Cordis

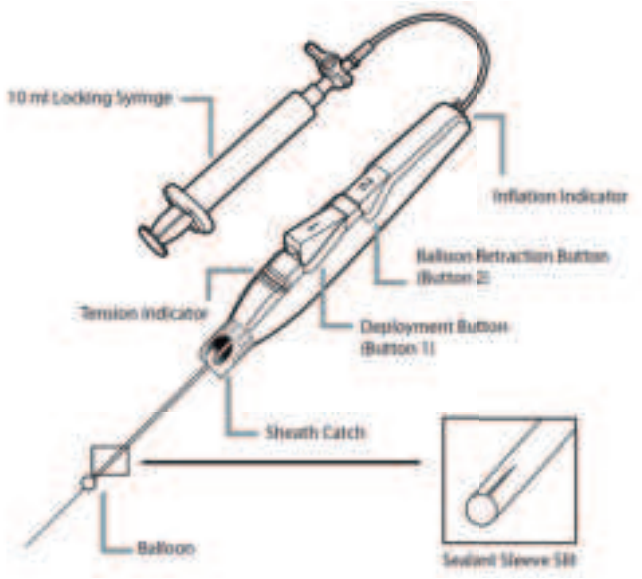
MYNX CONTROL™ VASCULAR CLOSURE DEVICE | VENOUS

LBL10364.4

Instructions for Use
MYNX CONTROL™ VENOUS Vascular Closure Device 6F-12F
MX61260

Explanation of symbols on labels and packaging:	
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not re-use
	Use-by date
	Lot number
	Sterilized using irradiation
	Consult instructions for use or consult electronic instructions for use
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Upper limit of temperature
	Catalogue number
	Manufacturer
	n units per box
	Prohibition
	Wait for two minutes
	Do not re-sterilize
	Caution
	Keep away from sunlight
	Non-Pyrogenic
	10 ml LOCKING SYRINGE
	Medical Device
	Single sterile barrier system; Sterilized using irradiation

Figure 1: MYNX CONTROL VENOUS VCD 6F-12F



ENGLISH

STERILE. Sterilized with electron beam radiation. Nonpyrogenic. For one use only. Do not re-sterilize. Store in a cool, dark, dry place.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Instructions for Use

The device brand name is the Cordis **MYNX CONTROL™ VENOUS Vascular Closure Device (VCD) 6F-12F**

To ensure proper deployment and use of this device and to prevent injury to patients, read all information contained in these instructions for use.

DEVICE DESCRIPTION

The **MYNX CONTROL VENOUS VCD 6F-12F** is designed to achieve femoral vein hemostasis via delivery of the **GRIP TECHNOLOGY**™ sealant, an extravascular, water-soluble synthetic hydrogel, using a balloon catheter in conjunction with a standard procedural sheath. The **GRIP TECHNOLOGY**™ sealant is made of a polyethylene glycol (PEG) material which expands upon contact with subcutaneous fluids to seal the venotomy. The sealant is resorbed by the body within 30 days. The **MYNX CONTROL VENOUS VCD 6F-12F** sheath catch is designed to accommodate large Catheter Sheath Introducers up to 12F inner diameter.

The **MYNX CONTROL VENOUS VCD 6F-12F** is supplied with a 10 ml locking syringe used for balloon inflation and deflation.

The device contains no components manufactured from latex rubber. The catheter shaft has a silicone lubricant to facilitate insertion and withdrawal into compatible sheaths.

Refer to Figure 1 for the **MYNX CONTROL VENOUS VCD 6F-12F** components.

INTENDED PURPOSE
The **MYNX CONTROL VENOUS VCD 6F-12F** is intended to achieve femoral vein hemostasis.

INDICATIONS FOR USE

The **MYNX CONTROL VENOUS Vascular Closure Device (VCD) 6F-12F** is indicated for use to seal femoral venous access sites while reducing times to hemostasis, ambulation, and discharge eligibillityin patients who have undergone catheter-based procedures utilizing 6F to 12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs.

PATIENT TARGET GROUP
The patient target group includes individuals who have undergone catheter-based procedures utilizing 6F to 12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs. The patient target group of this device is based on the patient's anatomy and compatibility with the device.

