The VASCADE® Vascular Closure System Performance Guarantee Risk-Sharing Agreement: Low Prevalence of Closure-Related Complications

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Abstract: Objective: The National Cardiovascular Data Registry indicates bleeding complications occur among 5.8% of patients undergoing percutaneous coronary intervention (2008–2011); however, trials have demonstrated that the VASCADE® Vascular Closure System (VCS) lowers rates of access site closure–related complications. With an estimated cost of $5,440 per bleeding complication, reducing complications may lead to substantial cost savings. By connecting quality metrics to costs, risk-sharing agreements (RSAs) can improve outcomes and patient satisfaction while managing financial risk. Here, we describe real-world experience and practical implications of femoral arterial vascular closure using the VCS by examining qualifying complications from participating institutions enrolled in a novel RSA, the Performance Guarantee (PG) partnership, reported during 2016–2020.

Methods: PG is a risk-sharing partnership between participating institutions and Cardiva, focused on reducing complications during catheter-based vascular procedures. If a qualified access site closure–related bleeding complication occurs while using the VCS, Cardiva provides a $1,000 credit to the participating institution to share the costs of that complication. The program involves simplified documentation (no protected health information required) and incentivizes reporting of procedural complications.

Results: PG was implemented across 104 US centers during 2016–2020. Among those, 71,700 VCS units were distributed, and 62 qualifying complications were reported, equivalent to a complication rate of <0.1% (<1 in 1,000).

Conclusions: VCS use lowers vascular complications relative to national registries, thereby lowering length of stay and complication costs. The novel PG RSA raises awareness of procedural complications, incentivizes reporting, and supports a continuous quality improvement process, all while sharing financial risk.

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Key words: Percutaneous coronary intervention, cost savings, documentation

Introduction

Recent estimates suggest that over 965,000 percutaneous coronary interventions are performed in the United States annually.[1] Although the prevalence of radial catheterization is increasing, many cardiac procedures and most peripheral angiography and interventional procedures are performed via femoral vascular access.[2] According to information from the CathPCI Registry, based on the National Cardiovascular Data Registry, among the percutaneous coronary interventions reported in 2014 a total of 172,880 (25.2%) were performed via radial access and 510,783 (74.5%) were performed via femoral access.[3]

Among patients undergoing percutaneous diagnostic and interventional cardiovascular procedures, recent estimates suggest that the prevalence of femoral access site complications ranges from 1% to 11%, with a higher frequency of complications for interventional procedures[4]; indeed, some reports suggest that these rates have remained largely unchanged over the past decade.[5,6] A 2020 analysis of vascular complications following percutaneous coronary interventions reported that major vascular complications requiring treatment occurred in 53/2833 (1.9%) cases over 42 months; of these, 24.5% required surgical repair and 75.5% were treated endovascularly.[7]

Results from a study of the CathPCI Registry indicate that between 2008 and 2011, the rate of bleeding complications among patients undergoing a percutaneous coronary intervention (within 72 hr of the procedure) was 5.8%.[8] The average increase in cost per access site attributed to a bleeding complication is $5,440.[9] Therefore, the average predicted cost of these bleeding complications per 1,000 cases is $315,520. Given these estimates, a 1% reduction (to 4.8%) in the rate of complications per 1,000 patients corresponds to a cost savings of $54,400. In short, improvements in percutaneous coronary intervention complication rates can lead to better clinical outcomes and improved patient satisfaction, and may lead to substantial cost reductions. This is particularly noteworthy given the increasing awareness among physicians and hospitals of practicing cost-conscious medical care.

Initial studies with early-generation vascular closure devices suggested they were associated with higher rates of vascular complications, compared with manual compression.[5,10] Although the risk of complications vary between devices, more recent studies

Figure 1. VASCADE® VCS. VASCADE® Mid-bore VCS for access site closure following vascular catheterization procedures. VCS, vascular closure system.

