**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 (see Figure 1).

The system is designed to deliver a resorbable Collagen Patch extra-vascularly at the vessel puncture site to aid in achieving haemostasis. 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 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. The following version of the VASCADE MVP VVCS is available:

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

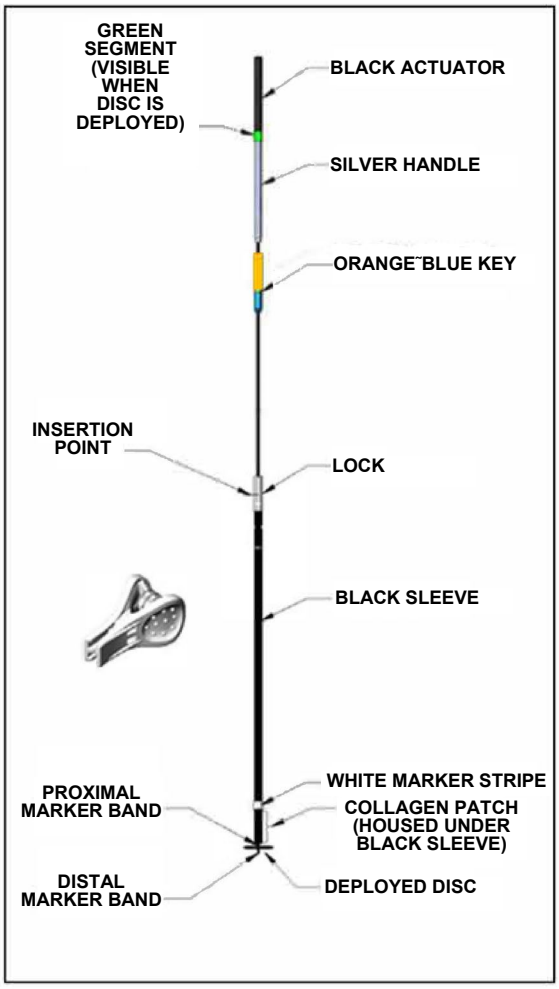



**Figure 1. VASCADE MVP VVCS**

## 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 haemostasis and time to discharge eligibility compared to manual compression, and enabling same-day discharge in patients who have undergone catheter-based procedures using 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 in the implant is derived from animal tissue.
- The materials used in the device do not contain or consist of carcinogenic, mutagenic or reprotoxic (CMR) substances or endocrine disruptors.

[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 percutaneous closure of femoral venous access sites and have undergone catheter-based procedures using 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 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 | 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 |

*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 Implant Card to be given to the patient.
    - One (1) Patient Implant Leaflet with instructions on how to fill in 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-sterilise. VASCADE is intended to be used once only for a single patient. Product reuse or re-sterilisation 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 shelf life on the label.
- Check for the absence of vessel tortuosity or side branches within 3-4 cm from the distal opening of the sheath and that the end of the sheath is not resting against the vessel wall. This is to prevent vascular injury during Catheter placement. If necessary, retract the sheath slightly to a non-tortuous location, making sure not to lose vascular access.
- DO NOT RELEASE the Collagen Patch if any part of the White Marker Stripe is showing (e.g. tissue tract is too short), 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 image guidance.

### PRECAUTIONS

- VASCADE should only be used by a trained, licensed physician or healthcare professional.
    - Note: The training referred to here is previous training in vascular access and catheter placement and use. VASCADE does not require formal training beyond reading the Instructions for Use.
- Do not use in vessels with suspected intraluminal thrombus, haematoma, pseudoaneurysm or arteriovenous (AV) fistula. These conditions may interfere with the proper use and performance of the device.
- Do not use at the following access sites as the bleeding risk may increase:
    - Access site with suspected 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 haemostasis.
- 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 haemostasis 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 haematoma 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 injury.
- 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 removal of the sheath may hinder the Disc from tracking back to the vessel puncture site and cause Disc deformation. This may hinder achieving temporary haemostasis.
- 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 haemostasis 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 have not been evaluated in the following patients:**

