

# CLINICAL INSIGHTS

PATENTED TECHNOLOGY TO SEAL ACCESS SITES

## The Power of the Powder for Radial Hemostasis: Evaluation of BioSeal ADVANCED at Signature Healthcare Brockton Hospital

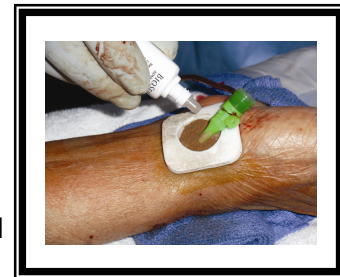
### BACKGROUND

The Helen Greene Cardiac Catheterization Suite of Signature Healthcare Brockton Hospital (Brockton, MA) is a 3,000-square foot unit comprised of two digital catheterization labs and a 6-bay holding area. The unit is staffed with two attending interventional cardiologists, two locum tenens, eight nurses and three cardiovascular technologists. 550 cardiac procedures are performed in the unit annually. Approximately 155 cases are interventional – about half are acute MIs and half are elective cardiac angioplasties.

Prior to 2010, most invasive cardiac procedures at Brockton were performed using the traditional femoral approach. To increase patient comfort and reduce complications, the cath lab began performing procedures using the transradial approach. This approach utilizes the radial artery located in the wrist. Generally, patients who undergo procedures through radial access experience fewer bleeding and vascular complications. Also, patients can sit up and ambulate faster following the procedure. Today, 85% of the unit's case volume employs radial access for diagnostic and interventional procedures.

### INTRODUCTION

Increased focus on the transradial approach at Brockton found the cath lab staff searching for a solution to quickly and effectively achieve hemostasis since there are no traditional closure devices for the wrist. The staff evaluated the Terumo TR band Compression Device but found it to be uncomfortable for patients and labor-intensive for the recovery staff.



Chief Cardiovascular Technician, Richard Botto learned about the efficacy of BioSeal to achieve rapid hemostasis following femoral procedures (mean time to hemostasis (TTH) of less than 4 minutes) from a study published in the *Journal of Vascular and Interventional Radiology*. He speculated that the lab could achieve fast hemostasis and reduce hold times for radial procedures using BioSeal thus increasing patient comfort. He specifically wanted to evaluate the efficacy of the product for patients with elevated Activated Clotting Times (ACTs).

BioSeal ADVANCED is a topical hemostatic powder that controls external bleeding from sheath removal following vascular access procedures. The powder is a mixture of a hydrophilic polymer and potassium ferrate. The powder forms an occlusive seal through simultaneous iron-mediated agglomeration of blood solids/proteins and rapid dehydration of the blood. This seal stops blood flow and provides a microbial barrier. Seal formation is independent of the clotting cascade so BioSeal is effective for patients on anticoagulant therapy or those with bleeding disorders.

### THE EVALUATION

During a five-month period, February to June 2011, BioSeal ADVANCED Powder was applied to 64 patients following radial access procedures as an adjunct to manual pressure. Procedures included 58 diagnostic catheterizations and six percutaneous transluminal coronary angioplasties.

Following product application, Brockton cath lab staff recorded TTH, time to ambulation (TTA) and time to discharge (TTD) for each patient. Demographic information including age, sex, known medical

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conditions, medications (including anticoagulants), blood pressure, INR, platelet level and ACT level was also recorded.

As previously noted, the objective of the trial was to evaluate the efficacy of BioSeal ADVANCED to achieve hemostasis for patients undergoing invasive cardiac procedures through transradial access, particularly for those with elevated ACT levels. Secondary objectives were to report the incidence of complications such as hematomas or rebleeds that occurred during the evaluation.

## RESULTS

**Average TTH was 4 minutes for all patients in the study.**

**Average hold time was 13 minutes.** Standard protocol at Brockton for holding pressure is 10 to 15 minutes. Technicians checked for hemostasis, which was achieved in a matter of minutes, but they were required to continue holding per current protocol.

**Average TTA was 2 hours.** Once hemostasis is achieved and patients are splinted, protocol dictates that they may sit up. However, the patient is still held in recovery so that sedation can wear off.

**Average TTD during the study was 4 hours. Note that since the evaluation, the physicians have signed off on a 2-hour time to discharge.**

Anticoagulation regimen for evaluated patients was as follows: **88% of patients were heparinized, 61% of patients were on aspirin therapy, 24% of patients were administered Angiomax and 11% of patients were administered Integrillin.**

**ACT level for all patients administered Angiomax were > 400 at sheath pull. For these patients, TTH averaged 7 minutes and hold time, 18 minutes.**

**There was no difference in efficacy based on drug therapies or blood chemistry.**

**NO incidents of rebleeding were noted.** In two cases (3.1%) oozing was noted after a 12 minute hold time, however an additional 10 minutes of pressure achieved hemostasis in both cases.

**NO Hematomas reported.**

## IMPLICATIONS FOR PRACTICE

Through an evaluation of BioSeal ADVANCED Powder for hemostasis following radial access, the Helen Greene Cardiac Catheterization Suite has **experienced a significant time savings since using BioSeal.** An overall average TTH of 4 minutes for all patients and 7 minutes for those patients with very elevated ACTs, in addition to a recently physician-approved change to a 2 hour TTD has increased efficiency and throughput for the lab.

Studies have shown that bleeding complications from radial procedures are generally fewer than traditional femoral procedures. Brockton's BioSeal evaluation produced no hematomas, no rebleeds and only two incidents of oozing. Also significant is patients' preference for radial access procedures over femoral access. Per Richard Botto, "Ask a patient who has had both types of procedures and they'll tell you there is no comparison. Radial is the only way to go. With BioSeal, patients can sit up within minutes of sheath pull and they report less back and body pain. They are much more comfortable and they can go home earlier after a procedure." According to Richard, BioSeal has allowed the lab to increase the number of radial procedures performed in the lab. "Everything we do is for clinical benefit and patient comfort. BioSeal ADVANCED is a great tool in that quest."