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 or swelling in the groin
- Redness and/or warmth to the touch
- Numbness, tingling or pain in the extremity when walking
- Other unusual symptoms

SJM.com
Why did I receive a FemoSeal 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 FemoSeal Closure device from St. Jude Medical.
With the FemoSeal 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 FemoSeal device work?
The FemoSeal device is made of three bioabsorbable components: an inner seal, an outer disc and a suture. A delivery system allows the physician to guide the inner seal into the artery through the hole created during the procedure. The inner seal is drawn in against the wall of the artery while the suture allows the outer disc to lock against the outer wall of the artery to create a secure seal over the entry point. A sterile dressing is then applied to the site.

How should I care for the site when I return home?
The following are guidelines suggested by St. Jude Medical for post-procedure site care and activities.

**Note:** These materials are not intended to replace your doctor’s advice. For any questions or concerns you 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 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.

- Please carry your Patient Information Card for 90 days.
- This product is MR safe and does not contain latex.
Patient Information Card

Patient Name

Hospital Name

Physician Name

Physician Phone Number

Device Placement Date

Please keep this card with you for the next 90 days.
**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 FemoSeal™ Device and show this card to the physician.

**Physician Instructions**

This patient has received an FemoSeal™ Vascular Closure Device. Before considering FemoSeal Device use, a femoral angiogram of the site is indicated. The device has three absorbable components: a inner seal, an outer disc and a suture. For additional information, please contact the physician noted on the reverse side. The FemoSeal Device components are not made of latex. This product is MRI compatible.
Please indicate FemoSeal Device placement site, date, deployment time and ambulation time on label. Attach label to patient’s chart.

**FemoSeal™ Vascular Closure Device**

INSERTED (check one): RIGHT ☐  LEFT ☐

Femoral Artery

Date: ________________________________

Deployment Time: ____________________________

Ambulation Time: ____________________________

Deployed By: _____________________________

Lot Number: ______________________________
Attach label to top of sterile FemoSeal Device dressing site.