# Clinical Highlights

*A publication delivering concise clinical data*

VASCULAR CLOSURE

## Staged Procedures in Interventional Radiology: A Safe Clinical Alternative Using the Angio-Seal™ Vascular Closure Device


PRESENTED BY

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### INTRODUCTION

Dr. Curtis J. Brasseur is the Vice-Chair of the Radiology Department at Berkshire Medical Center in Pittsfield, MA which is a 300-plus bed, not-for-profit institution with a staff of 15 in the Interventional Radiology Department. On a typical day they will complete 8-10 procedures in the lab. Dr. Brasseur and the Interventional Radiology staff believe excellent clinical outcomes, improved lab efficiencies and patient comfort are important factors in the successful management of their patients.

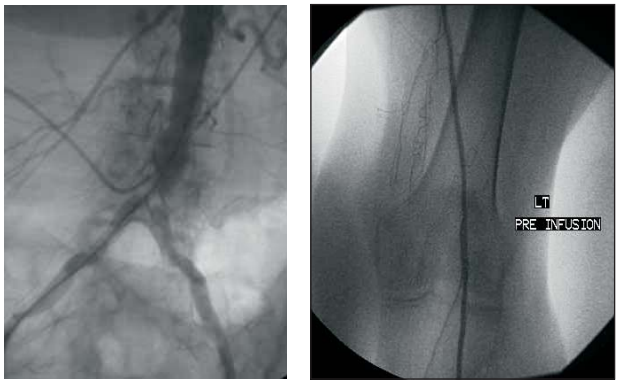
The Angio-Seal™ Vascular Closure Device was introduced into the interventional radiology lab two years ago and has positively impacted clinical practice and improved patient satisfaction. In select patients, Dr. Brasseur has been able to provide alternative treatments when utilizing an Angio-Seal™ Device to seal the femoral arteriotomy after an angiography procedure is complete. An example of such an experience is highlighted below.

### PATIENT HISTORY

A 64 year-old female with a history of smoking, diabetes and hypertension presented with a chief complaint of “cold left foot.”

### CATHETERIZATION PROCEDURE AND TREATMENT

Diagnostic angiography was performed by accessing the right common femoral artery (CFA) and inserting a 4F catheter. Angiography showed that this patient had bilateral iliac artery stenosis located at the abdominal aortic bifurcation and acute thrombus in the left lower extremity (LLE). The 4F catheter was then exchanged for a 7F introducer sheath. A 7F introducer sheath was also used to access the left CFA. Peripheral angioplasty and stenting were done to each of the iliac lesions. Due to the patient’s overall health and risk factors, Dr. Brasseur chose to treat the thrombus in a separate procedure the following day. He sealed both the right and the left femoral arteriotomies, using an Angio-Seal™ Vascular Closure Device.




**Initial Angiogram**

The next day, the second stage of the intervention, thrombolysis of the clot in the LLE was completed, using tPA. Dr. Brasseur re-accessed the left common femoral artery approximately 1cm. proximal to the original Angio-Seal™ Device, using an antegrade approach. Thrombolytic tPA was administered and the clot was successfully dissolved. After the thrombolysis procedure was completed, hemostasis was obtained by using an Angio-Seal™ Device. Between the two procedures, the patient received a total of three Angio-Seal™ Devices to ensure hemostasis. The patient had no complications with these two separate procedures.

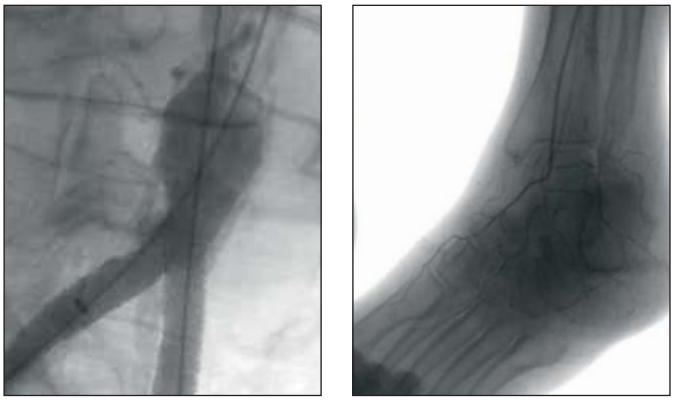
Follow-up at four months revealed the patient to be asymptomatic with good pulses.

## DISCUSSION

Dr. Brasseur feels strongly that the Angio-Seal™ Devices allowed him to provide the patient optimal treatment options with the least amount of risk. Dr. Brasseur states, "Without the effective hemostasis provided by the Angio-Seal™ Device, thrombolysis after two very recent, large arterial punctures (7F) would pose a risk of bleeding. The two-stage procedure reduced the chance of complications in this patient."

If an Angio-Seal™ Device had not been used in the procedure, Dr. Brasseur and his staff would have treated this patient in a single-stage procedure, leaving two sheaths and a catheter for thrombolysis in the patient for an extended period of time after the angioplasties and stenting in the iliacs were done. This would have been much more uncomfortable for the patient and posed a greater risk of complications. In particular, a 7F sheath would have remained in the non-affected leg overnight.

Dr. Brasseur concludes, "The Angio-Seal™ Device provided an optimal treatment alternative for this patient. It provided immediate hemostasis in a patient who received a potent thrombolytic (tPA) with three recent arteriotomies. The patient was not restricted to lying flat for several hours; she was able to have the head of her bed elevated and was very comfortable after each of the procedures. Since immediate vessel re-access is possible with the Angio-Seal™ Device, there is no issue should this patient require further angio procedures. The Angio-Seal™ Device provided the safest, most comfortable option in this situation."



**Post-Procedure Images**

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIAC SURGERY CARDIOLOGY NEUROMODULATION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**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

**Indications:** St. Jude Medical Angio-Seal™ Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8F Angio-Seal™ device and a 6 French or smaller procedural sheath for the 6F Angio-Seal™ device. The Angio-Seal™ STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement. Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation, or edema.