INSTRUCTIONS FOR USE

VASCADE MVP® Venous Vascular Closure System (VVCS)

6-12F (Venous) MD

CAUTION – Device is restricted to sale to or on the order of a physician.

Description

The VASCADE MVP® Venous Vascular Closure System (VVCS) is intended to seal the femoral venous access site(s) after an endovascular procedure. The system consists of a sterile disposable Vascular Closure Catheter, which houses a resorbable Collagen Patch, and a sterile Clip (refer to Figure 1).

The system is designed to deliver a resorbable Collagen Patch, extra-vascularly, at the vessel puncture site to aid in achieving hemostasis. The patch expands due to rehydration in the presence of blood in the tissue tract to provide an extravascular seal. A radiopaque proximal marker band on the Catheter provides means to verify placement of the patch in the tissue tract adjacent to the femoral vessel site before the release of the patch. A second distal marker band locates the distal tip of the VASCADE Disc. In addition, the Disc is echogenic. There is the following version of the VASCADE MVP VVCS:

- For use in 6F to 12F ID (max 15F OD) 12 cm[1] introducer sheaths

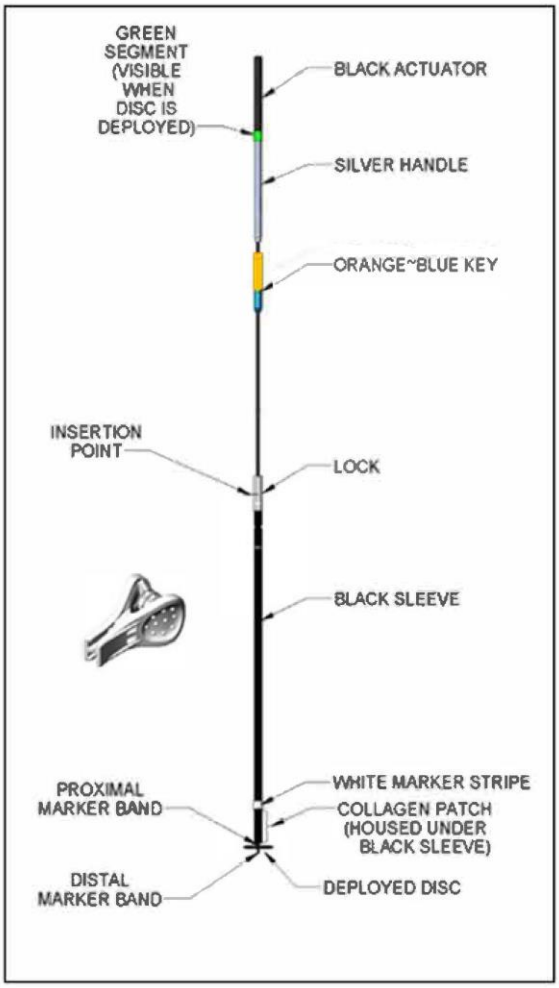


Figure 1. VASCADE MVP VVCS

Indications For Use

The VASCADE MVP Venous Vascular Closure System (VVCS) Model 800-612C is indicated for the percutaneous closure of femoral venous access sites while reducing time to ambulation, total post-procedure time, time to hemostasis, and time to discharge eligibility compared to manual compression, and enabling same day discharge in patients who have undergone catheter-based procedures utilizing 6 – 12F inner diameter (15F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs.

Contraindications

The device should not be used in patients with a known allergy to bovine derivatives.

Note:

- Clinicians are responsible for informing patients in advance of the procedure that the collagen implant is an animal tissue derivative.
- The materials incorporated into the device do not contain or consist of carcinogenic, mutagenic or toxic to reproduction (CMR) substances or endocrine-disrupting substances.

[1]Overall length of the sheath (including the hub) needs to be less than 15 cm.

Intended Purpose

VASCADE Family devices are intended for the percutaneous closure of femoral vessel access sites in patients who have undergone catheter-based procedures.

Patient Target Group

The VASCADE MVP Venous Vascular Closure System (VVCS) is indicated for patients who require the percutaneous closure of femoral venous access and have undergone catheter-based procedures utilizing 6 – 12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs.

Intended User

Physicians and technicians with experience accessing femoral vasculature via introducer sheaths.

Clinical Benefits

Clinical benefits are rapid closure of the vessel holes, which may increase comfort after the procedure and may allow patients to start walking sooner.

Technical Specifications

Device	Model	Sheath Size		Sheath Length	Disc Diameter	Collagen Patch* Length	Collagen Dry Weight	Device Working Length	Device Max OD (with Collapsed Disc)
		Inner Diameter (ID)	Max Outer Diameter (OD)						
VASCADE MVP VVCS	800-612C	6-12F	15F	Up to 12 cm	7.7 mm	15 mm	12 mg ± 3 mg	15 cm	2.1 mm

*Collagen Patch is made of Type I Bovine Collagen delivered in a compressed form. The collagen implant is a biological material compatible with Magnetic Resonance Imaging (MRI).

Contents of Packaging

Each shelf carton contains at minimum:

- Multiple single-use devices (quantity per labeling)
- Each single-use sterile device is provided with:
    - One (1) Sterile Clip
    - One (1) Patient Implant Card to be provided to the patient.
    - One (1) Patient Implant Leaflet with instructions on how to complete the Patient Implant Card.
- One (1) printed Instructions for Use.

Safety Messages

⚠ WARNINGS

- Do not use VASCADE if access is through a previously placed permanent closure device such as a metal clip and/or permanent suture. Interference between the two closure devices may result.
- Do not deploy a second Collagen Patch at the same access site within 30 days. The previously implanted Collagen Patch may be inadvertently introduced into the femoral vessel.
- Do not deploy the VASCADE Disc in a stent. Do not pull the deployed VASCADE Disc through a stent. Damage to the product may occur.
- Do not reuse or re-sterilize. VASCADE is intended to be used once only for a single patient. Product reuse or re-sterilization may result in transmission of infectious or blood-borne diseases and/or death.
- Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. Damaged or opened packages may compromise product functionality.
- Do not use if product is beyond the expiration date. Product performance has not been established beyond the labeled shelf life.
- Verify there is no vessel tortuosity or side branches within 3-4 cm from the distal opening of the sheath, and the end of the sheath is not resting against the vessel wall. This is to prevent vascular injury from advancing the Catheter. If required, retract the sheath slightly to a non-tortuous location, avoiding losing vessel access.
- If any portion of the White Marker Stripe is showing (e.g., tissue tract is too short), DO NOT RELEASE the Collagen Patch, as this may increase the risk of infection if the collagen protrudes from the skin.
- Do not deploy the extravascular Collagen Patch if there is a suspicion that the Disc is not seated against the intimal aspect of the vessel puncture site to avoid releasing the patch in the vessel. Partial or complete obstruction of blood flow may result. This step requires imaging.

