Real World Safety Data
Analysis of Active Vascular Closure Surveillance Programs

Summary: Active surveillance programs enable a continuous quality improvement process and may rapidly identify potential safety signals, as evidenced by Resnic et al. Haemonetic's award-winning Performance Guarantee (PG) risk-sharing program forms a partnership with healthcare providers to improve patient outcomes through the monitoring and reporting of access-site complications, all while sharing the financial risk.

The NEW ENGLAND JOURNAL of MEDICINE

Resnic, et. al. **Registry-Based Prospective, Active Surveillance of Medical-Device Safety**, N Engl J Med 376;6, Feb 2017.

- **Objective:** Prospective, active surveillance of the CathPCI Registry with a propensity-matched safety analysis comparing Mynx® device to other vascular closure devices
- **Results:** Data analysis revealed a significantly higher risk of vascular complications, access-site bleeding requiring treatment, and postprocedural blood transfusion among patients treated with the Mynx® device as compared to alternative closure devices
- **Conclusion:** A strategy of prospective, active surveillance of a clinical registry rapidly identified potential safety signals, with initial alerts occurring within the first 12 months of monitoring

	Mynx® Device	Alternative Device*
Surveillance Type	Prospective, active surveillance of CathPCI registry	
Sample Size	73,124	73,124
Vascular Complications	1.21% (883)	0.76% (555)
P-Value	<0.001	

VDM Vascular Disease Management

Bertolet, et. al. **The VASCADE® PG risk-sharing agreement: low prevalence of closure-related complications**, VDM, 17(12): E221-E226, Dec 2020.

- **Objective:** Review of real-world experience and practical implications of femoral arterial vascular closure by examining qualifying complications from participating institutions enrolled in the VASCADE® Performance Guarantee risk-sharing program
- **Results:** Across 104 US participating centers between 2016-2020, 62 qualifying complications were reported out of 71,700 distributed VCS units yielding a complication rate of <0.1% (<1 in 1,000). Single-center observations included a 3% absolute reduction of vascular complications and a 3-hour average earlier discharge, resulting in $45,000 in cost savings per 100 patients
- **Conclusion:** The PG risk-sharing agreement raises awareness of procedural complications, incentivizes reporting, and supports a continuous quality improvement process, all while sharing financial risk

	VASCADE®
Surveillance Type	Active surveillance of VASCADE® PG program
Sample Size	71,700
Vascular Complications	<0.1% (62)

* VASCADE® was not included in the alternative device arm of the CathPCI Registry.
** Qualifying complications that meet the Performance Guarantee criteria as defined in the RESPECT randomized clinical trial.

HAEMONETICS®

VASCADE® Performance Guarantee

Close Confidently. Performance Guaranteed.

Real World Economic Cost of Complications

The National Cardiovascular Data Registry indicates bleeding complications occur among 5.8% patients undergoing percutaneous coronary interventions (2008-2011); however, the RESPECT trial[1] demonstrated that VASCADE® lowers rates of access-site complications.

- 5.8% bleeding rate in CathPCI Registry[2]
- $4,800 average increase in cost per complication[3]
- $48,000 savings per 1% reduction in complications per 1,000 patients

Sharing Risk by Sharing Costs™

We stand behind the performance of our vascular closure system and are proud to offer and award-winning outcomes-based risk sharing program. In the event of a qualified complication, we will offset some of the associate costs.

- Partnership to reduce access site complications
- Partially offset the costs of complications
- Simple design and easy to implement

100+	83,000+	<0.1%	~4,800+	$23M+
Customer Sites	Devices Sold[4]	Complication Rate[4]	Potential Complications Prevented[2]	Potential Cost Saved[3]

To learn more about the VASCADE® Performance Guarantee, contact your Haemonetics Territory Manager or call 800.537.2802

[1] RESPECT Clinical Trial demonstrated VASCADE was superior for minor complications and non-inferior for major complications when compared to manual compression.

[2] Rao et al. An Updated Bleeding Model to Predict the Risk of Post-Procedure Bleeding Amound Patients Undergoing Percutaneous Coronary Intervention. JACC Cardiovasc Int, 2013; 6: 897-904.

[3] Resnic et al. Cost-Minimization Analysis of the Angioseal Vascular Closure Device following Percutaneous Coronary Intervention. Am J Cariol. 2007 March 15; 99(6): 766-770.

[4] Internal data Q2 2016 - Q3 2020.

Please consult product labels and instructions for use for indications, contraindications, warnings, precautions, and adverse events. See VASCADE® IFU 2611 Instructions for Use.

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