- Less than 18 years of age.
- Pregnant and/or lactating women.
- Pre-existing immunodeficiency disorder and/or chronic use of systemic steroids.
- Known significant coagulation defect/bleeding disorders such as thrombocytopenia (platelet count < 100,000/$mm^3$), thrombasthenia, haemophilia, von Willebrand's disease or anaemia (haemoglobin < 10 g/dL and haematocrit < 30%).
- Previous vascular grafts or surgery at the target vessel access site.
- Symptomatic ipsilateral lower extremity ischaemia.
- 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 $kg/m^2$) 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
- Arteriovenous fistula
- Bleeding from the puncture site
- Bruising at the puncture site
- Death
- Deep vein thrombosis
- Device failure/malfunction
- Oedema
- Embolism (thrombus, air, calcific debris, device)
- Haematoma
- Infection
- Inflammatory response
- Intimal tear/dissection
- Laceration of the vessel wall
- Lower extremity ischaemia
- 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 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 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 haemostasis 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, randomised (1:1), controlled, multi-centre clinical trial conducted at 13 sites in the USA. Randomisation 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.<br>• Able and willing to sign an Informed Consent Form.<br>• Eligible candidates for an elective, non-emergency catheter-based procedure via the common femoral vein using a 6F to 12F introducer sheath who were also eligible for post-procedure manual compression.<br>• Minimum of 3 and maximum of 4 femoral venous access sites.<br>• Minimum of 2 access sites per leg.<br>• 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.<br>• Any pre-existing immunodeficiency disorder.<br>• Chronic use of high dose systemic steroids.<br>• History of bleeding diathesis, coagulation defect or hypercoagulability.<br>• Platelet count < 100,000 cells/$mm^3$.<br>• Severe comorbidities with life expectancy of less than 12 months in the opinion of the site investigator.<br>• History of femoral arteriotomy or venotomy within the last 10 days.<br>• History of vascular complications or residual haematoma.<br>• Treatment with an intravascular closure device within the last 30 days or scheduled for femoral venous or arterial access within the next 30 days.<br>• History of DVT, pulmonary embolism, thrombophlebitis, significant anaemia or renal insufficiency.<br>• Extreme morbid obesity (BMI > 45 $kg/m^2$) or underweight (BMI < 20 $kg/m^2$).<br>• Unable to routinely walk at least 6.1 metres without assistance.<br>• Use of low molecular-weight heparin (LMWH) within 8 hours before or after the procedure;<br>• 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.<br>• Procedural complications that would interfere with normal time to recovery, ambulation or discharge.<br>• Difficulty with needle puncture or insertion of the introducer sheath.<br>• Sheath placement cephalad to lower half of the femoral head or the inferior epigastric vein origin from the external iliac vein.<br>• Obvious intraprocedural bleeding or thrombotic complications.<br>• 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 randomised 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. Two (2) subjects did not complete the study (i.e., did not complete the 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% |
| Administration of anticoagulant/antiplatelet drugs within 24 hours before the procedure | 84% | 85% |
| Intraoperative administration of heparin | 85% | 90% |
| Protamine used (heparinised subjects) | 92% | 91% |
| Activated clotting time (ACT) (seconds) at the end of the catheterisation procedure (heparinised 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 3). The major complication rate*s* 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 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 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 hospitalisation | 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 haemostasis | 0 | 0.0% | 0 | 0.0% |
| Access site-related haematoma > 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% |
| Localised 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 4 for definitions of primary and secondary effectiveness endpoints.

**Table 4: Effectiveness Endpoint Definitions**

| | |
|---|---|
| **Primary Effectiveness Endpoint** | **Time to Ambulation (TTA):** elapsed time between removal of the device (i.e. removal of the device for VASCADE and removal of the sheath for MC) and when ambulation was achieved (patient standing and walking at least 6.1 metres without evidence of re-bleeding from the femoral access sites. Per-patient analysis. |
| **Secondary Effectiveness Endpoints** | **Time to Haemostasis (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 haemostasis). 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:** Achievement of final haemostasis using any method and freedom from major vascular complications for 30 days. Per-patient analysis. |
| | **Device Success (DS):** Successful deployment of the delivery system, delivery of the collagen patch and achievement of haemostasis with 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** | |
|---|---|---|---|---|---|---|---|---|
| | **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 | |

| 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 |
| 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 summarised 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, inability to deploy disc, inability to achieve temporary haemostasis 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 switched to manual compression.

Table 8 shows the proportion of subjects with 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 characterise 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 favoured the 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<br><br>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<br><br>Scale 0–10 with 0 as 'very dissatisfied' and 10 as 'very satisfied' | Patients Randomised to VASCADE MVP, score if bedrest were **hypothetically 2–3 hours longer** | | |
| | Duration (N) | 2.6 ± 3.1 (98) | - |
| | Discomfort | 2.7 ± 2.9 (98) | - |
| | Pain | 3.2 ± 3.4 (98) | - |
| | Patients Randomised 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 use of pain medication for the treatment arm (see Table 11).