⚠ PRECAUTIONS

- VASCADE should only be used by a trained, licensed physician or healthcare professional.
    - Note: Training referred to here is previous training for accessing vessels, and positioning and using catheters. VASCADE does not require formal training beyond reviewing the content provided in this Instructions for Use.
- Do not use in vessels with suspected intraluminal thrombus, hematoma, pseudoaneurysm, or arteriovenous (AV) fistula. These conditions may complicate proper device use and performance.
- Do not use in the following access sites as bleeding risk may increase:
    - Access site where there is suspicion of a back wall stick.
    - Access site noted to be side stick.
    - Access site is “high” above the inguinal ligament (cephalad to lower half of the femoral head or the inferior epigastric artery origin from the external iliac artery/ inferior epigastric vein entry into the external iliac vein).
- During access, be careful that the tissue tract is not pushed laterally or medially before accessing the vessel. This is to avoid misalignment of the tissue tract and the Collagen Patch relative to the vessel puncture site once the device is removed from the vessel, which may prolong time to hemostasis.
- If more than one access is made in the vessel, keep a minimum of 6 mm separation between the access sites. This is to allow the disc to track back to the vessel wall. Temporary hemostasis may not be achieved if the venotomies are too close to each other.
- Do not use if intra-procedural bleeding around the introducer sheath is noted, including hematoma formation (sign of possible multiple wall stick). This may suggest problems with the access site.
- Do not use in a procedural sheath > 12 cm in length (or > 15 cm in overall length) or with a diameter other than 6-12F. This may complicate Disc deployment.
- Do not advance VASCADE into the patient if resistance is felt due to risk of vascular damage.
- Do not soak the VASCADE Catheter in saline. This may result in Catheter pull-through during the sleeve retraction step. Momentarily insert only the Catheter tip in saline solution immediately before use to avoid over-hydration of the patch.
- Do NOT continue to pull on the Black Actuator once it is locked in place, as this may damage the device.
- Compressing the access site during sheath removal may not allow the Disc to track back to the vessel puncture site and may cause Disc deformation. This may hinder achieving temporary hemostasis.
- Applying too much upward tension on the Black Actuator may cause Disc to pull out of vessel. Should this occur, convert to Institution’s Manual Compression Protocol.
- Not achieving temporary hemostasis may be an indication that the Disc is not against the vessel wall. Releasing the Collagen Patch may result in all or a portion of the Patch to be deployed in the vessel.
- VASCADE should be stored at room temperature (15° – 25°C), otherwise proper device performance may be affected.

Special Patient Populations

NOTE: The safety and effectiveness of the device has not been evaluated in the following patients who are/have:

- Less than 18 years of age.
- Pregnant and/or lactating women.
- Pre-existing immunodeficiency disorder and/or chronic use of systemic steroids.
- Known significant coagulopathy/bleeding disorders such as thrombocytopenia (platelet count <100,000/mm^3), thrombasthenia, hemophilia, von Willebrand's disease or anemia (hemoglobin <10 g/dL and hematocrit <30%).
- Previous vascular grafts or surgery at the target vessel access site.
- Symptomatic ipsilateral lower extremity ischemia.
- Femoral vessel lumen less than 6 mm in diameter.
- Length of tissue tract (distance between the anterior vessel wall and skin) estimated to be less than 2.5 cm.
- Fibrinogen level < 150 mg/dl if the patient received a fibrinolytic agent.
- Extreme morbid obesity (BMI > 45 kg/m2) or underweight (BMI < 20 kg/m^2).

Serious Incident Reporting

A notice from the user and/or patient that any serious incident has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Adverse Events

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

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

Clinical Studies

The safety and effectiveness of the VASCADE MVP was evaluated in the following clinical studies to support the approved indications for use: the AMBULATE Trial and the AMBULATE Same Day Discharge Study series. The following provides the design and results of each respective study.

VASCADE MVP 6-12F VVCS – AMBULATE Clinical Trial

Study Design and Baseline

Table 1: AMBULATE Study Design

AMBULATE Trial	
Objective	Evaluate safety and effectiveness of VASCADE 6-12F VVCS to seal multiple femoral venous access sites and reduce times to hemostasis and ambulation vs. Manual Compression (MC) after catheter-based procedures (interventional electrophysiology procedures for the ablation of cardiac arrhythmias, which included atrial fibrillation, atrial flutter, atrial fibrillation-flutter, supraventricular tachycardia, and ventricular tachycardia) performed through 6-12F introducer sheaths.
Design*	Prospective, randomized (1:1), controlled, multi-center clinical trial conducted at 13 sites in the USA. Randomization was stratified to account for patients with varying numbers of access sites, namely 3 access sites/patient and 4 access sites/patient, in a 1:1 treatment device to control arm ratio to ensure treatment and control arms have the same proportion of access sites/patient. All patients were scheduled to return for follow-up examinations at 30 ± 7 days post-procedure. Post-procedure, patients were evaluated for any major or minor complications or adverse event including bleeding, neurological and other potential device or procedure-related adverse effects.
Inclusion Criteria	• ≥ 18 years of age. • Able and willing to sign an Informed Consent Form. • Acceptable candidates for an elective, non-emergent catheter-based procedure via the common femoral vein using a 6F to 12F introducer sheath who were also acceptable candidates for post-procedure manual compression. • Minimum of 3 and maximum of 4 femoral venous access sites. • Minimum of 2 access sites per leg. • Able and willing to complete a 30-day ± 7 days follow-up evaluation.
Exclusion Criteria	• Active systemic or cutaneous infection or inflammation in vicinity of the groin. • Any pre-existing immunodeficiency disorder. • Chronic use of high dose systemic steroids. • History of bleeding diathesis, coagulopathy or hypercoagulability. • Platelet count < 100,000 cells/mm^3. • Severe comorbidities with life expectancy less than 12 months in the opinion of the site investigator. • Had undergone femoral arteriotomy or venotomy within the previous 10 days. • Experienced previous vascular complications or residual hematoma. • Had been treated with an intravascular closure device within the previous 30 days or who were scheduled for femoral venous or arterial access within the next 30 days. • History of DVT, pulmonary embolism, thrombophlebitis, significant anemia or renal insufficiency. • Extreme morbid obesity (BMI > 45 kg/m^2) or underweight (BMI < 20 kg/m^2). • Inability to routinely walk at least 20 ft. without assistance. • Use of low molecular-weight heparin (LMWH) within 8 hours before or after the procedure; • Concomitant procedures or conditions that would interfere with an ambulation attempt at 2-3 hours post-procedure.
Intra-Operative Exclusion Criteria	• Any attempt at femoral arterial access. • Procedural complications that would interfere with routine recovery, ambulation, or discharge times. • Difficulty with needle puncture or insertion of the introducer sheath • Sheath placement cephalad to lower half of the femoral head or the inferior epigastric vein origin from the external iliac vein. • Obvious intraprocedural bleeding or thrombotic complications. • Any sheath use < 6 or > 12F inner diameter or tissue tract < 2.5 cm deep.

*An ultrasound sub-study with exams were performed on 49 patients at the 30 ± 7-day follow-up visit.

**202 out of 204 randomized subjects (99%) completed a 30-day follow-up visit, with 175 patients (85.8%) completing the 30-day (± 7 days) follow-up visit per protocol. Two (2) subjects did not complete the study (i.e., did not complete 30-day visit or call).

The baseline demographic and clinical characteristics of the 2 treatment groups were similar (Table 2).

Table 2: AMBULATE Study Population, Baseline, and Procedure Characteristics

	VASCADE MVP	MC
Number of subjects (204 total)	100	104
Age (years), mean	61.5 ± 11.6	63.4 ± 11.1
BMI (kg/m^2), mean	29.5	29.7
Female (%)	33%	38%
Pre-procedure anticoagulant / antiplatelet administration within the previous 24 hours	84%	85%
Intra-procedural heparin administered	85%	90%
Protamine used (heparinized subjects)	92%	91%
Activated clotting times (ACTs) (seconds) at the end of the catheterization procedure (heparinized subjects), mean	298.6	285.9

Safety Results

Primary and secondary safety endpoints were rate of access site-related major and minor complication rates through follow-up, respectively (Table 3). The major complication rate*s* are clinically the same *(*0%*)* for both VASCADE MVP and Manual Compression (MC). The VASCADE MVP minor complication rate is numerically lower than MC and is clinically similar.

