AccessClosure inc.

THE MATRIX VSG™ SYSTEM
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 (USA) law restricts this device to sale by or on the order of a physician.

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THE MATRIX VSG™ SYSTEM INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Matrix VSG™ System is comprised of a synthetic polyethylene glycol (PEG) hydrogel that is delivered extravascularly using a balloon catheter to seal femoral arterial access sites. During hydrogel delivery, the balloon catheter provides temporary hemostasis at the access site of the vessel. The PEG precursor solutions are injected into the extravascular tissue tract above the access site where they crosslink, forming a flexible and tissue-adherent hydrogel that provides local hemostasis. After delivery of the precursor solutions, the balloon catheter is deflated and removed along with the introducer sheath. The formed hydrogel resorbs completely within 30 days.

INDICATIONS FOR USE

The Matrix VSG System 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 to the use of the Matrix VSG System.

WARNINGS

- Do not use if the Matrix VSG System 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 Matrix VSG System is for single use only.

PRECAUTIONS

- The Matrix VSG System should only be used by licensed physicians (or other health care professionals authorized by or under the direction of such physicians) possessing adequate training in the use of the Matrix VSG System, e.g., participation in a Matrix VSG System operator training program or equivalent.
- Maintain sterile technique at all times when using the Matrix VSG System.
- The Matrix VSG System must be used within 15 minutes after polymer reconstitution.
- Dispose of contaminated device, components, and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.
- Do not use the Matrix VSG System in patients with known allergy to PEG.
- Use of the Matrix VSG System may cause a minor or major local access site inflammatory reaction associated with the hydrogel polymer that is formed. These inflammatory reactions occurred infrequently during the United States multicenter clinical study of the Matrix VSG System and were resolved. The user of the device should be aware of this potential complication.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the Matrix VSG System have not been established in the following patient populations:

- Patients younger than 18 years of age
- Patients who are pregnant or lactating
- Patients with morbid obesity (BMI > 40 kg/m^2)
- Patients with sheath sizes other than 5F, 6F, or 7F or sheath lengths greater than 15 cm
- Patients with small common femoral arteries (< 6.5 mm in diameter)
- Patients with puncture located outside the common femoral artery or at the level of bifurcation, antegrade puncture, multiple arterial punctures, suspected posterior wall puncture, or side branch puncture
- Patients with clinically significant peripheral vascular disease
- Patients with prior surgical procedure, PTA, stent placement, vascular graft, or intra-aortic balloon pump at the puncture site
- Patients with suspected hematoma, intraluminal thrombus, pseudoaneurysm, AV fistula, or vessel dissection at the conclusion of endovascular procedure
- Patients who received an ipsilateral closure device before the manufacturer's recommended timeframe for re-access
- Patients with an ipsilateral venous sheath or patients with intra-procedural bleeding around the arterial or venous sheath
- Patients with bleeding disorders such as thrombocytopenia (platelet count < 100,000), hemophilia, von Willebrand's disease, or significant anemia (Hgb < 10g/dL, Hct < 30%)
- Patients with documented INR > 1.5, patients currently receiving glycoprotein IIb/IIIa platelet inhibitors, or patients with an ACT > 350 seconds at the conclusion of the endovascular procedure
- Patients with uncontrolled hypertension (systolic BP > 180 mm Hg or diastolic BP > 110 mm Hg) despite therapy
- Patients currently receiving chronic corticosteroid therapy ≥ 1 month in duration
- Patients with evidence of infection, local inflammation, or an indwelling sheath in place > 90 minutes

ADVERSE EVENTS

The Matrix VSG System, Model 100-CM5, was evaluated in a controlled, multi-center, randomized clinical trial involving 500 patients randomized to either Matrix VSG System (n=336) or compression (n=164) using a 2:1 ratio to achieve femoral arterial access site hemostasis following diagnostic angiography (n=251) or interventional procedures (n=249). **Table 1** reports the number and percentage of Matrix or compression complications reported during the clinical trial. **Table 2** and **Table 3** include the major and minor complications reported for patients undergoing diagnostic procedures and patients undergoing interventional procedures, respectively.

