Patient Device Information

COPY-CORDIS-23027 Rev.1

MYNX CONTROL® Vascular Closure Device 5F/6F/7F

What MYNX CONTROL® VCD is Used For

The MYNX CONTROL® Vascular Closure Device (VCD) is used to seal femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.

Product Description

The MYNX CONTROL® VCD is designed to achieve femoral artery hemostasis via delivery of an extravascular, water-soluble synthetic hydrogel sealant; using a balloon catheter in conjunction with a standard procedural sheath. The implanted sealant is made of a polyethylene glycol (PEG) material which rapidly expands upon contact with blood around the puncture site, stops bleeding, and immediately seals the hole. The sealant is resorbed by the body within 30 days; leaving nothing behind but a healed vessel

The MYNX CONTROL® 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 polyethylene glycol (PEG).

Active Ingredient

- Polyethylene glycol (PEG)

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?

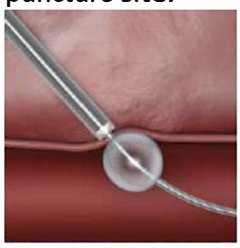
Traditionally, physicians have closed the access site with manual compression or mechanical clamps. These methods require heavy pressure on your leg for 15-30 minutes and sometimes even longer. This pressure can be uncomfortable and requires you to lie in bed for at least 6-8 hours following the procedure.

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

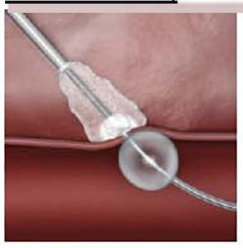
How Does MYNX CONTROL® VCD Work?

The MYNX CONTROL® VCD uses a soft, sponge-like material (MYNX™ Sealant) to close the small hole in your blood vessel after your procedure. It works by rapidly absorbing the blood around the puncture site, which stops the bleeding and immediately seals the hole.

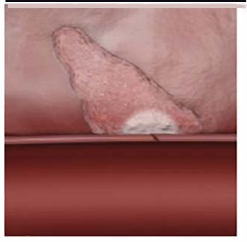
Your doctor will insert the MYNX™ Sealant just above the puncture site.



The MYNX™ Sealant instantly expands to fill the entire puncture area on contact, which stops the bleeding.



The MYNX™ Sealant will be completely absorbed by your body within 30 days, leaving nothing behind but a healed blood vessel.



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Caution

The MYNX CONTROL™ VCD contains polyethylene glycol (PEG). The device should not be used in patients with a known allergy to PEG.

The MYNX CONTOL™ VCD should only be used by a trained licensed physician or doctor.

Adverse Effects

The MYNX CONTROL™ VCD carries the same risks associated with any surgery:

- Infection
- Pain at the surgery site
- Bruising or swelling at the surgery site
- Bleeding at the surgery site

The following potential complications, which may be related to the endovascular procedure or the vascular closure, may occur: allergic reaction, inflammation, interrupted blood flow, blood clot, vessel injury requiring surgical repair, or death.

Device Interaction and MRI Information

The MYNX CONTROL™ 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 MYXN CONTROL™ 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.
- 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).

Cardinal Health, 5452 Betsy Ross Drive, Santa Clara, California 95054, USA

email: anz-product-complaints@cordis.com

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

Discharge Information

Normal Observations

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

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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

Cardinal Health, 5452 Betsy Ross Drive, Santa Clara, California 95054, USA