PERFORMANCE CHARACTERISTICS
The **MYNX CONTROL VENOUS VCD 6F-12F** is designed to achieve femoral vein hemostasis via delivery of an extravascular, water-soluble synthetic sealant using a balloon catheter in conjunction with a standard procedural sheath. The balloon catheter is designed to be introduced into the femoral introducer sheath and provide temporary hemostasis. The hydrogel sealant is housed next to the balloon and delivered in the extravascular space above the venotomy via actuation of a Button in the delivery system when an appropriate tension is applied on the balloon to achieve temporary hemostasis. Upon delivery, the hydrogel sealant expands by absorption of the body fluids to achieve hemostasis.

CONTRAINDICATIONS

There are no known contraindications for the **MYNX CONTROL VENOUS VCD 6F-12F**.

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 CONTROL VENOUS VCD 6F-12F** 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. Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.

Do not use the **MYNX CONTROL VENOUS VCD 6F-12F** if the puncture site is located above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a hematoma/bleed. Verify the location of the puncture site via imaging.

Do not use the **MYNX CONTROL VENOUS VCD 6F-12F** if the puncture is through the posterior wall as such punctures may result in a retroperitoneal hematoma/bleed.

SHEATH INTRODUCERS INCOMPATIBLE WITH MYNX CONTROL VENOUS VCD 6F-12F

USE ONLY WITH A STANDARD SHEATH INTRODUCER with up to 12 cm effective length. Cordis test results have shown that the sheath introducer listed in Table 1 is incompatible with the **MYNX CONTROL VENOUS VCD 6F-12F** due the hemostatic valve design.

Table 1: Incompatible sheath introducer for all French sizes specific to the **MYNX CONTROL VENOUS VCD 6F-12F** range. The third-party trademarks used herein are trademarks of their respective owners.

MANUFACTURER	DESCRIPTION
Cook	Check-Flo™ Performer™ Introducer

The **MYNX CONTROL VENOUS VCD 6F-12F** should not be used if a < 6F or > 12F procedural sheath (inner diameter) is used at closure.

PRECAUTIONS

The **MYNX CONTROL VENOUS VCD 6F-12F** should only be used by a trained licensed physician or healthcare professional.

The **MYNX CONTROL VENOUS VCD 6F-12F** should not be used in patients with a known allergy to PEG.

The safety and effectiveness of the lubricated device has not been established, or is unknown, in vascular regions other than those specifically indicated. Do not expose lubricated catheter shaft to organic solvents or antiseptic solutions. Avoid wiping of the lubricated catheter shaft. In case of resistance with sheath introducer, exercise caution in removing the device and exchange device for a new one. Failure to abide by the warnings in this labeling might result in damage to the device lubrication, which may necessitate intervention or result in serious adverse events.

Exposure to temperatures above 25°C (77°F) may damage the components.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the **MYNX CONTROL VENOUS VCD 6F-12F** have not been established in the following patient populations:

- Pediatric patients or others with small common femoral veins (< 5 mm in diameter)
- Patients with clinically significant peripheral vascular disease in the vicinity of the puncture
- Patients with chronic use of systemic steroids
- Patients with prior surgical procedure, PTA, stent placement, or vascular graft in the common femoral vein
- Patients with bleeding disorders such as thrombocytopenia (platelet count <100,000/mm^3), hemophilia, von Willebrand's disease or anemia (Hgb < 10 g/dL, Hct < 30%)
- Patients with uncontrolled hypertension (systolic BP > 180 mm Hg)
- Patients with morbid obesity (BMI > 45 or < 20kg/m^2)
- Patients who are pregnant or lactating

POTENTIAL ADVERSE EVENTS

Complications may occur and may be related to the procedure or the vascular closure device. They include, but are not limited to:

- Allergic reaction
- Arterio-venous fistula
- Bleeding from the access site
- Bruising at the access site
- Death
- Deep vein thrombosis
- Device failure/malfunction
- Ecchymosis
- Edema
- Embolization (tissue, thrombus, air, calcific debris, device)
- Hematoma
- Infection
- Inflammatory reaction
- Intimal tear / dissection
- Laceration of the vessel wall
- Loss of lower extremity pulse
- Lower extremity ischemia
- Nerve injury
- Oozing from the access site
- Perforation of the vessel wall
- Pseudoaneurysm
- Pulmonary embolism
- Puncture site pain
- Retroperitoneal bleeding
- Superficial vein thrombosis
- Vascular injury
- Vascular occlusion
- Vasovagal response
- Venous thrombus
- Wound dehiscence

For the specific adverse events that occurred during the ReliaSeal Clinical Trial, please see ReliaSeal Clinical Trial Results.

