CARDIVA MEDICAL, INC.

VASCADE MVP® XL Venous Vascular Closure System (VVCS)

INSTRUCTIONS FOR USE
Model 800-1012XL| 10-14F (Venous)

MD

CAUTION – Federal (USA) law restricts this device to sale by or on the order of a physician

DESCRIPTION

The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1012XL is intended to seal the femoral vein access site(s) at the completion of the procedure. The system consists of a sterile disposable Vascular Closure Catheter which houses a resorbable Collagen Patch, and the VASCADE MVP XL Clip (refer to Figure 1). The system is designed to deliver a resorbable Collagen Patch, extra-vascularly, at the venotomy site to aid in achieving hemostasis. The patch expands as a result of 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 aid in verifying placement of the patch in the tissue tract adjacent to the femoral venotomy site prior to the release of the patch. A second distal marker band locates the distal tip of the VASCADE MVP XL Disc. The following version of the VASCADE MVP XL is available:

- For use in 10F to 14F inner diameter (17F maximum outer diameter), 12cm[1] introducer sheaths.

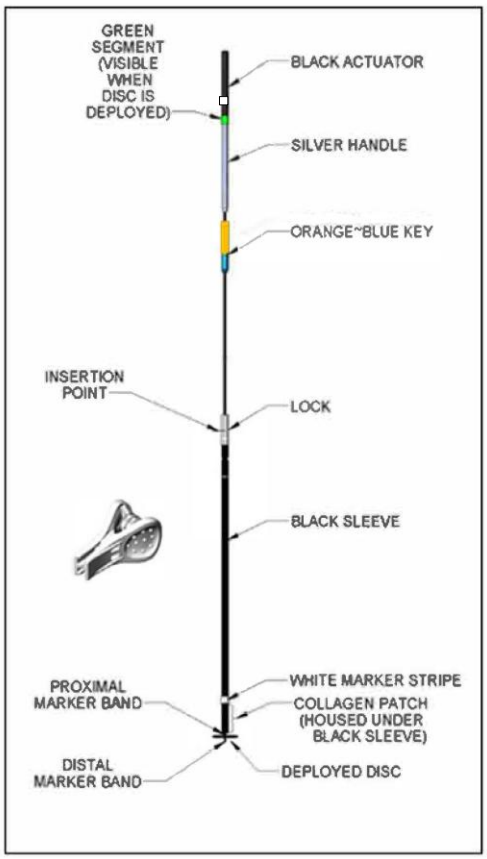


Fig. 1 – VASCADE MVP® XL Venous Vascular Closure System (VVCS)

INDICATIONS FOR USE

The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1012XL 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 in patients who have undergone catheter-based procedures utilizing 10 – 14F inner diameter (17F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs.
The VASCADE MVP XL Venous Vascular Closure System (VVCS) Model 800-1012XL is also indicated for enabling same day discharge in patients who have undergone catheter-based cardiac arrhythmia ablation procedures utilizing 10 – 14F inner diameter (17F maximum outer diameter) procedural sheaths, with single or multiple access sites in one or both limbs.

CONTRAINDICATIONS

The VASCADE MVP XL VVCS should not be used in patients with a known allergy to bovine derivatives.

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

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 XL Venous Vascular Closure System (VVCS) Model 800-1012XL is indicated for patients who require percutaneous closure of femoral venous access sites and have undergone catheter-based procedures using 10–14F inner diameter (17F maximum outer diameter) procedural sheaths with single or multiple access sites in one or both limbs.

INTENDED USER

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

CLINICAL BENEFITS

Clinical benefits are rapid closure of vascular access sites, which may increase comfort after the procedure and allow patients to start walking again sooner.

TECHNICAL SPECIFICATIONS

Device	Sheath Size Compatibility (French)		Sheath Length	Disc Size	Collagen Patch* Length	Collagen Dry Weight	Device Working Length	Maximum OD (with collapsed Disc)
	Inner Diameter	Max Outer Diameter (approx)						
VASCADE MVP XL VVCS Model 800-1012XL	10F – 14F	17F	up to 12 cm	8.3 mm	15 mm	19 mg ± 3 mg	15 cm	2.5 mm

*The 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 PACKAGE

Each shelf carton contains at minimum:

- Multiple single-use devices (quantity per labelling)
- Each single-use sterile device is supplied with:
    - One (1) Sterile Clip.
    - One (1) Patient Information Guide.
- One (1) printed Instructions for Use.

SAFETY MESSAGES

⚠ WARNINGS

- Do not reuse or re-sterilize. The VASCADE MVP XL 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 any vascular injury as a result of advancing the catheter. If required, retract the sheath slightly to a non-tortuous location, being careful not to lose vessel access.
- If any portion of the White Marker Stripe is showing DO NOT RELEASE the Collagen Patch as this may increase the risk of infection.
- Do not deploy the VASCADE MVP XL Disc in a stent. Do not pull the deployed VASCADE MVP XL Disc through a stent. Damage to the product may occur.
- Do not use VASCADE MVP XL 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 the Collagen Patch if there is a suspicion that the VASCADE MVP XL Disc is not seated against the intimal aspect of the venotomy site to avoid releasing the Collagen Patch in the vessel. Partial or complete obstruction of blood flow may result. Ensure that the Disc is in contact with the intimal aspect of the venotomy before deploying the extra-vascular Collagen Patch**.** This is indicated by having temporary hemostasis and further verified by either fluoroscopy or ultrasound imaging.
- Do not deploy a second collagen patch at the same access site within 60 days. The previously implanted collagen patch may be inadvertently introduced into the femoral vessel.
- Grip the Lock to retract Black Sleeve. Do not grip the device distal to the Lock as this may result in operator injury which could lead to possible infection.

⚠ PRECAUTIONS

- The VASCADE MVP XL should only be used by a trained licensed physician or healthcare professional.
    - Note the training referred to here is previous training for accessing vessels, and positioning and using catheters. The VASCADE MVP XL device does not require formal training beyond review of the content provided in this IFU.
- Do not use in access sites where there is suspicion of a “backwall” stick. Increased bleeding risk may occur.
- Do not use if venotomy is noted to be a “side stick.” Bleeding risk may increase.
- Do not use if venotomy site is noted to be “high,” above the Inguinal Ligament (cephalad to lower half of the femoral head or the inferior epigastric artery origin from the external iliac artery). This may increase the risk of bleeding.
- During access care should be taken so that the tissue tract is not pushed laterally or medially prior to accessing the vessel. This is to avoid misalignment of the tissue tract and the Collagen Patch relative to the venotomy site once the device is removed from the vessel, which may result in prolonged time to hemostasis.
- If more than one access is made in the vein, keep a minimum of 8 mm separation between the access sites (~1 cm at skin level). 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 in a vein with suspected intraluminal thrombus, hematoma, pseudoaneurysm, or arteriovenous fistula. These conditions may complicate proper device use and performance.
- 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.
- 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 > 12cm in length (or >15cm in overall length) or with an inner diameter other than 10-14F. This may complicate Disc deployment.
- Do not advance VASCADE MVP XL VVCS Catheter into the patient if resistance is felt due to risk of vascular damage.
- Do not soak the VASCADE MVP XL VVCS Catheter in saline. Momentarily insert only the Catheter tip in saline solution immediately before use to avoid over-hydration of the patch, which may result in difficulty of retracting the sleeve and causing Catheter pull through during the sleeve retraction step.
- 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 venotomy and may cause Disc deformation. This may lead to inability to achieve temporary hemostasis.
- Applying too much upward tension on the Silver Handle may cause Disc to pull out of vessel. Should this occur, convert to your institution's manual compression protocol.