Table 3: AMBULATE As-Reported Major and Minor Closure-Related Complications, Number of Limbs with Each Event

Access Site Closure-Related Complications at 30 Days by Event	**VASCADE MVP** (N=199)		**MC** (N=209)	
Any major venous access site closure-related complication	0	0.0%	0	0.0%
Access site-related bleeding requiring transfusion	0	0.0%	0	0.0%
Vascular injury requiring surgical repair	0	0.0%	0	0.0%
Access site-related infection confirmed and requiring intravenous antibiotics and/or extended hospitalization	0	0.0%	0	0.0%
New onset permanent access site-related nerve injury (i.e., persisting for > 30 days)	0	0.0%	0	0.0%
New onset access site-related nerve injury in the ipsilateral lower extremity requiring surgical repair	0	0.0%	0	0.0%
Pulmonary embolism requiring surgical or endovascular intervention and/or resulting in death	0	0.0%	0	0.0%
Pulmonary embolism NOT requiring surgical or endovascular intervention and/or NOT resulting in death	0	0.0%	0	0.0%
Any Minor Venous Access Site Closure-Related Complication	2	1.0%	5	2.4%
Access site-related bleeding requiring > 30 minutes of continual manual compression to achieve initial venous hemostasis	0	0.0%	0	0.0%
Access site-related hematoma > 6 cm documented by ultrasound	0	0.0%	2	1.0%
Late access site-related bleeding (following hospital discharge)	0	0.0%	0	0.0%
Ipsilateral deep vein thrombosis, confirmed by ultrasound/imaging	0	0.0%	0	0.0%
Localized access site infection confirmed and treated with intramuscular or oral antibiotics	1	0.5%	1	0.5%
Arteriovenous fistula requiring treatment	0	0.0%	0	0.0%
Arteriovenous fistula not requiring treatment	0	0.0%	1	0.5%
Pseudoaneurysm requiring thrombin/fibrin adhesive injection or ultrasound-guided compression	1	0.5%	0	0.0%
Pseudoaneurysm not requiring treatment	0	0.0%	0	0.0%
Access site-related vessel laceration	0	0.0%	0	0.0%
Access site-related wound dehiscence	0	0.0%	0	0.0%
Transient access site-related nerve injury	0	0.0%	1	0.5%

Effectiveness Results

A total of 204 of the 204 enrolled patients in the AMBULATE Trial were evaluable for effectiveness. See Table 4 for definitions of primary and secondary effectiveness endpoints.

Table 4: Effectiveness Endpoint Definitions

Primary Effectiveness Endpoint	**Time to Ambulation (TTA):** elapsed time between device removal (i.e., device removal for VASCADE and sheath removal for MC) and when ambulation was achieved (patient standing and walking at least 20 feet without evidence of re-bleeding from the femoral access sites. Per-patient analysis.
Secondary Effectiveness Endpoints	**Time to Hemostasis (TTH):** elapsed time between device removal (i.e., device removal for VASCADE and sheath removal for MC) and the first observed and confirmed hemostasis). Per-access site analysis.
	Total Post Procedure Time (TPPT): elapsed time between removal of the last procedural device/catheter for the index procedure and when subject is able to successfully ambulate. Per-patient analysis.
	Time to Discharge Eligibility (TTDE): elapsed time between final device removal (i.e., device removal for VASCADE and sheath removal for MC) and when the patient is eligible for hospital discharge based solely upon an assessment of the access site. Per-patient analysis.
	Time to Discharge (TTD): elapsed time between final device removal (i.e., device removal for VASCADE and sheath removal for MC) and hospital discharge. Per-patient analysis.
	Time to Closure Eligibility (TTCE): elapsed time between removal of the last procedural device/catheter for the index procedure and the removal of the first VASCADE device (treatment arm) or removal of the first sheath (control arm). Per-patient analysis.
	Procedure Success: Attaining final hemostasis using any method and freedom from major vascular complications through 30 days. Per-patient analysis.
	Device Success (DS): Ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the VASCADE alone or with adjunctive compression. Per attempted access site analysis (treatment arm only).

Primary and secondary effectiveness endpoints are shown in Table 5. The results are:

- For the primary ANCOVA model adjusting for the stratification factor, i.e. the number of access sites, the VASCADE MVP treatment effect for TTA compared to MC was -3.32 hours (2.8 ±1.3 hours for VASCADE MVP vs. 6.1 ±1.6 hours for manual compression; p<0.0001), indicating VASCADE MVP superiority.
- TPPT and TTDE demonstrated superiority over manual compression.
- TTH was noninferior to manual compression per the pre-specified analysis. TTH results implied superiority over manual compression.

Table 5: Primary and Secondary Effectiveness Endpoints

Outcome	**VASCADE MVP**			**Manual Compression**			**ANCOVA Analysis**	
	Total	**3 Access Sites**	**4 Access Sites**	**Total**	**3 Access Sites**	**4 Access Sites**	**Parameter Estimate** (95% CI)	***P* value**
TTA (hours)							-3.32 (-3.71, -2.92)	<0.0001
N	N=100	N=31	N=69	N=104	N=34	N=70		
Mean ± SD	2.8 ± 1.3	2.5 ± 0.8	2.9 ± 1.5	6.1 ± 1.6	5.9 ± 1.2	6.2 ± 1.7		
Median (min, max)	2.2 (2.0, 11.5)	2.2 (2.0, 5.6)	2.3 (2.0, 11.5)	6.1 (3.4, 15.7)	5.3 (4.2, 9.1)	6.2 (3.4, 15.7)		
TPPT (hours)							-3.69 (-4.10, -3.27)	<0.0001
N	N=100	N=31	N=69	N=104	N=34	N=70		
Mean ± SD	3.1 ± 1.3	2.7 ± 0.8	3.3 ± 1.5	6.8 ± 1.7	6.4 ± 1.3	6.9 ± 1.9		
Median (min, max)	2.6 (2.2, 11.8)	2.4 (2.2, 5.9)	2.7 (2.2, 11.8)	6.4 (4.2, 15.9)	6.2 (4.5, 9.8)	6.6 (4.2, 15.9)		
TTH (minutes)							GEE Model -7.5 (-8.7, -6.3)	<0.0001
N	N=369	N=93	N=276	N=382	N=102	N=280		
Mean ± SD	6.1 ± 3.7	5.4 ± 2.0	6.3 ± 4.1	13.7 ± 6.5	11.4 ± 6.4	14.5 ± 6.4		
Median (min, max)	5.1 (0.4, 33.3)	5.1 (1.3, 23.3)	5.1 (0.4, 33.3)	11.7 (0.6, 37.1)	10.0 (2.9, 32.7)	12.5 (0.6, 37.1)		
TTDE (hours)							-3.41	<0.0001