Table 1: Reported Major and Minor Complications (Event-Based)—All Patients

Complication	Matrix (n=336) % (n)	Compression (n=164) % (n)	p-value
Major Complications:[1]			
Pseudoaneurysm requiring intervention[2]	0.3% (1)	0.0% (0)	1.00
Leg Ischemia	0.3% (1)	0.0% (0)	1.00
Localized Infection Treated with IV Antibiotics	0.3% (1)	0.0% (0)	1.00
Inflammation Treated with IV Antibiotics or Extended Hospitalization[3]	1.2% (4)	0.0% (0)	0.31
Total	2.1% (7)	0.0% (0)	0.10
Minor Complications:[1]			
Pseudoaneurysm not requiring treatment	0.6% (2)	0.0% (0)	1.00
Pseudoaneurysm treated with thrombin injection	0.9%(3)	0.0% (0)	0.55
Hematoma ≥ 6 cm	1.2% (4)	0.6% (1)	1.00
Bleeding Requiring > 30 min Compression	0.0% (0)	0.6% (1)	0.33
Bleeding Following Hospital Discharge	0.3% (1)	0.0% (0)	1.00
Ipsilateral Lower Extremity Emboli	0.3% (1)	0.0% (0)	1.00
Ipsilateral Deep Vein Thrombosis	0.3% (1)	0.0% (0)	1.00
Inflammation Treated with PO Antibiotics	1.5% (5)	0.0% (0)	0.18
Total	5.1% (17)	1.2% (2)	0.04

[1] Those protocol-stipulated major and minor complications that are not listed in the table did not occur in either the Matrix or the compression patients.
[2] Pseudoaneurysm requiring ultrasound guided compression.
[3] Treatment with IV antibiotics (n=3) or treatment with oral antibiotics and re-hospitalization for incision and drainage (n=1).

Table 2: Reported Major and Minor Complications (Event-Based)—Diagnostic Patients

Complication	Matrix (n=168) % (n)	Compression (n=83) % (n)	p-value
Major Complications:[1]			
Pseudoaneurysm requiring intervention	0.0% (0)	0.0% (0)	NA
Leg Ischemia	0.0% (0)	0.0% (0)	NA
Localized Infection Treated with IV Antibiotics	0.0% (0)	0.0% (0)	NA
Inflammation Treated with IV Antibiotics or Extended Hospitalization	1.2% (2)	0.0% (0)	1.00
Total	1.2% (2)	0.0% (0)	1.00
Minor Complications:[1]			
Pseudoaneurysm not requiring treatment	0.6% (1)	0.0% (0)	1.00
Pseudoaneurysm treated with thrombin injection	0.0% (0)	0.0% (0)	NA
Hematoma ≥ 6 cm	0.6% (1)	1.2% (1)	0.55
Bleeding Requiring > 30 min Compression	0.0% (0)	0.0% (0)	NA
Bleeding Following Hospital Discharge	0.6% (1)	0.0% (0)	1.00
Ipsilateral Deep Vein Thrombosis	0.0% (0)	0.0% (0)	NA
Inflammation Treated with PO Antibiotics	1.2% (2)	0.0% (0)	1.00
Total	3.0% (5)	1.2% (1)	0.67

[1] Those protocol-stipulated major and minor complications that are not listed in the table did not occur in either the Matrix or the compression patients.

Table 3: Reported Major and Minor Complications (Event-Based)—Interventional Patients

Complication	Matrix (n=168) % (n)	Compression (n=81) % (n)	p-value
Major Complications:[1]			
Pseudoaneurysm requiring intervention	0.6% (1)	0.0% (0)	1.00
Leg Ischemia	0.6% (1)	0.0% (0)	1.00
Localized Infection Treated with IV Antibiotics	0.6% (1)	0.0% (0)	1.00
Inflammation Treated with IV Antibiotics or Extended Hospitalization	1.2% (2)	0.0% (0)	1.00
Total	3.0% (5)	0.0% (0)	0.18
Minor Complications:[1]			
Pseudoaneurysm not requiring treatment	0.6% (1)	0.0% (0)	1.00
Pseudoaneurysm treated with thrombin injection	1.8%(3)	0.0% (0)	0.55
Hematoma ≥ 6 cm	1.8% (3)	0.0% (0)	0.55
Bleeding Requiring > 30 min Compression	0.0% (0)	1.2% (1)	0.33
Bleeding Following Hospital Discharge	0.0% (0)	0.0% (0)	NA
Ipsilateral Lower Extremity Emboli	0.6% (1)	0.0% (0)	1.00
Ipsilateral Deep Vein Thrombosis	0.6% (1)	0.0% (0)	1.00
Inflammation Treated with PO Antibiotics	1.8% (3)	0.0% (0)	0.55
Total	7.1% (12)	1.2% (1)	0.07

[1] Those protocol-stipulated major and minor complications that are not listed in the table did not occur in either the Matrix or the compression patients

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The combined rate of major complications was the primary safety endpoint of the trial. A major complication was defined as vascular repair; surgically treated or permanent nerve injury at the access site; access site-related transfusion; any new ipsilateral lower extremity ischemia; access site-related infection treated with intravenous (IV) antibiotics or extended hospitalization; inflammatory reaction treated with IV antibiotics, surgical intervention, or extended hospitalization; and generalized infection or septicemia treated with IV antibiotics. There were seven (7) reported major complications in the Matrix group compared to no reports of major complications in the compression group.

