Cordis

ORDERING INFORMATION

THE MYNXGRIP® Vascular Closure Device includes:

(1) Balloon catheter with integrated sealant

(1) 10ml locking syringe

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

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**

℞ ONLY

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.

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.

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 osseus 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.

CAUTION: Federal (USA) 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.

MYNXGRIP®

MYNXGRIP VASCULAR CLOSURE DEVICE

FINISH STRONG

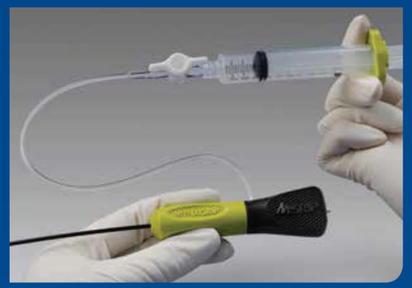
Cordis

MYNXGRIP®

MYNXGRIP VASCULAR CLOSURE DEVICE

REMOVE DEVICE

- Hold the MYNXGRIP® Vascular Closure Device by the shuttle while removing from the tray



PREPARE BALLOON

- Fill locking syringe with 2-3ml 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

STEP 1: ACHIEVE TEMPORARY HEMOSTASIS

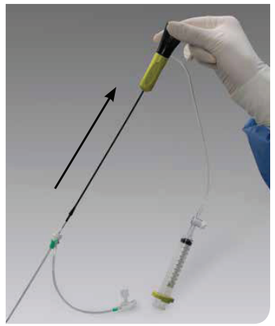
INSERT DEVICE

Insert the MYNXGRIP® Device into existing procedural sheath up to the white shaft marker

INFLATE THE BALLOON

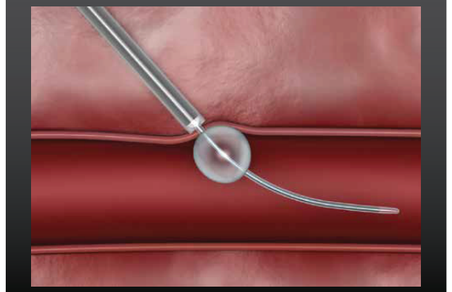
Inflate the balloon until the black marker is fully visible on the inflation indicator and close stopcock

GENTLY PULL BACK TWO STOPS



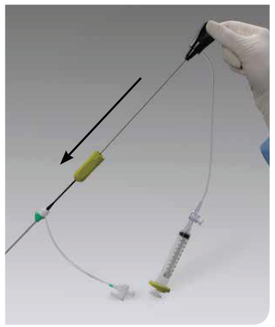
- Grasp black handle and withdraw catheter until the balloon abuts the distal tip of the procedural sheath (first point of resistance)
- Continue to withdraw until the balloon abuts the arteriotomy site (second point of resistance)
- While holding adequate tension on device handle, open stopcock on procedural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

RESULT
CONFIRM POSITION AT THE ARTERIOTOMY



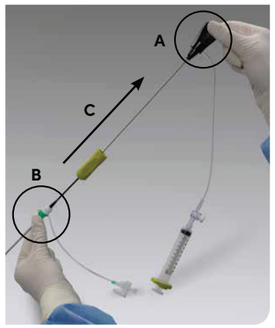
STEP 2: PLACE THE SEALANT

ADVANCE THE SEALANT



With stopcock open, detach shuttle and advance until resistance is felt

UNSHEATH THE SEALANT

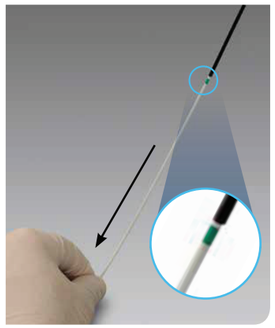


A. Lighten hold on black handle

B. Grasp procedural sheath and withdraw it from tissue tract

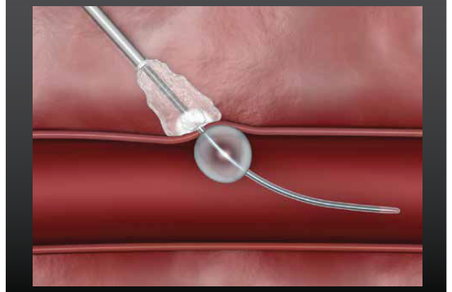
C. Continue retracting until shuttle locks onto black handle

ADVANCE PAST SINGLE GREEN MARK



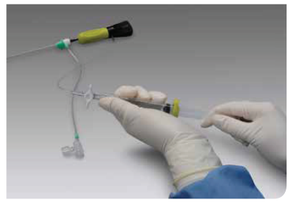
- Ensure adequate tension is employed on the black handle to keep balloon abutted against the arteriotomy
- Immediately grasp advancer tube at skin and gently advance until single marker is fully visible
- Hold for up to 30 seconds
- Lay device down for up to 90 seconds

RESULT
SEALANT IS IN PLACE



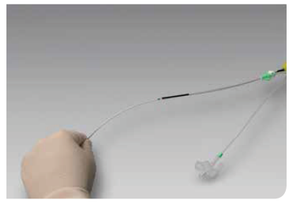
STEP 3: REMOVE THE DEVICE

LOCK, STABILIZE, DEFLATE



LOCK SYRINGE

- Lock syringe to maximum negative position



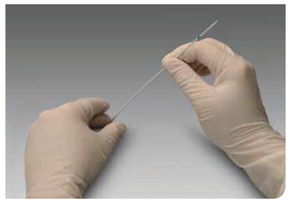
STABILIZE ARTERY

- 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



REMOVE CATHETER AND ADVANCER TUBE

- Withdraw catheter through the advancer tube lumen

NOTE: If unusual resistance is felt during catheter withdrawal, pull the advancer tube and balloon catheter together through the tissue tract

- Remove advancer tube from the tissue tract
- Fingertip compression can be applied for up to 60 seconds or as needed
- Assess for hemostasis and reapply additional fingertip compression until sterile dressing is applied and hemostasis is achieved

RESULT
SECURE EXTRAVASCULAR CLOSURE