Outcome	VASCADE MVP			Manual Compression			ANCOVA Analysis	
	Total	3 Access Sites	4 Access Sites	Total	3 Access Sites	4 Access Sites	Parameter Estimate (95% CI)	*P* value
N	N=100	N=31	N=69	N=104	N=34	N=70	(-3.87, -2.96)	
Mean ± SD	3.1 ± 1.3	2.7 ± 0.8	3.2 ± 1.5	6.5 ± 1.9	6.2 ± 1.3	6.6 ± 2.2		
Median (min, max)	2.5 (2.3, 11.7)	2.5 (2.3, 5.9)	2.6 (2.3, 11.7)	6.3 (4.3, 21.3)	5.7 (4.6, 9.4)	6.5 (4.3, 21.3)		
TTD (hours)								
N	N=100	N=31	N=69	N=104	N=34	N=70	-0.04 (-3.25, 3.17)	0.98
Mean ± SD	21.8 ± 13.4	20.5 ± 10.8	22.3 ± 14.5	21.8 ± 9.5	22.7 ± 10.6	21.4 ± 9.0		
Median (min, max)	22.3 (2.3, 96.1)	22.9 (2.3, 48.2)	22.3 (3.5, 96.1)	22.1 (5.7, 72.9)	22.8 (5.7, 71.5)	21.6 (5.8, 72.9)		
TTCE (minutes)*								
N	N=100	N=31	N=69	N=104	N=34	N=70	-	-
Mean ± SD	10.5 ± 6.0	9.0 ± 4.1	11.1 ± 6.6	37.6 ± 33.2	32.2 ± 27.6	40.3 ± 35.5		
Median (min, max)	10.1 (1.7, 47.5)	9.8 (1.7, 17.5)	10.2 (2.0, 47.5)	25.2 (1.8, 132.3)	21.1 (2.0, 108.9)	27.8 (1.8, 132.3)		

*per protocol, TTCE is only descriptively summarized without hypothesis testing.

Proportions of subjects achieving TTA at various fixed time points during the AMBULATE Trial are shown in Table 6.

Table 6: Proportion of Patients Achieving Ambulation at Fixed Time Points (Per-Patient Analysis)

Time Point	VASCADE MVP (N=100)		MC (N=104)	
≤ 1 hours	0	0%	0	0%
≤ 2 hours	1	1%	0	0%
≤ 3 hours	78	78%	0	0%
≤ 4 hours	84	84%	1	1%
≤ 5 hours	93	93%	18	17%
≤ 6 hours	98	98%	48	46%
≤ 7 hours	99	99%	87	84%
≤ 8 hours	99	99%	93	89%
≤ 9 hours	99	99%	100	96%
≤ 10 hours	99	99%	103	99%
≤ 12 hours	100	100%	103	99%
≤ 24 hours	100	100%	104	100%

Table 7 shows the proportion of subjects achieving Device Success. Device issues were limited to known device performance issues based on VASCADE MVP product family such as device pull-through, unable to deploy disc, unable to achieve temporary hemostasis, and use error.

Table 7: VASCADE MVP Device Success (Device Arm Only) Per Access Site

Device Success	Number of Access Sites	Successes	Percent
Per Intent to Treat*	369	351	95%
Actual Devices Attempted	363	351	97%

*Note: 6 device access sites converted to manual compression.

Table 8 shows the proportion of subjects achieving Procedure Success.

Table 8: Proportion of Procedure Success

Procedure Success	VASCADE MVP (N=100)		Manual Compression (N=104)	
Yes	98	98%	103	99%
Unknown*	2	2%	1	1%

*VASCADE MVP: One subject had final follow-up 20 days early (3 days post-procedure), and one subject was lost to follow-up | MC: One subject was lost to follow-up.

Patient Experience Survey Results

Patient Satisfaction was evaluated for all subjects. Patients were given a Patient Experience Survey to complete after successful TTA at the time of TTDE to characterize their comfort experience while on bedrest post-procedure. The completed Survey was collected at the time of completion. The surveys were comprised of comparative study questions regarding patient actual experience (Table 9), as well as questions for scenarios with hypothetically longer (device patients) or shorter (MC patients) bedrest periods (Table 10). In all cases, patient satisfaction scores favored device over manual compression.

Table 9: Patient Experience Survey – Comparative Experience

Bedrest Experience		VASCADE MVP (Mean +/- SD)	Manual Compression (Mean +/- SD)	% Difference (MVP-MC)/MC
Patient Reported Satisfaction Scores Scale 0-10 with 0 as 'very dissatisfied' and 10 as 'very satisfied'	All Patients, current procedure bedrest experience			
	N	100	102	
	Duration	8.3 ± 2.4	5.1 ± 3.4	63%
	Discomfort	7.2 ± 3.1	5.3 ± 3.1	36%
	Pain	7.5 ± 3.2	6.0 ± 3.4	25%
	Patients with a previous ablation procedure, comparison to previous experience			
	N	30	39	
	Duration	7.9 ± 2.3	5.6 ± 3.0	41%
	Discomfort	7.5 ± 2.1	5.4 ± 2.8	39%
	Pain	7.7 ± 2.8	5.5 ± 2.9 (N=38)	40%

Table 10: Patient Experience Survey Summary – Patient Preference for Hypothetically Longer or Shorter Bedrest Durations

Bedrest Experience		VASCADE MVP Mean +/- SD (N)	Manual Compression Mean +/- SD (N)
Patient Reported Satisfaction Scores Scale 0-10 with 0 as 'very dissatisfied' and 10 as 'very satisfied'	Patients Randomized to VASCADE MVP, score if bedrest were **hypothetically 2-3 hours longer**		
	Duration	2.6 ± 3.1 (98)	-
	Discomfort	2.7 ± 2.9 (98)	-
	Pain	3.2 ± 3.4 (98)	-
	Patients Randomized to Manual Compression, score if bedrest were **hypothetically 2-3 hours shorter**		
	Duration	-	9.1 ± 1.7 (102)
	Discomfort	-	8.4 ± 2.2 (101)
	Pain	-	8.2 ± 2.5 (100)

SD = Standard Deviation

Pain Medication Results

Pain medication administration during bedrest was measured as a secondary factor of patient satisfaction. Medication administered for pain or anxiety while the subject was on initial bedrest (i.e., post-procedure through successful TTA) was recorded for all subjects. In an ad-hoc analysis, it was found that there was a reduction in the usage of pain medications for the treatment arm (see Table 11).

Table 11: Pain Medication Usage

Pain Medication Usage	VASCADE MVP (N=100)		Manual Compression (N=104)		% Improvement
Yes	24	24%	51	49%	51%
No	76	76%	53	51%	

Additionally, medication was administered for anxiety in 4.0% of the VVCS subjects, and in 1.9% of the manual compression subjects.

The objective of the registries were to collect procedural outcomes data when the Cardiva VASCADE MVP VVCS was used to seal femoral venous access sites at the completion of catheter-based ablation procedures for atrial fibrillation with or without another arrhythmia, performed through 6 – 12F inner diameter (maximum 15F OD) introducer sheaths in patients who were discharged on the same day as the procedure (retrospective study) or who were candidates for same day discharge (prospective studies). These studies add to the body of knowledge for patient profiles subject to safe same day discharge by focusing on patients who: 1) received VASCADE MVP VVCS for closure involving multiple access sites in one or both limbs; and 2) were being treated for atrial fibrillation (AF) with or without another arrhythmia. A-fib ablation procedures, being generally longer and/or more complex than those of other arrhythmias, are intended to provide a greater challenge for establishing the safety profile for same day discharge than other arrhythmias.

