PREPARATION

Prepare Balloon
• Fill locking syringe with 2-3 ml of sterile saline.
• Attach to stopcock and draw vacuum.
• Inflate balloon until black marker on inflation indicator is fully visible.
• Deflate balloon and leave syringe at neutral.
• Do not remove sealant sleeve.

POSITIONING

Position Device in Artery
• Insert dilator into the Mynx Ace introducer hub.
• Insert a 0.035" guidewire into existing procedural sheath. Remove sheath leaving the guidewire in the artery.
• Advance introducer over guidewire until pulsatile blood flow is observed through the dilator port. Continue to advance introducer approximately 2 cm.
• Remove dilator and guidewire.

ORDERING INFORMATION

The MYNX ACE® Vascular Closure Device includes:
(1) MYNX ACE® Device including balloon catheter and integrated sealant
(1) 10 ml locking syringe
(1) Introducer
(1) Dilator
(1) 0.035" / 0.89 mm Guidewire with J–Straightener

SIZE
6F / 7F
ORDER NUMBER
MX6740

To order the MYNX ACE® Vascular Closure Device 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
The MYNX ACE® Vascular Closure Device 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
The MYNX ACE® Device should only be used by a trained licensed physician or healthcare professional. The MYNX ACE® Device should not be used in patients with a known allergy to PEG.

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. The MYNX ACE® Device 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 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 the MYNX ACE® Device 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 (USA) law restricts these devices to sale by or on the order of a physician. For information on indications, contraindications, warnings, precautions, and adverse events, see Full Instructions for Use. For Healthcare Professional Only.

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**RELIABLE CLOSURE AS EASY AS 1, 2, 3**

**STEP 1: POSITION BALLOON**

- **Insert Device**
  Insert catheter tip into valve of introducer, penetrate valve with sealant sleeve, and continue to advance until connector prongs on device handle lock into the introducer.

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

- **Position Balloon**
  Grasp device handle and pull gently to retract the device until the balloon abuts the arteriotomy.

**STEP 2: DEPLOY SEALANT**

- **Deploy Sealant**
  Press and release button #1 then pull back on the device handle until button #1 is no longer visible. This retracts the introducer and exposes the sealant.

- **Compress Sealant**
  - Maintain tension and depress button #2. This compresses the sealant against the arteriotomy.
  - Lay the device down for up to 2 minutes.

**STEP 3: REMOVE THE DEVICE**

- **Stabilize Artery**
  - Retract syringe plunger to lock position.
  - Apply light fingertip compression proximal to the insertion site then lightly grasp introducer at skin with thumb and forefinger and realign with the tissue tract.

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

- **Remove Device**
  - Pick up device handle and realign with the tissue tract. Slide back button #3. This pulls the deflated balloon into the device.
  - Remove device from patient.
  - Fingertip compression can be applied for up to 1 minute or as needed. Apply a sterile dressing once hemostasis is achieved.