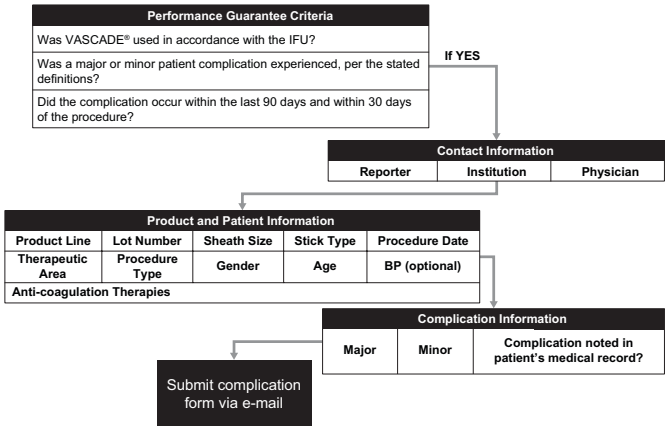

Figure 2. VASCADE® VCS Performance Guarantee complication reporting form. To report a qualifying access site–related complication, institutions complete a short, one-page form that does not require any protected health information, meaning it can be submitted via email. BP, blood pressure; IFU, instructions for use; VCS, vascular closure system.

have demonstrated that vascular closure devices are generally safe relative to manual compression and allow for earlier mobility following the procedure, earlier patient discharge, improved patient satisfaction, and reduced groin complications (in particular, bleeding complications).[4,11-13] These improvements may be related to newer generations of vascular closure devices as well as greater operator experience, which likely lead to reduced cost and complications.[4,5]

The VASCADE® Vascular Closure System (VCS; Cardiva Medical, Inc., Santa Clara, CA, USA) is approved for use by the US Food and Drug Administration (FDA)[14] and holds a CE mark for use in Europe[14] for closure of 5-7 Fr (inner diameter) arterial and venous femoral access sites (**Figure 1**). Another device, the VASCADE® MVP[15] is indicated for larger bore venous femoral access closure up to 12 Fr (inner diameter). In the prospective, randomized RESPECT pivotal study, compared with manual compression, the VCS was associated with faster times to hemostasis, ambulation, and discharge as well as a lower incidence of minor complications.[11] In fact, patients who underwent femoral access procedures and received the VCS had a median time to hemostasis of 3.0 min, median time to ambulation of 3.2 hr, and median time to discharge of 3.6 hr compared with 20.0 min, 5.2 hr, and 5.7 hr, respectively, for manual compression. Importantly, the manual compression and the VCS treatment arms had no major complications,[11] distinguishing the VCS as one of the few closure devices with this safety record.[16]

The VCS was also evaluated in a real-world setting through a multi-center, single-arm, post-market registry. The ANTEGRADE-PVD registry included patients who underwent procedures involving antegrade femoral access for treatment of peripheral arterial disease, with the VCS used during access site closure. Among the 52 enrolled patients, procedural success was achieved for 98% of patients, mean time to hemostasis was 5.87 ± 2.44 min, and mean time to discharge was 5.97 ± 5.85 hr; major and minor access site–related complications each occurred in 1.9% of patients.[17]

It has become apparent that the VCS has several advantages. It can be placed through a standard 12-cm introducer sheath requiring no special catheters or sheath exchanges. The retractable nitinol footplate facilitates placement in femoral arteries with vascular disease. The extravascular bioabsorbable closure minimizes intravascular device-related complications and does not stimulate intense fibrosis at the closure site. Finally, deployment is rapid, usually taking less than 30 seconds to place.[18]

Health care systems are in the process of a payment-related paradigm shift, in favor of a focus on value rather than volume.[19,20] This shift is based on the notion that value-based care models lead to better clinical outcomes, lower costs, and improved patient satisfaction. In keeping with those goals, risk-sharing agreements (RSAs) must be developed between health care providers and manufacturers to connect quality metrics (outcomes) with costs to derive value for patients and the clinic, while also managing financial risks.[21]

The goal of the VCS is to substantially reduce the rate of access site complications among patients undergoing catheter-based vascular procedures. To that end, the VCS Performance Guarantee is an RSA implemented by Cardiva Medical, Inc. that forms a partnership with health care providers to focus on improving patient outcomes and reducing complications by sharing the cost of qualified complications that result following use of the VASCADE® VCS. This novel RSA incentivizes the reporting of vascular access site complications.