Table 12: Same Day Discharge Studies Safety and Effectiveness Results

Study	Population	Performance			Safety	
		VASCADE MVP Success (Freedom from Access Site-Related Complications)		Procedure Success (Freedom from Next Day Procedure-Related Complications)	Access Site Closure Related Complications	
		Next Day	Follow-Up		Major	Minor
Retrospective (AF All-Comers) Procedures: Dec 2018-Feb 2020 | 497 Patients | 4 sites | Standard of Care f/u	Discharged Same Day	99.8% (496/497)	99.8% (496/497)	99.6% (495/497)	0.0% (0/827)	0.1% (1/827)
Prospective SDD#1 (Paroxysmal AF) June 2020-Nov 2020 | 151 Patients | 8 sites | 15-day f/u	Discharged Same Day	99.3% (137/138)	99.3% (137/138)	99.3% (137/138)	0.0% (0/193)	1.0% (2/193)
	Discharged Same Day out of ITT	90.7% (137/151)	90.7% (137/151)	90.7% (137/151)		
	ITT	99.3% (150/151)	99.3% (150/151)	99.3% (150/151)		
Prospective SDD#2 (Persistent AF) Feb 2021-Jun 2021 | 203 Patients | 13 sites | 15-day f/u	Discharged Same Day	100.0% (185/185)	100.0% (185/185)	99.5% (184/185)	0.0% (0/272)	0.7% (2/272)
	Discharged Same Day out of ITT	91.1% (185/203)	91.1% (185/203)	90.6% (184/203)		
	ITT	100.0% (203/203)	100.0% (203/203)	99.0% (201/203)		

Clinical Studies Conclusions

The results from the AMBULATE Trial demonstrate that patients who underwent catheter-based procedures utilizing 6 – 12F inner diameter (15F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs, and who were treated with the Cardiva VASCADE MVP VVCS have had statistically and clinically significant decreased time to ambulation, total post-procedure time, and time to discharge eligibility when compared to patients treated with manual compression. Additionally, time to hemostasis for VASCADE MVP compared to manual compression results were noninferior and statistically imply superiority.

In addition, the trial demonstrated that the rates of total combined major complications were clinically the same (0%) between the VASCADE MVP VVCS and manual compression patients, and that the rates of total combined minor complications were clinically similar between the VASCADE MVP VVCS and manual compression patients (1.0% VVCS vs. 2.4% manual compression).

Finally, the procedure success rate for patients treated with the VASCADE MVP VVCS was similar to patients treated with standard manual compression (98% VVCS vs. 99% manual compression). Patient satisfaction scores favored the device and pain medication use was lower in the device group compared to the manual compression group.

The results from the AMBULATE VASCADE MVP Same Day Discharge Retrospective and Prospective Registries demonstrate that VASCADE MVP does enable same day discharge in patients who underwent catheter-based procedures utilizing 6 – 12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs, and who were treated with the VASCADE MVP VVCS. This is demonstrated by the high success rate of all performance procedural outcomes, and no major and the low minor access site closure-related complication rates. Additionally, the high success rates of the procedural performance outcomes indicate physicians were able to accurately assess patient eligibility for same day discharge.

Instructions for Use
Device Preparation and Procedure

General Use Instructions

⚠ **WARNINGS**

- Do not use VASCADE if access is through a previously placed permanent closure device such as a metal clip and/or permanent suture. Interference between the two closure devices may result.
- Do not deploy a second Collagen Patch at the same access site within 30 days. The previously implanted Collagen Patch may be inadvertently introduced into the femoral vessel.
- Do not deploy the VASCADE Disc in a stent. Do not pull the deployed VASCADE Disc through a stent. Damage to the product may occur.

⚠ **CAUTIONS**

- VASCADE should only be used by a trained, licensed physician or healthcare professional.
    - Note: Training referred to here is previous training for accessing vessels, and positioning and using catheters. VASCADE does not require formal training beyond reviewing the content provided in this Instructions for Use.
- Do not use in vessels with suspected intraluminal thrombus, hematoma, pseudoaneurysm, or arteriovenous (AV) fistula. These conditions may complicate proper device use and performance.
- Do not use in the following access sites as bleeding risk may increase:
    - Access site where there is suspicion of a back wall stick.
    - Access site noted to be side stick.
    - Access site is “high” above the inguinal ligament (cephalad to lower half of the femoral head or the inferior epigastric artery origin from the external iliac artery/ inferior epigastric vein entry into the external iliac vein).
- Do not use in a procedural sheath > 12 cm in length (or > 15 cm in overall length) or with a diameter other than 6-12F. This may complicate Disc deployment.
- VASCADE should be stored at room temperature (15° – 25°C), otherwise proper device performance may be affected.

NOTES

- See Figure 1 for an image of the device.
- Use the device only as described in the Technical Specifications (see Page 2).

PREPARATION STEPS: Patient Access Considerations and Prepare Device

Prep-A: Patient Access Considerations and Preparation for Closure

Access

1. Access is gained at the beginning of the index procedure for initial procedure sheath placement. Image-guided access is recommended to limit potential access site issues, such as multiple sticks, backwall stick, high stick, side stick, through-and-though, or unintentionally nicking a nearby vein or artery. During access, where more than one hole is unintentionally made in a vessel or more than one vessel is perforated at a single access site, a closure device should not be used as it may result in a hematoma. For high stick, retroperitoneal bleed may result.
2. Evaluate patient body build or use ultrasound to provide reasonable assurance that the tissue tract is greater than 2.5 cm.

Prior to Closure

3. Confirm a single wall common femoral vessel puncture site.
4. Record an anterior oblique fluoroscopic image with contrast or an ultrasound image (optional) so that the vessel puncture site location can be subsequently compared to the position of the radiopaque marker (or echogenic disc) just before Collagen Patch release. Reference Step 1 Part B for imaging steps during closure.
5. Verify sheath compatibility (e.g., length) and perform sheath exchange if required. Reference Technical Specifications.

Multi-Site Access & Closure

6. The distance between the access sites should be kept at a minimum of 6 mm. Keep the stick separation at the skin level at a minimum of 6 mm and drive the needles to the vein at the same angle to keep the separation between the adjacent venotomies at a minimum of 6 mm. Imaging techniques such as ultrasound can be used to confirm the separation is as recommended.
7. If more than one sheath is used in the same vein, it is recommended to close the proximal venotomy first to facilitate device placement and imaging prior to Collagen Patch release.

⚠ CAUTIONS

- During access, be careful that the tissue tract is not pushed laterally or medially before accessing the vessel. This is to avoid misalignment of the tissue tract and the Collagen Patch relative to the vessel puncture site once the device is removed from the vessel, which may prolong time to hemostasis.
- If more than one access is made in the vessel, keep a minimum of 6 mm separation between the access sites. This is to allow the disc to track back to the vessel wall. Temporary hemostasis may not be achieved if the venotomies are too close to each other.

Prep-B: Unpack the Device

1. Inspect the package for damage (breaks, tears, open seals, water damage, etc.).
2. Verify that the use-by date has not passed.
3. Verify that the correct product and size is used.
4. Remove the tray from the foil pouch using standard sterile technique (see Aseptic Presentation below).
5. Remove Catheter and Clip from the tray.

Aseptic Presentation

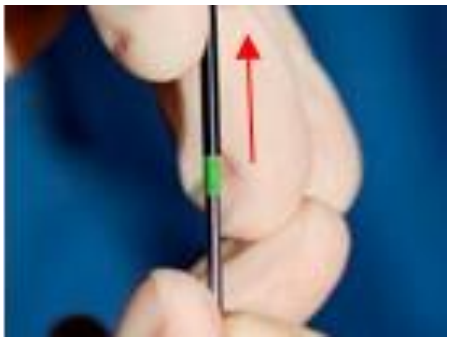
1. Position near the sterile field. Be sure the scrubbed person receiving the product is prepared and ready to receive it with a clear space in the field.
2. All packaging for sterile products has a designated side to open from. Locate this side and slowly peel the package open.
3. Open the packaging with arms extended to avoid accidental contact with product or sterile field. Secondary sterile packaging containing the product must not contact the edges of external packaging as they are not considered sterile. Create a large enough opening in the package to remove the product's interior packaging without touching the non-sterile areas.
4. Present the product to the scrubbed person.
5. Discard packaging following facility protocol.