SPECIAL PATIENT POPULATIONS

NOTE: The safety and effectiveness of VASCADE MVP XL have 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 disorder such as thrombocytopenia (platelet count <100,000/mm^3), thrombasthenia, hemophilia, von Willebrand's disease or anemia (Hemoglobin <10g/dL, Hematocrit <30%);
- Previous vascular grafts or surgery at the target vessel access site;
- Femoral venous lumen less than 6 mm;
- Length of the tissue tract, the distance between the anterior venous wall and skin, is estimated to be less than 2.5cm;
- Extreme morbid obesity (BMI > 45 kg/m^2) or underweight (BMI < 20 kg/m^2);
- Uncontrolled systolic hypertension (SBP > 180 mmHg) or hypotension (SBP < 90 mmHg)

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 FDA.

Adverse Events

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

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

CLINICAL STUDIES

The safety and effectiveness of the VASCADE MVP XL was evaluated in the following clinical study to support the approved indications for use: the AMBULATE EXPAND Trial. The safety and efficacy 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 design and results of each study are provided below.

VASCADE MVP XL VVCS – AMBULATE EXPAND CLINICAL TRIAL

Study Design and Baseline

Table 1: AMBULATE EXPAND Study Design

AMBULATE EXPAND Trial	
Objective	The objective of this study was to establish the safety and effectiveness of the VASCADE MVP XL when compared to Performance Goals (PGs) and Clinical Acceptance Criteria (CAC) for closing percutaneous femoral venous access sites at the completion of catheter-based procedures with 16-17F OD procedural sheaths.
Design*	A multi-center, prospective, single arm, pivotal trial designed to evaluate the safety and effectiveness of the VASCADE MVP XL for the management of the femoral venotomy after catheter-based interventions performed utilizing 16-17F OD sheaths. The patient population included adults (age 18 to 80 years) undergoing procedures requiring vessel closure. The study was conducted at 8 sites in the United States and patients enrolled in the trial participated for approximately 30 days (± 7 days).

Pre Operative Inclusion Criteria	• 18 to 80 years of age (inclusive)
	• Capable and willing to give informed consent
	• Planned non-emergent catheter-based procedure via:
	  ○ Study Limb (Required): The common femoral vein using one 16-17F† OD introducer sheath
	  ▪ †Minimum 10F ID
	  ○ Non-Study Limb (optional): The common femoral vein of the Non-Study Limb using up to three (3) 5-12F ID (max 15F OD) introducer sheaths
	• Able and willing to complete a 30 day +/- 7 days follow-up visit

Pre-Operative Exclusion Criteria	• Currently involved in any other investigational clinical trial that may interfere with the outcomes of this study, in the opinion of the Investigator
	• Pre-existing immunodeficiency disorder and/or chronic use of high dose systemic steroids
	• Known history of bleeding diathesis, bleeding problems following medical procedures, or coagulopathy
	• Known baseline hemoglobin < 10 g/dl, hematocrit < 30%, platelet count < 100,000 cells/mm^3
	• Severe co-existing morbidities, with a life expectancy of less than 12 months in the opinion of the Investigator
	• Known history of deep vein thrombosis or pulmonary embolism in the last 12 months
	• Known allergy/adverse reaction to bovine derivatives
	• Active systemic infection, or cutaneous infection or inflammation in the vicinity of the groin
	• Unable to ambulate at least 20 ft at baseline
	• Pregnant (known or suspected) or lactating
	• Extreme morbid obesity (BMI greater than 45 kg/m^2) or underweight (BMI less than 20 kg/m^2)
	• Known planned procedures or known concomitant condition(s) that may extend ambulation attempts beyond 2-3 hours, and/or hospitalization time (e.g., staged procedure, serious co- morbidity), in the opinion of the Investigator
	• Femoral vessel closure in either limb with any of the following conditions:
	  ○ Planned femoral access in the next 60 days to reflect the device re-access period
	  ○ Any residual hematoma, significant bruising, or known associated vascular complications
	  ○ Use of an intra-vascular closure device within the previous 90 days
	  ○ Access within < 10 days
	• Currently known implanted vascular grafts/stents at the access site that would interfere with the planned closure procedure, in the opinion of the Investigator

Intra-Operative Exclusion Criteria	• Administration of low molecular weight heparin (LMWH) within 8 hours before or planned after the procedure
	• Uncontrolled systolic hypertension (SBP > 180 mmHg) or hypotension (SBP < 90 mmHg) immediately prior to enrollment
	• Subject may be ineligible to ambulate per protocol for any reason, for example:
	  o Any procedural complications, medical conditions (e.g., extended diuresis required), or issues with Non-Study Access Site closure that may extend recovery, ambulation and discharge times
	  o The subject should not attempt ambulation according to the protocol requirements for any reason, in the opinion of the Investigator
	• Any attempted femoral arterial access in either limb during the procedure
	• The Investigator deems that a different method should be used to achieve hemostasis of the Study Access Site than stipulated per protocol (e.g., manual compression)
	• Disease state or other source of interference that would interfere with the use of the device, in the opinion of the Investigator (e.g., vascular grafts or surgery at the target vessel puncture site)
	• The following are exclusions for ALL access sites immediately prior to enrollment unless otherwise noted:
	  o Difficult insertion of procedural sheath or needle stick problems at the onset of the procedure (e.g., multiple stick attempts, unintentional vessel stick with hematoma, "back wall stick") in any of the vessel punctures
	  o Access site configurations and procedure sheath size outside of the protocol range:
	  ▪ Study Limb (required) – MVP XL Study Device
	  • OD: < 16F or > 17F venous or
	  • ID: < 10F or
	  • More than one access site in the Study Limb
	  ▪ Non-Study Limb (optional) – VASCADE Family Commercial Device:
	  • OD: > 15F or
	  • ID: < 5F or > 12F venous or
	  • More than 3 access sites in the Non-Study Limb or
	  • Non-Study Access site(s) are in the same limb as the Study Limb
	  o Vessel access site location is noted to be "high" or not at the common femoral vessel (above the inguinal ligament, cephalad to lower half of the femoral head or the inferior epigastric vein origin from the external iliac vein)
	  o Intra-procedural bleeding around sheath, forming hematoma, and/or suspected vascular complications
	  o Length of the tissue tract, the distance between the anterior vessel wall and skin, is estimated to be less than 2.5 cm
	  o Femoral vessel diameter less than 6 mm at access site
	• The Non-Study Access Site(s) were not closed successfully with VASCADE commercial device(s) with final hemostasis confirmed prior to Study Access Site closure

* 29 subjects (with evaluable images) were included in a sub-study in which they underwent ultrasound evaluation at the Study Access Site between the time when successful ambulation was documented and 5 calendar days post-procedure.

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

Number of subjects	77
Age (years), mean (±SD)	67.2 (±9.8)
BMI, mean	29.3
Female (%)	27.3%
Administration of anticoagulant/antiplatelet medications prior to procedure	98.7%
Intra-procedural administration of heparin	100%
Protamine used (heparinized subjects)	84.4%
Activated clotting time (ACT) (seconds) at the end of the catheterization procedure (heparinized subjects), mean	363.7

Safety Results

The primary and secondary safety endpoints were major and minor access site closure-related complications in the Study Limb, attributed directly to the investigational closure method within 30 days post-procedure. The primary and secondary safety endpoint analyses were performed on the Intent to Treat (ITT) population, as adjudicated, per protocol. The major access site closure-related

complication rate, 0.0%, was statistically lower than the PG of 10% (p=0.0003) and the one-sided upper 97.5% Confidence Interval (CI) was 4.7%, which was less than the PG; thus the study met the primary safety endpoint. The CAC for the minor access site closure-related complication rate was set at 3.0%. There were no minor access site closure-related complications observed (0.0%); thus the study met the secondary safety endpoint.