**Table 11: Use of Pain Medication**

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

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

## 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.

**Table 12: 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 |
| **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) | | |

## Conclusions of the Clinical Studies

The results from the AMBULATE Trial demonstrate that patients who underwent catheter-based procedures using 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 showed a statistically and clinically significantly shorter time to ambulation, total post-procedure time and time to discharge eligibility compared to patients treated with manual compression. Additionally, VASCADE MVP was non-inferior to manual compression with regard to time to haemostasis, the results statistically implying 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 favoured 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 is associated with same-day discharge in patients who underwent catheter-based procedures using 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 absence of major and low rate of minor access site closure-related complications. 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: The training referred to here is previous training in vascular access and catheter placement and use. VASCADE does not require formal training beyond reading the Instructions for Use.
- Do not use in vessels with suspected intraluminal thrombus, haematoma, pseudoaneurysm or arteriovenous (AV) fistula. These conditions may interfere with the proper use and performance of the device.
- Do not use at the following access sites as the bleeding risk may increase:
    - Access site with suspected 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 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 procedural 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-through 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 haematoma. For high stick, retroperitoneal bleeding 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 swap for a different sheath if necessary. 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 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 haemostasis.
- 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 haemostasis 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. Check that the expiry date has not passed.
3. Check 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 the Catheter and Clip from the tray.

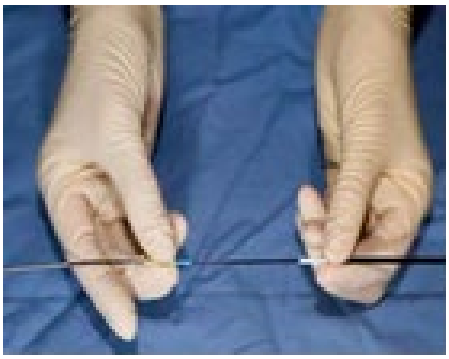
**Aseptic Presentation**

1. Place near the sterile field. Check that the scrubbed person to whom the product is passed is ready to receive it with a clear space in the field.
2. All sterile packages have a designated side to open from. Locate this side and slowly peel the package open.
3. Open the package with arms extended to avoid accidental contact with the product or sterile field. The secondary packaging is not considered sterile and must not touch the edges of the primary packaging. Create a large enough opening in the package to remove the primary packaging without touching the non-sterile areas.
4. Present the product to the scrubbed person.
5. Discard packaging following facility protocol.

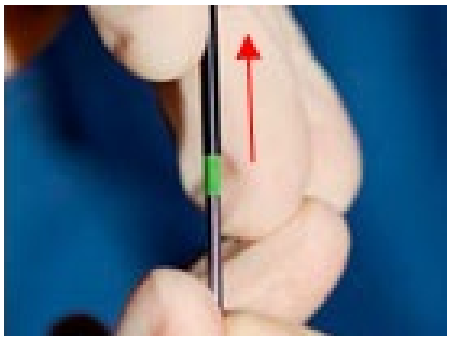
**⚠ WARNINGS**

- Do not reuse or re-sterilise. VASCADE is intended to be used once only for a single patient. Product reuse or re-sterilisation 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 shelf life on the label.

**Prep-C: Inspect the Device**



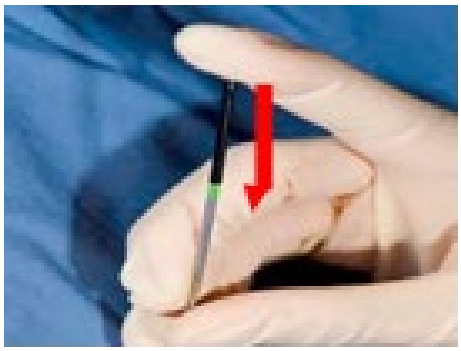
Perform the following inspection to prevent premature Collagen exposure:
1. Black Sleeve is locked in position.
2. Collagen Patch is not exposed.
3. Key is not engaged in the Lock and the Key is located at the proximal end of the device.



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

Check the Disc shape:
1. Circular appearance.
2. Symmetrical appearance.
3. 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 haemostasis 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**

Check for the absence of vessel tortuosity or side branches within 3-4 cm from the distal opening of the sheath and that the end of the sheath is not resting against the vessel wall. This is to prevent vascular injury during Catheter placement. If necessary, retract the sheath slightly to a non-tortuous location, making sure not to lose vascular access.