⚠ WARNINGS

- Do not reuse or re-sterilize. VASCADE is intended to be used once only for a single patient. Product reuse or re-sterilization may result in transmission of infectious or blood-borne diseases and/or death.
- Do not use if components or packaging appear to be damaged or defective or if any portion of the packaging has been previously opened. Damaged or opened packages may compromise product functionality.
- Do not use if product is beyond the expiration date. Product performance has not been established beyond the labeled shelf life.

Prep-C: Inspect the Device

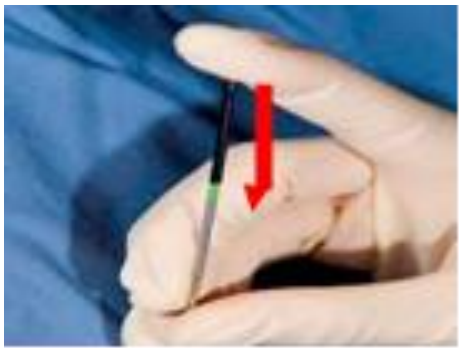
Prevent premature Collagen exposure during the following inspection:
1. Black Sleeve is locked in position.
2. Collagen Patch is not exposed.
3. Key is not engaged in the Lock, and the Key is located at the proximal end of the device.



Check the Disc function:
1. Firmly hold the Silver Handle.
2. Pull back the Black Actuator until it locks.
3. The Green Segment will be visible.

Check the Disc shape:
1. A circular appearance.
2. A symmetrical appearance.
3. An intact membrane.

If there are any device defects, do not use the device. Report and return to the manufacturer.



Collapse the Disc by pressing the Black Actuator tip. Device is ready for use.

Prep-D: Prepare the Sheath

1. Verify that the sheath is not positioned in a tortuous vessel (i.e., by examining the sheath placement images obtained earlier).
2. If required, retract the sheath slightly to a non-tortuous location and verify the sheath is still positioned within the vessel.
3. Flush the sheath with sterile saline solution.

Note: If more than one sheath is in the vein, retract the most proximal sheath (top sheath) so that the distal opening of that sheath is proximal to the distal opening of other sheaths by 3-4 cm. This is to eliminate interference of a deployed Disc with other indwelling sheaths during device deployment. **Care must be taken not to lose vessel access.** Deploy the device and obtain hemostasis in the most proximal sheath first (as per steps outlined below). Then move distally to repeat the steps to obtain closure for the other sheaths.

WARNING

Verify there is no vessel tortuosity or side branches within 3-4 cm from the distal opening of the sheath, and the end of the sheath is not resting against the vessel wall. This is to prevent vascular injury from advancing the Catheter. If required, retract the sheath slightly to a non-tortuous location, avoiding losing vessel access.

CAUTION

Do not use if intra-procedural bleeding around the introducer sheath is noted, including hematoma formation (sign of possible multiple wall stick). This may suggest problems with the access site.

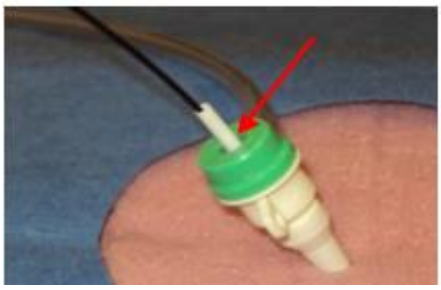
STEP 1 PART A: Exchange Sheath for VASCADE and Achieve Temporary Hemostasis

Step 1.1: Dip Device Tip in Saline

Dip device tip in saline momentarily up to the White Marker Stripe and quickly remove.

⚠ **CAUTION**
Do not soak the VASCADE Catheter in saline. This may result in Catheter pull-through during the sleeve retraction step. Momentarily insert only the Catheter tip in saline solution immediately before use to avoid over-hydration of the patch.

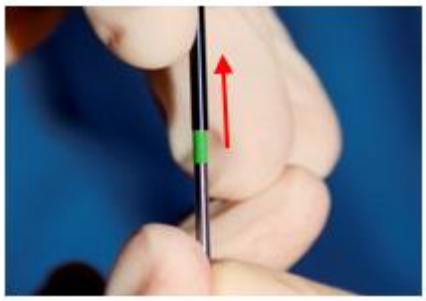
Step 1.2: Insert VASCADE

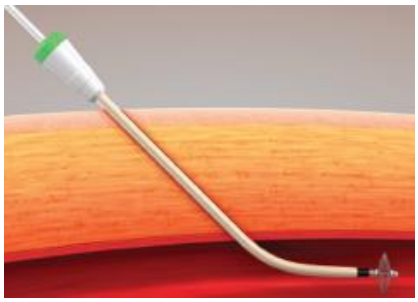


1. With the Disc collapsed, gently insert VASCADE into the introducer sheath hub until Lock is midway into the hub. Use short strokes to insert the device. There should be about 0.5-inch (13 mm) of the Lock exposed.
2. Confirm the Lock is NOT fully inserted into the sheath.

⚠ **CAUTION**
Do not advance VASCADE into the patient if resistance is felt due to risk of vascular damage.

Step 1.3: Deploy the Disc



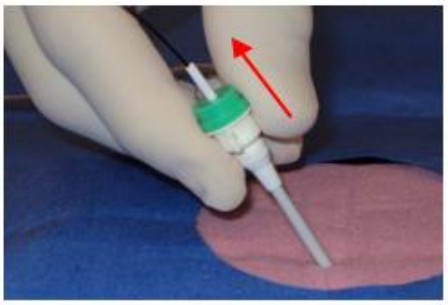


Deploy the Disc by firmly holding the Silver Handle and pulling back the Black Actuator until it locks.

NOTE
The Green Segment will be visible. If the Disc is not correctly deployed, the Black Actuator will slide back to its original position, and the Green Segment will disappear. Repeat the step to deploy the Disc as needed.

⚠ **CAUTION**
Do NOT continue to pull on the Black Actuator once it is locked in place, as this may damage the device.

Step 1.4: Remove the Sheath

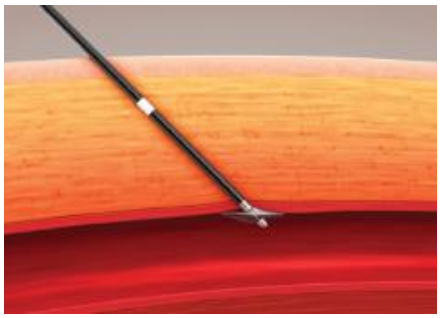


1. Gently remove sheath without applying any compression at the access site and without holding the VASCADE Catheter.
2. As the sheath slides over the VASCADE Catheter, grasp the Catheter close to the Lock as it exits the sheath.
3. Continue sliding the sheath over VASCADE and discard sheath.

⚠ **CAUTION**

Compressing the access site during sheath removal may not allow the Disc to track back to the vessel puncture site and may cause Disc deformation. This may hinder achieving temporary hemostasis.

Step 1.5: Achieve Temporary Hemostasis



Apply gentle tension on the Black Actuator until temporary hemostasis is achieved.

In the case of a failed access site where manual compression is needed, refer to the Converting to Manual Compression (MC) instructions (below).

NOTES

1. If the White Marker Stripe is visible above the skin, then the length of the tissue tract may not be long enough for the Collagen Patch.
2. If any portion of the White Marker Stripe is showing, convert to MC (below).

⚠ **WARNING**

If any portion of the White Marker Stripe is showing (e.g., tissue tract is too short), DO NOT RELEASE the Collagen Patch, as this may increase the risk of infection if the collagen protrudes from the skin.

