MYNX™

Mynx™ Vascular Closure Device

INSTRUCTIONS FOR USE

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

Caution: Federal Law restricts this device to sale by or on the order of a physician

access | closure

AccessClosure, Inc.
645 Clyde Avenue
Mountain View, CA 94043, USA
Phone: +1 / 650 903 1000
Fax: +1 / 650 903 1018

DEVICE DESCRIPTION

The Mynx Vascular Closure Device (Mynx) is designed to achieve femoral artery hemostasis via delivery of an extravascular, water-soluble synthetic sealant using a balloon catheter in conjunction with a standard procedural sheath. The sealant is made of a polyethylene glycol (PEG) material which expands upon contact with subcutaneous fluids to seal the arteriotomy. The sealant is resorbed by the body within 30 days.

Mynx is supplied with a 10 ml locking syringe used for balloon inflation and deflation. There are no components manufactured from latex rubber.

INDICATIONS FOR USE

Mynx 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.

CONTRAINDICATIONS

There are no known contraindications for Mynx.

WARNINGS

Do not reuse on resterilize. The Mynx is for single use only.

Do not use if the sterilization indicator dot on the pouch is yellow/gold.

Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened.

PRECAUTIONS

Mynx should only be used by a trained licensed physician or healthcare professional.

Mynx should not be used in patients with a known allergy to PEG.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of Mynx have not been established in the following patient populations:

- ☐ Pediatric patients or others with small common femoral arteries (<5 mm in diameter)
- ☐ Patients with clinically significant peripheral vascular disease in the vicinity of the puncture
- ☐ Patients with prior surgical procedure, PTA, stent placement, or vascular graft in the common femoral artery
- ☐ Patients with bleeding disorders such as thrombocytopenia (platelet count <100,000/mm^3), hemophilia, von Willebrand's disease or anemia (Hgb <10g/dL, Hct < 30%)
- ☐ Patients with uncontrolled hypertension (systolic BP >180 mm Hg)
- ☐ Patients with morbid obesity (BMI > 40 kg/m^2)
- ☐ Patients who are pregnant or lactating

- Patients with documented INR > 1.5 or patients currently receiving glycoprotein IIb/IIIa platelet inhibitors

ADVERSE EVENTS

Mynx was evaluated in a prospective multi-center, non-randomized clinical trial involving 190 patients to achieve femoral arterial access site hemostasis following diagnostic angiography (n=95) or interventional procedures (n=95). The control arm (standard compression) from the MATRIX VSG™ System Clinical Trial (MATRIX) was used as a historical control group. Table 1 is a report of the total number and the rate of major and minor complications in the Mynx Trial and the standard compression arm of the MATRIX Trial.

Table 1: Reported Major and Minor Complications (Intent-to-Treat)

All Patients

Major Complications by Event All Patients	Mynx* (n=190)	Standard Compression (Historical Control) (n=164)	p-value†
Vascular Repair	0.0% (0/190)	0.0% (0/164)	N/A
Permanent Access Site-Related Nerve Injury	0.0% (0/190)	0.0% (0/164)	N/A
Surgery For Access Site-Related Nerve Injury	0.0% (0/190)	0.0% (0/164)	N/A
Access Site-Related Bleeding Requiring Transfusion	0.5% (1/190)	0.0% (0/164)	0.0021
New Ipsilateral Lower Extremity Ischemia Requiring Invasive/Non Invasive Intervention	0.0% (0/190)	0.0% (0/164)	N/A
Access Site-Related Infection - Major	0.0% (0/190)	0.0% (0/164)	N/A
Local Access Site Inflammatory Reaction - Major	0.0% (0/190)	0.0% (0/164)	N/A
Generalized Infection	0.0% (0/190)	0.0% (0/164)	N/A
Any Major Complication	**0.5% (1/190)**	**0.0% (0/164)**	0.0021
Minor Complications By Event All Patients	**Mynx* (n=190)**	**Standard Compression (Historical Control) (n=164)**	**p-value†**
Pseudoaneurysm – Treated With Thrombin Injection	0.5% (1/190)	0.0% (0/164)	0.0021
Pseudoaneurysm - Not Requiring Treatment ‡	2.6% (5/190)	0.0% (0/164)	0.0831
AV Fistula	0.0% (0/190)*	0.0% (0/164)	N/A
Hematoma ≥ 6 cm	3.2% (6/190)*§	0.6% (1/164)	0.0853
Access Site-Related Bleeding Requiring > 30 min to Achieve Hemostasis	0.0% (0/190)	0.6% (1/164)	0.0002
Late Access Site-Related Bleeding (Following Hospital Discharge)	0.0% (0/190)	0.0% (0/164)	N/A
Ipsilateral Lower Extremity Arterial Emboli	0.0% (0/190)	0.0% (0/164)	N/A
Transient Loss of Ipsilateral Lower Extremity Pulse	0.0% (0/190)	0.0% (0/164)	N/A
Ipsilateral Deep Vein Thrombosis	0.0% (0/190)*	0.0% (0/164)	N/A
Transient Access Site-Related Nerve Injury	0.0% (0/190)	0.0% (0/164)	N/A

