measured at 7.4 in a saline extraction of a laboratory-created seal).

BioSeal CVC is a bone dry potassium ferrate/strong acid cation exchange resin powder. The dry powder absorbs blood liquid and rejects blood solids, forming an interfacial layer of blood solids between the skin and the powder. The blood liquids dissolve the ferrate. The iron cations coagulate interfacial proteins, forming a seal over the wound, independent of the clotting cascade. As more liquid is pulled through the seal, more blood solids accumulate under the seal until eventually the seal plugs and nothing oozes out and nothing can get in. Hemostasis is achieved.

Table 2.

Patient Age Code and Number of PICC Insertions

| Code   | Age Range (yrs) | No. insertions | %       |
|--------|-----------------|----------------|---------|
| 1      | <1 -10          | 4              | 2.1%    |
| 2      | 11-20           | 5              | 2.6%    |
| 3      | 21-30           | 12             | 6.3%    |
| 4      | 31-40           | 21             | 11.0%   |
| 5      | 41-50           | 26             | 13.6%   |
| 6      | 51-60           | 36             | 18.8%   |
| 7      | 61-70           | 35             | 18.3%   |
| 8      | 71-80           | 32             | 16.8%   |
| 9      | 81-90           | 19             | 10.0%   |
| 10     | 91-100          | 1              | 0.5%    |
| Totals |                 | 191            | 100.00% |

The powder also exchanges protons for cations, for example, from the cell wall of a bacterium. The interfacial pH drops to 2 and the bacterium cell wall is weakened. A microbial barrier is created (Picture 2).

#### Methodology

The retrospective evaluation was granted exempt status by the Institutional Review Board at Florida Hospital on 9/14/09. Data was collected in a de-identified format by the research team. Subjects could not be identified in the data set.

During a 39-day period, BIOSEAL CVC™ Powder was evaluated for all PICC line insertions (418) and for occasional bleeding at dressing changes or line discontinuations. Following product application, VAS PICC nurses completed written evaluations (case reporting form- CRF, Figure 1) to rate the efficacy of BioSeal CVC™ Powder as compared to the controls, gauze and oxidized cellulose gauze and record time-to-hemostasis. All CRF’s were reviewed for additional comments and information that revealed potential complications such as infections, bleed through, skin-impressions or rash due to product used on the PICC insertions during the study period. Historical control was for a one (1) year period and extracted from internal reports for comparison.

Patient subjects ranged in age from 14 days to 93 years. For analysis purposes the patient ages were grouped and coded. Of the 418 CRFs, 191 or 46% contained data for patient age. The average age was between 51-60 years. However, more than half of the patients were between 51-80 years. Table 2 depicts the frequency distribution of the patient population who received PICC line insertions during the 39 day study period. Patient sex was recorded on 235 of 418 CRFs for a 56% response. The distribution was 132 females and 103 males. Race was recorded on 403 of 418 CRFs for a 96% response. The distribution was as follows: 260 Caucasian, 83 Black, 48 Hispanic, 9 Asian, and 3 other. The ‘other’ response was not further defined by the VAS





**Table 3. Patient Demographics**

| Demographic                            | Responses/#CRF | % response | Result/Response | % result |
|--|----------------|------------|-----------------|----------|
| Clotting Difficulty                    | 341/418        | 82%        | 64/341          | 19%      |
| PT/INR high                            | 28/418         | 7%         | 22/28           | 79%      |
| Platelets low                          | 42/418         | 10%        | 33/42           | 76%      |
| Anticoag/Antiplatelet or Antibiotic Tx | 93/418         | 22%        | 47 on – 46 not  | n/a      |
| Cardiovascular drugs                   | 91/418         | 22%        | 7/91 Active tx  | 8%       |
| Analgesics                             | 91/418         | 22%        | 6/91            | 7%       |
| Insulin                                | 91/418         | 22%        | 2/91            | 2%       |

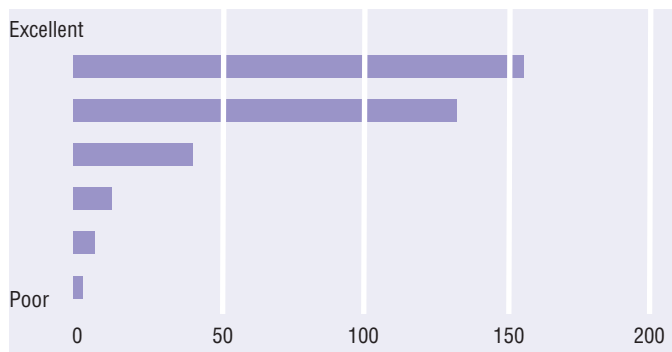
**Table 4. Hospital Unit/Dept. Code and Number of PICC Insertions**

| Code | Room Nos.  | Care Description                   | No. Insertions | %              |
|------|------------|------------------------------------|----------------|----------------|
| 1    | 1400s      | General Rehab                      | 3              | 1.0%           |
| 2    | 2500s      | Medical Unit - North               | 13             | 4.4%           |
| 3    | 2600-2700  | E Med Surg                         | 29             | 9.8%           |
| 4    | 3200-3300s | Cardiac Intensive Care (CICU)      | 59             | 20.0%          |
| 5    | 3500-3700s | Cardiac (Intervention, Rehab, etc) | 37             | 12.5%          |
| 6    | 4300s      | Surgical South                     | 6              | 2.0%           |
| 7    | 5200-5240  | Neuro Critical Care                | 23             | 7.8%           |
| 8    | 5250s      | ICU                                | 16             | 5.4%           |
| 9    | 5300s      | Neuroscience Unit                  | 6              | 2.0%           |
| 10   | 6200-6300s | Peds                               | 6              | 2.0%           |
| 11   | 7200s      | Tower 7                            | 19             | 6.4%           |
| 12   | 7300s      | Fracture Care Center               | 7              | 2.3%           |
| 13   | 8200s      | Tower 8                            | 21             | 7.1%           |
| 14   | 9200s      | Oncology                           | 17             | 5.8%           |
| 15   | 10200s     | Tower 10                           | 27             | 9.2%           |
| 16   | ED         | Emergency                          | 7              | 2.3%           |
|      |            |                                    | <b>296</b>     | <b>100.00%</b> |

