Angio-Seal™
**Vascular Closure Device**

# Restick

## Following Initial Angio-Seal Device Use Shown to be Safe

**Safety of Restick Confirmed by Clinical Study**


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# Safety of Restick Confirmed in Restick Study

The safety and efficacy of a restick of the same artery following an initial Angio-Seal™ Device deployment was evaluated in 181 patients.

## PATIENTS

Patients were included in the study if they had an Angio-Seal™ Device deployment and subsequently underwent arterial access using the same artery that had previously been closed with an Angio-Seal™ Device within 90 days of the original device placement.

## FINDINGS

"The major finding of this study is that arterial restick following initial Angio-Seal™ Device placement can be performed safely without dislodgment of the device and without significant vascular complications.

Moreover, arterial closure of the vessel can be performed safely with a variety of techniques, including a second Angio-Seal™ Device."[1]

# Restick Labeling Approved for Angio-Seal™ Vascular Closure Device

Labeling has been approved confirming the safety of restick of the same artery following initial Angio-Seal™ Vascular Closure Device use.

"If repuncture at the same location of previous Angio-Seal™ Device use is necessary in < 90 days, reentry 1cm proximal to the previous access site can be performed safely, based on published medical literature."[1]

### Vascular Complications (N = 181)[1]

| | | PROPORTION | 95% CONFIDENCE INTERVAL |
|---|---|---|---|
| Large hematoma (≥ 10cm) | 3 | 0.0166 | 0.0043 - 0.0515 |
| Vessel occlusion | 0 | 0 | 0 - 0.0259 |
| Pseudoaneurysm | 0 | 0 | 0 - 0.0259 |
| AV fistulae | 0 | 0 | 0 - 0.0259 |
| Major bleeding | 0 | 0 | 0 - 0.0259 |
| Vascular repair | 0 | 0 | 0 - 0.0259 |
| Death | 0 | 0 | 0 - 0.0259 |

### Procedural Characteristics (N = 181)[1]

| DAYS POST FIRST ANGIO-SEAL™ DEVICE | | |
|---|---|---|
| 1-7 | 81 | (45%) |
| 8-30 | 34 | (19%) |
| 31-90 | 66 | (36%) |

[1] Applegate RJ, Rankin KM, Little WC, Kahl FR, Kutcher MA. Restick following initial Angio-Seal™ use. *Catheter Cardiovasc Interv.* Feb 2003;58(2):181-184.

"To our knowledge, there are no published reports of attempts to reaccess an artery in which an Angio-Seal™ Device has been deployed, that have led to vascular compromise or loss of hemostasis."[1]

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.




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