Access Site-Related Vessel Laceration	0.0% (0/190)	0.0% (0/164)	N/A
Access Site Wound Dehiscence	0.0% (0/190)	0.0% (0/164)	N/A
Local Access Site Infection - Minor	0.0% (0/190)	0.0% (0/164)	N/A
Local Access Site Inflammatory Reaction - Minor	0.0% (0/190)	0.0% (0/164)	N/A
Any Minor Complication	**3.7% (7/190)**	**1.2% (2/164)**	0.0921

* Does not include four (4) non-device related events consisting of: AV Fistula (n=2), Ipsilateral Deep Vein Thrombosis (n=1), and Hematoma (n=1).

§ Does not include 1 patient with a pre-existing hematoma prior to deployment of Mynx.

‡ In a subset of Mynx patients, ultrasound assessment was performed prior to patient discharge which revealed some patients had developed small pseudoaneurysms which resolved spontaneously. The events are reported in the table above, but are not included in the overall rate of minor complications.

† p-value based on test for non-inferiority.

Table 2: Reported Major and Minor Complications (Intent-to-Treat) Diagnostic Patients

Major Complications By Event Diagnostic Patients	Mynx* Diagnostic (n=95)	Standard Compression (Historical Control) Diagnostic (n=83)	p-value†
Vascular Repair	0.0% (0/95)	0.0% (0/83)	N/A
Permanent Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/83)	N/A
Surgery For Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/83)	N/A
Access Site-Related Bleeding Requiring Transfusion	0.0% (0/95)	0.0% (0/83)	N/A
New Ipsilateral Lower Extremity Ischemia Requiring Invasive/Non Invasive Intervention	0.0% (0/95)	0.0% (0/83)	N/A
Access Site-Related Infection - Major	0.0% (0/95)	0.0% (0/83)	N/A
Local Access Site Inflammatory Reaction - Major	0.0% (0/95)	0.0% (0/83)	N/A
Generalized Infection	0.0% (0/95)	0.0% (0/83)	N/A
Any Major Complication	**0.0% (0/95)**	**0.0% (0/83)**	N/A
Minor Complications By Event Diagnostic Patients	**Mynx* Diagnostic (n=95)**	**Standard Compression (Historical Control) Diagnostic (n=83)**	**p-value†**
Pseudoaneurysm – Treated With Thrombin Injection	1.1% (1/95)	0.0% (0/83)	0.0459
Pseudoaneurysm - Not Requiring Treatment ‡	1.1% (1/95)	0.0% (0/83)	0.0459
AV Fistula	0.0% (0/95)*	0.0% (0/83)	N/A
Hematoma ≥ 6 cm	2.1% (2/95)*§	1.2% (1/83)	0.0599
Access Site-Related Bleeding Requiring > 30 min to Achieve Hemostasis	0.0% (0/95)	0.0% (0/83)	N/A
Late Access Site-Related Bleeding (Following Hospital Discharge)	0.0% (0/95)	0.0% (0/83)	N/A
Ipsilateral Lower Extremity Arterial Emboli	0.0% (0/95)	0.0% (0/83)	N/A
Transient Loss of Ipsilateral Lower Extremity Pulse	0.0% (0/95)	0.0% (0/83)	N/A
Ipsilateral Deep Vein Thrombosis	0.0% (0/95)	0.0% (0/83)	N/A
Transient Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/83)	N/A
Access Site-Related Vessel Laceration	0.0% (0/95)	0.0% (0/83)	N/A
Access Site Wound Dehiscence	0.0% (0/95)	0.0% (0/83)	N/A
Local Access Site Infection - Minor	0.0% (0/95)	0.0% (0/83)	N/A
Local Access Site Inflammatory Reaction - Minor	0.0% (0/95)	0.0% (0/83)	N/A
Any Minor Complication	**3.2% (3/95)**	**1.2% (1/83)**	0.1458

* Excludes non-device related events consisting of: AV Fistula (n=2) and Hematoma (n=1).

