PATIENT INFORMATION LEAFLET

FemoSeal™ Vascular Closure System
Product Code: C11202

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

Table of Contents:

SECTION	DESCRIPTION
1	What is FemoSeal used for?
2	Who is allowed to use FemoSeal?
3	How does the FemoSeal system work?
4	Who is FemoSeal used for?
5	What is FemoSeal made of?
6	How should I care for the site when I return home?
7	When should I call my doctor?
8	Potential Adverse Events
9	Incident Reporting
10	Contact Information

1. WHAT IS FEMOSEAL USED FOR?

Intended use:
FemoSeal Vascular Closure System is a medical device intended for closure of an arterial puncture after percutaneous catheterization through the common femoral artery.

2. WHO IS ALLOWED TO USE FEMOSEAL?

Intended users:
FemoSeal Vascular Closure System's intended users are physicians with training qualifying them to perform arterial access and closure for endovascular procedures through the common femoral artery and have participated in a Terumo Medical Corporation FemoSeal physician instruction program.

3. HOW DOES THE FEMOSEAL SYSTEM WORK?

FemoSeal Vascular Closure System is made of three bioabsorbable components: an inner seal, an outer locking 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 against the wall of the artery while the suture allows the outer locking 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. All three components dissolve and are fully absorbed into your body[1].

4. WHO IS FEMOSEAL USED FOR?

Target patient populations:

The safety and effectiveness of FemoSeal Vascular Closure System has been established in the patients 18 years of age and older who have undergone percutaneous catheterization using a 7F (2.33 mm) or smaller procedural sheath.

5. WHAT IS FEMOSEAL MADE OF?

FemoSeal Vascular Closure System consists of the following components and materials.

Part Number	Description	Materials
1	0.038" (0.97 mm) Guidewire with a guidewire J-straightener	Guidewire: Stainless Steel J-Straightener: Polypropylene, white pigment Clip: Polyethylene Tubing: Polyethylene
2	FemoSeal Dilator	Hub: Tetrahydrofuran, Blue pigment, Polybutylene terephtalate (PBT) Tube: High density polyethylene (HDPE), black pigment Lubricant: Silicone oil
3/4 FemoSeal Unit	Molded RD7 – Inner Seal and Outer locking Disc *	Copolymer between glycolide, trimethylene carbonate, ε-caprolactone, and TMP: trimethylolpropane (initiator)
	Multifilament *	Segmented copolymer between L,L-Lactide, trimethylene carbonate, ε-caprolactone, and 1,3 propanediol (initiator) Coating is copolymer between glycolide, ε-caprolactone, and L-lysine
	Tamping Tube	Polypropylene
	Pusher	Stainless steel
	Slider	Polybutylene terephthalate (PBT)
	Housing	Polybutylene terephthalate (PBT)
	Button	Polybutylene terephthalate (PBT)
	Button Lid	Polyoxymethylene (POM)
	Sleeve	Polybutylene terephthalate (PBT)
	Spacer	Polybutylene terephthalate (PBT)
	Cone	Polypropylene
	Housing Lid	Polybutylene terephthalate (PBT)
	Safety Catch	Polybutylene terephthalate (PBT), blue pigment

Part Number	Description	Materials
	Sleeve Lid	Polybutylene terephthalate (PBT)
	Tube Gasket	Silicone shore A 70
	Housing Gasket	Silicone shore A 70
	Spring	Stainless Steel
	Cone Housing Sheath	Polypropylene Silicone Dow Corning 360, Hexane

***Implantable portion of device; Implantable components are MRI safe**

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

The following are guidelines suggested by Terumo for post-procedure site care and activities[2].

Note: This information and materials are not intended to replace your physician'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[2].
- For 48-72 hours, you should avoid excessive physical activity or lifting anything over 4.5 kgs[2].
- Avoid driving on the day of your discharge[2].

Care for the wound as directed.

- It is normal to feel a small lump, about the size of a pea, and/or mild tenderness in the groin area[2].
- Discomfort is common during the healing process after intravascular procedures[2].
- 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[2].

7. 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** (**Note:** Please carry your **Patient Information Card** *which you will receive after your procedure* for **18 months**. The device components of FemoSeal Vascular Closure System may take up to **18 months** to fully absorb).

SYMPTOMS

- Fever
- Rash
- Bleeding
- Wound drainage
- Persistent tenderness or swelling in the groin
- Redness and/or warmth to the touch
- Tingling or pain in the extremity when walking
- Numbness
- Bruising at the puncture site
- Other unusual symptoms

8. POTENTIAL ADVERSE EVENTS

Known or foreseeable adverse events, harms, and complications associated with the use of FemoSeal Vascular Closure System include:

Adverse Events, Harms, and Complications:

- *Allergic Reaction*
- *Aneurysm*
- *AV Fistula*
- *Blood Loss/Bleeding*
- *Death*
- *Device Failure*
- *Ecchymosis*
- *Embolism*
- *Foreign Body Reaction*
- *Hematoma*
- *Hemorrhage*
- *Infection*
- *Inflammatory Reaction*
- *Numbness*
- *Pain*
- *Patient Discomfort*
- *Procedure delay*
- *Pseudoaneurysm*
- *Retroperitoneal Bleed*
- *Sepsis*
- *Thromboembolism*
- *Thrombosis*
- *Vessel occlusion/Lower Limb ischemia*
- *Vessel Perforation*
- *Vessel Tissue Dissection/Laceration*

9. INCIDENT REPORTING

Reporting Serious Incidents: Any occurrence of serious incident should be reported to both the manufacturer of the device **(Terumo Medical Corporation)**, and to the **Therapeutic Goods Administration (TGA)**, using the contact information provided below.

10. CONTACT INFORMATION

1. **Therapeutic Good Administration (TGA):**
   www.tga.gov.au

2. **Manufacturer:**
   Terumo Medical Corporation
   265 Davidson Avenue, Suite 320
   Somerset, NJ 08873 USA
   +1 732 302 4900
   +1 800 283 7866

3. **Distributor/Sponsor:**
   Terumo Australia Pty Ltd
   Macquarie Park NSW 2113 Australia
   T: 1800 837 866
   T: 0800 66 77 57
   E: cs_australia@terumo.co.jp

REFERENCES:
[1]Holm et al. Randomized comparison of manual compression and FemoSeal™ vascular closure device for closure after femoral artery access coronary angiography: the closure devices Used in everyday Practice (CLOSE-UP) study. Eurointervention 2014;9:183-190.
[2]Wallace et al. Femoral artery closure after cardiac catheterization. Critical Care Nurse Vol 29, No. 1, Feb. 2009.