The combined rate of minor complications was the secondary safety endpoint. A minor complication was defined as pseudoaneurysm or AV fistula not requiring treatment, pseudoaneurysm treated with thrombin injection, hematoma ≥ 6 cm, access site-related bleeding requiring > 30 minutes to re-achieve hemostasis, late access site-related bleeding, ipsilateral lower extremity arterial emboli, transient loss of ipsilateral lower extremity pulse, ipsilateral deep vein thrombosis, transient access site-related nerve injury, access site-related vessel laceration, access site wound dehiscence, access site infection treated with intramuscular or oral antibiotics, and access site inflammation treated with oral antibiotics. There were seventeen (17) reports of minor complications in the Matrix group compared to two (2) in the compression group.

None of the complications were considered unanticipated events. The observed rates of major complications support the trial hypotheses that the combined rate of major complications for the Matrix arm are non-inferior to those of the compression group. There were no deaths during the study.

The following potential adverse reactions or conditions may also be associated with the Matrix VSG System or endovascular procedures:

- Allergic reaction
- Foreign body reaction
- Nerve injury
- Bleeding requiring transfusion
- Vessel laceration
- Wound dehiscence

CLINICAL TRIAL

The Matrix VSG System, Model 100-CM5, was evaluated in a controlled, multi-center, randomized clinical trial designed to evaluate the safety and effectiveness of the Matrix VSG System in sealing femoral arterial access sites when compared to compression. The study was conducted in the United States at 13 institutions involving 500 patients randomized to either Matrix VSG System or compression using a 2:1 ratio. Patients eligible for participation included candidates for early ambulation and patients who were clinically indicated for a diagnostic or an interventional endovascular procedure involving access through the femoral artery using a 5F, 6F, or 7F sheath.

Patients were required to be at least 18 years of age, to have signed an Informed Consent Form, and to have undergone a catheterization procedure through the femoral artery. Patients were excluded if they presented with clinically significant peripheral vascular disease; prior procedure in the ipsilateral common femoral artery ≤ 30 days; known allergy to contrast medium or device materials; a myocardial infarction ≤ 72 hours prior to procedure; uncontrolled hypertension; existing bleeding disorder; common femoral artery diameter < 6.5 mm; pre-existing hematoma, intraluminal thrombus, pseudoaneurysm, AV fistula, or any type of dissection; fibrotic, calcified, or > 50% stenotic femoral artery; puncture below or at the common femoral artery bifurcation, or in the profunda femoris or superficial femoral artery; pre-existing bleeding around the arterial sheath; ipsilateral venous sheath; multiple arterial sticks; suspected posterior femoral arterial wall puncture; antegrade puncture; ACT > 350 seconds at the conclusion of the endovascular procedure; current treatment with glycoprotein IIb/IIIa inhibitors; or planned extended hospitalization.

The majority of the patients were male [72.4% (362/500)] with all patients' ages ranging from 28.4 to 87.8 years. Of the 500 patients enrolled, 50% were diagnostic patients and the remaining 50% were interventional patients.

The effectiveness endpoints were tested by two-sided hypotheses in which the mean values for the Matrix VSG System and compression treatment groups were compared.

The results of the effectiveness measures are summarized in **Table 4** for all study patients. **Table 5** and **Table 6** include the effectiveness measures for patients undergoing diagnostic procedures and patients undergoing interventional procedures, respectively.

Table 4: Effectiveness Results – All patients

Effectiveness Measures	Matrix* n=336	Compression* n=164	P-value
Time to Hemostasis (mins) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=335 5.3 ± 13.4 2.0 (2.0,3.0) (1.0, 165.0)	n=161 25.4 ± 16.2 20.0 (15.0, 30.0) (6.0, 120.0)	< 0.0001
Time to Ambulation (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=336 3.9 ± 6.1 2.1 (2.0, 2.7) (1.0, 71.8)	n=160 7.4 ± 4.8 6.0 (4.5, 7.4) (1.6, 26.9)	< 0.0001
Time to Discharge - Actual (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=334 19.6 ± 26.3 18.1 (4.1, 24.0) (1.7, 216.6)	n=160 20.1 ± 36.1 14.8 (6.3, 22.0) (2.6, 404.8)	0.87
Time to Discharge Eligibility (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=330 14.7 ± 21.5 5.6 (3.1, 21.2) (1.7, 214.1)	n=159 13.0 ± 11.5 7.3 (5.5, 18.9) (2.4, 106.9)	0.25

*The number of patients used to calculate effectiveness measures differ from overall study sample size due to missing values.