§ Excludes 1 patient with pre-existing hematoma prior to deployment of Mynx.

‡ In a subset of Mynx patients, ultrasound assessment was performed prior to patient discharge which revealed some patients had developed small pseudoaneurysms which resolved spontaneously. The events are reported in the table above, but are not included in the overall rate of minor complications.

† p-value based on test for non-inferiority.

Table 3: Reported Major and Minor Complications (Intent-to-Treat) Interventional Patients

Major Complications By Event Interventional Patients	Mynx* Interventional (n=95)	Standard Compression (Historical Control) Interventional (n=81)	p-value†
Vascular Repair	0.0% (0/95)	0.0% (0/81)	N/A
Permanent Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/81)	N/A
Surgery For Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/81)	N/A
Access Site-Related Bleeding Requiring Transfusion	1.1% (1/95)	0.0% (0/81)	0.0459
New Ipsilateral Lower Extremity Ischemia Requiring Invasive/Non Invasive Intervention	0.0% (0/95)	0.0% (0/81)	N/A
Access Site-Related Infection - Major	0.0% (0/95)	0.0% (0/81)	N/A
Local Access Site Inflammatory Reaction - Major	0.0% (0/95)	0.0% (0/81)	N/A
Generalized Infection	0.0% (0/95)	0.0% (0/81)	N/A
Any Major Complication	**1.1% (1/95)**	**0.0% (0/81)**	0.0459
Minor Complications By Event Interventional Patients	**Mynx* Interventional (n=95)**	**Standard Compression (Historical Control) Interventional (n=81)**	**p-value†**
Pseudoaneurysm – Treated With Thrombin Injection	0.0% (0/95)	0.0% (0/81)	N/A
Pseudoaneurysm - Not Requiring Treatment ‡	4.2% (4/95)	0.0% (0/81)	0.4819
AV Fistula	0.0% (0/95)	0.0% (0/81)	N/A
Hematoma ≥ 6 cm	4.2% (4/95)	0.0% (0/81)	0.4819
Access Site-Related Bleeding Requiring > 30 min to Achieve Hemostasis	0.0% (0/95)	1.2% (1/81)	0.0060
Late Access Site-Related Bleeding (Following Hospital Discharge)	0.0% (0/95)	0.0% (0/81)	N/A
Ipsilateral Lower Extremity Arterial Emboli	0.0% (0/95)	0.0% (0/81)	N/A
Transient Loss of Ipsilateral Lower Extremity Pulse	0.0% (0/95)	0.0% (0/81)	N/A
Ipsilateral Deep Vein Thrombosis	0.0% (0/95)*	0.0% (0/81)	N/A
Transient Access Site-Related Nerve Injury	0.0% (0/95)	0.0% (0/81)	N/A
Access Site-Related Vessel Laceration	0.0% (0/95)	0.0% (0/81)	N/A
Access Site Wound Dehiscence	0.0% (0/95)	0.0% (0/81)	N/A
Local Access Site Infection - Minor	0.0% (0/95)	0.0% (0/81)	N/A
Local Access Site Inflammatory Reaction - Minor	0.0% (0/95)	0.0% (0/81)	N/A
Any Minor Complication	**4.2% (4/95)**	**1.2% (1/81)**	0.2950

* Excludes non-device related event consisting of: Ipsilateral Deep Vein Thrombosis (n=1).

‡ In a subset of Mynx patients, ultrasound assessment was performed prior to patient discharge which revealed some patients had developed small pseudoaneurysms which resolved spontaneously. The events are reported in the table above, but are not included in the overall rate of minor complications.

† p-value based on test for non-inferiority.

The following potential adverse reactions or conditions may also be associated with Mynx or with the diagnostic or interventional procedure: allergic reaction, foreign body reaction, infection, inflammation, or vessel laceration.

