ambulate

CLINICAL TRIAL

VASCULAR CLOSURE FOR EP PROCEDURES

Proven by EPs

VASCADE MVP was evaluated in the AMBULATE pivotal trial. Natale et al. AMBULATE was a multicenter, randomized clinical trial with 204 patients randomized 1:1 to VASCADE MVP or manual compression

VASCADE MVP®
VENOUS VASCULAR CLOSURE SYSTEM

VS.

MANUAL COMPRESSION

204 patients

SEP 2018 — OCT — NOV — DEC — JAN — FEB — MAR 2019

13 sites

28 investigators

The only FDA-approved closure device for use following cardiac ablations.

Time to Ambulation

3.9 hrs. REDUCTION

Reduction in Median Time to Ambulation[1]

Patient Satisfaction

63% IMPROVEMENT

Improvement in Patient Satisfaction[1]

Opioid Use

58% REDUCTION

Reduction in Opioid Use[1]

Designed for EP Procedures

- Simple and Easy to Use
- Enables Multiple Site Closures in Close Proximity
- Nothing Permanent Left Behind for Future Procedures

VASCADE MVP®
VENOUS VASCULAR CLOSURE SYSTEM

Early Ambulation.
Simple. Proven.

NOW FDA APPROVED

Indicated for 6-12F Inner Diameter Venous Vascular Closure

The Only Closure Device Indicated for Multi-site, Multi-limb Femoral Venous Closure

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VASCULAR CLOSURE FOR EP PROCEDURES

AMBULATE Pivotal Trial – Summary of Endpoint Analysis

Attribute			VASCADE MVP N=199	Manual Compression N=209	p-value
Safety Endpoint	Major Complications		0%	0%	–
	Minor Complications		1.0%	2.4%	0.45[4]
			N=100	N=104	
Efficacy Endpoint*	Time to Ambulation (TTA)	Mean	2.8 hours	6.1 hours	<0.0001[2]
		Median	2.2 hours	6.1 hours	<0.0001[2]
	Time to Closure Eligibility (TTCE)		10.5 mins	37.6 mins	<0.0001[2]
	Total Post-Procedure Time (TPPT)		3.1 hours	6.8 hours	<0.0001[2]
	Time to Discharge Eligibility (TTDE)		3.1 hours	6.5 hours	<0.0001[2]
	Time to Discharge (TTD)		21.8 hours	21.8 hours	0.98[2]
	Procedure Success		98%	99%	–
			N=369	N=382	
	Time to Hemostasis (TTH)		6.1 mins	13.7 mins	<0.0001[2]
			N=363	–	
	Device Success		97%	N/A	–

AMBULATE Pivotal – Patient Satisfaction Scores[5]

Attribute		VASCADE MVP N=100	Manual Compression N=102	Nominal p-value[3]	Outcome
Patient-Reported Satisfaction Scores	All Patients				
	Duration, current episode	8.3±2.4	5.1±3.4	<0.0001	Scores 63% higher for MVP
	Discomfort, current episode	7.2±3.1	5.3±3.1	<0.0001	Scores 36% higher for MVP
	Pain, current episode	7.5±3.2	6.0±3.4	0.001	Scores 25% higher for MVP
	Patients with a previous cardiac ablation procedure	N=30		N=39	
	Duration, compared to previous	7.9±2.3	5.6±3.0	0.001	Scores 41% higher for MVP
	Discomfort, compared to previous	7.5±2.1	5.4±2.8	0.001	Scores 39% higher for MVP
	Pain, compared to previous	7.7±2.8	5.5±2.9 (N=38)	0.002	Scores 40% higher for MVP

AMBULATE Pivotal Results – Pain Medications & Opioid Use

Pain Medication Usage	VVCS (N=100)		Manual Compression (N=104)		Nominal p-value[4]
Yes	24	24%	51	49%	0.0003
Reduction in Overall Pain Meds			51%		

Opioid Usage	VVCS (N=100)		Manual Compression (N=104)		Nominal p-value[4]
Yes	15	15%	37	36%	0.001
Reduction in Opioid Use			58%		

1. AMBULATE Clinical Study Report
2. p-values from two-sided t-test for means, and two-sided Wilcoxon rank sum test associated with medians, unadjusted for stratification factor
3. Nominal p-values by two-sided t-test, not pre-specified, however actual results imply superiority
4. Nominal p-value by 2-sided Fisher's exact test
5. Patient satisfaction surveys administered prior to discharge. Rated on scale of 1–10, with "10" being most satisfied. Data are presented as mean ± SD.

* Mean timepoints shown, unless otherwise noted

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LIT 4621 Rev B