CLOSES WITH SECURITY. LEAVES WITHOUT A TRACE.*









Close with Confidence. Leave Nothing Behind*.

MYNX CONTROL® Vascular Closure Device features a redesigned, ergonomic handle to facilitate ease-of-use and predictable deployment.

The Science of Active Extravascular Sealing



MYNX CONTROL® VCD is comprised of two configurations of polyethylene glycol (PEG), for durable haemostasis.

Proven PEG Material

- SAFE No foreign-body reaction or scar tissue formation¹
- **SYNTHETIC** Non-thrombogenic¹
- HYDROLYTIC DEGRADATION Fully resorbs through hydrolysis—no enzymatic breakdown¹

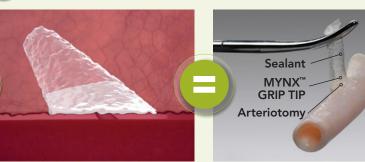
Dual-mode Active Sealing



- Activated by body temperature and pH
 Interlocks with contours of the vessel
 Expands to 3-4 times its original size on contact with blood and subcutaneous fluids, creating a matrix
 - Provides further support for the MYNX™ GRIP TIP

structure for clot formation







Secure Extravascular Closure in a wide range of clinical scenarios

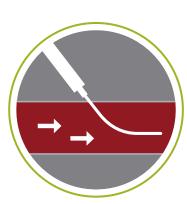
Clinically versatile, MYNX CONTROL® VCD offers dependable closure with nothing left behind*
—treats a wide range of patients and clinical scenarios.



Safe closure below the femoral **bifurcation**^{†2}



No footplates, sutures, or metal implants to impede **reaccess**

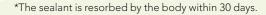


Useful on **antegrade** punctures³



Balloon **visualisation** verifies position





by actively attaching to the artery, for secure

mechanical closure



Safety by the Numbers.

MYNX[™] VCD has been clinically proven to reduce surgical complications, expedite recovery, shorten hospital stays, and increase patient comfort.^{2-7‡}

Safety and Efficacy in Interventions

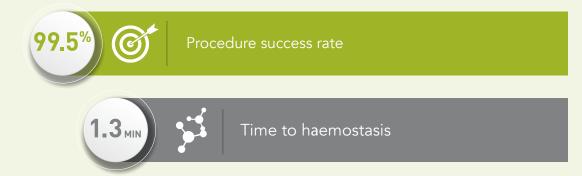
A single-center, multi-year comparative analysis involving **4,074** percutaneous coronary intervention (PCI) patients found MYNX™ VCD to be equally safe and effective as Angio-Seal™, with no intra-arterial components left behind.⁴

Access-site bleeding and vascular injury⁴

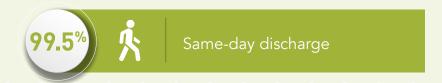


Safety in Clinical Trials and Real-world Use

In a prospective multi-center, non-randomised clinical trial (n=190) MYNX™ VCD demonstrated: ^{2,8}



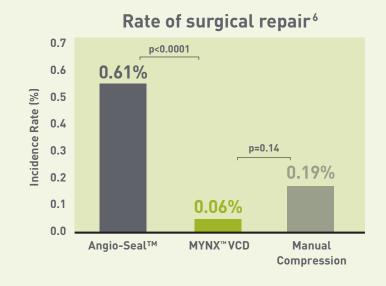
In a real-world cohort of 432 patients undergoing coronary angiography, MYNX™VCD demonstrated:⁵



‡Time to discharge eligibility as compared to manual compression. MATRIX Clinical Trial (IDE# G030182). Data on file.