CLINICAL TRIAL

Mynx was evaluated in a prospective, multi-center, non-randomized clinical trial designed to evaluate its safety and effectiveness in sealing femoral arterial access sites in patients following diagnostic or interventional catheterization procedures. The study was conducted in Germany at five institutions involving 190 patients. Patients eligible for participation included candidates for early ambulation and patients who were clinically indicated for a diagnostic or interventional procedure involving access through the femoral artery using a 5F, 6F or 7F sheath with an overall sheath length ≤ 15.7 cm.

The objective for the safety endpoints of the study was to demonstrate non-inferiority to a historical control group, and the objective for the effectiveness endpoints of the study was to demonstrate superiority to the historical group. The historical control group consisted of patients treated with standard compression who were enrolled in the control arm of the MATRIX Trial conducted under IDE# G030182.

Patients were required to be at least 18 years of age, to have signed an Informed Consent Form, and to have undergone a diagnostic or interventional procedure through the common femoral artery. Patients were excluded if they presented with clinically significant peripheral vascular disease, prior procedure in the ipsilateral common femoral artery ≤ 30 days before the Mynx study catheterization procedure, ipsilateral closure device, known allergy to contrast medium or device materials, a myocardial infarction with elevated ST segment ≤ 24 hours prior to procedure, uncontrolled hypertension, existing bleeding disorder, evidence of infection or local inflammation, chronic corticosteroid therapy ≥ 1 month duration, common femoral artery diameter < 5 mm, pre-existing bleeding around the procedural sheath, pre-existing hematoma, intraluminal thrombus, pseudoaneurysm, AV fistula, any type of dissection, fibrotic, calcified, or > 50% stenotic femoral artery, arterial puncture outside the common femoral artery, ipsilateral venous sheath, multiple arterial sticks, suspected posterior femoral arterial wall puncture, antegrade puncture, intra-aortic balloon pump, or planned extended hospitalization.

The majority of the patients were male (n=133) vs. female (n=57) with all patients' ages ranging from 40 to 85 years. Of the 190 patients enrolled, 50% were diagnostic patients and 50% were interventional patients. The average activated clotting time (ACT) for interventional patients was 223 ± 84 seconds with a range of 108-634 seconds, and for diagnostic patients, 187 ± 81 seconds with a range of 133-280 seconds.

EFFECTIVENESS RESULTS

The study objective for the primary effectiveness endpoints was to demonstrate that the Mynx patient results were superior to the historical control arm (standard compression patients from the MATRIX Trial). The results of the effectiveness measures are summarized in Table 4 for all patients and in Table 5 for diagnostic and interventional patients.

Table 4: Effectiveness and Secondary Endpoints
All Patients

Effectiveness All Patients	Mynx	Standard Compression (Historical Control)	p-value†
Time to Hemostasis (minutes)*			
mean ± standard deviation (n)	1.3 ± 2.3 (183)	25.4 ± 16.2 (161)	<0.0001
median (Q1, Q3) (n)	0.5 (0.0, 2.0) (183)	20.0 (15.0, 30.0) (161)	<0.0001
range (min, max) (n)	(0.0, 22.5)	(6.0, 120.0)	N/A
Time to Ambulation (hours)*			
mean ± standard deviation (n)	2.6 ± 2.6 (181)	7.4 ± 4.8 (160)	<0.0001
median (Q1, Q3) (n)	2.0 (1.8, 2.2) (181)	6.0 (4.5, 7.4) (160)	<0.0001
range (min, max)	(1.3, 20.0)	(1.6, 26.9)	N/A
Secondary Endpoints	**Mynx**	**Standard Compression (Historical Control)**	**p-value†**
Device Success	93.2% (177/190)	N/A	N/A
Procedure Success	99.5% (189/190)	100.0% (164/164)	1.0000

*The number of patients used to calculate effectiveness measures differ from overall study sample size due to missing values.
† p-value based on test for superiority.
Note: Times to ambulation varied across investigational sites due to individual hospital practices and protocol.