RELIASEAL CLINICAL TRIAL

MYNX CONTROL VENOUS VCD 6F-12F was evaluated for safety and effectiveness in a prospective, multi-center, randomized (2:1) clinical trial comparing **MYNX CONTROL VENOUS VCD 6F-12F** to manual compression (MC) in sealing femoral venous access sites in patients who have undergone catheter-based procedures utilizing one or more procedural sheaths up to 12F with single or multiple access sites in one or both limbs. The study enrolled a total of 314 subjects (44 roll-in and 270 randomized) across 13 U.S. sites. The study endpoint objectives were to demonstrate **MYNX CONTROL VENOUS VCD 6F-12F** non-inferiority safety (combined major venous access site closure- related complications through 30 days post procedure) and effectiveness superiority (Time to Ambulation (TTA) in hours and Time to Hemostasis (TTH) in minutes) compared to MC. The hypothesis for the primary safety endpoint was that the rate of CEC-adjudicated combined major venous access site closure-related complications through 30 days post-procedure for subjects treated with the Mynx CONTROL VENOUS VCD is non-inferior to the rate for subjects using manual compression. Subjects were followed for 30 days after the procedure. Seventy-two (72) subjects (47 **MYNX CONTROL VENOUS VCD** and 25 MC) were enrolled in a duplex ultrasound (DUS) sub study. These subjects had a DUS prior to discharge and, if any complications were noted at discharge, those subjects were required to undergo a DUS at their 30-day follow-up visit.

Patients were required to be ≥ 18 years of age, have signed the informed consent and have planned, elective, non-emergent catheter-based procedure(s) via the common femoral vein(s) using 6F – 12F introducer sheaths with no contraindications for emergent vascular surgery or manual compression of the venous access sites. Pregnant women or women who were lactating or planned to be pregnant were excluded. Patients were excluded if they used systemic steroids (IV or oral) within 30 days, had a history of bleeding disorders, deep vein thrombosis (DVT), pulmonary embolism (PE), or thrombophlebitis within 6 months, had a platelet count < 100,000 cells/mm^3, hemoglobin (Hgb) < 10 g/dl, hematocrit (Hct) < 30%, uncontrolled hypertension (HTN) with systolic BP > 180 mm Hg, or critical illness requiring blood pressure (BP) stabilization, serum creatinine > 2.5 mg/dL, body-mass index (BMI > 45 kg/m^2 or < 20 kg/m^2, any allergy to polyethylene glycol or contrast medium, active systemic infection or cutaneous infection or inflammation at the target access site, Covid-19 infection, positive test within 14 days or recent Covid-19 exposure, life expectancy < 30 days, would refuse a blood transfusion if needed. Patients were also excluded if they had previous vascular surgery or repair in the vicinity of the target access site within 90 days, recent (within 10 days) femoral arteriotomy or venotomy in either limb, use of VCD in either limb within 30 days, planned procedures involving femoral arterial or venous access in either limb within 30 days post procedure or prior to study exit including planned staged procedures or concomitant conditions/comorbidities that per investigator's judgement could extend ambulation attempts beyond 2-3 hours and/or require extended hospitalization or re-hospitalization, or were unable to walk at least 20 feet without assistance.

Exclusion criteria evaluated prior to randomization and related to the index procedure (defined as the endovascular procedure from time of first venous access to the removal of the final procedural or device sheath) included any attempt or inadvertent arterial access/puncture with hematoma, procedural complications that could interfere with routine recovery, ambulation or discharge eligibility times, discretionary physician preference for hemostasis approach, physician determination that the patient could not attempt protocol-required ambulation (subjects randomized to **MYNX CONTROL VENOUS VCD 6F-12F** were required to attempt ambulation within 2 – 2.5 hours from time of final VCD removal – delay > 2.5 hours was a protocol deviation), venous access site location above the inguinal ligament, intra-procedural bleeding around sheath, suspected intraluminal thrombus, hematoma, pseudoaneurysm or AV fistula, difficult insertion of procedural sheath or needle stick problems (e.g., multiple stick attempts, accidental arterial stick with hematoma, "back wall stick", etc.), or use of a < 6F or > 12F procedural sheath at any time during the procedure or at closure.