Table 5: Effectiveness Results – Diagnostic patients

Effectiveness Measures	Matrix n=168	Compression n=83	P-value
Time to Hemostasis (mins) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=168 3.6 ± 6.3 2.0 (2.0,3.0) (1.0, 60.0)	n=83 23.6 ± 17.1 19.0 (14.0, 25.0) (6.0, 120.0)	< 0.0001
Time to Ambulation (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=168 2.7 ± 3.9 2.1 (2.0, 2.2) (1.0, 52.1)	n=82 5.4 ± 2.7 5.2 (4.3, 6.1) (1.6, 26.9)	< 0.0001
Time to Discharge - Actual (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=167 8.8 ± 19.4 4.2 (3.2, 5.5) (1.7, 192.3)	n=82 17.3 ± 47.6 6.3 (5.4, 7.3,) (2.6, 404.8)	0.13
Time to Discharge Eligibility (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=166 5.5 ± 10.9 3.1 (2.6, 4.2) (1.7, 214.1)	n=83 9.6 ± 13.7 6.0 (4.9, 6.7) (2.4, 106.9)	0.02

Table 6: Effectiveness Results – Interventional patients

Effectiveness Measures	Matrix n=168	Compression n=81	P-value
Time to Hemostasis (mins) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=167 7.1 ± 17.8 2.0 (2.0,4.0) (1.0, 165.0)	n=78 27.3 ± 15.2 25.0 (19.0, 30.0) (10.0, 120.0)	< 0.0001
Time to Ambulation (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=168 5.1 ± 7.4 2.2 (2.0, 4.4) (1.3, 71.8)	n=78 9.4 ± 5.6 7.1 (5.5, 11.8) (2.5, 22.3)	< 0.0001
Time to Discharge - Actual (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=167 30.3 ± 28.0 23.5 (20.4, 26.3) (3.8, 216.6)	n=78 23.0 ± 16.9 20.6 (17.0, 23.4) (3.0, 140.0)	0.13
Time to Discharge Eligibility (hrs) Mean ± SD Median (25^{th}, 75^{th}) Range (min, max)	n=164 24.0 ± 25.3 20.7 (17.8, 23.6) (1.9, 214.1)	n=76 16.7 ± 6.8 17.5 (13.5, 20.6) (3.0, 38.4)	< 0.0001

Time to hemostasis and time to ambulation were the primary effectiveness endpoints of the trial. Time to hemostasis was defined as the time from sheath removal to when hemostasis was first observed. Time to ambulation was defined as the time from sheath removal to the time a patient walks at least 20 feet. The mean ± standard deviation (median) time to hemostasis was 5.3 ± 13.4 minutes (2 minutes) for the Matrix VSG group compared to 25.4 ± 16.2 minutes (20 minutes) for the compression group with $p < 0.0001$. The mean ± standard deviation (median) time to ambulation was 3.9 ± 6.1 hours (2 hours) for the Matrix VSG group compared to 7.4 ± 4.8 hours (6 hours) for the compression group with $p < 0.0001$. These results support the study hypotheses that the Matrix

VSG System reduced the time to hemostasis and ambulation when compared to standard compression.

Time to discharge and discharge eligibility were secondary effectiveness endpoints of the trial. Time to discharge was defined as the time from sheath removal to hospital discharge. Time to discharge eligibility was defined as the time from sheath removal to the time when the patient is medically able to be discharged based solely on the assessment of the access site, as determined by the patient's physician. The mean ± standard deviation (median) time to discharge for the Matrix VSG group was 19.6 ± 26.3 hours (18.1 hours) compared to 20.1 ± 36.1 hours (14.8 hours) for the compression group with $p = 0.87$. The mean ± standard deviation (median) time to discharge eligibility for the Matrix VSG group was 14.7 ± 21.5 hours (5.6 hours) compared to 13.0 ± 11.5 hours (7.3 hours) for the compression group with $p = 0.25$.

Table 7 includes the cumulative time to hemostasis, ambulation, discharge, and discharge eligibility for the two study groups.