Table 5: Effectiveness and Secondary Endpoints
Diagnostic and Interventional Patients

Effectiveness	Mynx Diagnostic	Standard Compression (Historical Control) Diagnostic	p- value†	Mynx Interventional	Standard Compression (Historical Control) Interventional	p-value†
Time to Hemostasis* (minutes)						
mean ± standard deviation (n)	1.0 ± 1.3 (92)	23.6 ± 17.1 (83)	<0.0001	1.5 ± 2.9 (91)	27.3 ± 15.2(78)	<0.0001
median (Q1, Q3) (n)	0.5 (0.0, 1.6) (92)	19.0 (14.0, 25.0) (83)	<0.0001	0.6 (0.0, 2.0) (91)	25.0 (19.0, 30.0) (78)	<0.0001
range (min, max)	(0.0, 6.0)	(6.0, 120.0)	N/A	(0.0, 22.5)	(10.0, 120.0)	N/A
Time to Ambulation* (hours)						
mean ± standard deviation (n)	2.5 ± 2.1 (91)	5.4 ± 2.7 (82)	<0.0001	2.8 ± 3.0 (90)	9.4 ± 5.6 (78)	<0.0001
median (Q1, Q3) (n)	2.0 (1.9, 2.3) (91)	5.2 (4.3, 6.1) (82)	<0.0001	1.9 (1.8, 2.2) (90)	7.1 (5.5, 11.8) (78)	<0.0001
range (min, max)	(1.4, 19.6)	(1.6, 26.9)	N/A	(1.3, 20.0)	(2.5, 22.3)	N/A

Secondary Endpoints	Mynx Diagnostic	Standard Compression (Historical Control) Diagnostic	p- value†	Mynx Interventional	Standard Compression (Historical Control) Interventional	p-value†
Device Success	93.7% (89/95)	N/A	N/A	92.6% (88/95)	N/A	N/A
Procedure Success	100% (95/95)	100% (83/83)	N/A	98.9% (94/95)	100% (81/81)	1.0000

*The number of patients used to calculate effectiveness measures differ from overall study sample size due to missing values.
† p-value based on test for superiority.
Note: Times to ambulation varied across investigational sites due to individual hospital practices and protocol.

Procedure success was defined as successfully achieving hemostasis using any method with freedom from major complications. Device success was defined as the ability to deploy the delivery system, deliver the sealant, and achieve hemostasis with Mynx at the femoral artery puncture site. The procedure success rate was 99.5% demonstrating successful hemostasis in all patients with only one major complication reported. The device success rate for Mynx was 93.2%.

Time to discharge was a secondary endpoint for the diagnostic patients only. The time to discharge was defined as the time from tamping tube removal to the time a patient was discharged from the hospital. The mean time to discharge was 32.3 ± 55.6 hours for the Mynx group compared to 20.1 ± 36.1 hours for the historical control standard compression group (p=0.02). In the subset of diagnostic patients, the mean time to discharge for Mynx patients was 35.3 ± 71.4 hours compared to 17.3 ± 47.6 hours for the historical control standard compression group (p=0.06). The mean time to discharge for Mynx interventional patients was 29.0 ± 31.1 hours compared to 23.0 ± 16.9 hours for the interventional historical control standard compression group (p=0.15). The differences in time to discharge may be due to the differences in standard of care for patients treated in Europe (Mynx patients) compared to patients treated in the United States (standard compression historical control group).

Table 6: Cumulative Time to Hemostasis
All Patients*

Time to Hemostasis (minutes)	Mynx (n=183)	Standard Compression (Historical Control) (n=161)
1	59.0% (108)	0.0% (0)
2	83.6% (153)	0.0% (0)
3	91.8% (168)	0.0% (0)
4	94.5% (173)	0.0% (0)
5	96.2% (176)	0.0% (0)
10	98.9% (181)	5.0% (8)
15	99.4% (182)	26.7% (43)
20	99.4% (182)	53.4% (86)
25	**100% (183)**	64.6% (104)
>30	**100% (183)**	**100% (161)**

Table 7: Cumulative Time to Ambulation
All Patients*

Time to Ambulation (hours)	Mynx (n=181)	Standard Compression (Historical Control) (n=160)
2	50.8% (92)	1.3% (2)
3	90.0% (163)	3.8% (6)
4	92.3% (167)	12.5% (20)
5	93.9% (170)	35.6% (57)
10	97.2% (176)	83.8% (134)
15	98.3%(178)	89.4% (143)
20	**100% (181)**	95.6% (153)
25	**100% (181)**	99.4% (159)
>30	**100% (181)**	**100% (160)**

*The number of patients differs from overall study sample size due to missing values

