ORDERING INFORMATION

THE MYNXGRIP® Vascular Closure Device includes:

(1) Balloon catheter with integrated sealant
(1) 10ml locking syringe

To order the MYNXGRIP® 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

SIZE | COLOR | MYNX ORDER NUMBER
--- | --- | ---
6F/7F | Green | MX6721
5F | Gray | MX5021

INDICATIONS FOR USE

The MYNXGRIP® Device is indicated for use to seal femoral arterial and femoral venous 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.

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 MYNXGRIP® Device is for single use only. The balloon catheter is loaded with a single hydrogel sealant. Reuse of the device would result in no delivery of hydrogel sealant. Do not use the MYNXGRIP® Device if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) (for arterial application) and/or above the inguinal ligament based upon osseous landmarks, since such a puncture site may result in a retroperitoneal hematoma/bleed. Perform a femoral angiogram or venogram to verify the location of the puncture site. Do not use the MYNXGRIP® 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.

PRECAUTIONS

The MYNXGRIP® Device should only be used by a trained licensed physician or healthcare professional. The MYNXGRIP® Device should not be used in patients with a known allergy to PEG.

Rx only

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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**STEP 1: ACHIEVE TEMPORARY HEMOSTASIS**

**INSERT DEVICE**
- Insert the MYNXGRIP® Device into existing procedural sheath up to the white shaft marker

**INFLATE THE BALLOON**
- Inflate the balloon until the black marker is fully visible on the inflation indicator and close stopcock

**GENTLY PULL BACK TWO STOPS**
- Grasp black handle and withdraw catheter until the balloon abuts the proximal tip of the procedural sheath (first point of resistance)
- Continue to withdraw until the balloon abuts the arteriotomy site (second point of resistance)
- While holding adequate tension on device handle, open stopcock on procedural sheath

**STEP 2: PLACE THE SEALANT**

**ADVANCE THE SEALANT**
- With stopcock open, detach shuttle and advance until resistance is felt

**UNSHEATH THE SEALANT**
- A. Lighten hold on black handle
- B. Grasp procedural sheath and withdraw it from tissue tract
- C. Continue retracting until shuttle locks onto black handle

**ADVANCE PAST SINGLE GREEN MARK**
- Ensure adequate tension is employed on the black handle to keep balloon abutted against the arteriotomy
- Immediately grasp advancer tube at skin and gently advance until single marker is fully visible
- Hold for up to 30 seconds
- Lay device down for up to 90 seconds

**STEP 3: REMOVE THE DEVICE**

**LOCK, STABILIZE, DEFLATE**
- Lock syringe to maximum negative position
- Stabilize by applying light-fingertip compression proximal to the insertion site
- Lightly grasp advancer tube at skin with thumb and forefinger; realign with tissue tract

**DEFlate THE 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 CATHETER AND ADVANCER TUBE**
- Withdraw catheter through the advancer tube lumen
- Finger compression can be applied for up to 60 seconds or as needed
- Assess for hemostasis and apply additional finger compression until sterile dressing is applied and hemostasis is achieved

**RESULT**
- Sealant is in place
- Confirm position at the arteriotomy
- Secure extravascular closure