Table 7. Cumulative Distributions of Time Variables

VARIABLE	MATRIX	Standard Compression
Time to Hemostasis		
≤ 2 min	66.9% (224/335)	0.0% (0/161)
≤ 5 min	85.7% (287/335)	0.0% (0/161)
≤ 10 min	89.9% (301/335)	5.0% (8/161)
≤ 15 min	94.9% (318/335)	26.7% (43/161)
≤ 20 min	96.4% (323/335)	53.4% (86/161)
≤ 50 min	98.5% (330/335)	94.4% (152/161)
Time to Ambulation		
≤ 2 hours	14.9% (50/336)	1.3% (2/160)
≤ 3 hours	77.7% (261/336)	3.8% (6/160)
≤ 4 hours	81.5% (274/336)	12.5% (20/160)
≤ 5 hours	87.5% (294/336)	35.6% (57/160)
≤ 10 hours	93.8% (315/336)	83.8% (134/160)
≤ 24 hours	98.5% (331/336)	99.4% (159/160)
Time to Actual Hospital Discharge		
≤ 2 hours	0.3% (1/334)	0.0% (0/160)
≤ 3 hours	7.5% (25/334)	1.3% (2/160)
≤ 4 hours	22.8% (76/334)	3.1% (5/160)
≤ 5 hours	35.3% (118/334)	11.3% (18/160)
≤ 10 hours	45.8% (153/334)	44.4% (71/160)
≤ 24 hours	75.1% (251/334)	85.0% (136/160)
≤ 48 hours	93.4% (312/334)	94.4% (151/160)
Time to Discharge Eligibility		
≤ 2 hours	4.2% (14/330)	0.0% (0/159)
≤ 3 hours	23.6% (78/330)	1.3% (2/159)
≤ 4 hours	38.5% (127/330)	3.8% (6/159)
≤ 5 hours	47.0% (155/330)	17.6% (28/159)
≤ 10 hours	54.2% (179/330)	54.1% (86/159)
≤ 24 hours	87.3% (288/330)	92.5% (147/159)
≤ 48 hours	96.1% (317/330)	99.4% (158/159)

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 Matrix VSG delivery system, inject the Matrix VSG precursors, and achieve hemostasis at the femoral artery puncture site. **Table 8** includes a summary of procedure and device success for the two study groups. The procedure success rate was 97.9% for the Matrix VSG group and 100% for the control group, demonstrating no statistically significant difference between the two groups (p=0.10). The device success rate for the Matrix VSG group was 90.5%. Procedure and device success rates are also stratified by type of endovascular procedure (diagnostic versus interventional procedure).

Table 8: Procedure and Device Success

Effectiveness Measures	Matrix	Compression	P-value
All Patients			
Device Success	90.5% (304/336)		
Procedure Success	97.9% (329/336)	100% (164/164)	0.10
Diagnostic Patients			
Device Success	94.0% (158/168)		
Procedure Success	98.8% (166/168)	100% (83/83)	1.00
Interventional Patients			
Device Success	86.9% (146/168)		
Procedure Success	97.0% (163/168)	100% (81/81)	0.18

Conclusions

The results from this clinical trial demonstrate that patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F, or 7F procedural sheath and have received the Matrix VSG System have statistically and clinically significant decreased times to hemostasis and ambulation compared to that for patients treated with standard compression. In vitro and in vivo testing and the clinical study together provide valid scientific evidence that the Matrix VSG System is safe and effective when used in accordance with its labeling.

In addition, patients who have undergone diagnostic endovascular procedures utilizing a 5F, 6F, or 7F procedural sheath and have received the Matrix VSG System have a statistically and clinically significant decreased time to discharge eligibility compared to that for patients treated with standard compression.

PRE-PROCEDURE

At the end of the endovascular procedure, a femoral arteriogram is necessary to confirm that:

- The puncture is located within the common femoral artery
- The femoral artery is > 6.5 mm in diameter
- There is evidence of adequate arterial flow
- No clinically significant peripheral vascular disease is present in the vicinity of the arterial sheath (external iliac, superficial femoral, or profunda femoris)

Additionally, do not proceed if there are multiple arterial punctures, or there is suspected posterior wall puncture or side branch puncture.

