CardioVascular Learning Network | CME

Unlocking Clinical and Economic Value Through VCD-Based Workflow Optimization in Hospitals and ASCs

Faculty

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Faculty Disclosures

- **Craig Walker, MD**: Stockholder—Euphrates Medical, Efemoral Medical, MicroMedical, Peytant Solutions, Inc.
- **Benjamin Jenny, MD, MBA, FACC**: Advisory Board—Haemonetics Corporation, Biosense Webster
- **Hafez Golzarian, DO, MBA** has disclosed no relevant financial relationship with any ineligible company (commercial interest)

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Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from Haemonetics Corporation

Learning Objectives

- Analyze case-based scenarios highlighting clinical and operational benefits of VCDs
- Evaluate the impact of VCDs on institutional efficiency and resource utilization
- Integrate evidence-based and case-based insights into clinical decision-making

VCD = vascular closure device.

The Basic Economics of Vascular Closure

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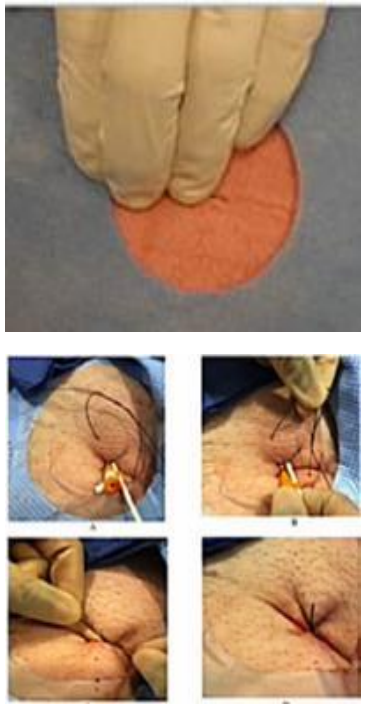
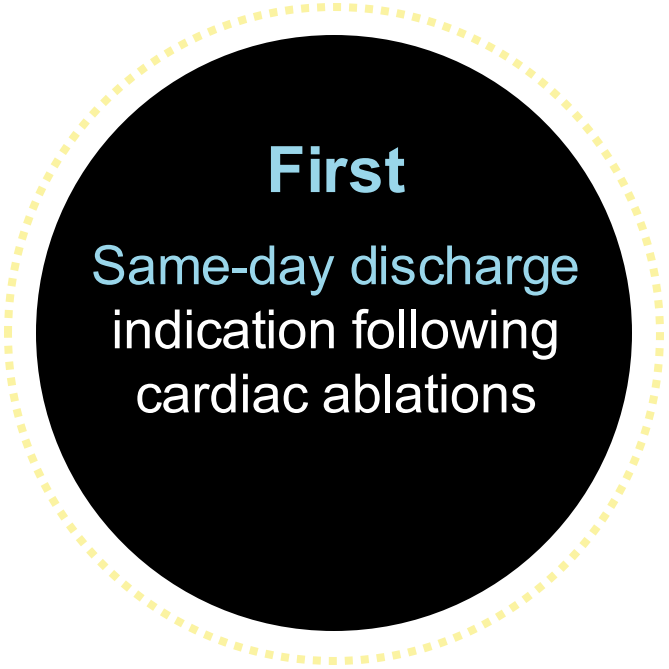
Perspective on Venous Vascular Closure

- Cardiac ablation closure has some unique needs compared to other technologies
- Ablation creates multiple access sites in close proximity, in the same veins
- Manual compression has been the standard of care, but requires long bed rest (6 hours) and can cause patient discomfort and the use of pain meds
- Figure-of-eight stitch has not been well-studied in large, multicenter prospective, randomized clinical trials for ablation
  - It can be painful for patients and requires removal of stitches post-operatively
- Suture-mediated closure (SMC) systems can be complex to use, and lack clinical trial evidence in multicenter, prospective, randomized trials in cardiac ablation
- Recent SMC research correspondence published in *JACC EP* reported complication rates compared to manual compression
  - At discharge, SMC had 3.8% major complication rate compared to 0% for manual compression (*P*=.243)



Kiani S, et al. *JACC Clin Electrophysiol*. 2022;8(6):803-805.

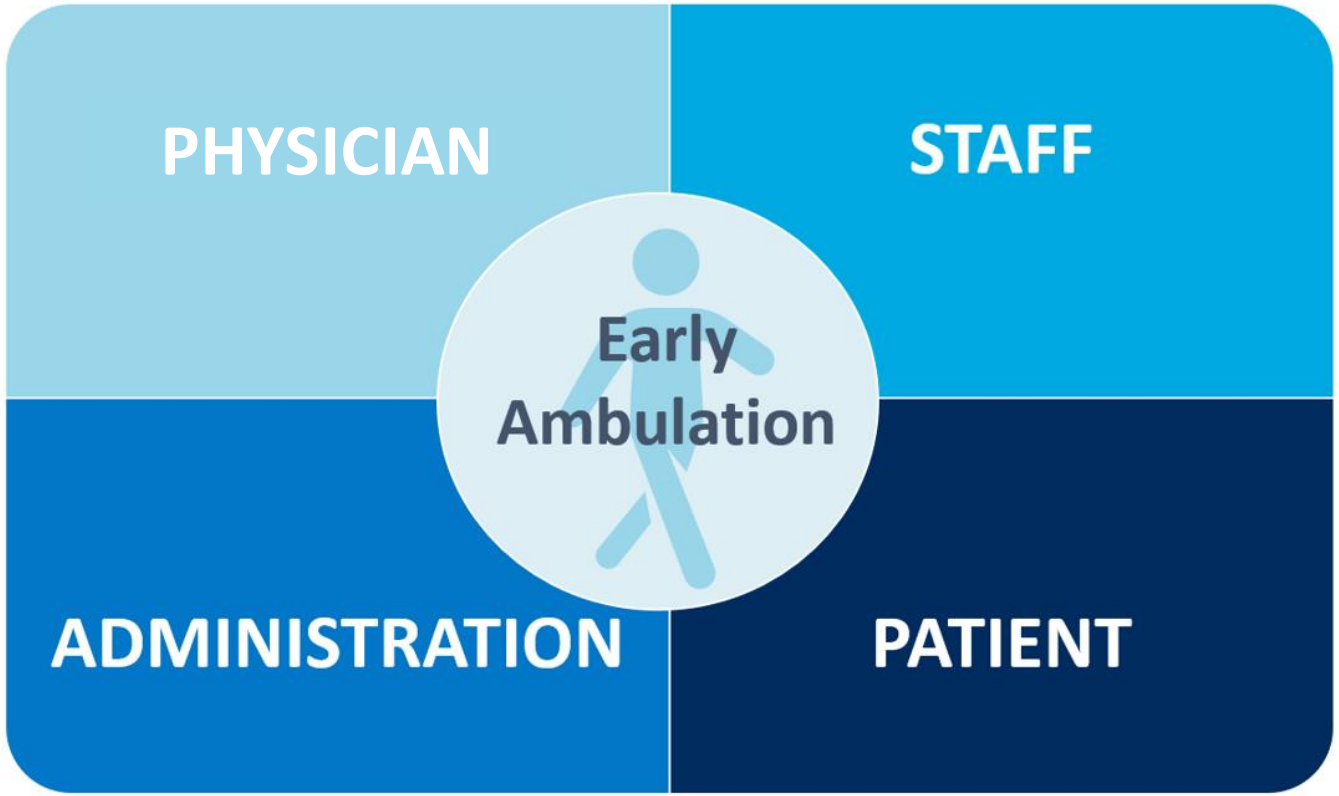
Leading Innovations in EP Vascular Closure



EP = electrophysiology.
Food and Drug Administration (FDA). Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf; pdf4/p040044c.pdf; pdf/P960043S097D.pdf.

Impact of Early Ambulation using Percutaneous Vascular Closure System

Enables all stakeholders to accomplish their goals and objectives



Early Ambulation Potential Goals and Objectives

- Same-day discharge
- Patient satisfaction
- Reduce opioids
- No/low foley and UTI
- Additional cases
- No/low protamine
- Greater throughput
- Manage limited bed space
- Faster lab turnover
- Lower overall costs
- Address staff shortages

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol.* 2021;32(2):191-199.

Percutaneous Vascular Closure System: Technical Overview

Extravascular Design

- No permanent or intraluminal implants

Simple and Easy to Use

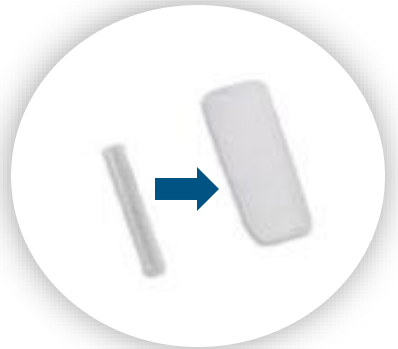
- Single operator
- No sutures, no materials left in the vessel

2 Mechanisms of Action

- Mechanical
- Physiological

Bioabsorbable and Thrombogenic Collagen Plug

- Expands to fill tissue tract



~13X

- Expansion of collagen patch

- Simple deployment
- Multiple site closure
- Allows for re-access*, for repeat ablation procedures
- Workflow enhancements and quicker time to ambulation compared to manual compression

***After 30 days.**

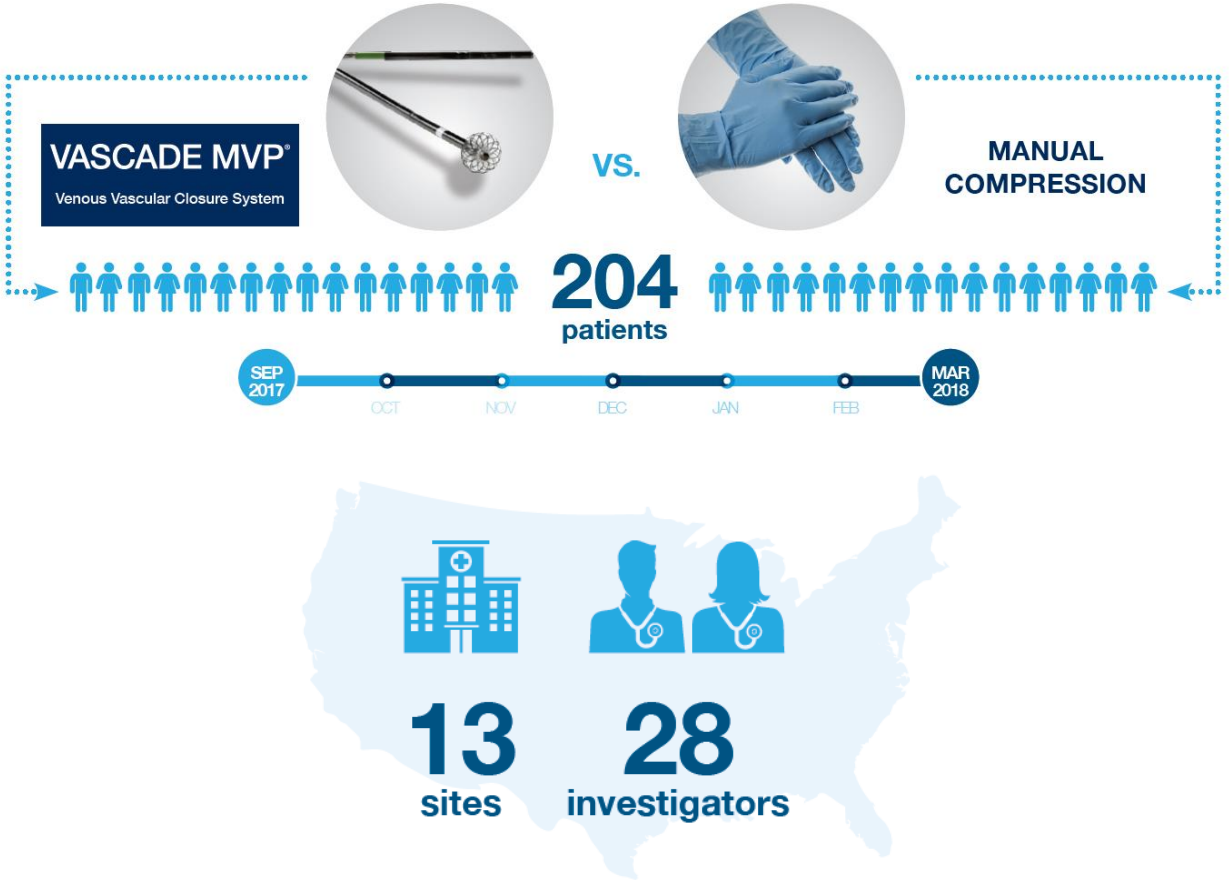
Food and Drug Administration (FDA). Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf.