**CAUTION**

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

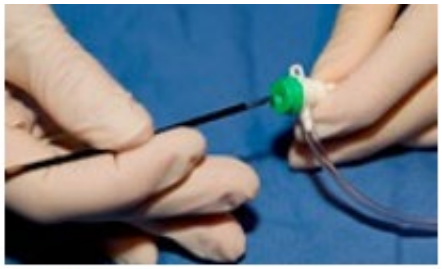
## STEP 1 PART A: Exchange Sheath for VASCADE and Achieve Temporary Haemostasis

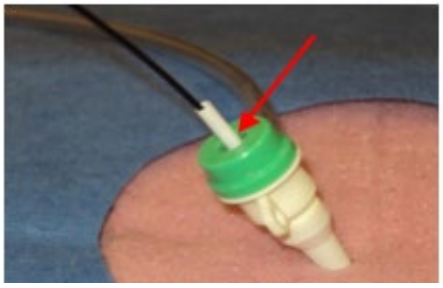
### Step 1.1: Dip Device Tip in Saline

Briefly dip the device tip in saline 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

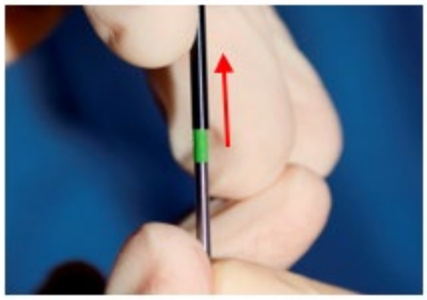


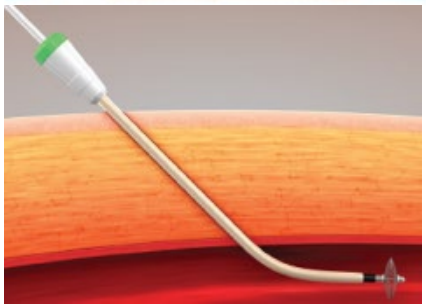


1. With the Disc collapsed, gently insert VASCADE into the introducer sheath hub until Lock is midway into the hub. Use short strokes to insert the device. About 0.5-inch (13 mm) of the Lock should remain exposed.
2. Verify that the Lock is NOT fully inserted into the sheath.

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

### Step 1.3: Deploy the Disc



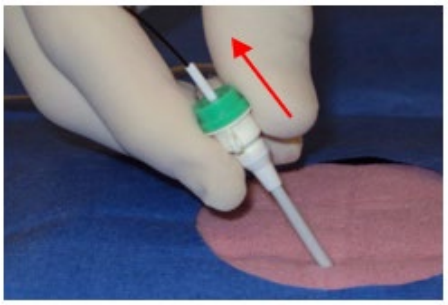


Deploy the Disc by firmly holding the Silver Handle and pulling back the Black Actuator until it locks in place.

**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

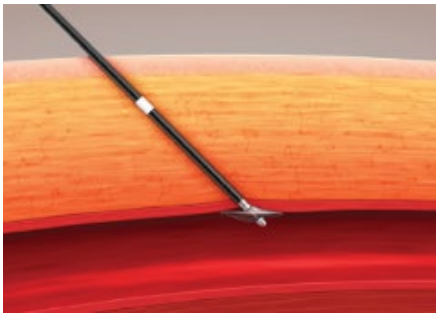


1. Gently remove sheath without applying any compression at the access site and without holding the VASCADE Catheter.
2. As the sheath slides over the VASCADE Catheter, grasp the Catheter close to the Lock as it exits the sheath.
3. Continue sliding the sheath over VASCADE and discard sheath.

⚠ **CAUTION**

Compressing the access site during removal of the sheath may hinder the Disc from tracking back to the vessel puncture site and cause Disc deformation. This may hinder achieving temporary haemostasis.

### Step 1.5: Achieve Temporary Haemostasis



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

In the case of a failed access site where manual compression is needed, refer to the Switching 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, switch to MC (below).

⚠ **WARNING**

DO NOT RELEASE the Collagen Patch if any part of the White Marker Stripe is showing (e.g. tissue tract is too short), 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 haemostasis 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: Switching to Manual Compression (MC)</u>**

**MC Assist**

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

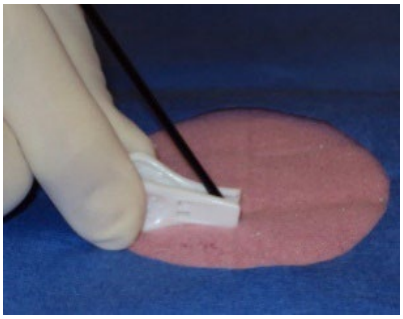
1. Apply the Clip (see Step 3.1) to the VASCADE Catheter to maintain temporary haemostasis.
2. Leave the device in place until the Activated Clotting Time (ACT) value normalises.
3. Collapse the Disc and remove VASCADE.
4. Achieve final haemostasis by applying MC per institutional protocol.