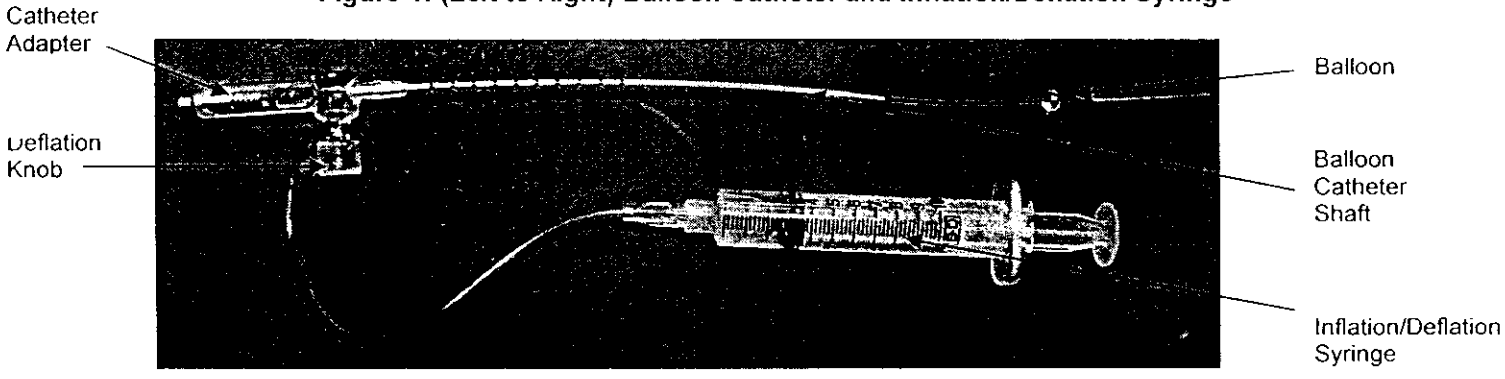
If any of the above conditions are not confirmed, do NOT continue the procedure with the Matrix VSG System. Use an alternative method of closure.

HOW SUPPLIED

Inspect the Matrix VSG System packaging and individual components. Do NOT use if the packaging or any of the components appear damaged.

The Matrix VSG System is supplied sterile and contains the following components as labeled in **Figure 1, Figure 2** and **Figure 3**. There are no components manufactured from latex rubber.

Figure 1: (*Left to Right*) Balloon Catheter and Inflation/Deflation Syringe



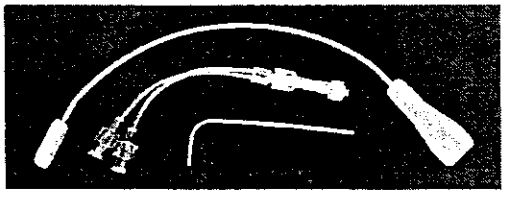


Figure 2: (*Top to Bottom*) Tensioner, Y Connector and Peel-Away Insertion Sleeve

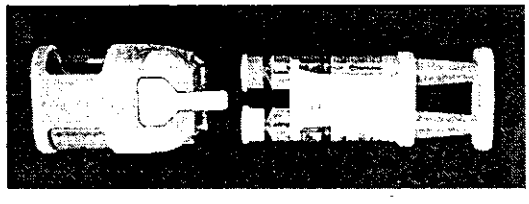


Figure 3: (*Left to Right*) Polymer Vial Carrier and Buffer Syringes

PROCEDURE

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.

The Matrix VSG System procedure is composed of three phases:

A. Prepare the Device

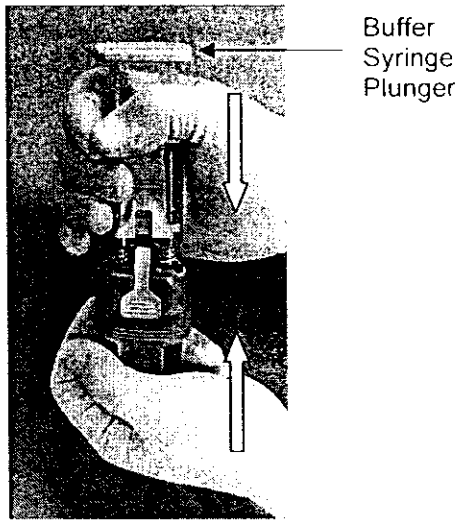
B. Locate the Arteriotomy

C. Seal the Access Site

A. PREPARE THE DEVICE

1. Carefully remove all components from the packaging.
   - **Inspect the polymer vial carrier to ensure that the powders are free flowing. If the powders are not free flowing, discard entire system.**
2. Prepare the Polymer
   a. Remove the buffer syringe caps. Hold the buffer syringe body and attach to the vial carrier (**Figure 4**). Firmly press the two components together until the vial carrier latch clicks into place.
      - **Do not hold and press down on the buffer syringe plunger prior to complete engagement of the two components.**

Figure 4



   b. Inject the entire contents of the buffer syringes into the polymer vials and gently shake the unit in the upright position until the powders are completely dissolved.
      - **The Matrix VSG System must be used within 15 minutes after polymer reconstitution.**
   c. Withdraw the entire contents of the polymer solutions from the vials into each buffer syringe.
   d. Depress the latch on the vial carrier to separate buffer syringes. Check to ensure that there is an equivalent amount of solution in each syringe (at least 2 ml) with no air bubbles.

e. Inject up to two drops of precursor solutions from each syringe onto the sterile field and mix together. The mixed solutions should form into a gel within 8 seconds.

