Patient Information Leaflet

COPY-CORDIS-25028 REV.1

Cordis MYNXGRIP™ Vascular Closure Device

Device Name and Model

Cordis MYNXGRIP™ Vascular Closure Device

Device Description

The MYNXGRIP Vascular Closure Device (VCD) incorporates a GRIP TECHNOLOGY sealant made from 100% polyethylene glycol (PEG). This material expands upon contact with subcutaneous fluids to seal the arteriotomy and is resorbed by the body within 30 days. The estimated sealant weight ranges from approximately 13 to 38 mg depending on the French size.

Components

- Supplied with a 10 mL locking syringe for balloon inflation and deflation.
- Contains no latex rubber components.
- MYNXGRIP™ 5F VCD features a grey shuttle.
- MYNXGRIP™ 6F/7F VCD features a green shuttle.

Intended Purpose

The MYNXGRIP VCD is intended to achieve femoral artery and/or femoral vein hemostasis.

Patient Target Group

The patient target group includes individuals who have undergone diagnostic and/or interventional catheterization procedures utilizing a 5F, 6F or 7F procedural sheath. The patient target group of this device is based on the patient's anatomy and compatibility with the device.

Operating Instructions

This device is placed by a trained healthcare professional immediately after your catheter procedure to help seal the artery in your groin. The device delivers a small soft seal made of polyethylene glycol (PEG) just outside the artery to stop bleeding.
The seal works right away and is absorbed naturally by your body within about 30 days. You do not need to operate or adjust the device yourself.

After the procedure:

- Follow your doctor's instructions for wound care and activity.
- Keep the area clean and dry until your doctor says it is healed.
- Avoid heavy lifting, strenuous exercise, or bending at the hip until cleared by your doctor.
- Attend all follow-up appointments so your doctor can check healing.

Contact your healthcare provider immediately if you notice:

- Persistent or heavy bleeding at the puncture site
- Swelling, redness, warmth, or drainage
- Severe pain or numbness in the leg
- Fever or chills

Warnings and Precautions

This device can only be placed by trained medical staff during your procedure.
It is used once and then disposed of — it cannot be reused.
Tell your doctor if you have an allergy to polyethylene glycol (PEG).
If you have unusual bleeding, swelling, severe pain, or numbness in your leg after the procedure, seek medical attention immediately.
Always follow the wound care and activity instructions your doctor gives you after the procedure.

Potential Complications

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

- Vascular injury requiring repair
- Permanent access site-related nerve injury
- Surgery for access site-related nerve injury
- Access site-related bleeding requiring transfusion
- New ipsilateral lower extremity ischemia requiring invasive/non-invasive intervention
- Access site-related infection – Major
- Local access site inflammatory reaction – Major
- Generalized infection
- Retroperitoneal bleed
- Vessel Occlusion
- Pulmonary embolism
- Death

Other less serious potential risks associated with femoral artery closure procedures could occur more

frequently and include, but are not limited to, the following:

- Pseudoaneurysm – Treated with thrombin injection
- Pseudoaneurysm – Not requiring treatment
- AV Fistula
- Hematoma ≥ 6 cm
- Access site-related bleeding requiring > 30 min to achieve hemostasis
- Late access site-related bleeding (following hospital discharge)
- Ipsilateral lower extremity arterial emboli
- Transient loss of ipsilateral lower extremity pulse
- Ipsilateral deep vein thrombosis
- Transient access site-related nerve injury
- Access site-related vessel laceration
- Access site wound dehiscence
- Local access site infection – Minor
- Local access site inflammatory reaction – Minor
- Allergic reaction
- Ecchymosis
- Foreign body/local reaction

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

The GRIP TECHNOLOGY sealant is made of 100% polyethylene glycol (PEG) material which expands upon contact with subcutaneous fluids to seal the arteriotomy.

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.