CLOSES WITH SECURITY.
LEAVES WITHOUT A TRACE.

MYNX CONTROL™

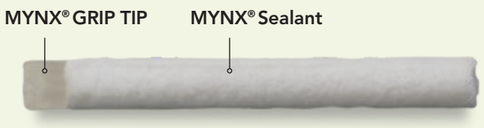
VASCULAR CLOSURE DEVICE

Cordis®
A Cardinal Health company

Close with Confidence. Leave Nothing Behind.

The innovative design and predictable deployment of MYNX CONTROL™ Vascular Closure Device (VCD) delivers outstanding performance and control, for consistently secure arterial closures.

The Science of Active Extravascular Sealing



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

Proven PEG Material

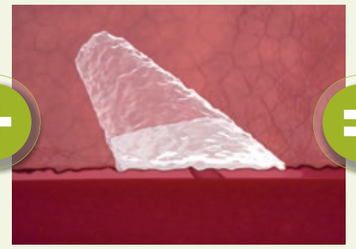
- **SAFE** No foreign-body reaction or scar tissue formation[1]
- **SYNTHETIC** Non-thrombogenic[1]
- **HYDROLYTIC DEGRADATION** Fully resorbs through hydrolysis—no enzymatic breakdown[1]

Dual-mode Active Sealing

1 MYNX® GRIP TIP

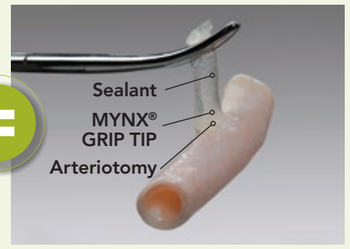
- Activated by body temperature and pH
- Interlocks with contours of the vessel by actively attaching to the artery, for secure mechanical closure

2 MYNX® SEALANT COLUMN



- Expands to 3-4 times its original size on contact with blood and subcutaneous fluids, creating a matrix structure for clot formation
- Provides further support for the MYNX® GRIP TIP

FULLY EXTRAVASCULAR CLOSURE



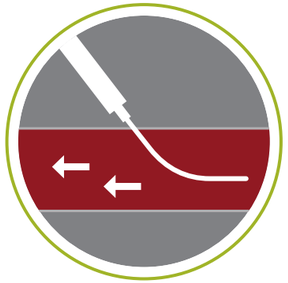
30 DAY RESORBABILITY*

*The sealant hydrolyzes within 30 days; the body's own healing mechanisms are the sole mechanism of action beyond 30 days. P. 2; MYNX CONTROL FDA Submission: # P040044/S079

Secure Extravascular Closure in a wide range of clinical scenarios

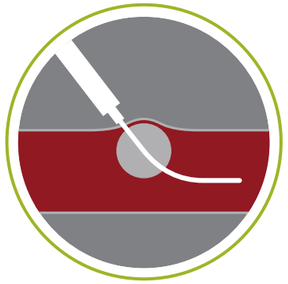
With exceptional versatility, MYNX CONTROL™ VCD offers dependable closure with nothing left behind*—even in cases where using a different vascular closure device might be unsuitable.

Safe for **bifurcations**[2†]



Useful on **antegrade** punctures[3]

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



Balloon **visualization** verifies position

†Confirm vessel size is ≥ 5 mm

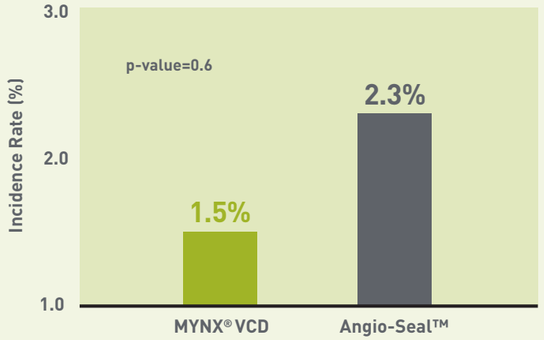
Safety by the Numbers.

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

Established 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 injury[4]



Proven Safe in Clinical Trials and Real-world Use

In a prospective multi-center, non-randomized clinical trial (n=190) MYNX® VCD demonstrated:[2,8]

- **99.5%** Procedure success rate
- **1.3 MIN** Time to hemostasis

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

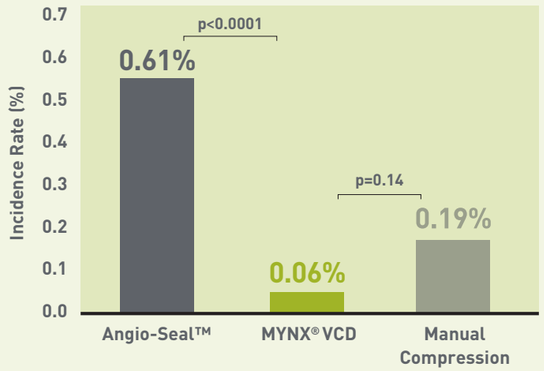
- **99.5%** Same-day discharge

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

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 catheterization, compared to Angio-Seal™ and manual compression.[6]

Rate of surgical repair[6]

