CAP

ambulate
Portfolio of Studies

US PIVOTAL | CE MARK | CAP | IMPACT

PRIMARY OBJECTIVES

Objective of the AMBULATE CAP Study is to demonstrate the safety and effectiveness 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 – 12 F introducer sheaths, while allowing for one or more of the following: elimination of the Foley catheter, elimination of protamine, or allowing same (calendar) day discharge for the appropriate patient population.

STUDY DESIGN

- Prospective, multi-center, single-arm
- Up to 500 patients and 5 centers (Limited to AMBULATE US Pivotal Study enrolling centers)
- Targeting EP Ablation Procedures

SAFETY ENDPOINTS

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

PRIMARY EFFECTIVENESS ENDPOINT

- Combined Rate of Procedure Success

SECONDARY EFFECTIVENESS ENDPOINTS

- No Foley Success Rate
- No Protamine Success Rate
- Same Calendar Day Discharge Success Rate

IMPORTANT NOTES

- VASCADE MVP® is now FDA approved (model 800-612c-10u)
- Enrollment in the CAP Study is closed

CARDIVA MEDICAL, INC.

www.cardivamedical.com