AMBULATE Pivotal Trial

Prospective, Multicenter, Randomized 1:1 Clinical Trial

Study Overview

- **Randomized clinical trial** – 204 patients, 13 sites, 28 physicians, randomized 1:1 against manual compression
- **Primary endpoints** – time to ambulation, major access site complications
- **Secondary endpoints** – time to hemostasis, total post-procedure time, time to discharge eligibility, time to discharge, time to closure eligibility, procedure success, device success, minor access site complications
- **Additional data** – patient satisfaction, pain meds



Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

AMBULATE Pivotal Trial

Safety and Efficacy Endpoint Definitions

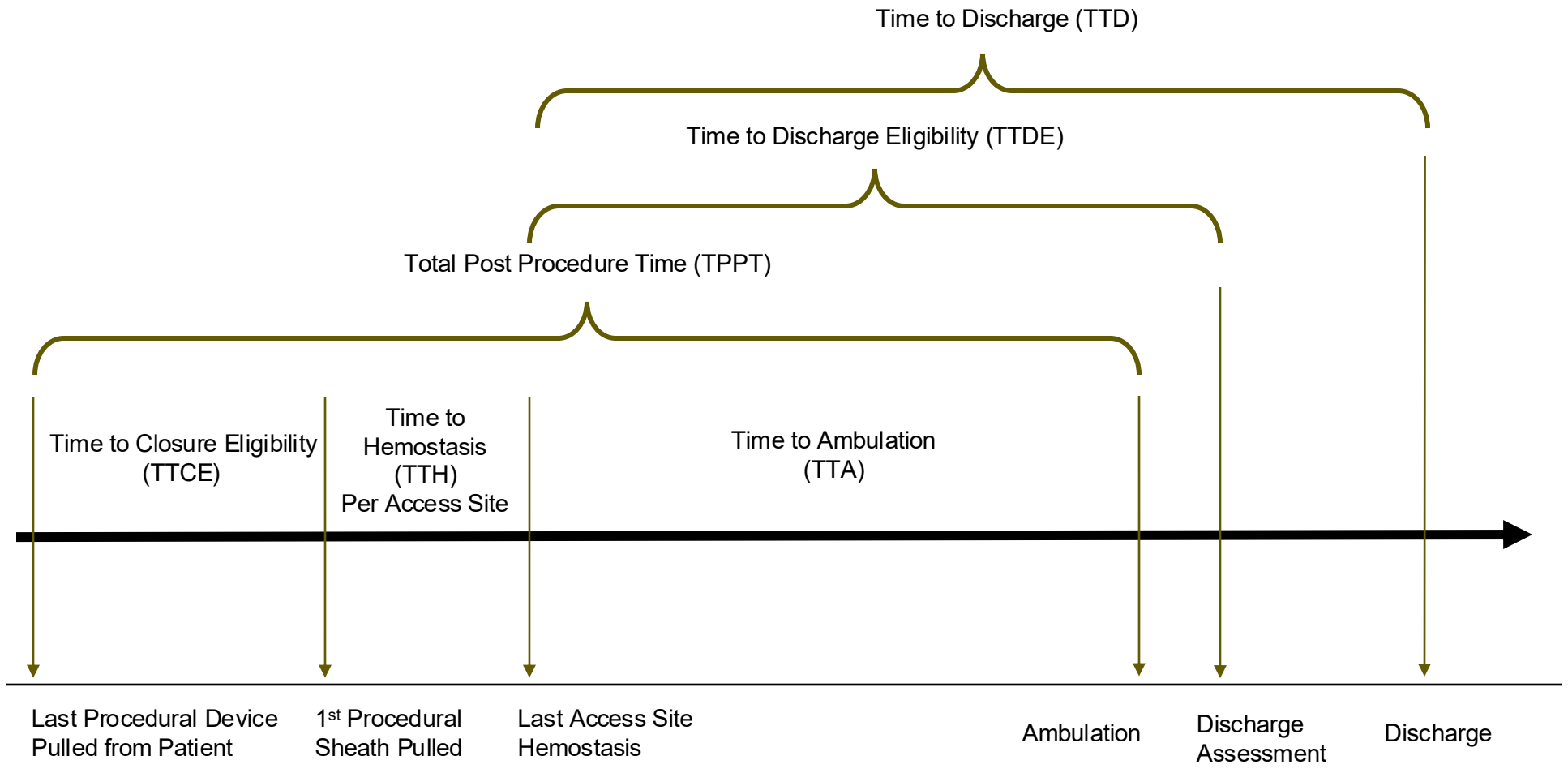
- **Major Complications**: Access site-related bleeding requiring transfusion, vascular injury requiring surgical repair, etc.
- **Minor Complications**: Access site-related bleeding requiring >30 min of continuous manual compression, site hematoma >6 cm, etc.
- **Time to Closure Eligibility**: Time between removal of last procedural device and removal of MVP or sheath
- **Time to Hemostasis**: Time between removal of MVP or sheath and first observed/ confirmed venous hemostasis
- **Total Post-Procedure Time**: Time between removal of last procedural device and when patient can ambulate
- **Time to Discharge Eligibility**: Time between removal of MVP or sheath and when subject is available for discharge based on access site
- **Time to Ambulation**: Time between removal of last MVP or sheath and when patient stands and walks 20 feet without re-bleeding

MVP = micro vascular plug.

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

AMBULATE Pivotal Trial

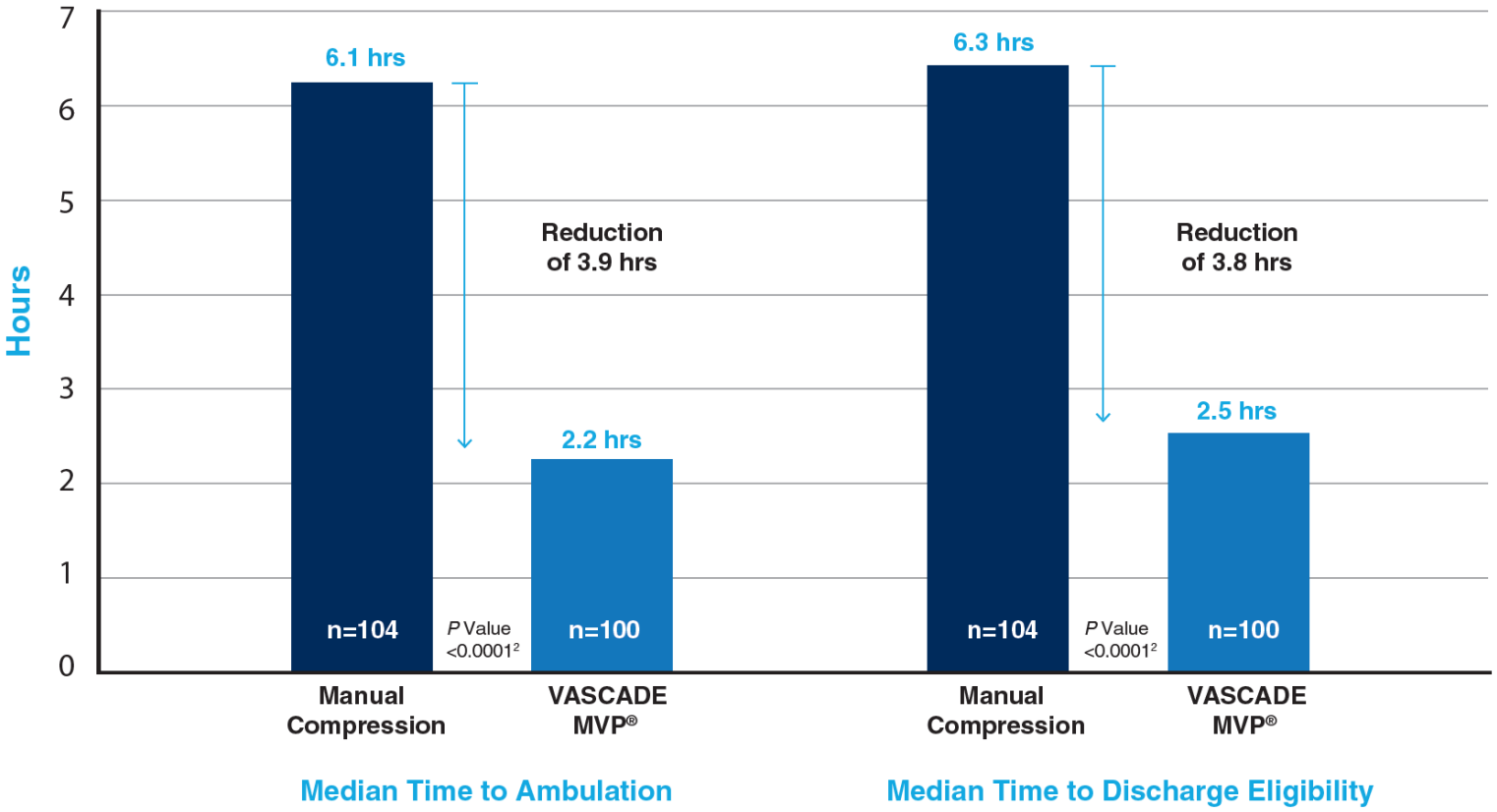
Endpoint Definitions



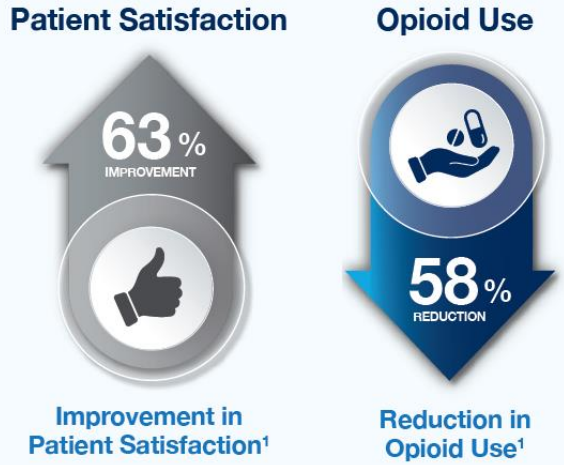
Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

AMBULATE Pivotal Trial

Percutaneous Venous Vascular Closure System vs Manual Compression



SAFETY ENDPOINT	VASCADE MVP® n=199 limbs	Manual Compression n=209 limbs	*P* Value
Major complications [4]	0%	0%	–
Minor complications [5]	1.0%	2.4%	0.45[3]



[1]Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied; [2]Nominal p-value by 2-sided Fisher's exact test, both by limb and by patient; [3]P-value by 2-sided Fisher's exact test; [4]Major venous access site closure-related complications through the follow-up period; [5]For venous access site closure-related complications through 15-day follow-up or standard of care follow-up, and for procedure-related complications the next day.