Methods

As part of the VCS Performance Guarantee, in the event of a qualified access site–related bleeding complication when using the VCS, Cardiva Medical Inc. will share with the enrolled hospital

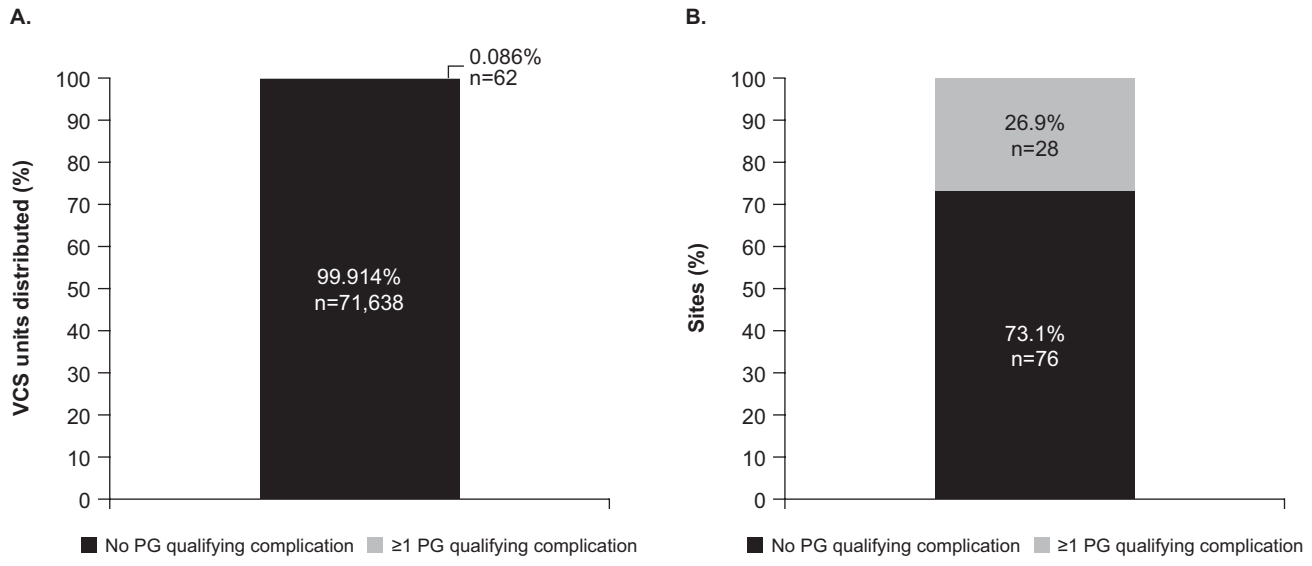

Figure 3. Performance Guarantee qualifying complications overall (A) and among 104 sites (B) since 2016. Since mid-2016, a total of 71,700 VASCADE® VCS units have been distributed to 104 participating centers. In that time, 62 access site–related complications that meet the Performance Guarantee criteria have been reported. Results are based on internal data between Q2 2016 and Q1 2020. PG, Performance Guarantee; VCS, vascular closure system.

or practice the cost associated with managing the complication,[19] thus sharing any perceived risk of implementing new technology. The VCS Performance Guarantee also prescribes use of the femoral access technique that minimizes patient risk for complication. In addition to the emphasis on reducing complications, the Performance Guarantee program provides an incentive to immediately report complications and to ultimately eliminate underreporting of procedural complications. Furthermore, the program provides a focus on quality metrics and the underlying causes by including a quarterly business review, a mechanism by which to review complication rates in an effort to facilitate continuous improvement.

The VCS Performance Guarantee is a standalone agreement, not a market share agreement tied to pricing. Only patients who received the VCS can be covered by the Performance Guarantee, and all device operators must be trained and have used ≥10 devices. All patients treated with the VCS, in accordance with the instructions for use, at a participating institution are eligible. Qualified complications were defined using the FDA-approved criteria used in the RESPECT pivotal study.[11] In the event that ≥1 qualified complications occurs when the Performance Guarantee is in place, Cardiva Medical, Inc. will provide a $1,000 credit, memo, or check to the hospital to share in the cost of the qualified complications. Reporting of complications in the Performance Guarantee program requires timely completion and submission of a one-page form (**Figure 2**). It should be noted that the reporting form does not require any protected health information; in fact, the completed form can easily be submitted to the device manufacturer via e-mail. Qualified access site–related bleeding complications are described in **Table 1**.

Single-site cost calculations were performed using observational room costs of $100/hour. A cost of $5,440 was attributed to any bleeding complication.[9] With vascular closure, we noted patients were able to be discharged an average of 3 hours sooner than non-closure patients, and they experienced an absolute 3% reduction of vascular complications.

