

# VASCADE MVP<sup>®</sup>

## VENOUS VASCULAR CLOSURE SYSTEM

### Results of the AMBULATE Clinical Trial Evaluating the VASCADE MVP<sup>®</sup> System Compared to Manual Compression for Multi-Vessel Closure Following EP Procedures<sup>1</sup>

#### Study Overview

- National Principal Investigators
  - Dr. Andrea Natale - Executive Medical Director, Texas Cardiac Arrhythmia Institute
  - Dr. Mintu Turakhia - Associate Professor, Stanford University School of Medicine
  - Dr. Steve Compton - Alaska Heart & Vascular Institute
- Prospective, multi-center, randomized 1:1 against manual compression
- 204 patients, 13 sites, 28 physicians
- All patients had multiple (3 or 4) mid-bore (6-12F Inner Diameter sheath) femoral venous access sites
- The treatment group had all sites closed with the VASCADE MVP<sup>®</sup> while the control group had all sites closed using Manual Compression
- Both Cryo and RF energy sources were used

#### Study Results Summary

##### Time-To-Ambulation<sup>2</sup> (p < 0.0001)

**64%** reduction in median TTA      **3.9** hours median reduction in TTA

##### Patient Satisfaction<sup>3</sup> (nominal p-value < 0.0001)

**63%** increase in patient satisfaction for duration of bed rest      **8.3** out of 10 **vs.** **5.1** out of 10

##### Reduction of Opioid Use<sup>4</sup> (nominal p-value = 0.001)

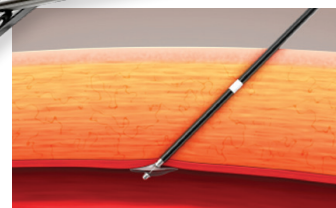
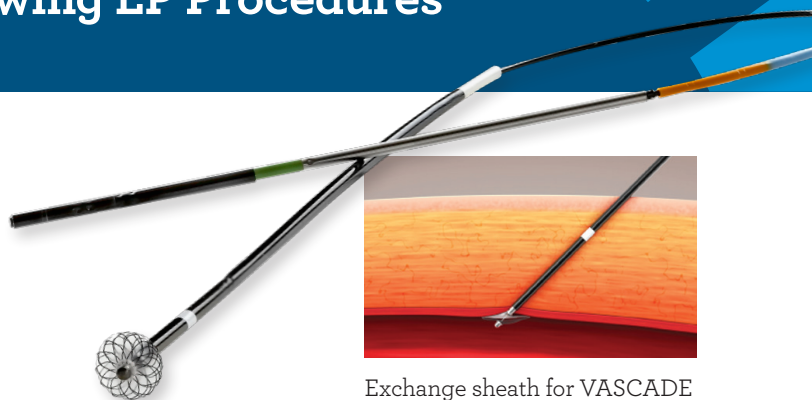
**58%** fewer patients received opioids      **15%** of VASCADE MVP<sup>®</sup> patients **vs.** **36%** of Manual Compression patients

1. AMBULATE Clinical Study Report

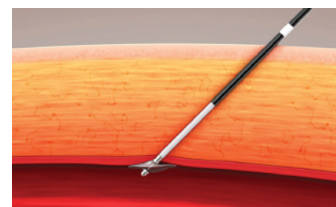
2. p-values from two-sided t-test for means, and two-sided Wilcoxon rank sum test for medians, unadjusted for stratification factor

3. Nominal p-values by two-sided t-test, not pre-specified, however actual results imply superiority

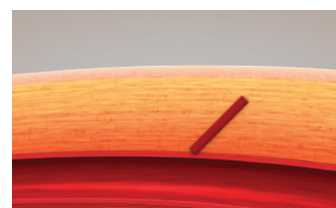
4. Nominal p-values by two-sided Fisher's exact test, not pre-specified, however actual results imply superiority



Exchange sheath for VASCADE and verify disc location\*



Release collagen patch\*



Remove VASCADE and obtain hemostasis\*

\* Procedure steps are a high level representation for communication purposes. Instructions for Use (IFU) contain all the procedural steps and associated precautions, warnings and adverse events regarding use of device.

## 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 <sup>1</sup>	
		N=100	N=104		
Efficacy Endpoint*	Time to Ambulation (TTA)	Mean	2.8 hours	6.1 hours	<0.0001 <sup>1</sup>
		Median	2.2 hours	6.1 hours	<0.0001 <sup>1</sup>
	Time to Closure Eligibility (TTCE)	10.5 mins	37.6 mins	<0.0001 <sup>2</sup>	
	Total Post-Procedure Time (TPPT)	3.1 hours	6.8 hours	<0.0001 <sup>2</sup>	
	Time to Discharge Eligibility (TTDE)	3.1 hours	6.5 hours	<0.0001 <sup>2</sup>	
	Time to Discharge (TTD)	21.8 hours	21.8 hours	0.98 <sup>2</sup>	
	Procedure Success	98%	99%	–	
			N=369	N=382	
	Time to Hemostasis (TTH)	6.1 mins	13.7 mins	<0.0001 <sup>2</sup>	
			N=363	–	
Device Success	97%	N/A	–		

1. p-value by 2-sided Fisher's exact test

2. p-values from two-sided t-test for means, and two-sided Wilcoxon rank sum test for medians, unadjusted for stratification factor

3. p-value from two-sided test

\* Mean timepoints shown, unless otherwise noted

## AMBULATE Pivotal – Patient Satisfaction Scores

Attribute	VASCADE MVP N=100	Manual Compression N=102	Nominal p-value <sup>1</sup>	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

Patient satisfaction surveys administered prior to discharge.

Rated on scale of 1-10, with "10" being most satisfied.

Data are presented as mean ± SD.

1. nominal p-value by two-sided Fisher's exact test, not prespecified, however actual results imply superiority

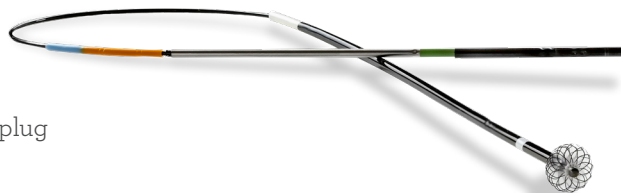
## AMBULATE Pivotal Results – Pain Medications & Opioid Use

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

1. nominal p-value by two-sided Fisher's exact test, not prespecified, however actual results imply superiority

## VASCADE MVP® Technology

- Extravascular design
- Simple and easy to use
- Bioabsorbable and thrombogenic collagen plug



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