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

AMBULATE Pivotal Trial

Summary of Endpoint Analysis – Venous Vascular Closure System

	VASCASE MVP® n=100 patients	Manual Compression n=104 patients	*P* Value
Median Time to Ambulation (TTA)	2.2 hours	6.1 hours	<0.0001†
Median Time to Discharge Eligibility (TTDE)	2.5 hours	6.3 hours	<0.0001†
	VASCASE MVP® n=199 limbs	**Manual Compression n=209 limbs**	***P* Value**
Major Complication Rate§	0%	0%	-
Minor Complication Rate‖	1.0%	2.4%	.45‡
	VASCASE MVP® n=100 patients	**Manual Compression n=104 patients**	**Nominal *P* Value**
Patient Bed Rest Duration Satisfaction*	8.3±2.4	5.1±3.4	<0.0001‡
63% increase in patient satisfaction with bed rest duration with VASCASE MVP®			
	VASCASE MVP® n=100 patients	**Manual Compression n=104 patients**	**Nominal *P* Value**
Opioid Use – Yes	15 (15%)	37 (36%)	0.001
58% reduction in opioid use with VASCADE MVP®			

*Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied; †P-values from 2-sided Wilcoxon rank-sum test for medians, unadjusted for stratification factor; ‡P-value by 2-sided Fisher's exact test; §Major venous access site closure-related complications through the follow-up period; ‖For venous access site closure-related complications through 15-day follow-up or standard of care follow-up, and for procedure-related complications the next day.

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124.

MYNX CONTROL® Vascular Closure System

Safety and Efficacy of a Novel Sealant-Based Vascular Closure Device Following Electrophysiology Procedures: ReliaSeal Trial

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Funding: This study was funded by Cordis.

Keywords: atrial fibrillation | catheter ablation | duplex ultrasound | early ambulation | vascular closure device | venous closure

Summers J, et al. *J Cardiovasc Electrophysiol*. 2025;36(5):1022-1031.

ReliaSeal Trial – Primary Endpoints

Primary Effectiveness

- Time to Ambulation (TTA)
- Time to Hemostasis (TTH)

Primary Safety

- Rate of CEC adjudicated combined **major** venous access site closure-related complications through 30 days post-procedure, attributed directly to VCD or manual compression without other likely cause

CEC = clinical event committee.

Summers J, et al. *J Cardiovasc Electrophysiol*. 2025;36(5):1022-1031.

ReliaSeal Trial Primary Endpoints: Results

Endpoints		MYNX Control®	Manual Compression
Effectiveness	Time to Ambulation (hrs) (mean ± SD)	2.6 ± 1.03	5.1 ± 4.35
	Time to Hemostasis (mins) (mean ± SD)	2.1 ± 1.79	11.4 ± 7.19
Safety	Major complications of the target access site within 30 days	0.0%	0.8%

- TTA for participants using the MYNX CONTROL® VENOUS VCD was **significantly less** than for those where MC was used
- TTH for the MYNX group was assessed on an access site level and was determined to be significantly less than MC group
- The primary safety endpoint was met and demonstrated a >5% noninferiority window

Summers J, et al. *J Cardiovasc Electrophysiol*. 2025;36(5):1022-1031.

AMBULATE IMPACT Study

Impact on Patient Workflow Efficiencies

Literature Search Results: Workflow-Related Costs

Category	Parameter	Unit of Estimate	Estimate	Source
EP Lab Costs	Non-MD Staff labor	Nursing cost per hour	$69	Sekhar, 2017
	Anesthesiology	Cost per hour	$260	Hogan, 2010
	Lab room cost	Lab cost per hour*	$210	Sekhar, 2017
Overnight Stay Cost	Overnight stay- General room	Cost of overnight stay	$2,116	Kaiser Family Foundation

Additional Costs Not Quantified Above

Opportunity cost of potential additional procedures and patient admissions that could be possible with faster throughput in the lab, recovery, and general unit.

***Cost measured as cath lab holding cost per hour per patient; **Cost of patients with routine postoperative care in outpatient setting. Includes labor and non-labor costs.**

Sekhar A, et al. *ICJ Heart Vasc*. 2016;13:6-13. Hogan PF, et al. *Nurs Econ*. 2010;28(3):159-169. Kaiser Family Foundation. Accessed October 22, 2025. https://www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day.

AMBULATE IMPACT – Economic Study

Objective

- Characterize potential economic impact of early ambulation post-ablation

Methods

- Workflow analysis at 2 electrophysiology sites
  - Valley Health, Ridgewood, NJ
  - Texas Cardiac Arrhythmia, Austin, TX
- Economic analysis conducted via national Medicare database and literature review

Third Party Analysis

- Precision Health Economics

Workflow Savings Categories

- ✓ Shorter EP Lab time
- ✓ Clinical events – UTI, others
- ✓ Less resource utilization
- ✓ Shorter length of stay

Potential Average per Patient Savings
(vs manual compression, custom account value calculator)

$1200 – $2300

Savings Not Included

- Potential for added procedures
- Patient satisfaction benefits

UTI = urinary tract infection.

AMBULATE IMPACT – Venous Vascular Closure System Objectives

Quantification of Potential Cost Savings at Patient Level

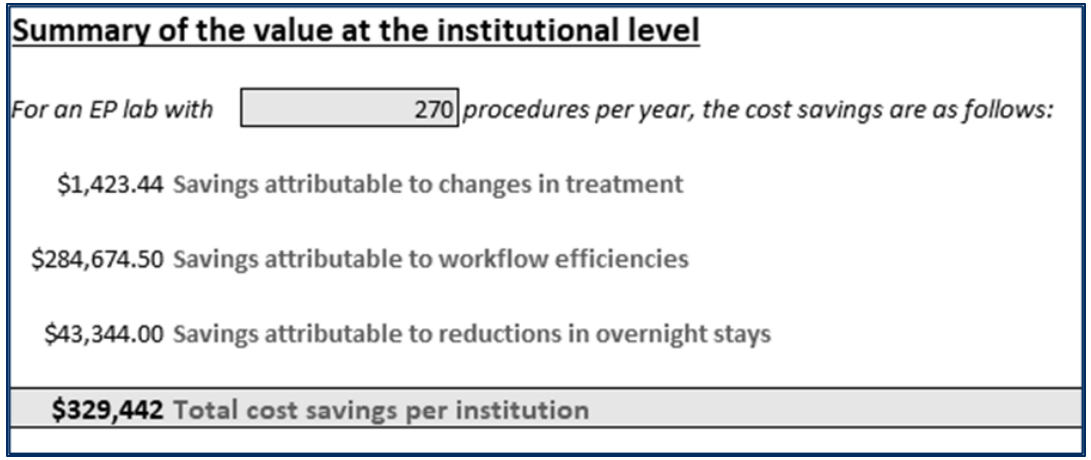
Summary of the value at the patient level	
$5.27	Savings attributable to changes in treatment
$1,054.35	Savings attributable to workflow efficiencies
$160.53	Savings attributable to reductions in overnight stays
$1,220	Total cost savings per patient

Reducing Time to Hemostasis (TTH) and Time to Ambulation (TTA) may result in three areas of savings

1. Changes in treatment by reducing the cardiac ablation procedure time, there may be less need for certain components of care (eg, urinary catheters and associated UTI infections)
2. Workflow efficiencies by reducing procedure time, staff may be freed up to support patient-related and other lab duties
3. Overnight stays by reducing the procedure time and TTA, some patients may be able to go home on the same day as the procedure, thereby reducing the need for an overnight stay

AMBULATE IMPACT – Venous Vascular Closure System Objectives

Quantification of Potential Cost Savings at Institutional Level



Summary of the value at the institutional level

For an EP lab with 270 *procedures per year, the cost savings are as follows:*

$1,423.44	Savings attributable to changes in treatment
$284,674.50	Savings attributable to workflow efficiencies
$43,344.00	Savings attributable to reductions in overnight stays
$329,442	Total cost savings per institution

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1. Changes in treatment by reducing the cardiac ablation procedure time, there may be less need for certain components of care (eg, urinary catheters and associated UTI infections)
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Closing Thoughts

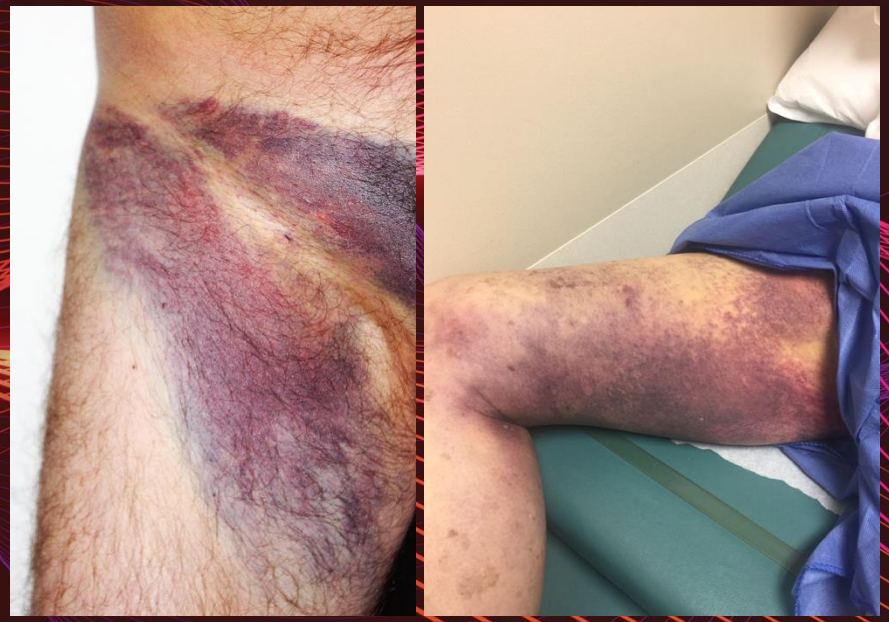
Venous Vascular Closure Devices

- Provide a superior solution to manual compression
- Allow hospital facilities and physicians to maximize productivity while minimizing costs
- Expand the cases that can be performed in the growing ASC environment

ASC = ambulatory surgery center.

CardioVascular Learning Network | CME

Vascular Closure Devices in the ASC Setting



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Implications of Access Site Complications

- Usually associated with **pain and patient dissatisfaction**
- Usually requires **stopping anticoagulation prematurely**
- May require **hospitalization and transfusion**
- Are associated with **vagal syndromes and hypotension**
- Are associated with **lower long-term patency**
- Dramatically **increase costs**
- Have been associated with **increased mortality**
- Time and personnel intensive
- Are one of the most common causes of **malpractice suits**

O'Donnell TFX, et al. *J Vasc Surg*. 2021;73(4):1253-1260. Smeds MR, et al. UpToDate. Published April 29, 2024. Accessed October 21, 2025. https://www.uptodate.com/contents/access-related-complications-of-percutaneous-access-for-diagnostic-or-interventional-procedures.

Vascular Closure Devices Have Been Designed to Decrease Access Complications and Speed Up Time-to-Discharge

- All vascular closure devices are designed for single-wall sticks
- Vascular closure devices have associated complications, particularly in small diseased vessels **(choose carefully)**
- There is a **learning curve** with vascular closure tools
- Certain vascular devices work better in special applications
- There is a cost to vascular closure devices that varies

O'Donnell TFX, et al. *J Vasc Surg*. 2021;73(4):1253-1260. Smeds MR, et al. UpToDate. Published April 29, 2024. Accessed October 21, 2025. https://www.uptodate.com/contents/access-related-complications-of-percutaneous-access-for-diagnostic-or-interventional-procedures.