Table 8: Cumulative Time to Discharge Diagnostic Patients*

Time to Discharge (hours)	Mynx Diagnostic (n=79)	Standard Compression Diagnostic (n=82)
2	0.0% (0)	0.0% (0)
3	2.5% (2)	1.2% (1)
4	16.5% (13)	4.9% (4)
5	19.0% (15)	18.3% (15)
10	25.3% (20)	81.7% (67)
15	29.1% (23)	82.9% (68)
20	38.0% (30)	84.1% (69)
25	67.1% (53)	89.0% (73)
30	82.3% (65)	91.5% (75)
> 30	**100% (79)**	**100% (82)**

*The number of patients differs from overall study sample size due to missing values

Overall, the primary effectiveness endpoints were successfully met in the Mynx study. Patients treated with Mynx had reduced times to hemostasis and ambulation compared to patients treated with standard compression. In addition, the Mynx procedures demonstrated a high level of both procedural and device success.

CONCLUSIONS

The results from this clinical trial demonstrate that patients who have undergone diagnostic or interventional procedures utilizing a 5F, 6F or 7F procedural sheath and treated with Mynx have superior times to hemostasis and ambulation compared to patients in the standard compression control arm of the Matrix Trial.

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 Vascular Closure Device is supplied sterile. Do not use if Mynx components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened.

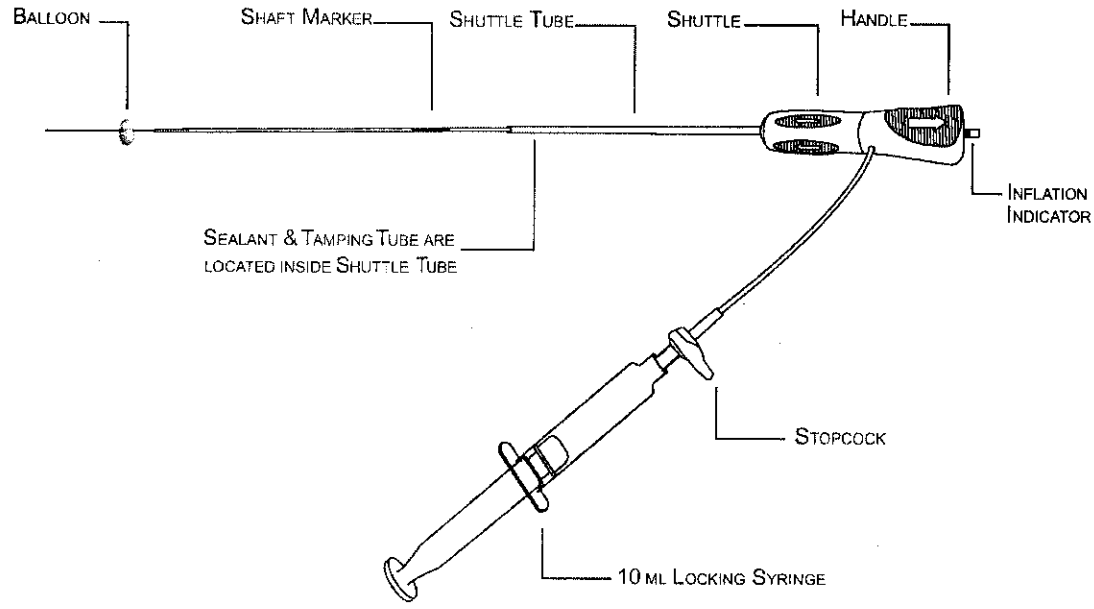
WARNING: DO NOT REUSE OR RESTERILIZE. Mynx is for single use only.

The Mynx Vascular Closure Device includes (**Figure 1**):

(1) Balloon catheter with integrated sealant

(1) 10 ml locking syringe

Figure 1: Mynx Vascular Closure Device



PROCEDURE PREPARATION

Confirm that the introducer sheath is 6F or 7F with an overall length not exceeding 15.7 cm.

NOTE:

- 5F or smaller sheaths must be exchanged to 6F or 7F before inserting Mynx.
- If a patient has had a procedure sheath left in place for an extended period of time, consideration should be given to the use of prophylactic antibiotics before inserting Mynx.
- When a venous sheath has been placed in the same leg as the arterial sheath, the venous sheath should be removed and hemostasis obtained prior to the use of Mynx.

