

EXOSEAL® Vascular Closure Device

What EXOSEAL® Vascular Closure Device is Used For

The EXOSEAL® Vascular Closure Device (VCD) is indicated for femoral artery puncture site closure, reducing time to hemostasis and ambulation in patients who have undergone diagnostic or interventional procedures using a standard corresponding French size vascular sheath introducer with up to 12cm working length

Product Description

The EXOSEAL® VCD is designed to achieve femoral artery hemostasis via delivery of an absorbable plug. Hemostasis is achieved when the absorbable plug is placed on top of the puncture site. The plug is absorbed by the body within 30 days, with complete absorption between 60 and 90 days post-implant. EXOSEAL® VCD has been tested to show that it is safe for use in humans, and complies with the applicable requirements of the implantable medical devices. The device contains no components manufactured from latex rubber.

The device materials and substances that are intended to directly or indirectly contact the patient will pose no risk to the patient; except for those who are allergic to polyglycolic acid.

Active Ingredient • Polyglycolic acid

About Your Catheterization Procedure

During your catheterization procedure, your physician will make a small puncture in a blood vessel near your groin area. A small hollow tube called a sheath will be placed through this puncture site that allows the physician to perform your procedure. At the end of the procedure, the sheath is removed and there will be a small hole in your blood vessel. Similar to a cut on your skin, it is important to close this hole to prevent bleeding.

How Is Closure Achieved?

Traditionally, physicians have closed the access site with manual compression or mechanical clamps. These methods require heavy pressure on your leg for 15-30 minutes and sometimes even longer. This pressure can be uncomfortable and requires you to lie in bed for at least 6-8 hours following the procedure.

As an alternative to manual compression, EXOSEAL® VCD immediately seals the puncture site to stop the bleeding without lengthy and often painful pressure applied to your leg.

How Does EXOSEAL® Vascular Closure Device Work?

The EXOSEAL™ VCD consists of a plug applicator and an absorbable plug to close the small hole in your blood vessel after your procedure.

Caution

The EXOSEAL® VCD contains polyglycolic acid. The device should not be used in patients with a known allergy to polyglycolic acid.

The EXOSEAL® VCD should only be used by a trained licensed physician or doctor.

Adverse Effects

The EXOSEAL® VCD carries the same risks associated with any surgery. For more information regarding the risks, consult your doctor.

Device Interaction and MRI Information

The EXOSEAL® VCD is non-conducting and non-magnetic, and poses no risk that could arise from interactions with equipment or other medical technologies such as Magnetic Resonance Imaging (MRI).

Post-Procedure Care

Although the EXOSEAL® VCD immediately seals the puncture site after your catheterization procedure, your blood vessel still needs time to heal. Even if you do not feel any pain or discomfort during your first few days home following your procedure, take time to rest and allow the natural healing process to occur. Here are some general post-procedure discharge guidelines. Please talk to your doctor about any limitations in your activities following your procedure.

Taking Care of Your Puncture Site

- Re-apply a clean, dry band-aid every day for five days or until a scab has formed at the site. Change the band-aid as needed.
- Keep the site clean and dry.

Patient Device Information

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EXOSEAL® Vascular Closure Device

- You may shower 24 hours after the procedure, but do not bathe or use a pool until the wound has completely closed.
- Gently clean your puncture site with soap and warm water.
- After showering, gently pat-dry the site with a clean towel; then let the site air-dry before covering with a band-aid.
- Limit tight-fitting clothes or underwear that may irritate the puncture site until the site has healed.

Daily Activities

Day of discharge

- NO driving.

Modify activity for a minimum of 3 days

- NO heavy lifting of anything over 5 pounds or 2.3 kgs (equivalent to a 1/2 gallon or 1.9 liters of milk).
- NO pushing or pulling.
- NO vigorous activity or straining.
- Avoid stairs unless necessary: if necessary, take them slowly.
- Coughing, sneezing, or straining for a bowel movement: support your groin by pressing with your palm on top of the dressing/ bandage.
- Sexual activity: check with your doctor.
- NO strenuous exercise.
- Avoid driving unless necessary.

Talk to your doctor about returning to work; which depends on your type of work, your procedure, and any medication you may be taking.

Precaution

Any serious incident that occurs in relation to the device should be reported to Cordis US Corp. and to the Therapeutic Goods Administration (TGA).

Cordis Corp.

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email: anz-product-complaints@cordis.com

TGA:

<http://www.tga.gov.au/reporting-problems>

For healthcare professionals only.

IMPORTANT INFORMATION: Prior to use, refer to the "Instructions for Use" supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings, and precautions. As part of the Cordis policy of continuous product development, we reserve the right to change product specifications without prior notification. Please contact your Cordis representative for additional product availability information

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Discharge Information

Normal Observations

- A small lump and/or mild tenderness in your groin area
- Some bruising or discomfort

Please contact your doctor immediately if you experience any of the following signs and/or symptoms:

- Persistent tenderness or swelling at the puncture site
- Significant pain at the puncture site or leg
- Bleeding/ oozing at the puncture site
- Increasing redness, warmth, bruising, or swelling at the puncture site
- Numbness or tingling in the leg
- Drainage from the puncture site
- Non-healing wound
- Fever or chills
- Any other unusual symptoms

Legal Manufacturer

Cordis Corp.

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