Economics of VCD in ASC Setting

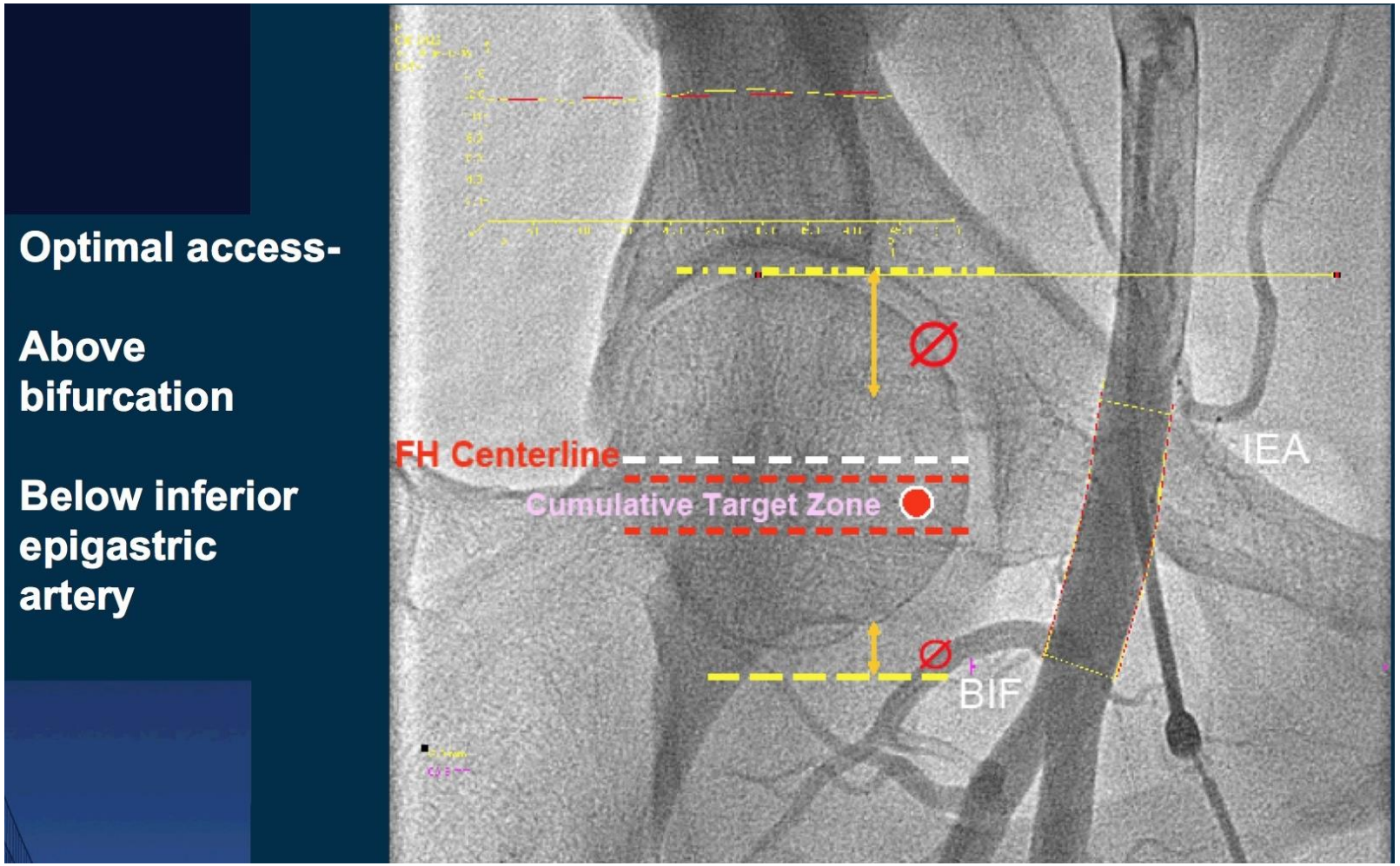
- **ASCs receive much less payment for treatments than hospitals**
  - Patients pay less
  - The survival of ASCs requires cost control
- There is a **significant cost** to every minute in an ASC
  - Personnel cost (time)
  - Opportunity cost if dealing with active bleeding
  - Potential need for transfer or use of covered stent if bleeding occurs
- VCDs can reduce bleeding complications but have an **initial cost**
  - Many ASCs will not use closure tools because of initial cost, but I believe these are outweighed by the cost associated with bleeding complications
- Uncomplicated procedures result in **happy patients** and more referrals from them

Pang N, et al. *Cardiovasc Ther*. 2022;2022:8569188.

Mechanism of Closure Devices

- **Active Approximation**: AngioSeal, PerClose, QuickClose, StarClose, Celt
- **Passive Closure (extravascular)**: Duett, Exoseal, Mynx, VasoSeal
- **Facilitated Manual Compression**: Vascade
- **Patch-D-Stat**: Neptune, Syvek, etc.

Arterial Puncture Site and Technique Is Crucial, Particularly in Femoral Artery Access

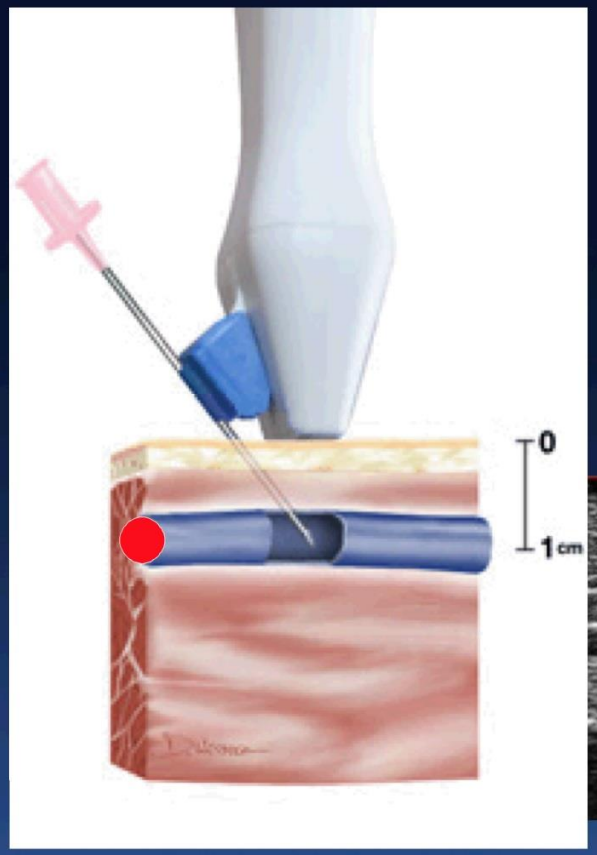


IEA = inferior epigastric artery; FH = femoral head; BIF = bifurcation.

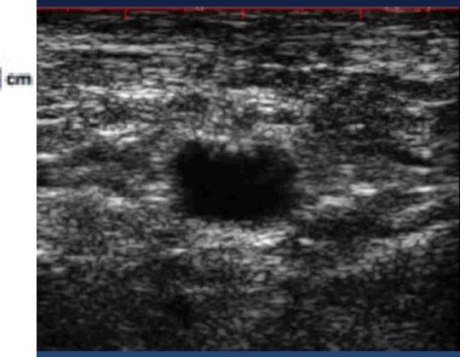
Access Assistance

Ultrasound Guided Femoral Artery Access

Site-Rite5, Bard Access, Inc.
18g needle guide #9001C0212



Better resolution, and depth than possible previously



Artery Access in Any Vessel

- Front wall stick desirable-micropuncture desirable
- Pulsatile flow before advancing wire
- Wire exits needle without resistance – don’t push
- Gain familiarity with wires
- Don’t be afraid to ask for help

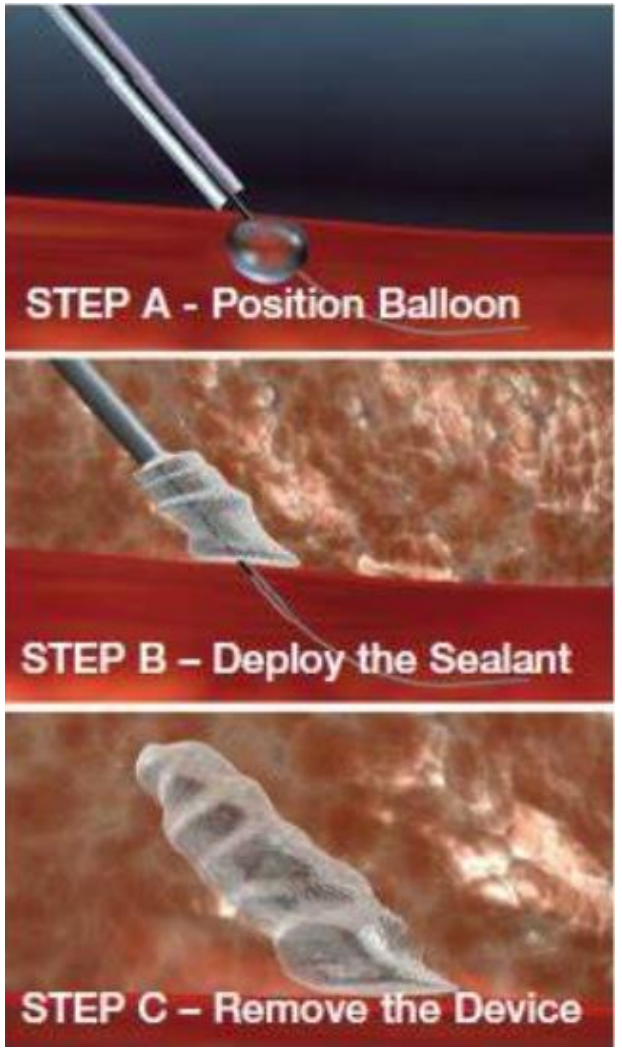
Bleeding Risk from Low to High in Arteries

- Radial artery access **(low bleeding risk)**
- Retrograde femoral artery access **(moderate bleeding risk)**
- Antegrade femoral artery access **(high bleeding risk)**
- Brachial artery access **(very high bleeding risk)**

- Larger French sheaths are always more likely to result in bleeding
- Higher level of anticoagulation results in more bleeding
- Localized atherosclerosis at puncture site – more bleeding and occlusion of vessel
  - In the ASC, most of my cases have advanced vascular disease

MYNX CONTROL™

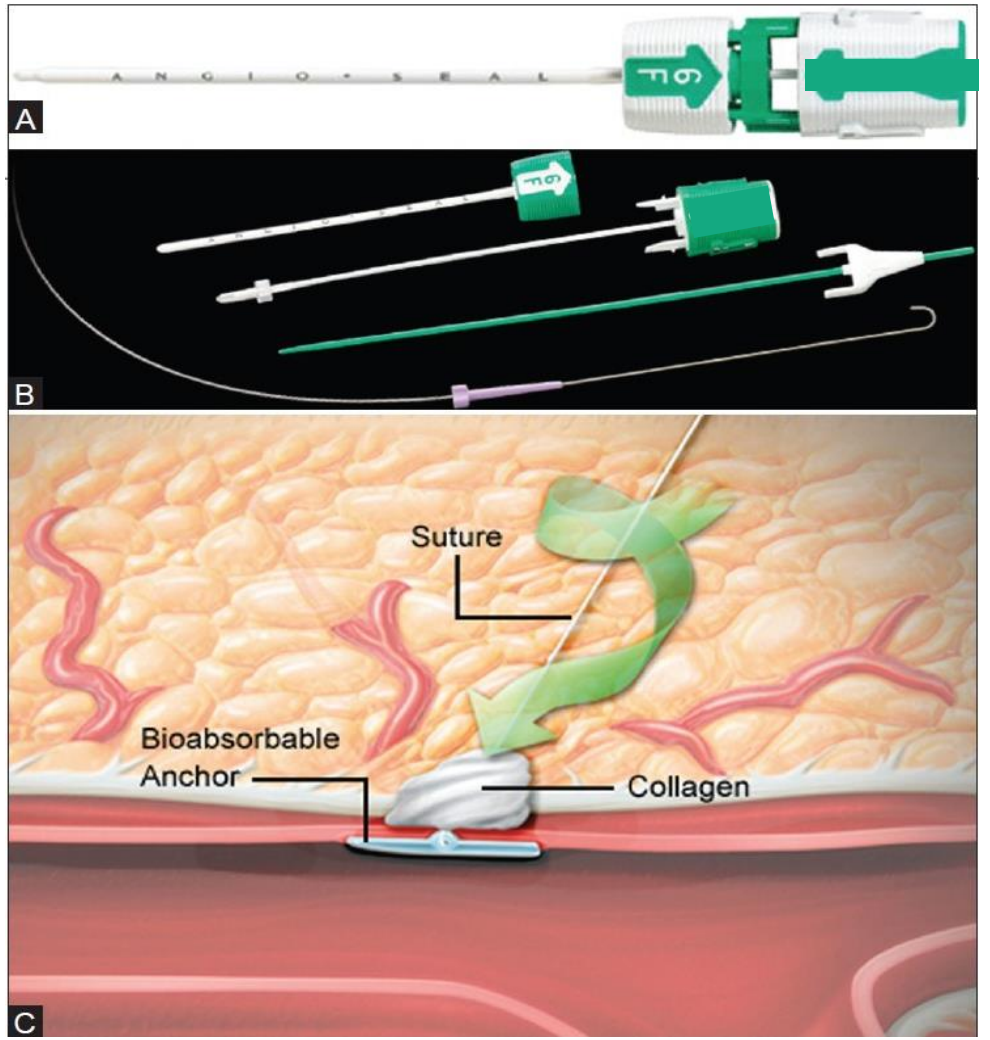
- After insertion, the 6 mm semi-compliant balloon is inflated and pulled back to the arteriotomy, creating temporary hemostasis
- The sealant is delivered and compressed a fixed distance onto the extravascular arteriotomy site, where it interlocks with the surface of the vessel wall and expands to fill the tissue tract
- The balloon is deflated, and the device is removed



FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf4/p040044c.pdf.

