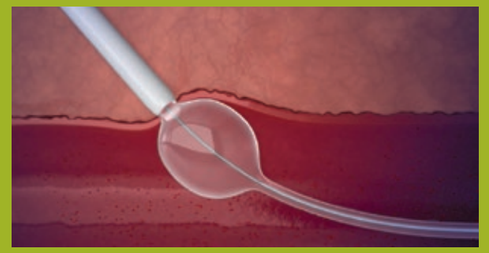
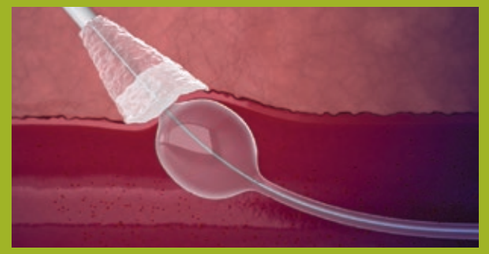
SECURE CLOSURE RESULTS

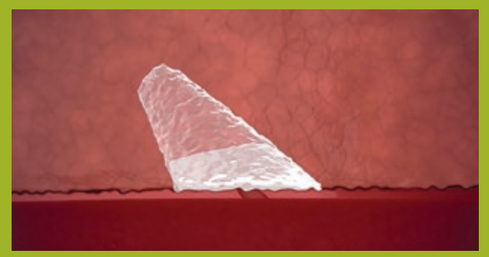
POSITION THE BALLOON
RESULT: TEMPORARY HEMOSTASIS



DEPLOY THE SEALANT
RESULT: CONSISTENT DELIVERY



REMOVE THE DEVICE
RESULT: SECURE EXTRAVASCULAR CLOSURE



SECURE CLOSURE

SAFETY AND PATIENT COMFORT

EASE OF USE

℞ ONLY

ORDERING INFORMATION

The MYNX CONTROL™ Vascular Closure Device includes:

(1) MYNX CONTROL™ VCD including balloon catheter and integrated 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**

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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MYNX CONTROL™
VASCULAR CLOSURE DEVICE

PROCEDURE GUIDE

Cordis®
A Cardinal Health company

MYNX CONTROL™
VASCULAR CLOSURE DEVICE

PREPARATION

Prepare Balloon

- Fill locking syringe with 2 to 3 mL of sterile saline, attach to stopcock and draw vacuum. Check luer connector and tighten if necessary.
- Inflate the balloon until the black marker on the inflation indicator is fully visible. Check for leaks in the balloon and syringe connector; retighten if necessary. Do not use the device if the balloon does not maintain pressure.
- Check for air bubbles in the balloon. If air bubbles are visible, deflate the balloon, draw vacuum to remove bubbles and re-inflate.
- Deflate balloon and leave syringe at neutral.

POSITION THE BALLOON

Insert Device

- Insert the MYNX CONTROL™ Vascular Closure Device into the procedural sheath through the sheath valve.
- Advance the catheter until the sheath catch nears the hub of the sheath.
- Rotate the sheath catch as needed to hook onto the side port of the procedural sheath.

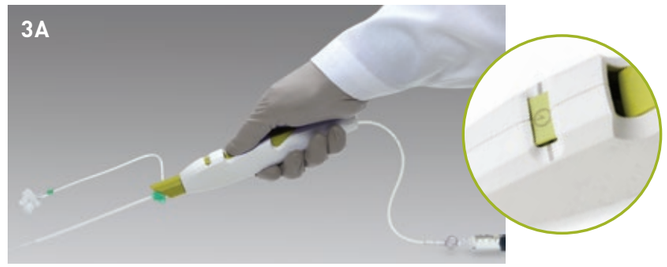
Inflate Balloon

- Inflate the balloon until the black marker is fully visible on the inflation indicator and close stopcock.

Position Balloon

- Grasp the device handle and align the device with the tissue tract.
- Pull gently to retract the device until the black line in the tension indicator window aligns with the markers on the side, indicating the balloon is abutting the arteriotomy with the correct amount of tension.

DEPLOY THE SEALANT



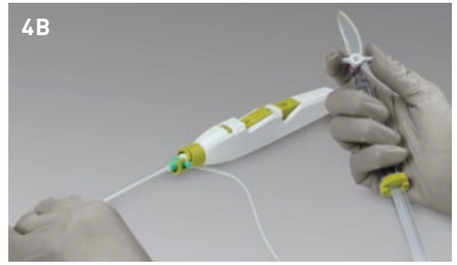
Deploy Sealant

- While maintaining tension **press button #1** until it is fully aligned with the handle, and the clock symbol is visible in the tension indicator window. This deploys and compresses the sealant against the arteriotomy.
- Lay the device down for **two minutes**.

LOCK–STABILIZE–DEFLATE

Lock Syringe

- Retract syringe plunger to lock position.



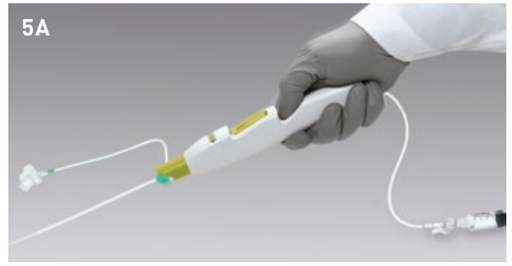
Stabilize Artery*

- Apply light fingertip compression proximal to the insertion site and then lightly grasp the device at skin with thumb and forefinger and realign with the tissue tract.

Deflate Balloon

- Open the stopcock to deflate the balloon.
- To ensure complete balloon deflation, wait until air bubbles and fluid have stopped moving through the inflation tubing.

RETRACT THE BALLOON



- Pick up the device handle and realign with the tissue tract. **Depress button #2** to pull the deflated balloon into the device.

REMOVE THE DEVICE

- While maintaining fingertip compression on the skin, remove the device from the patient.
- Continue to apply fingertip compression for up to **one minute** or as needed.
- Apply a sterile dressing once hemostasis is achieved.

*Failure to complete step may result in bleeding/hematoma.