CE MARK

ambulate
Portfolio of Studies

US PIVOTAL | CE MARK | CAP | IMPACT

PRIMARY OBJECTIVES

- Demonstrate the safety and performance of the Cardiva VASCADE MVP® Venous Vascular Closure System (VVCS) in sealing femoral venous access sites at the completion of catheter-based procedures performed through 6 – 12F introducer sheaths.

STUDY DESIGN

- Prospective, multi-center, single-arm
- 40 patients, 5 centers, 11 Enrolling Physicians

SAFETY ENDPOINTS

- Rate of combined major (primary) and minor (secondary) venous access site closure-related complications through 30 days

PRIMARY / SECONDARY EFFECTIVENESS ENDPOINT

- Primary - Time To Ambulation (TTA). Secondary - Total Post Procedure Time (TPPT)

Procedure Type	N (40)	%
AFib (4pts also w/ AFlutter)	36	90.0%
AFlutter	1	2.5%
Other	3	7.5%

Energy Source	N (40)	%
RF	28	70%
Cryo	12	30%
Other (both)	0	0%

SAFETY END POINTS

(N=78 -Measured by Limb) 1 pt. Lost to Follow up)	N	%
Major venous access site closure-related complications through 30 days post-procedure	0	0.0%
Minor venous access site closure-related complications through 30 days post-procedure	1	1.3%

SAFETY END POINTS

Time to Ambulation (hours)	All Subjects
N	40
Mean	2.65
Std Deviation	0.95
Median	2.21
95% CI	2.34-2.95

Total Post-Procedure Time (hours)	All Subjects
N	40
Mean	2.91
Std Deviation	0.99
Median	2.48
95% CI	2.59-3.23

IMPORTANT NOTES

- VASCADE MVP® is now FDA approved (model 800-612c-10u)
- CE Mark pending. Results are being released in conjunction and coordination with notified body

CARDIVA MEDICAL, INC.

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