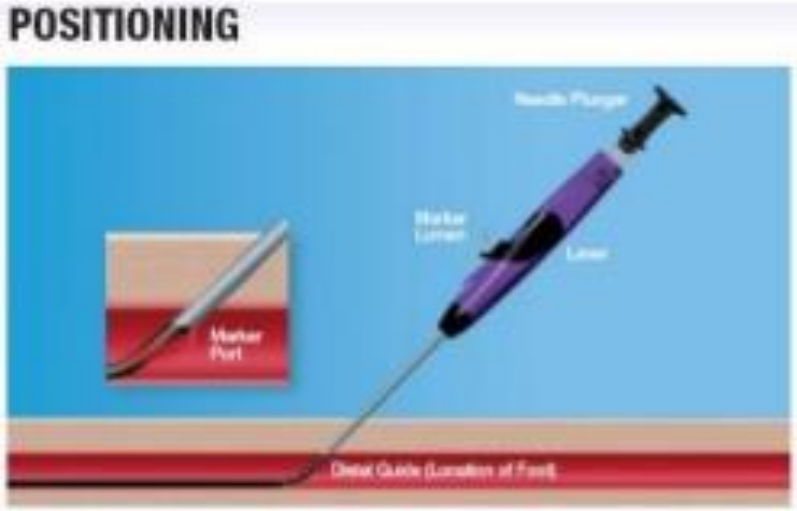
ANGIO-SEAL®

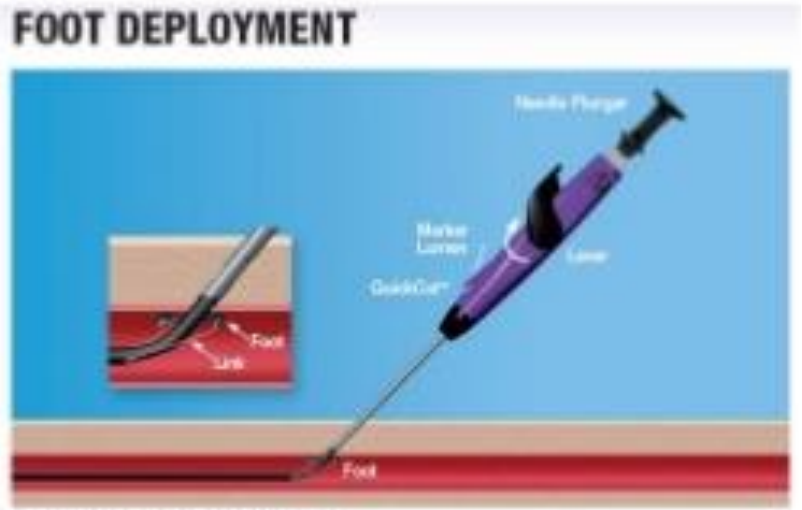
- Exchange the procedure sheath with the Angio-Seal locator system
- Blood flow through the locator visually confirms proper sheath position in the artery
- Insert the Angio-Seal device into the sheath until you hear a “click”
- Gently pull back on the locking cap until you hear another “click”
- The anchor is now locked in place and device is ready to be deployed
- Gently pull back on the Angio-Seal device until the suture has stopped spooling
- Maintain upward tension on the device and gently advance the compaction tube until resistance is felt
- Cut the suture and remove the device

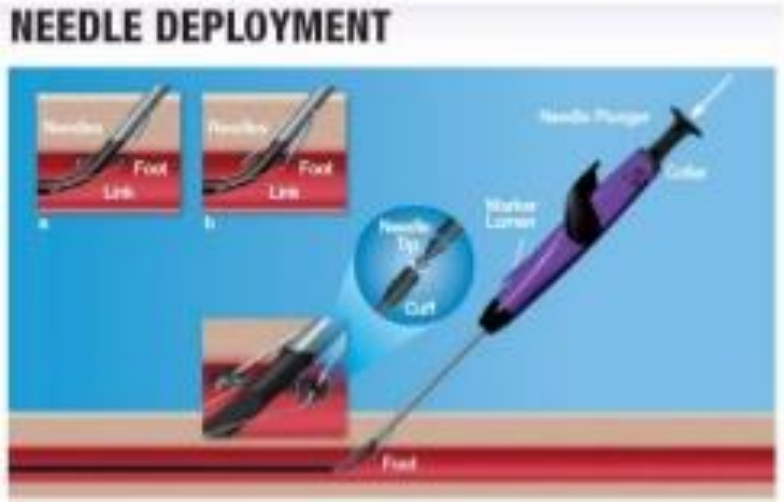


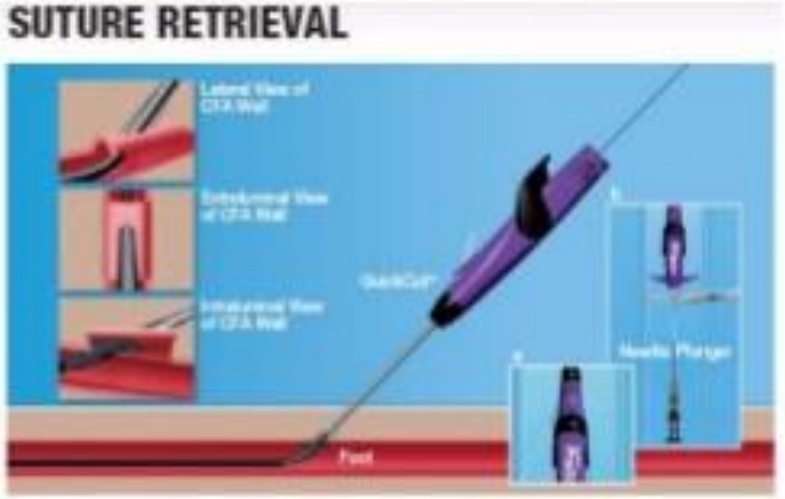
FDA. Accessed October 21, 2025. www.accessdata.fda.gov/cdrh_docs/pdf/p930038.pdf. Modi S, et al. *Indian J Radoil Imaging*. 2013;23(2):134-138.