Table 1. Performance guarantee–qualified access site–related bleeding complications[a]

Major complications
Access-related bleeding requiring transfusion
Retroperitoneal hemorrhage requiring transfusion or surgery (unrelated to high stick or backwall stick)
Vascular injury requiring repair (via surgery)
Infection related to access
Pulmonary embolism
Minor complications
Access site–related hematoma >6 cm
Arteriovenous fistula
Pseudoaneurysm (clinically significant requiring treatment with thrombin injection; unrelated to high stick or backwall stick)
Retroperitoneal hemorrhage not requiring transfusion or surgery

[a]Excludes certain cases described in the instructions for use, in the contraindications as well as the warning and precautions sections.

Results

From mid-2016 through early 2020, a total of 104 centers in the United States implemented the VCS Performance Guarantee. Overall, 71,700 VCS units were distributed and 62 qualifying complications were reported (**Figure 3A**). Among the 104 participating centers, 28 sites reported ≥1 qualifying complication (**Figure 3B**). The majority of the 62 qualifying complications were due to hematoma (40%), pseudoaneurysm (26% thrombin +

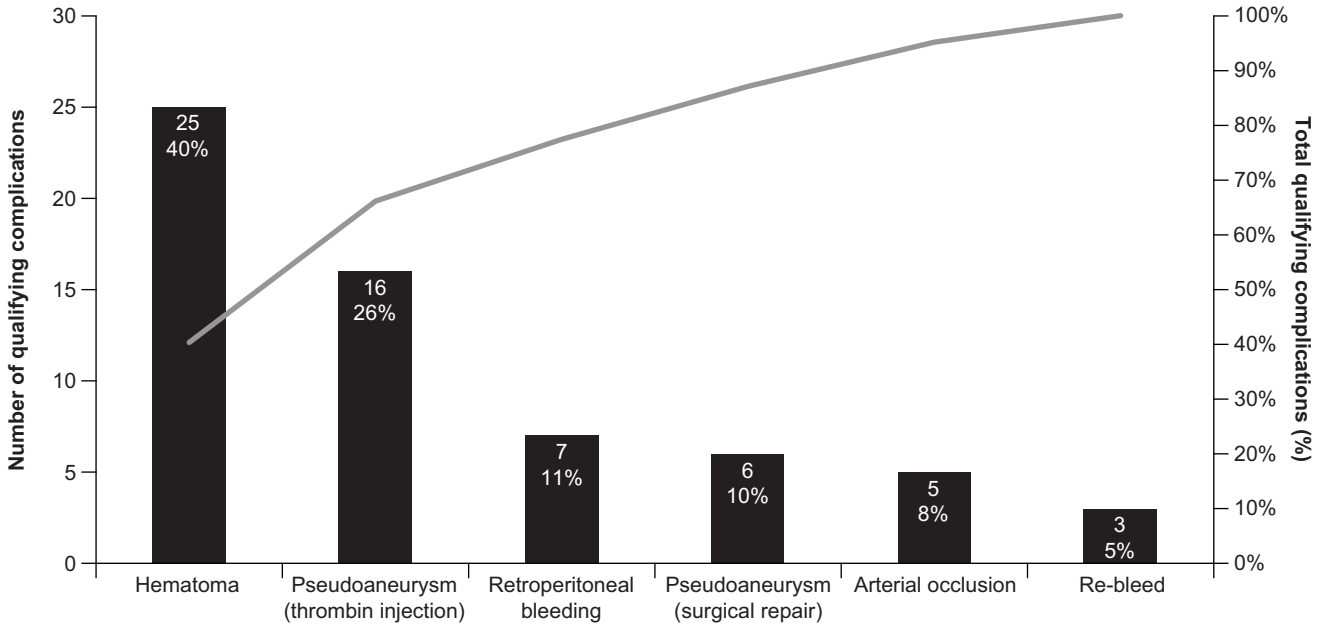

Figure 4. Qualifying complications reported in the Performance Guarantee program, reported between mid-2016 and Q1 2020.

10% surgery), and retroperitoneal bleed (11%; **Figure 4**). In total, the number of qualifying complications account for <0.1% (<1 in 1,000) of the total VCS units distributed to participating centers.

Discussion

Previous studies with the VCS have demonstrated significant reductions in post-procedure time relative to manual compression.[11,12] In addition to potential cost savings associated with reduced complications, institutional cost savings may also result from shorter lengths of stay in observation units for each patient. For example, in the AMBULATE trial VASCADE® was associated with an observation time 3 hr shorter than that with manual compression.[22] Based on our institutional observation cost of $100 per hour for a post-catheterization patient, the institutional cost savings would be $300 per patient. With respect to our facility in particular, for every 100 patients enrolled in this program, our institution estimates a cost reduction of nearly $15,000 for vascular access complications and an observation cost reduction of $30,000. Costs will, of course, vary among institutions throughout the country.