**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 Catheter



Continue to apply gentle tension by placing the Clip on 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 image guidance.

⚠ **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.

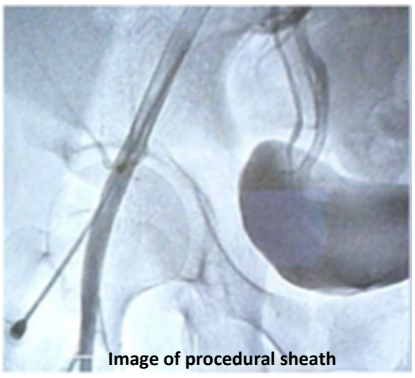


**Image of procedural sheath**

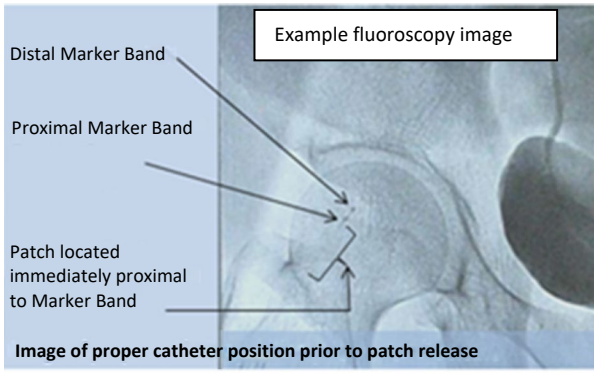
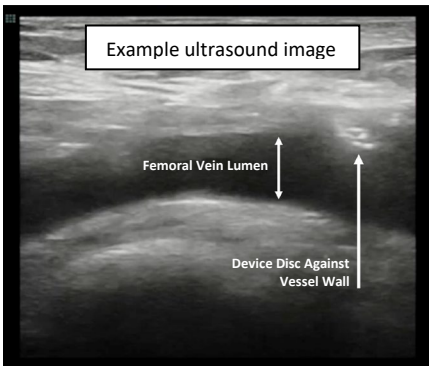
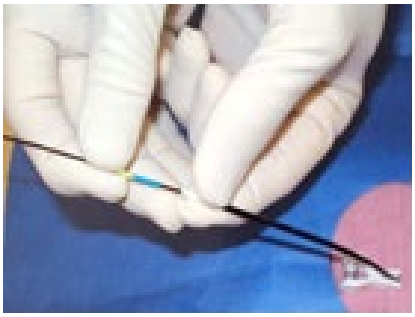



**Image of proper catheter position prior to patch release**

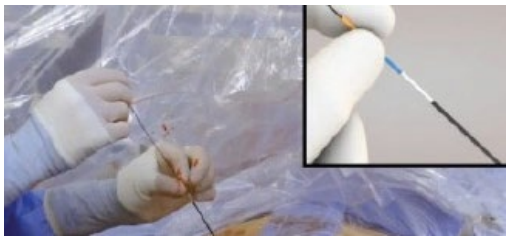


## STEP 2: Deploy Collagen

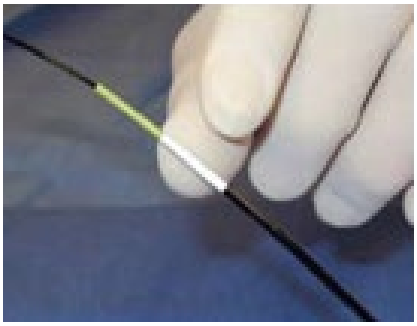
### Step 2.1: Unlock the Black Sleeve

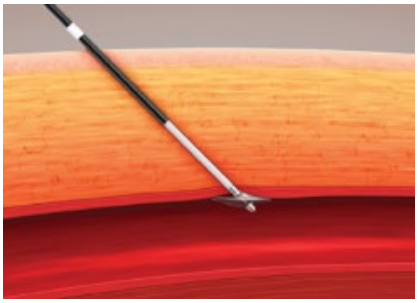


While continuing to apply gentle tension (through the Clip or by maintaining tension on the Black Actuator), slide the Key into the Lock. The blue segment should no longer be visible.