⚠ **CAUTIONS**

- Applying too much upward tension on the Black Actuator may cause Disc to pull out of vessel. Should this occur, convert to Institution's Manual Compression Protocol.
- Not achieving temporary hemostasis may be an indication that the Disc is not against the vessel wall. Releasing the Collagen Patch may result in all or a portion of the Patch to be deployed in the vessel.

<u>As Needed: Converting to Manual Compression (MC)</u>

MC Assist

Use the VASCADE Disc with the Clip to Maintain Temporary Hemostasis While ACT Normalizes (e.g., for anti-coagulated patients):

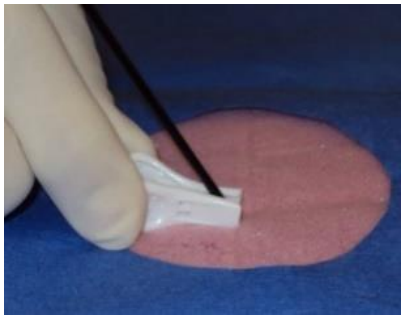
1. Apply the Clip (see Step 3.1) to the VASCADE Catheter to maintain temporary hemostasis.
2. Allow the device to stay in-dwelling for the Activated Clotting Time (ACT) level to normalize.
3. Collapse the Disc and remove VASCADE.
4. Achieve final hemostasis by applying MC per institutional protocol.

Alternative Option (e.g., for non-anti-coagulated patients):

1. Collapse the Disc and remove VASCADE.
2. Apply manual compression (MC) per institutional protocol.

STEP 1 PART B: Verify Disc Placement with Imaging

Step 1.6: Continue to Apply Upward Tension on the Cather



Continue to apply gentle tension by applying the Clip to the Black Sleeve at skin level or holding gentle tension on the Black Actuator.

Step 1.7: Use Imaging to Verify Deployed Disc Placement Prior to Deploying Collagen

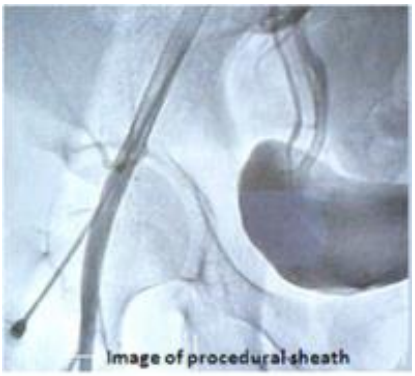
1. TO PREVENT INTRAVASCULAR COLLAGEN DEPLOYMENT, use imaging to verify Disc placement.
2. Confirm the position of the Disc (Catheter's proximal radiopaque marker for fluoroscopy, echogenic Disc for ultrasound).
3. This Disc should be positioned against the intimal surface of the vessel wall. Verify using imaging:
   - See below for an example of a fluoroscopic image demonstrating proper position of Disc. The proximal radiopaque marker should be at the vessel puncture site. This can be verified by comparing the marker's location to the vessel puncture site documented through fluoroscopic image recorded after introducer sheath placement. The Collagen Patch is immediately proximal to this proximal Marker Band. The Distal Marker Band locates the distal end of the Disc.
   - See below for an example of an ultrasound image demonstrating proper position of the echogenic Disc.

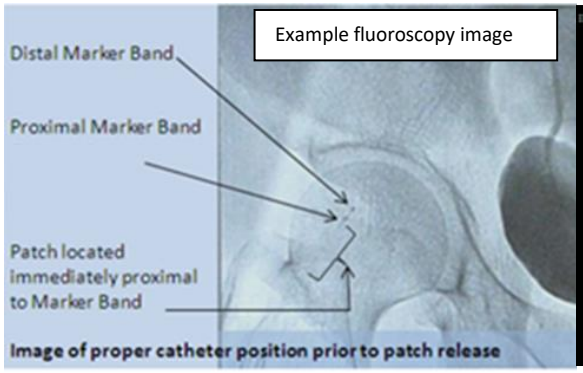
⚠ **WARNING**

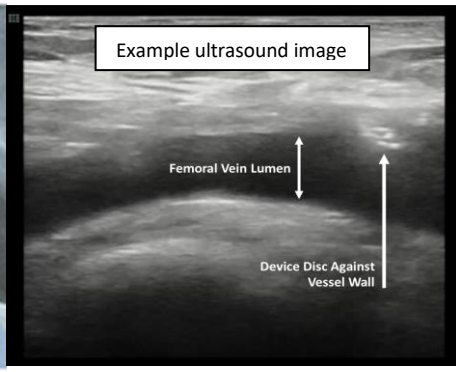
Do not deploy the extravascular Collagen Patch if there is a suspicion that the Disc is not seated against the intimal aspect of the vessel puncture site to avoid releasing the patch in the vessel. Partial or complete obstruction of blood flow may result. This step requires imaging.

⚠ **CAUTION**

Applying too much upward tension on the Black Actuator may cause Disc to pull out of vessel. Should this occur, convert to Institution's Manual Compression Protocol.

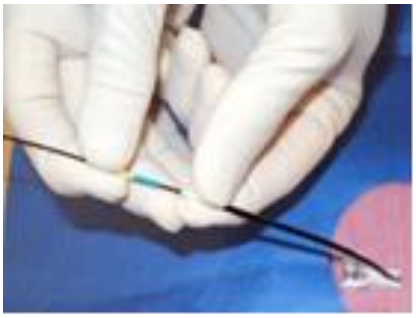




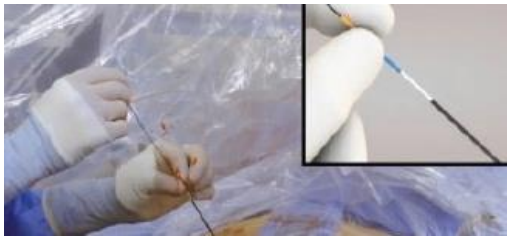


STEP 2: Deploy Collagen

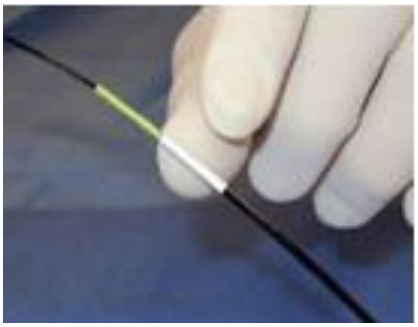
Step 2.1: Unlock the Black Sleeve

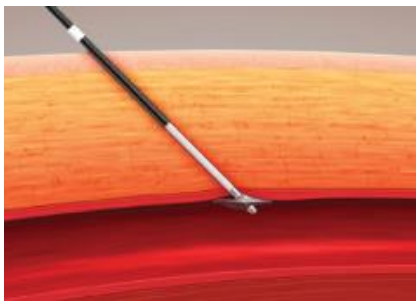


While still holding gentle tension (through Clip or keeping tension on the Black Actuator), slide Key into the Lock. The blue segment should no longer be visible.



Step 2.2: Retract the Black Sleeve to Expose the Collagen



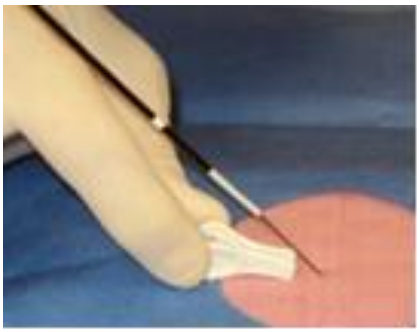


1. If the Clip is present, apply gentle upward tension on the Black Actuator and remove the Clip.
2. Keep applying gentle tension on the Black Actuator, grasp the Lock with the other hand, and apply gentle upward tension on the Lock toward the Silver Handle. The Black Sleeve will move freely after some initial resistance. A second resistance point may be felt after the sleeve is moved approximately 1.6 cm (0.6 inch).
3. Fully retract the Black Sleeve proximally to the Silver Handle. This exposes the Collagen Patch. The Green Tube is visible.