**Table 5. Infections & PICC Infection Rate (Period 1 vs. Period 2)**

| Period | Months        | No. PICC Infections | PICC Line Days | Total PICCs Inserted | PICC Infection Rate |
|--------|---------------|---------------------|----------------|----------------------|---------------------|
| 1      | May-Oct 2007  | 12                  | 25232          | 3210                 | 0.4756              |
| 2      | Nov 07-Apr 08 | 7                   | 24323          | 2850                 | 0.2878              |

**Figure 2. Product Effectively Stops Bleeding Code and Number of Responses**



of PICC line insertions by unit code frequencies are shown as a percentage of total in Table 4. Of the 418 CRFs there were 296 which contained data for the specific hospital unit/department where the PICC line insertion was performed.

#### Data Analysis

Four-hundred eighteen usable CRFs completed by VAS nurses during the study period were reviewed and the data analyzed.

Pearson correlation ( $p < 0.001$ ) was used to examine the relationship between all trial variables. The primary variable was the time-to-hemostasis (relative to user-recalled standard-of-care times) and all co-variables which may impact this. It is noted that most of the CRF questions relate to bleeding time, but also product ease-of-use. If wound site re-bleeds are eliminated or reduced compared to user-recalled standard-of-care frequency, the product was considered “preferable” by user-response.

The percent of cases achieving hemostatis within two minutes was calculated as a total as well as broken down between patients with and without clotting problems. The percentage of cases was calculated for which a dressing change was required. Incidence of complications was calculated via frequency tabulation and was compared to internally recorded historical data. Descriptive data were tabulated from pre-evaluation infection rate compared to post evaluation infection rate at FHO. Cost analysis was conducted by comparing cost of products and secondary care of each product (e.g., dressing changes), and calculation of care costs using nursing wages and time to complete tasks (Table 1).

#### Results

The CRF’s revealed that 98% of respondents considered BIOSEAL CVC™ Powder effective for controlling PICC line access site bleeding (Figure 2). BioSeal CVC™ Powder effectively stopped bleeding in  $\leq 2$  minutes in 94% of applications. A post hoc assessment of the data demonstrated an estimated 40% reduction in catheter-related bloodstream infections (CRBSIs) (Table 5), no site infections or other complications. Tissue integrity ratings were excellent satisfying one of the secondary objectives that had concerned VAS team members with the use of oxidized cellulose gauze or the gauze wick (Table 6).

**Table 6. Tissue Integrity Rating**

| Rating        | No. Responses | %     |
|---------------|---------------|-------|
| 6 (excellent) | 51            | 77.3% |
| 5             | 4             | 6.1%  |
| 4             | 7             | 10.6% |
| 3             | 2             | 3.0%  |
| 2             | 1             | 1.5%  |
| 1 (poor)      | 1             | 1.5%  |
| Totals        | 75            | 100%  |

#### Conclusions

Results demonstrated an overwhelming user-preference for BioSeal CVC™ Powder relative to the gauze control standard of care. The product was considered to be effective in controlling PICC line access site bleeding or oozing. There was no difference in efficacy based on patient demographics or concomitant drug therapies. Extended post trial use of the product demonstrated the complete elimination of the 48-hour dressing change and a significant decrease in CRBSIs.

In addition to a decrease in CRBSIs, the hospital has realized efficiencies through decreased nursing time, cost savings (before fewer dressing changes, eliminated oxidized cellulose gauze) and perceived patient comfort (around fewer site manipulations and no reported complications).

#### Discussion

During the evaluation of the BioSeal CVC product some important points were discovered that lead to further investigation by the Biolife company. One is the ‘tug’ which has become synonymous with the integrity of the seal in the catheter tract. The initial exterior seal that is produced and is what has been explained in this article eventually falls off naturally. The discovery was that upon discontinuation of the PICC catheter the VAS nurses documented on the CRFs that they experienced a non-painful ‘light tug’ upon beginning removal of the catheter. It has been shown through further investigation that this represents a ‘seal’ developed within the skin tract of the catheter pathway to the vessel. Therefore, unless the catheter has been ‘pulled back’ or migrated in any direction, the initial seal is maintained until the catheter is removed thus providing potentially long term protection. Based on this, another protocol has been initiated at Florida Hospital, all campuses for PICC care and maintenance. When a catheter has ‘moved’, another ‘seal’ is created with the application of BioSeal CVC.

In April 2010, Florida Hospital implemented the use of BioSeal CVC for the removal of all percutaneous non-PICC catheters. This initiative is in response to the Centers for Medicare and Medicaid ‘Never Event’ list for air embolism and Florida Hospital’s own favorable long term experience using BioSeal on PICC lines. Additionally, there is a committee working toward approval to place BioSeal CVC powder on all percutane-

ous central line insertions in addition to the policy for PICC placement. Currently BioSeal CVC is approved for any central line bleeding or oozing.

#### Financial Disclosure

Biolife, LLC provided financial support for the presentation of this project at the 2009 AVA Convention in Las Vegas, including travel and accommodations for the primary author. The study was conducted without any external funding.

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