Clinical Highlights

A publication delivering concise clinical data

VASCULAR CLOSURE

Interventional Radiology: Everyday Use of the Angio-Seal™ Vascular Closure Device

PRESENTED BY

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BACKGROUND

Stanford University Medical Center is a world-renowned institution, located in Stanford, California. Their interventional radiology lab does over 5,000 procedures annually, utilizing two suites and a CT scanner. The lab currently has a full staff of five attending physicians and three interventional fellows. Dr. Stephen Kee is an Associate Professor of Radiology and Surgery in Stanford University's Radiology Department.

Interest and utilization of vascular closure devices in endovascular labs has increased significantly over the last few years. Stanford's use of closure devices has continued to increase for several years, and has become a standard of care in both the radiology and cardiology labs.

As in many institutions, Stanford Hospital first began using closure devices back in 1997. Stanford initially used suture-mediated closure before the Angio-Seal™ Vascular Closure Device became the standard of care in both the cardiology and radiology suites. Today, 70% of all patients with a 5F-8F procedure sheath receive an Angio-Seal™ Device.

Although the Interventional Radiology Department at Stanford has utilized other closure devices, the Angio-Seal™ Device is currently used about 80% of the time. Dr. Kee believes this is largely due to ease-of-use and device reliability, which largely impact individual physician preferences. Dr. Kee states, "The STS PLUS platform, with its .035" guidewire compatibility, has increased patient comfort and physician confidence – particularly in patients where obesity and scar tissue can negatively impact procedure outcomes."He described the benefits of the Angio-Seal™ Device as falling into two categories: lab benefits and patient benefits.

LAB BENEFITS

- Fewer groin complications – the Angio-Seal™ Device decreases worry about potential groin complications due to high levels of anticoagulant medication
- Greater lab throughput – the procedure is completed in the lab
- More flexibility in patient scheduling and follow-up – in many cases patient therapy is driven in part by whether or not they will receive a closure device

PATIENT BENEFITS

- Earlier ambulation – one hour or less with 5F sheath
- Earlier discharge – decreased ambulation and discharge times
- Improved patient comfort – early ambulation is a key element to patient satisfaction

Dr. Kee states, "The single most important reason the Stanford lab uses vascular closure devices is the ease of transition to the next procedure. The Angio-Seal™ Device has reduced the down-time between cases and the lab has experienced a reduction in groin complications. "While Dr. Kee feels the lab benefits may outweigh the patient benefits, he stresses it is still very important to address the needs of patients whenever possible; particularly those who experience significant pain and discomfort when lying flat for extended periods of time.

Many of the patients seen in Stanford's Interventional Radiology suites are undergoing cancer therapy. Due to the issues involved in recovering from these procedures manual pressure is all but unbearable for this patient population. Thus, closure devices play an important role. It is comforting for both staff and patients to know that everything possible is being done to provide the best possible care. Also, many of the patients seen are discharged the same day. The Angio-Seal™ Device allows the staff to quickly and safely ambulate and discharge these patients.

Dr. Kee believes that the patients seen in their lab benefit from receiving a closure device. Although he uses the Angio-Seal™ Device whenever possible, there are a select group of patients who should not receive a closure device. Dr. Kee utilizes the following criteria for patient selection:

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INCLUSION CRITERIA

- Patients who have a 5F-8F procedure sheath and a good puncture location
- Interventional patients whose anti-coagulation therapy may be impacted without a closure device
- Patients who experience significant pain lying flat for extended periods of time
- Diagnostic patients who will be going home the same day

EXCLUSION CRITERIA

- Patients who have small vessels (<4mm in diameter)
- Patients who have a low “stick” location (puncture site at or distal to the bifurcation of the superficial femoral and profunda femoris arteries)
- Patients with severe PVD (Peripheral Vascular Disease) at the puncture site

Using the Angio-Seal™ Vascular Closure Device in the lab on a daily basis has allowed the lab to change their protocol, enabling earlier ambulation and discharge for many patients. Reducing the number of patients who receive manual pressure has also allowed the staff more time for other important tasks. This not only appeals to the staff, it provides greater overall satisfaction to patients receiving a vascular closure device.

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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, STS Plus and VIP 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, STS Plus and VIP 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.

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