NOTES

1. If the Black Sleeve does not retract easily, confirm the blue end of the Key is fully engaged in the Lock.
2. If the Collagen Patch is removed during sleeve retraction, continue procedure by converting to MC (see “Converting to Manual Compression (MC)”).

Step 2.3: Wait for Collagen Hydration



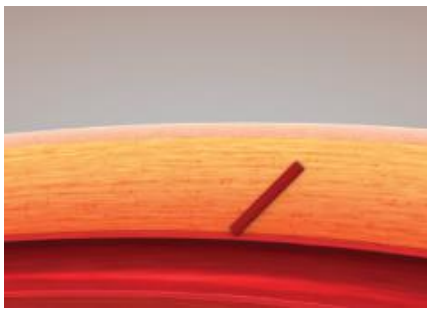
1. Apply Clip with minimal tension on the Catheter or otherwise hold gentle upward tension on Black Actuator to keep the disc up against the intima.
2. Allow approximately 30 seconds for collagen hydration (patch swell period) before stripping the collagen.

STEP 3: Achieve Final Hemostasis

Step 3.1: Prepare to Strip Collagen

1. Remove the Clip.
2. Grasp the Green Tube between the thumb and the index finger.

Step 3.2: Strip Collagen Using the Green Tube, Then Remove Device



Option 1: Move the Green Tube, Device Stationary

1. Advance the Green Tube down the tissue tract while maintaining gentle back tension on device to keep Disc position against the vessel wall. Slide the Green Tube back and forth 2-3 times to assure release of Collagen Patch. Leave the Green Tube in the forward position.
2. Relax tension on device and collapse the Disc (see below).
3. Apply compression at the vessel puncture site, and remove device.*
4. Apply compression until final hemostasis is confirmed.

Option 2: Move the Device, Green Tube Stationary (e.g., where Green Tube is not sufficiently visible to easily move such as patients with deeper tissue tracts)

1. Grasp the Green Tube and hold stationary with respect to the body.
2. Collapse the Disc (see below).
3. Retract device until resistance is met. Let go of the Green Tube.
4. Apply compression at the vessel puncture site, and remove the device.*
5. Apply compression until final hemostasis is confirmed.

*This action slides the collapsed Disc by the hydrated Collagen Patch without displacing the Collagen Patch.

Collapse the Disc:

1. With slack in the Catheter, press the Black Actuator tip.
2. Green Segment should not be visible.

Step 3.3: Confirm Final Hemostasis

1. Apply compression as needed until final hemostasis is achieved.
2. Observe the access site for final hemostasis per institution protocol.
3. Apply sterile dressing to site per institution protocol.

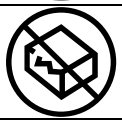
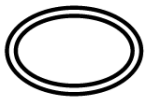
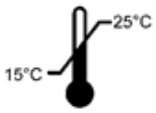
Step 3.4: In Recovery and Discharge

1. Maintain bed rest and periodically check site per institutional protocol pre and post ambulation.
2. If tissue tract ooze is present, apply compression.
3. Provide the completed Patient Implant Card to the patient prior to discharge.

Step 3.5: Dispose of Device

After use, dispose of the contaminated device and/or packaging materials using standard hospital procedures and universally accepted practices for bio-hazardous wastes.

Graphical Symbols on Packaging

Symbol	Standard / Regulation*	Standard Reference No. / Symbol Title	Definition
	ISO 15223-1	5.1.1 / Manufacturer	Medical device manufacturer.
	ISO 15223-1	5.1.3 / Date of Manufacture & 5.1.11 / Country of Manufacture	Indicates the date when the medical device was manufactured / to identify the country of manufacture of products (MX = Mexico).
	ISO 15223-1	5.1.2 / Authorized representative in the European Community	Authorized representative in the European Community.
	ISO 15223-1	5.1.4 / Use-By Date	Date after which the medical device is not to be used.
	ISO 15223-1	5.1.5 / Batch Code	Manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	5.1.6 / Catalogue number	Manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	5.1.8 / Importer	entity importing the medical device into the locale
	ISO 15223-1	5.1.10 / Model number	model number or type number of a product
	ISO 15223-1	5.2.4 / Sterilized using irradiation	Medical device that has been sterilized using irradiation.
	ISO 15223-1	5.2.6 / Do not re-sterilize	Medical device that is not to be re-sterilized.
	ISO 15223-1	5.2.8 / Do not use if package is damaged	Medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1	5.2.12 / Double sterile barrier system	Indicates two sterile barrier systems.
	ISO 15223-1	5.3.4 / Keep dry	Medical device that needs to be protected from moisture.
	ISO 15223-1	5.3.7 / Temperature limit	Temperature limits to which the medical device can be safely exposed.
	ISO 15223-1	5.4.2 / Do not reuse	Medical device intended for one use or for use on a single patient during a single procedure.
	ISO 15223-1	5.4.3 / Consult instructions for use or consult electronic instructions for use	Need for the user to consult the instructions for use.
	ISO 15223-1	5.4.4 / Caution	Caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Symbol	Standard / Regulation*	Standard Reference No. / Symbol Title	Definition
	ISO 15223-1	5.4.5 / Contains or presence of natural rubber latex & B.2 / Negation Symbol	Indicates that there is no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	ISO 15223-1	5.4.8 / Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin.
	ISO 15223-1	5.7.7 / Medical device	The item is a medical device.
	N/A	Prescription Device	Device is restricted to sale to or on the order of a physician.
	N/A	Package quantity	Quantity of systems in package.
	EU MDR	The requirements for accreditation and market surveillance relating to the marketing of products / CE Mark with Notified Body Reference ####	Signifies European conformity (CE) mark. Indicates conformity of products where the Notified Body performed conformity assessment. Notified Body reference # is displayed.

*Standards and Regulations:
ISO 15223-1: Medical devices-Symbols to be used with medical device labels, labeling, and information to be supplied.
EU MDR: Regulation (EU) 2017/745, Medical Device Regulation

Patient card and leaflet symbols are defined in the leaflet.

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Limited Warranty

Cardiva Medical, Inc. warrants that each VASCADE MVP Venous Vascular Closure System is free from defects in workmanship and material under normal use and service, and provided it is used prior to the stated expiration date. Cardiva Medical, Inc. will not be liable for any incidental, special or consequential loss, damage, or expense direct or indirect from the use of its product. Liability under this warranty is limited to refund or replacement of any device that has been found by Cardiva Medical, Inc. to be defective at the time of shipment. Damage to the device through misuse, alteration, improper storage, or improper handling shall void this limited warranty. The remedies set forth in this warranty and limitation shall be the exclusive remedy available to any person. No employee, agent, or distributor of Cardiva Medical, Inc. has any authority to alter or amend this limited warranty or assume or bind Cardiva Medical, Inc. to any additional liability or responsibility with respect to this device. There is no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the Cardiva Medical, Inc. product(s) described herein.

Summary of Safety and Clinical Performance (SSCP)

The SSCP is available in the European Database on Medical Devices (EUDAMED: https://ec.europa.eu/tools/eudamed).