A total of 270 subjects were randomized, 177 to **MYNX CONTROL VENOUS VCD 6F-12F** and 93 to manual compression with even age distribution (mean 69 years of age) and a larger cohort of men than women (2:1) also evenly distributed in both randomized cohorts.

RELIASEAL CLINICAL TRIAL RESULTS

SAFETY RESULTS

The 177 subjects randomized to **MYNX CONTROL VENOUS VCD 6F-12F** received 503 devices to close 470 access sites (236 limbs) all with technical device success and zero (0) major complications of the target limb(s) access sites within 30 days. Activated clotting time (ACT) was collected at the conclusion of the procedure with mean ACT for subjects reported as 315.4 ± 89.13 seconds and 326.9 ± 72.19 seconds in the **MYNX CONTROL VENOUS VCD 6F-12F** group (50/177) and MC group (24/93), respectively. There were no minor complications of the target limb access site within 30 days in the **MYNX CONTROL VENOUS VCD 6F-12F** group. Minor complications of the target limb access site within 30 days were reported in 5.0% (6 limbs) of the MC group. A clinical events committee (CEC) reviewed major and minor complications. The Major Complications and Minor Complications within 30 days, as adjudicated by the CEC, in all Randomized Subjects are listed in Tables 2 and 3, respectively.

Table 2: CEC Adjudicated Major Complications Directly Attributed to the VCD/Manual Compression within 30 days – Intent to Treat (ITT) Subjects

Major Venous Access Site Closure-Related Complications at 30 Days by Event	MYNX CONTROL VENOUS VCD 6F-12F (N=177 Subjects)		Manual Compression (N=93 Subjects)	
Major Complications of the Target Limb Access Site within 30 Days	0	0.0%*	1	0.8%*
Access site-related bleeding requiring transfusion, surgical intervention, or rehospitalization	0	0.0%	1	0.8%
Vascular injury requiring surgical repair	0	0.0%	0	0.0%
Access site-related infection	0	0.0%	0	0.0%
Access site-related nerve injury	0	0.0%	0	0.0%
Pulmonary embolism	0	0.0%	0	0.0%

*Results calculated on a per limb basis

Table 3: CEC Adjudicated Minor Complications Directly Attributed to the VCD/Manual Compression within 30 days – Intent to Treat (ITT) Subjects

Minor Venous Access Site Closure-Related Complications at 30 Days by Event	MYNX CONTROL VENOUS VCD 6F-12F (N=177 Subjects)		Manual Compression (N=93 Subjects)	
Minor Complications of the Target Limb Access Site within 30 Days	0	0.0%*	6	5.0%*
Pseudoaneurysm - Treated with thrombin injection, fibrin adhesive injection, or ultrasound guided compression and documented by ultrasound	0	0.0%	0	0.0%
Pseudoaneurysm - Not requiring treatment	0	0.0%	1	0.8%
AV Fistula	0	0.0%	0	0.0%
Access site related Hematoma > 6 cm documented by ultrasound	0	0.0%	1	0.8%
Access site-related bleeding requiring > 30 min to achieve hemostasis	0	0.0%	1	0.8%
Late access site-related bleeding (following hospital discharge eligibility)	0	0.0%	2	1.7%
Transient loss of ipsilateral lower extremity pulse	0	0.0%	0	0.0%
Ipsilateral deep vein thrombosis documented by ultrasound	0	0.0%	0	0.0%
Transient access site-related nerve injury	0	0.0%	0	0.0%
Access site-related vessel laceration	0	0.0%	0	0.0%
Access site wound dehiscence	0	0.0%	0	0.0%
Local access site infection confirmed by culture and sensitivity, treated with intramuscular or oral antibiotics - Minor	0	0.0%	0	0.0%
Local access site inflammatory reaction - Minor	0	0.0%	0	0.0%
Allergic reaction	0	0.0%	0	0.0%
Ecchymosis	0	0.0%	1	0.8%