The low rate of complications (<0.1%) reported above is consistent with two previous studies of VASCADE® closure devices, the RESPECT pivotal study (ClinicalTrials.gov Identifier: NCT01297322)[11] and the ANTEGRADE-PVD post-market registry study.[17] The open-label RESPECT trial reported minor complications among 1% of patients treated with the VCS closure device compared with 7% of patients treated with manual compression; no major complications were reported for either treatment group.[11] In the ANTEGRADE-PVD study, the major and minor complication rates were each 1.9% among patients treated with the VCS.[17] Furthermore, according to a recent systematic review, among a handful of clinical trials, rates of complications for several active closure devices ranged from 0.5% to 7% (**Table 2**).[16] As such, the rate of complications reported for the RSA Performance Guarantee program (<0.1%) is lower than that reported for several other vascular closure devices, including the aforementioned clinical studies of VASCADE® closure devices.[11,17] This finding is particularly noteworthy because procedures included in the Performance Guarantee program involved a real-world patient population, in stark contrast to the select patients who meet eligibility for randomized controlled trials.[4]

Table 2. Access site–related complications among studies of active vascular closure devices

Device	Complication rate (vs. manual compression)[a]
Angioseal Vascular Closure Device (Terumo Medical Corporation, Somerset, NJ, USA)	0.5–7%[16]
Mynx Vascular Closure Device (Cardinal Health, Dublin, OH, USA)	0.5% (major complications)[16]
Starclose SE™ Vascular Closure System (Abbott, Abbott Park, IL, USA)	2.2%[23]
VASCADE® VCS (clinical trial data)	1.1%[11,17]
VASCADE® VCS Performance Guarantee	<0.1%

Abbreviation: VCS, vascular closure system.

[a]Includes rates of major complications, minor complications, and major bleeding.

Key factors for successful implementation of an RSA include the following: an easily defined patient population, easily identifiable outcome measures not involving longitudinal follow-up, a device that effectively addresses a medical problem (eg, it has a larger effect size), and outcomes for which results are quickly perceptible (1 year is recommended).[20,21] In fact, the VCS Per-

formance Guarantee is optimally designed to meet these ideal characteristics. In addition to being an incentive to immediately report complications, the Performance Guarantee complication reporting process is simple and does not require protected health information, allowing the form to be submitted via e-mail. As such, this simple and quick process represents an excellent step toward eliminating underreporting of procedural complications. The Performance Guarantee program does have limitations, including minimum threshold qualifier for institutions to implement the program and guidance that the VCS must be the sole extravascular product (in addition to Perclose and Angio-Seal™).

Conclusion

The VCS Performance Guarantee program is a unique and viable RSA partnership between Cardiva Medical, Inc. and participating institutions that demonstrates the integration of industry with end-users in a value-based care environment. The program incentivizes the reporting of complications and has been described as an early-warning system due to increased awareness of the complications associated with vascular closure. Moreover, the Performance Guarantee supports a continuous quality-improvement process—the manufacturer and institution will have heightened awareness if a complication occurs and, therefore, can closely monitor the situation to make any necessary changes,[21] ultimately leading to better outcomes for patients. In this era of value-based care, the need for improvements in procedural efficiency and reductions in resource usage have driven the adoption of vascular closure devices. These improvements are particularly important given the cost of vascular access complications and the available range of closure methods.[4,11] The results from recent studies with the VCS have demonstrated hastened time to hemostasis, time to ambulation, and time to discharge eligibility. Consistent with the low rate of complications reported here, the Performance Guarantee program represents an opportunity to minimize the rate of access site complications and eliminate under-reporting while reducing overall health care costs and improving patient care. ■