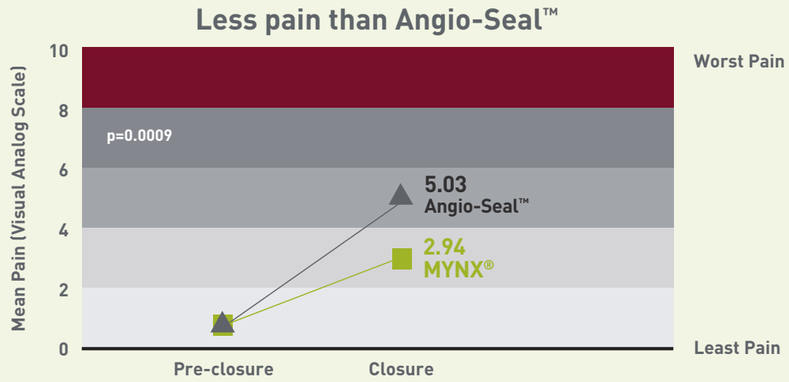


- 10x fewer secondary surgeries than Angio-Seal™[6]
- 3x fewer secondary surgeries than manual compression[6]
- MYNX® VCD complications did not involve embolism or artery damage, worsening of peripheral vascular disease, or necessitate device removal[6]

Increased Patient Comfort

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

Less pain than Angio-Seal™



Made for Predictable Deployment. Designed for Ease of Use.

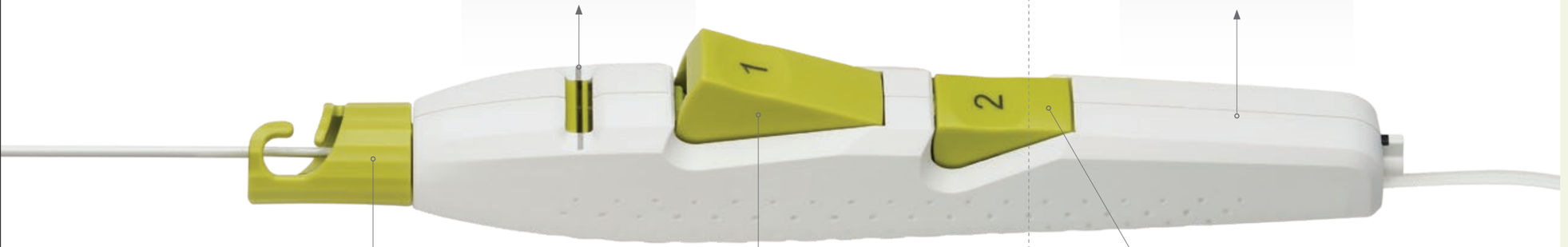
The next-generation MYNX CONTROL™ Vascular Closure Device (VCD) deployment system is purpose-designed to enhance safety and deliver reliable performance.

Tension Indicator

Provides visual confirmation of device position for proper sealant deployment

Ergonomic Handle

Facilitates ease of use for predictable deployment



Sheath Catch

Compatible with procedural sheath—eliminates the need for sheath exchanges§

Button #1

Deploys and compresses the sealant

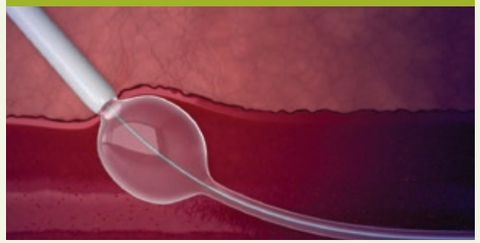
Button #2

One-step balloon withdrawal

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

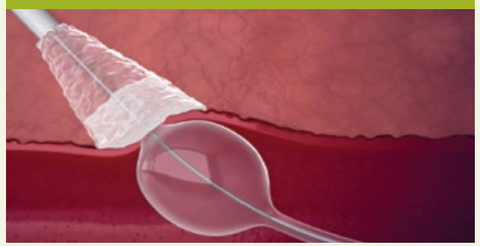
Procedure Steps

1. DEPLOY THE BALLOON



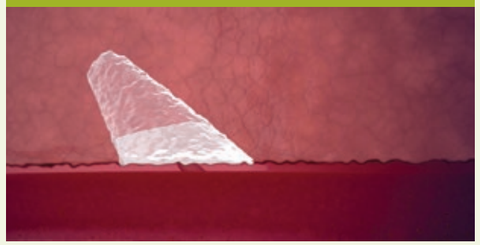
Achieve temporary hemostasis and position at the arteriotomy.

2. PLACE THE SEALANT



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

3. REMOVE THE DEVICE



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

4. FINAL RESULT

The sealant dissolves within 30 days leaving nothing behind but a healed artery.

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 maximize predictability, safety, and ease of use.

SECURE CLOSURE

SAFETY AND PATIENT COMFORT

EASE OF USE

Ordering Information

The MYNX CONTROL™ VCD includes:

(1) MYNX CONTROL™ VCD including balloon catheter and integrated polyethylene glycol sealant

(1) 10 mL locking syringe

SIZE	ORDER NUMBER
5F	MX5060
6F / 7F	MX6760

To order the MYNX CONTROL™ VCD in the United States contact your local Cordis sales rep or customer service at 800.327.7714. To learn more visit cordis.com/mynx.

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. MynxGrip 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 randomized 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).

INDICATIONS FOR USE: MYNX CONTROL™ VCD is indicated for use 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.

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 12 cm effective length or incompatible sheaths listed in Table 9 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 RESTERILIZE. 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 hematoma/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 hematoma/bleed.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

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.

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