### Step 2.2: Retract the Black Sleeve to Expose the Collagen



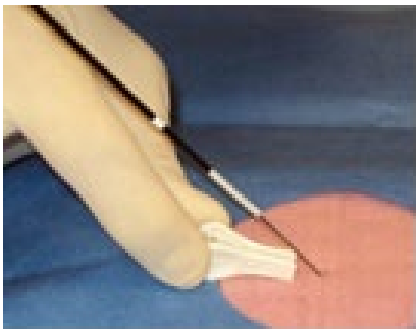


1. If the Clip is present, apply gentle upward tension on the Black Actuator and remove the Clip.
2. While continuing to apply gentle tension on the Black Actuator, grasp the Lock with the other hand, and apply gentle upward tension on the Lock toward the Silver Handle. The Black Sleeve will move freely after some initial resistance. A second resistance point may be felt after the sleeve is moved approximately 1.6 cm (0.6 in).
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)”).

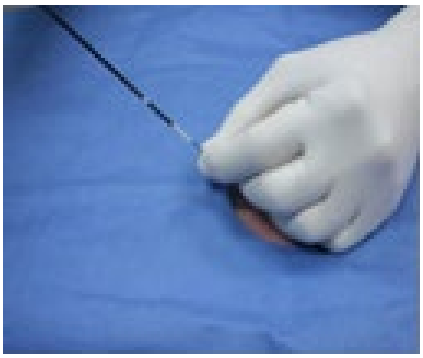
### Step 2.3: Wait for Collagen Hydration



1. Apply the Clip on the Catheter using minimal tension or apply gentle upward tension on the 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.

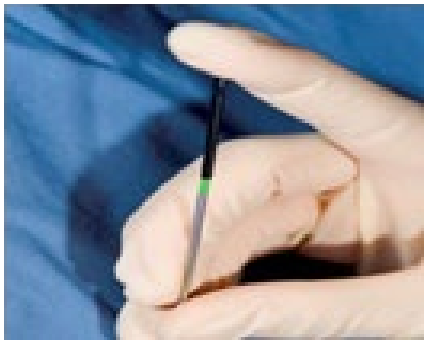
## STEP 3: Achieve Final Haemostasis

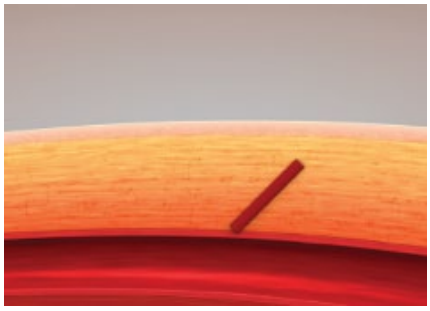
### Step 3.1: Prepare to Strip Collagen



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 the device to keep the Disc positioned against the vessel wall. Slide the Green Tube back and forth 2-3 times to ensure the release of the Collagen Patch. Leave the Green Tube in the forward position.
2. Relax tension on device and collapse the Disc (see below).
3. Apply compression to the vessel puncture site and remove the device.*
4. Apply compression until final haemostasis is confirmed.

Option 2: Move the Device while keeping the Green Tube Stationary (e.g., where the Green Tube is not sufficiently visible to easily move it, such as in 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 to the vessel puncture site and remove the device.*
5. Apply compression until final haemostasis 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. The Green Segment should not be visible.

### Step 3.3: Confirm Final Haemostasis

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

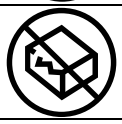
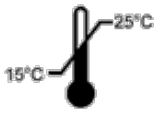
### Step 3.4: In Recovery and Discharge

1. Maintain bed rest and periodically check site per institutional protocol pre and post ambulation.
2. If tissue tract oozing is present, apply compression.
3. Give the patient the completed Patient Implant Card 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 waste.

## Graphic 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 / Authorised representative in the European Community | Authorised 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 / Sterilised by irradiation | Medical device that has been sterilised by irradiation. |
|   | ISO 15223-1 | 5.2.6 / Do not re-sterilise | Medical device that is not to be re-sterilised. |
|  | ISO 15223-1 | 5.2.8 / Do not use if packaging is damaged | Medical device that should not be used if the packaging 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 / Read instructions for use or 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. |

| 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.<br><br>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 information to be supplied by the manufacturer.
**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 expiry date. Cardiva Medical, Inc. will not be liable for any incidental, special or consequential loss, damage or expense directly or indirectly derived 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).