Perclose ProGlide® Device

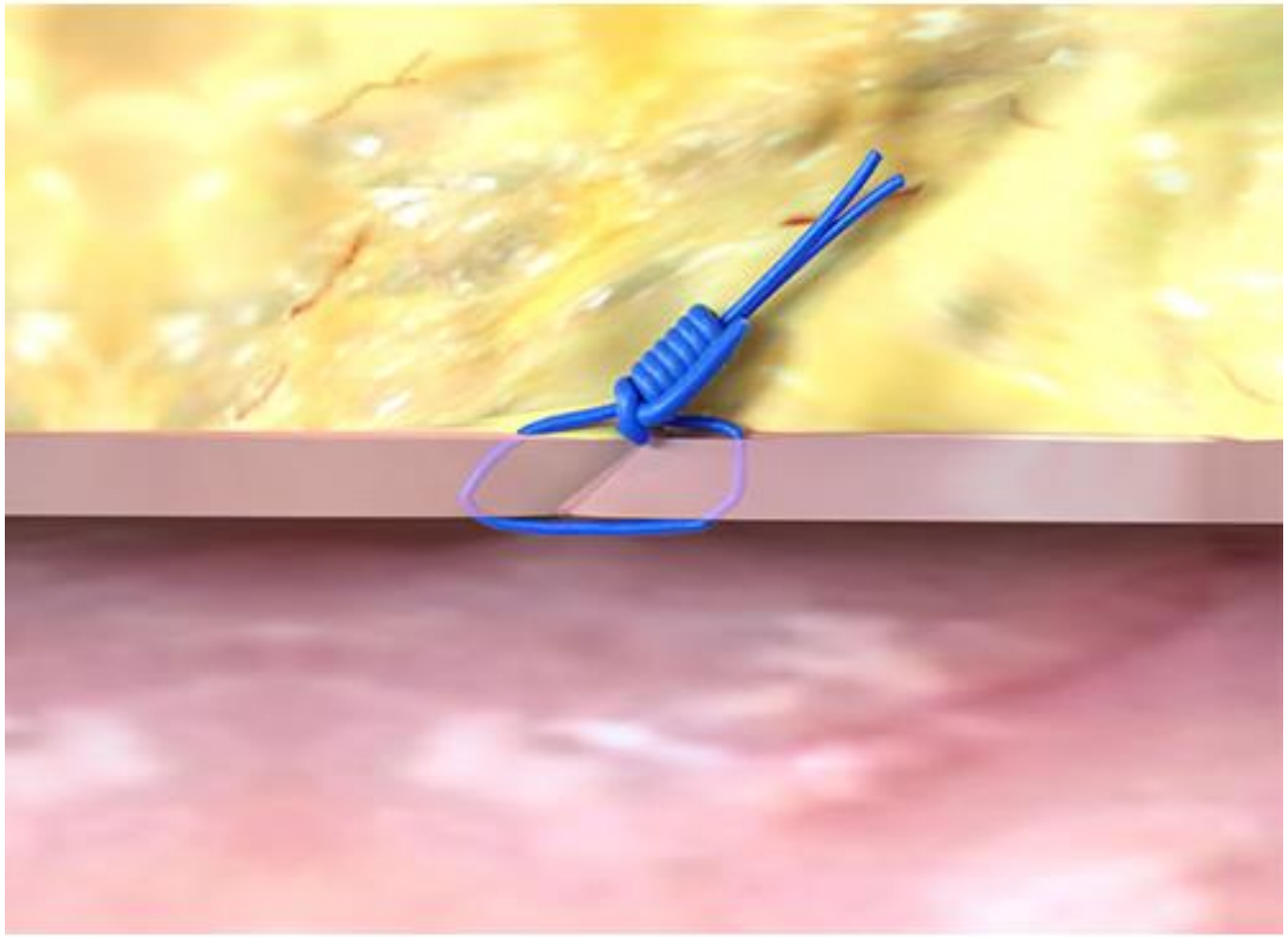






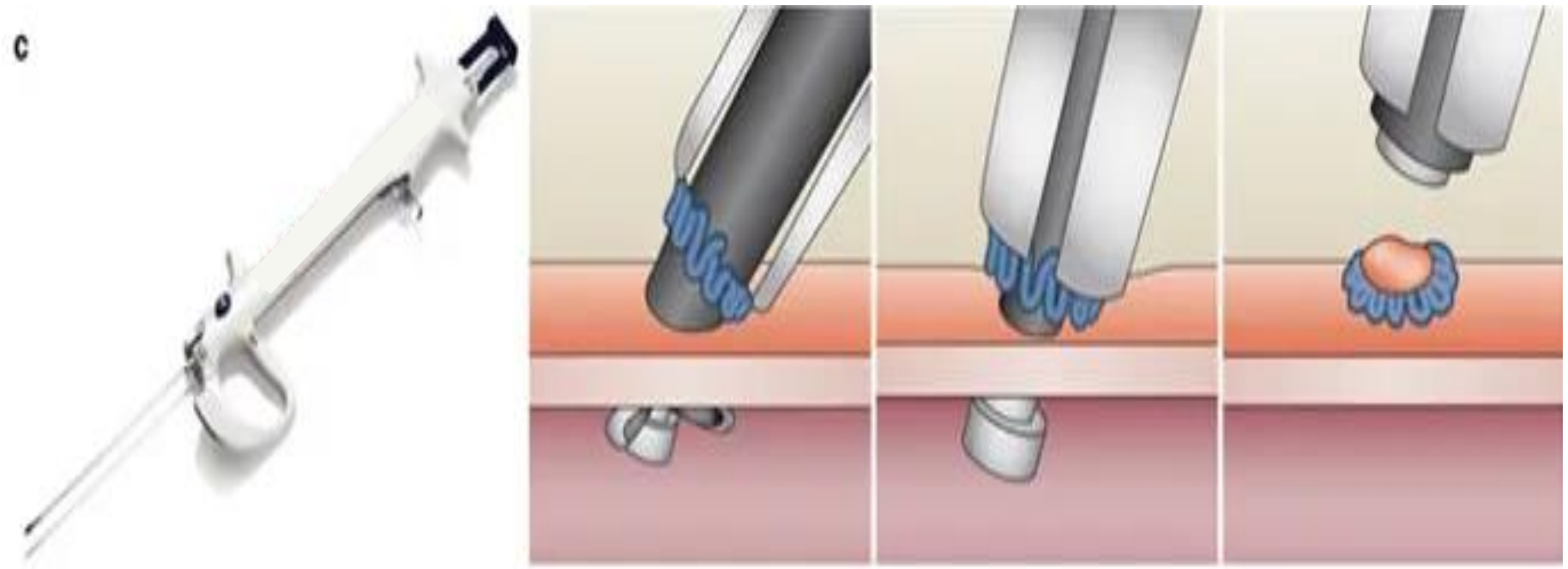


FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf/P960043S097D.pdf. Murphy K, et al. Interventional Neuroradiology. Techniques in Interventional Radiology. Springer, London; 2014.



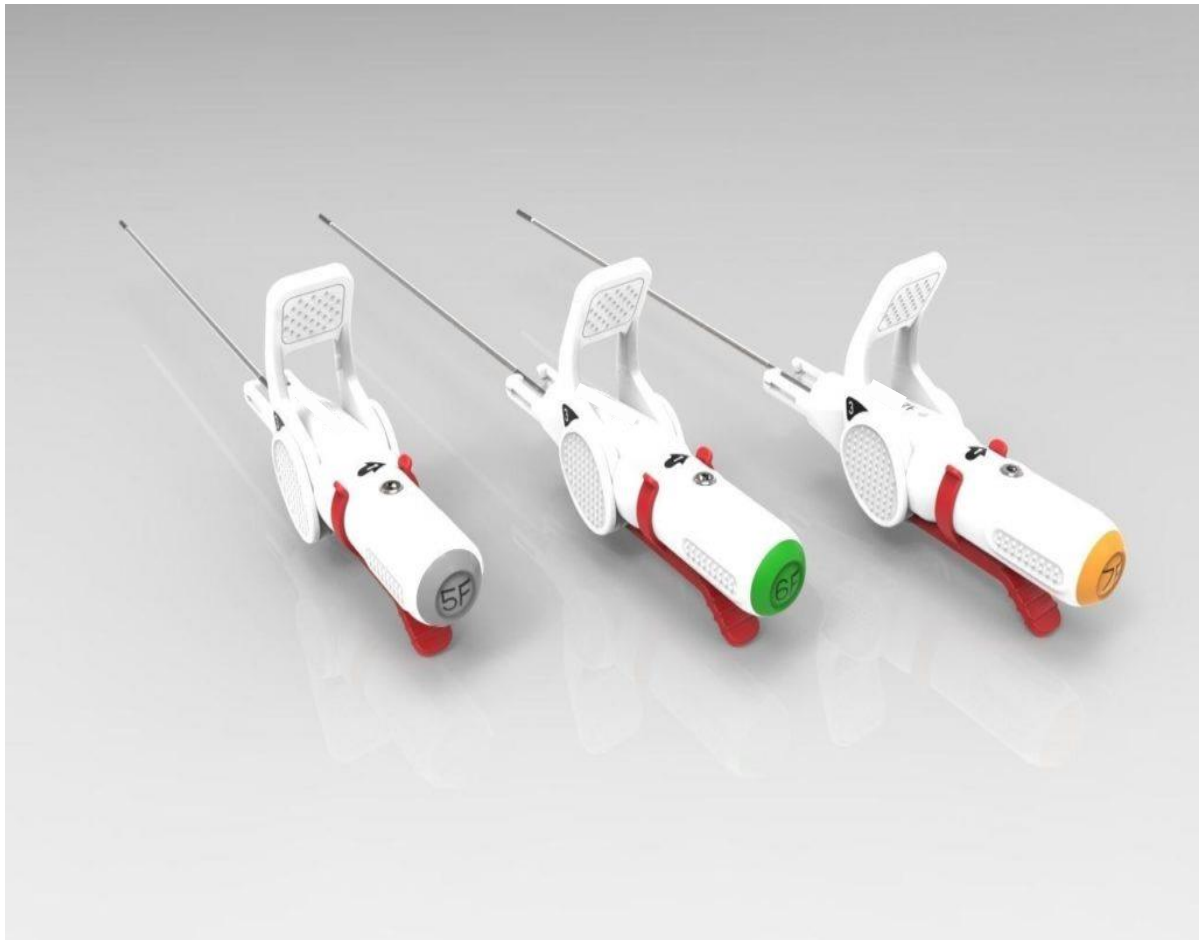
Courtesy of vascular.abbott.com.

STARCLOSE™



FDA. Accessed October 21, 2025. www.accessdata.fda.gov/cdrh_docs/pdf5/p050007c.pdf. Roy S, et al. *Min Invasive Ther Allied Tech*. 2013;23(1):32-39.

Celt ACD®

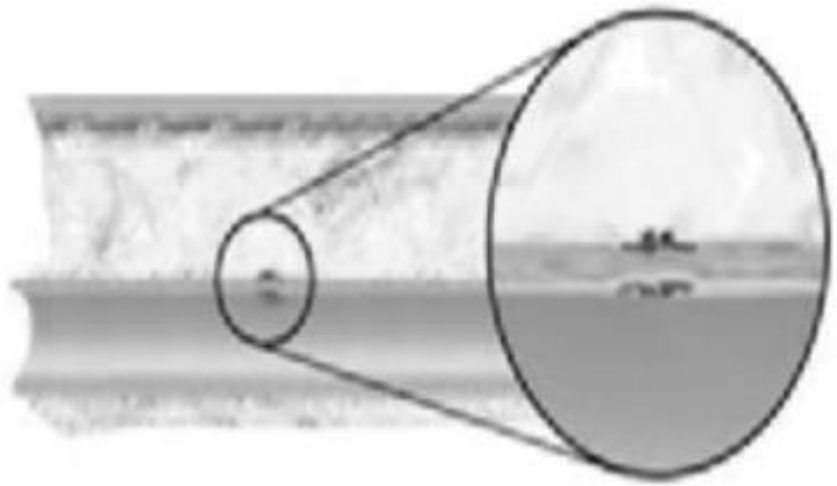


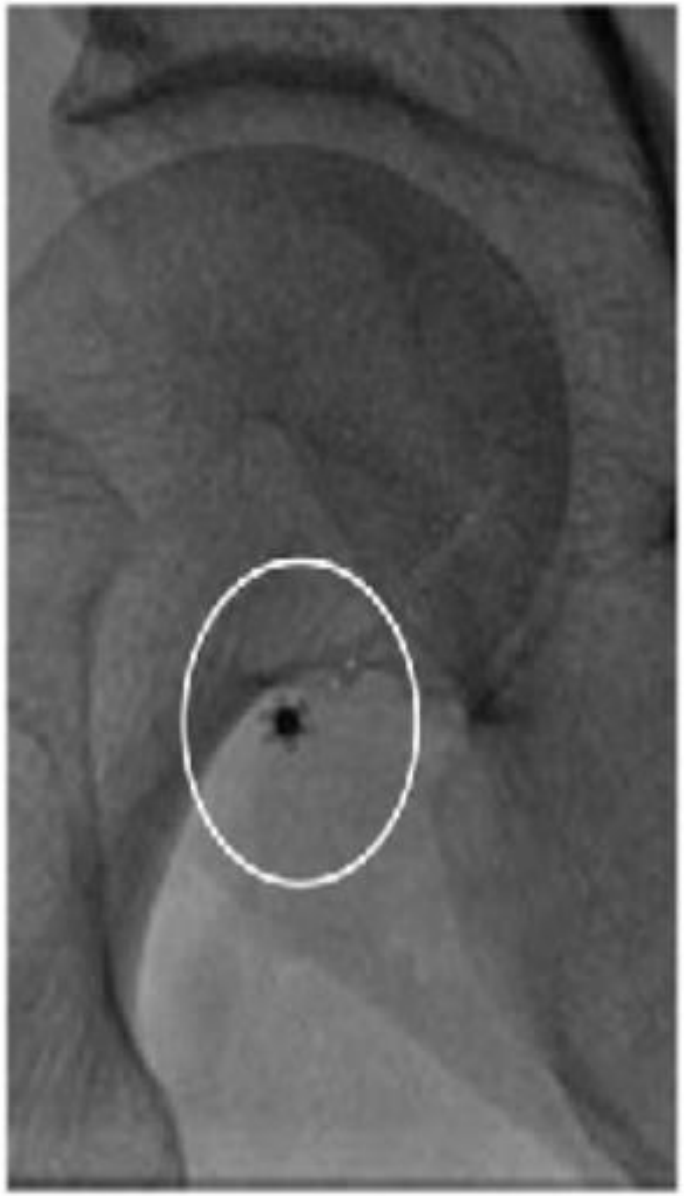
STEP 1
Clockwise rotation of handle to open distal set of wings (inside puncture site)

STEP 2
Anti-clockwise rotation of handle to open proximal set of wings (outside of puncture site)

STEP 3
Release implant providing almost immediate haemostasis

FDA. Accessed October 21, 2025. www.accessdata.fda.gov/cdrh_docs/pdf15/P150006c.pdf. Medical EXPO. Accessed October 21, 2025. https://www.medicalexpo.com/prod/endocor/product-75348-697125.html.





Francis S, et al. Presented at: The 2022 European Congress of Radiology; March 2-6, 2022; Virtual. Abstract C-21582.

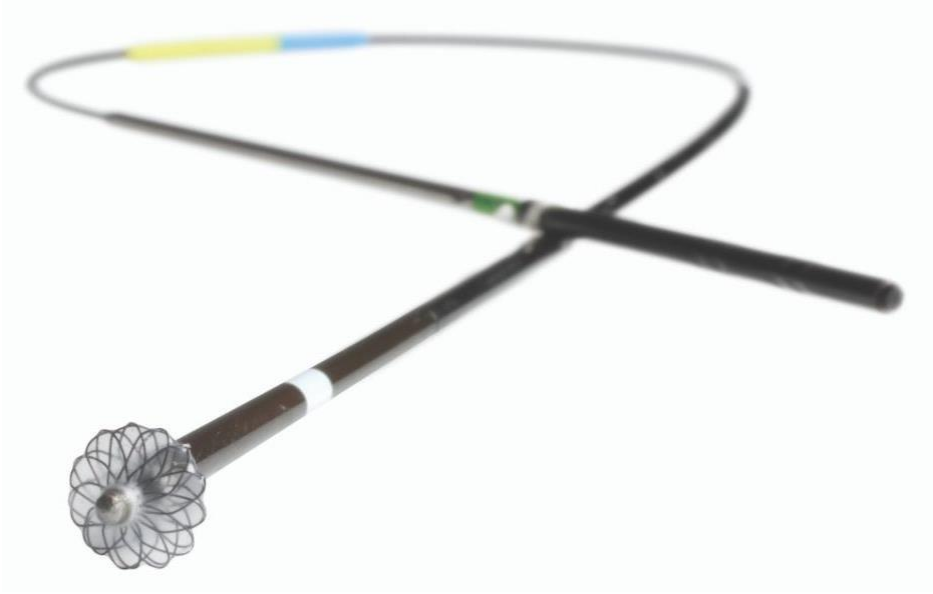
In My ASC, the Most Utilized Device Is VASCADE™, as Nothing Is Left Inside the Vessel

- VASCADE™ does require additional manual pressure
- I can immediately re-access patient if necessary
- It is crucial to make sure the device is appropriately delivered to the arteriotomy site to allow placement of the collagen plug to the exterior surface of vessel in access track
- Very low risk of acute occlusion of diseased vessels
- I have used each of the previously mentioned VCDs in certain specific cases as well

FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf.