- **If the solution does not form into a gel, discard entire system.**

f. Attach the Y-connector to the buffer syringes but do not pre-inject the solution into the Y-connector.

3. Prepare the Balloon Catheter and Tensioner

a. Remove the protective tubing from the balloon catheter shaft.

b. Draw 3 – 5 ml of sterile saline into the inflation/deflation syringe and attach the syringe to the catheter extension line.

c. Pull back the inflation/deflation syringe plunger and lock into the extended position. Depress the deflation knob on the side of the catheter adapter then release the knob to aspirate the air out of the catheter. Slowly release the inflation/deflation syringe plunger to the neutral position.

d. Slowly depress the inflation/deflation syringe plunger until the inflation indicator extends out of the proximal end of the adapter to inflate the balloon. Refer to **Figure 5** for proper inflation. Pull back the inflation/deflation syringe plunger until it locks into the extended position.

- **Balloon under inflation or over inflation may affect device performance. When inflating the balloon, the position of the black marker band must be verified and should not extend short of or beyond the proximal end of the adapter (Figure 6 and Figure 7 depict incorrect inflation).**
- **Wait about 5 – 10 seconds to verify the balloon remains fully inflated. Do not use the device if the balloon does not remain inflated.**

CORRECT (Proper Inflation)

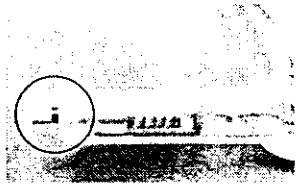


Figure 5

INCORRECT (Under Inflation)

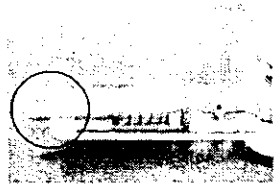


Figure 6

INCORRECT (Over Inflation)

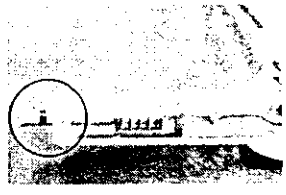


Figure 7

e. Depress the deflation knob to completely deflate the balloon. Slowly release the inflation/deflation syringe plunger to the neutral position.

f. Prepare the tensioner by rotating the bottom plate to snap it into place.

B. Locate the Arteriotomy

Prior to deploying the balloon catheter, ensure that all procedural devices have been removed from the sheath.

1. Fill a 10 ml syringe with 5 ml of sterile saline and thoroughly flush the introducer sheath. Leave the syringe attached to the sidearm of the introducer sheath and close the stopcock.

2. Insert the distal tip of the balloon catheter through the introducer sheath until the catheter shaft is fully advanced against the introducer sheath.

- **An optional peel-away insertion sleeve is provided to facilitate catheter introduction.**

3. Inflate the balloon, then pull back the inflation/deflation syringe plunger until it locks into the extended position. Refer to **Figure 5** for proper inflation.
4. Hold the catheter adapter and gently pull back the catheter until the first resistance is felt (**Figure 8** illustrates balloon against the sheath). Continue to pull back the catheter until the second resistance is felt (**Figure 9** illustrates balloon against the arteriotomy).

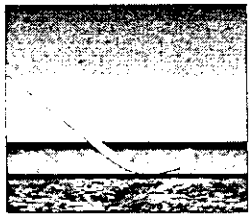


Figure 8

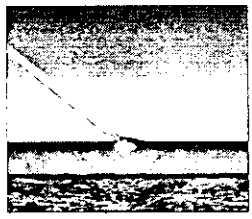


Figure 9

5. Continue to hold tension. Place the tensioner between the skin and the adapter in order to maintain temporary hemostasis (**Figure 10**).

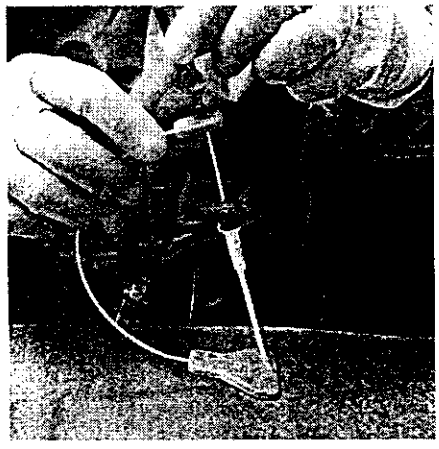
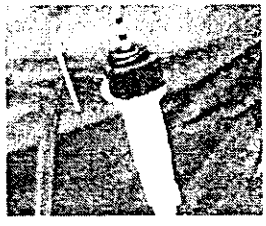