Reduced Risk and Severity of Complications

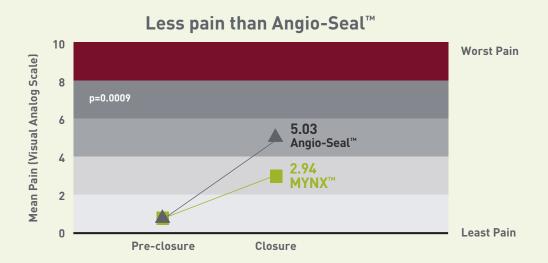
In a retrospective, single-center review of **11,006** cardiac and peripheral vascular procedures, MYNX[™] VCD was proven to reduce the risk and severity of surgical complications following catheterisation, compared to Angio-Seal[™] and manual compression.⁶



- 10x fewer secondary surgeries than Angio-Seal™6
- 3x fewer secondary surgeries than manual compression⁶
- MYNX[™] VCD complications did not involve embolism or artery damage, worsening of peripheral vascular disease, or necessitate device removal⁶

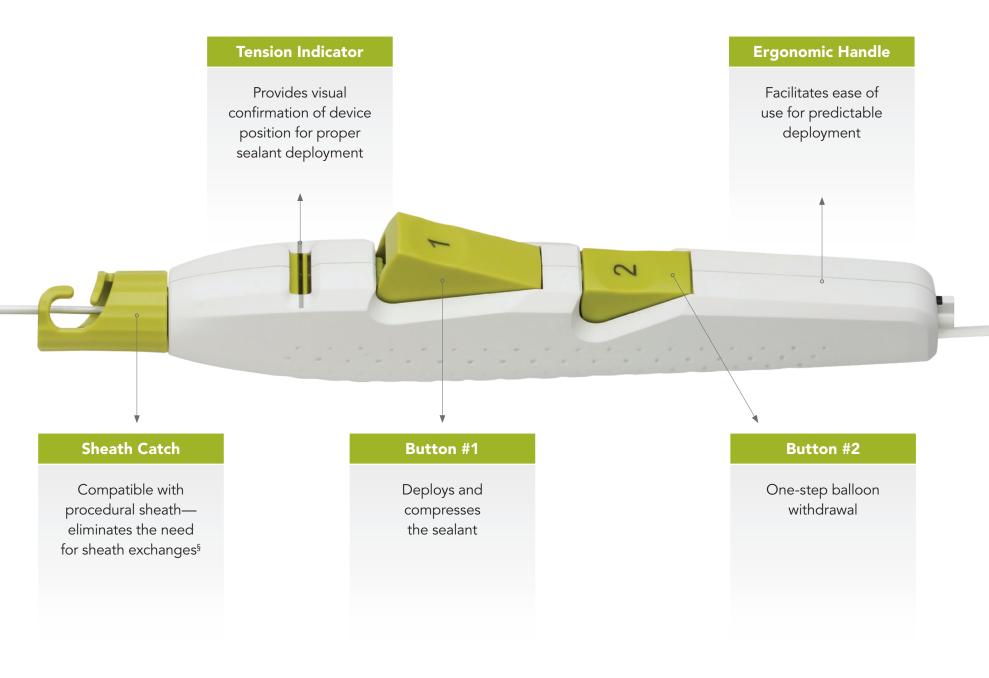
Increased Patient Comfort

In a blinded, randomised clinical study, pain at closure and pain increase from baseline to close were significantly lower for MYNX™ VCD than Angio-Seal™.⁷



Made for Predictable Deployment. Designed for Ease of Use.

The next-generation MYNX CONTROL® Vascular Closure Device (VCD) deployment system is purpose-designed to enhance safety and deliver reliable performance.



§MYNX CONTROL® VCD is incompatible with Medtronic Input® Introducer (11cm) sheaths, Cook Check-Flo® Performer® Introducer sheaths, and procedural sheaths longer than 12cm in effective length.

Procedure Steps



Achieve temporary haemostasis and position at the arteriotomy.



The MYNX™ GRIP TIP securely adheres to the artery and MYNX™ Sealant fills the tissue tract.



Platelets and blood cells collect inside the sealant's porous matrix.