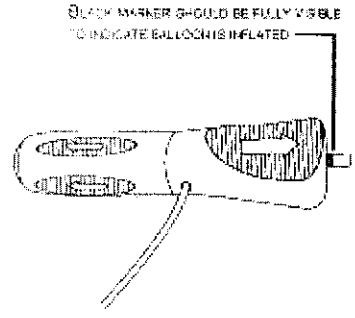
Confirm via femoral arteriogram:

- Common femoral artery single wall puncture.
- Evidence of adequate flow.
- There is no evidence of significant PVD in the vicinity of the puncture.

DEVICE PREPARATION

- Flush the procedural sheath with sterile heparinized saline.
- Remove the Mynx syringe and catheter from the tray.
- 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 balloon until black marker on inflation indicator is fully visible (**Figure 2**).
  - Check for leaks in the balloon and syringe connector; retighten if necessary.
  - Discard if the balloon does not maintain pressure.
- Deflate balloon and leave syringe at neutral. Do not lock.
- Submerge tip of shuttle tube in saline bath for 3-5 seconds prior to insertion. The sealant may swell 1-2 mm beyond black shuttle tube and become slightly exposed.

Figure 2: Mynx Inflation Indicator



PROCEDURAL STEPS

STEP 1: POSITION BALLOON

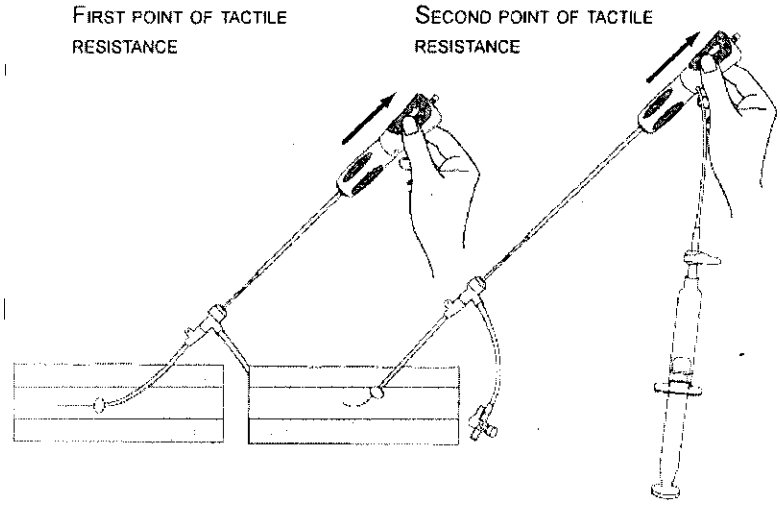
- Insert Mynx into the procedural sheath up to the white shaft marker.
- Inflate the balloon until the black marker is fully visible on the inflation indicator (**Figure 2**), and close stopcock.
- Grasp handle and withdraw catheter until the balloon abuts the distal tip of the procedural sheath (**Figure 3a**). Continue to withdraw the balloon catheter until the balloon abuts the arteriotomy site (**Figure 3b**).

Figure 3a

FIRST POINT OF TACTILE RESISTANCE

Figure 3b

SECOND POINT OF TACTILE RESISTANCE



The balloon is now providing temporary hemostasis and the tip of the introducer sheath is just above the vessel

STEP 2: DEPLOY SEALANT

- While maintaining minimal tension on the balloon catheter, open procedural sheath stopcock, then detach shuttle and advance until resistance against the balloon is felt (**Figure 4a**).
- Release tension from device handle, grasp procedural sheath and withdraw it from tissue tract. Continue retracting until shuttle locks onto handle (**Figure 4b**).
- Grasp tamping tube at skin and gently advance 2 markers (**Figure 5**), then lay the device down. Turn stopcock and lock syringe to deflate balloon, allowing several seconds for complete deflation.