*Results calculated on a per limb basis

EFFECTIVENESS RESULTS

Time to Ambulation (TTA) in the **MYNX CONTROL VENOUS VCD 6F-12F** group was significantly less than in the MC group, with a mean of 2.6 ± 1.03 hours vs. 5.1 ± 4.35 hours, respectively ($p < 0.001$). In addition, Time to Hemostasis (TTH) (analyzed per access site) was significantly reduced in the **MYNX CONTROL VENOUS VCD 6F-12F** subjects compared to the MC (2.1 ± 1.79 minutes vs. 11.4 ± 7.19 minutes, respectively); $p < 0.001$ demonstrating superiority of the **MYNX CONTROL VENOUS VCD 6F-12F** over MC for TTA and TTH statistically. Subjects treated with the **MYNX CONTROL VENOUS VCD 6F-12F** also showed a statistically significant shorter Time to Discharge Eligibility (TTDE/Secondary Effectiveness) compared to subjects treated with MC (3.1 ± 1.24 vs. 5.5 ± 4.58 hours, respectively); $p < 0.001$. The results of the primary endpoints are presented in Table 4 and the results of the secondary effectiveness endpoints are presented in Tables 5a and 5b.

Table 4: Primary Effectiveness Results (TTA and TTH) – Intent to Treat (ITT) Subjects

	MYNX CONTROL VENOUS VCD 6F-12F (N=177 Subjects)	**Manual Compression (N=93 Subjects)**	**P-Value**
Time to Ambulation (hr)			p<0.001
N (number of subjects)	172	91	
Mean ± SD	2.6 ± 1.03	5.1 ± 4.35	
Median (IQR)	2.28 (2.08 - 3.08)	3.90 (2.97 - 5.15)	
Min, Max	(0.83 – 6.42)	(1.15 – 31.17)	
Time to Hemostasis (min)			p<0.001
N (number of access sites)	470	249	
Mean ± SD	2.1 ± 1.79	11.4 ± 7.19	
Median (IQR)	2 (1 - 3)	10 (6 - 15)	
Min, Max	(0 - 19)	(0 - 37)	

Table 5a: Secondary Effectiveness Results (TTDE) – Intent to Treat (ITT) Subjects

	MYNX CONTROL VENOUS VCD 6F-12F (N=177 Subjects)	**Manual Compression (N=93 Subjects)**	**P-Value**
Time to Discharge Eligibility (hr)			
N (number of subjects)	173	91	p<0.001
Mean ± SD	3.1 ± 1.24	5.5 ± 4.58	
Median (IQR)	2.67 (2.35 - 3.52)	4.25 (3.12 - 5.67)	
Min, Max	(0.83 - 8.05)	(1.15 - 31.17)	

Table 5b: Secondary Effectiveness Results (Procedural and Device Success) – Intent to Treat (ITT) Subjects

	MYNX CONTROL VENOUS VCD 6F-12F (N=177 Subjects)	**Manual Compression (N=93 Subjects)**
Procedural Success		
N (number of subjects)	100% (171/171)	98.9% (89/90)
Device Success		
N (number of access sites)	100% (470/470)	N/A

CLINICAL BENEFITS

Reliable closure of femoral vein access sites

CONCLUSIONS

The results from the ReliaSeal Trial demonstrate that patients who underwent catheter-based procedures utilizing 6F - 12F procedural sheaths, with single or multiple access sites in one or both limbs, and who were treated with the **MYNX CONTROL VENOUS VCD 6F-12F** have had statistically and clinically significant decreased time to ambulation and time

to discharge eligibility when compared to patients treated with manual compression. Additionally, time to hemostasis for MYNX CONTROL VENOUS VCD 6F-12F were superior compared to manual compression.

In addition, the trial demonstrated that the rates of total combined major complications were non-inferior for the **MYNX CONTROL VENOUS VCD 6F-12F** (0.0%) compared to manual compression (0.8%) patients. The rates of total combined minor complications were lower for **MYNX CONTROL VENOUS VCD 6F-12F** (0.0%) compared to manual compression (5.0%) patients.

Also, the **MYNX CONTROL VENOUS VCD 6F-12F** arm demonstrated a high procedural success rate (100%) and a high device success rate (100%).

PROCEDURE AND DEVICE PREPARATION

The techniques and procedures described in these Instructions for Use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

HOW SUPPLIED

The **MYNX CONTROL VENOUS VCD 6F-12F** is supplied sterile.

WARNING: Do not use if the **MYNX CONTROL VENOUS VCD 6F-12F** components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened.

WARNING: DO NOT REUSE OR RESTERILIZE. The **MYNX CONTROL VENOUS VCD 6F-12F** is for single use only.

The **MYNX CONTROL VENOUS VCD 6F-12F** includes **(Figure 1)**:

(1) **MYNX CONTROL VENOUS VCD 6F-12F** including balloon catheter and integrated sealant

(1) 10 ml locking syringe.