Figure 10

6. Withdraw the introducer sheath hub up to 5 mm or 1 marker band (**Figure 11**).
   - **Each reference marker is spaced 5 mm apart.**

Figure 11



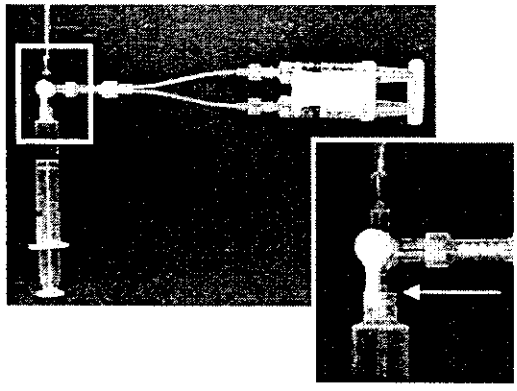
7. Draw a vacuum on the syringe attached to the introducer sheath to confirm temporary hemostasis. Leaving the syringe attached, turn the stopcock off to syringe. Repeat as necessary to ensure tract is as dry as possible.
   - **If bleeding is noted in the sidearm of the sheath, do not continue the procedure with the Matrix VSG System; use an alternative method for closure.**

- **In order to avoid inadvertent hydrogel injection, do not inject the Matrix VSG System precursor solutions if temporary hemostasis is not obtained with the balloon catheter.**

C. SEAL THE ACCESS SITE

1. Attach the Y-connector to the sidearm of the introducer sheath and confirm stopcock remains off to syringe (**Figure 12**).

Figure 12

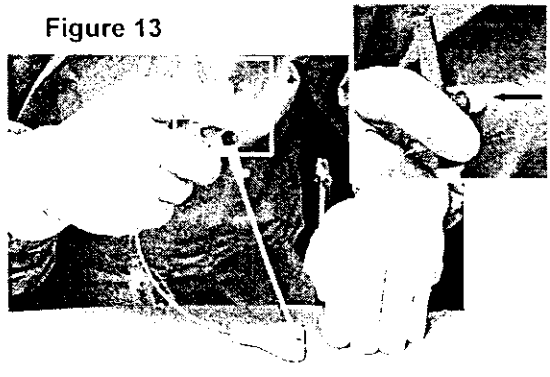


2. Prior to injection, hold the buffer syringes with one hand and the introducer sheath with the other hand.
3. Inject the entire contents of the syringes in one continuous motion over approximately 3 to 5 seconds. As soon as gel injection is completed, retract the sheath approximately 10 mm or 2 marker bands.

   - **A continuous injection of the precursor solutions is necessary. A pause and/or injection rate slower than recommended could cause premature gelation of the polymer during delivery.**

4. Following gel injection, wait up to 10 seconds, locate the femoral pulse, then apply firm pressure proximal to the puncture site, ensuring that there is no bleeding.
5. While maintaining firm pressure, relieve the tension on the catheter by depressing the tensioner and deflate the balloon completely by depressing the deflation knob until the inflation indicator fully retracts (**Figure 13**). Remove the balloon catheter, introducer sheath and tensioner as one unit. If bleeding persists, increase pressure until bleeding stops.

Figure 13



6. Maintain firm pressure for 2 minutes and check for hemostasis.
7. If arterial bleeding persists, continue to apply firm pressure until hemostasis is achieved.

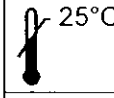
POST-PROCEDURE PATIENT MANAGEMENT

1. Clean the puncture site and apply an appropriate dressing.
2. Assess and manage the puncture site per hospital protocol.
3. Follow physician orders regarding patient ambulation and discharge.

PRODUCT INFORMATION DISCLOSURE

AccessClosure, Inc. has exercised reasonable care in the manufacture of the Matrix VSG System. 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 Matrix VSG System 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 the Matrix VSG System. AccessClosure, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the Matrix VSG System.

SYMBOLS

	Manufacturer
	Lot Number
	Model Number
	Use by
	Sterile – Method of Sterilization Using Irradiation
	Do Not Reuse - Single Use Only
	Do Not Use if Package is Open or Damaged
	Maximum Temperature, 25°C
	Keep Dry – Protect From Moisture
	Consult Instructions for Use
Rx only	Caution – Federal (USA) law restricts this device to sale by or on the order of a physician.

Matrix VSG™ System is a trademark of AccessClosure, Inc.

US and foreign patents pending.

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