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REPRINT

ANGIO-SEAL™ VASCULAR CLOSURE DEVICE

Continues to Lead the Vascular Closure Industry in Sales and Performance.

Since 2001, the **Angio-Seal**™ Vascular Closure Device from **St. Jude Medical** has been chosen by more clinicians than any other to seal the femoral artery following catheterization procedures. In fact, the company shipped over one million devices in 2003 alone.

St. Jude Medical is also the only company whose closure device can claim the ability to ambulate 6F diagnostic patients in less than 20 minutes, and discharge one hour after ambulation*. The study results are summarized below.

These two facts, along with the reliable Angio-Seal™ device performance customers have come to depend on, underline how vascular closure is becoming a worldwide standard of care. In addition, the device is helping more hospitals to cut costs and improve lab efficiency while providing patients with exceptional care and comfort.

METHODS:
Patients who met all inclusion and no exclusion criteria were enrolled during a pre-procedure screening evaluation. Four U.S. investigational centers participated in the study. The primary endpoints studied were 1) rate of major complications, 2) time to ambulation and 3) time to discharge.

RESULTS:
A total of 132 patients (75% male; mean age 61.89 years) received the 6F Angio-Seal™ STS device from March 14, 2002 through September 6, 2002 after diagnostic angiography and were included in analyses of study endpoints. The evaluation of time to ambulation and time to discharge were relative to the time of deployment being defined as time "zero." The median time to ambulation from device deployment was 9.00 minutes (mean 18.95 ± 30.7 minutes) and the median time to discharge from deployment was 70.00 minutes (mean 78.65 ± 32.54). Hypothesis testing on the median yielded a p-value of <0.001 for time to ambulation and <0.001 for time to discharge, supporting the study hypothesis that the median time to ambulation is less than one hour and the median time to discharge is less than three hours. If the time of discharge is evaluated relative to the time of ambulation, with the time of ambulation defined as time "zero," the median time to discharge is 60 minutes (mean 59.91 ± 15.87 minutes). No "Major" complications were reported for the study patients, with only one "Minor" complication noted. Hypothesis testing yielded a p-value of 0.005, supporting the conclusion that the major complication rate is less than 5%.

CONCLUSIONS:
Results of the clinical study demonstrate that patients that have undergone diagnostic angiography and have received a 6F Angio-Seal™ device can safely and effectively ambulate in less than 20 minutes and be discharged one hour post ambulation.

* Patients receiving a 6F Angio-Seal™ STS device following a diagnostic procedure may be ambulated in less than 20 minutes and discharged 60 post-ambulation.

Rx Only

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: St. Jude Medical Angio-Seal™ vascular closure product family, including the Millennium, STS and STS Plus 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 and STS Plus platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to ambulate safely as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to ambulate safely 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.

For more information concerning St. Jude Medical and its products, call 1-800-328-3873, or visit the company Web site at www.sjm.com.

Endpoint	Study Patients
Time to ambulation (minutes post deployment)	
Mean ± Std. Dev. (95% C.I.)	18.95 ± 30.71 (13.64, 24.26)
Median (95% C.I.)	9.00 (7, 15)
Range	1 to 323
(N)	(131)
Time to discharge (minutes post deployment)	
Mean ± Std. Dev. (95% C.I.)	78.65 ± 32.54 (73.01, 84.30)
Median (95% C.I.)	70.00 (67, 75)
Range	38 to 368
(N)	(130)
Time to discharge (minutes post ambulation)	
Mean ± Std. Dev. (95% C.I.)	59.91 ± 15.87 (57.15, 62.66)
Median	60.00
Range	20 to 120
(N)	(130)
Endpoint	**Study Patients**
Major complications (N)	0 (n=125)
ostelisit; p-value -	2.56; 0.005
Minor complications	1