

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, bruising at the puncture site, other unusual symptoms.

For the complete Instructions for Use, explanation of symbols provided on your Patient Information Card, and the Summary of Safety and Clinical Performance (SSCP) refer to : <https://www.terumomedical-labeling.com>.



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A PATIENT'S GUIDE TO

Angio-Seal™

Vascular Closure Device

ACTIVE VASCULAR CLOSURE

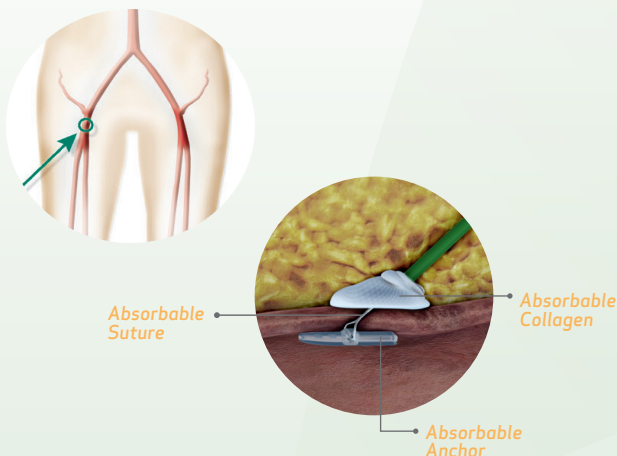


Your physician has decided to use the Angio-Seal™ Vascular Closure Device. This guide will provide you with further information about Angio-Seal™ and will give you some guidelines for your return home.

- Please carry your Patient Information Card for 90 days. At that time the Angio-Seal™ Device components are fully absorbed.
- The implanted components of the device are MRI safe. The device is not made with natural rubber latex.

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 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 implantable components resorb within 90 days¹.



HOW SHOULD I CARE FOR THE SITE WHEN I RETURN HOME?

The following are guidelines suggested by Terumo for post-procedure site care and activities².

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.

- Support the puncture site when coughing, sneezing or straining.
- You may shower, but do not take a bath, use a hot tub or swim until the skin site is healed².
- For 48–72 hours, you should refrain from straining or lifting anything over 4.5 kgs².
- Avoid driving on the day of your discharge².

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 area².
- Discomfort is common during the healing process, after intravascular procedures².
- 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 heals².

¹ Tellez et al. In vivo intravascular ultrasound analysis of the absorption rate of the Angio-Seal vascular closure device in the porcine femoral artery. EuroIntervention. 2010 Jan;5(6):731-6.

² Hamel et al. Femoral artery closure after cardiac catheterization. Critical Care Nurse Vol 29, No. 1, Feb. 2009.