

Vascular Quality Initiative®

vascularqualityinitiative.org

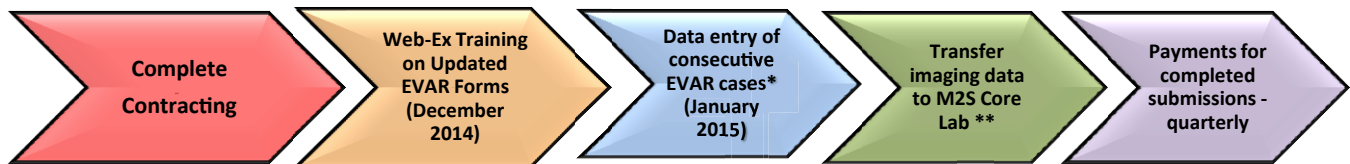
SVS PSO Aorfix™ Post Approval Surveillance Project

The SVS PSO, in collaboration with the FDA, and Lombard Medical are conducting a new quality improvement project: A Prospective, Non-Randomized, Multi-Center Evaluation of the Long-Term Safety and Effectiveness of the Lombard Medical Aorfix™ AAA Flexible Stent Graft System. Non-identifiable data will be shared with Lombard Medical for this project.

Surveillance Project Details:

- Multi Center, Prospective, Nonrandomized
- 50 Participating Sites
- 234 EVAR Patients treated per Aorfix™ IFU
- Evaluating freedom from aneurysm-related mortality based on follow up at 30 days post-index procedure and annually through 5 years
- FDA post market surveillance through VQI does not require IRB review or patient consent
- VQI Endovascular AAA Registry captures outcomes data
- M2S Core Lab services capture imaging data
- Sites selected will be reimbursed for their data entry and image transfer efforts

Process:



*All VQI Bylaws Apply

**Transfer images to M2S Core Lab via ArmorCar® (DAC®) or Virtual DICOM ArmorCar (vDAC®).

Regulatory:

All data submitted for this project are part of the SVS PSO normal activity to improve the safety and effectiveness of vascular healthcare, and are covered under existing contracts with each site. As with all data submitted to a Patient Safety Organization, specific patient consent and IRB approval is not required.

Steering Committee:

Dr. James Black (Chair)
Dr. Jason Lee

Dr. Jens Eldrup-Jorgensen
Dr. Salvatore T. Scali

Dr. Mark Fillinger
Dr. Michael Singh