Figures 4a and 4b

ADVANCE SHUTTLE, GRASP INTRODUCER SHEATH AND RETRACT UNTIL SHUTTLE LOCKS ON HANDLE

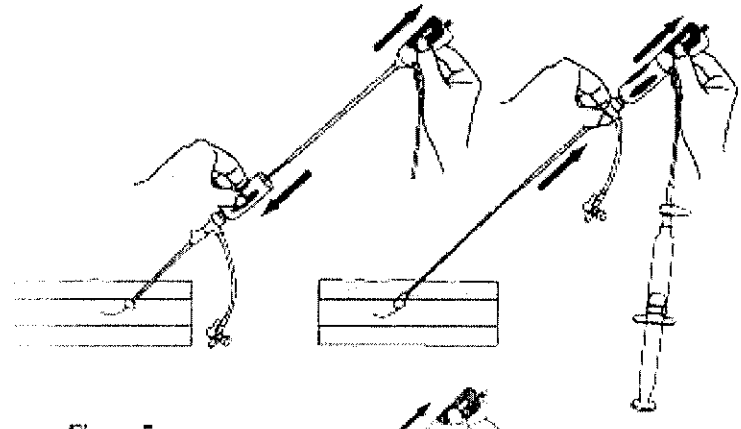
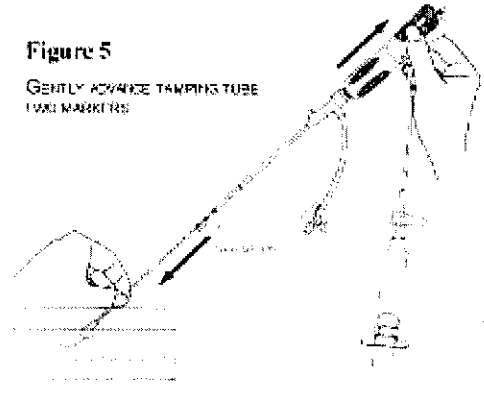


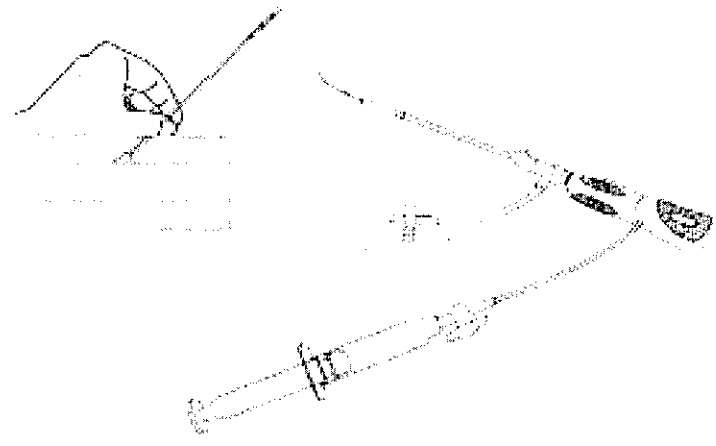
Figure 5

GENTLY ADVANCE TAMPING TUBE TWO MARKERS



- **STEP 3: REMOVE DEVICE**
- Grasp tamping tube at skin with thumb and forefinger, applying light fingertip compression.
- Grasp handle and pull balloon catheter through the tamping tube lumen.
- Remove tamping tube from the tissue tract. Fingertip compression can be applied for up to 2 minutes as needed (**Figure 6**).
- Once patient is assessed for hemostasis, firm fingertip compression should be re-applied and maintained until sterile dressing is applied. If hemostasis is not achieved after deploying Mynx, apply additional compression until hemostasis is achieved.

Figure 6

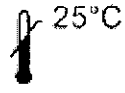


It is recommended that the patient follow physician orders regarding patient ambulation and discharge.

PRODUCT INFORMATION DISCLOSURE

AccessClosure, Inc. has exercised reasonable care in the manufacture of Mynx. AccessClosure, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond AccessClosure, Inc.'s control, directly affect the Mynx and the results obtained from its use. AccessClosure, Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of Mynx. AccessClosure, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with Mynx.

RX ONLY

	Do Not Reuse - Single Use Only		Use By Date
LOT	Lot Number	STERILE R	Sterilized using Irradiation
	Read Instructions for Use		Manufacturer
	Keep Dry – Protect from Moisture	 25°C	Maximum Temperature, 25°C
	Do Not Use if Package is Open or Damaged	REF	Model Number
		CONTENTS	Contents of the package

Mynx™ is a trademark of AccessClosure, Inc.

This product and/or its manufacture are covered by one or more of the following U.S. patents: 6,605,294 and 6,887,974. European patent: 1,631,197 B1. Further U.S. and foreign patents are pending.