Table 3: AMBULATE EXPAND As-Adjudicated Major and Minor Closure-Related Complications

Access Site Closure-Related Complications through 30 Days by Event	**VASCADE MVP XL (N=77)**	
	n	**%**
Any Major Venous Access Site Closure-Related Complication	**0**	**0%**
Access site bleeding requiring transfusion	0	0%
Vascular injury requiring surgical repair (via surgery, transcatheter embolization, balloon angioplasty or stent graft)	0	0%
Access site-related infection confirmed by culture and sensitivity, requiring intravenous antibiotics and/or extended hospitalization	0	0%
New onset permanent access site-related nerve injury in the ipsilateral lower extremity (i.e., persisting for 30 days)	0	0%
New onset access site-related nerve injury in the ipsilateral lower extremity requiring surgical repair	0	0%
Pulmonary embolism requiring surgical or endovascular intervention and/or resulting in death, to be confirmed by CT pulmonary angiography or lung ventilation/perfusion scan (VQ scan) or autopsy	0	0%
Pulmonary embolism NOT requiring surgical or endovascular intervention and/or NOT resulting in death, to be confirmed by CT pulmonary angiography or lung ventilation/perfusion scan (VQ scan)	0	0%
Any Minor Venous Access Site Closure-Related Complication	**0**	**0%**
Access site-related bleeding requiring > 30 minutes of continuous manual compression to achieve initial venous hemostasis	0	0%
Access site-related hematoma $\geq$ 6 cm documented by ultrasound	0	0%
Late access site-related bleeding requiring non-surgical intervention (following hospital discharge)	0	0%
Ipsilateral deep vein thrombosis, confirmed by ultrasound/imaging	0	0%
Access site-related vessel laceration	0	0%
Localized access site infection confirmed by culture and sensitivity, treated with intramuscular or oral antibiotics	0	0%
Arteriovenous fistula not requiring treatment, documented by ultrasound/imaging	0	0%
Pseudoaneurysm requiring treatment (thrombin/fibrin adhesive injection or ultrasound-guided compression), documented by ultrasound	0	0%
Pseudoaneurysm not requiring treatment, documented by ultrasound	0	0%
New onset transient access site-related nerve injury in the ipsilateral lower extremity (i.e., persisting for < 30 days)	0	0%

Effectiveness Results

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 Study Device removal and when subject stands and walks 20 feet without evidence of venous re-bleeding from the Study Access Site (per-subject analysis).
Secondary Effectiveness Endpoints	**Time to Hemostasis (TTH):** elapsed time between Study Device removal and first observed and confirmed venous hemostasis, for the Study Access Site (per-access site analysis).
	Total Post Procedure Time (TPPT): elapsed time between removal of the last procedural device/catheter for the index procedure in the Study Access Site and when subject was able to successfully ambulate based on the Study Access Site (per-subject analysis).
	Time to Discharge Eligibility (TTDE): elapsed time between Study Device removal and when subject is eligible for discharge based solely on the assessment of the Study Access Site (per-subject analysis).

	Time to Discharge (TTD): elapsed time between Study Device removal, and when subject is discharged from the institution (per-subject analysis).
	Procedure Success (PS): Attainment of final hemostasis at all venous access sites and freedom from major venous access site closure-related complications through 30 days (per-subject analysis).
	Device Success (DS): The ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the Study Device (per-access site analysis).

TTA, TPPT, and TTDE were evaluated using the mITT population (N=76) which excluded subjects for which durations were lengthened due to the Non-Study Access Site only per protocol. TTH and device success were evaluated using the ITT population (N=77). Procedure Success was descriptively reported using the ITT population using as adjudicated safety results. Five (5) subjects had unknown discharge times, therefore descriptive reporting of TTD was performed on a sample size of N=72 subjects.

Mean time to ambulation was 3.2 hours +/- 2.8 hours. Using a one-sample t-test, time to ambulation was significantly shorter than the PG of 6.1 hours ($p<0.0001$). The one-sided upper 97.5% confidence interval (CI) was 3.8 hours which is less than the PG, therefore the primary efficacy endpoint was successfully met. All secondary effectiveness endpoints with clinical acceptance criteria (CACs), TTH, TPPT, and TTDE, were met as the means were all similar to or less than the respective CAC.

Primary and secondary effectiveness endpoints which were compared against PG and CACs are shown in Tables 5 while secondary effectiveness endpoints descriptively reported are shown in Table 6 and Table 7.

Table 5: Primary and Secondary Effectiveness Endpoints – TTA, TTH, TPPT, and TTDE

Endpoint	**TTA (hrs)**	**TTH (mins)**	**TPPT (hrs)**	**TTDE (hrs)**
Population	mITT	ITT	mITT	mITT
Level	Subject	Access Site	Subject	Subject
n	76	77	76	76
Mean ± SD	3.2±2.8	2.7±2.7	3.3±2.8	3.4±2.8
Median (min, max)	2.6 (2.0, 23.5)	2.3 (0.0, 14.5)	2.6 (2.1, 23.6)	2.7 (2.0, 23.7)
Acceptance Criteria	Upper bound of one-sided 97.5% CI < 6.1, p<0.025	Less than or similar to CAC of 9.8 minutes	Less than or similar to CAC of 4.4 hours	Less than or similar to CAC of 4.4 hours
p-value	<0.0001	N/A	N/A	N/A
Met Acceptance Criteria	Yes	Yes	Yes	Yes

Table 6: Descriptive Secondary Effectiveness Endpoints-Procedure and Device Success

	Procedure Success	**Device Success**
Success- Yes (%)	**77 (100%)**	**76 (98.7%)**
Success-No (%)	**0 (0%)**	**1 (1.3%)***

*Device issue included a device pull through which is a known risk of the VASCADE MVP product family.

Table 7: Descriptive Secondary Effectiveness Endpoint- TTD

ITT Population	**TTD (hrs)**
Level	Subject
n	72*
Mean ± SD	12.3±18.9
Median (min, max)	4.7 (2.6, 147.8)

*5 subjects had unknown discharge times and were excluded from analysis

Table 8: Additional Analyses - Same Day Discharge (SDD)

	Pivotal Subjects (N=77)		SDD Next Day VASCADE MVP XL VVCS Model 800-1014XL Success**	
	n	%	n	%
Yes	52	67.53	52	100
No	25*	32.47	0	0

*Study did not include inclusion/exclusion criteria related to same day discharge intent. Of the 25 non-SDD subjects, 18 did not have a delay in hospital discharge beyond routine institutional practice. The remaining 7 subjects had discharge delays, including 5 due to medical reasons and 2 due to unknown or other reasons. No major or minor complications per protocol in any of these subjects.

**Aligned with Primary Performance Endpoint in prior Vascade MVP SDD Studies (see IFU Section below titled VASCADE MVP 6-12F VVCS - AMBULATE Same-Day Discharge Studies).

Roll-In Subjects

The roll-in subjects are summarized separately and a summary of their baseline characteristics, safety and effectiveness endpoints are provided below in Tables 9 – 11. There was nothing concerning related to safety and effectiveness endpoints reported for the roll-in patients when compared to the primary analysis cohort.