VASCADE™

- The VASCADE™ Vascular Closure System (VCS) is indicated for femoral arterial or femoral venous access site closure while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures using a 5F, 6F, or 7F procedural sheath
- The VASCADE™ VCS is also indicated to reduce time to discharge eligibility when used for femoral arterial closure in patients who have undergone diagnostic endovascular procedures using a 5F, 6F, or 7F procedural sheath



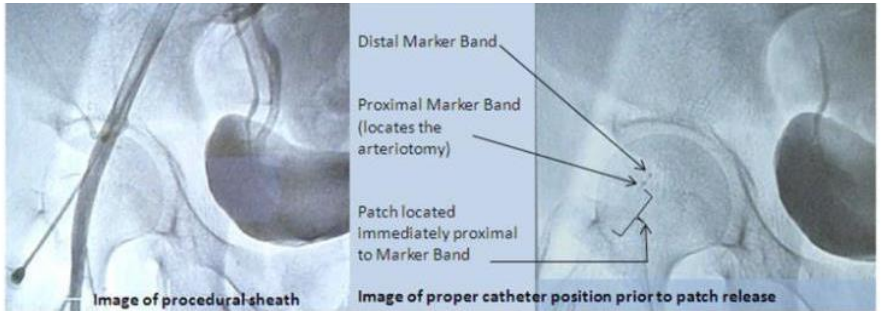
FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf.

Verify Disc Location

VASCADE™ Vascular Closure System

WARNING: It is important to ensure that the disc is in contact with the intimal aspect of the arteriotomy or venotomy before deploying the extravascular collagen patch to avoid releasing the collagen patch in the vessel. This is indicated by having temporary hemostasis and further verified by either fluoroscopy or ultrasound imaging.

- Verify disc is against the vessel wall by comparing location of proximal marker to angiogram of the sheath
- Proximal marker should be at arteriotomy site
  - This would ensure proper placement of the collagen patch in tissue tract
- If proximal marker is not at arteriotomy, remove clip, apply tension to device to position disc against intima; reapply clip; verify location by fluoroscopy
  - Tip: If possible, try not to move imaging head during the two images; the imaging head at 20˚ LAO position should not interfere with procedure
  - Note: Disc may not be visible under fluoroscopy; proximal and distal markers at each end of the disc will be visible



FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf.

Expose Collagen Patch

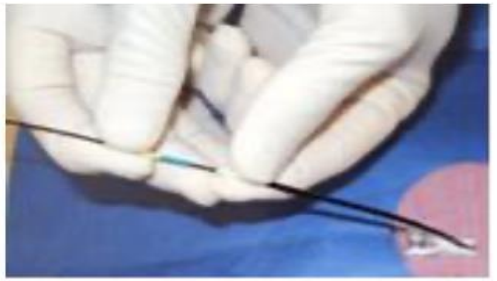


Fig. 12 – Unlock the Black Sleeve by sliding Yellow-Blue Key into the Lock

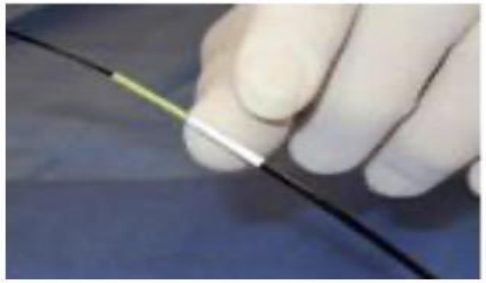


Fig. 13 – Retract the Black Sleeve by grasping the Lock and applying gentle upward tension toward the Silver Handle

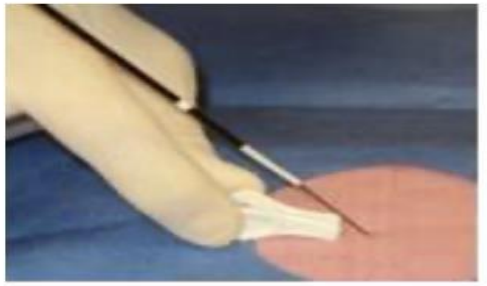


Fig. 14 – Reapply Clip during the Collagen Patch swell period

VASCADE™ Vascular Closure System

- Once disc location is verified, expose the extravascular resorbable collagen patch by unlocking the black sleeve
  - While maintaining gentle back tension from the silver handle, this is done by sliding the yellow-blue key down core wire and inserting into lock, ensuring no blue is visible (Figure 12)
- Once the sleeve is unlocked, and while still holding on to the lock, remove clip with the right hand, and gently slide the lock back along angle of entry to retract the black sleeve (Figure 13)
  - 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)
- Proceed to fully retract the black sleeve proximally to the silver handle; this action exposes the collagen patch extravascularly, which will swell at the arteriotomy or venotomy site.
  - The collagen patch may be allowed to swell for up to 30 seconds prior to removal of the VASCADE™ VCS catheter
  - The clip should be reapplied during the collagen patch swell period with minimal tension on the catheter (Figure 14)

FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf.

Closure Clinical Data in Retrograde Femoral Artery Access with Bivalirudin

Association Between Use of Bleeding Avoidance Strategies and Risk of Periprocedural Bleeding Among Patients Undergoing PCI

Stephen P. Marso, MD et al.

Bleeding Rates by Pre-PCI Risk of Bleeding and Use of Bleeding Avoidance Strategies[a]

Risk Category [b]	MC n=529,247	VCDs n=363,583	Bivalirudin n=353,769	VCDs + Bivalirudin n=276,336
Overall	14,742 (2.8%)	7642 (2.1%)	5547 (1.6%)	2498 (0.9%)
Low (<1%)[c]	1349 (0.9%)	1063 (0.9%)	637 (0.6%)	368 (0.4%)
Intermediate (1%-3%)[d]	5996 (2.3%)	3377 (1.9%)	2413 (1.4%)	1121 (0.8%)
High (>3%)[e]	7397 (6.1%)	3202 (4.6%)	2497 (3.8%)	1009 (2.3%)

PCI = percutaneous coronary intervention; MC = manual compression.
[a]*P*<.001 for all comparisons within bleeding avoidance strategy groups; [b]Risk categories based on NCDR CathPCI bleeding risk model; [c]Data available for 475,152 patients; [d]Data available for 746,727 patients; [e]Data available for 301,056 patients.
Marso SP, et al. *J Am Med Assoc*. 2010;303(21):2156-2164.

Closure Clinical Data in Retrograde Femoral Artery Access with Bivalirudin

Practices and Complications of Vascular Closure Devices and Manual Compression in Patients Undergoing Elective Transfemoral Coronary Procedures

Smilowitz NR, Kirtane AJ, Guiry M, Gray WA, Dolcimascolo P, Querijero M, et al.

Study Objective	Evaluate patterns of use and outcomes associated with vascular closure devices and manual compression.		
Study Design	Retrospective, single-center review		
VCDs Used	Angio-Seal, Perclose-Proglide, StarClose, Mynx. *Results were reported for all VCDs combined, not per device.*		
Study Period	January 2008 to December 2010		
N	9108 consecutive patients; elective coronary angiography or intervention with femoral artery access		
Complications	VCDs: N=6527 (%)	MC: N=2581 (%)	*p*
	42 (0.64%)	32 (1.24%)	0.004
Conclusions	• VCDs were associated with a lower complication rate than MC • VCD use was a predictor of decreased complications		

Smilowitz NR, et al. *Am J Cardiology*. 2012;110(2):177-1782.

Vascular Closure in Antegrade Femoral Artery Access

- Title: A Multi-Center, Prospective, Post-Market Registry to Evaluate Procedural Outcomes Using the Cardiva Medical VASCADE™ VCS for the Management of the Femoral Arteriotomy After Percutaneous Endovascular Procedures Via Antegrade Access
- Authors: Craig Walker, MD; Stefan Keisz, MD; Barry Bertolet, MD; David Weatherford, MD; Pradeep Nair, MD; Mehdi Shishehbor, DO, PhD, MPH
- Objective: To evaluate short-term outcomes when sealing antegrade femoral puncture sites with an extravascular site closure system after peripheral endovascular procedures
- Methods: Prospective, multi-center, US post-market registry assessing the extravascular use of VASCADE™ VCS after antegrade femoral access for treatment of PAD
- Primary efficacy outcome was TTH
- Secondary efficacy outcomes included TTA and TTD
- Procedural outcomes and complications were assessed through hospital discharge and 30 (±) 7 days

First-ever prospective, multi-center, U.S. antegrade study

Note: The safety and effectiveness of VASCADE™ VCS have not been evaluated by Haemonetics in the following patients who have fluoroscopically visible calcium or atherosclerotic disease within 1 cm of the puncture site.

U.S. = United States.

NIH. Accessed October 21, 2025. https://clinicaltrials.gov/study/NCT02948257.

Vascular Closure in PAD Intervention

Summary

- 52 patients enrolled
- Mean age: 66.7 ± 9.86 years
- 33% Female
- Mean BMI: 28.3 ± 4.46

Study population with significant PAD (86% of patients with Rutherford Score 3-5)

Index Limb Assessment

	N	Percent
Rutherford Score		
Stage 2 - Moderate Claudication	6	12%
Stage 3 - Severe Claudication	21	40%
Stage 4 - Ischemic rest pain	10	19%
Stage 5 - Minor tissue loss	14	27%
Data missing*	1	2%
Previous Amputation on Index Limb		
No	47	90%
Yes	5	10%

BMI = body-mass index.

NIH. Accessed October 21, 2025. https://clinicaltrials.gov/study/NCT02948257.

Vascular Closure in PAD Intervention

Procedural Data and Lesion Characteristics

	N=52	
Femoral Artery Branch – Access Site	n	%
Common Femoral Artery (CFA)	19	37%
Superficial Femoral Artery (SFA)	32	62%
Data Missing[1]	1	2%
Techniques Used to Gain Access	n	%
Ultrasound-guided	7	13%
Fluoro-guided	30	58%
Micropuncture	40	77%
Final Sheath Diameter	n	%
5 Fr	11	21.15%
6 Fr	31	59.60%
7 Fr	10	19.23%

	N=52	
Procedure Target(s) for Ipsilateral Interventions	n	%
SFA	28	53.85%
Popliteal	15	28.85%
TPT	7	13.46%
AT/PT	23	44.23%
Peroneal	5	9.62%
Other	7	13.46%
Activated Clotting Time (seconds)	n	%
n	23	44.23%
Mean		245.3
Standard Deviation		24.9
Median		248
Min		192
Max		286

[1]One subject did not have clear documentation of the access site location in the medical records.

NIH. Accessed October 21, 2025. https://clinicaltrials.gov/study/NCT02948257.