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REFERENCES

1. iData Research. Over 965,000 angioplasties are performed each year in the United States. Available at: https://idataresearch.com/over-965000-angioplasties-are-performed-each-year-in-the-united-states/. Accessed 3/26/20.
2. Sandhu K, Butler R, Nolan J. Expert opinion: transradial coronary artery procedures: tips for cuccess. *Interv Cardiol.* 2017;12(1):18-24.
3. Masoudi FA, Ponirakis A, de Lemos JA, et al. Trends in U.S. cardiovascular care: 2016 report from 4 ACC national cardiovascular data registries. *J Am Coll Cardiol.* 2017;69(11):1427-1450.
4. Noori VJ, Eldrup-Jorgensen J. A systematic review of vascular closure devices for femoral artery puncture sites. *J Vasc Surg.* 2018;68(3):887-899.
5. Bhatty S, Cooke R, Shetty R, Jovin IS. Femoral vascular access-site complications in the cardiac catheterization laboratory: diagnosis and management. *Interv Cardiol.* 2011;3(4):503-514.
6. Bogabathina H, Shi R, Singireddy S, et al. Reduction of vascular complication rates from femoral artery access in contemporary women undergoing cardiac catheterization. *Cardiovasc Revasc Med.* 2018;19(6S):27-30.
7. Schahab N, Kavsur R, Mahn T, et al. Endovascular management of femoral access-site and access-related vascular complications following percutaneous coronary interventions (PCI). *PLoS One.* 2020;15(3):e0230535.
8. Rao SV, McCoy LA, Spertus JA, et al. An updated bleeding model to predict the risk of post-procedure bleeding among patients undergoing percutaneous coronary intervention: a report using an expanded bleeding definition from the National Cardiovascular Data Registry CathPCI Registry. *JACC Cardiovasc Interv.* 2013;6(9):897-904.
9. Resnic FS, Arora N, Matheny M, Reynolds MR. A cost-minimization analysis of the angio-seal vascular closure device following percutaneous coronary intervention. *Am J Cardiol.* 2007;99(6):766-770.
10. Dangas G, Mehran R, Kokolis S, et al. Vascular complications after percutaneous coronary interventions following hemostasis with manual compression versus arteriotomy closure devices. *J Am Coll Cardiol.* 2001;38(3):638-641.
11. Hermiller JB, Leimbach W, Gammon R, et al. A prospective, randomized, pivotal trial of a novel extravascular collagen-based closure device compared to manual compression in diagnostic and interventional patients. *J Invasive Cardiol.* 2015;27(3):129-136.
12. Natale A, Al-Hmad A, Bailey S, et al. Venous vascular closure system (VVCS) vs. manual compression (MC) for EP catheter ablation: The AMBULATE Randomized Trial. *Circulation.* 2018;138(25):e751-e782.
13. Mohanty S, Trivedi C, Beheiry S, et al. Venous access-site closure with vascular closure device vs. manual compression in patients undergoing catheter ablation or left atrial appendage occlusion under uninterrupted anticoagulation: a multicentre experience on efficacy and complications. *Europace.* 2019;21(7):1048-1054.
14. Cardiva Medical® announces FDA approval of VASCADE® vascular closure system for use in femoral vein closure. VASCADE now indicated for both arterial and venous vascular closure, greatly expanding market [press release]. 2018. Accessed September 2, 2020.
15. Cardiva Medical Inc. VASCADE® MVP venous vascular closure system (VVCS) instructions for use model 800-612C. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016S024C.pdf. Accessed 11/23/20.
16. Sheth RA, Walker TG, Saad WE, et al. Quality improvement guidelines for vascular access and closure device use. *J Vasc Interv Radiol.* 2014;25(1):73-84.
17. Walker C, Kiesz S, Bertolet B, Weatherford D, Nair PK, Shishehbor MH. A multi-center, prospective, post-market registry to evaluate

procedural outcomes using the Cardiva Medical VASCADE Vascular Closure System (VCS). *Vascular Disease Management*. 2018;15(9):E102-E109.
18. Cardiva Medical Inc. VASCADE® vascular closure system (VASCADE VCS) instructions for use 5F and 6/7F. Available at: https://www.cardivamedical.com/site/assets/files/1052/ifu_2611-r-_vascade_instructions_for_use.pdf. Accessed November 23, 2020.
19. Durham C. Finding value in medical technology. *Cath Lab Digest*. 2017;25(12).
20. Liu H, Chen C. Finding good candidates for risk-sharing arrangements. Available at: https://www.mddionline.com/finding-good-candidates-risk-sharing-arrangements. Accessed August 11, 2020.
21. Madassery S. Creating clinical and economic value through risk-sharing agreements. *Cath Lab Digest*. 2019;27(3).
22. Natale A, Mohanty S, Liu PY, et al. Venous vascular closure system versus manual compression following multiple access electrophysiology procedures: The AMBULATE Trial. *JACC Clin Electrophysiol*. 2020;6(1):111-124.
23. Abbott. Starclose SE Vascular Closure System Instructions for Use. https://vascular.eifu.abbott/en/hcp/home.html. Accessed 12/21/20.