Closes with Security. Leaves Without a Trace.*

MYNX CONTROL® Vascular Closure Device (VCD) integrates dual-mode active sealing and resorbability with a next-generation delivery system to maximise predictability, safety, and ease of use.











EASE 0

Ordering Information

The MYNX CONTROL® VCD includes:

- (1) MYNX ${\sf CONTROL}^{\it B}{\sf VCD}$ including balloon catheter and integrated polyethylene glycol sealant
- (1) 10ml locking syringe

SIZE ORDER NUMBER

5F MX5060E 6F/7F MX6760E

To order the MYNX CONTROL® VCD contact your local Cardinal Health representative or customer service 1800 077 421.

REFERENCES: 1. Scheinert D, Sievert H, Turco MA, et al. The safety and efficacy of an extravascular, water-soluble sealant for vascular closure: Initial clinical results for MYNX™. Cathet Cardiovasc Intervent. 2007 Oct;70:627-633. 2. MYNX CONTROL® Vascular Closure Device Instructions for Use. 3. Pruski

MJ Jr, Blachut AM, Konkolewska M, et al. MYNX[™]GRIP for closure of antegrade puncture after peripheral interventions with same-day discharge. *Vasc Endovasc Surg*. 2017 Feb;51(2):67-71. **4.** Baker NC, Escarcega RO, Lipinski MJ, et al. Active versus passive anchoring vascular closure devices following percutaneous coronary intervention: a safety and efficacy comparative analysis. *J Interv Cardiol*. 2016 Feb; 29(1): 108-112. **5.** Hutchings D, Hayat A, Karunakaran A, Malik N. Success, Safety, and Efficacy of the MYNX[™] Femoral Closure Device in a Real-World Cohort: Single-Center Experience. *J Invasive Cardiol*. 2016 Mar;28(3): 104-108. **6.** Noor S, Meyers S, Curl R. Successful reduction of surgeries secondary to arterial access site complications: a retrospective review at a single center with an extravascular closure device. *Vasc Endovascular Surg*. 2010 Jul;44(5):345-349. **7.** Fargen KM, Hoh BL, Mocco J. A prospective randomised single-blind trial of patient comfort following vessel closure: extravascular synthetic sealant closure provides less pain than a self-tightening suture vascular compression device. *J NeuroInterv Surg*. 2011 Sep; 3(3): 219-223. **8.** MATRIX Clinical Trial (IDE# G030182). Data on file.

INDICATIONS FOR USE: MYNX CONTROL® VCD is indicated for use to seal femoral arterial access sites while reducing times to haemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilising a 5F, 6F, or 7F procedural sheath.

PRECAUTIONS: MYNX CONTROL® VCD should only be used by a trained licensed physician or healthcare professional. MYNX CONTROL® VCD should not be used in patients with a known allergy to PEG. MYNX CONTROL® VCD should not be used with sheaths longer than 12cm effective length or incompatible sheaths listed in Table 1 of the Instructions for Use.

WARNINGS: Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. DO NOT REUSE OR RESTERILISE. MYNX CONTROL® VCD is for single use only. The catheter is loaded with a single hydrogel sealant. Reuse of the device would result in no delivery of hydrogel sealant. Do not use MYNX CONTROL® VCD if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in

a retroperitoneal haematoma/bleed. Perform a femoral angiogram to verify the location of the puncture site. Do not use MYNX CONTROL® VCD if the puncture is through the posterior wall or if there are multiple punctures, as such punctures may result in a retroperitoneal haematoma/bleed.

For Healthcare Professionals Only. Important information: Prior to use, refer to the Instructions for Use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions. As part of its continuous product development policy, Cordis reserves the right to change product specifications without prior notification. CORDIS, the Cordis LOGO and MYNX CONTROL are trademarks of Cardinal Health and may be registered in Australia and/or in other countries. © 2019 Cardinal Health. All Rights Reserved.

^{*}The sealant is resorbed by the body within 30 days.