Table 9: Roll-in Subjects Demographics and Baseline Characteristics

Number of subjects	8
Age (years), mean (±SD)	72.5 (±6.7)
Sex Assigned at Birth, Female/Male (%)	50/50%
Gender, Female/Male (%)	50/50%
Ethnicity, Not Hispanic or Latino/Unknown (%)	87.5/12.5%

Table 10: Roll-in Subjects Safety Endpoints

Access Site Closure-Related Complications through 30 Days by Event	Study Limbs (N=8)	
	n	%
Any Major Venous Access Site Closure-Related Complication	0	0%
Any Minor Venous Access Site Closure-Related Complication	0	0%

Table 11: Roll-in Subjects Effectiveness Endpoint

Endpoint	TTA (hrs)	TTH (mins)	TPPT (hrs)	TTDE (hrs)
Level	Subject	Access Site	Subject	Subject
n	7*	8	7*	7*
Mean ± SD	2.7 ± 0.6	3.4 ± 1.5	2.7 ± 0.6	2.8 ± 0.6
Median (min, max)	2.5 (2.1, 3.7)	3.6 (0.8, 5)	2.5 (2.2, 3.9)	2.6 (2.2, 3.9)

*One roll-in subject was unable to complete the ambulation assessment (TTA) due to her clinical condition (which was not access site closure-related). Since an ambulation delay impacts the timing when discharge eligibility is assessed (TTDE) and the overall procedure time (TPPT) per protocol, these two endpoints (TTDE and TPPT) are also unavailable for this subject.

VASCADE MVP 6–12F VVCS – AMBULATE CLINICAL TRIAL

Study Design and Baseline

Table 12: 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 United States. Randomization was stratified to account for patients with different numbers of access sites, i.e. 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 had the same average number 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 events, including bleeding as well as neurological and other potential device- or procedure-related adverse events.
Inclusion Criteria	• ≥ 18 years of age. • Able and willing to sign an Informed Consent Form. • Undergoing elective, non-emergent, catheter-based procedures via the common femoral vein(s) using a 6F to 12F inner diameter introducer sheath • 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, coagulation defect or hypercoagulability. • Platelet count < 100,000 cells/mm^3. • Severe comorbidities with life expectancy of less than 12 months in the opinion of the site investigator. • History of femoral arteriotomy or venotomy within the last 10 days. • History of vascular complications or residual hematoma. • Treatment with an intravascular closure device within the last 30 days or 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). • Unable 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 normal time to recovery, ambulation or discharge. • 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 use of a sheath < 6 or > 12F inner diameter or tissue tract < 2.5 cm deep.

*49 patients were included in a sub-study in which they underwent ultrasound examinations at the 30 ± 7-day follow-up visit.

**202 of 204 randomized subjects (99%) completed the 30-day follow-up visit, with 175 patients (85.8%) completing the 30-day (± 7 days) follow-up visit per protocol. One (1) patient in each treatment group was lost to follow up and one (1) device patient completed the follow up-visit at 3 days post-procedure.

The baseline demographic and clinical characteristics of the 2 treatment groups were similar (Table 13).

Table 13: 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, mean	29.5	29.7
Female (%)	33%	38%
Administration of anticoagulant/antiplatelet drugs within 24 hours before the procedure	84%	85%
Intraoperative administration of heparin	85%	90%
Protamine used (heparinized subjects)	92%	91%
Activated clotting time (ACT) (seconds) at the end of the catheterization procedure (heparinized subjects), mean	298.6	285.9

Safety Results

The primary and secondary safety endpoints were the rates of access site-related major and minor complications during follow-up (Table 14). The major complication rates were clinically the same *(0%)* for VASCADE MVP and Manual Compression (MC). The VASCADE MVP minor complication rate was numerically lower than for MC and clinically similar.

Table 14: 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 bleeding requiring transfusion	0	0.0%	0	0.0%
Vascular injury requiring surgical repair	0	0.0%	0	0.0%
Access site infection confirmed and requiring intravenous antibiotics and/or prolonged 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%
Bleeding from the access site 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%
Delayed bleeding from the access site (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 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 15 for definitions of primary and secondary effectiveness endpoints.

Table 15: Effectiveness Endpoint Definitions

Primary Effectiveness Endpoint	**Time to Ambulation (TTA):** elapsed time between removal of the final VASCADE MVP device (treatment arm) or removal of the final sheath (control arm), and time when subject stands and walks 20 feet without evidence of venous re-bleeding from the femoral access sites. Per-patient analysis.
Secondary Effectiveness Endpoints	**Time to Hemostasis (TTH):** elapsed time between removal of the device (i.e. removal of the device for VASCADE and removal of the sheath 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 removal of the device (i.e. removal of the device for VASCADE and removal of the sheath for MC) and when the patient is eligible for hospital discharge based solely on an assessment of the access site. Per-patient analysis.

	Time to Discharge (TTD): elapsed time between final removal of the device (i.e. removal of the device for VASCADE and removal of the sheath for MC) and hospital discharge. Per-patient analysis.
	Total 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: Attainment of final hemostasis at all venous access sites and freedom from major venous access site closure-related complications through 30 days. Per-patient analysis.
	Device Success (DS): The ability to deploy the delivery system, deliver the collagen, and achieve hemostasis with the VASCADE MVP. Per-access site (device arm only).

Primary and secondary effectiveness endpoints are shown in Table 16. 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 16: Primary and Secondary Effectiveness Endpoints

Outcome	VASCADE MVP			Manual Compression			ANCOVA	
	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 (-3.87, -2.96)	<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	3.2 ± 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)							-0.04 (-3.25, 3.17)	0.98
N	N=100	N=31	N=69	N=104	N=34	N=70		
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)							-27.23 (-33.86, -20.60)	<0.0001
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		

Outcome	VASCADE MVP			Manual Compression			ANCOVA	
	Total	3 Access Sites	4 Access Sites	Total	3 Access Sites	4 Access Sites	Parameter Estimate (95% CI)	*P* value
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 17

Table 17: 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 18 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, inability to deploy disc, inability to achieve temporary hemostasis and use error.

Table 18: VASCADE MVP Device Success (Device Arm Only) Per Access Site

Device Success	Number of Access Sites	Successes	Percent
Actual Devices Attempted	363	351	97%

Table 19 shows the proportion of subjects with Procedure Success.

Table 19: 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 20), as well as questions for scenarios with hypothetically longer (device patients) or shorter (MC patients) bedrest periods Table 21). In all cases, patient satisfaction scores favored device over manual compression.

Table 20: Patient Experience Survey – Comparative Experience

Bedrest Experience		VASCADE MVP (Mean +/- SD)	Manual Compression (Mean +/- SD)	% Difference (MVP-MC)/MC
Patient Reported Satisfaction Scores	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%

Bedrest Experience		VASCADE MVP (Mean +/- SD)	Manual Compression (Mean +/- SD)	% Difference (MVP-MC)/MC
Scale 0-10 with 0 as 'very dissatisfied' and 10 as 'very satisfied	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 21: 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. Medication was administered for pain in 24% of the VASCADE MVP subjects, and in 49% of the manual compression subjects. Medication was administered for anxiety in 4% of the VVCS subjects, and in 2% of the manual compression 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 22).

Table 22: 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%	

VASCADE MVP 6–12F VVCS – AMBULATE Same-Day Discharge Studies

The objective of the registries was 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 eligible 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. Ablation for atrial fibrillation, which is generally longer and/or more complex than for other arrhythmias, provides a greater challenge for establishing the safety profile for same-day discharge than ablation for other arrhythmias.