Vascular Closure in PAD Intervention

Procedural Outcomes – Performance*

Time to Hemostasis (minutes)	
N	52
Mean	5.87
Standard Deviation	2.44
Median	5.07
Min	4.58
Max	19.83

98% device and
98% procedure success rates

Procedural Outcomes – Safety (98%)

Type of Major Complication (N=52)	Number	%
Any major access site closure-related complication (total)	1	1.9%
Vascular injury requiring repair and access site re-bleeding requiring transfusion	1**	1.9%
New ipsilateral lower extremity ischemia causing a threat to the viability of the limb, requiring surgical or percutaneous intervention	0	0.0%
Access site-related infection requiring intravenous antibiotics and/or extended hospitalization	0	0.0%
New onset neuropathy in the ipsilateral lower extremity requiring surgical repair	0	0.0%

*Protocol mandated 5-minute hold; **Both events occurred in 1 subject.
NIH. Accessed October 21, 2025. https://clinicaltrials.gov/study/NCT02948257.

Vascular Closure in PAD Intervention

Comparison of Closure of Antegrade Puncture after Peripheral Endovascular Interventions

	VASCADE™ VCS	ANGIO-SEAL®	EXOSEAL™	MYNX®
Literature	ANTEGRADE – PVD Study (VASCADE)	Akard, et al (2018) (ANGIO-SEAL)	Schmelter, et al (2013) (EXOSEAL)	Pruski, et al (2017) (MYNXGRIP)
Study Type	Prospective Multi-Center (U.S.)	Retrospective Single Center (U.S.)	Prospective Single Center (OUS)	Prospective Single Center (OUS)
Number of Patients	52	50	93	66
Procedure Success	98%	-	96%	-
Device Success	98%	98%	96%	94%
Minor Complications	1.9% (1)	8% (4)	7.5% (7)	7.6% (5)
Major Complications	1.9% (1)	2% (1)	3.2% (3)	0% (0)
Complication-Free Patients	96.2%	90%	89%	92%

OUS = outside of the United States.

NIH. Accessed October 21, 2025. https://clinicaltrials.gov/study/NCT02948257. FDA. Accessed October 21, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf; pdf/p930038.pdf; pdf10/p100013c.pdf; pdf4/p040044c.pdf. Akard W, et al. *Am J Interv Radiol.* 2018;2(3):1-7. Schmelter C, et al. *Cardiovasc Intervent Radiol.* 2013;36(3):659-668. Pruski MJ, et al. *Vasc Endovascular Surg.* 2017;51(2):67-71.

Procedure Opportunities by Physician Specialty

	ELECTROPHYSIOLOGIST	INTERVENTIONAL CARDIOLOGIST	INTERVENTIONAL RADIOLOGIST	VASCULAR SURGEON	INTERVENTIONAL NEUROLOGIST
VASCADE MVP®	· Electrophysiology Studies · Cardiac Ablations · Lead Extraction · Left Atrial Appendage Closure (LACC)	· Peripheral Venous Stenting · Venous Thrombectomy · IVC Filter Placement/Retrieval · Left Atrial Appendage Closure (LACC) · Congenital Defect Repair (ASD/PFO) · Pulmonary Pressure Monitor (Cardiomems™) · Carotid Revascularization/TCAR (venous return sheath) · Catheter Directed Thrombolysis	· Peripheral Venous Stenting · Venous Thrombectomy · IVC Filter Placement/ Retrieval · Catheter Directed Thrombolysis	· Peripheral Venous Stenting · Venous Thrombectomy · IVC Filter Placement/ Retrieval · Carotid Revascularization/ TCAR (venous return sheath) · Catheter Directed Thrombolysis	· N/A
VASCADE®	· 5-7F Arterial Lines (during Cardiac Ablations)	· Coronary Artery Dx & Ix · Peripheral Artery Revascularization · Structural Heart - TAVR/TMVR (secondary access) · Carotid Artery Stenting · Renal Artery Stenting	· Peripheral Artery Revascularization · Renal Artery Stenting · Oncology Embolization (TACE, Y-90, PAE) · AVM Embolization (GI Bleed, UFE)	· Peripheral Artery Revascularization · Carotid Artery Stenting · Renal Artery Stenting	· Cerebral Embolization · Cerebral Artery Thrombectomy · Cerebral Angioplasty/Stenting

VASCADE™: 5-7F femoral arterial and venous
VASCADE MVP™: 6-12F (15F max OD) femoral venous

OD = outer diameter.
The procedures listed are for informational use only, as an example of procedures that may fall within the indicated arteriotomy and venotomy sizes. Please consult package inserts for more detailed safety information and instructions for use.

Known VCD Complications – All Devices

- Embolization of parts of the device, such as footplate
- Abrupt closure if back artery is involved or a plug is occlusive in an area of stenosis
- Embolization of a plug if deployed within the vessel rather than immediately at the arterial site
- Certain devices may preclude re-access of a vessel
- Risk of injection of material into artery (hemostatic meds)
- Risk of stent migration if footplate of device becomes untangled

Conclusions

- Vascular closure devices have been shown in certain patient populations to **decrease bleeding complications, time to hemostasis, and time to ambulation**
  - **Patient choice is crucial!**
- Understanding and perfecting technique of use of several devices with a specific mode of action is better for **maintaining patency and minimizing complications**
- Key to success is dictated by **access technique, vessel health, and proficiency in deployment**
- Bailout methods for dealing with complications will dictate comfort in management
- **Present closure devices still have limitations,** but when used appropriately, can facilitate good clinical outcomes and can be cost-effective

CardioVascular Learning Network | CME

Optimizing Workflow: Case-Based Insights

Hafez Golzarian, DO, MBA
Cardiovascular Disease Fellow
University of Houston/HCA Houston Healthcare
Houston, Texas

Case

- 68-year-old Female with history of hyperlipidemia, uncontrolled hypertension, coronary artery disease, class III obesity, and paroxysmal atrial fibrillation undergoes elective successful WATCHMAN™ LAAO
- Activated clotting time (ACT) = 325 sec
- Access site closure method: Manual pressure
- Duration: 10 min
- Three staff in the room
  - Two of them taking turns holding pressure

LAAO = left atrial appendage occlusion.

Case (cont.)

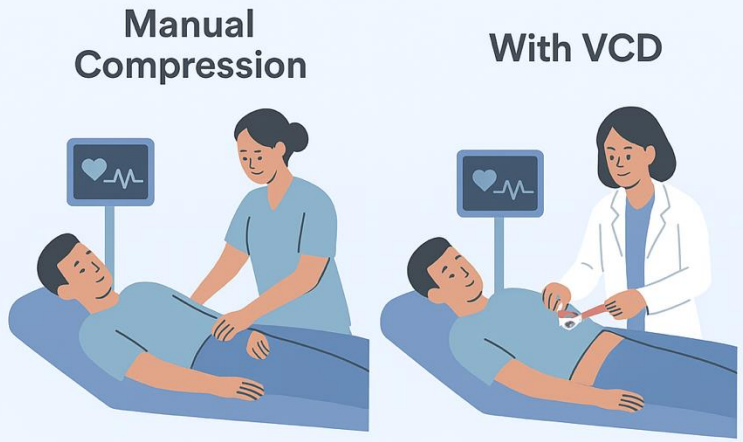
- STEMI activation from the ED
- Room not ready and flipped yet
- Our patient transfers to recovery unit—develops large groin hematoma and more bleeding from site
- Another 10 min of manual pressure applied
- Patient shouts in discomfort—asks for physician to come talk to her
- Nurse attempts to contact physician, but he is unavailable
- After two hours, physician calls back, asks patient to be admitted for overnight observation
- Patient files complaint for unpleasant experience

STEMI = ST-elevation myocardial infarction; ED = emergency department.

Why We Switched to VCDs

- Accelerates the workflow
  - Reduced compression time
  - Faster patient ambulation
  - Increased patient throughput
    - Same-day discharges
    - Faster room turnovers
    - Prevents delays in care for emergencies
  - Reduced nursing workload
- Improved patient comfort and satisfaction
- Improved staff satisfaction
- Predictable

Vascular Closure Devices Improve Workflow



	Manual Compression	With VCD
Time to hemostasis	15–30 min	2–5 min
Bed rest time	4–6 hr	1–2 hr
Staff time	High	Low
Throughput	Limited	Increased

Received: 7 January 2024 | Revised: 30 July 2024 | Accepted: 19 August 2024

DOI: 10.1002/ccd.31209

ORIGINAL ARTICLE - CLINICAL SCIENCE

Efficacy and safety of the VASCADE® MVP venous vascular closure device in patients undergoing percutaneous left atrial appendage occlusion with WATCHMAN

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Abstract

Background: The VASCADE MVP venous vascular closure system is commonly used for percutaneous venotomy closure in catheter-based procedures utilizing sheath sizes 6-12 French. However, its application with larger sheaths such as ones required in left atrial appendage occlusion (LAAO) has yet to be explored.

Aims: This study compared the efficacy and safety of VASCADE MVP versus conventional Figure-of-8 sutures (Fo8) for femoral venotomy closure in patients un-

Golzarian H, et al. *Catheter Cardiovasc Interv*. 2024;104(6):1260-1266.

Efficacy of Venotomy Closure with VASCADE® MVP Compared to Conventional Methodology

Findings	Fo8 ($n = 99$)	VASCADE ($n = 107$)	P value
Procedure success rate	98 (99.0)	101 (94.4)	0.069
Time to hemostasis (mean ± SD)	334.8 ± 336.2 sec	152.9 ± 142.2 sec	< 0.001
≤1 min	7 (7.1)	31 (29.0)	< 0.001
≤5 min	59 (59.6)	87 (81.3)	0.001
≤10 min	87 (87.9)	105 (98.1)	0.004
>10 min	11 (11.1)	2 (1.9)	0.006

Values represent *n* (%). % are expressed compared to the number of patients in the given sample. *P* value was calculated comparing the VASCADE cohort with the conventional cohort.

Golzarian H, et al. *Catheter Cardiovasc Interv*. 2024;104(6):1260-1266.

Major Post-Procedural Complications within 30 Days

Major Complications	Fo8 ($n = 99$)	VASCADE ($n = 107$)	*P* value
MACE(%)	3(3.0)	1(1.0)	0.276
Fistula needing vascular repair (%)	1(1.0)	0	0.298
Access site bleed requiring PRBC transfusion (%)	3(3.0)	0	0.070
Access site infection (%)	0	0	–
Access site–related nerve injury (%)	0	0	–
Pseudoaneurysm (%)	0	0	–
Venous embolization (%)	0	0	–

Values represent *n* (%). % are expressed compared to the number of patients in the given sample. *P* value was calculated comparing the VASCADE cohort with the conventional cohort.

Golzarian H, et al. *Catheter Cardiovasc Interv*. 2024;104(6):1260-1266.

Categorical Readmissions and Minor Complications within 30 days

Minor complications	Fo8 ($n = 99$)	VASCADE ($n = 107$)	P value
Hematoma ≤5 cm (%)	2 (2.0)	2 (1.9)	0.936
Ecchymosis (%)	16 (16.2)	5 (4.7)	0.007
>20 min to hemostasis (%)	2 (2.0)	0	0.139

Readmission Type	Fo8 ($n = 99$)	VASCADE ($n = 107$)	P value
Access Site-Related (%)	1(1.0)	0 (0.0)	0.298
Gastrointestinal Bleed (%)	5 (5.1)	4(3.7)	0.646
Other (%)	12 (12.1)	5(4.7)	0.052

Values represent n (%). % are expressed compared to the number of patients in the given sample. P value was calculated comparing the VASCADE cohort with the conventional cohort.

Golzarian H, et al. *Catheter Cardiovasc Interv*. 2024;104(6):1260-1266.

Summary

Workflow Area	Manual Compression	With VCD	Workflow Impact
Time to hemostasis	15–30 min	2–5 min	Faster turnover
Bed rest time	4–6 hr	1–2 hr	Quicker discharge
Staff time	High	Low	More efficient
Complication predictability	Variable	Consistent	Fewer delays
Throughput	Limited	Increased	More cases/day

Golzarian H, et al. *Catheter Cardiovasc Interv*. 2024;104(6):1260-1266.