- Please carry your Patient Information Card for 90 days. At that time the Angio-Seal Device components are fully absorbed.
- This product is MRI compatible and does not contain latex.

Please indicate Angio-Seal Device placement site, date, deployment time and ambulation time on label. Attach label to patient's chart.

Angio-Seal™
Vascular Closure Device

INSERTED: ☐RIGHT ☐LEFT (check one)
Femoral Artery

Date: _____

Deployment Time: _____

Ambulation Time: _____

Deployed By: _____

Lot Number: _____

Clinical Information Service
Toll Free1 (888) 864-7444

Attach label to top of sterile Angio-Seal Device dressing site.

Angio-Seal™
Vascular Closure Device

Patient Information Card

_____
Patient Name

_____
Hospital Name

_____
Physician Name

_____
Physician Phone Number

_____ ☐ Right ☐ Left Femoral Artery
Device Placement Date Device Placement Location

Please keep this card with you for the next 90 days.

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ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Rx Only
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.

Product referenced is approved for CE Mark.

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Item 100021178EN
ART100021178 Ver. A

A Patient's Guide to Angio-Seal™, A Vascular Closure Device

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Why did I receive an Angio-Seal Device?

After a catheterization procedure, physicians may close the puncture site (the area where the doctor inserts the catheter) by applying pressure to the site or by using a closure device. The process of applying pressure, also called manual compression, requires at least 15 minutes of pressure on the puncture site followed by 4 to 8 hours of bedrest. Instead, your physician chose to use the Angio-Seal Closure Device from St. Jude Medical.

With the Angio-Seal Device, the bleeding stops much more rapidly and with little or no manual compression, so you can get up and walk around sooner. You may also be discharged from the hospital sooner than if you had received only manual compression.

How does the Angio-Seal Device work?

The Angio-Seal Device is made of three absorbable components: a small anchor, collagen and a suture. A delivery system allows the physician to guide the anchor into the artery through the hole created during the procedure. The anchor is drawn in against the wall of the artery while the suture allows the collagen to compact to create a secure seal over the entry point. A sterile dressing is then applied to the site. All three components dissolve and are absorbed into your body in about 90 days.

What conditions should I discuss with my physician or nurse before leaving the hospital?

Notify your physician or nurse if you have any of the following conditions:

- Allergy to absorbable suture, beef and/or collagen products
- Uncontrollable high blood pressure
- Circulation problems
- Previous vascular surgery in leg arteries
- Pregnancy or lactation
- Autoimmune disease

How should I care for the site when I go home?

The following are guidelines suggested by St. Jude Medical for early post-procedure site care and activities.

Note: *These materials are not intended to replace your doctor's advice or information. For any questions or concerns you may have regarding the medical procedures, devices and/or your personal health, please discuss with your physician.*

After you are discharged from the hospital, you should modify your activities.

- You may shower, but do not take a bath, use a hot tub or swim until the skin site is healed.
- For 48–72 hours, you should refrain from straining or lifting anything over ten pounds.
- Avoid driving on the day of your discharge.

Care for the wound site as directed.

- It is normal to feel a small lump, about the size of a pea, and/or note mild tenderness in the groin area.
- Some bruising or discomfort is common during the healing process after intravascular procedures.
- After 24 hours, remove the dressing. Gently clean the site with mild soap and water. Dry the area and cover it with an adhesive bandage. Change the bandage if it becomes soiled or wet. Cover the area daily with a new bandage until the skin heals.

When should I call my doctor?

If you experience any of the following symptoms please contact your physician immediately at the number listed on your Patient Information Card:

- Fever
- Rash
- Bleeding
- Wound drainage
- Persistent tenderness in the groin or swelling
- Redness and/or warmth to the touch
- Numbness, tingling or pain in the extremity when walking
- Other unusual symptoms

Patient Instructions

Carry this card with you in your wallet for the next 90 days. Immediately report persistent tenderness in the groin area; bleeding; swelling; wound drainage; numbness or tingling in the leg; fever; or redness, warmth, bruising at the puncture site; or any other unusual observation at the puncture site to the physician listed on the reverse side of this card. If another procedure is necessary within 90 days of this one, inform the physician that you received the Angio-Seal™ Device and show this card to the physician.

Physician Instructions

This patient has received an Angio-Seal™ Vascular Closure Device. The device is absorbed within 90 days of placement. If repuncture at the same location of previous Angio-Seal Device is necessary in 90 days, re-entry 1 cm proximal to the previous access site can be performed safely, based on published medical literature*. Before considering Angio-Seal Device use, a femoral angiogram of the site is indicated. The device has three absorbable components: an anchor deployed intra-arterially, a small amount of collagen positioned on the outer wall of the artery and a suture trimmed below the skin. For additional information, please contact the physician noted on the reverse side. The Angio-Seal Device components are not made of latex. This product is MRI compatible.

*Applegate R; Rankin K; Little W; Kahl F; Kutcher M., "Restick following initial Angio-Seal™ Device use. Catheterization and Cardiovascular interventions" – *Official Journal of the Society for Cardiac Angiography and Interventions*, Feb 2003; 58(2) p181-4.