The primary performance endpoint was Same Day Discharge (SDD) Next Day VASCADE MVP Success, defined as subjects who did not require next day hospital intervention due to access site closure-related complications. Secondary performance endpoints were: 1) Same Day Discharge Next Day Procedure Success defined as subjects who did not require next day hospital intervention due to the following procedure-related reasons: pericardial effusion – worsening or late onset; recurrent arrhythmia requiring cardioversion; decompensated heart failure; urinary retention issues; other reason, as adjudicated by independent physician review; and 2) Same Day Discharge Follow-Up VASCADE MVP Success defined as subjects who did not require hospital intervention within the post-

procedure follow-up period (SOC > 7 days for Retrospective and 15 +/-5 days for Prospective SDD#1) due to access site closure-related complications.

Table 23: Same-Day Discharge Studies Safety and Effectiveness Results

Study	Population	Performance			Safety		
		VASCADE MVP Success (Freedom from Access Site Complications)		Procedure Success (Freedom from Next Day Procedure-Related Complications)	Access Site Closure Related Complications		
		Next Day	Follow-Up		Major	Minor	Individual Complication Event Rate (Non-Endpoint Analysis)
Retrospective (AF All-Comers) Procedures: 2018-12 – 2020-02 | 497 Patients | 4 sites | Standard of Care f/u	Discharged Same Day	99.8% (496/497) 95%CI (0.99, 1.00)	99.8% (496/497) 95%CI (0.99, 1.00)	99.6% (495/497) 95%CI (0.99, 1.00)	0.0% (0/827) 95% CI (0.00, 0.00)	0.1% (1/827)* 95% CI (0.00, 0.01)	0.1% (1/827)*
Prospective SDD#1 (Paroxysmal AF) 2020-06 – 2020-11 | 151 Patients | 8 sites | 15-day f/u	Discharged Same Day	99.3% (137/138) 95% CI (0.96, 1.00)	99.3% (137/138) 95% CI (0.96, 1.00)	99.3% (137/138) 95% CI (0.96, 1.00)	0.0% (0/193) 95% CI (0.00, 0.02)	1.0% (2/193)** 95% CI (0.00, 0.04)	1.6% (3/193)**
	Discharged Same Day out of ITT	90.7% (137/151) 95% CI (0.85, 0.94)	90.7% (137/151) 95% CI (0.85, 0.94)	90.7% (137/151) 95% CI (0.85, 0.94)			
	ITT	99.3% (150/151) 95% CI (0.96, 1.00)	99.3% (150/151) 95% CI (0.96, 1.00)	99.3% (150/151) 95% CI (0.96, 1.00)			

*1 event occurred in 1 subject (1 limb) - Late access site-related bleeding (following hospital discharge)

**3 events occurred in 2 subjects (2 limbs) - Late access site-related bleeding (following hospital discharge) in one subject and transient access site-related nerve injury and arteriovenous fistula not requiring treatment in one subject

Table 24 Same Day Discharge Prospective Registry Device Success

Definition	n (%)	95% CI
The proportion of access sites successfully closed with VASCADE MVP	452/456 (99.1%)	(0.98, 1.00)

Study Summary – Retrospective Registry

All of the patients in the study were patients undergoing interventional electrophysiology procedures for the ablation of cardiac arrhythmias which included atrial fibrillation with or without another arrhythmia. Only adult patients discharged the same day and whose femoral venous access sites were closed with VASCADE MVP were enrolled in order to support the desired indication. A total number of 1,687 access sites in 497 subjects (827 limbs) were closed in this registry with an average of approximately 3 access sites per subject. Most commonly, subjects had 4 access sites (256/497, 51.5%). One patient had only 1 access site (0.2%) while the remaining patients had 2 to 3 access sites (48.3%). All subjects but one had multiple access sites placed in either one limb (ipsilateral access) or both (bilateral access) limbs using 2 to 4 sheaths, with an average of approximately 3 sheaths per patient. The majority of sheath configurations (50.5%) was bilateral (2x2) followed by ipsilateral (0x3) configuration (22.5%).

Adults age ≥ 18 were eligible if they met the following inclusion criteria: ≥18 years of age; underwent catheter-based ablation for atrial fibrillation with or without another arrythmia; VASCADE MVP was the only closure device utilized; were discharged the same calendar day as the index procedure; completed a SOC follow-up > 7 days post-procedure. Subjects were excluded if Subjects were excluded from this registry if they met the following criteria: any additional procedure(s) involving femoral arterial or venous access in either limb within the standard of care follow up period as defined by each site (minimum 7 days post-procedure). Post-procedure through follow up, patients were evaluated for any major or minor complications or adverse event including bleeding, neurological and other potential device or procedure-related adverse effects which required hospital intervention through next-day post-procedure. The medical record was reviewed for all adverse events from the date of the procedure through the follow-up visit conducted per the sites' standard of care. An independent physician adjudicator evaluated potential endpoint events and serious adverse events.

Study Summary – Prospective Registry

All of the patients in the study were patients undergoing interventional electrophysiology procedures for the ablation of cardiac arrhythmias which included paroxysmal atrial fibrillation with or without another arrhythmia. At the completion of the ablation procedure, patients who met all the pre- and all intra-operative eligibility criteria were enrolled in the registry and were eligible to receive the Cardiva MVP VVCS for femoral venous hemostasis as part of the registry. Once enrolled into the registry, it was required to complete all evaluations and follow-up requirements.

A total number of 456 access sites in 151 subjects (193 limbs) were closed in this prospective registry. Most commonly, subjects had 3 access sites (456/151, 59%). One patient had 5 access sites (0.7%) while the remaining patients had 2 or 4 access sites (40.4%). All subjects had multiple access sites placed in either one limb (ipsilateral access) or both (bilateral access) limbs using 2 to 5 sheaths, with an average of approximately 3 sheaths per patient. The majority of sheath configurations was ipsilateral: 51% (0x3); 19.9% (0x2), and 1.3% (0x4).

Adults age ≥ 18 were eligible if they met the following inclusion criteria: ≥18 years of age; capable and willing to give informed consent; acceptable candidate for an elective, non-emergent catheter-based paroxysmal atrial fibrillation ablation procedure with or without another arrhythmia via the common femoral vein(s) using a 6 to 12 Fr inner diameter (max 15F OD) introducer sheath; accompanied by a person who will be available to assist the subject for 24 hours post-procedure and/or has access to emergency services; Is willing/able to stay overnight at the hospital per physician discretion; able and willing to complete two follow-up contacts at 2-4 days and 15 (± 5) days post-procedure; acceptable candidate for emergent vascular surgery, and/or manual compression of the venous access site. Subjects were excluded if they meet any of the following criteria prior to initiation of the index procedure: Advanced refusal of blood transfusion, if it should become necessary; active systemic infection, or cutaneous infection or inflammation in the vicinity of the groin; pre-existing immunodeficiency disorder and/or chronic use of high dose systemic steroids; known history of bleeding diathesis, coagulopathy, hypercoagulability, or current platelet count < 100,000 cells/mm3; severe co-existing morbidities, with a life expectancy of less than 12 months; currently involved in any clinical trial that may interfere with the outcomes of this study in the opinion of investigator; femoral arteriotomy in either limb with any of the following conditions: a. access within < 10 days; b. any residual hematoma, significant bruising, or known associated vascular complications c. use of a vascular closure device within the previous 30 days; femoral venotomy in either limb with any of the following conditions: a. access within < 10 days, b. any residual hematoma, significant bruising, or known associated vascular complications, c. use of a vascular closure device; any planned procedure involving femoral arterial or venous access in either limb within the next 30 days; any history of deep vein thrombosis, pulmonary embolism or thrombophlebitis; significant anemia with a hemoglobin level less than 10 g/dL or a hematocrit less than 30%; females who are pregnant, planning to become pregnant within 3 months of the procedure, or who are lactating; extreme morbid obesity (BMI greater than 45 kg/m2) or underweight (BMI less than 20 kg/m2); unable to routinely walk at least 20 feet without assistance; known allergy/adverse reaction to bovine derivatives; administration of low molecular weight heparin (LMWH) within 8 hours before or after the procedure; planned procedures or concomitant condition(s) that may extend ambulation attempts beyond routine ambulation and/or hospital discharge time (e.g., staged procedure, serious co-morbidity, uncontrolled obstructive sleep apnea, congestive heart failure), in the opinion of the Investigator; current diagnosis of persistent or permanent atrial fibrillation. Additional intra-operative inclusion and exclusion criteria were required based on intra-operative screening. Discharge evaluation criteria were: physician or designee must perform discharge evaluation; subject has successfully ambulated without bleeding from access site; subject has been able to void; no clinically significant ECG findings; subject is accompanied by a responsible person who will be near them for the next 24 hours. An independent physician adjudicator evaluated potential endpoint events and serious adverse events.