Also, included in the packaging: One (1) patient brochure for each device.

PROCEDURE PREPARATION

When using the **MYNX CONTROL VENOUS VCD 6F-12F** confirm that the procedural sheath is 6F to 12F inner diameter with effective working length not exceeding 12 cm.

WARNING: USE ONLY WITH A STANDARD SHEATH INTRODUCER with up to 12 cm effective length.

WARNING: Do not use **MYNX CONTROL VENOUS VCD 6F-12F** if a < 6F or > 12F inner diameter procedural sheath is used at closure.

WARNING: The **MYNX CONTROL VENOUS VCD 6F-12F** is not compatible with Cook Check-Flo™ Performer™ Introducer

PRECAUTION: The MYNX CONTROL VENOUS VCD 6F-12F should not be used in patients with a known allergy to polyethylene glycol (PEG).

NOTE:

- If a patient has had a procedural sheath left in place for an extended period of time, consideration should be given to the use of prophylactic antibiotics before inserting the **MYNX CONTROL VENOUS VCD 6F-12F**.
- If the puncture is at or below the femoral bifurcation, the balloon may be prepped with a diluted contrast solution (50% contrast / 50% saline), in place of 100% saline in order to visualize the balloon while pulling back to the venotomy and to ensure that the balloon properly abuts the venotomy.
- Do not use 100% contrast solution as this will impact balloon inflation / deflation.

Confirm via imaging prior to using the **MYNX CONTROL VENOUS VCD 6F-12F**:

- Common femoral vein without posterior wall puncture.
- Evidence of adequate flow.
- No evidence of significant PVD in the vicinity of the puncture.

WARNING: Do not use the **MYNX CONTROL VENOUS VCD 6F-12F** if the puncture site is located above the inguinal ligament based upon bony landmarks.

WARNING: Do not use **MYNX CONTROL VENOUS VCD 6F-12F** if the puncture is through the posterior wall

DEVICE PREPARATION AND POSITIONING

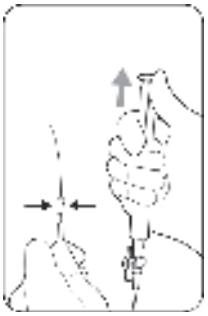
- Flush the procedural sheath with sterile heparinized saline.

PRECAUTION: Do not expose lubricated catheter shaft to organic solvents or antiseptic solutions.

- Remove device components from packaging
- Prepare balloon
  - Fill locking syringe with 2 to 3 ml of sterile saline (or a 50/50 saline/contrast mixture if fluoroscopy will be used to confirm balloon positioning), attach to stopcock and draw vacuum.
    - Check Luer connector and tighten if necessary.
  - Inflate the balloon until the inflation indicator on the back of the device handle extends so that the entire black marker is fully visible with white border on either side.
    - Check for leaks in the balloon and syringe connector; retighten if necessary.
    - Discard the device if the balloon does not maintain pressure.
    - Check for air bubbles in the balloon. If air bubbles are visible, deflate the balloon and draw vacuum with the syringe to remove bubbles. Re-inflate and re-check the balloon to ensure no air bubbles are present.

– Deflate the balloon and leave syringe at neutral. Do not lock. **(Figure 2)**

Figure 2: Deflate Balloon and Leave Syringe at Neutral

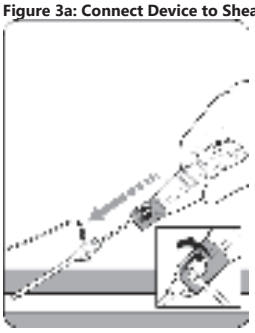


PROCEDURAL STEPS

STEP 1: POSITION BALLOON

- Carefully hold and insert the atraumatic catheter tip of the **MYNX CONTROL VENOUS VCD 6F-12F** through the sheath valve. Align the device to the relative angle of the procedural sheath and carefully advance the catheter until the sheath catch is adjacent to the hub of the sheath. Rotate the sheath catch as needed to hook onto the sideport of the procedural sheath. **(Figure 3a)**

Figure 3a: Connect Device to Sheath



- Orient the device such that the tension indicator window on the handle assembly is clearly visible to the user.
- Inflate the balloon until the inflation indicator on the back of the device handle extends so that the entire black marker is fully visible with white border on either side and close stopcock. **(Figure 3b and 3c)**

