Patient Information Leaflet

COPY-CORDIS-25026 REV.1

Cordis EXOSEAL™ Vascular Closure Device

Device Name and Model

Cordis EXOSEAL™ Vascular Closure Device

Device Description

The EXOSEAL Vascular Closure Device consists of a plug applier (Handle Assembly + Delivery Shaft) and an absorbable plug made from 100% polyglycolic acid (PGA).
The plug is preloaded inside the delivery shaft and is placed on the outside of the femoral artery via a compatible vascular sheath introducer (5F, 6F, or 7F; up to 12 cm working length). It seals the puncture site (arteriotomy) without the need to change the sheath.
The plug begins absorbing within 30 days and is fully absorbed within 60–90 days.
The device contains no latex.

Intended Purpose

The EXOSEAL VCD is intended to achieve femoral artery hemostasis.

Patient Target Group

The patient target group includes individuals who have undergone diagnostic and/or interventional catheterization procedures utilizing a standard 5F, 6F or 7F vascular sheath introducer with up to a 12 cm working length. The patient target group of this device is based on the patient's anatomy and compatibility with the device.

Operating Instructions

The device is implanted by trained healthcare professionals in a hospital or clinical setting. Patients do not operate or adjust it themselves. The device contains a small absorbable plug that seals the artery from the outside. The plug gradually dissolves over 60–90 days.
Follow all instructions from your doctor about wound care, activity restrictions, and medications after the procedure. Attend all scheduled follow-up appointments so your doctor can check healing.
Always tell healthcare providers, including radiology staff, that you have recently had a vascular closure device placed before undergoing tests or procedures.
Carry the patient implant/care card for at least 30 days after your procedure.

Warnnings and Precautions

Tell your doctor if you have an allergy to polyglycolic acid (PGA).
Tell your doctor if you are pregnant, planning pregnancy, breastfeeding, or under 18 years old.
Inform your doctor if you bruise or bleed easily or have a bleeding/clotting disorder.
Let your doctor know if you have had reactions to contrast dye used in X-rays or CT scans.
Avoid lifting objects heavier than 4.5 kg (10 lbs) for one week, or until your doctor says the wound has healed.
Watch for signs of infection: redness, swelling, drainage, warmth, fever, or chills.
If you notice excessive bleeding, swelling, severe pain, or loss of pulse in the leg, seek urgent medical attention.

Patients should be informed that a reabsorbable Plug has been used to close the access site.
Patients should be told to expect soreness or tenderness during the first week, as well as light drainage. Bruising may last up to two weeks.
Physicians should be alerted to the following:
- Excessive bleeding
- Swelling of the groin or leg
- Pain in the groin or leg
- Any sign of infection (redness, swelling, drainage, warmth, fever, chills, non-healing of wound)

Patients should be provided with an "Instructions & Care Information" card to be carried for at least 30 days following implantation of the EXOSEAL VCD. This card should be presented to the healthcare practitioner upon re-hospitalization within the 30-day timeframe.
Activity limits and specific wound care instructions should be provided by the physician. Normal activity, including driving, can usually be resumed within two days. It is recommended that no lifting of objects greater than 10 lbs is done for one week, or until the wound has healed.

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Potential Complications

The most serious recognized risks associated with femoral artery closure procedures occur rarely and include, but are not limited to, the following:

- Access site-related bleeding requiring transfusion
- Access site-related infection
- Access site-related nerve injury requiring surgical repair
- Death
- New lower extremity ischemia
- Permanent access site-related nerve injury
- Retroperitoneal Bleed
- Vascular injury requiring repair

Other less serious potential risks associated with femoral artery closure procedures could occur more frequently and include, but are not limited to, the following:

- Access site hematoma
- Access site-related vessel laceration
- Access site wound dehiscence
- Arteriovenous fistula
- Deep vein thrombosis
- Ecchymosis
- Lower extremity arterial emboli
- Peripheral artery total occlusion
- Prolonged access site-related bleeding
- Pseudoaneurysm
- Rebleeding following initial hemostasis requiring intervention
- Transient access site-related nerve injury
- Transient loss of lower extremity pulse
- Vasovagal response

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

Plug: 100% Polyglycolic Acid (PGA) synthetic absorbable polymer (weight: 6–15 mg, depending on French size)

Other components: Handle Assembly, Delivery Shaft
Latex: Not made from natural rubber latex

Adverse Event Report

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

TGA:
http://www.tga.gov.au/reporting-problems (website)

Sponsor:
Cordis Australia Pty Ltd.
Level 14/3 Parramatta Square
153 Macquarie Street, Parramatta, NSW, 2150
Email: anz-product-complaints@cordis.com

Manufacturer

Cordis US Corp.
14201 North West 60th Avenue
Miami Lakes, Florida 33014, USA

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, suggested procedure, warnings and precautions. Please contact your Cordis representative for additional product information.