Conclusions of the Clinical Studies

The results from the AMBULATE EXPAND Study demonstrate that the VASCADE MVP XL Study Device is safe and effective when used for percutaneous closure of femoral venous access sites in patients who have undergone catheter-based procedures utilizing 16-17F outer diameter (OD) procedural sheaths while reducing time to ambulation, time to hemostasis, total post-procedure time, and time to discharge eligibility.

The AMBULATE EXPAND study achieved clinically acceptable ambulation times compared to the Performance Goal. On average, the time to ambulation was 3.2 ± 2.8 hours which compares favorably against the established efficacy Performance Goal of 6.1 hours (97.5% CI Upper Limit: 3.8; $p<0.0001$). In addition, the major access site closure-related complication rate was 0% which compares favorably against the established safety Performance Goal of 10% major access site closure-related complication rate (97.5% CI Upper Limit:4.7%; $p=0.0003$).

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 Venous Vascular Closure System (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).

Also, the procedure success rate for patients treated with the Cardiva 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 Registry demonstrate that VASCADE MVP enables safe same day discharge in subjects 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 Cardiva VASCADE MVP Venous Vascular Closure System (VVCS).

Study success demonstrated that 99.8% of patients treated for a-fib that were discharged the same day and did not require additional hospital intervention post discharge for access site closure-related complications. Similarly, 99.6% of patients treated for a-fib that were discharged the same day did not require additional hospital intervention post discharge for procedure-related complications. There were no major complications 0% (0/827) and the minor complication rate was 0.1% (1/827).

The results from the AMBULATE VASCADE MVP Same Day Discharge Prospective Registry demonstrate that VASCADE MVP enables safe same day discharge in subjects who underwent catheter-based procedures for paroxysmal atrial fibrillation with or without another arrhythmia utilizing 6 – 12F inner diameter procedural sheaths, with single or multiple access sites in one or both limbs, and who were treated with the Cardiva VASCADE MVP Venous Vascular Closure System (VVCS).

Study success demonstrated that 99.3% of patients treated for paroxysmal a-fib that were discharged the same day and did not require additional hospital intervention post discharge for access site closure-related complications. Similarly, 99.3% of patients treated for paroxysmal a-fib that were discharged the same day did not require additional hospital intervention post discharge for procedure-related complications. There were no major complications 0% (0/193) and the minor complication rate was 1.0% (2/193).

Given the high success rates of the procedural performance outcomes, the study also demonstrated that physicians were able to accurately assess patient suitability for same day discharge when utilizing the VASCADE MVP device for femoral access site closure of multiple access sites in the same vessel in one or both limbs.

General Use Instructions

⚠ **WARNINGS**

- Do not use VASCADE MVP XL 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 60 days. The previously implanted collagen patch may be inadvertently introduced into the femoral vessel.
- Do not deploy the VASCADE MVP XL Disc in a stent. Do not pull the deployed VASCADE MVP XL Disc through a stent. Damage to the product may occur.

⚠ **PRECAUTIONS**

- The VASCADE MVP XL should only be used by a trained licensed physician or healthcare professional.
  - Note the training referred to here is previous training for accessing vessels, and positioning and using catheters. The VASCADE MVP XL device does not require formal training beyond review of the content provided in this IFU.
- Do not use in a vein with suspected intraluminal thrombus, hematoma, pseudoaneurysm, or arteriovenous fistula. These conditions may complicate proper device use and performance.
- Do not use in access sites where there is suspicion of a "backwall" stick. Increased bleeding risk may occur.
- Do not use if venotomy is noted to be a "side stick." Bleeding risk may increase.
- Do not use if venotomy site is noted to be "high," above the Inguinal Ligament (cephalad to lower half of the femoral head or the inferior epigastric artery origin from the external iliac artery). This may increase the risk of bleeding.
- Do not use in a procedural sheath > 12 cm in length (or >15 cm in overall length) or with a diameter other than 10-14F. This may complicate Disc deployment.

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 Device Preparation

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. Ultrasound-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. At the time of initial introducer sheath placement, patient body habitus should be evaluated to provide reasonable assurance that the distance between the femoral venotomy and the skin surface is greater than 2.5cm.

Prior to Closure

3. After introducer sheath placement, an anterior oblique fluoroscopic image with contrast or ultrasound image may be digitally recorded and stored, so that the venotomy site location can be estimated and compared to the position of the proximal radiopaque marker just prior to Collagen Patch release.
4. The proximal radiopaque marker is located immediately distal to the Collagen Patch.

Multi-Site Access & Closure

5. If more than one sheath is planned to be placed in the same vein, the distance between the access sites should be kept at a minimum of 8 mm. Keep the stick separation at the skin level at a minimum of 8 mm and drive the needles to the vein at the same angle to keep the separation between the adjacent venotomies at a minimum of 8 mm. Imaging techniques such as ultrasound can be used to confirm the separation is as recommended.
6. 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.

⚠ CAUTION:

- During access care should be taken so that the tissue tract is not pushed laterally or medially prior to accessing the vessel. This is to avoid misalignment of the tissue tract and the Collagen Patch relative to the venotomy site once the device is removed from the vessel, which may result in prolonged time to hemostasis.
- If more than one access is made in the vein, keep a minimum of 8 mm separation between the access sites (~1 cm at skin level). 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.
- 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.

Prep-B: Unpack the Device

1. Inspect the package for damage (breaks, tears, open seals, water damage, etc.).
2. Verify that expiration date has not passed.
3. Using standard sterile technique (See Aseptic Presentation below), remove the tray containing the VASCADE MVP XL VVCS Catheter and Clip from the foil pouch.
4. Carefully remove VASCADE MVP XL VVCS Catheter and Clip from the tray.

Aseptic Presentation

- Inspect the product packaging. Observe for any breaks, holes, or openings that would compromise the integrity and sterility of the product.
- Read the label. Check the expiration date and verify correct product/size is used.
- 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.
  - All packaging for sterile products has a designated side to open from. Locate this side and slowly peel the package open.
  - Open the packaging with arms extended to avoid accidental contact with the product or the sterile field. Be sure the secondary sterile packaging containing the product does not come in contact with the edges of the external packaging as they are not considered sterile. Create a large enough opening in the package to remove the interior packaging containing the product without touching the non-sterile areas.
- Present the product to the scrubbed person.
- Discard packaging following facility protocol

⚠ WARNINGS

- Do not reuse or re-sterilize. The VASCADE MVP XL 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

Fig. 2 – Verify Orange-Blue Key is not engaged in the Lock and Black Sleeve is locked in position

1. Examine the device by first verifying that the Black Sleeve is locked in position and the Collagen Patch is not exposed.
2. Also verify that the Orange-Blue Key **(Figure 2)** is not engaged in the Lock (the Lock is located at the proximal aspect of the Black Sleeve), and the Orange-Blue Key is located at the proximal end of the Catheter Shaft.