Figure 3b: Inflate Balloon

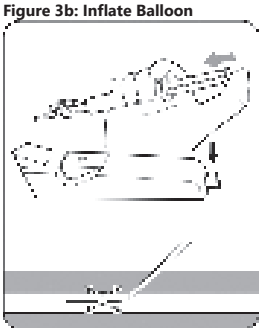


Figure 3c: Close Stopcock

- Align the device with the tissue tract. Pull gently to retract the device and procedural sheath until the black line in the tension indicator window aligns with the marks on both sides of the white handle. This indicates that the balloon is abutting the venotomy and that the device is positioned to appropriately deliver the sealant extravascular to the venotomy. **(Figure 4)**

Figure 4: Tension Indicator

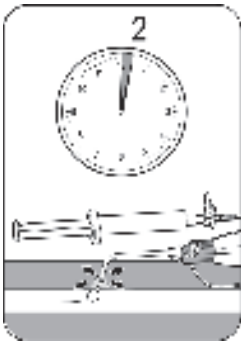
STEP 2: DEPLOY SEALANT

- While maintaining tension alignment of the markings, ***firmly press button #1*** until it is fully depressed. The clock symbol will become visible in the tension indicator window. This deploys and compresses the sealant against the venotomy for effective adhesion. **(Figure 5a)**

Figure 5a: Deploy Sealant

- Lay the device down for ***2 minutes***, allowing the sealant to actively absorb body fluid and swell within the tissue tract. **(Figure 5b)**

Figure 5b: Lay Device Down for 2 Minutes



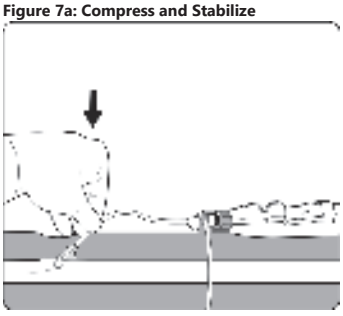
STEP 3: REMOVE DEVICE

- Fully retract the syringe plunger to lock position in order to draw vacuum. **(Figure 6)**

Figure 6: Lock Syringe Plunger

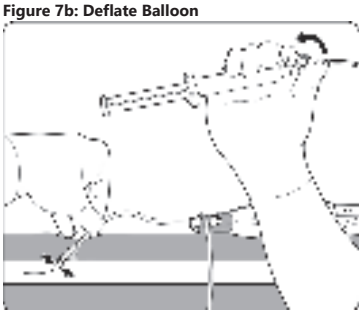
- Apply light fingertip compression proximal to the insertion site and then lightly grasp. the device at skin with thumb and forefinger to ***stabilize*** and realign with the tissue tract. **(Figure 7a)**

Figure 7a: Compress and Stabilize



- Open the stopcock to ***deflate the balloon***. **(Figure 7b)**

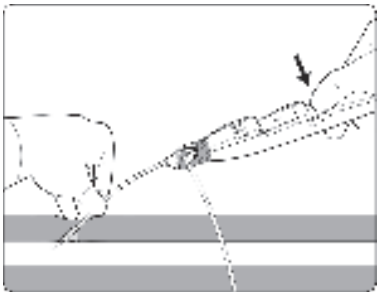
Figure 7b: Deflate Balloon



  – To ensure complete balloon deflation, wait until air bubbles and fluid have stopped moving through the inflation tubing.

- Pick up the device handle and realign with the tissue tract. ***Fully depress button #2*** to retract the deflated balloon into the device catheter. **(Figure 7c)**

Figure 7c: Retract Balloon



- While maintaining fingertip compression on the skin, remove the device with procedural sheath from the patient.
- Continue to apply fingertip compression for up to ***1 minute*** or as needed. **(Figure 8)**

Figure 8: Apply Fingertip Compression

- Apply a sterile dressing once hemostasis is achieved.

It is recommended that the patient follow physician orders regarding patient ambulation and discharge. Refer to Patient Brochure for post-care instructions.

After use, all components used, and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state, and federal laws and regulations.

DEVICE RELATED ADVERSE EVENT REPORTING

Any adverse event (clinical incident) involving the Cordis MYNX CONTROL VENOUS VCD 6F-12F should be reported to Cordis immediately. To report an incident in the U.S.A., call the Product Quality Services Department at 1-800-327-7714.

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