The AMBULATE EXPAND Trial[1]

Introduction

This study demonstrated the safety and efficacy of the VASCADE MVP® XL venous vascular closure system when compared to performance goals (PG) and clinical acceptance criteria (CAC) for closing percutaneous femoral venous access sites at the completion of catheter-based procedures utilizing 16-17F OD procedural sheaths.

Study Design & Endpoints

Study Design

- Single-arm, multicenter prospective study
- N=77 patients; 82% PFA, 8% LAAC, 10% Concomitant ablation / LAAC
- 8 unique U.S. centers
- 23 enrolling investigators

Efficacy Endpoints

- Time to Ambulation (TTA)
- Time to Hemostasis (TTH)
- Time to Discharge Eligibility (TTDE)
- Total Post-Procedure Time (TPPT)
- Time to Discharge (TTD)
- Procedure Success
- Device Success

Safety Endpoints

- Major and Minor Venous Access Site Closure-Related Complications[†,‡]

Conclusion

VASCADE MVP XL system provides safe and effective percutaneous closure of femoral venous access sites after catheter-based procedures using 16-17F OD sheaths. Compared to standard performance goals and clinical acceptance criteria, VASCADE MVP XL reduced TTA, TTH, TTDE and TPPT.

RESULTS

* In Per Protocol population (N=66)
† Major venous access site closure-related complications through 30-day follow up
‡ Minor venous access site closure-related complications through 30-day follow up

1. VASCADE MVP XL IFU 4911

www.haemonetics.com
800-537-2802

HAEMONETICS®