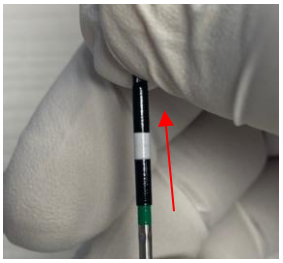


Fig. 3 – Pull back on Black Actuator Tip to deploy the Disc

3. Inspect the Catheter further by examining the deployed VASCADE MVP XL VVCS Disc.
    a) To deploy the Disc, hold the Silver Handle firmly and pull back on the Black Actuator until it locks in place.
    b) When the Disc is locked in the deployed position, the Green Segment will become visible as shown in **Figure 3**.

4. Examine the Disc, which should appear circular and symmetrical with an intact membrane.
    a) **Figure 4** shows the deployed and collapsed Disc.

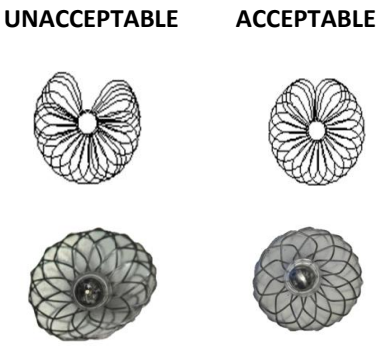


Fig. 4 – Deployed & Collapsed Disc

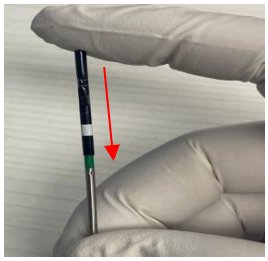


Fig. 5 – Collapse Disc by pressing Black Actuator Tip like a ballpoint pen

5. After examination, collapse the Disc by pressing the Black Actuator tip down **(Figure 5)**. The tip of the VASCADE MVP XL VVCS Catheter should return to its original profile.

Prep-D: Prepare the Sheath

1. Verify that the sheath is not positioned in a tortuous vessel, by examining the sheath placement images obtained earlier.
2. If required, retract the sheath slightly to a non-tortuous location. Verify that the sheath is still positioned within the vein.
3. Flush the sheath with sterile saline solution prior to insertion of the device.

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 VASCADE MVP XL VVCS 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 any vascular injury as a result of advancing the catheter. If required, retract the sheath slightly to a non-tortuous location, being careful not to lose 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

Prior to insertion of device in the introducer sheath, momentarily insert the tip of the VVCS Catheter in saline solution up to the White Marker Stripe and quickly remove.

⚠ **CAUTION**
Do not soak the VASCADE MVP XL VVCS Catheter in saline. Momentarily insert only the Catheter tip in saline solution immediately before use to avoid over-hydration of the patch, which may result in difficulty of retracting the sleeve and causing Catheter pull through during the sleeve retraction step.

Step 1.2: Insert VASCADE

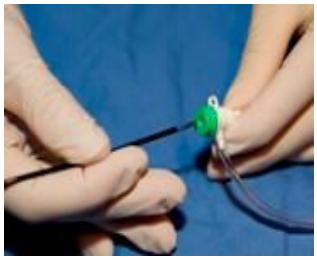


Fig. 6 – Insert device into hub of introducer sheath

1. Gently insert the VASCADE MVP XL VVCS Catheter (with Disc collapsed) into the introducer sheath hub as shown in **Figure 6**. Use short strokes to insert the device.

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

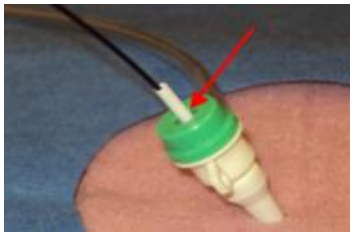


Fig. 7 – Insert device half way of the Lock

2. Insert the VASCADE MVP XL VVCS Catheter such that approximately half of the Lock is visible. Make certain that the Lock is NOT fully inserted into the sheath. See **Figure 7** for correct placement.

Step 1.3: Deploy the Disc

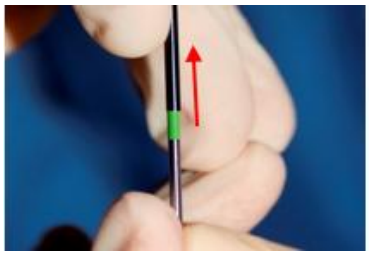


Fig. 8 – Pull back on Black Actuator Tip to deploy the VASCADE MVP XL VVCS Disc

Deploy the Disc by holding the Silver Handle and pulling back the Black Actuator until it locks in place as shown in **Figure 8.**

NOTE: When the Disc is properly deployed, the Green Segment will become visible distal to the Black Actuator. If the catheter is not properly locked in place, the Black Actuator will slide back to its original position and the Green Segment will disappear indicating that the Disc is not properly deployed. In this case repeat the step for deploying the Disc by pulling the Black Actuator more firmly until it locks in place.

⚠ **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

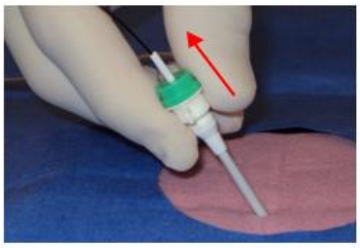


Fig. 9 – Grasp hub of sheath and remove over catheter

1. Gently remove sheath, without applying any compression at the access site or holding the VASCADE MVP XL VVCS Catheter**,** as shown in **Figure 9.**
2. As the sheath slides over the VASCADE MVP XL VVCS Catheter, grasp the Catheter as the sheath exits the body.
3. Continue sliding the sheath over the VASCADE MVP XL VVCS Catheter and discard sheath.

⚠ **CAUTION**
Compressing the access site during sheath removal may not allow the Disc to track back to the venotomy and may cause Disc deformation. This may lead to inability to achieve temporary hemostasis.

Step 1.5: Achieve Temporary Hemostasis

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

Note whether any portion of the White Marker Stripe, which is located near the distal aspect of the Black Sleeve, is visible above the skin. If it is, then the length of the tissue tract is less than 2.5 cm, indicating the tissue tract may not be long enough for the Collagen Patch.

NOTE: If any portion of the White Marker Stripe is showing and the collagen patch is not to be deployed, the VASCADE MVP XL VVCS Catheter should be removed by collapsing the Disc and manual compression should be applied per institutional protocol.

⚠ **WARNING**
If any portion of the White Marker Stripe is showing DO NOT RELEASE the Collagen Patch as this may increase the risk of infection.

STEP 1 PART B: Verify Disc Placement with Imaging

Step 1.6: Continue to Apply Upward Tension on the Catheter

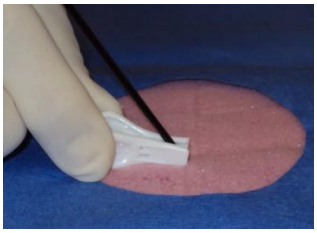


Fig. 10 – Apply Clip to Black Sleeve at skin level

Once temporary hemostasis is achieved, apply the Clip to the Black Sleeve at skin level as shown in **Figure 10.**

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

Verify that deployed Disc is positioned against the intimal surface of the vessel at the venotomy site, either by fluoroscopy (to verify that the more proximal radiopaque marker is positioned at the venotomy), or by ultrasound.

- The Collagen Patch is located immediately proximal to the Proximal Marker Band.
- The Distal Marker Band locates the distal end of the Disc.

⚠ **CAUTION**

Applying too much upward tension on the Silver Handle may cause Disc to pull out of vessel. Should this occur, convert to your **institution's manual compression protocol.**

⚠ **WARNING**

It is important to ensure that the Disc is in contact with the intimal aspect of the venotomy before deploying the extra-vascular Collagen Patch to avoid releasing the Collagen Patch in the vessel**. This is indicated by having temporary hemostasis and further verified by either fluoroscopy (Figure 11a) or ultrasound imaging (Figure 11b)**.

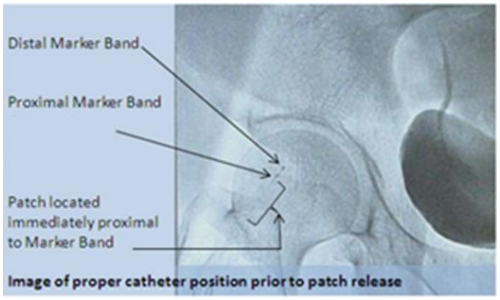


Fig. 11a – Fluoroscopic image demonstrating proper position of Disc

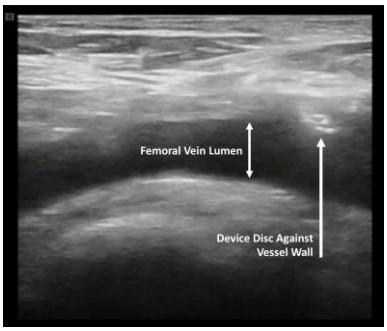


Figure 11b Ultrasound image demonstrating proper position of Disc

STEP 2: Deploy Collagen

Step 2.1: Unlock the Black Sleeve

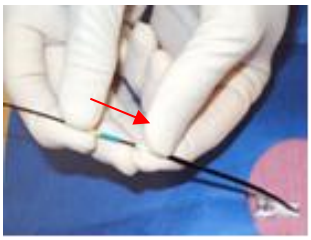


Fig. 12 – Unlock the Black Sleeve by sliding Orange-Blue Key into the Lock

Once the Disc location is verified, expose the extra-vascular resorbable Collagen Patch by unlocking the Black Sleeve. This is done by grasping the Lock with the left hand, between the thumb and the index finger, and grasping the Orange-Blue Key with the right hand and then sliding the Orange-Blue Key into the Lock until no blue color is visible, as shown in **Figure 12**.

Step 2.2: Retract the Black Sleeve to Expose the Collagen

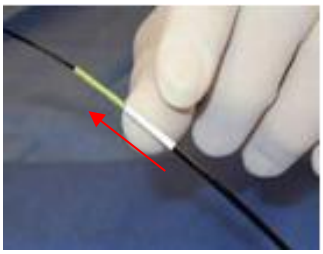


Fig. 13 – Retract the Black Sleeve by grasping the Lock and applying gentle upward tension toward the Silver Handle

1. Once the Sleeve is unlocked and while still holding on to the Lock, remove the Clip with the right hand.
2. Retract the black sleeve as shown in **Figure 13**. While holding slight tension on the Black Actuator, gently slide the lock back along the angle of entry to retract the black sleeve. Alternatively, grasp the device shaft about 2 cm above the Lock. Holding the device shaft stationary, pull the lock back to initiate the sleeve retraction. The Black Sleeve will move freely after some initial resistance (after the Sleeve has moved approximately 2cm).
3. Continue to gently slide the Lock back along the angle of entry to the Silver Handle. This action exposes the Collagen Patch extra-vascularly, which will swell at the venotomy site.

⚠ **WARNING**

Grip the Lock to retract Black Sleeve. Do not grip the device distal to the Lock as this may result in operator injury which could lead to possible infection.

NOTE: If the Black Sleeve does not retract easily, recheck that the blue end of the Orange-Blue Key is fully engaged in the Lock.

NOTE: If the Collagen Patch is removed during sleeve retraction, collapse the Disc, remove the Catheter and apply manual compression, per institutional protocol.

Step 2.3: Wait for Collagen Hydration

Fig. 14 – Reapply Clip during the Collagen Patch swell period

1. The Collagen Patch may be allowed to swell for up to 30 seconds prior to removal of the VASCADE MVP XL VVCS Catheter.
2. The Clip may be reapplied during the Collagen Patch swell period with minimal tension on the Catheter **(Figure 14)**.

STEP 3: Achieve Final Hemostasis

Step 3.1: Prepare to Strip Collagen

Fig. 15 – Grasp Green Tube prior to collapsing the Disc

1. AFTER 15-30 seconds of patch swell time and PRIOR TO collapsing the Disc, remove the Clip.
2. Rest the palm of the hand on the patient and grasp the green tube between the thumb and the index finger as shown in **Figure 15.**

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

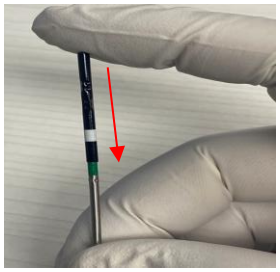


Fig. 16 – Collapse the Disc by pressing on the Black Actuator Tip

1. Push the green tube in the proximal direction approximately 1.5 cm while gently pulling back on the VASCADE MVP XL VVCS Catheter to maintain Disc position against vessel wall. The green tube may be slid back and forth 2-3 times in order to assure release of the Collagen patch from device. Upon completion of this step, leave the green tube in the forward position.
2. Apply gentle compression at the site and collapse the Disc by pressing on the Black Actuator Tip as shown in **Figure 16**.
3. Apply gentle manual compression at the site as the VASCADE MVP XL VVCS Catheter is removed. Continue to apply manual compression.

NOTE: Prior to the VASCADE MVP XL VVCS Catheter removal confirm that the Disc is completely collapsed by verifying that the Green Segment on the handle is no longer visible. Care should be taken not to compress too firmly over the VVCS catheter during the removal step of the device so that the catheter can be easily removed and without displacement of Collagen Patch.

Step 3.3: Confirm Final Hemostasis

1. Observe for complete hemostasis.
2. Manual compression can be used to decrease or stop any tract ooze until full hemostasis is achieved.

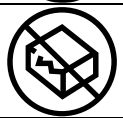
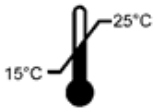
Step 3.4: In Recovery and Discharge

1. Apply sterile dressing to site per institution protocol.
2. Maintain bed rest and periodically check site until patient is ready to ambulate.
3. Complete information on Patient Implant Card and provide to the patient.

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 THE VASCADE MVP XL VVCS PACKAGING

Symbol	Standard / Regulation*	Standard Reference No. / Symbol Title	Definition
	ISO 15223-1	5.1.1 / Manufacturer	Medical device manufacturer
	ISO 15223-1	5.1.4 / 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	5.1.10 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 resterilize	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 re-use	Medical device that is 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 the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	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.

Symbol	Standard / Regulation*	Standard Reference No. / Symbol Title	Definition
	21 CFR 801.109	Prescription Device	Product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a physician.
	N/A	Package quantity	Quantity of systems in package

**Standards and Regulations:*
ISO 15223-1: *Medical devices-Symbols to be used with information to be supplied by the manufacturer*
US FDA Title 21 CFR 801.109*: Prescription Devices*

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https://hospital.haemonetics.com/vascular-closure

LIMITED WARRANTY

Cardiva Medical, Inc. warrants that each VASCADE MVP XL Venous Vascular Closure System (VVCS) 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 a credit for 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.